KYOWA KIRIN

Annual Report 2021

For the year ended December 31, 2021

Kyowa Kirin Co., Ltd.

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Scope of This Report
Kyowa Kirin Co., Ltd. and its consolidated subsidiaries
* Indication is provided in cases where the scope of reporting differs.

Reporting Period
January to December 2021
* The latest information at the time of publication is also included where possible.

Disclaimer
Statements concerning future plans and forecasts are based on information currently available to the Company and certain assumptions that the Company believes to be reasonable. Actual results and performance may differ due to various risks and uncertainties. Statements concerning ethical pharmaceuticals and products under development are not intended as advertising, promotions, or medical advice.

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Motohiko Kawaguchi
Managing Executive Officer
Director, Finance Department
(In charge of Corporate Communications and Procurement Departments)

About the publication of the Integrated Report

Kyowa Kirin's Integrated Report is published for our shareholders, investors, and a wide range of stakeholders. It introduces our business—both in its financial and non-financial aspects—as we aim to contribute to the health and wellbeing of people around the world by creating new value. In producing this report, we referred to the International Integrated Reporting Framework proposed by the Value Reporting Foundation (VRF) and the Guidance for Collaborative Value Creation Guidance issued by Japan's Ministry of Economy, Trade and industry (METI).

Production of this report was led by the IR Group of the Corporate Communications Department, in collaboration with the Corporate Planning Department and other departments across the organization. As head of the Corporate Communications Department, I have confirmed that the content of this report is accurate.

We hope that this report may be of use as a tool for communication with our stakeholders, leading to the creation of new shared value.

Environment
Social
Governance
Guidance for Collaborative Value Creation

Message from the President

Masashi Miyamoto, Ph.D.
Representative Director President and Chief Executive Officer

Bringing smiles to patients is what motivates us

FY2021 Review

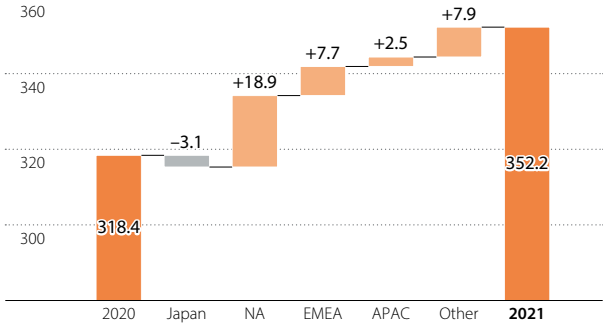
We achieved our targets for FY2021, with revenue and profits both increasing year on year. It was also a solid start to our new five-year Medium Term Business Plan, which launched in 2021. Moreover, we made good progress with our R&D pipeline, underscoring how we are working to maximize the Group's corporate value for the longer term.

Since 2019, we have been putting in place our One Kyowa Kirin (OKK) matrix management structure, which combines a regional organization based on four regions and a functional organization based on R&D, quality assurance and other functions. OKK is designed to support the Group's future growth and is already delivering major benefits. This year, we started adding a product organization (product franchises) to the OKK structure. Our goal is to create and provide unique value to patients, rather than simply reinforcing the Group's regions and functions. To do that, we realized we needed to add a franchise-based perspective to OKK. We currently only have three global strategic products, but we plan to incorporate next-generation strategic products in the future.

FY2020 vs FY2021 –Revenue–

(Billions of yen)

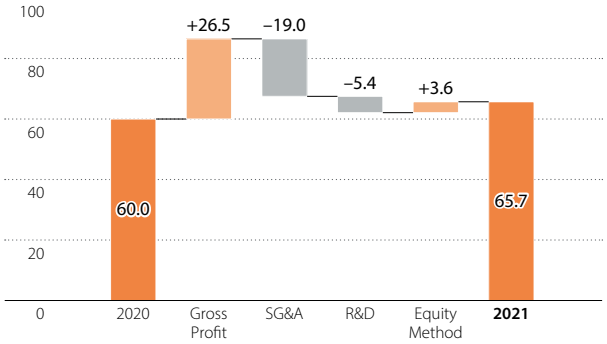
+33.9 billion yen (+11%)



FY2020 vs FY2021 –Core Operating Profit–

(Billions of yen)

+5.7 billion yen (+10%)



Progress with Medium Term Business Plan and Future Initiatives

Provide pharmaceuticals for unmet medical needs

One of our main missions for FY2022 is to build our own commercial organization for Crysvita in North America – the product's biggest market. We plan to transfer the commercial activities of Crysvita from Ultragenyx Pharmaceutical Inc. to Kyowa Kirin in April 2023. With that timeframe in mind, we are working closely with Ultragenyx to smoothly transfer sales know-how, including marketing approaches, to our proprietary commercial organization. Crysvita is still unavailable in some regions. We will therefore continue to negotiate promptly and resolutely with the regulatory authorities in each country to ensure that more patients gain access to the drug.

In next-generation global strategic products, atopic dermatitis treatment KHK4083 looks increasingly promising as a major product. We have signed an agreement to jointly develop and commercialize KHK4083 with US biopharmaceutical company Amgen Inc., which has experience and a portfolio focused on inflammatory diseases and skin disorders. While many companies are active in this treatment field, Amgen has strong development, manufacturing and sales capabilities, making it the ideal global partner to maximize the value of KHK4083. Amgen also has the expertise to help us identify other indications for KHK4083 outside atopic dermatitis.

Meanwhile, we continue to make steady progress with the development of investigational cancer treatment ME-401 with partner MEI Pharma, Inc. Further investment is needed, but we believe it has significant potential to become a major product in the future.

In July 2021 we submitted a new drug application (NDA) in Japan for nephrology development product RTA 402 for the treatment of Alport Syndrome. We are also conducting Phase 3 trials for the treatment of diabetic kidney disease. We plan to submit an application after obtaining solid clinical evidence that includes long-term safety data. Additionally, we have built up sufficient clinical data for KHK7791, a treatment being studied for hyperphosphatemia in patients on maintenance dialysis. One of our tasks going forward will be to prepare an NDA for the drug in Japan.

While we continue to make progress with these next-generation strategic products, we recognize the need to strengthen our preclinical pipeline and output from early stage research and discovery activities. All product candidates do not necessarily progress to the clinical stage, so we have to expand the volume of preclinical compounds. We plan to direct more of our energy into this area, as it will also have a major impact on Kyowa Kirin's trajectory ten years from now. The key will be open innovation. To further accelerate open innovation, we revamped the structure of the R&D Division in April 2021, creating a research organization that draws on even greater input from external expertise. Also, we plan to launch a corporate venture capital (CVC) fund to give us greater access to early-stage technologies and development candidates. In this way, we plan to combine in-house research capabilities with the skills and resources of external partners to create a stronger pipeline that supports the Group's sustained growth.

We will expand our pipeline to support sustained growth

Next-generation Strategic Products

	Country/region*1	Indication*2	Approval year*3	Total addressable market*4	No. of patients*5
KHK4083	NA/EU/JP	Atopic dermatitis	2025/2026	★★★	16,000K
KW-6356	NA/EU/JP	Parkinson's disease	2026	★★★	3,500K
ME-401	NA/EU/JP	Follicular lymphoma Marginal zone lymphoma	TBD	★★★	–800K
RTA 402	JP/Asia	Alport syndrome Diabetic kidney disease Autosomal dominant polycystic kidney disease (ADPKD)	TBD 2024 2025	★★★	2,500K–
KHK7791	JP	Hyperphosphatemia under maintenance dialysis	2023	★☆☆	250K

*1 Products may not be approved/launched in all countries or regions shown in the table
*2 Indications may ultimately differ to expectations due to status of approvals from regulatory authorities
*3 Expected year of first approval
*4 Expected total addressable market based on the indications and countries/regions shown in the table, not projected sales or targets of the Company; ★ = less than ¥50bn, ★★ = ¥50–100bn, ★★★ = Over ¥100bn
*5 Total number of estimated patients in all countries/regions shown in the table.
Note: The size of the total addressable market and patient numbers are based on our estimates

Address patient-centric healthcare needs

Our goal is to bring smiles to the faces of people battling disease, and the people around them. To do that, we need to know what really troubles them and provide tailored treatments and support. This in essence is our approach to patient advocacy.

For example, Crysvita is approved as a novel therapeutic antibody treatment for X-linked hypophosphatemia (XLH), and only Kyowa Kirin and our partners can provide its value to patients. However, treatment has to start with the patients themselves – they or their friends or family may notice something is not quite right, prompting the individual to undergo a medical examination that leads to a diagnosis of XLH. That's when we can begin providing value. In many cases, people do not know they have XLH, preventing them from receiving appropriate treatment. Raising awareness of the condition is therefore very important. We are playing our part through patient awareness and patient support activities. We are also taking a similar approach with other conditions such as cutaneous T-cell leukemia, Parkinson's disease and kidney disease.

To improve patient quality of life (QOL), we need to consider whether developing and providing new pharmaceuticals by itself achieves that goal. In other words, as a pharmaceutical company we have to take an even broader view as we work hard to provide value to patients that goes beyond pharmaceutical products. In that respect, Kyowa Kirin still has much to do, and I believe activities in these areas can also lift the value of our pharmaceutical products, while also strengthening Kyowa Kirin's presence in the market.

Retain the trust of society

We aim to establish a robust production system that can reliably supply high-quality pharmaceuticals to patients who need them worldwide. As part of that, we are reinforcing quality assurance systems and supply-chain management. This will take time, but we will keep making our efforts for this area.

As a company, we also have to respond to global climate change. Helping to establish a sustainable society will be a key part of our efforts. Under the Kirin Group Environmental Vision 2050, the Kirin Group, of which Kyowa Kirin is a member, is targeting net zero greenhouse gas emissions across its entire value chain. We are also collaborating with this effort to achieve this goal by reducing greenhouse gas emissions in our operations. In addition, we well also continue to implement a range of initiatives, such as conserving energy, introducing and expanding the use of renewable energy, and switching from fossil fuels to electricity. We will continue to work with Kirin Holdings to ensure we pass on a healthy planet to future generations.

Reinforce human resources and structures that support the creation of life-changing value

We have been reforming Kyowa Kirin's corporate culture since 2019, under the slogan KABEGOE (activities that spur cooperation across different organizations within the Group). We want to create an organization that is always learning, based on a culture of constant change and evolution.

I often get asked by employees about the final objectives and goals of KABEGOE activities, but there is no natural end to them. Once we reach the summit of a mountain, the next summit comes into view. In other words, reforming our corporate culture is an enduring mission that helps us constantly evolve and learn. Embedding KABEGOE activities across the Group will accentuate Kyowa Kirin's uniqueness as a company, giving us the strength to take on the world's pharmaceutical majors.

We also want these reforms to encourage our employees worldwide – regardless of region, division, or position – to truthfully explore their own visions for work and their future. Ideally, these visions will be endorsed by their superiors and incorporated organically within the vision for their organizations, and ultimately for the Group as a whole.

We can
do much more to
bring smiles
to patients

DX strategy

The main focus of our digital transformation (DX) strategy is to ensure as efficient global operations as possible for a company of our size. We are therefore prioritizing the construction of systems that optimize operations across the entire Kyowa Kirin Group, rather than individual systems for each function. In other words, instead of piecemeal DX, we need a comprehensive blueprint for a DX strategy that covers the whole Group. We are currently discussing the Group's DX priorities and have already started investing in priority areas that have been finalized.

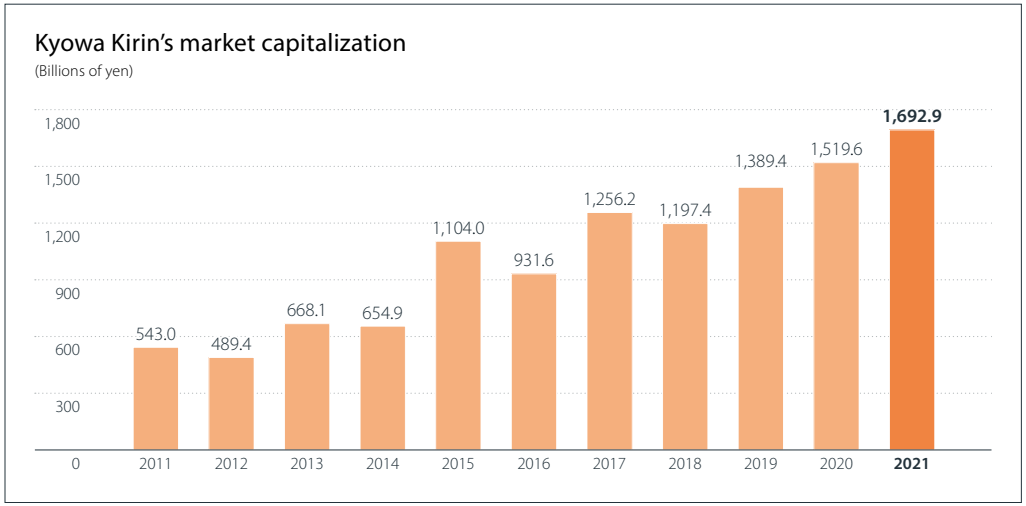
Of course, we won't be able to fully leverage DX if we only strengthen our systems and infrastructure. We also urgently need to cultivate human resources who are skilled in business strategy as well as IT and digital infrastructure. That could also mean using external consultants and experts to drive forward our DX strategy from the perspective of both infrastructure and human resources and processes.

Looking to the future

As shown by the current pandemic, it is very difficult to predict changes in society. More than ever, given the uncertain outlook, we have to create a flexible organization that can adapt to any change to ensure we continue to meet the needs of society well into the future. Most important, we need a corporate culture that readily embraces new values and a highly adaptable management strategy. We will of course design our product pipeline with a medium-term horizon and continue to communicate our scenario for sustained growth, but first and foremost, we have to be prepared mentally to respond to any major unforeseeable changes that could lie ahead.

Also, we want to add more people to our workforce with a bold outlook – employees who are not afraid of change or making mistakes. As I always tell our executives and employees, we should never discount individual visions that set out clear goals. Sometimes, people get frustrated or give up on their vision when faced with problems. That's when they need to ask themselves whether the vision in their mind's eye really does have value. That makes it harder for them to give up. These individual visions also drive the whole company. I believe that linking their visions with our Group Vision will translate into sustainable growth for the Group.

Over the last decade we have steadily increased Kyowa Kirin's corporate value, supported by our shareholders and investors. However, I think Kyowa Kirin has much more to give. As a Japan-based Global Specialty Pharmaceutical Company, we are only just spreading our wings and taking flight. I hope we can count on your continued support in the journey ahead.



We are building a flexible organization that can adapt to any change

History of Value Creation

Kirin 1885

Establishment of the Japan Brewery Company, the forerunner of Kirin Brewery Co., Ltd.

Kirin 1907

Establishment of Kirin Brewery Co., Ltd.

Kyowa Hakko 1949

Establishment of Kyowa Hakko Kogyo Co., Ltd. as a secondary company of Kyowa Sangyo Co., Ltd, in accordance with the Enterprise Reorganization Act

Kyowa Hakko 1956

Succeeded in isolating and commercializing the anti-tumor agent Mitomycin C

Kyowa Hakko 1951

Kyowa Hakko entered the pharmaceutical business

At a time when tuberculosis was considered a terminal disease, Kyowa Hakko had been conducting research into streptomycin, an anti-tubercular drug. But we had not been able to achieve the level of mass production that would make it commercially viable. After introducing manufacturing technology from the U.S. company Merck, we succeeded in mass-producing streptomycin for the first time in Japan. In doing so, we contributed to the eradication of tuberculosis in Japan.

Kirin 1982

Kirin Brewery decided to enter the pharmaceutical business

By 1982, calls within the company to diversify business had become louder. A new R&D Department was established at the head office and a full-fledged pharmaceutical business was launched. The Research Institute for Production Development foundation began full-scale research towards the commercialization of erythropoietin.

Kirin 1984

Establishment of Kirin-Amgen

Kirin-Amgen, Inc. (currently Amgen K-A, Inc.), a joint venture with U.S. company Amgen, was established for the research and development of erythropoietin. Kirin-Amgen later grew into a company that holds rights to major products with annual sales exceeding ¥1 trillion. This brought global recognition of Kirin's pharmaceutical business.

Kirin 1988

Promoting open innovation

In 1988, targeting future expansion into immunology research, the Company supported the establishment of the La Jolla Immunology Institute, one of the world's leading immunology laboratories. The partnership, which continues to the present day, went on to contribute to the discovery of KHK4083. It has provided learning opportunities for many of our researchers to experience cutting-edge research.

Kirin

Establishment of technology for producing fully human antibodies

Human antibodies can be used in the treatment of infectious diseases, cancer, and other diseases. The development of technology to enable their mass production had been long awaited. Our researchers became the first in the world to devise Human Artificial Chromosome (HAC) technology. They succeeded in developing mice that produce fully human antibodies. This further expanded the pharmaceutical potential of antibodies.

2008

Launch of Kyowa Hakko Kirin Co., Ltd.

In October 2008, Kyowa Hakko Kirin was formed through the merger of Kyowa Hakko Kogyo and Kirin Pharma. This began the challenge of becoming a Japan-based Global Specialty Pharmaceutical Company (GSP)—with the aim of becoming a world-class biotechnology R&D-driven life science company.

Kyowa Hakko 2003

Establishment of POTELLIGENT and BioWa

Having established POTELLIGENT, a breakthrough antibody production technology that dramatically increases the activity of antibodies, Kyowa Hakko established BioWa, Inc. in the US in 2003 to start a licensing business for this technology, out of a determination to help more people. Through their strong desire to make use of this technology, the researchers overcome repeated challenges. This culminated in the creation of world's first antibody drug utilizing POTELLIGENT, Poteligeo.

To the Future

Our challenge continues into the future

When asked to describe Crysvita, one patient thought for a moment and replied, "Life Changing."

2018
Launch of Crysvita in Europe and the US

X chromosome-linked hypophosphatemic rickets (XLH) is a rare disease that affects 1 in 20,000 people. Previously, patients had suffered from growth failure and pain that kept them awake at night, with treatment limited to symptomatic therapy. Patients with this genetic disease have suffered across generations, with both parents and children affected. Crysvita became the first essential treatment for XLH, for which there had been no adequate therapy.

2019
Launch of the One Kyowa Kirin structure

In response to the growth of global strategic products, Kyowa Kirin launched a matrix management structure combining the regional organizations of Japan, EMEA, North America, and APAC with functional organizations that transcend regions. The close collaboration and checks and balances between the two types of organizations have made it possible to improve operational efficiency and strengthen governance.

2021
Concluded an agreement with Amgen for joint development and marketing of KHK4083/AMG 451

2020
Construction begins on a new quality building at the Takasaki Plant.

2020
Launch of Poteligeo in Europe

2021
Evolution of the One Kyowa Kirin structure

To strengthen activities with a greater focus on patients, a product organization was added to the regional and functional organizations. We aim to further maximize the value of our global strategic products.

2019
Kyowa Hakko Bio Co., Ltd. is transferred to Kirin Holdings Company, Limited.

2019
Launch of Crysvita in Japan

2019
Launch of Nourianz in the US

2018
Launch of Poteligeo in the US

2018
Launch of Fasenra in Europe, US, and Japan

Fasenra is an antibody drug discovered by Kyowa Hakko and licensed to AstraZeneca's for development and marketing. It has grown to become one of AstraZeneca's blockbuster products.

2013
Launch of Nouriast in Japan

With dopaminergic drugs dominating the mainstream, the research and development into this non-dopaminergic drug had presented a series of challenges. The project was encouraged by a corporate culture of embracing challenges. In 2013, the effort finally bore fruit.

2012
Launch of Poteligeo in Japan

At the time, Adult T-cell Leukemia-Lymphoma (ATL) was an incurable disease for which there was no effective treatment. All those involved in the research and development of this drug a steadfast determination to carry their efforts through to completion, with the creation of a drug. In 2012, Poteligeo was launched as the world's first antibody drug utilizing POTELLIGENT technology.

2012
Establishment of Fujifilm Kyowa Kirin Biologics Co. Ltd., a joint venture with Fujifilm Corporation

2011
Acquired UK company ProStrakan as a subsidiary

2010
Completed construction of one of Japan's leading production facilities for drug substances for antibodies at the Bio Process Research and Development Laboratories

2014
Acquired UK company Archimedes as a subsidiary

2016
Completed construction of a new biopharmaceutical API manufacturing building at the Takasaki Plant, increasing production capacity.

Our Philosophy and Core Value

OUR PHILOSOPHY

The Kyowa Kirin Group companies strive to contribute to the health and wellbeing of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

Innovation

Transform lives with passion and excitement.

Challenge the status quo in all of our work.

CORE VALUES

Commitment to Life

Work for the most precious presence on this planet.

Create value for patients, caregivers, healthcare professionals, and customer.

Integrity

Do the right things.

Be sincere and ethical consistently.

Make a better world through good business practices.

Teamwork/Wa

One for all, all for one.

Work in diverse teams and respect each other.

Go beyond boundaries and collaborate with stakeholders.

Our Vision toward 2030

Kyowa Kirin will realize the successful creation and delivery of life-changing value* that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

Provide pharmaceuticals for unmet medical needs

We are focused on developing medicines for diseases where there is a clear patient need for new options. We make full use of multiple therapeutic modalities, including biotechnology such as antibody technology, and beyond, building on our Kyowa Kirin established strengths.

Address patient-centric healthcare needs

We will meet the needs of patients and society by providing value across the entire patient care pathway, delivering cutting-edge science and technology, grounded in our in-depth pharmaceutical knowledge and expertise.

Retain the trust of society

We pursue world-class product quality and operational excellence to grow our business in ways which build long-term trust with our stakeholders.

* Make patients smile through dramatic improvements in quality of life by identifying the unmet medical needs of people battling with medical conditions and by creating and supplying new drugs or services that help them overcome those challenges.

Value Creation Story

Input

Human capital
Create a unified team brimming with diversity
- Number of employees (global): 5,752
- Percentage of management positions held by women (Japan): 12.4%
- Percentage of leaders who are women (global): 29%

Intellectual capital
Pursuing life-changing value creation with a focus on "Only-one"
- R&D expenses: ¥57.7 billion
- R&D expense ratio: 16.4%

Manufactured capital
Ensuring a stable supply of pharmaceuticals of reliable quality
- Manufacturing sites (global): 3 sites

Social and relationship capital
Evolution of "One Kyowa Kirin" and earning the trust of stakeholders
- Number of countries with operations: 42

Natural capital
Helping protect the environment
- Energy consumption: 1,004,699 GJ
- Water consumption (water withdrawal): 1,672 thousand m^3

Financial capital
Growth investments for sustainable growth and maximization of corporate value
- Total assets: ¥921.9 billion
- Total capital: ¥737.2 billion

Value creation process (business process)
Strategies for achieving the Medium Term Business Plan

Stakeholders
Future generations, Local community, Investors, Customers, Shareholders, Health care providers, Company employees, Patients, ...

Provide pharmaceutical products for unmet medical needs

Address patient-centric healthcare needs

Retain the trust of society

Strengthen our talent and infrastructure to realize life-changing value

CSV Management (Co-creation of Value)

- Value creation in the process of delivering medicines to patients
- Value creation in products, quality, and distribution
- Value creation to meet UMN through R&D

Management Philosophy Core Values

Addressing materiality

Output

Social value
Continuously create and provide life-changing value

Economic value
FY2021 Actual
- Revenue ¥352.2 billion
- Core operating profit ¥65.7 billion
- Core operating profit ratio 18.6%
- ROE 7.3%

Cycle of augmenting corporate value

Outcome

Achieving our vision for 2030

Materiality

— Identifying material issues to address during the Medium Term Business Plan from 2021 —

By identifying priority issues that the Group needs to address from both a social and business perspective, we aim to help build a sustainable society while also growing our business.

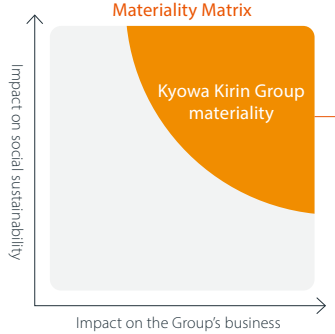
STEP 1 List issues
- List issues to be discussed (competitor, sector and expert review, data analysis)

STEP 2 Assess impact on social sustainability and business
- Prioritize listed issues from a social perspective (media surveys, trend surveys)
- Prioritize listed issues from a business perspective (analysis of internal documents, hearings with management, internal workshops)

STEP 3 Identify materiality (material issues)
- Formulate a materiality matrix

STEP 4 Confirm validity and finalize
- Conduct dialogue with stakeholders
- Discuss and confirm materiality in internal meetings attended by management
- Embed materiality in the Medium Term Business Plan
- Finalize at Board of Directors meeting

Materiality Matrix



		Main initiatives (KPI)	Related SDGs
Growth opportunities	**— Make as many people as possible smile —** ○ Continuous innovation ○ Patient advocacy ○ Access to medicine	▸ Providing pharmaceuticals for UMN P20 ▸ Initiatives for Patients P28 ▸ Number of countries where the product is marketed	3 GOOD HEALTH AND WELL-BEING 9 INDUSTRY, INNOVATION AND INFRASTRUCTURE 17 PARTNERSHIPS FOR THE GOALS
Growth foundations	**— Foster even greater trust in Kyowa Kirin —** ○ Corporate governance ○ Quality assurance and a stable supply of products Ensuring patient safety and appropriate use of medicines Supply chain management Legal compliance and ethical business practices Anti-counterfeiting Reinforce risk management Respecting human rights Transparency and disclosure; engagement	▸ Corporate governance P46 ▸ Providing high-quality pharmaceuticals to patients around the world P33	10 REDUCED INEQUALITIES 12 RESPONSIBLE CONSUMPTION AND PRODUCTION 16 PEACE, JUSTICE AND STRONG INSTITUTIONS
Organizational culture and talent	**— Create a unified team brimming with diversity —** ○ Diversity, equity and inclusion Occupational health and safety Employee development and provide opportunities for employees to grow	▸ One team of diverse people working to realize life-changing value P42 ▸ Percentage of management positions held by women (Japan) ▸ Percentage of leaders who are women (global) ▸ Percentage of paid leave taken (Japan) ▸ Walking campaign participation rate (Japan)	5 GENDER EQUALITY 8 DECENT WORK AND ECONOMIC GROWTH
Social foundations	**— Ensure a thriving global environment for future generations —** ○ Climate change mitigation and adaptation Biodiversity Reducing environmental impact Water resources management Philanthropic activities (advancement of medical science)	▸ Ensuring a thriving global environment for future generations P35 ▸ Reduction of CO_2 emissions (compared to 2019)	4 QUALITY EDUCATION 6 CLEAN WATER AND SANITATION 7 AFFORDABLE AND CLEAN ENERGY 13 CLIMATE ACTION 15 LIFE ON LAND 17 PARTNERSHIPS FOR THE GOALS

○: Material issues during this fiscal year

Overview of Medium Term Business Plan

In February 2021, the Kyowa Kirin Group announced a Medium Term Business Plan for the period 2021 to 2025.

The plan sets out the strategies for the next five years to achieve our qualitative and quantitative goals in 2025 and our longer-term vision for the Group.

We also adjusted the Group's material issues (materiality), aiming to generate growth while also satisfying the demands and expectations of society.

- Maximize the value of global products
- Establish framework to ensure stable global supplies
- Build a drug pipeline to drive growth beyond 2025
- Launch services that go beyond pharmaceuticals
- Foster a corporate culture suited to global business development

Philosophy

Vision

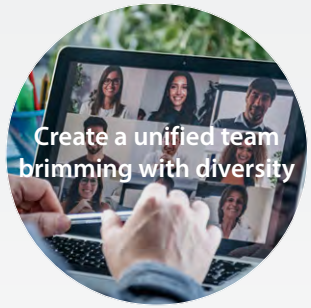
To be in 2025

Strategy

- Address patient-centric healthcare needs
- Provide pharmaceuticals for unmet medical needs
- Retain the trust of society
- Reinforce human resources and structures that support the creation of Life-changing value

ROE	**10%** or higher
Revenue growth rate	**CAGR 10%** or higher
R&D expense ratio	Targeting **18–20%** to support **active investment**
Core operating profit ratio	**25%** or higher by FY2025
Dividend payout ratio	**Sustained dividend hikes** with **40%** (based on core EPS)

Kyowa Kirin's Materiality



CSV* management

Contribute to the SDGs

* In our management philosophy, we are committed to creating new value by capitalizing on the Kyowa Kirin Group's strengths in life sciences and technologies with the aim of contributing to the health and well-being of people around the world. What we mean by "new value" is value that can be shared with society, or in other words, "Creating Shared Value (CSV)."
We practice CSV management aimed at realizing improved corporate value through the creation of both social and economic value.

Financial Strategy

Motohiko Kawaguchi
Managing Executive Officer
Director, Finance Department

Aiming to establish a stable earnings structure and generate sustained growth as a Global Specialty Pharmaceutical Company (GSP)

Medium Term Business Plan Progress Review

In the FY2021–2025 Medium Term Business Plan, we are targeting sustainable growth beyond FY2025 and increased corporate value over the medium- to long-term. To measure progress, we are using return on equity (ROE) as a key performance indicator (KPI). Our aim is to rapidly achieve ROE of 10% or higher so that ROE consistently exceeds the expected cost of capital. We also aim to increase ROE over the longer term.

To achieve our ROE objectives, we need to continuously increase the Group's growth potential, capability to innovate and profitability. We have selected three KPIs to measure our progress in those areas: revenue growth rate, R&D expenses ratio and core operating profit ratio.

First, let's look at the revenue growth rate (growth potential benchmark). During the five years of the Medium Term Business Plan, we are targeting average annual top-line growth of 10% or higher. We aim to do that by implementing further steps to increase sales and maximize the value of existing global strategic products, and by steadily rolling out the next generation of strategic products. Second, the R&D expenses ratio (capability to innovate benchmark). Our goal is to expand the drug pipeline to accelerate and drive the Group's growth beyond FY2025 by consistently and actively investing in research and development, aiming for an R&D expenses ratio target of 18–20%. At the same time, we will work to improve profitability by reducing the selling, general and administrative expenses ratio through tighter cost control to achieve our third KPI, a core operating profit ratio (profitability benchmark) of 25% or higher by FY2025, the final year of the plan.

By implementing measures to achieve the three KPIs, we aim to deliver profit growth that outpaces revenue growth in order to improve ROE over the medium- to long-term, supporting sustained increases in the dividend. Ultimately, our objective is to establish a stable earnings structure and generate continued growth as a Global Specialty Pharmaceutical Company (GSP).

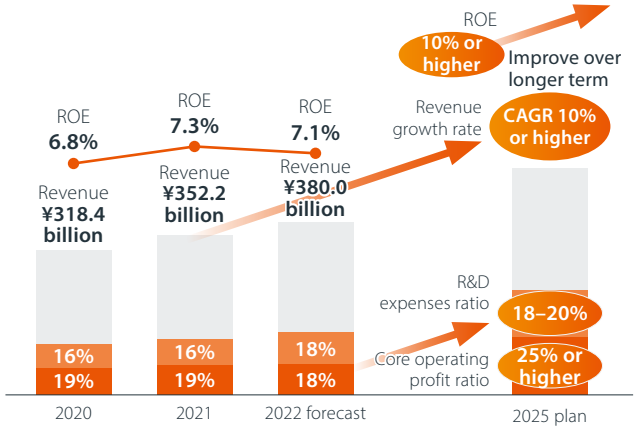
In FY2021, revenue and profits both rose year on year. Revenue increased ¥33.9 billion (+11%) to ¥352.2 billion, driven by top-line growth for Crysvita and other global strategic products, core operating profit rose ¥5.7 billion (+10%) to ¥65.7 billion (core operating profit margin of 18.6%), and profit attributable to owners of parent increased ¥5.3 billion (+11%) to ¥52.3 billion. Despite the pandemic, we achieved our first-year targets for revenue, core operating profit and profit attributable to owners of parent in the Medium Term Business Plan. ROE also improved from 6.8% last year to 7.3%.

In FY2022, the second year of the plan, Japan's drug price standards are to be lowered, but we forecast revenue will increase ¥27.8 billion year on year to ¥380.0 billion (average annual growth of 9.3% vs. FY2020 base year), supported by further growth for global strategic products, mainly in North America and EMEA, and by higher licensing revenue. We forecast selling,

Financial KPIs (Numerical guidance)

ROE	**10% or higher** (achieve target early / maintain or increase over the medium- to long-term)
Revenue growth rate	**CAGR*1 10% or higher**
R&D expenses ratio	Targeting **18–20% to support active investment**
Core operating profit ratio*2	**25% or higher** by 2025
Dividend payout ratio	Targeting **sustained dividend hikes with 40%** (based on core EPS*3)

*1 Average growth rate over a five-year period, with FY2020 as the base year.
*2 Core operating profit: "Gross profit" – "Selling, general and administrative expenses" – "Research and development expenses" + "Share of profit (loss) of investments accounted for using equity method."
*3 "Core profit" ("Profit attributable to owners of parent" – "Other income and expenses" (excluding impact from applicable taxes)) / average number of shares during fiscal year.



general and administrative expenses will increase ¥18.4 billion (+13%) year on year, reflecting continued active investment in digital IT platforms and human resources to maximize the value of global strategic products and rapidly establish a global business base. We also anticipate a one-time investment of roughly ¥5.0 billion to prepare for the start of proprietary commercialization of Crysvita in North America from spring 2023. We plan to spend ¥70.0 billion on research & development (18.4% R&D expenses ratio), up ¥12.3 billion (+21%) year on year, mainly to push forward late-stage development of next-generation drugs such as KHK4083. Based on these assumptions, we forecast core operating profit of ¥67.0 billion, up ¥1.3 billion (+2%) year on year, giving a core operating profit margin of 17.6%. By continuing to actively invest in our business in FY2022, we will build a robust GSP business base to support global growth over the medium and long term.

Cash allocation

In our five-year cash allocation plans in the FY2021–2025 Medium Term Business Plan, we assume the source of funds will be new operating cash flow of ¥800 billion or higher (before deduction of R&D expenses) generated during the plan's five years.

Our top priority for cash allocation is R&D, strategic and capital investments to sustain growth beyond FY2025 and to maximize corporate value.

R&D investment

During the FY2021–2025 Medium Term Business Plan, we aim to continue investing heavily in R&D, based on an R&D expenses ratio of 18–20% (R&D investment as a percentage of revenue). In R&D activities, we will channel resources into the development of next-generation strategic products to maximize the value of our pipeline. We also plan to actively invest in areas that support innovation over the long term, such as multi-modality technology platforms that drive the creation of groundbreaking new treatments, aiming to consistently create new products that bring life-changing value to patients.

In FY2021, we invested ¥57.7 billion in R&D, equivalent to 16.4% of revenue. The main area of spending was late-stage development expenses for next-generation products such as ME-401, RTA402 and KHK7791. We also concluded an agreement with Amgen Inc. in June 2021 to jointly develop and commercialize KHK4083, aiming to accelerate and expand the scope of development activities.

Strategic investment

We will actively utilize external resources for strategic partnering (in-licensing, tie-ups, etc.) and M&A to tap external innovation, such as drug discovery technologies created through open innovation and new compounds for our pipeline. We will also target faster, sustained growth by expanding our global pipeline over the medium and long term, generating synergies with existing global strategic products, and increasing opportunities to create unique value. The Strategic Investment Review Committee, which is led by CEO Masashi Miyamoto, meets roughly twice a month to actively discuss potential targets for strategic growth investments.

In FY2021, strategic investments included a €20 million upfront payment for a licensing contract with AM-Pharma B.V. to secure exclusive rights to develop and commercialize Ilofotase Alfa in Japan. We also made an upfront payment to Synaffix B.V. for a licensing contract to use the company's antibody-drug conjugates (ADCs) drug discovery technology. Additionally, we made multiple investments in venture capital funds as a way of increasing rapid access to the latest drug discovery technology and product information.

Capital investment (capex)

We will invest heavily to create a more competitive business structure to help us maximize the value of global strategic products. In particular, we will focus on establishing a robust quality assurance and production system that can reliably supply safe, high-quality pharmaceuticals to patients worldwide. As the Group's operations become increasingly global, we also aim to rapidly establish a global business foundation that supports Kyowa Kirin's sustained growth as a GSP. Specifically, investment will be needed to build a platform that allows us to strategically utilize IT and digital tools and to reinforce global governance and risk management systems.

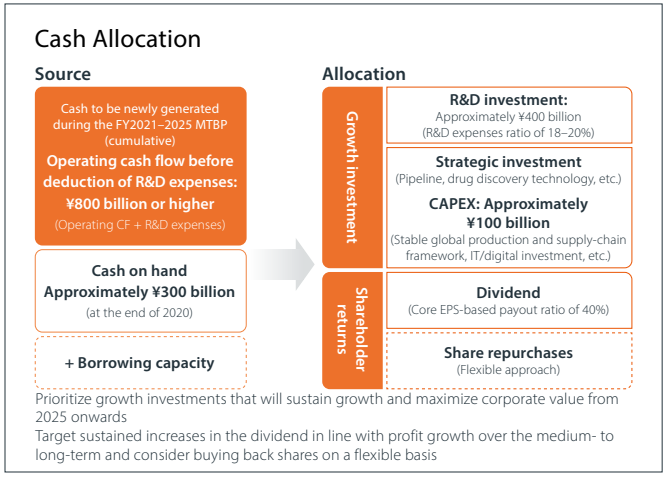
In FY2021, capital investment totaled ¥14.5 billion (including intangible assets and long-term advance payments). Capital investment was mainly used to build and reinforce production systems to ensure the stable supply of global strategic products, and for IT and digital infrastructure to support global ERP and quality assurance systems.

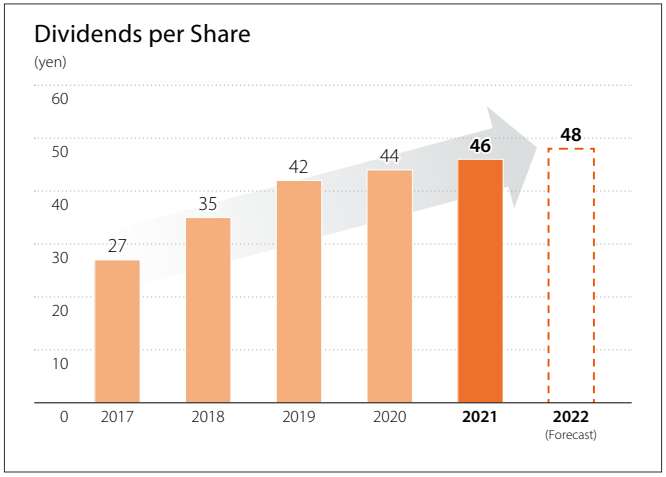
When evaluating the profitability of potential investments or development projects, we mainly use two quantitative standards: net present value (NPV) and expected present value (EPV). Both standards are based on the hurdle rate (by region), which reflects the expected cost of capital (WACC) for investors. In investment decisions, we focus on whether the investment will contribute to an increase in corporate value over the medium- to long-term by generating returns in excess of the cost of capital.

Shareholder returns

In the FY2021–2025 Medium Term Business Plan, we are targeting a consolidated dividend payout ratio of 40% based on core EPS, aiming to steadily increase returns for investors by raising the dividend in line with profit growth over the medium- to long-term. In line with that policy, we paid an FY2021 dividend of ¥46.00 per share (dividend payout ratio of 43.2%), an increase of ¥2.00 from FY2020. In addition, we plan to raise the FY2022 dividend to ¥48.00 (dividend payout ratio 47.9%), which will be the sixth consecutive increase. We will also flexibly consider buying back shares, taking into account the share price and other factors.

To generate sustained growth and maximize corporate value as a Japan-based GSP, we will enhance the Group's growth potential, capability to innovate, and profitability in order to improve ROE over the medium- to long-term and support sustained increases in the dividend.





AT A GLANCE Headline News

June 2021

Concluded an agreement with Amgen, Inc. of the U.S. for the co development and commercialization of KHK4083, a therapeutic drug for atopic dermatitis

See P24 for details.

August 2021

Signed a license agreement with Synaffix for ADC creation technology

See P22 for details.

October 2021

Signed a three-way research collaboration agreement with xFOREST and Axcelead on drug discovery targeting RNA structure

See P22 for details.

November 2021

Received Silver certification in the PRIDE Index 2021, which evaluates LGBTQ-related initiatives

See P43 for details.

November 2021

Announced our endorsement of the Task Force on Climate-related Financial Disclosures (TCFD)

See P37 for details.

December 2021

Participation in STEP, a rare disease information community established by the NPO ASrid

See P29 for details.

December 2021

Expanded collaboration with InveniAI on AI-driven drug discovery

See P22 for details.

December 2021

Formulated the Global DE&I Statement

See P43 for details.

January 2022

Introduced Aqua Premium at Fuji Research Park and CMC Research Center

See P35 for details.

March 2022

Graded as an enterprise with excellent health and productivity under the Certified Health for the first time, and Productivity Management Organization Recognition Program (White 500) for the sixth consecutive year

See P45 for details.

Financial Highlights

POINT

Revenue

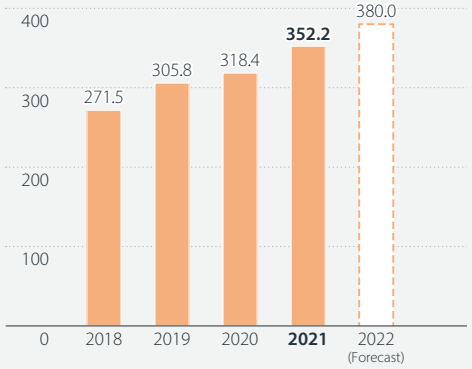
Revenue in Japan declined year on year, reflecting cuts to NHI drug prices for two consecutive years in 2020 and 2021 and the end of co-promotion arrangements for several products in 2020. However, revenue increased overseas, driven by steady growth for global strategic products in EMEA and North America. Technology out-licensing revenue also grew. As a result, revenue increased ¥33.9 billion (+11%) year on year, and the overseas revenue ratio rose six percentage points to 54%.

Core Operating Profit

Selling, general and administrative expenses and research & development expenses both increased year on year, reflecting higher Crysvita profit-sharing expenses in North America, active investment in digital IT platforms and human resources to maximize the value of global strategic products and rapidly establish a global business base, and progress with late-stage development of ME-401, KHK7791 and other products. However, core operating profit increased ¥5.7 billion (+10%) year on year, supported by higher gross profit in line with the rise in revenue and by an increase in share of profit (loss) of investments accounted for using the equity method.

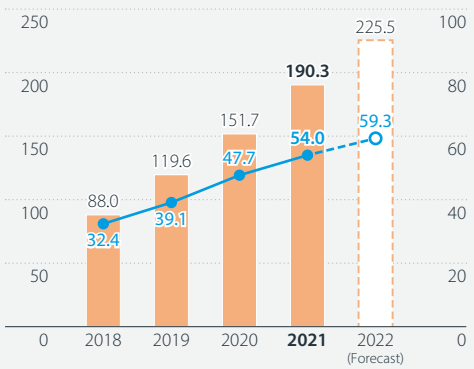
Revenue

(Billions of yen)



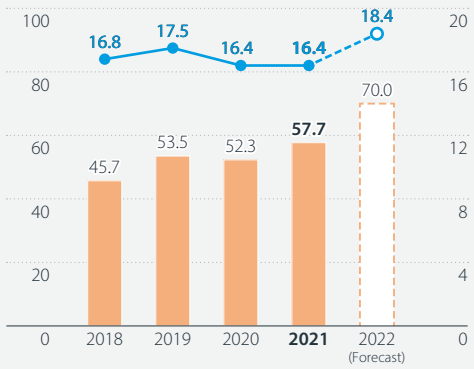
Overseas Revenue/Overseas Revenue Ratio

(Billions of yen) (%)



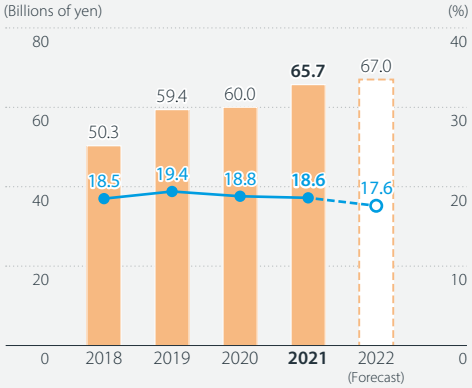
R&D Expenses/R&D Expense Ratio

(Billions of yen) (%)



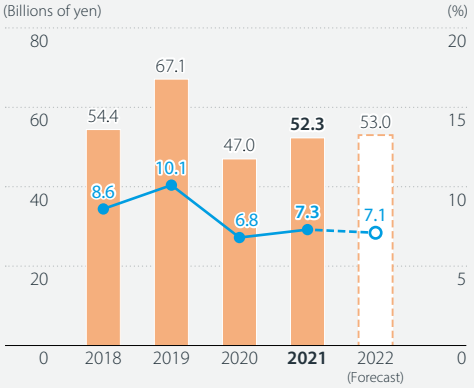
Core Operating Profit/ Core Operating Profit Ratio

(Billions of yen) (%)



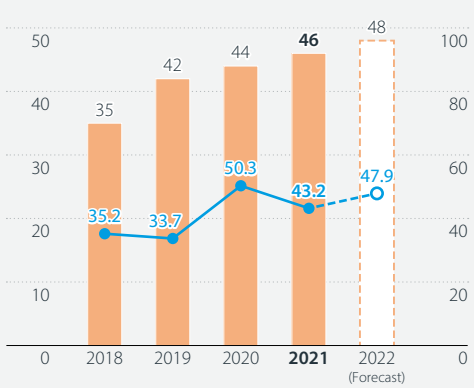
Profit Attributable to Owners of Parent/ Return on Equity (ROE)

(Billions of yen) (%)



Cash Dividends/Payout Ratio*

(Yen) (%)

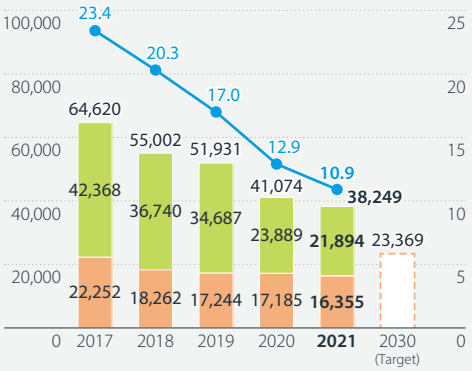


* Dividend payout ratio for 2021 and 2022 are the ratio of dividends to core profit (Profit attributable to owners of parent – Other income and expenses (excluding tax effects)).

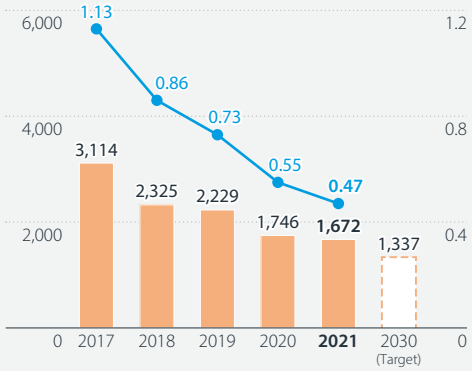
ESG Highlights

Please see ESG Data Collection for details.
https://www.kyowakirin.com/sustainability/esg_data/index.html

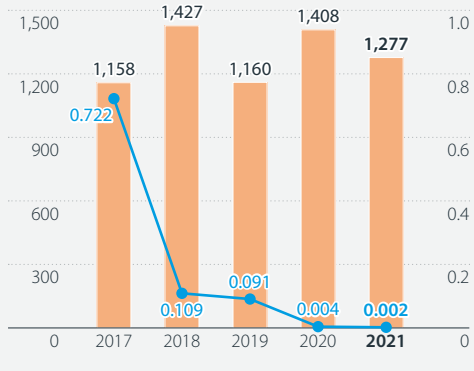
CO_2 Emissions*1



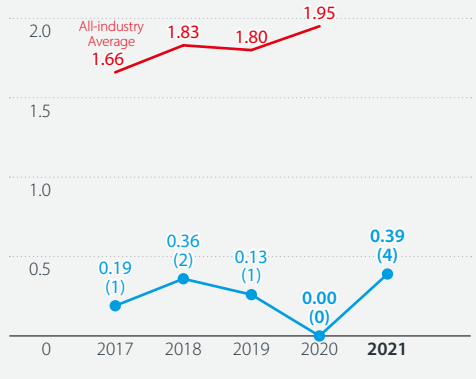
Water Use*1



Waste Generation*2

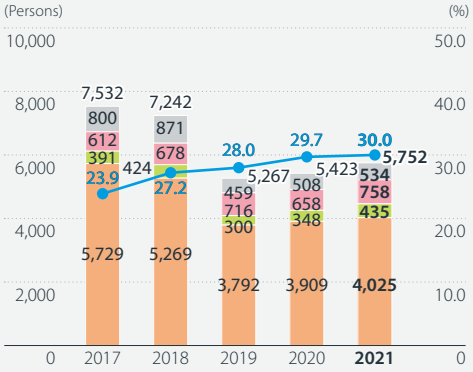


Accident Frequency Rate*3,4

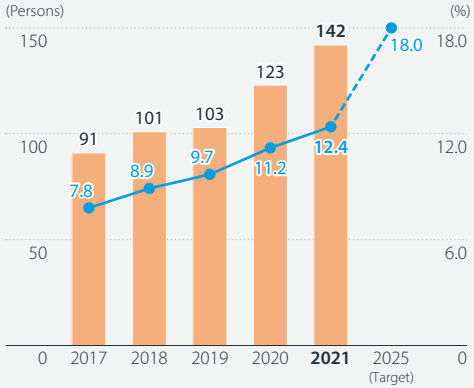


The numbers in parentheses are the number of accidents that required time off from work.

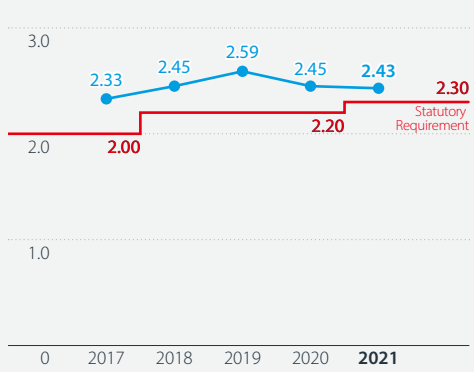
Number of Employees/ Ratio of Overseas Employees



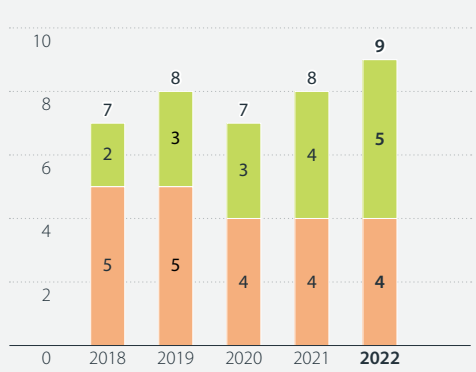
Number of Female Managers/ Ratio of Female Managers*5



Ratio of Workers with Disabilities*6



Number of Directors



*1 Covers plants and research laboratories worldwide.
*2 Covers plants and research laboratories in Japan.
*3 Covers plants/laboratories of Kyowa Kirin/Kyowa Medex/Kyowa Hakko Bio /Kyowa Pharma Chemical until 2018, all locations of Kyowa Kirin in 2019 and 2020, all locations in Japan and overseas plants/laboratories of the Kyowa Kirin group in 2021.
*4 The rates indicate the number of casualties from fatal lost-time accidents per million working hours.
*5 Covers Kyowa Kirin
*6 As of June each year.

Pipeline (As of December 31, 2021)

antibody protein small molecule ◎New Molecular Entity Progress with approvals in Jan–Dec 2021

Nephrology

As of December 31, 2021

Code Name & Generic Name <Formulation>	Mechanism of Action	Indication	Area	Stage	In-House or Licensed
				Ph I / Ph II / Ph III / Filed / Approved	
KHK7580 Evocalcet <Oral>	Calcimimetic	Secondary Hyperparathyroidism	CN/Asia	Ph III	Mitsubishi Tanabe Pharma
◎RTA 402 Bardoxolone Methyl <Oral>	Antioxidant Inflammation Modulator	Alport Syndrome	JP	Filed	Reata
		Diabetic Kidney Disease	JP	Ph III	
		Autosomal Dominant Polycystic Kidney Disease	JP	Ph III	
KW-3357 Antithrombin Gamma <Injection>	Recombinant Human Antithrombin	Preeclampsia	JP	Ph III	In-House
KHK7791 Tenapanor <Oral>	NHE3 Inhibitor	Hyperphosphatemia in Patients on Dialysis	JP	Ph III	Ardelyx

Oncology

KW-0761 Mogamulizumab <Injection>	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	CH/SA/AU	Approved	In-House
			KR	Approved	
			CN/CA/KW	Filed	
KRN125 Pegfilgrastim <Injection>	Long-Acting Granulocyte Colony-Stimulating Factor	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogeneic Blood Stem Cell Transplantation	JP	Filed	Amgen-KA
		Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	JP	Ph II	
		Automated Injection Device for Decreasing the Incidence of Febrile Neutropenia in Patients Receiving Cancer Chemotherapy	JP	Filed	
◎KHK2455 <Oral>	IDO1 Inhibitor	Solid Tumor	NA	Ph I	In-House
		Urothelial carcinoma	NA	Ph I	
			Europe	Ph I	
◎ME-401 Zandelisib <Oral>	PI3Kδ Inhibitor	Follicular Lymphoma and Marginal Zone Lymphoma	JP/NA/Europe/Asia/Oceania/Others	Ph III	MEI Pharma
		Follicular Lymphoma	NA/Europe/Asia/Oceania	Ph II	
		Marginal Zone Lymphoma		Ph II	
		Indolent B-cell Non-Hodgkin's Lymphoma	JP	Ph II	
		B-cell malignancies	JP	Ph I	

Glossary	
Phase I Clinical Trial	Studies in small numbers of healthy people (patients in some cases) to verify safety issues including side effects.
Phase II Clinical Trial	Studies in small numbers of patients to verify effective and safe dosage and regimen.
Phase III Clinical Trial	Studies in large numbers of patients to confirm efficacy and safety in comparison with standard drugs or placebo.

* All trials are conducted under supervision of clinical doctors and with the consent of participants.

Immunology/Allergy

As of December 31, 2021

Code Name & Generic Name <Formulation>	Mechanism of Action	Indication	Area	Stage					In-House or Licensed
				Ph I	Ph II	Ph III	Filed	Approved	
KHK4827 Brodalumab <Injection>	Anti-IL-17 Receptor A Fully Human Antibody	Ankylosing Spondylitis	TW/MY						Amgen-KA
		Ankylosing Spondylitis, non-radiographic axial spondyloarthritis	TL						
		Systemic Sclerosis	JP						
		Palmoplantar Pustulosis	JP						
◎KHK4083/AMG 451 Rocatinlimab <Injection>	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	JP/NA/Europe						In-House

Central Nervous System

KW-6002 Istradefylline <Oral>	Adenosine A_{2A} Receptor Antagonist	Parkinson's Disease	Europe						In-House
◎KW-6356 <Oral>	Adenosine A_{2A} Receptor Antagonist/Inverse Agonist	Parkinson's Disease	JP						In-House
◎KHK6640 <Injection>	Anti-Amyloid Beta Peptide Antibody	Alzheimer's Disease	JP/Europe						Immunas Pharma

Other

KRN23 Burosumab <Injection>	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	CN/BH/SA/SG/AU						In-House
			TL/MY						
		Tumor Induced Osteomalacia (TIO)	IS/CA						
			CN						
			Europe						
AMG531 Romiplostim <Injection>	Thrombopoietin Receptor Agonist	Treatment of Aplastic anemia (AA) which is refractory to immunosuppressive therapy or immunosuppressive therapy being not suitable	KR						Amgen-KA
		Treatment of adult aplastic anemia refractory to conventional therapies	MY/SG						
		Treatment of adult patients with chronic immune thrombocytopenia (ITP) who are refractory to other treatments and Treatment of adult patients with aplastic anemia who are refractory to conventional therapy	TL						
		Immune Thrombocytopenia (ITP)	CN						
		Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	JP/Asia				Ph II/Ph III		
KW-3357 Antithrombin Gamma <Injection>	Recombinant Human Antithrombin	Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Europe						In-House
KHK4951		Wet Age-Related Macular Degeneration	JP						In-House

Value Creation Strategies

Providing pharmaceuticals for unmet medical needs

Our mission is to develop new medicines for patients with autoimmune and inflammatory diseases. I work diligently with everyone in the Kyowa Kirin US Research team and through collaboration with the Kyowa Kirin US Open Innovation Group to identify and evaluate novel therapeutic targets for our drug discovery pipeline. Importantly, we also incorporate innovative technologies into our drug discovery efforts to continuously demonstrate the competitive edge of the new therapeutics that we are developing.

Ava Song, Ph.D.
Associate Director, Research
Kyowa Kirin, Inc.

Amid constant change in the pharmaceutical sector, our job is to find ways of translating the latest life sciences research into life-changing value – or as we like to say, smiles for patients. We are combining Kyowa Kirin's strengths in drug discovery technology and disease research with recent advances in AI and digital tools, while also constantly exploring, innovating and seeking out new challenges to create groundbreaking new drugs.

Hayato Yabuuchi
Senior Scientist, Research Core Function Laboratories,
Research Unit, Kyowa Kirin Co., Ltd.

The environment around pharmaceutical research is changing at a breathtaking pace. To ensure we continue to create new value that patients really need, Kyowa Kirin employees have to constantly change as well. We are contributing to Kyowa Kirin's research activities – and the smiles of patients – by building systems that respond to changes in the environment and by providing proactive support to help employees transform themselves.

Yumi Ota
Tokyo Research Park, Kyowa Kirin Co., Ltd.

Value Creation Strategies

Three Global Strategic Products

Kyowa Kirin sells three pharmaceutical products – Crysvita, Poteligeo and Nouriast/Nourianz – that are helping to bring smiles to people battling disease worldwide. Based on our Group Policy for Access to Medicines, we are working to increase access to pharmaceutical products across the value chain in order to deliver our life-changing value to as many patients as possible, while also supporting Kyowa Kirin's growth as a Global Specialty Pharmaceutical Company.

Crysvita

(Burosumab – anti-FGF23 fully human monoclonal antibody)

X-linked hypophosphatemia (XLH) and tumor-induced osteomalacia (TIO)

CRYSVITA® burosumab

Crysvita is a therapeutic antibody developed by Kyowa Kirin for the treatment of X-linked hypophosphatemia (XLH) and tumor-induced osteomalacia (TIO). XLH is a rare genetic condition that causes abnormalities in phosphate homeostasis. People with XLH have a genetic defect on the X-chromosome, which causes excessive loss of phosphate through the urine and poor absorption from the gut due to over-production of a hormone known as fibroblast growth factor-23 (FGF23), resulting in low levels of phosphate in the blood. The condition is estimated to occur in one in 20,000 people. In children with XLH, chronic hypophosphatemia causes bone deformity and stunted growth, while adults with XLH suffer from walking difficulties due to lower limb deformity, as well as bone and joint pain, muscle weakness and dental issues, leading to a material decline in patient QOL. Unlike XLH, TIO is not a genetic disorder. TIO arises from causal tumors that produce excess levels of FGF23. The symptoms rapidly resolve if the causal tumors can be resected, but there are cases in which the tumors are not detected or resection is not feasible.

The only previously available treatment consists of oral phosphate and/or vitamin D replacement. However, patients typically have to take medication 4-5 times per day and the benefits of treatment must be balanced against the risk of side-effects such as nephrocalcinosis and hyperparathyroidism. Crysvita is a recombinant fully human monoclonal IgG1 antibody against FGF23. Biweekly or monthly injections of Crysvita block excess FGF23, recovering reabsorption of phosphate in the kidneys in patients with XLH and TIO. Crysvita also increases production of vitamin D, which improves intestinal absorption of phosphate and reabsorption of phosphate in the kidneys, helping to boost serum levels of phosphorus.

Clinical development of Crysvita, which started in the US in 2006, initially faced the problem of low numbers of people with the condition. However, development rapidly accelerated from 2013 when we teamed up with Ultragenyx Pharmaceutical Inc., giving us access to the company's extensive experience and networks in the field of rare diseases. After further work, Crysvita launched in the US and Europe in 2018 and in Japan in 2020.

Crysvita was developed to treat a rare condition, so epidemiological data is lacking and some patients are not properly diagnosed or even receive treatment. We will continue to maximize the value of our product through activities to raise awareness among patients, their families and medical professionals, and by talking directly with patients in order to identify and help address their unmet medical needs.

As of the end of 2021, Crysvita was sold in 35 countries and regions, contributing to improvements in QOL for around 4,000 patients worldwide. Global revenue in 2021 totaled ¥85.5 billion and we are aiming to increase that to ¥115.2 billion in 2022. We plan to expand sales of Crysvita to more than 50 countries and regions by 2025.

Poteligeo

(Mogamulizumab – anti-CCR4 humanized antibody)

ATL, PTCL and CTCL

POTELIGEO® (mogamulizumab)

Poteligeo is Kyowa Kirin's first therapeutic antibody to receive manufacturing and marketing approval and was the first drug worldwide to be produced using our proprietary antibody-enhancing POTELLIGENT platform. In Japan, the drug received approval for the treatment of adult T-cell leukemia-lymphoma (ATL) in 2012, followed by additional indications for peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) in 2014. After undergoing successful global clinical trials run by Kyowa Kirin, Poteligeo received manufacturing and marketing approval from regulatory authorities in several countries, launching in the US in 2018 and in Europe in 2020 for the treatment of mycosis fungoides and Sézary syndrome, the two most common subtypes of CTCL.

The discovery of anti-CD20 antibodies for the treatment of B-cell lymphomas led to much excitement in the oncology field in the late 1990s, but research into ATL and other T-cell lymphomas with low prevalence rates lost ground in the US and Europe. However, we continued to focus on developing antibodies directed against CC chemokine receptor 4 (CCR4), ultimately leading to the creation of our anti-CCR4 antibody Poteligeo with the POTELLIGENT platform. Through further joint research with senior associates at external research centers and medical institutions, we subsequently identified CCR4 expressed in ATL and other T-cell lymphomas, and as a consequence, clinical implications and treatment potential. Poteligeo is now on sale in 13 countries worldwide (as of end-2021), with more markets in the pipeline. Global revenue in 2021 was ¥17.3 billion and we are targeting ¥24.5 billion in 2022.

Nouriast/Nourianz

(Istradefylline – adenosine A_{2A} receptor antagonist)

Parkinson's disease (PD) experiencing "off" episode

NOURIANZ® (istradefylline) tablets

Nouriast/Nourianz is a Kyowa Kirin-developed world-first small molecule drug with a selective adenosine A_{2A} receptor antagonist mechanism. Launched in Japan in 2013 and the US in 2019, the drug was approved for the indication of improving wearing-off phenomena in Parkinson's disease patients receiving treatment with levodopa.

Parkinson's disease is a progressive neurodegenerative disease characterized by motor symptoms such as slow movement, rigidity, tremors and postural reflex disorders. The cause is progressive degeneration associated with decreased levels of dopamine in certain parts of the brain, namely the substantia nigra and striatum. Since dopamine deficiency causes Parkinson's disease, the symptoms can be improved by increasing dopamine levels in the brain. However, over time, the efficacy of this treatment declines and patients start to experience "wearing-off" phenomena several hours after the dopamine is administered.

Adenosine A_{2A} receptors are one of the receptors of adenosine, a substance widely distributed in the human body. In the brain, adenosine A_{2A} receptors are considered to be present specifically in the basal ganglia, of which degeneration or abnormality is noted in Parkinson's disease. The basal ganglia are known to play an important role in motor control. Nouriast/Nourianz has been found to be effective in alleviating wearing-off phenomena by blocking adenosine A_{2A} receptors in the brain. As the world's only adenosine A_{2A} receptor antagonist, Nouriast/Nourianz is helping Parkinson's disease patients manage their condition.

Revenue in Japan and the US in 2021 totaled ¥13.2 billion and we are targeting ¥15.0 billion in 2022.

Value Creation Strategies

Striving to create life-changing "Only-one value" that brings smiles to patients

Guided by the key phrase – "Provide "Only-one value" to Patients. This is our Dream," Kyowa Kirin's R&D Division continues to take on a wide range of challenges with the aim of bringing smiles to people battling with medical conditions. We are harnessing the power of our diverse team of researchers with a passion for innovation to create unique, life-changing value.

The R&D Division is also working to foster "Our R&D Spirits" – our vision for what each person in the global R&D organization should be and wants to be, based on the Core Values of the Kyowa Kirin Group. By promoting the vision, we aim to motivate employees to take on new challenges while respecting independent thought and actions.

A new R&D organization – Bringing together technology, disease research and open innovation –

In April 2021, we opened a new Research Unit to combine previously fragmented research teams. The aim is to promote more dynamic, closer cooperation between technology research, disease research and open innovation. This integrated approach is allowing us to pursue synergies and allocate resources more appropriately within the unit, while also enabling comprehensive management of all research activities. The unit is working with our research base in San Diego in the US to foster much deeper collaboration, such as actively dispatching researchers from Japan, in order to realize global network-based drug discovery activities. We also continue to work closely with the La Jolla Institute for Immunology, also based in San Diego, as part of broader efforts to expand the product pipeline at the research stage.

The unit will continue to maintain Kyowa Kirin's existing strengths in disease intelligence and its internal and external networks, while also advancing what we call technology-driven drug discovery through open innovation and collaboration with multiple external domestic and overseas R&D facilities, as well as our own R&D sites in Japan and the US, to establish new modality technologies and build a unique pipeline by harnessing those technologies.

Working to creating new value – Groundbreaking drug discovery technologies that harness advances in science –

Kyowa Kirin is driving technology-driven drug discovery by pursuing its own unique technologies and combining them with the latest advances in science and new technologies born from open innovation.

In next-generation antibody treatments, we are using proprietary bispecific antibodies to create new antibody drugs, aiming to create first-in-class treatments that bring together technology and biology. In 2021, a number of bispecific antibodies in our pipeline moved smoothly into the preclinical stage and we made good progress with several late-discovery pipeline themes. Also, leveraging our strengths in proprietary antibody research, we continue to work on the development of advanced antibody-drug conjugates (ADCs). In August 2021, we concluded a licensing agreement with Synaffix B.V. to use its cutting-edge proprietary ADC discovery technology platform, allowing us to accelerate the targeted development of ADCs for specific conditions. While our ADC pipeline is currently in the preclinical stage, we are working to strengthen the Group's R&D pipeline by creating multiple groundbreaking therapeutic candidates, including in the late-discovery phase.

In recent years, **the nucleic acid drug field** has seen tremendous advances with the launch of new drugs based on antisense oligonucleotides (ASO) or small interfering RNA (siRNA), and the commercialization of messenger ribonucleic acid (mRNA) vaccines to prevent COVID-19. Utilizing chemical synthesis technologies backed by our track record in nucleic acid research, we are developing proprietary protein expression transport technology. Our aim is to derive new value from the unique characteristics of nucleic acid drugs by using the technology to sustain levels of protein expression to treat and prevent various conditions.

In small molecule drugs, we are building a more dynamic and competitive drug discovery technology platform by effectively combining our novel drug discovery technologies with the extensive technologies and expertise of Axcelead Drug Discovery Partners Inc. in small molecule drug discovery. We aim to overcome the barriers of existing small molecule drugs to access previously unreachable drug discovery targets. In addition, xFOREST Therapeutics Co., Ltd. joined Kyowa Kirin and Axcelead in 2021 to work on drug discovery research targeting RNA structures. xFOREST is providing its proprietary FOREST technologies, a suite of large-scale parallel analysis platforms, to promote novel small-molecule drug discovery research for RNA structures.

Meanwhile, in the field of **AI drug discovery**, we are using AI to accelerate the cycle of discovery from hypothesis proposal to concept verification. Working with InveniAI LLC, our AI technology partner since 2018, we continue to work on identifying novel targets for our next-generation antibody technology and explore new disease applications. We also expanded our longstanding relationship with InveniAI in December 2021 with a new joint research agreement to use its AI technologies in drug discovery across multiple therapeutic areas. By combining InveniAI's strengths in the digital field with our technologies and by deepening ties between our respective research teams, we aim to create a new generation of innovative drug candidates.

Synaffix connect to cure
AXCELEAD Drug Discovery Partners
xFOREST Therapeutics
InveniAI Innovate with Intelligence

Value Creation Strategies

Tackling unique research themes unhindered by existing thinking

The R&D Division is working to generate patient-centric life-changing value with clear competitive advantages by building mechanisms to create a research pipeline in therapeutic areas where there are no effective treatments, backed by groundbreaking core technologies and multiple modalities. As part of efforts to drive advances in technology by combining modalities and to generate value that goes beyond pharmaceuticals, we have also launched a new scheme to seek research theme ideas from inside the Company. The aim is to identify innovative Kyowa Kirin-inspired research themes focused on life-changing value, unhindered by existing thinking and approaches.

Cultivating personnel who embody "Our R&D Spirits"

We have formulated Personnel Management Policy in R&D, a shared policy for the R&D Division to realize the objectives of "Our R&D Spirits." The policy clearly defines the roles every employee needs to fulfill in the R&D Division for all job-types and teams, whether research, engineering or development. We have also established an awards system to encourage actions and share approaches that embody "Our R&D Spirits." The five awards, which all bear the "Our R&D Spirits" motto, are "Be the Best in Science Award," "Passion for Innovation Award," "Challenge Award," "Teamwork Award," and the "Grand Prize." We will add a new award from 2022, "Our R&D Spirits Special Award," to recognize employees who take on bold challenges without fear of failure. The aim is to foster an organizational culture that is even more conducive to tackling new challenges.

Multiple research groups have received the "Be the Best in Science Award" for creating new technologies and using them in pipeline drug discovery.

Kyowa Kirin will continue to boldly create life-changing "Only-one value" without fear of failure to bring smiles to people battling medical conditions. Building on the success of our global strategic products, as well as next-generation strategic products in our pipeline, we will step up R&D efforts to rapidly deliver new life-changing value to as many patients as possible worldwide.

R&D concepts

Technology

Continue to evolve our antibody technology, while also pursuing the possibilities of diverse modalities and building a platform that leads to innovative new therapies

Disease Biology

Continue to provide "Only-one value drug" for unmet medical needs, while utilizing the disease science* cultivated to date within Kyowa Kirin

* Nephrology, Oncology, Immunology & allergy and CNS

Create Life-changing value with clear competitive advantages

Open Innovation (OI)

Continue to work on collaborative research activities with academia, startups and other partners, combine with rapid access to information gained from investment in VC/CVC funds, and tap into external innovation through advanced OI activities

Value Creation Strategies

Next-Generation Strategic Products

The five development pipeline drugs introduced in this section are designated as "next-generation strategic products." These drugs are part of Kyowa Kirin's tireless efforts to continue creating life-changing value and increase the Group's corporate value over the medium and long term.

KHK4083/AMG 451 (rocatinlimab)

Plans for 2022: • Initiate Ph3 program

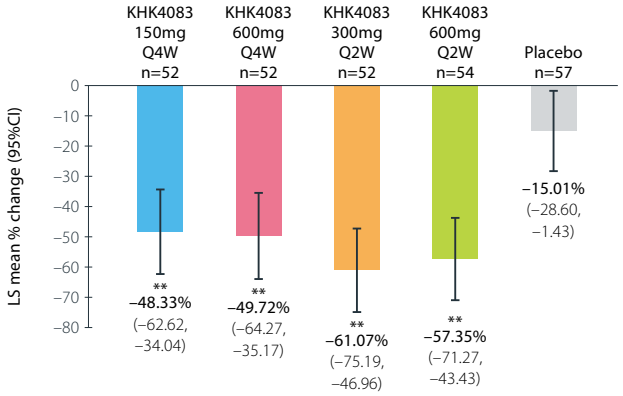
KHK4083/AMG 451 is an anti OX40 fully human monoclonal antibody created by Kyowa Kirin in collaboration with the U.S. La Jolla Institute for Immunology.

Activated T cells express OX40, OX40 expression has also been reported in lesions of atopic dermatitis, suggesting that they may play key roles in the pathogenesis of the disease. KHK4083/AMG 451 is expected to treat the condition of atopic dermatitis by inhibition of activated OX40 expressing T cells and reduces their number.

In a global Phase 2b clinical trial conducted in patients with moderate to severe atopic dermatitis, KHK4083/AMG 451 group showed statistically significant improvement over the placebo-treated group in assessing clinical symptoms using EASI score, vIGA™ score and pruritus NRS score. In addition, the clinical efficacy indicators continue to improve after week 16. Adverse events reported were mainly mild to moderate in intensity.

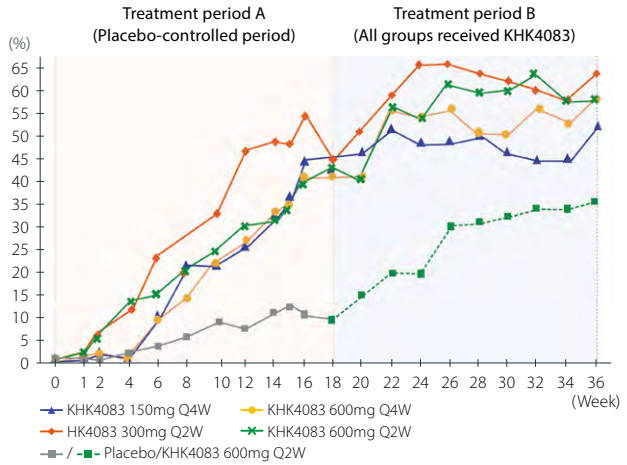
In June 2021, we signed an agreement with U.S. Amgen Inc, a world-class biotech company with extensive experience in developing and marketing products targeted for inflammatory diseases, to jointly develop and commercialize KHK4083/AMG 451, aiming to maximize the product value. Upfront payments of $400 million were received in conjunction with the contract of the agreement, and in the future we will receive milestone payments (up to $850 million) based on the progress of development and sales, and royalties based on sales performance.

Ph2b Primary Endpoint: % change from baseline in EASI score at W16 (Last Observation Carried Forward, Full Analysis Set)



EASI, Eczema Area and Severity Index; Q2W, every 2 weeks; Q4W, every 4 weeks
** p<0.001 for difference versus placebo

Ph2b Secondary Endpoint: EASI-75 Responder Proportion



EASI-75: EASI score of 75% or greater improvement from baseline

Overview of development, sales and other criteria

	US	Europe and Asia (ex. JP)	JP
Development	• Amgen leads development • Share development cost	• Amgen leads development • Share development cost	• Kyowa Kirin leads development
Commercialization	• Amgen commercializes and books sales • Kyowa Kirin co-promotes and shares promotion cost	• Amgen commercializes and books sales • Kyowa Kirin has opt-in rights for co-promotion	• Kyowa Kirin commercializes and books sales
Sales royalties	• Double-digit royalty to Kyowa Kirin	• Double-digit royalty to Kyowa Kirin	
Commercial supply	• Amgen supplies	• Amgen supplies	• Kyowa Kirin supplies

Value Creation Strategies

ME-401 (zandelisib)

Plans for 2022:
- Present detailed FL cohort data from TIDAL study at medical conferences
- Acquire topline data from Phase 2 study for indolent B-cell non-Hodgkin's lymphoma in Japan

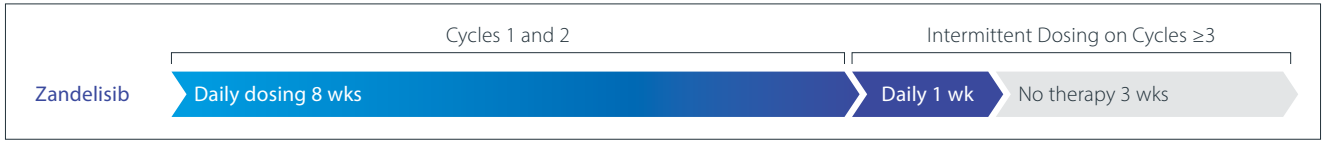
ME-401 is a selective phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor under co-development with MEI Pharma, Inc. of the US as an oral treatment for patients with B-cell malignancies. PI3K is a family of phosphorylated enzymes involved in cellular functions such as cell metabolism, proliferation and survival, and are recognized as part of the PI3K/Akt signaling pathway, which is commonly involved in the activation of cancer cells. PI3K has multiple isoforms, with the δ isoform essential to normal B-cell activation, proliferation and survival. Increased expression of PI3Kδ has been observed in many B-cell malignancies. ME-401 is a selective PI3Kδ inhibitor, raising expectations that it can be effective in limiting the proliferation of malignant B-cells.

ME-401 has also shown prolonged accumulation at tumor tissue due to high affinity characteristics with PI3Kδ, as well as a high volume of distribution throughout the body tissues. Through the use of unique dosing regimens that leverage these distinctive properties, ME-401 has the potential to become a treatment with highly balanced efficacy and safety. The US Federal Drug Administration (FDA) has granted ME-401 Fast Track and Orphan Drug rare disorder designation for the treatment of patients with relapsed or refractory (R/R) follicular lymphoma (FL).

In 2021, in the global Phase 2 TIDAL study evaluating ME-401 as monotherapy across two study cohorts – the first for R/R FL and the second for R/R marginal zone lymphoma (MZL), in both patients after at least two prior systemic therapies – the primary endpoint of the study for the FL cohort was achieved. The TIDAL study is continuing in order to gain follow-up data on safety and duration of response in the FL cohort, and for further study of the MZL cohort.

Other studies are also being conducted. The Phase 3 COASTAL study is evaluating ME-401 plus rituximab in comparison to the standard of care chemotherapy plus rituximab in patients with R/R FL or MZL who received at least one prior line of therapy. Another Phase 2 study in Japan is evaluating ME-401 in patients with indolent B-cell non-Hodgkin's lymphoma without small lymphocytic lymphoma, lymphoplasmacytic lymphoma and Waldenström's macroglobulinemia, a global Phase 1 study is looking at the effectiveness of combination treatment with zanubrutinib, and a global Phase 2 study is evaluating ME-401 as a combination treatment with rituximab and venetoclax for chronic lymphocytic leukemia. We will continue to push ahead with this development to maximize the value of ME-401.

Zandelisib Global Ph^2 TIDAL Study Topline Data (Follicular lymphoma cohort)



Overall Response Rate (ORR)
95% CI (59.8, 79.5)
70.3%

Complete Response Rate (CR)
95% CI (25.4, 45.9)
35.2%

Duration of Response
Insufficiently mature to estimate final DOR: with median follow-up time for response of 8.4 months, median DOR had not been reached
N=91 in the primary efficacy population for the evaluation of ORR and DOR.

Discontinuation Rate Due to Any Drug Related Adverse Event
9.9%

Adverse Events of Special Interest (Grade ≥3)
1.7% ALT/AST Elevation
5.0% Diarrhea
0.8% Pneumonitis
1.7% Colitis
2.5% Mucositis
3.3% Rash
≤ 5% each

Median Follow-up of 9.4 Months (0.8–24)
N=121 in the total study population for the evaluation of safety.

Note: ORR assessed by IRC after a minimum follow-up of 6 months and represents the primary endpoint of the TIDAL study. Safety and duration of response data are as of the data cutoff date; the data cutoff date is approximately 6 months after the last patient in the primary efficacy population received their first dose of zandelisib. With exception of the ORR and CR data reported in the primary follicular lymphoma efficacy population of 91 patients, the data provides an initial look at the data as of the data cutoff date and is interim and subject to change as more patient data become available. Because this data is from an ongoing study, the final data may differ materially from this data.

Value Creation Strategies

KW-6356

Plans for 2022: • Begin Phase 3 study

KW-6356 is a small-molecule adenosine A_{2A} receptor antagonist / inverse agonist developed by Kyowa Kirin. Like istradefylline (KW-6002), our existing Parkinson's disease treatment sold in Japan and the US as Nouriast and Nourianz, respectively, KW-6356 targets adenosine A_{2A} receptors.

Parkinson's disease is a progressive neurodegenerative disease characterized by motor symptoms such as bradykinesia, rigidity, tremor and postural instability related to the decreasing of dopamine concentrations in the substantia nigra and striatum. Since dopamine deficiency causes Parkinson's disease, Levodopa-containing medications can improve the symptoms by increasing the dopamine concentrations in the brain. However, over time, the efficacy of these therapies declines and patients start to experience "wearing-off" phenomena several hours after these therapies are administered.

Adenosine is a substance widely present in the human body. Adenosine A_{2A} receptors are one of the receptors of adenosine, and are specifically present in the basal ganglia. Parkinson's disease is known as the disease of the basal ganglia, which plays an important role in motor control. It is reported that the expression of Adenosine A_{2A} receptors on the basal ganglia is increased in Parkinson's disease, and considered to influence on the motor control. Istradefylline helps to alleviate wearing-off phenomena by blocking adenosine A_{2A} receptors in the brain.

KW-6356 has shown higher affinity and selectivity for adenosine A_{2A} receptors than istradefylline and acts as both a receptor antagonist and inverse agonist, raising expectations that the drug can be used for broader patients as the next generation of istradefylline.

Two studies have been completed so far – a Phase 2a study in Japan evaluating treatment in patients with early stage Parkinson' disease patient who has not received PD medication and a Phase 2b study in Japan with Parkinson's disease patients who are on treatment with levodopa-containing therapy. Efficacy and tolerability were confirmed in both studies.

RTA 402 (bardoxolone methyl)

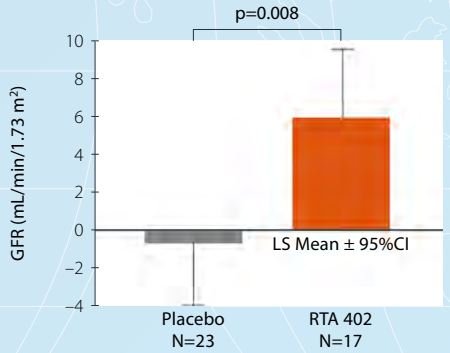
Plans for 2022: • Complete final patient monitoring for Phase 3 AYAME study (last patient out/LPO)

RTA 402 is a small-molecular compound licensed from Reata Pharmaceuticals, Inc. (US). It is expected that RTA 402 could improve kidney function, by activating nuclear factor erythroid 2-related factor 2 (Nrf2), a transcription factor that has a key role in the body's protective response to stress.

In the phase 2 clinical study in patients with Diabetic Kidney Disease conducted in Japan (TSUBAKI), administration of RTA 402 resulted in a significant improvement in glomerular filtration rate (GFR*) measured using the inulin clearance method, in addition to the estimated GFR. The results of TSUBAKI were well received and prompted the Japanese Ministry of Health, Labour and Welfare to grant priority review and designation system (SAKIGAKE designation) to RTA 402 for treatment of Diabetic Kidney Disease.

In Japan, regulatory authority review of NDA for Alport Syndrome, the phase 3 study in patients with Diabetic Kidney Disease (AYAME) and the phase 3 study in patients with Autosomal Dominant Polycystic Kidney Disease (FALCON) are currently ongoing.

* GFR is the volume of urine processed by the kidneys per minute. While the estimated GFR (eGFR) based on the serum creatinine level is widely used to assess kidney function in clinical practice, GFR based on the inulin clearance method is used when more accurate readings are required, such as to evaluate the suitability of a kidney donor. The international standardized approach for measuring GFR using the inulin clearance method involves continuous infusion of 1% inulin saline solution and measuring inulin levels in the urine and blood three times in a period of 30 minutes to gain average clearance values.



KHK7791 (tenapanor hydrochloride)

Plans for 2022: • Submit application for manufacturing and marketing approval to PMDA

KHK7791 is a selective sodium-hydrogen exchanger 3 (NHE3) inhibitor licensed from US company Ardelyx, Inc.

NHE3 is a protein found in the membranes of intestinal epithelia cells and regulates the exchange of sodium ions and protons in cells. By blocking the movement of NHE3, KHK7791 increases the concentration of protons within the cell. The increase in proton concentration causes a reduction in phosphate uptake by tight junctions that regulate phosphate absorption in the GI tract, helping to control the body's absorption of phosphate.

In a Phase 3 study in Japan evaluating efficacy and safety in hyperphosphatemia patients on hemodialysis in Japan, KHK7791 met its primary efficacy endpoint of a change in baseline serum phosphorous levels at week eight from the start of the drug administration, showing a statistically significant decrease in serum phosphorous levels relative to the placebo cohort.

We plan to begin pharmaceutical application procedures after receiving all the clinical data from three other Phase 3 studies – phosphate binder-combination parallel-group comparative study in hyperphosphatemia patients under maintenance dialysis, long-term phosphate binder switch study, and hyperphosphatemia patients on peritoneal dialysis study.

Value Creation Strategies

Address patient-centric healthcare needs

The drugs that pharmaceutical companies create can offer broad value for patients beyond just treating disease. (For example, they lead to time savings, labor productivity, hope, and next-generation innovation). Patients can speak to these values. We will listen to patients and make sure that their voices are heard properly—not only within our company but also more broadly by society as a whole. That is how we can continue helping to bring more smiles to people living with disease.

Yoshimi Gibbs
Manager, Patient Advocacy, PR Group, Corporate Communications
Kyowa Kirin Co., Ltd.

Our support has helped advocacy groups sustain and adapt their patient education programs throughout the pandemic, and it has opened new discussions and dialogues with the community about what is optimal care for a disease. Together with the other regions, we've also been working to build internal capabilities aligned with Kyowa Kirin's global mission – providing a new roadmap for consulting patients in Research, Development, and Commercialization. Understanding how we can involve patients in our work is important for everyone across the Company, no matter what title they hold. It both provides opportunities to increase the value of our medicines and also gives meaning to what we do.

Lauren Walrath
Vice President, Public Affairs
Kyowa Kirin, Inc.

Patients are the reason we go to work every day, they can keep us true to our purpose. It is my objective to connect the XLH patient communities across the borders, so that their voice can be amplified and they can also seek support from each other.

Natasha Lin
Manager, Patient Advocacy, Medical Affairs
Kyowa Kirin Asia Pacific Pte. Ltd.

Value Creation Strategies

Initiatives for Patients

How Support of Patient Advocacy Groups Benefits Patients and Caregivers

Kyowa Kirin is proud to provide support that helps to sustain disease awareness and education programs valued by patients and their families, and to collaborate on new research that brings a better understanding of their needs and experiences.

Through this work, we also gain important insights that inform our drug development and commercialization priorities.

This ensures a more patient-centric approach to decision-making.

X-linked hypophosphataemia (XLH)

Raising awareness of XLH

EMEA

Kyowa Kirin, whose EMEA regional office is based in the UK, has engaged in dialogue with XLH UK, a UK-based Patient Advocacy Group (PAG) for the rare disease XLH. Through this dialogue, Kyowa Kirin learned about the lack of early access to appropriate medical treatment for XLH due to a low level of awareness. As a first step toward improving this situation, we partnered with XLH UK to arrange an opportunity for PAGs from several countries to meet in 2018. This involved gathering PAG representatives from 12 countries around the world to start discussions about establishing an international PAG for XLH. The purpose of establishing this international PAG is to establish global interdisciplinary standards for treatment and research—something that cannot be achieved by one PAG acting by itself. Such standards will ensure that all patients can receive the same level of disease management. With this goal in mind, the International XLH Alliance was founded in 2019 by PAGs from different countries. The International XLH Alliance exhibited a booth at the International Conference on Children's Bone Health in Austria and began its activities as an international PAG. In 2020, the International XLH Alliance and Kyowa Kirin jointly published a white paper entitled "The unrecognized burden of XLH in adults." This highlighted the lack of ongoing specialist care or broad professional involvement for adults with XLH, due to low awareness of the impact that XLH has during adult life.

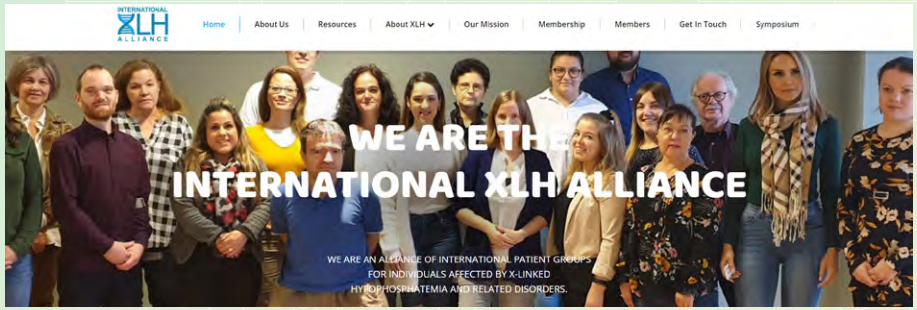
We are continuing our dialogue with the International XLH Alliance. As part of this, we are discussing the development of a medical genealogy tool to reduce the number of XLH patients who are not diagnosed early or properly diagnosed.

APAC

Networking of patient support groups is important for ensuring that the voices of patients with rare diseases can be heard. However, many countries in the APAC region only have PAGs for rare diseases, rather than dedicated PAGs. Drawing from our experience in Europe, on October 23*1 last year we organized the Asia Pacific XLH Patient Networking Meeting on World XLH Day. The conference was attended by 20 participants, including XLH patients, caregivers, and PAG representatives from seven countries and regions. It provided an opportunity to network, share the patient journey*2 of XLH patients, and promote best practices for raising awareness of XLH. This networking group will continue to conduct various activities to raise awareness of the XLH disease.

*1 The date of 10/23 was chosen because 10 is written as X in Roman numerals and 23 refers to from FGF23, a hormone involved in the development of XLH.

*2 The process a patient undergoes—including their behavior, thoughts, and feelings—from recognizing a change in their physical condition to undergoing treatment at a hospital or with medication to when their symptoms and quality of life change.



International XLH Alliance website
https://xlhalliance.org/

Asia Pacific XLH Patient Networking Meeting held on World XLH Day

Value Creation Strategies

Japan

Like the APAC Region, Japan does not have an XLH-specific patient advocacy group. In response to this situation, we implemented a needs assessment survey of XLH patients and specialists. The survey was conducted in collaboration with ASrid, a non-profit organization dedicated to connecting various stakeholders in the field of rare and intractable diseases with the aim of solving problems in this area. Based on the results of the survey, in July 2020 we launched Kurukotsu Hiroba, a disease awareness website for FGF23-related hypophosphatemic rickets/osteomalacia. This website lists not only the names of hospitals, but also specialists with experience and areas of medical practice (pediatric, adult, and TIO). The aim is to create an environment that ensures that patients and their families who are anxious to learn about their illnesses can reach one of the few specialists available. In addition, since 2019 we have supported RDD in Japan, an event held on the last day of February every year on Rare Disease Day (RDD).

In December 2021, we joined STEP, a rare disease information community established by ASrid, with the aim of further increasing disease awareness.

STEP, whose name is an abbreviation of "Strategic Translational Action for Empowering Patients," is a platform aimed at building strategic bridges to empower patients and their families. STEP aims to empower various stakeholders by disseminating information on the pathophysiology of rare diseases, research, and the patient community through a website that is curated by physicians. It also holds lectures and other events to meet the needs of patients and their families. Going forward, the launches of two activities are planned: 1) "STEP Bone disease," which will target rare/intractable bone system diseases and metabolic bone diseases; and 2) "STEP Learning," an entry point for learning knowledge and information in the field of rare/intractable diseases. In particular, it is planned that "STEP Bone disease" will use a white paper on adult XLH patients published by the International XLH Alliance and introduce the activities of XLH patients around the world in Japanese.

We at Kyowa Kirin hope that through this kind of information dissemination, we can further raise awareness of the disease and contribute to putting smiles on the faces of people living with disease.

Launch of Kurukotsu Hiroba, a disease awareness website for FGF23-related hypophosphatemic rickets/osteomalacia.
https://www.kurukotsu.com/

RDD in Japan is an annual event held on the last day of February, World Rare Diseases Day (RDD).

STEP
Strategic Translational Action for Empowering Patient

Rare disease information community "STEP"

Value Creation Strategies

Cutaneous T-Cell Lymphoma

Lifting Patient Voices, Supporting Meaningful Connections in Rare Cancer

For patients with rare diseases, the road to diagnosis and treatment can be a long one. This is true as well for patients with cutaneous T-cell lymphoma (CTCL), a rare form of blood cancer. Because it first appears on the skin, it is often mistaken for common skin conditions like eczema or psoriasis, which can delay diagnosis by years or even decades*1.

Given its rarity, patients are eager to connect with and learn from others who share their diagnosis. Research indicates that in addition to their health-care teams, patients rely heavily on advocacy groups and online forums for information about their disease, and when assessing and evaluating treatment options*2. Yet making a community connection and finding credible resources can be challenging depending upon where you live.

To address this need, Kyowa Kirin continues to support the efforts of the Lymphoma Coalition, the Cutaneous Lymphoma Foundation and other advocacy organizations, to build an international network of support for those living with CTCL. Across wider Europe, Kyowa Kirin International support has enabled patient groups to offer peer-to-peer activities, education, and more information for patients, and the publication of patient-led research to educate various stakeholders on the patient experience and priorities for improving care.

To aid healthcare professionals in their discussions with patients, Kyowa Kirin International is developing CTCL Answers, an online resource that will provide practical information about CTCL tailored to different timepoints in a patient's journey and connect patients to the advocacy community for additional support. The development of this tool is being informed by members of the medical and patient advocacy community and will be piloted in the United Kingdom and Saudi Arabia in 2022.

In the United States, a strong CTCL advocacy community offers a range of live and virtual programming for people to learn about the disease and connect with others with similar experiences. In addition to supporting these efforts, Kyowa Kirin also conducted research to better understand the patient journey and areas for additional education and support. From that research, we learned that as the disease progresses and treatments fail, patients are actively searching for information about new treatment options; ideally, they want to hear from other patients about their experiences on treatment, and ultimately they want to have hope*2.

This insight was the genesis of the company's first patient ambassador program, featuring the stories of real patients – including their journey to diagnosis, experiences on treatment and what motivates them to never give up.

"I wanted to share my story to encourage others to never give up, to keep pushing for answers," said Jeff B, patient ambassador. "It's easy to feel overwhelmed, and to give up. By learning how to advocate for myself, I was able to finally find the right specialists, the right diagnosis and ultimately, the right treatment for me."

Since the Ambassador program launch in September 2021, more than 5,000 people have gained a deeper understanding of the CTCL patient experience through compelling video testimonials and personal histories now on the Patient Stories page of poteligeo.com, new educational programming, and a feature article in Coping Magazine. The program will continue to expand in 2022, with the addition of new ambassadors, outreach efforts, and patient support services.

*1 Cutaneous T-Cell Lymphoma. Cutaneous Lymphoma Foundation. https://www.clfoundation.org/
*2 Data on file. Kyowa Kirin Inc., Bedminster, NJ USA

CUTANEOUS LYMPHOMA FOUNDATION

LYMPHOMA COALITION

Jeff B, patient ambassador

Value Creation Strategies

Parkinson's disease

A Focus on Caregivers – The Unsung Heroes of a Patient's Healthcare Team

Kyowa Kirin recognizes the significant role caregivers play in the lives of patients within the disease areas we support. They are especially important for patients with neurodegenerative diseases like Parkinson's disease. However, our research found that resources targeted to caregiver needs were limited.

To better understand the caregiver's point of view, needs, and opportunities to meaningfully contribute, we collaborated with two North American patient advocacy groups – the Davis Phinney Foundation and Parkinson & Movement Disorder Alliance (PMD Alliance) on a survey that launched in April of 2020 during Parkinson's Disease Awareness Month. We found that survey respondents spent an average of 45 hours per week on tasks for their loved ones, less than 1 in 3 had planned for their future, and 9 in 10 desired more guidance about treatment options.

These insights informed our Parkinson's advocacy strategy and activities in 2021 and inspired the Davis Phinney Foundation and PMD Alliance to develop educational webinars and resources to specifically address the needs identified by this research. We were honored when this project earned the distinction of being named a Scrip Awards 2021 Finalist for Community Partnership of the Year, validating our efforts to remain a visible and valued member of the patient and caregiver community.

"I think the data from your Parkinson's caregiver survey framed programs that opened important conversations and provided practical tools for people." Anissa M. Vice President, Programs, PMD Alliance

In 2022, we will again survey the community to gain deeper insights into the caregiver experience, with the goal of improving their knowledge of Parkinson's and its symptoms so they feel empowered to have more proactive and productive communications with the patient's care team.

Embedding Patient Perspectives in the Development Lifecycle

The value of collaborating with patient advocacy groups extends to drug development activities. Early engagement with patient advocacy groups can provide insight to the design of clinical trials, and produce additional data about the treatment experience that is often valued by patients and clinicians. That is why it was critical for Kyowa Kirin to seek insight from advocates on our Parkinson's pipeline development program.

We convened a virtual advisory board in December 2021 comprised of representatives from advocacy groups in both North America and Japan. The goals of the meeting were to:

- Understand the perceived value of proposed indications for patients and caregivers
- Obtain advocate input on Phase III protocol and study design, and
- Discuss advocate perspectives on additional patient reported outcomes and patient research that would complement the clinical data collection

The advisory board provided Kyowa Kirin with actionable insights we will use to ensure our clinical development efforts are patient-centric, with lower barriers to trial recruitment, enrollment and retention.

DAVIS PHINNEY Foundation For Parkinson's every victory counts®

PMD Alliance Parkinson & Movement Disorder Alliance

Value Creation Strategies

Retain the trust of society

The CMC Research Center is mainly responsible for a wide range of activities from early development to post-launch of small molecule drugs. These include formulation design, investigational drug manufacturing test method development, study of scale-up to commercial production, and technology transfer to manufacturing sites. I want to see new medicines delivered to patients as soon as possible. At the same time, I keep an equal focus on doing whatever I can now to help ensure a stable supply of safe, reliable, and high-quality medicines. Whenever I struggle with a decision, I think first about what is in the patient's best interest. I remind myself to smile for the sake of the patient's smile, and I carry out my duties with sincerity.

Ayuko Akiyama
Analysis Group 2, CMC Research Center
Kyowa Kirin Co., Ltd.

Our mission is to assure that the medicines our patients rely on are safe and effective. Quality is at the heart of everything we do. This is what builds a lasting trust between the patient and Kyowa Kirin. Our medicines have a profound positive effect not just on the individual patient but also on their families' and friends' quality of life. This is what makes them smile which in turn makes me smile!

Fatos Bejta
Head of Global Audit and R&D Quality,
Global Quality Assurance, Kyowa Kirin International plc

As we grow in a fast paced environment, building internal team and personal development capabilities aligned with that of Kyowa Kirin's global outlook will continue to drive the value of our products, people and processes. Alongside the other regions, understanding how we can continually improve supply capabilities and expand into new territories are at the centre of daily activities. Bringing smiles to more patients across the globe.

Emily Newlands
Supply Chain Manager, Rare Disease
Business Unit
Kyowa Kirin International plc

Value Creation Strategies

Providing high-quality pharmaceuticals to patients around the world

Ensuring a stable supply of high-quality pharmaceuticals is paramount for a pharmaceutical company.
Achieving and maintaining this requires each function to perform its duties properly. It is also vital that each employee feels responsible for continuing to bring smiles to patients.

High-quality pharmaceuticals to the world

Kyowa Kirin has two key production bases, Takasaki City, Gunma Prefecture and Ube City, Yamaguchi Prefecture. The Takasaki area is primarily a base for biopharmaceuticals, and is home to the Bio Process Research and Development Laboratories, which develops production technologies and handles regulatory filings, and the Takasaki Plant, which manufactures and formulates bulk pharmaceuticals for investigational drugs and marketed products. Taking advantage of their geographical proximity, our teams work closely together. Such collaboration makes this location a world-class biopharmaceutical research and manufacturing base.

Bio Process Research and Development Laboratories

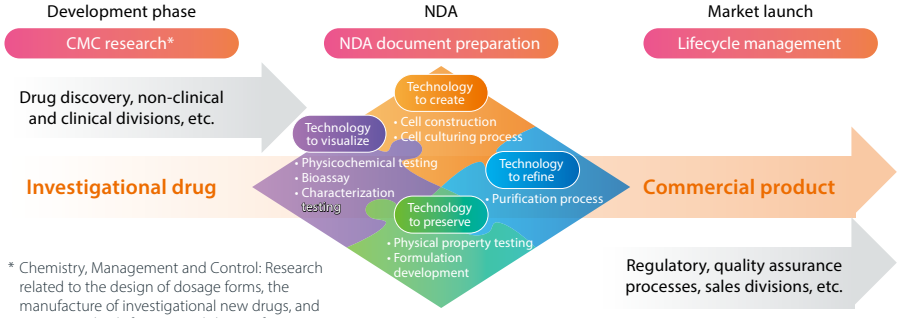
We support high-quality biopharmaceutical production technology through our biopharmaceuticals research in the areas of drug substance, formulation, and analysis.

In our active drug substance research, based on state-of-the-art process science, we apply genetic recombination technology to stably introduce genes that produce drug candidates into cells and establish methods for culturing and purifying the products. We then scale this up to produce drug substances with high levels of quality, safety, efficacy, and economy. With biopharmaceuticals, the higher the target protein secretion ability of the production cells used, the higher the productivity—and the greater the potential for reducing production costs. In this respect, Kyowa Kirin has world-class levels of productivity.

In our formulation research, we focus on drug substances that have been identified as drug candidates, formulating them so that they can be used safely by patients. We evaluate the stability of drug substances with various characteristics, conducting scale-up studies and other groundwork for formulation and commercialization. We are also developing new dosage forms for previously launched drugs to make them easier to use, such as pre-filled syringes for vials and automatic injection devices that eliminate the need for hospital visits.

In analytical research, we establish analytical methods for the characterization and stability testing of drug candidates. We then evaluate these methods to establish quality standards.

Factors in biopharmaceutical production technology



* Chemistry, Management and Control: Research related to the design of dosage forms, the manufacture of investigational new drugs, and testing methods for APIs and dosage forms.

Takasaki Plant

Takasaki Plant is a state-of-the-art biopharmaceutical production plant with production lines both for investigational drugs and for launched products. It complies with the international standard Good Manufacturing Practice (GMP). Our manufacturing and quality functions work closely together to produce high-quality pharmaceutical products that customers can use with confidence. Our teams handle a wide range of verification work—from raw materials to manufacturing processes, testing and inspection, and final shipping decisions—before our products are sent around the world.

Drug substances for biopharmaceuticals are produced by mass cultivation of genetically engineered animal cells and microorganisms. The system for this process involves a large tank (reactor) with a capacity of 10,000 liters. However, maintaining productivity while scaling up from lab scale to large-scale production is not a simple matter. The Takasaki Plant has established a system that uses a large-scale commercial production process to ensure stable production and high productivity. This involves precise, smooth technology transfer in close cooperation with the adjacent Bio Process Research and Development Laboratories. Key to enabling this are our high level of experience, accumulated from the many biopharmaceuticals we have produced over the years, and the cutting-edge technological capabilities we have developed through that experience.

We are advancing several capital investment projects in the Takasaki area. The largest of these is the construction of a new seven-story building to accommodate our quality teams. The total investment of this project is expected to be ¥14 billion. Previously, our quality control and quality assurance functions were dispersed throughout the Takasaki area. By gathering these teams together in the new building, we aim to improve operational efficiency and enhance communication, ensuring fast, accurate execution of operations. We will also introduce state-of-the-art analytical equipment with a view to addressing future regulation changes. This will help us to ensure a stable supply of high-quality biopharmaceuticals.

Rendering of the exterior of the new quality building

Biopharmaceutical drug substance production facilities

Value Creation Strategies

Supporting a stable supply with strong teamwork

The most important elements for ensuring a stable supply are stable plant operations and precise demand forecasting. As well as investments in IT and digital and in people development aimed at optimizing factory utilization, Kyowa Kirin is also focusing on supply chain management (SCM). The number of countries in which global strategic products such as Crysvita are sold is steadily increasing, and overseas sales are growing every year. This has led to a growth in the number of entities involved—from manufacturing sites to distribution centers and other outsourcing partners—which has increased the complexity of our supply chain. The SCM Function is responsible for accurately monitoring and controlling this complex situation. Their task is to ensure that Kyowa Kirin's pharmaceutical products reach the patients who need them, when they need them, and in precisely the quantity needed.

To optimize the supply chain, it is important to ensure that the IT and digital technology and organizational systems are in place, however, collaboration and teamwork with internal and external stakeholders are also critical. The SCM Function must control the supply-demand balance with a high degree of precision to ensure a stable supply. It does this by serving as a coordinator, building strong partnerships internally—particularly with the quality assurance, production, and sales functions and externally with contract manufacturers and logistics companies. At the same time, by further evolving S&OP* initiatives, the SCM Function helps to optimize inventory levels while supporting rapid decision-making by management. Furthermore, we are also discussing from a Business Continuity Plan (BCP) standpoint with the aim of maintaining a stable supply in the event of supply risks like the recent COVID-19 pandemic or a natural disaster. As part of this, we are considering dispersing our manufacturing and storage locations for global strategic products and other products over multiple sites.

* Abbreviation for Sales and Operations Planning. A system that enables sales and production/operational divisions to confirm plans and results, both in quantitative and monetary terms. S&OP ensures alignment on the optimal plan for the company, increasing the accuracy and speed of decision making to support the achievement of the company's financial targets.

Building a world-class Quality Assurance (QA) system

Pharmaceuticals are products that directly affect human lives. At a pharmaceutical company, quality is the responsibility of each employee. Without robust quality and compliance, we cannot earn the trust of patients, healthcare professionals, or national regulatory authorities. Kyowa Kirin's Global QA Function is responsible for confirming that all processes involved in the production of products and investigational drugs are conducted properly and in compliance with relevant laws and regulations. In this way, the function fulfills its role of ensuring that there are no problems with the quality of the drugs delivered to patients.

We have been steadily strengthening our global quality assurance system since 2019, when we began globalizing our business in earnest with the launch of global strategic products in Europe and the United States. As part of this effort, we formulated the Kyowa Kirin Group Quality Policy and the Global Quality Roadmap to 2025. In one particularly important measure, we have adopted an enterprise/electronic quality management system (eQMS). This system is scheduled to be fully operational in 2022. The scope of our quality assurance operations covers a wide range of areas, from deviation control, corrective action/preventive action (CAPA), and training to document management, auditing, supplier management, and change management. With the introduction of this system, we will switch from traditional paper-based operations to fully electronic processes. This will enable us to meet, to a globally consistent standard, the requirements of relevant laws and regulations in each country.

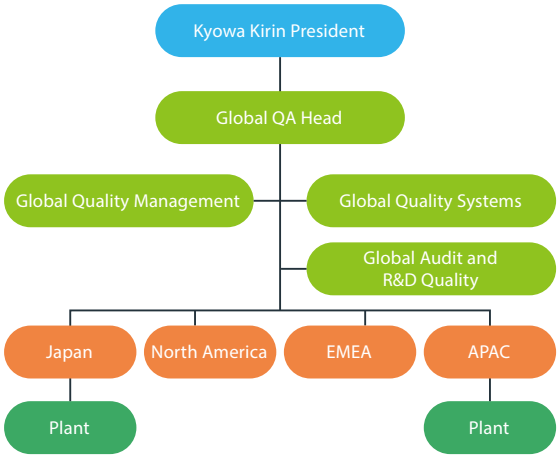
Until 2021, we focused on reinforcing our foundations as a global company. Going forward, we will carry out further operational improvements and training to foster a quality culture as we aim to build a world-class quality assurance system that will give us an edge over our competitors.

Kyowa Kirin Group Quality Policy

We contribute to the health and well-being of people around the world by ensuring the highest quality commercial and clinical medicines are available and by always adhering to global quality, safety and compliance policies.

1. We utilize People, Process, Systems / Technology to conduct reliable and ethical activities in alignment with our compliant and effective GxP quality management system.
2. We maintain healthy relationships with all stakeholders and properly oversee suppliers and contractors.
3. We comply with all GxP global laws, guidelines and industry rules in our activities.
4. We utilize data and risk principles to drive decisions based on long-term outcomes, while always keeping our patients at the center of our decisions.
5. We foster a positive quality culture and always strive to continuously improve.

Global QA Structure



Value Creation Strategies

Ensure a thriving global environment for future generations

We are actively working to conserve the environment for future generations. As part of this commitment, we aim to decarbonize our company, including the value chain.

Environmental Management

Kyowa Kirin has incorporated priority environmental issues into its FY2021–2025 Medium Term Business Plan. We formulated these based on a consideration of impact on the sustainability of society and of impact on the Group's business. We then set targets for each year and implement measures accordingly. In particular, we have positioned climate change mitigation and adaptation and water resource management as core environmental issues. As well as our annual targets, we have set medium- and long-term targets, developing a range of measures to achieve these.

We have established and are operating a governance structure for Kyowa Kirin's environmental management. The Executive Vice President has been appointed as its chief executive officer. (For details, see 'Responding to the Task Force on Climate-related Financial Disclosure (TCFD) — Governance (relating to environmental issues)' on P37.)

In our daily environmental management activities, we operate all of our domestic plants and research laboratories in accordance with the ISO 14001 environmental management system.

Addressing climate change

The Kirin Group, of which Kyowa Kirin is a member, has formulated the Kirin Group Environmental Vision 2050. In its vision, the Kirin Group has set a goal of achieving "Net zero" greenhouse gas emissions in its entire value chain by 2050 as a "Society overcoming climate change," a society in 2050 that we want to create together regarding climate change.

Kyowa Kirin has also raised its own target in 2021, setting a new target of reducing CO_2 emissions in 2030 by 55% from the 2019 level. We will help achieve this vision by using the network of the Kirin Group and actively developing climate change measures that take advantage of business characteristics.

As specific commitments related to climate change, we are committed to "Promoting early reduction of CO_2 emissions" through "Energy conservation" and "Expansion of renewable energy" including capital investment, and "Promoting energy conversion." We have created a road map for achieving the 2030 target and are implementing various measures.

In 2020, we introduced Aqua Premium at the Kyowa Kirin Takasaki Plant—in a first in the pharmaceutical manufacturing industry in Japan*1. On January 1, 2022, we also introduced Aqua Premium at the Fuji Plant, switching 100% of the purchased electricity used to electricity derived from hydroelectric power sources that do not emit CO_2. As a result, of the approximately 72,400,000 kWh in electricity consumed annually by Kyowa Kirin, approximately 45,400,000 kWh will be switched to hydroelectric power sources*2. This is expected to reduce our annual CO_2 emissions by approximately 39% (approximately 20,000 tons). All electricity used at the head office is already derived from renewable energy sources*3.

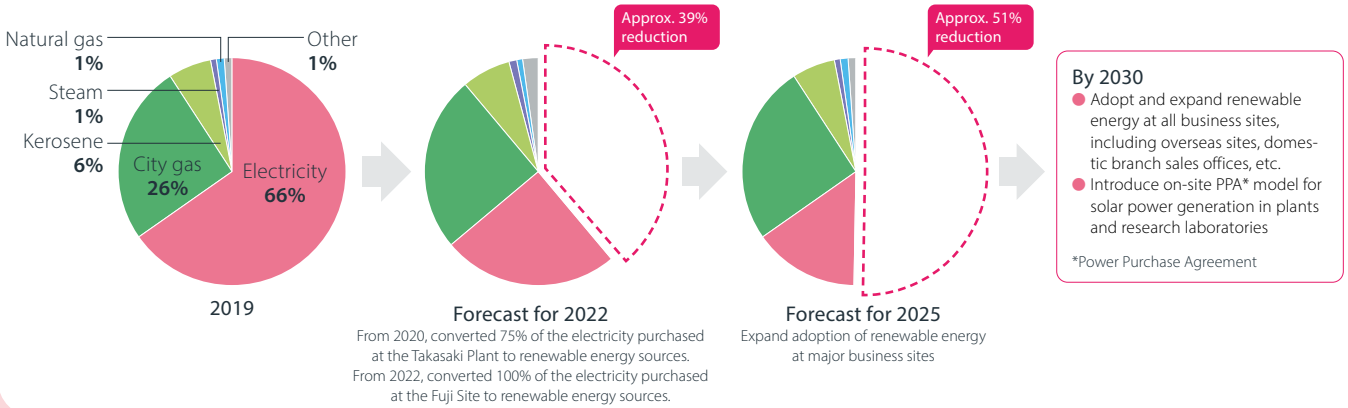
We plan to introduce and expand renewable energy to our major business locations in Japan by 2025, and to all of our group business locations, including overseas sites and domestic branch offices, by 2030. In addition, we are considering the introduction of large-scale solar power generation facilities through an on-site PPA model at our domestic plants and research laboratories. We are also examining the introduction of solar power generation facilities at our overseas plant.

Each plant and research laboratory*4 sets its own energy intensity reduction targets for a single year, implementing measures to improve production efficiency. Unit energy consumption in FY2021 was 3.5% lower than the previous year (global target: 1% lower than the previous year).

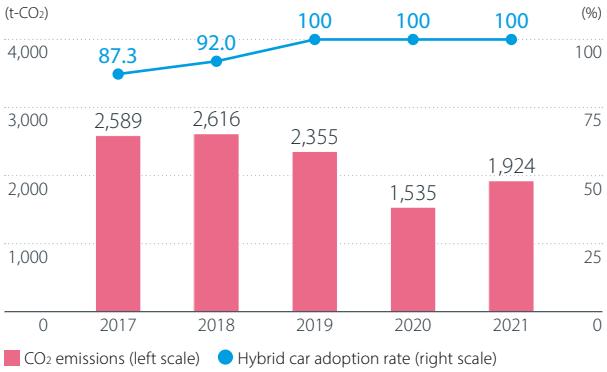
In addition, all domestic sales vehicles (company cars) have been switched to hybrid cars since FY2019 (maintaining a 100% hybrid car adoption rate) as a result of a continuing initiative we started in 2009. Furthermore, in FY2021, we adopted new approaches to our communication activities, including holding interviews, briefings, and seminars online. These measures, combined with the impact of COVID-19, resulted in a significant reduction in CO_2 emissions.

*1 A rate plan offered by TEPCO Energy Partner, Inc. that supplies only electricity from hydroelectric power plants that do not emit CO_2. The plan is the first of its kind in Japan.
*2 Calculated based on FY2020 data for Kyowa Kirin Group's plants and research laboratories in Japan and overseas
*3 Otemachi Financial City Grand Cube, where Kyowa Kirin's head office is located, has adopted RE100-compliant electricity derived from renewable energy sources.
*4 Kyowa Kirin Group's plants and research laboratories in Japan and overseas plant

Trends in CO_2 emissions reduction (all plants and research laboratories in Japan and overseas)



CO_2 emissions from sales vehicles and hybrid car adoption rate



Water resources management

Kyowa Kirin conducts water risk assessments (water shortage/water stress, flooding, and water pollution of water sources) at each plant in Japan and overseas. The assessments identified risks at the Ube Plant of drought and of flooding caused by storm surge. It was also found that Kyowa Kirin China Pharmaceutical Co., Ltd. in Shanghai faced the risk of water shortage and of flooding. No risk was detected in the water risk assessment for the Takasaki Plant, although some flood damage is assumed in a local flooding simulation published by the Ministry of Land, Infrastructure, Transport and Tourism.

In response to these results, alongside soft measures such as reviewing or formulating plant BCPs for large-scale natural disasters, we are also implementing hard measures such as flood prevention measures at facilities to avoid or minimize these risks.

Under the Kirin Group Environmental Vision 2050, Kyowa Kirin is working to conserve water and protect water resources in accordance with the Kyowa Kirin Group Environmental Policy.

In 2021, we reviewed our previous 2030 water consumption reduction target and set a new 2030 water consumption reduction target of a 40% reduction from 2019 levels. To reduce water withdrawal, we will systematically decommission and reorganize facilities while making effective investments in equipment such air-cooled refrigeration units. As of the end of FY2021, we have achieved a 25.0% reduction from the 2019 level against our 2030 water withdrawal reduction target. Furthermore, to improve the efficiency of water use, each year, each plant and research laboratory sets and manages its own water consumption intensity. In 2021, our water consumption intensity was 4.1% lower than the previous year.

Biodiversity

At Kyowa Kirin, we are using our procurement activities to help protect the world's forests and reduce our impact on biodiversity. Specifically, we have adopted FSC®-certified paper*5 for materials such as company envelopes, company brochures, and cardboard product packaging. In accordance with the Kirin Group Action Plan for Sustainable Use of Biological Resources, which was revised in 2021, we continue to study applications for FSC®-certified paper. In addition to expanding its use for domestic product packaging cardboard boxes, we are considering using it for materials such as product inner boxes. We have also begun considering the use of FSC®-certified paper overseas, at business sites and for products.

As part of its activities to preserve ecosystems and ensure biodiversity, Kyowa Kirin has been working to protect water resources through its engagement in the Kirin Group's water-source preservation project since FY2007. The Takasaki and Ube plants carry out weeding, planting and tree thinning to create forest areas that provide water resources. In addition, for the fifth year running, Kirin Holdings Company, Limited has been recognized as the highest Water Security A List company by CDP, an international non-profit organization that provides an environmental data disclosure system. CDP praised the Kirin Group, of which Kyowa Kirin is a member, for its efforts to protect water resources.

Kyowa Kirin business sites also work with various local communities to preserve ecosystems, including releasing young amago trout into rivers and protecting grasslands of Akiyoshidai in Yamaguchi Prefecture. The Fuji site continues to collaborate with local government on activities such as Shizuoka Prefecture's River Friendship Program, which organizes cleanups of local rivers, and a campaign to clean up trash from areas around Mount Fuji. Through these activities, we will continue to support local communities and raise awareness of the importance of preserving the beauty of the natural environment and protecting biodiversity.

In our research, development, and manufacturing of pharmaceutical products, we have established an in-house committee to ensure compliance with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms ("the Cartagena Act") and to conduct appropriate management. At the 2021 Genetically Modified Organism Committee meeting, we shared the results of the audits in each department, and also assessed measures that we are currently implementing to prevent deviation from the Cartagena Act.

The Kirin Group is advancing a range of initiatives in this area, including the Kirin Group Declaration of Support for Biodiversity Conservation, formulated in 2010, and the Kirin Group's Guidelines on Sustainable Sourcing of Biological Resources, formulated in 2013.

*5 Kyowa Kirin has obtained an FSC® promotion license (FSC® N003037).

TOPIC

— Working together as one Group to protect the environment —

Adoption of FSC®-certified paper

Forestry activities to preserve water resources

Mount Fuji trash cleanup campaign

Value Creation Strategies

Responding to the Task Force on Climate-related Financial Disclosures (TCFD)

Since announcing our endorsement of the TCFD recommendations in 2021, Kyowa Kirin has identified the risks and opportunities that climate change poses to our business, as well as the impacts of these risks and opportunities. We have organized our findings into four areas: governance, strategy, risk/opportunity management, and indicators and targets in line with TCFD recommendations.

Governance (relating to environmental issues)

Issues related to risks and opportunities in climate change, as well as environmental activity policies and results are positioned as important matters in the Group's environmental management. These issues are reported, deliberated upon, and decided by the CSR Committee, which is chaired by the Representative Director and Executive Vice President, who has the highest responsibility for overall environmental management. The content of these discussions is reported to the Board of Directors. In addition, from FY2020 we put in place a TCFD Study Team within the CSR Management Department, which is responsible for the environmental management control function. This team studies the identification and evaluation of climate change-related risks and opportunities and our response to them. Risks and opportunities that have been identified are regularly reviewed and brought to the CSR Committee, which then reports on the progress of responses and addresses climate-related issues as part of management strategy.

Strategy

We aim to achieve a world in which the average temperature increase is limited of 1.5°C or less, as outlined in the Paris Agreement. We are reviewing our climate change response based on the results of our scenario analysis of climate change-related risks and opportunities and also in the context of the Kirin Group Environmental Vision 2050. We are incorporating these findings into our business strategy and advancing measures accordingly.

As mitigation measures, to support the achievement of net zero greenhouse gas emissions throughout the value chain by 2050, we have upwardly revised our 2030 CO_2 reduction target to a level corresponding to the Science-Based Target (SBT) 1.5°C target*. We have established a roadmap for achieving this target and are promoting measures such as the early introduction and expansion of renewable energy, energy conservation, and energy conversion. In this way, we are responding to risks associated with the transition to a decarbonized society.

As an adaptive measure, we will formulate a Business Continuity Plan (BCP) for large-scale natural disasters. This will address the impact on global production activities arising from flooding of plant and research laboratory premises. We respond to physical risks by implementing flooding prevention measures and capital investment as required. Going forward, we will continue to minimize risk by assessing and addressing the impact throughout our supply chain.

On the other hand, an increase in the number of hay fever sufferers had led to expectations of an opportunity for the allergy drug market. However, we believe the actual impact on sales revenue will be limited. We will continue to consider new developments in this field to meet medical needs based on our management philosophy.

* Science-based corporate greenhouse gas emissions reduction targets consistent with the Paris Agreement levels

Risk/opportunity management

To identify risks and opportunities, we comprehensively assess—based on scenario analysis for each risk and opportunity—the expected timing and probability of occurrence, the scope and magnitude of impact, and the nature of countermeasures. We manage these risks and opportunities by identifying those that have a significant impact on business, that involve a high degree of social responsibility, or have a high probability of occurrence. We monitor and manage, on a quarterly basis, our measures to address the risks we have identified.

Metrics and targets

In 2021, we set a new 2030 CO_2 emissions reduction target of 55% reduction from 2019 levels. This is based on the SBT 1.5°C target. In addition to creating a roadmap for achieving these new targets, we have incorporated them into our FY2021–2025 Medium Term Business Plan. We set and manage annual targets for each fiscal year, studying and developing measures to achieve them.

In addition, the Kirin Group has set a goal, based on the Kirin Group Environmental Vision 2050, of achieving net-zero greenhouse gas emissions for the entire value chain by 2050. As medium-term targets, the Group has upwardly revised its greenhouse gas reduction target to a 50% reduction in Scope 1 + Scope 2 and a 30% reduction in Scope 3 by 2030 compared to 2019 (approved for the SBT 1.5°C target). A target of 100% renewable energy sources for electricity consumption has been set for 2040 (RE100 member). Kyowa Kirin has developed its 2030 targets and measures in alignment with these medium- and long-term goals of the Kirin Group.

For details, please refer to our website.
https://www.kyowakirin.com/sustainability/environment/tcfd/index.html

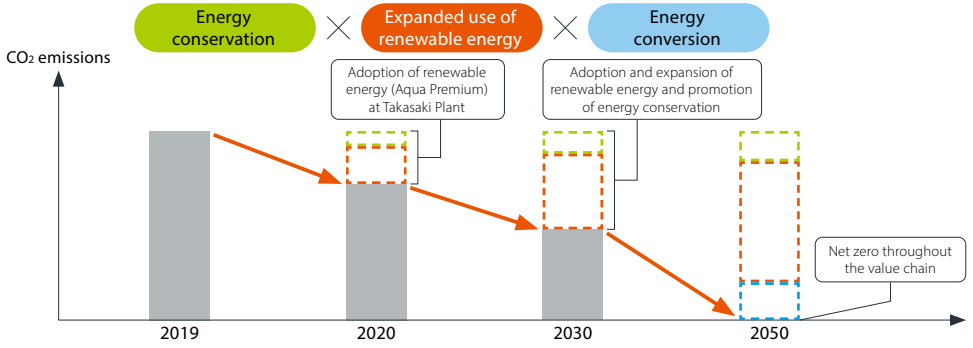
Analysis of risks, opportunities and financial impact related to climate change

Pink: Risk. Blue: Opportunity

Scenario classification		Climate change-related drivers with impact assessment	Potential impact	Change through response (resilience)
Transition risk	Policy and regulations	Carbon pricing (decarbonization, emissions trading schemes)	Small	±0
		Tighter CO_2 emission regulations	Slight	Small
	Population/economy/ geopolitics	Population growth in emerging economies/economic globalization	±0	±0
	Community	Changing social values	Slight	±0
Physical risk	Increase in average temperature and change in rainfall pattern (acute)	Extreme temperature rises	Small	Small
		Increased torrential rains, typhoons, and floods	Large	Slight
	Increase in average temperature, changes in rainfall pattern (chronic)	Changes in hay fever patients	Medium	Medium
		Increased energy consumption due to increased air conditioning load	Small	Small

- Achieve 2030 target early and reduce CO_2 emissions
- Review workplace BCPs for major natural disasters
- Disaster preparedness of facilities

Image of net zero in the value chain



CO_2 emissions reduction image

Value Creation Foundation

We are building a robust business base to support sustainable growth of both Kyowa Kirin and the society

Ensuring a healthy global environment is vital to business

Protecting the global environment is a universal challenge, with companies in many industries now needing to step up their response. For Kyowa Kirin, with its international business presence, our sense of responsibility is especially acute. Our parent company, Kirin Holdings, is at the forefront of tackling environmental issues in Japan. Following that lead, Kyowa Kirin, as part of the Kirin Group, is working to reduce its impact on the global environment by switching to renewable energy and systematically minimizing energy use at manufacturing facilities. Our goal is to achieve a 55% reduction in CO_2 emissions by 2030 compared with 2019.

Also, in 2021, Kyowa Kirin declared its support for the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD). In line with the TCFD, we have identified and evaluated business risks and opportunities from expected changes in the climate and developed response measures based on our findings. Our analysis concluded that the Group faces particularly significant physical risks from increased incidence of heavy rain storms, typhoons and flood events. In response, we are implementing flood countermeasures at production plants and relocating key facilities to high-rise buildings or higher ground, while also developing mechanisms to ensure business continuity in the event of a disaster. We aim to take every possible step, based on the scenario that a thousand-year event could happen tomorrow. We intend to continue reinforcing climate change risk mitigation measures, as any prolonged shutdown of plants or research laboratories could have a material impact on our ability to supply medicines to patients in need.

Maximizing the potential of Kyowa Kirin's organization and individuals—the source of our growth

Kyowa Kirin's workforce is a single team of individuals with diverse skills and characteristics. We are putting considerable effort into reforming our corporate culture to support Kyowa Kirin's growth as a global company. To continue creating life-changing value, we need individuals who have clear personal goals and who can actively adapt to achieve them, rather than employees who passively wait for and follow instructions. We want to create a corporate culture where employees take the initiative and are open to change. With that goal in mind, we are implementing KABEGOE activities, which go beyond the boundaries of each part of our organization. After launching in Japan, the

Yutaka Osawa
Representative
Director of the Board,
Executive Vice President

activities are being rolled out across our workforce worldwide, driven by our global leaders, and KABEGOE is increasingly becoming a key word for Kyowa Kirin Group employees everywhere. Over the last few years, we have put in place the One Kyowa Kirin (OKK) management structure based on a regional organization and a functional organization. To accelerate the Group's transformation, we have improved OKK by adding a product-based perspective. KABEGOE activities that spur organic cooperation between different organizations within the Group will be key to making OKK a success. The OKK structure will not function properly if each of its three components follow their own paths of suboptimization, so the key ingredient will be proactive communication between the leaders in each of the organizations – regions, functions and products – to ensure full optimization across the entire Group. That means each leader needs to take an even wider view and further enhance communication with their counterparts, in addition to exercising leadership in their own areas of responsibility. To steadily cultivate leaders with these skills, we are actively working with external consultants to train and foster human resources. Furthermore, outside directors of the Board of overseas region have been driving the development of human resources by providing advice to leaders in each region, based on their wealth of external knowledge and experience.

Drawing on diverse views to ensure effective board meetings

During the development of our current Medium Term Business Plan, which was released in 2021, the Board of Directors thoroughly discussed the new Vision and targets. As part of the discussions, Outside Directors gave advice on how the Company should incorporate the latest international thinking on social issues such as the environment and human rights. This process illustrates how the current board is a highly effective body with the ability to examine issues from a sustainability and governance perspective, as well as more conventional themes such as growth strategy.

We also have a very good balance of skills among board members, from corporate management and business strategy, to law, administration and finance. Moreover, many board members have experience at companies with global business operations, giving Kyowa Kirin access to expertise that will support its future development on the global stage. The board is not shy of heated debate, either, with Outside Directors fully engaged in discussions thanks to detailed inputs from documents provided before meetings. I believe this rigorous scrutiny from outside the company is key to the effective running of the board, and is something we look for from our Outside Directors. I hope the board meetings will continue to feature lively and effective debate, led by the Chair of the Board, Outside Director Akira Morita.

Addressing unmet medical needs

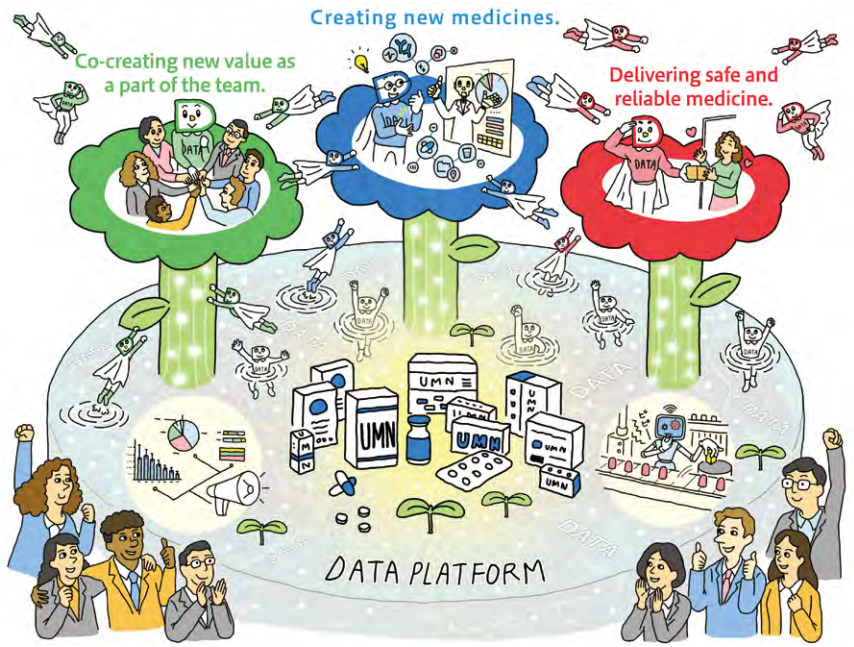
Many of our stakeholders understand that Kyowa Kirin has the potential to develop groundbreaking new drugs, as they are well-informed about our research capabilities and unique technologies. We are very grateful to have this support. At the same time, we face growing calls to rapidly develop new drugs for patients who are not served well by current medical treatments. While Kyowa Kirin is still small compared with leading global pharmaceutical companies, our size means we can pursue flexible alliance strategies and unique research themes to tackle medical conditions that major firms are reluctant to approach. By leveraging these unique Kyowa Kirin strengths, we will continue to address unmet medical needs.

Digital Transformation Strategy

We will use internal and external data to deliver a world full of smiles to all stakeholders around the world, including patients and their families, healthcare professionals, and employees.

Digital Vision 2030

By 2030, Kyowa Kirin aims to be a global specialty pharmaceutical company with originality—one that uses data to discover unmet medical needs, delivering new services, including pharmaceutical products, and creating value. We will accumulate data obtained and created through the full range of processes from drug discovery, production, and distribution to sales and by medical professionals and patients. We will build a unique data platform that organically links these processes to use the data as a source of new value. We will use this data platform to co-create with various stakeholders, serving as part of a team centered around medical professionals and patients. In this way we will move beyond the creation of innovative drugs to contribute broadly to maintaining and enhancing health.



Creation of new medicines that meet the UMN

- We will strengthen the development of lifechanging drugs for diseases for which treatment satisfaction is not sufficient. We will actively apply AI and other digital technologies while using Kyowa Kirin's science, technology, and proprietary data platform and incorporating external data and knowledge into our drug discovery.
- Using the new value generated from the data, we will help deliver value in various forms—such as disease awareness, diagnosis and treatment assistance—in addition to conventional treatment centered on pharmaceuticals.

Patient-centric healthcare needs

- We will help patients by partnering with families, medical professionals, and a wide range of other stakeholders. We will provide various healthcare programs and information to help prevent, diagnose and treat serious illness and also to improve patients' quality of life.
- Through a patient communication platform that uses our accumulated data and digital technology, we aim to provide useful information to patients, their families, and medical professionals. We aim to help predict disease risk, to detect the risk of serious illness early, and to issue alerts for early medical intervention.
- As we work to bring smiles to all people around the world, we will repeatedly visualize and accumulate data. Through this process, we will nurture the growth of our next value offering.

Earning the trust of society

- We will maximize our use of IoT devices and digital technologies such as AI-based image analysis, smart glasses, and sensors. This will enable us to advance the automation and digitalization of our factory operations, creating more space for our employees and organization to thrive. We will deliver peace of mind and smiles to patients. We will pursue quality improvements with a sense of sincerity and honesty and work to achieve faster and safer production and delivery of pharmaceutical products.
- We will visualize safety by gathering data on delivery conditions along the supply chain. This will enable us to deliver high-quality medicines to patients, while also supporting activities aimed at achieving the SDGs, such as thoroughly eliminating counterfeit and illicitly distributed medicines.
- We strive to provide a variety of delivery methods, as part of our personalized response to rare diseases and other areas. By delivering safety and security to meet the needs of each patient, we will help bring new experiences and smiles to all.

To realize our digital vision, we will pursue a digital strategy based on the concept of "Best of Breed" (combining elements that are best suited to particular operations). In this, we will focus on using data to connect the entire value chain, transforming into a data-driven organization, and developing innovative pharmaceuticals and applying these to adjacent areas to deliver value.

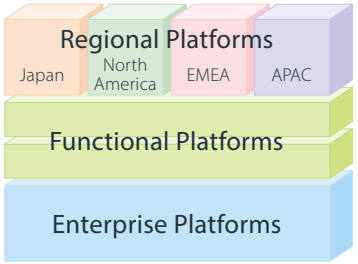
Three Pillars of Digital Strategy

1 Digital for **Operation**

Achieving Operational Excellence

Using optimization to generate resources for investing in the future

The Kyowa Kirin Group will achieve operational excellence through the construction of a global ICT infrastructure that uses an optimal combination of the following elements: a regional platform that responds with agility and flexibility to the unique characteristics of each region and market; a functional platform that enables each function to be optimized separately; and a globally integrated enterprise platform. In addition, to support new working styles in the new normal of today, we will create a secure, connected environment that enables employees to work anytime, anywhere. We will accelerate productivity gains through this digital shift in our operations.



2 Digital for **Innovation**

Transformation to a circular value chain of data

Adding value to internal assets to create new value

We will establish a circular value chain of data that maximizes the value of existing drugs and creates life-changing new drugs. This will work by circulating various data assets accumulated through past business activities across divisions within the Group. In the future, we aim to create new solutions beyond providing pharmaceuticals, through collaboration with various stakeholders and through the use of real-world data.

3 **Foundation** for Digital

Reinforcing our digital transformation infrastructure

Building a foundation of people and data to support digitization

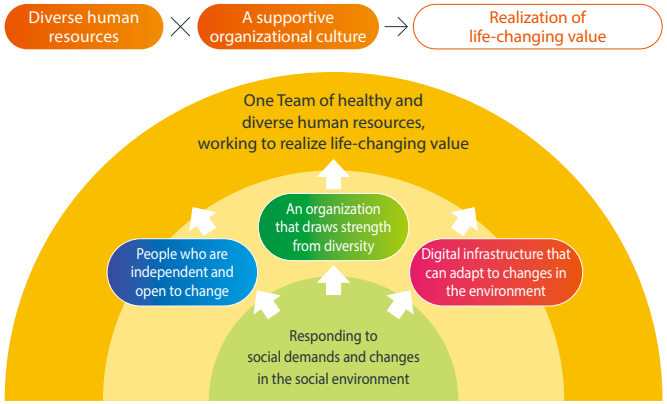
To develop a platform that supports innovation through a circular value chain of data, we will focus on building a company-wide data infrastructure, developing our organization and talent, and pursuing external collaboration. We will create an organization dedicated to digital transformation, which will acquire and develop digital talent such as data scientists. Alongside this, we will develop a company-wide data strategy and an ICT environment and operational processes. With this platform in place, we will pursue collaboration with external partners who have unique technologies and build a solid foundation for promoting digitalization that will help create value that is unique to Kyowa Kirin.

Human Resources

One Team of healthy and diverse human resources, working to realize life-changing value

Overall strategy

At Kyowa Kirin, we see human resources as the source of our innovation. One of the pillars of our management strategy in the 2021-2025 Medium Term Business Plan is "Strengthen our talent and infrastructure to realize life-changing value." We want to maximize each individual's capabilities, developing our people and our organization to continue creating new value through an openness to change. We have established Global Talent Management Basics for 2021-2025 as the vision for our human resources function. By working toward the realization of this vision, we will contribute to the promotion of the Group's management strategy. Ultimately that will enable us to create value that brings smiles to patients' faces.



Using employee engagement surveys

Kyowa Kirin has established important indicators for realizing a corporate culture in which a wide range of people can play an active role. We periodically conduct an employee engagement survey called the Global Engagement And Motivation Survey to observe how these indicators are assessed over time. We pay particular attention to employee engagement and employee enablement as important indicators for maximizing each employee's capabilities. The results of the survey enable us to identify group-wide issues and issues specific to each region/function. We work to make improvements by reflecting countermeasures into our action plans and implementing them. In addition, we are steadily implementing a PDCA cycle that measures the effectiveness of our countermeasures through periodic surveys. The results of these findings are then reflected into further measures. Through these efforts, we aim to create One Team where healthy and diverse human resources can work together to realize life-changing value.

Key Findings of 2021 Survey

- The survey scores showed a number of improvements on the previous year. The "Employee engagement" score was 68% (up +1 percentage point from the previous survey) and the "Employee enablement" score was 65% (+2 percentage points from the previous survey).
- The scores for "Strategy and direction," "Diversity," "Respect for the individual," "Degree of authority and autonomy," "Leadership," "Growth opportunities," and "Education and training" were either above or level with the average for pharmaceutical companies or the global average for high-performing companies. In particular, the following items had scores of 75% or higher, indicating a recognition of these areas as clear strengths: "Strategy and direction" at 76% (up 2 percentage points); "Respect for the individual" at 75% (up 3 percentage points); "Degree of authority and autonomy" at 75% (up 2 percentage points); and "Diversity and inclusion" at 76% (up 4 percentage points).
- The score for "Business processes and organizational structure" showed a trend of improvement compared to the previous survey. But we see this as an ongoing task and will make further efforts going forward.

Number of people surveyed / Response rate

- Number of people surveyed: 5,880
- Number of respondents: 5,646
- Response rate: 96%

Question categories

Employee engagement / Strategy and direction / Leadership / Quality and customer orientation / Respect for the individual / Growth opportunities / Compensation and benefits / Employee enablement / Performance management / Degree of authority and autonomy / Resources / Education and training / Cooperative framework / Business processes and organizational structure / Management philosophy and values / Code of conducts and compliance / Expectations work styles / Diversity and inclusion /Company quality culture

Benchmark data

Global corporate average; global average of high-performing companies, corporate average of pharmaceuticals companies, Japan corporate average, regional and country averages

Global Talent Management Basics for 2021–2025

- Align talent management processes with Kyowa Kirin Group's Mission, Vision, Values and business strategies.
- Attract diverse, world-class talent and create an environment that enables them to have long and successful careers and unleash their full potential to foster innovation and contribute to Kyowa Kirin Group's success in bringing smiles to people who face disease.
- As a Japan-based Global Specialty Pharmaceutical Company, emphasize people development and create talent pipelines for critical global positions.
- Provide equal opportunities for growth to all people and recognize their successes while creating an inclusive environment that allows people to demonstrate their diverse strengths.
- Use cutting-edge technology to support and strengthen talent management on a global level.
- Encourage line managers and employees to take ownership in talent management.

External evaluation

- Health Management Issues 2022
- Platinum Kurumin
- PRIDE Index 2021 (Silver)
- Certified Health and Productivity Management Organization 2022 (White 500)
- Eruboshi (3 stars)

Developing a global talent management system

In FY2021, we launched a global process for discovering, training, and selecting next-generation leader candidates to lead the One Kyowa Kirin structure. Previously, our talent management had used separate systems for each region. Developing the Global Succession Plan has brought greater visibility to our succession pipeline at a global level. That has made it possible to formulate more effective development plans based on the talent profile of each candidate. In the Japan region, we are promoting a systematic and strategic approach to talent development. We have launched a new training program for next-generation management human resources development, aiming to enhance our pipeline of future successors to management personnel.

From FY2022, we plan to implement a global human resources system (HRIS) for further accelerating the development and deployment of talent across regions and functions. The system will enable real-time sharing of data about excellent talent throughout our global organization. We have revised our global mobility rules to enable transfers across regions. We have also established a program for short-term assignments.

We operate a shared global rewards policy for the leadership of the One Kyowa Kirin organization, aimed at attracting top talent and encouraging individual employees to strive for higher goals and continue their growth. We continually review our rewards programs and processes to ensure market competitiveness, pay-for-performance, and transparency.

We evaluate positions within the Group using a shared set of guidelines that apply across regions and functions. We are also working to develop a shared global grade system. Our aim is to create a rewards program and career framework that aligns with our business needs and our growing corporate culture.

DE&I as a driving force for achieving our vision

Kyowa Kirin considers Diversity, Equity and Inclusion (DE&I) to be fundamental to our organization. It provides a source of innovation that drives sustainable growth. It guides our social responsibility as a Japan-based Global Specialty Pharmaceutical Company. It supports our creation of a workplace where employees can maximize their potential based on relationships of trust. It is vital to our success as we strive to create life-changing value and deliver this to patients around the world. In December 2021, we developed the Global DE&I Statement to promote understanding of DE&I and our actions to achieve it. We will continue to identify priority issues globally and in each region in line with this Statement, promoting proactive measures accordingly. As a near-term global priority, we aim to ensure that there is strong representation of women leaders in the One Kyowa Kirin structure. We have set a numerical target of increasing the percentage of global leader roles held by women from 29% at the end of FY2021 to 40% by 2030.

Japan

In Japan, we are working steadily and swiftly to provide an environment where a wide range of employees can perform at their best.

In particular, we have positioned women's empowerment and gender equality as priority issues. Our goal is to have at least 18% of management positions held by women by the end of 2025. In addition, we introduced an online nursing care support service and a nursery school enrollment support service. These services enable employees to continue their careers while balancing personal responsibilities like nursing care and childcare with professional ones. In addition, we are preparing to set up in-house nursery schools in the Mishima area in 2022 and in the Takasaki area in 2023.

People with disabilities comprise 2.43% of our Group workforce in Japan. We have decided to join the Accessibility Consortium of Enterprises (ACE) with the aim of pursuing further hiring of persons with disabilities.

We received a Silver rating in the PRIDE Index 2021, in recognition of our LGBTQ initiatives. Developed by the voluntary organization Work with Pride in 2021, this index evaluates efforts by companies and organizations to support members of the LGBTQ community and other sexual minorities.

APAC

As a melting pot of diverse ethnicities and cultures, the APAC region has a wide range of DE&I-related priorities from country to country. In FY2021, we placed particular emphasis on supporting women's success in the workplace. We raised awareness about unconscious bias towards women who are undergoing major life events such as pregnancy, childbirth, childcare as well as about the use of gender-neutral language in the workplace. In FY2022, we plan to strengthen outreach to the leadership team in particular, with the aim of forming a commitment from top management.

North America

In the North America region, emphasis on the importance of DE&I efforts only magnified during 2021. The Executive Committee was now comprised of 50% female leaders. A taskforce comprised of cross-functional employees and Executive Committee Sponsors was also formed to make further progress in this space. The steps taken in 2021 included offering employees the opportunity to attend confidential listening circles hosted by an external facilitator. We have also created a DE&I calendar of events to recognize awareness months and days for a specific group, culture or cause. We are committed to the launch of Employee Resource Groups and focus on Talent Acquisition, DE&I Training, Mentoring, Corporate Social Responsibility and Patient Research and Education.

EMEA

An Employee Resource Group employee-led network has also been launched in the EMEA region. We have organized workgroups around themes such as women, people with disabilities, people of color and minorities, and LGBTQ people. The aim of these workgroups is to promote inclusion of minority groups in the workplace through a bottom-up approach involving networking and various improvement activities.

We empathize with individual employees as they deal with various life events. We are working to support them by upgrading our systems to accommodate a variety of work patterns. The introduction of hybrid working models and compressed work allows individuals more flexibility in arranging where and when they work. As part of our support for employees raising children, we have also expanded our childcare leave system as well as our support for women returning to work after parental leave.

Our DE&I Statement

At Kyowa Kirin, we embrace and proactively promote Diversity, Equity and Inclusion in the workplace as an embodiment of our Core Values.

Commitment to Life:
Diversity, equity and inclusion in our teams enables us to reflect the people and communities we serve and be sensitive to their needs, putting patients at the heart of everything we do

Innovation:
We believe in diversity of thought where all employees are encouraged to share fresh new ideas, are listened to and empowered to deliver innovative solutions for patients around the world

Integrity:
We strive to create an environment where everyone has a sense of belonging and is free from any form of inequitable treatment

Teamwork/Wa:
We will build an inclusive culture that enables our employees to bring their whole, authentic selves to work, where we can grow together, feel valued and respected, and achieve our shared corporate Vision.

Seizing the opportunities of the changing times and optimize our future of work

Adapting the Hybrid Working Model to create greater value

The COVID-19 pandemic forced various inconveniences upon us, limiting our ability to work at the office or to visit customers. At the same time, we have made many adjustments as we adapted to the dramatically changing environment, adopting new ways of working. While we will continue to optimize our work patterns through trial and error in each region, we have proposed a hybrid working model. We have put in place three basic policies for this new way of working, through which we aim to create life-changing value and bring smiles to patients around the world.

Japan

In the Japan region, prior to the pandemic we had introduced several systems for enabling work flexibility: a work-from-home system; a flextime system with no core hours; and a discretionary work system for specialized work. We are applying these systems as appropriate for various job characteristics, promoting work styles that maintain a balance between advancing our business and controlling the spread of infection. We are advancing various measures to improve the effectiveness of hybrid working. Among these, we circulated a guide about the differences between face-to-face communication and remote work and how to use each one effectively. We are also reviewing our office functions.

APAC

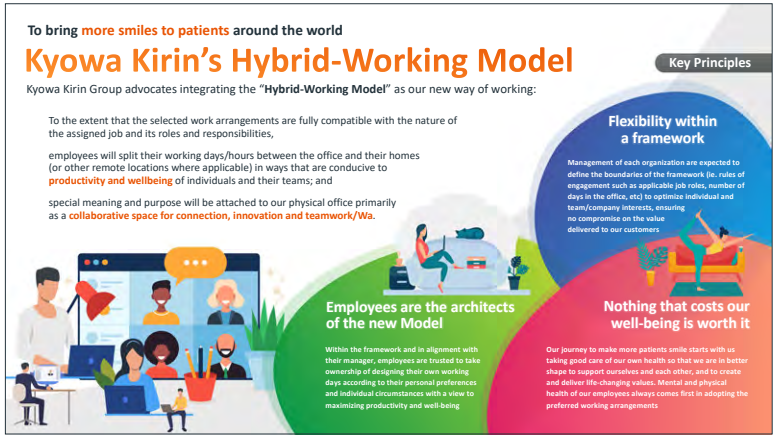
At Kyowa Kirin Asia Pacific, the APAC region headquarters company located in Singapore, we have established a system called "Flexi-Work." In our attempt at figuring out what would be the most effective ways of working for us, we established several "personas" to outline differences in work characteristics. (For example, person A spends a lot of time handling in-person tasks in the office, while person B has many online meetings in the evening, etc.) Using this model, we examined how to combine office work and working from home in a way that would suit these characteristics. We aim to provide greater work flexibility for our employees while also achieving the Company's goal of maximizing the value we deliver to patients.

North America

The North America region experienced many insights and learnings during the pandemic along with employee feedback via surveys relative to flexible work. As plans for return to work were underway, they introduced the Hybrid Working model where employees were only expected to work in the office 2–3 days a week so they could experience work from home and still benefit from in person collaboration for enhanced connections with teams and innovation. In addition to this offering, office based employees can also partake in a Work from Anywhere benefit for 4 weeks per year, flextime and summer hours with half days on Fridays between Memorial Day and Labor Day.

EMEA

The EMEA Region has seized the shift to remote work that was triggered by the pandemic as an opportunity for positive change. Reducing restrictions for many positions on where employees work has broadened the pool of potential hires and helped to attract the best talent. The hybrid working model also allows employees to work from a country of their choice within the EMEA region for up to 30 days per year. Employee attitude surveys have shown that allowing a variety of work styles has increased engagement.

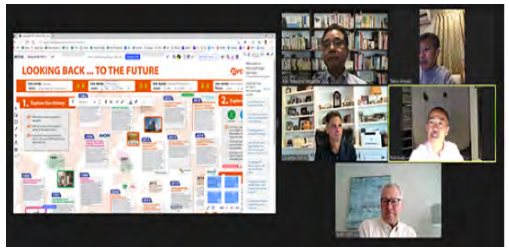


Corporate Culture Reforms

In Japan, we have been reforming Kyowa Kirin's corporate culture under the slogan "KABEGOE," which means "overcoming barriers". We have begun rolling out this initiative to other regions.

Members of the One Kyowa Kirin (OKK) leadership team including regional presidents and global function heads attended an initial two-day OKK Culture Workshop. The aim of this event was to deepen participants' understanding of the Company's vision and values through a discussion of the Group's past, present, and future. Participants were encouraged to think of actions toward "overcoming barriers" in terms of their own personal situation. There was intense debate on the day, reminding participants of the importance of creating value through alignment of all Group employees. Similar workshops have been rolled out in each region in stages, beginning in the second half of 2021.

In addition, we have updated our existing President's Award, renaming it the Commitment to Life Award. The new award will promote corporate culture reforms by recognizing achievements that embody Kyowa Kirin's values and the "KABEGOE" spirit. We received more than 70 entry submissions for the award from around the world, despite this being its first year of operation under the new program.



OKK Culture Workshop

TOPIC

Japan initiatives

Middle management support measures

We are focusing on providing support to middle management. We see their engagement as key to guiding the evolution of our corporate culture. Even the most gifted business leader cannot change an organization singlehandedly. The middle serves as the nucleus of an organization. It facilitates dialogue between management and staff, enabling barriers to be overcome. We launched this program in 2021 and it already has over 400 middle managers participating.

Health and Productivity Management
Create an organization in which an active and diverse group of people can work toward driving innovation creation

The Kyowa Kirin Group Wellness Action program aims to inspire employees and those around them to pursue behavioral change to improve their own health ("wellness action"). The program helps employees reduce health risks and improve their well-being, so that they can contribute to the Company and society as a whole. The status of each measure is checked and evaluated both quantitatively and qualitatively at management strategy meetings and other meetings.

In recognition of these efforts and achievements, the Company was included for the first time in the 2022 Health and Productivity Stock Selection, having met the prescribed criteria in the Health and Productivity Management Survey conducted by the Ministry of Economy, Trade and Industry. In addition, the Company has been recognized as a certified Health and Productivity Management Organization 2022 (White 500) for the sixth consecutive year since the program was launched.

Kyowa Kirin Group Wellness Action 2025

Objective

Employees and people around us	Society	Company
• Reduce risks to our mental & physical health • Improve the well-being	• Cope with social issues* * e.g. medical cost increase, obesity, activity qty decrease, imbalanced diets • Promotion of the Wellness Action has a good influence on outside of the company	• Enhance corporate value by improving performance of each one of us • Develop corporate culture to get over the wall through the Wellness Action

Ideal behavior	Employees and people around us work on the Wellness Action with our own motivation & excitement

Make employees active	Behavioral change for health				
Increase ratio of Most Effective Employees [Target in 2025] To exceed FY2020 result	Habit of exercise	Habit of meals	Habit of sleep	Non-smoking	Others

Kyowa Kirin Group Talent Management Policy

Employees	Acting autonomously and take on the challenge	⇄	Encouraging its employees to co-create new value	Kyowa Kirin

Business philosophy, Vision, Core values, and code of conduct of Kyowa Kirin Group

Japan

We have established Wellness Action 2025 GOALS as KPIs for Health and Productivity Management*1 and are focusing on behavioral change of each individual. We also assess the effectiveness of our health management using the Health Investment Management Accounting Guidelines. As part of the Kirin Group CSV management, we conduct Slow Drink, an annual training program on moderate drinking. The percentage of employees who abstain from drinking or are in low-risk drinking groups (less than AUDIT-10) employees is increasing every year. (It stood at 88.5% in FY2021, up 0.7 percentage points from the previous year.)

In addition, we implemented a walking campaign to provide opportunities for physical activity and stimulate communication amid restrictions on going out. Co-organized with our health insurance association, this "collabo-health"*2 project was attended by more than 3,000 people, more than 70% of our workforce. Furthermore, the smoking rate among our employees has remained below 5% since 2020—a decrease of more than 16 percentage points since we began measures to address this area. From a labor productivity standpoint, the outcome is estimated to have had a more than 60-fold return on investment.

*1 Health and Productivity Management is a registered trademark of the NPO Kenkokeiei.
*2 "Collabo-health" refers to collaborative activities organized through coordination between corporate health insurance associations and companies to enhance the health of employees and their families.

Behavior Change for Health Key Goals: Wellness Action 2025 GOALS			
Exercise	**Meals**	**Sleep**	**Vacation**
Walking campaign: average of 5,000 steps and participation rate of 80%	Percentage of employees who logged all their meals for two weeks out of the year: 80%	Percentage of employees who knew the best sleep habits for them: 80%	Average vacation days taken: 16 + days

Behavior Change for Health Priority Goals Kirin Group CSV Commitments (2021 Indicators)		
Drinking alcohol	**Rest**	**Mental health**
Score of AUDIT-10 or below: 78%	Response indicating positive work-life balance: Over 60%	Liveliness score: 115

APAC

To show our appreciation to employees as they continued to work from home, we had a COVID-19 Care Pack, Singapore National Day Pack, Mooncakes for Mid-Autumn Festival, and Christmas cookies delivered to their homes. We also held webinars to support the mental health of our employees. These provided opportunities to learn about the basic principles of mindfulness and the power of resilience through which we can overcome hardship and quickly recover from adversity.

North America

To emphasize the importance of mental health during the COVID-19 pandemic, we provided a "Recovery Day" off to all employees in May 2021. We also marked Mental Health Awareness month in May by offering various programs to our employees targeted at total well-being. We also introduced measures such as meeting free Friday afternoons, stretch breaks during meetings, camera free options for walking meetings, use of technology tools like Cortana (Microsoft assistant tool for personal productivity). We provided fitness programs including the Gympass (corporate fitness platform)and access to wellbeing apps and counseling. We sponsored a 30 day walking challenge and a healthy-self campaign.

EMEA

We held social activities and team challenges to foster a sense of comradery among employees and to help them and their families maintain their mental and physical wellbeing. Due to the popularity of the 2020 exercise project "Race to Dubai," an extended version, "Vendee Globe," was implemented in February 2021. Employees fully applied themselves to the activities which included not only exercise but also meditation and mindfulness.

Governance

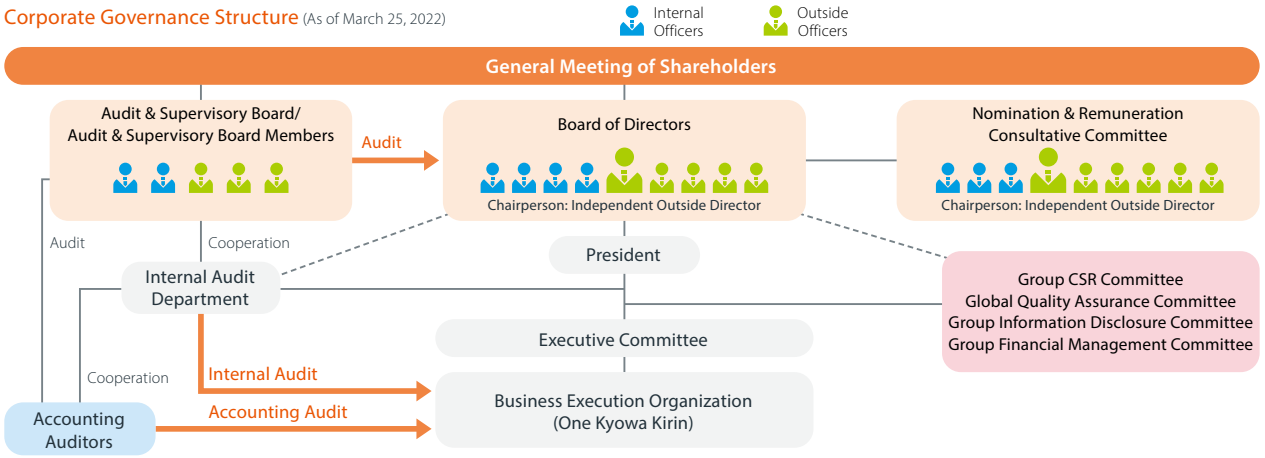
Basic Policy on Corporate Governance

Based on our Medium Term Business Plan and on our philosophy that "The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies," in order to achieve sustainable growth and increase corporate value over the medium to long term, we, as a company responsible for delivering social infrastructure, work on the enhancement of our corporate governance by ensuring transparency and fairness in decision-making, and establishing structures for timely and decisive decision-making and execution of management duties, and for appropriate monitoring and supervisory functions.

The Company has implemented all principles of the Corporate Governance Code in accordance with the principles for the prime market, which are applicable from April 4, 2022, and reports in accordance with the revised Code of June 2021.

A Transparent Governance Structure That Leverages the Strengths of Outside Officers

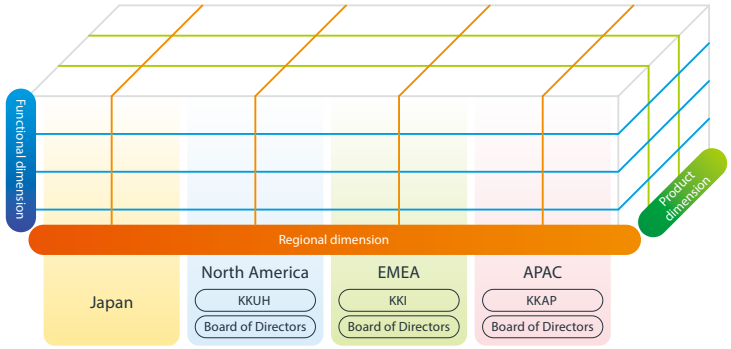
Corporate Governance Structure (As of March 25, 2022)



Initiatives to Strengthen Governance

- Established One Kyowa Kirin, a matrix management system comprising a four-unit regional dimension, a functional dimension, and a product (franchise) dimension, to enable governance of the rapidly globalizing executive organization
- Personnel for key positions in regions and functions are nominated by the Nomination & Remuneration Consultative Committee.
- To strengthen the regional executive oversight function, a board of directors has been established at each regional operating company. Outside Directors are nominated by the Nomination & Remuneration Consultative Committee based on factors such as experience in the global pharmaceutical business.

Matrix Management (One Kyowa Kirin)



Directors and Board of Directors

Taking into account its fiduciary duties and accountability to shareholders, the Board of Directors works diligently to realize the Company's corporate philosophy, and secure the Group's sustainable growth while increasing corporate value over the medium to long term, by establishing effective and efficient corporate governance. The Board of Directors makes decisions on significant matters pertaining to business execution by the Group. This includes the long-term management vision, medium-term and annual business plans of the entire Group and key Group companies, as well as statutory matters. The Board of Directors is also responsible for supervising the execution of Directors' duties, formulating basic policies on sustainability and supervising related initiatives, and establishing an adequate internal control system for the entire Group in cooperation with the internal audit department.

In addition to items stipulated by law and the Articles of Incorporation, the Board of Directors stipulates matters to be resolved by the Board of Directors in the Regulations of the Board of Directors and delegates other authority related to business execution to the executive officers in charge of each business operation.

With respect to the Board's composition, the maximum number of Directors is 10, in accordance with the Articles of Incorporation. Upon considering the skill set—that is, knowledge, experience, capabilities and insights—necessary to become a Global Specialty Pharmaceutical Company and ensuring diversity, we established a transparent governance system, which is well-balanced as a whole. In order to ensure the effectiveness of objective management oversight, five independent Directors have been appointed to the Board from outside the Company, which is the majority of the total number of current Directors, and the position of Board Chair is assumed by Mr. Akira Morita, who is an independent Outside Director. Policies and procedures for the selection of director candidates are discussed by the Nomination & Remuneration Consultative Committee and decided by the Board of Directors. As of March 25, 2022, the Company's Board of Directors consists of nine Directors (eight male and one female, including five Outside Directors).

Audit & Supervisory Board Members and the Audit & Supervisory Board

As an independent body mandated by shareholders, the Audit & Supervisory Board and its members audit the Directors as they carry out their duties as means to supervising and verifying the status of establishing sound management for the Group's sustainable growth and enhancement of corporate value over the medium to long term. Leveraging the ability of full-time Members to gather information within the Group as well as their independence, Audit & Supervisory Board Members actively express their opinions at Board of Directors' meetings. At the same time, Audit & Supervisory Board Members also strive to put in place and improve the framework used to ensure the effectiveness of auditing by each Member. Furthermore, in order to better provide information to Outside Directors, Audit & Supervisory Board Members exchange opinions with Outside Directors, and provide information which they have obtained through their auditing activities.

The Audit & Supervisory Board comprises persons with appropriate knowledge of finance and accounting matters. In accordance with the Company's Articles of

Incorporation, the Audit & Supervisory Board has at least three members, at least half of whom are outside Audit & Supervisory Board Members. As of March 25, 2022, the Company had five Audit & Supervisory Board Members (three male and two female, including three Outside Audit & Supervisory Board Members).

Nomination & Remuneration Consultative Committee

The Company established the Nomination & Remuneration Consultative Committee as an advisory body to the Board of Directors. Its purpose is to supplement the functions of the Board of Directors and further enhance the transparency of our governance system. The Committee deliberates and decides on the Company's nomination and remuneration from an objective and fair perspective, and reports to the Board of Directors. The Nomination & Remuneration Consultative Committee consists of 10 members, of whom the majority (7) are independent Directors. The chairperson of the Committee is selected from among the independent Outside Directors.

The Nomination & Remuneration Consultative Committee deliberates and decides on proposals for policies regarding: the appointment and removal of directors, executive officers, Audit & Supervisory Board Members and candidates for these officers; appointment and removal of senior directors; duties of individual directors; the policy for determining the successor of the current CEO of the Group; candidates for presidents and other key positions at individual Group companies; remuneration systems, levels, and remuneration amounts for Directors, Executive Officers, Audit & Supervisory Board Members, and for presidents and other key positions at individual Group companies. After deliberating on and deciding these matters from an objective and fair perspective, the Committee presents proposals to the Board of Directors.

CEO Succession Planning

The Nomination & Remuneration Consultative Committee conducts ongoing discussions about the selection and development of individuals who, from the perspective of KKC, would be ideally qualified for the position of CEO and reports its findings to the Board of Directors. The discussion theme includes knowledge, skills and experience needed for the role of CEO, as well as the following ideal profile of CEO, for example:

- Deep understanding of and full commitment to the Company's philosophy and core values
- Strong sense of responsibility toward society (patients) and the Company (employees)
- Determination to create value for society and to change the Company for the better
- Competence to create a future vision for the Company and penetrate it beyond national borders

Criteria regarding the Independence of Outside Officers

Kyowa Kirin has put in place and made public details of its own unique set of selection standards in connection with the criteria used to ensure the independence of outside officers. To ensure the transparency and objectivity of our governance function while exerting proper management oversight, the Company referred to the provisions for independent outside officers stipulated in the enforcement rules for securities listing regulations of the Tokyo Stock Exchange as well as the independent directors' nomination reference model created by the Japan Association of Corporate Directors in 2011, as well as the independence criteria for Outside Directors and Outside Audit & Supervisory Board Members that the Kyowa Kirin Group itself established to ensure independence in relation to our Group.

Functions of Outside Directors and Outside Audit & Supervisory Board Members

In order to improve the fairness and transparency of its corporate governance while ensuring the Group's sustainable growth and boosting corporate value over the medium to long term, Kyowa Kirin appoints at least one-third (5 out of 9 directors) independent Outside Directors who meet the Company's criteria for independence as Outside Directors.

Our Outside Directors have various backgrounds, expertise, and experience. They apply their wealth of experience and knowledge to the management of the Company, supervising the Company's management from an objective and fair perspective. The Company's Outside Audit & Supervisory Board Members apply their expertise, knowledge, and experience to auditing the Company's management from an objective and neutral standpoint, ensuring the reliability and soundness of our management.

Board Members with a Wide Array of Skills

The Board of Directors comprises diverse individuals with various skills (knowledge, experience, etc.). This is to enable the Board of Directors to fulfill its decision-making and management oversight functions appropriately and to enhance the transparency of our governance structure.

	Name	Outside Independent	Nomination & Remuneration Consultative Committee	Professional skills							
				Corporate management/ Business strategy	Global business	Finance, accounting and banking	Legal, governmental affairs and compliance	HR and labor	Healthcare	R&D	Production and SCM
Directors	Masashi Miyamoto		●	●	●		●		●	●	
	Yutaka Osawa		●	●			●		●	●	●
	Toshifumi Mikayama		●	●	●				●	●	
	Takeshi Minakata			●	●				●		●
	Akira Morita [The Board chair]	●	●				●		●		
	Yuko Haga	●	●	●	●				●		
	Jun Arai	●	Chairperson	●	●	●					
	Takashi Oyamada	●	●	●	●	●		●			
	Yoshihisa Suzuki	●	●	●	●					●	●
Audit & Supervisory Board Members	Hiroshi Komatsu			●	●	●			●		
	Masaki Ueno				●	●	●				
	Keiji Kuwata			●							●
	Tomomi Yatsu	●	●			●	●				
	Mayumi Tamura	●	●	●	●	●					

Reinforcement of the Effectiveness of the Board of Directors

To identify gaps between expected roles and responsibilities of the Board of Directors set forth in the "Kyowa Kirin Corporate Governance Policy" and the actual state of the Board of Directors in 2020–2021, we conducted an evaluation on the effectiveness of the Board of Directors. With respect to the evaluation of the Board's effectiveness, from the perspective of ensuring the effectiveness of governance, we identified wide-ranging issues, not limited to operational issues of the Board of Directors.

Based on the evaluation score, comments in the survey and interviews, external advisor's opinion, and exchange of opinions at the Board, we concluded that the effectiveness of the Board of Directors was secured. This year, we added questions for the members of the Nomination & Remuneration Consultative Committee, an advisory body to the Board of Directors, and concluded that the appropriateness of access to information as well as agenda/deliberation are ensured.

1. The evaluation method for Board effectiveness in 2021

Since 2020 when the current mid-term business plan was formulated, for the purpose of identifying issues from the mid- to long-term perspective, in addition to a survey, we have conducted interviews with some officers. This year, we interviewed the chairperson of the Board of Directors and the chairperson of the Nomination & Remuneration Consultative Committee, both of who are independent officers. Furthermore, taking into account the results of the survey and interviews, we organized a meeting where only independent officers exchange their opinions, followed by the exchange of opinions among all Directors and Audit & Supervisory Board Members; and then made an evaluation.

Main themes of the survey and interview questions

1) Growth Strategy/Medium Term Business Plan
2) Global Governance System
3) Governance System as a Listed Subsidiary
4) Ensuring Diversity of the Board of Directors
5) Capital Strategy
6) Risk Management (improvement of the system)
7) Use of Optional Approach (deliberation on remuneration)
8) Use of Optional Approach (deliberation on nomination)
9) Dialogue with Shareholders
10) Sustainability
11) Topics of Deliberations
12) Training for Directors and Audit & Supervisory Board Members

2. FY2021 issues and FY2022 initiatives

Based on the evaluation results of the Board's effectiveness, we plan to implement the following measures for improvement in 2022:

1) Advancing discussion on capital strategy

Reporting on the long-term product portfolio will be regularly made to the Board of Directors as a Board meeting agenda, and the Board will have more opportunities to discuss investment priorities, etc. from the mid- to long-term perspective.

2) Discussion for further strengthening risk management

The Board will share information on risk management, including what was implemented, the current risk management structure and issues, and the future plans, and have more opportunities to discuss matters from the mid- to long-term perspective.

3) Advancing discussion on sustainability

Under the theme of updating non-financial KPIs and materiality, the Board will have more opportunities to discuss priorities, relationship with the business strategy, etc. Furthermore, we will increase opportunities for regularly monitoring the progress of individual activities related to sustainability and exchanging opinions.

4) Discussion of diversity on the Board of Directors, etc.

We will increase opportunities for the Nomination & Remuneration Consultative Committee to discuss the Board composition and required skills for a Global Specialty Pharmaceutical Company. We will arrange opportunities for the Committee to report such discussions to the Board of Directors, and opportunities for the Board to discuss the matters.

5) Further improving operation of the Board of Directors to increase its effectiveness

The Board of Directors will appropriately delegate its authority to business executives, and strive to secure sufficient time for deliberations at Board meetings on important matters including various strategies. Furthermore, we will arrange opportunities outside the boardroom to exchange opinions, thus increasing opportunities for discussions with the business executives.

3. Achievements in addressing issues identified in the 2020–2021 evaluation

1) Medium- to long-term global governance system

We increased opportunities for discussion from the global and medium- to long-term perspectives, including Board meetings and special management meetings. In July 2021, we revised our global governance structure, transitioning to a new One Kyowa Kirin system based on regional, functional, and product dimensions.

2) Training for Directors and Audit & Supervisory Board Members

We conducted online training for officers on corporate governance, DX, ESG, etc. which are relevant to our business challenges.

3) Strategic dialogue with shareholders

The Board of Directors discussed the policy for disclosure of the Medium Term Business Plan as well as opinions from stakeholders including shareholders and investors. An ESG briefing session was held with the participation of Outside Directors, creating new opportunities for dialogue with shareholders.

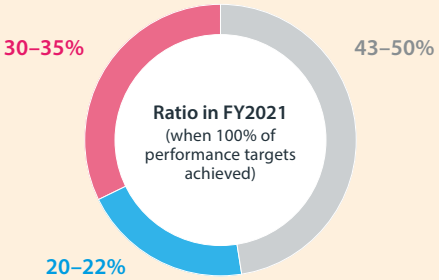
Basic policy on remuneration of Directors and Audit & Supervisory Board Members

Remuneration for Directors and Audit & Supervisory Board Members is designed to increase commitment to the Company's further sustainable growth and improvement in corporate value, to attract and retain suitable talent who aspire to help the Company make the leap forward to a Global Specialty Pharmaceutical Company, to motivate executives to contribute to the Company by fulfilling their respective duties as Directors or Audit & Supervisory Board Members and determined through a transparent and appropriate process by adopting an objective viewpoint. In order to realize this basic policy, investigations and deliberations on executives' remuneration are conducted by the Nomination & Remuneration Consultative Committee, which consists of a majority of independent officers, and is chaired by an independent Director.

Claw back provision

Kyowa Kirin has established a claw back provision that allows the Nomination & Remuneration Consultative Committee to request the return of Executive Director and Executive Officer remuneration in the case of such events as illegal acts or violations of laws and regulations.

Ratio of Fixed Compensation and Variable Compensation



- Base compensation in a fixed amount
- Short-term incentive compensation (variable): Annual performance-based bonus
- Medium- and long-term incentive compensation (variable): Share-based remuneration with restrictions on transfer and performance-linked share-based remuneration (Performance Share Unit)

Executive Remuneration

	Fixed compensation	Short-term incentive compensation (variable)	Medium- and long-term incentive compensation (variable)	
Type	Basic Remuneration	Annual Performance-Linked Bonus	Share-based remuneration	
			Share-based remuneration with restrictions on transfer	Introduction of performance-linked share-based remuneration (Performance Share Unit) from FY2021
Payment eligibility	Directors and Audit & Supervisory Board Members	Executive (Internal) Directors	Executive (Internal) Directors	
Purpose (Incentive for Officers)	Provide remuneration commensurate with the role and responsibilities of each officer, referencing peer company size and remuneration levels	Raise awareness toward the need to contribute to improving business performance each fiscal year	Have Directors of the Board of the Company share in the benefits and risks of share price fluctuations with the shareholders, and provide greater incentive to the Directors of the Board of the Company to elevate the share price and boost corporate value	Provide incentives for achieving the Medium Term Business Plan and the sustainable enhancement of corporate value by clarifying the link between remuneration, corporate performance and the Company's stock value, and promote further value sharing with shareholders
Payment method	Cash	Cash	Stock	Stock and cash (in roughly equal amounts)
Payment schedule	Monthly	A certain time each year (generally April)	A certain time each year (generally April)	
Evaluation indicator	—	Annual targets (revenue and net profit)	—	ROE / Revenue CAGR / core operating profit ratio
Factor for determining the amount of remuneration	Role and responsibilities	Achievement of targets (Payment rate of 0% to 200%) * Non-financial target for the Director responsible for compliance only	Base amount determined based on basic remuneration and stock price	Base amount determined based on basic remuneration, stock price, and achievement of targets for three consecutive fiscal years (Variation rate of 0% to 150%)
Approximate ratio (when performance targets are achieved)	1	Around 0.4 to 0.5	Around 0.6 to 0.8	

Remuneration*1 by position (FY2021)

Position	Total Remuneration (Millions of yen)	Breakdown of Remuneration (Millions of yen)				Number of Eligible Officers
		Basic Remuneration	Annual Performance-Eligible Officers Linked Bonus*2	Share-based remuneration with restrictions on transfer*2	Performance-linked share-based remuneration*2, 3	
Directors (Excluding Outside Directors)	331	181	66	64	19	3
Company Auditors (Excluding Outside Company Auditors)	29	29	—	—	—	1
Outside Directors	62	62	—	—	—	5
Outside Audit & Supervisory Board Members	60	60	—	—	—	4

Note 1. The above information includes one Outside Director and one Outside Audit & Supervisory Board Member who retired at the end of the Ordinary General Meeting of Shareholders held last year.
Note 2. The amounts of performance-linked annual bonuses, share-based remuneration with restriction on transfer, and performance-linked share-based remuneration were recorded as expenses for the current fiscal year. As for the performance-linked share-based remuneration, both cash and non-cash portions are to be paid/provided after the relevant performance evaluation period.
Note 3. The number of restricted shares provided to Executive Directors in the current fiscal year was 20,364 shares (the paid-in amount per share was 3,145 yen, which is the closing price on March 23, 2021).
Note 4. The above information does not include one Director and one Audit & Supervisory Board Member who have served without pay.

Continued efforts as a listed subsidiary to strengthen governance

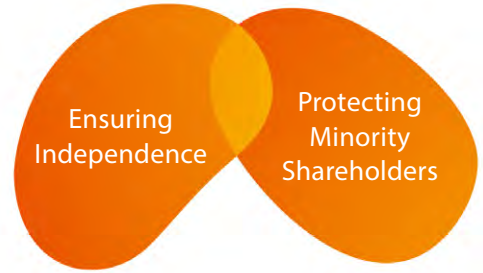
Past Initiatives

Ensuring management independence

- The Integration Agreement clearly states that management independence is ensured, requiring reasonable efforts to maintain Kyowa Kirin as a listed company
- M&A decisions are made solely by the Company, without the need for prior consultation with the parent company
- In accordance with the Company's own investment policy, the interest rate on loans is determined based on reasonable judgment after considering market interest rates based on the loan period, and the loan period is shortened (in principle, one month)

Decision-making process that starts with protecting minority shareholders

- Directors from the parent company do not participate in resolutions when they are special interested parties
- A third-party committee was established at the time of the transfer of Kyowa Hakko Bio to ensure impartiality in decisions



Future Initiatives (from March 2022)

- Strengthen minority shareholder protection by securing a majority of independent Outside Directors
- Enhance system corresponding to revised CG Code and new market requirements

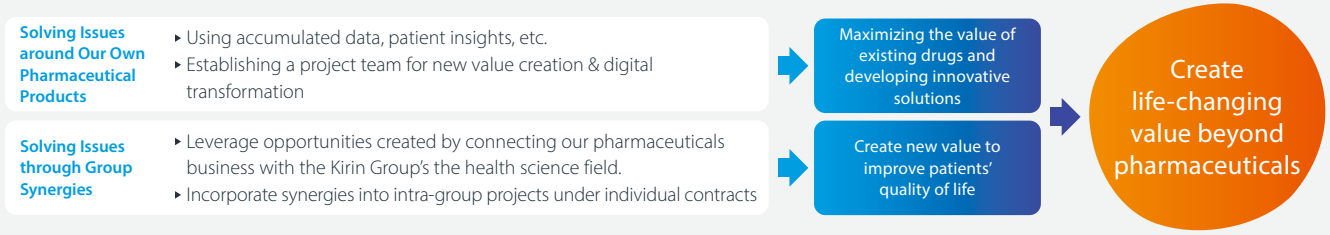
FOCUS ON

Synergies with the Kirin Group

The Kirin Group aims to become one of the world's leading CSV companies by creating value in areas ranging from food to medicine. We are the only Kirin Group company whose core business is medicine.

We believe that the management resources of the Kirin Group are extremely useful for realizing our goal of creating life-changing value. The Kirin Group's knowledge and expertise contributes greatly to our business. In production management and engineering, it helps us establish our business foundation. In environmental conservation and supply stability, it helps us fulfill our social responsibility.

We also believe that connecting the health science field, on which the Kirin Group focuses, and the medical field, in which we are involved, offers many opportunities for us to pursue our goal of going beyond pharmaceuticals to meet society's medical needs.



Internal Control

The Company steadily maintains and operates the following set of internal control systems, based on the fundamental principles of the internal control system of its parent company, Kirin Holdings Company, Limited and in line with the Companies Act, Article 362, paragraph 4, item vi: "The development of systems necessary to ensure that the execution of duties by directors complies with laws and regulations and the articles of incorporation, and other systems prescribed by the applicable Ordinance of the Ministry of Justice as systems necessary to ensure the properness of operations of a Stock Company." The status of maintenance and operation was reported and confirmed by the Board of Directors on January 17, 2022.

1. System to ensure compliance of execution of duties by the Directors and employees of the Company and its subsidiaries (hereinafter referred to as "the Kyowa Kirin Group") with laws and regulations and the articles of incorporation ("Compliance System")
2. System to ensure the proper preservation and maintenance of information regarding the execution of duties by the Directors of the Company ("System of Information Preservation and Maintenance")
3. Regulations and other systems related to the risk management of the Kyowa Kirin Group in the event of loss and other circumstances ("System for Risk Management")
4. System to ensure the effective and efficient execution of duties by the Directors of the Kyowa Kirin Group ("Effective and Efficient Performance System")
5. System for reporting to the Company on matters concerning the execution of duties by the Directors of Kyowa Kirin Group and system to ensure the properness of operations of other duties by the corporate group comprising the Kyowa Kirin Group and the parent company ("System for reporting for execution of duties and other Group internal control system")
6. Matters related to employees that assist the Audit & Supervisory Board Members of the Company upon their request for assistance, matters related to the independence of the relevant employees from the Directors of the Company and matters related to effectiveness of directions given to such employees by the Audit & Supervisory Board Members of the Company (hereinafter collectively referred to as "Systems related to Audit & Supervisory Board Members")
7. System to ensure reporting to the Audit & Supervisory Board Members of the Company by the Directors and employees of the Company, and by the Directors, Audit & Supervisory Board Members, and employees of the Kyowa Kirin Group subsidiaries
8. System to ensure that anyone who has made a report as described in the preceding provision to the Audit & Supervisory Board Members of the Company, shall not be subjected to any unfair treatment due to the report made.
9. Matters regarding procedures for advance payment or reimbursement of expenses incurred in connection with the execution of duties of the Audit & Supervisory Board Members of the Company.
10. Other systems to ensure the effectiveness of audit by the Audit & Supervisory Board Members of the Company (status of internal control system)

Stakeholder Engagement

Engagement 1

IR activities focused on dialogue with shareholders

Kyowa Kirin believes that constructive dialogue with investors and shareholders will lead to further improvements in corporate governance and, in turn, to increased corporate value over the medium to long term. Based on this understanding, the Company vigorously engages in IR activities spearheaded by the president, executives responsible for corporate planning, product strategy, finance, and R&D as well as the three full-time staff that make up the IR team. By ensuring that the information gathered from these activities is properly conveyed to management, positive steps are being taken to practice productive two-way communication. In FY2021, we were able to carry out IR activities with the help of outside directors (ESG briefings and individual interviews). Meanwhile, during the COVID-19 pandemic, by taking full advantage of web and tele-conferencing tools, we have engaged in dialogue with investors and shareholders to an even greater extent than before the pandemic.

IR Activities (implemented in FY2021)

Financial results briefings / telephone conferences	4 times
IR events (topics: tie-ups, ESG, pipeline)	3 times
IR meetings with the President	33 times (95 companies in total)
IR meetings with other senior management	38 times (42 companies in total)
IR meetings with IR staff	139 times (271 companies in total)

Engagement 2

Comprehensive Information Disclosure

Recognizing the need for transparency and fairness, Kyowa Kirin makes every effort to ensure the disclosure of high-quality information in accordance with its disclosure policy in order to improve dialogue with investors and shareholders. In addition to the Timely Disclosure Network (TDnet) system provided by the Tokyo Stock Exchange, Kyowa Kirin uses its own shareholder and investor website, in principle available in both Japanese and English with the exception of certain information, as a tool to ensure immediate and fair disclosure of information.

Company's Shareholder and Investor Website
https://ir.kyowakirin.com/en/index.html

Engagement 3

Shareholder meetings focused on dialogue

Convocation notifications concerning the General Meeting of Shareholders are, in accordance with the Corporate Governance Code, sent around three weeks prior to the meeting so that shareholders have sufficient time to consider the proposals to be voted on, and also are electronically posted on our website, etc. Furthermore, in consideration of foreign investors, English translations regarding the convocation notices and usage of the electronic voting platforms are made available. Securities Reports are also disclosed prior to meetings. From the shareholder meeting held in March 2021, we posted the video of the day and a summary of shareholder Q&A on the website following the meeting. At the shareholder meeting held in March 2022, we allowed shareholders not participating in person on the day of the meeting to participate via live streaming and submit questions in advance. We will continue to aim for more open shareholder meetings going forward.

Engagement 4

High marks from external bodies

In recognition of its strong environmental, social and governance (ESG) practices, Kyowa Kirin is included in multiple socially responsible investment (SRI) indexes in Japan and overseas.

FTSE Blossom Japan Sector Relative Index

FTSE4Good

FTSE Blossom Japan

S&P/JPX Carbon Efficient Index

2021 Sompo Sustainability Index

2021 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

2021 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

! FTSE Russell (a trading name of FTSE International Limited and Frank Russell Company), based on the results of a third-party investigation, certifies that Kyowa Kirin Co., Ltd. has met the requirements for inclusion in the FTSE Blossom Japan Index and has become a constituent member of the index. The FTSE Blossom Japan Index was created by global index provider FTSE Russell and is designed to measure the performance of Japanese companies that demonstrate excellent environmental, social and governance (ESG) practices. The FTSE Blossom Japan Index is widely used to create and evaluate sustainable investment funds and other financial products.

! The inclusion of Kyowa Kirin Co., Ltd. in any MSCI index, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement or promotion of Kyowa Kirin Co., Ltd. by MSCI or any of its affiliates. The MSCI indexes are the exclusive property of MSCI. MSCI and the MSCI index names and logos are trademarks or service marks of MSCI or its affiliates.

Discussion with Outside Directors

Yuko Haga, Ph.D.
Outside Director

Jun Arai
Outside Director

Kyowa Kirin is committed to sound and transparent management, as we work to achieve sustainable growth and enhance our corporate value over the medium to long term.

This discussion between our outside directors focused on the relationship between the management of our business and our stakeholders.

Management that responds to social change

Haga: The Kyowa Kirin Group has continued to grow as a pharmaceutical company that provides high-quality pharmaceuticals to people living with illness, helping to improve their quality of life. I believe that, even amid dramatic changes in our society, our purpose as a company remains constant.

We have set forth a new vision through to 2030, aligned to the Medium Term Business Plan that we announced in 2021. As I see it, the new vision articulates the role that Kyowa Kirin has fulfilled over the years, to renew our recognition of that role. In terms of specific measures to achieve the vision, however, we were very conscious of the changing external environment as we carried out discussions in the Board of Directors.

Arai: I believe that this pandemic will trigger a major paradigm shift in the pharmaceutical industry. The traditional approach—individual companies separately researching, developing, and providing their own pharmaceuticals—puts constraints on quantity and speed. That approach is ineffective when it comes to responding to a pandemic like this one. But when companies collaborate, effective vaccines and treatments can be delivered rapidly to those who need them. I feel that the efforts to end this pandemic have produced a model for this kind of co-creation of knowledge.

Kyowa Kirin is undergoing a major evolution as a Japan-based Global Specialty Pharmaceutical Company (GSP). We have begun our greatest challenge—spreading our wings around the world through collaborations and partnerships. We are facing a big wave of change. I believe that overcoming this and accomplishing our challenge will strengthen our sense of purpose for the Kyowa Kirin Group.

Haga: I too see the potential for a paradigm shift. What would happen, first of all, is a game change—a complete transformation of the competition within the pharmaceutical industry. We will have to develop strategies for achieving our goals, together with industries and companies that we would not have expected to be working with. It is important for us to recognize and anticipate such changes alongside developing specific plans. For example, one such example is the idea of what Kyowa Kirin can do beyond the narrow field of pharmaceuticals and in the broader field of healthcare. Many companies from different industries have already entered the healthcare field. So it is time to explore what kind of companies we can partner with to contribute to society while using our own strengths.

Strengthening our global governance structure

Arai: We have been working to strengthen our global governance structure. But when it comes to the question of whether our system is suitable for the world stage, I feel that there is still a gap between where we are and the ideal position.

One major challenge is to clarify who makes decisions within the global business structure. In 2019 we launched One Kyowa Kirin, a global matrix organizational structure. We appointed personnel to head each of the regional and functional organizations. However, we don't see the establishment of this system as the goal. We need to be agile. We need to improve the matrix structure wherever there are obstacles to decision-making. We have already made some modifications, mainly to the sales system. But it is like the blood circulation in the body—if there are areas of poor circulation you have to get the blood flowing again. We must avoid overlooking problems, monitoring the matrix carefully and updating it as appropriate. The global business

environment is changing minute by minute. If we get complacent, our growth will slow down. I believe that this is something that management should be keenly aware of.

Haga: Your blood metaphor is exactly right. In business management, there are many cases where something that is going well right now will not be going well a year later. At Kyowa Kirin, our growth is accelerating. So our field-level strategies in each region should be changing every year to adapt to the environment. We need to closely monitor our system in detail to ensure that blood is flowing correctly and communication is smooth. This is one particular area where I believe our objective viewpoint as outside directors can be useful.

Currently, as outside directors we have the opportunity to interview each regional head and functional head. Here, too, I check that the blood is flowing well throughout the organization. I compile any issues that I find and make recommendations to the Board of Directors. It is important to use those insights as opportunities to upgrade the organization. In particular, the value created by Kyowa Kirin only emerges when the entire value chain is properly connected. For this reason, I would like to see each head to work not only within his or her own jurisdiction, but also with a bird's-eye view of the whole business. From that perspective, they should consider who it would be best to collaborate with.

I have also had the opportunity to talk with the internal audit department. I appreciate that they audit the Company extremely well, not only for compliance, but also for management risks. With that said, it is not yet clear to us outside directors who will have responsibility for addressing the issues that have been identified. This is an issue that needs to be recognized.

Arai: Going forward, it will become increasingly important to keep a global perspective in our thinking. The domestic business is still quite large, but its prospects for future growth are limited. In contrast, we can expect further growth in Europe, the United States, and Asia. In fact, global topics tend to be the main focus of discussions at Board of Directors meetings. The pandemic underscored just how much variation there is in policies and regulations from country to country and region to region. The world is far from uniform. I believe that we have witnessed once again the difficulty of bringing together all of our bases around the world. We must engage in thorough discussions on how we can strengthen our global governance.

Engagement with shareholders and investors

Arai: President Miyamoto's attitude is to provide as much information as possible to shareholders and investors and to respond sincerely to their requests. At the General Meeting of Shareholders, the question-and-answer session is very thorough. We outside directors also participate in the meeting and sometimes explain the Company's management situation.

We are currently in the growth phase as we transform into a GSP, so I am sure we will experience many failures going forward. That is why I would like to promote constructive dialogue with our shareholders and investors—about how we can overcome our failures and channel them toward the next stage. I believe that maintaining this kind of transparency in our approach will help us build relationships of trust with all our shareholders.

Haga: Exactly. Openly explaining both successes and failures is really important in investor relations. To that end, it is important to have a system in place for prompt reporting of problems to the Board of Directors as they arise. In this regard, Kyowa Kirin promptly reports problems to the Board of Directors without concealment. I find this reassuring. It shows that this is an environment that is conducive to me carrying out my role as an outside director.

Arai: Recently I had the opportunity to have a discussion with investors on the subject of ESG. I get the sense that the pandemic has taken investors' interest in ESG to another level. Kyowa Kirin defined new material issues in 2021, including improving access to medicines and mitigating and adapting to climate change. Steadily implementing activities to address these critical issues will be an important growth strategy for the Group. I see a need to further enhance ESG information disclosure so that investors can understand this strategy.

Protecting minority shareholders

Arai: Information related to transactions between the parent and the Company is reported accurately to the Board of Directors. As outside directors, we assess such transactions as sound. In our view, minority shareholders are not being disadvantaged.

An appropriate parent-subsidiary relationship is one in which the parent company and the subsidiary have a shared vision that the parent company and the subsidiary should pursue. This vision is incorporated into each other's strategies and activities, creating a positive cycle. I call this a forward rotation of parent-subsidiary listings. Keeping this cycle in rotation ensures that the interests of all minority shareholders are protected. But when the cycle is reversed—because of inconsistency with Group values— that becomes a problem. It causes a disadvantage by interfering with the strategies that each entity should be advancing.

Just as Kyowa Kirin is undergoing a period of major change, so too is our parent company, Kirin Holdings, whose movements are becoming more dynamic than ever. That is why I see it as increasingly important for us as outside directors to fulfill our role of determining whether the relationship with parent company is in forward or reverse rotation.

Haga: You are right. As outside directors, we provide an objective perspective. It is very important to have eyes watching for signs of a reverse rotation. We will continue to supervise the Company with a stricter eye. As we do so, we will always keep in mind that transactions with conflicts of interest can result in an immediate loss of the trust that we have earned over the years from investors and shareholders.

To our shareholders and investors

Arai: Kyowa Kirin is undergoing a transformation from our past domestic-centered business to GSP. That process is a difficult path, with ups and downs. Compared to the world's top pharmaceutical manufacturers, there is still a gap in terms of the governance structure and organization as I mentioned earlier. I believe that explaining things clearly to our shareholders and investors will be vital as we move forward. We need to gain their understanding that we are a company that will overcome this gap and continue to grow. Achieving short-term goals is also important. But I hope that shareholders and investors can guide and encourage us from a long-term perspective, based on and an understanding of where Kyowa Kirin is relative to its goals. We will of course actively disclose comprehensive and detailed information.

Haga: We appreciate the valuable feedback we receive regularly from our shareholders and investors. For our group to grow in the future, we must continue to take appropriate risks. In other words, we must promote offensive governance as well as defensive governance. I would like to advise the Board of Directors on how to manage this risk. I recommend that at times they should be bold enough to take on risks. Of course, we will fully explain these risks to our shareholders and investors.

We will continue to welcome feedback from everyone, including on the contents of this annual report. Even harsh criticism gives us insights that we can reflect into our management. We thank you for your continued support.

Management

Aiming to be a company that brings smiles to the faces of patients by continuing to provide **life-changing** value.

Directors' Profiles

Representative Director of the Board, President and Chief Executive Officer

Masashi Miyamoto, Ph.D.

Apr. 1985 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Apr. 2011 Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Mar. 2012 Executive Officer, Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Jul. 2014 Executive Officer, Director, Strategic Product Portfolio Department and Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2015 Executive Officer, Director, Strategic Product Portfolio Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2017 Director of the Board, Managing Executive Officer, Strategic Product Portfolio Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2017 Director of the Board, Managing Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Representative Director of the Board, President, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Dr. Masashi Miyamoto is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Representative Director of the Board, using his extensive experience and high level of insight regarding overall business management, to push forward various measures for CSV management and for making a leap forward to become a global specialty pharmaceutical company with his strong leadership, and to promote sustainable growth as well as efforts aimed at enhancing the corporate value of the Group.

Representative Director of the Board, Executive Vice President

Yutaka Osawa

Apr. 1984 Joined Kyowa Hakko Kogyo Co., Ltd.
Apr. 2007 Director, Pharmaceutical Production Development Department, Kyowa Hakko Kogyo Co., Ltd.
Oct. 2008 Director, CMC Development Department, Development Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2009 Director, Production Planning Department, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2013 Executive Officer, Director, Production Planning Department, Production Division, Kyowa Hakko Kirin Co., Ltd.
Apr. 2014 Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2017 Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Director of the Board, Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2019 Representative Director of the Board, Executive Vice President, Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Mr. Yutaka Osawa has profound knowledge and a high level of insight gained through his extensive experience regarding research and development, overseas development and manufacturing, and is the right person to fully perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, and to firmly deliver the important mission of ensuring stable supply of high quality products as a pharmaceutical company.

Director of the Board, Executive Vice President

Toshifumi Mikayama, Ph.D.

Apr. 1983 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Mar. 2004 General Manager, Planning Division, Pharmaceutical Division, Kirin Brewery Company, Limited
Jul. 2007 Director of the Board, Executive Officer, Head, Research Division, Kirin Pharma Company, Limited
Oct. 2008 Executive Officer, Head, Research Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2010 Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2012 Managing Executive Officer, Director, Overseas Business Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2014 Director of the Board, Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Director of the Board, Senior Managing Executive Officer, Kyowa Hakko Kirin Co., Ltd.
Mar. 2021 Director of the Board, Executive Vice President, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
The Company has judged that Dr. Toshifumi Mikayama is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, using his extensive experience and high level of insight regarding overall business management, and to promote overseas business continuously while driving the Company forward in its efforts to become a global specialty pharmaceutical company.

Director of the Board

Takeshi Minakata

Apr. 1984 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Mar. 2007 Deputy General Manager, Toride Plant, Kirin Brewery Company Limited
Mar. 2009 Deputy General Manager, Production Control Department of Production Division, Kirin Brewery Company, Limited
Oct. 2010 Kirin Liaison Technical Director, Lion Nathan National Foods Pty Ltd (presently Lion Pty Ltd)
Mar. 2012 General Manager, Corporate Planning Dept., Kirin Brewery Company, Limited
Jan. 2013 Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited (presently Kirin Holdings Company, Limited)
Executive Officer, General Manager, Planning Dept., Kirin Brewery Company, Limited
Mar. 2015 Senior Executive Officer, Director, Corporate Strategy, Kirin Holdings Company, Limited
Senior Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited
Apr. 2016 Director and President of Myanmar Brewery Limited
Senior Executive Officer, Kirin Holdings Company, Limited
Mar. 2018 President and CEO, KYOWA HAKKO BIO CO. LTD.
Mar. 2020 President and CEO, KYOWA HAKKO BIO CO. LTD.
Senior Executive Officer, Kirin Holdings Company, Limited
Jan. 2022 Senior Executive Officer, in charge of Health Business Strategy, Kirin Holdings Company, Limited (to present)
Mar. 2022 Director of the Board, Kyowa Kirin Co., Ltd. (to present)
Director of the Board, Senior Executive Officer, in charge of Health Business Strategy, Kirin Holdings Company, Limited (to present)

Reasons for Selection
The Company has judged that Mr. Takeshi Minakata is the right person to perform the role of decision making on material matters of management and supervising the execution of operations as Director of the Board, using his extensive experience and high level of insight regarding overall business management. He is expected to promote tight-knit cooperation with Kirin Group companies—which have diverse business platforms—with the aim of providing solutions that respond to various medical needs to facilitate people's health and well-being.

Director of the Board
Outside
Independent

Akira Morita

Oct. 1993 Professor, Faculty of Law and Economics, Chiba University
Apr. 1994 Professor, The University of Tokyo Graduate Schools for Law and Politics
Apr. 2004 Dean, Professor, Graduate School of Public Policy, The University of Tokyo
Jul. 2008 Director, Policy Alternatives Research Institute, The University of Tokyo
Apr. 2011 Chairman, Central Social Insurance Medical Council, Ministry of Health, Labour and Welfare
Apr. 2012 Professor, Department of Political Studies, Faculty of Law, Gakushuin University
Jun. 2012 Emeritus Professor, The University of Tokyo (to present)
May 2013 Chair of the Board (presently Representative Director), Japan Usability Medical Information Promote Conference
Apr. 2014 Director-General, National Institute of Population and Social Security Research
Aug. 2014 Adjunct Professor, National Graduate Institute for Policy Studies
Apr. 2017 Professor, Department of Policy Studies, Tsuda University (to present)
Visiting Professor, Mie University Graduate School of Medicine
Outside Member, Administrative Council, The University of Tokyo (to present)
Apr. 2018 Director-General, Research Institute of Science and Technology for Society, Japan Science & Technology Agency
Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Apr. 2019 Visiting Professor, Kanagawa University of Human Services (to present)
Jul. 2020 Representative Director, Next Generation Fundamental Policy Research Institute (to present)

Reasons for Selection
The Company has judged that Mr. Akira Morita will utilize his academic experience and extensive knowledge as a researcher in the field of policy studies as well as his experience serving on deliberating committees for national and local government, and is the right person to contribute toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's management the perspective of protecting the rights of general shareholders.

Director of the Board
Outside
Independent

Yuko Haga, Ph.D.

Apr. 1989 Senior Consultant, Tokyo Office, Price Waterhouse Consultants
Apr. 1991 Representative, Haga Management Consulting Office (to present)
Jun. 2000 Director, Link World Co., Ltd.
Feb. 2010 Director, Social Welfare Corporation Fujikenikukai (to present)
Apr. 2010 Visiting Professor, Department of Policy Management, Faculty of Policy Management, Shobi University
Apr. 2017 Associate Professor, Graduate School of Management, NUCB Business School
Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Apr. 2020 Professor, Graduate School of Management, NUCB Business School (to present)
Jun. 2020 Outside Director, MinebeaMitsumi Inc. (to present)

Reasons for Selection
The Company has judged that Ms. Yuko Haga will utilize her wealth of experience in the fields of medical treatment, nursing care, and healthcare, gained from her wide-ranging activities as a management consultant, as well as her insight as a researcher in corporate strategy, and is the right person to contribute toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's management the perspective of protecting the rights of general shareholders.

Director of the Board
Outside
Independent

Jun Arai

Apr. 1983 Joined Shell Sekiyu K.K.
Sep. 2002 General Manager, Management Information, Showa Shell Sekiyu K.K.
Apr. 2004 General Manager, Accounting, Showa Shell Sekiyu K.K.
Mar. 2005 Executive Officer, General Manager, Accounting, Showa Shell Sekiyu K.K.
Mar. 2006 Director, responsible for Accounting, Showa Shell Sekiyu K.K.
Mar. 2007 Managing Director, responsible for Corporate Planning, Finance, Financial Information Assurance, Corporate Governance, Showa Shell Sekiyu K.K.
Aug. 2008 Representative Director, Acting President, Showa Shell Sekiyu K.K.
Nov. 2008 Representative Director, President, Showa Shell Sekiyu K.K.
Mar. 2013 Representative Director, Group Chief Operating Officer, Showa Shell Sekiyu K.K.
Mar. 2014 Representative Director, President, Showa Yokkaichi Sekiyu Co., Ltd.
Apr. 2016 Outside Director, Daiwa SB Investments Ltd.
Mar. 2017 Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2019 Outside Director, Sumitomo Mitsui DS Asset Management Company, Limited (to present)
May 2020 Outside Corporate Auditor, Ryohin Keikaku Co., Ltd. (to present)
Mar. 2021 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
Mr. Jun Arai was appointed outside Audit & Supervisory Board Member of the Company in March 2017. In his career, he has served for accounting and financial departments at Showa Shell Sekiyu K.K. for many years, and he has experienced in corporate management as a Representative Director and President, and he has utilized his considerable knowledge gained from that experience in his active performance as Audit & Supervisory Board Member. The company has judged that he is the right person to fulfill the role of decision making on material matters of management and supervising the execution of operations.

Director of the Board
Outside
Independent

Takashi Oyamada

Apr. 1979 Joined The Mitsubishi Bank, Limited (presently MUFG Bank, Ltd.)
Jan. 2006 Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd. (presently MUFG Bank, Ltd.)
Jun. 2009 Managing Director, The Bank of Tokyo Mitsubishi UFJ, Ltd.
Member of the Board of Directors, Mitsubishi UFJ Financial Group, Inc.
May 2012 Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
May 2013 Senior Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2014 Representative Director, Deputy President, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2015 Member of the Board of Directors, Representative Corporate Executive, Deputy President and Group COO, Mitsubishi UFJ Financial Group, Inc.
Apr. 2016 Representative Director, President & CEO, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Member of the Board of Directors, Mitsubishi UFJ Financial Group, Inc.
Jun. 2017 Senior Advisor, The Bank of Tokyo-Mitsubishi UFJ, Ltd. (to present)
Jun. 2018 Representative Director and Vice Chair, The Japan Institute of International Affairs (to present)
Dec. 2018 Outside Director, Mitsubishi Research Institute DCS Co., Ltd. (to present)
Jun. 2019 Outside Director, Mitsubishi Electric Corporation (to present)
Jun. 2019 Outside Director, Isetan Mitsukoshi Holdings Ltd. (to present)
Mar. 2021 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection
Mr. Takashi Oyamada possesses an extremely high-level of knowledge on management from his long experience as a banking executive, and he has knowledge and insight into a broad range of industries based on his abundant experience in the financial sector. The Company has judged that he is the right person to make decisions on material matters and supervise the execution of operations.

Director of the Board
Outside
Independent

Yoshihisa Suzuki

Apr. 1979 Joined ITOCHU Corporation
Apr. 2003 General Manager, Aerospace, Space and Electronics Division, ITOCHU Corporation
Jun. 2003 Executive Officer, ITOCHU Corporation
Apr. 2006 Managing Executive Officer, ITOCHU Corporation
Executive Vice President and CAO, ITOCHU International Inc.
Apr. 2007 President and CEO, ITOCHU International Inc.
Jun. 2011 Executive Vice President, JAMCO Corporation
Jun. 2012 President and CEO, JAMCO Corporation
Jun. 2016 Senior Managing Executive Officer, Member of the Board, ITOCHU Corporation
Apr. 2018 President and Chief Operating Officer (COO), Member of the Board, ITOCHU Corporation
Apr. 2020 President and Chief Operating Officer (COO), Chief Digital Officer (CDO), and Chief Information Officer (CIO), Member of the Board, ITOCHU Corporation
Apr. 2021 Vice Chairman, Member of the Board, ITOCHU Corporation
Mar. 2022 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)
Apr. 2022 Vice Chairman, ITOCHU Corporation (to present)

Reasons for Selection
Mr. Yoshihisa Suzuki has experience in being in charge of divisions related to aviation and electronic information and in corporate management as Representative Director and President at ITOCHU Corporation. Moreover, he also possesses experience in corporate management as President of an overseas subsidiary of the said company and Representative Director and President of a manufacturing company, and has useful knowledge and insight based on his abundant experience in Japan and abroad. The Company has judged that he is the right person to make decisions on material matters and supervise the execution of operations, and accordingly selected him as a candidate for outside Director of the Board. He also has experience in activities in the business community including KEIDANREN (Japan Business Federation). The Company expects that he will provide supervision of the Company's management from an independent standpoint based on his experience gained as a corporate manager and through activities in the business community.

Company Auditors' Profiles/Executive Officers

Company Auditor

Hiroshi Komatsu

Apr. 1986 Joined Kyowa Hakko Kogyo Co., Ltd.
Feb. 2009 CFO, Hematech, Inc.
Apr. 2012 Manager, Corporate Planning Department, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
Apr. 2015 Deputy Director, General Affairs Department, Kyowa Hakko Kirin Co., Ltd.
Apr. 2016 Deputy Director, General Affairs Department, and Leader, Corporate Secretariat Group, General Affairs Department, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Audit & Supervisory Board Member (Full-time), Kyowa Hakko Kirin Co., Ltd. (to present)

Reasons for Selection

The Company has judged that Mr. Hiroshi Komatsu has profound knowledge and insight gained through his broad range of experiences in accounting, finance, research and development, management of overseas subsidiaries, corporate planning and other areas as well as the ethical standards, fair and equal judgment required as an Audit & Supervisory Board Member and is the right person to appropriately perform the duties as an Audit & Supervisory Board Member of the Company by ensuring that the audit and supervisory functions are fully effective across a broad range of fields.

Company Auditor

Keiji Kuwata

Apr. 1985 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Sep. 2010 Director of the Board, General Manager, Eastern-Japan Regional Division, Kirin Logistics Co., Ltd. (presently Kirin Group Logistics Company, Limited)
Apr. 2015 Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited (presently Kirin Holdings Company, Limited)
Mar. 2016 Director, Corporate Strategy, Kirin Holdings Company, Limited
Mar. 2018 Senior Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited
Mar. 2019 Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
Company Auditor (Full-time), Kirin Holdings Company, Limited (to present)

Reasons for Selection

The Company has judged that Mr. Keiji Kuwata is the right person to appropriately perform the duties as a Company Auditor of the Company among the Group's broad fields, since he has long served in corporate planning, logistics and other fields in the Kirin Group, has a wealth of experience and profound insight into Group management in general, while also appropriately performing his role as a Director responsible for corporate strategy of the Kirin Holdings Company, Limited.

Company Auditor

Outside

Independent

Mayumi Tamura

Apr. 1983 Joined Sony Corporation (presently Sony Group Corporation)
Sep. 1991 Joined JOHNSON COMPANY, LIMITED
Jul. 2002 Executive Officer, Johnson Diversey Co. Ltd. (presently CxS Corporation)
Dec. 2004 CFO, adidas Japan K.K.
Jun. 2007 Executive Officer, Senior Vice President and CFO, Seiyu KK (presently Seiyu GK)
May 2010 Executive Officer, SVP and CFO, Walmart Japan Holdings GK (presently Walmart Japan Holdings KK) Executive Officer, SVP and CFO, Seiyu GK
Jun. 2015 Outside Corporate Auditor, Honda Motor Co., Ltd.
Jun. 2017 Outside Director, Audit and Supervisory Committee Member, Honda Motor Co., Ltd.
Outside Director, Hitachi High-Technologies Corporation (presently Hitachi High-Tech Corporation)
Jun. 2019 Outside Director, SHIMIZU CORPORATION (to present)
Mar. 2022 Outside Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection

Ms. Mayumi Tamura has been active as Outside Audit & Supervisory Board Member and Outside Director of companies, and also has experience in engaging in support for diversity and inclusion as a board member of an incorporated NPO. Furthermore, she possesses advance knowledge and experience gained by being in charge of finance/accounting and corporate planning at various global companies for many years, and in-depth insight as CFO. The Company has deemed her to be an appropriate person capable of supervising the Company and expressing audit opinions from an independent perspective based on such experience, knowledge and insight, and accordingly selected her as a candidate for outside Audit & Supervisory Board Member.

Company Auditor

Outside

Masaki Ueno

Apr. 1998 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Mar. 2012 General Manager, Legal Department, Kirin Holdings Company, Limited
Jan. 2013 General Manager, Legal Department, Kirin Company, Limited
Director of Group Legal, Kirin Holdings Company, Limited (presently Kirin Holdings Company, Limited)
Apr. 2015 Executive Officer, General Manager, Legal Department, Kirin Company, Limited, Executive Officer, Director of Group Legal, Kirin Holdings Company, Limited
Apr. 2019 Executive Officer, General Manager, Legal Department, Kirin Holdings Company, Limited
Mar. 2020 Outside Audit & Supervisory Board Member (Full-time), Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection

The Company has judged that Mr. Masaki Ueno having long served in legal departments in the Kirin Group, he has a high level of insight and experience regarding corporate legal affairs including global M&A; and thus, together with his experience in the Corporate Strategy & Planning Department of Kirin Holdings Company, Limited, that he is a suitably qualified person with the ability of providing broad supervision of the Group and giving audit opinions based thereon.

Company Auditor

Outside

Independent

Tomomi Yatsu

Apr. 1983 Joined Tokyo Electron Ltd.
Oct. 1986 Joined Deloitte Touche Tohmatsu LLC
Sep. 1990 Registered as Certified Public Accountant
Oct. 2001 Joined New Tokyo International Law Office Admitted to Tokyo Bar Association
Jun. 2009 Outside Auditor, Calbee, Inc.
Jun. 2010 Outside Audit & Supervisory Board Member, Taiko Pharmaceutical Co., Ltd.
Mar. 2012 Outside Audit & Supervisory Board Member, KOKUYO Co., Ltd.
Mar. 2015 Outside Audit & Supervisory Board Member, Yamaha Motor Co., Ltd.
Apr. 2015 Partner, TMI Associates
Jun. 2016 Outside Director, SMBC Nikko Securities Inc. (to present)
Jun. 2017 Outside Audit & Supervisory Board Member, IHI Corporation
Mar. 2019 Outside Corporate Auditor, Kuraray Co., Ltd. (to present)
Mar. 2021 Outside Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)

Reasons for Selection

Ms. Tomomi Yatsu is both a certified public accountant and an attorney at law. She also has an immense wealth of experience serving as outside audit & supervisory board member and outside director of corporations. The Company has deemed her to be an appropriate person capable of supervising the Company and expressing audit opinions from an independent perspective through her sophisticated knowledge and insight as an accounting and legal expert and in-depth knowledge and insight as an audit & supervisory board member of corporations.

Executive Officers

Senior Managing Executive Officer

Wataru Murata
Director
Human Resources Department

Managing Executive Officers

Takeyoshi Yamashita, Ph.D.
Vice President, Head of Strategy Division

Hiroshi Sonekawa
Director
Vice President, Head of Sales & Marketing Division

Motohiko Kawaguchi
Director
Finance Department

Executive Officers

Yasuo Fujii
Director
Business Development Department

Shin Inoue
Director
Area Marketing Strategy Department, Sales & Marketing Division

Fumihiko Kanai
Established Medicine Strategy Department, Strategy Division

Koichiro Ishimaru
Director
Corporate Social Responsibility Management Department

Yoshifumi Torii, Ph.D.
Vice President, Head of R&D Division and Head of Development Unit

Hiroki Takamatsu
Vice President,
Head of Quality Assurance Division

Tomohiro Sudo
Director
Global Product Strategy Department, Strategy Division

Kenji Shibata, Ph.D.
Director
Internal Audit Department

Shoko Itagaki
Director
Corporate Planning Department, Strategy Division

Toshiyuki Kurata
Vice President, Head of Production Division

Atsushi Matsumoto, Ph.D.
President & CEO
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Yoshiko Mori
Vice President,
Head of Pharmacovigilance Division

Compliance

Kyowa Kirin recognizes that compliance entails quickly grasping the needs of society while conducting business in an ethical manner.

Code of Conduct and Group Policies

Kyowa Kirin has put in place the Kyowa Kirin Group Code of Conduct, which provides principles and guidelines for the overall behavior of everyone who works in the Kyowa Kirin Group. The Code of Conduct has been translated into various languages and disseminated to the Group's employees all around the world. All executives and employees of the Group pledge to comply with the Code of Conduct. Understanding of and adherence to the Code of Conduct are monitored through such means as employee awareness surveys. We will also encourage all partners in our supply chain to comply with the Code of Conduct. In addition, we have put in place Kyowa Kirin Group Policies that outline guiding principles for individual areas of business.

The Code of Conduct and Group Policies are continuously reviewed in light of changes in the internal and external environment and laws and regulations. Their establishment, revision, or abolition is approved by the Board of Directors.

Kyowa Kirin Group Management Philosophy—Group Policy System
https://www.kyowakirin.com/sustainability/index.html

Governance

Kyowa Kirin has put in place a Global CSR Head and a CSR Management Department to support the Global CSR Head. Operating under the supervision of the Representative Director and Executive Vice President, the Global CSR Head formulates and implements compliance measures while liaising with the Regional CSR Heads*1, who are responsible for compliance in the four regions of Japan, North America, EMEA and APAC.

Regional CSR Committees have been established in each region to discuss compliance-related matters, with quarterly meetings held to discuss the status of global and region-specific activities and issues*2. Group CSR Committee, where the Executive Vice President chairs and relevant persons participate from four regions, is held once a year. The important matters discussed at these committee meetings are reported to the Board of Directors.

*1 The present Global CSR Head serves concurrently as the Regional CSR Head for Japan.
*2 Important issues discussed at each Regional CSR Committee are compiled by the secretariat and reported to the Regional CSR Committee held in Japan.

Education and Training

Kyowa Kirin conducts various training programs aimed at fostering a corporate culture that enables executives and employees to adapt flexibly to changes in social norms. These include a corporate ethics lecture for executives, group training sessions and e-learning. In 2021, training on the Code of Conduct was provided to all executives and employees (target: 6,631 people), including contract and temporary employees. A course completion rate of 100% was achieved. Other training sessions were also held on topics such as bribery and corruption, promotional codes, and information security.

We also conduct a Kirin Group-wide compliance and human rights awareness survey and a Kyowa Kirin Group-wide employee awareness survey every year. The survey results are used to identify changes in employee awareness and issues that need to be resolved. These insights are then applied to initiatives at Kyowa Kirin Group.

Whistleblowing System

The Kyowa Kirin Group has put in place the Compliance Line, whistleblowing system, in order to prevent, detect at an early stage and correct acts that are against the Kyowa Kirin Group Code of Conduct, as well as acts that seriously damage the brand value of the Kyowa Kirin Group. We have introduced a process under which reports concerning directors are passed directly to company auditors. On top of the strict adherence to confidentiality and a rule that those reporting an incident will not be subjected to any retaliation, steps have been taken to establish an internal and external point of contact for reporting that can be accessed by telephone, electronic and postal mail as well as online tools. Reports can also be filed anonymously. In this manner, every effort is being made to create a simple and easy reporting environment. Moreover, messages from the CEO on such topics as the importance of the Compliance Line, confidentiality and non-retaliation are sent out on a continuous basis. The point here is to ensure that employees gain a better understanding of the system through group training and e-learning and while maintaining a continuous awareness toward each point of contact for reporting. Details of the Compliance Line are readily available on the Company's website and posters displayed throughout the workplace. In 2021, the Compliance Line received a total of 24 reports in Japan and overseas. In response to Japan's revised Whistleblower Protection Act, which takes effect from June 2022, we are confirming the design and operation of our system, revising internal rules, and making continuous improvements.

Overseas subsidiaries operate local whistleblowing systems in each region. We also established and operate a global line that enables overseas subsidiaries' employees to report directly to the Group's head office in Japan in their local language.

Future Initiatives

Kyowa Kirin is strengthening its global compliance management system with the aim of becoming a global specialty pharmaceutical company. In 2021, we assessed the maturity of our compliance efforts in all areas of our compliance functions (organizational structure, human resources, policies and procedures, education and training, and risk management) and of our Group Policies. Based on the results of the assessment, we created a roadmap toward establishing the ideal compliance management system for our Group. Using this roadmap, the entire group will work together to strengthen compliance as a whole.

Kyowa Kirin Group Code of Conduct (Summary)

Introduction
1. Purpose of this Code of Conduct
2. Scope of this Code of Conduct
3. Role of Officers
4. Role of Managers
5. Raising questions and concerns
6. Prohibition of retaliation
7. Response to non-compliant actions with this Code of Conduct

Chapter 1. Relationship with Society
Chapter 2. Relationship with Employees
Chapter 3. Compliance with Rules
Chapter 4. Respect for Human Rights
Chapter 5. Environmental Preservation
Chapter 6. Information Management
Chapter 7. Risk Management *3

*3 In 2021, we added a section on risk management. This describes specific actions for protecting the Kyowa Kirin Group and its stakeholders from threats, as well as appropriate risks that are necessary to create new value.

Risk Management

Kyowa Kirin conducts risk management to protect its corporate value from threats and to create new value from opportunities.

Kyowa Kirin Risk Management

Kyowa Kirin recognizes that the realization of its vision, based on its corporate philosophy will lead to sustainable growth and the enhancement of corporate value over the medium to long term. In order to safeguard its corporate value from threats, the Group engages in enterprise risk management. Through various opportunities and the taking of appropriate risks, our risk management endeavors also help create new corporate value.

Risk Management System

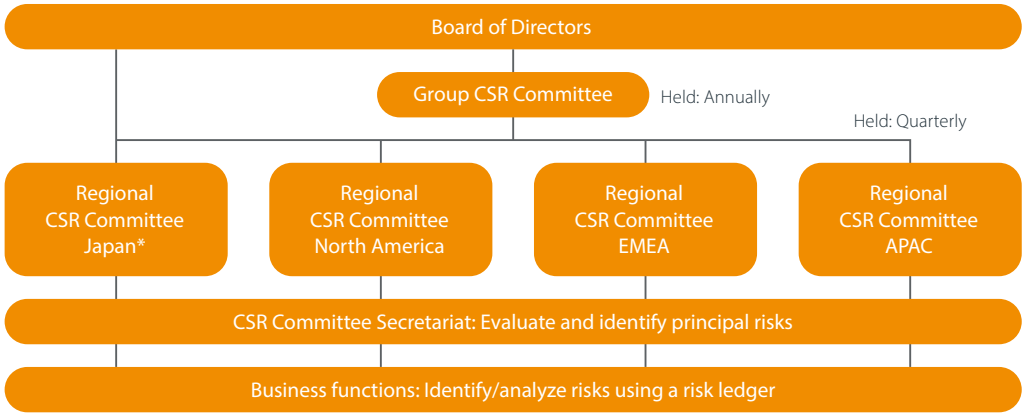
Business functions at Kyowa Kirin identify risks based on changes in the internal and external environment. Steps are also taken to analyze impact and likelihood of identified risks. After discussing and adjusting the results of this analytical assessment of internal and external environmental changes and risk trends while conversing with business functions, the CSR Committee secretariat organizes risks by category, assesses and identifies principal risks. In addition to deliberating on the appropriateness of identifying principal risks, Regional CSR Committees also monitor measures aimed at mitigating risks as well as progress while organizing and supervising the risk management of business functions. Moreover, the Group CSR Committee meets once a year to deliberate on the Group's overall risk management strategy and action plan, and to report on the status of activities during the year. Details of principal risk mitigation measures and monitoring results discussed by the Committee are reported to the Board of Directors.

We are also moving forward with the digitalization of our risk management system, having introduced an IT system for centrally managing the risks of the entire group in a database. After business functions register risk ledgers and incident information in the database, the information is shared using a workflow with divisions that specialize in risk management. This enables visualization of critical risks on a risk map. In this way we are working to develop a system that enables effective and efficient monitoring of risk.

Crisis Management System

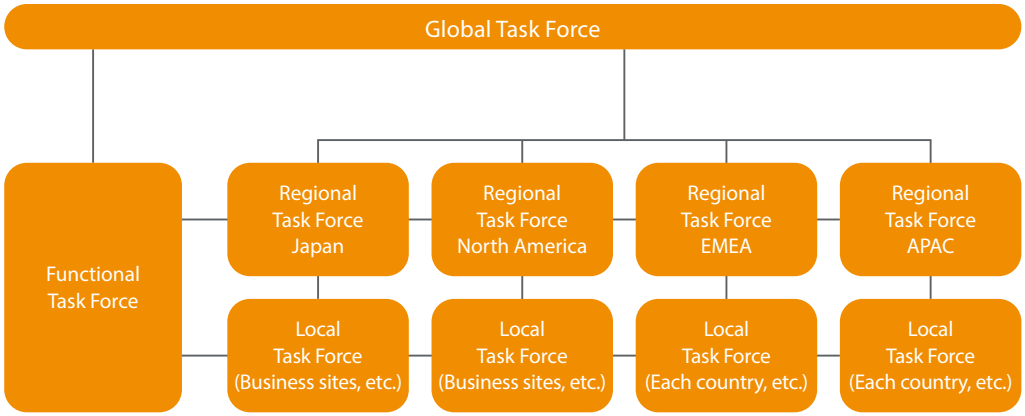
We define "crises" as situations that may have a profound impact on our business and require a rapid response among those that inhibit the achievement of our management goals. In addition, we define "crisis management" as activities that minimize the impact on our business when risks evolve into crises. Kyowa Kirin has established area task forces in three layers—global, regional, and local—and a functional task force that responds using specialized expertise. To quickly mitigate the impact of a crisis, each task force will execute crisis management autonomously, or in collaboration when a global response is required. In addition, we repeatedly conduct global crisis exercises (cyberattacks, pandemics, natural disasters, supply disruptions, etc.) to strengthen our crisis response and business continuity systems based on worst-case scenarios. Through these exercises, we improve our response capabilities, review our risk assessment and mitigation measures, and monitor to detect signs of emerging risks. In this way, we aim to create a resilient organization that is able to adapt flexibly to difficult situations.

Risk Management System



* Other regions' reports collated and presented in Japan.

Crisis Management System



Financial Information

WEB link

Key Financial Data

Cash Flow Data

Financial Summary

Adoption of International Financial Reporting Standards

The Group has adopted the International Financial Reporting Standards ("IFRS") since FY2017 to enhance the international comparability of its financial reporting for the capital market, and unify the process of the Group's accounting. In addition, financial data for FY2016, the fiscal year prior to the adoption of IFRS, is reformulated and displayed in an IFRS format.

Adoption of "core operating profit" (IFRS)

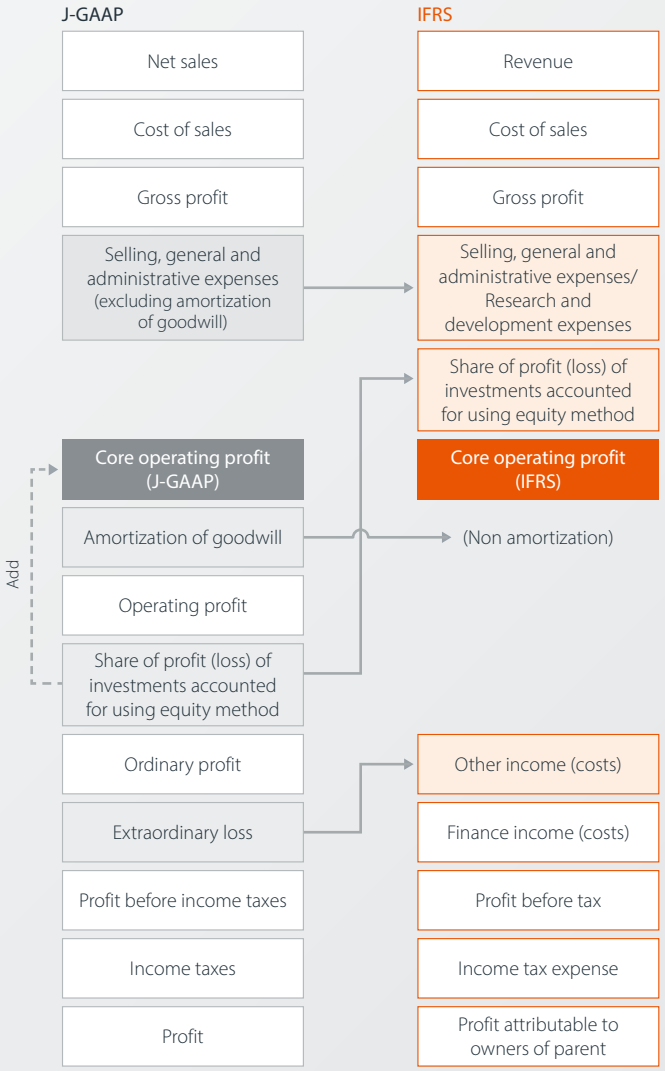
The Group has adopted "core operating profit" (IFRS) as an indicator showing recurring profitability from operating activities.

* Gross profit – Selling, general and administrative expenses – Research and development expenses + Share of profit (loss) of investments accounted for using equity method

Bio-Chemicals Business

Following the conclusion of an agreement on February 5, 2019 in which Kyowa Kirin Co., Ltd. (the "Company") agreed to transfer 95% of the shares of its consolidated subsidiary Kyowa Hakko Bio Co., Ltd. to Kirin Holdings Company, Limited, the Bio-Chemicals business is categorized as a discontinued operation from FY2019. Accordingly, the consolidated financial statements for FY2018 have been restated to reflect the change, and from FY2019, the Group has only one reportable segment: the "Pharmaceuticals business."

Major differences between IFRS and J-GAAP



Eleven-Year Selected Financial Data

	IFRS						J-GAAP					IFRS
	(Millions of yen)						(Millions of yen)					(Thousands of U.S. dollars*1)
For the Year:	**2021/12**	2020/12	2019/12	2018/12	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	**2021/12**
Revenue*2	**¥ 352,246**	¥ 318,352	¥ 305,820	¥ 271,510	¥ 353,380	¥ 347,956	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	¥ 343,722	**$3,062,478**
Gross profit*2	**264,398**	237,912	226,200	198,149	224,321	214,592	225,393	205,904	212,761	210,690	197,555	**2,298,710**
Selling, general and administrative expenses (including R&D expenses)*2	**203,287**	178,922	170,827	147,745	162,113	163,124	181,628	169,731	160,987	157,785	150,940	**1,767,407**
Core Operating Profit (J-GAAP: Operating profit)*2	**65,685**	59,955	59,353	50,306	57,731	39,116	43,765	36,173	51,773	52,905	46,614	**571,077**
Profit attributable to owners of parent	**52,347**	47,027	67,084	54,414	42,899	30,450	29,774	15,898	30,078	24,199	25,608	**455,116**
Capital expenditure and investments in intangible assets*2	**22,335**	34,782	22,586	13,489	20,714	33,270	20,039	29,487	35,183	27,808	19,697	**194,181**
Depreciation and amortization*2	**19,498**	20,466	18,797	16,243	22,032	23,784	23,126	23,885	21,592	20,904	22,833	**169,521**
R&D expenses*2	**57,679**	52,312	53,511	45,659	49,216	52,929	51,604	47,737	43,682	44,808	47,961	**501,467**
Cash Flows:												
Net cash provided by operating activities	**¥ 86,548**	¥ 39,502	¥ 53,655	¥ 56,181	¥ 64,902	¥ 66,881	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	**$ 752,459**
Net cash provided by (used in) investing activities	**(11,363)**	252,559	(933)	(39,929)	(45,265)	(49,824)	(57,747)	16,805	(77,163)	(98,772)	18,460	**(98,789)**
Net cash provided by (used in) financing activities	**(28,446)**	(26,003)	(47,371)	(16,501)	(18,287)	(13,871)	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	**(247,309)**
Cash and cash equivalents at the end of the period	**335,084**	287,019	20,762	15,867	14,685	13,076	12,784	17,013	19,242	50,334	107,555	**2,913,266**
At Year-End:												
Total current assets	**¥ 518,231**	¥ 442,482	¥ 448,610	¥ 385,844	¥ 348,150	¥ 314,999	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	**$4,505,575**
Total assets	**921,872**	801,290	784,453	741,982	708,295	683,801	720,764	719,135	719,257	679,342	658,873	**8,014,882**
Total current liabilities	**109,129**	80,749	87,530	80,459	78,409	88,072	84,823	85,182	85,076	85,774	78,465	**948,783**
Interest-bearing debt	**20,371**	17,842	17,185	2,527	2,814	7,000	4,840	4,868	6,207	5,699	6,042	**177,108**
Equity	**737,162**	698,396	678,250	649,621	616,028	577,036	614,858	605,368	595,415	555,898	540,023	**6,408,991**
Number of employees	**5,752**	5,423	5,267	7,242	7,532	7,465	7,435	7,424	7,152	7,243	7,229	**—**
Per Share Data:	(Yen)						(Yen)					(U.S. dollars*1)
Profit attributable to owners of parent*3	**¥ 97.43**	¥ 87.56	¥ 124.57	¥ 99.40	¥ 78.38	¥ 55.65	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	¥ 45.16	**$ 0.847**
Equity attributable to owners of parent	**1,371.90**	1,300.12	1,263.16	1,186.65	1,125.56	1,054.48	1,122.80	1,105.44	1,085.17	1,013.61	970.16	**11.929**
Cash dividends	**46**	44	42	35	27	25	25	25	25	20	20	**0.400**
Common Stock Price Range (Per share):												
High	**¥ 4,240**	¥ 3,060	¥ 2,594	¥ 2,478	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	**$ 36.86**
Low	**2,687**	1,849	1,674	1,894	1,515	1,412	1,094	1,006	833	757	628	**23.36**
Stock Information (Thousands of shares):												
Number of common stock issued	**540,000**	540,000	540,000	576,484	576,484	576,483	576,483	576,483	576,483	576,483	576,483	**—**
Weighted average number of common stock issued	**537,272**	537,109	538,542	547,412	547,290	547,224	547,285	547,348	547,391	548,449	567,029	**—**
Financial Ratios:	(%, except EBITDA)						(%, except EBITDA)					
Return on assets (ROA)	**6.1**	5.9	8.8	7.5	6.2	4.4	4.1	2.2	4.3	3.6	3.8	**—**
Core operating return on assets (J-GAAP: Operating profit)*2	**7.7**	7.6	7.8	6.9	8.3	5.6	6.1	5.0	7.4	7.9	6.9	**—**
Return on equity attributable to owners of parent (ROE)	**7.3**	6.8	10.1	8.6	7.2	5.3	4.9	2.7	5.2	4.4	4.7	**—**
Ratio of equity attributable to owners of parent to total assets	**80.0**	87.2	86.5	87.6	87.0	84.4	85.2	84.1	82.6	81.7	81.8	**—**
Core operating margin (J-GAAP: Operating profit)*2	**18.6**	18.8	19.4	18.5	16.3	11.2	12.0	10.8	15.2	15.9	13.6	**—**
EBITDA*2, *4 (Millions of yen)	**79,793**	72,974	63,750	83,421	78,220	66,981	78,018	64,101	83,190	78,160	79,864	**—**
Payout ratio*5	**43.2**	50.3	33.7	35.2	34.4	44.9	35.1	54.4	34.8	32.8	32.5	**—**

*1 U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥115.02=U.S.$1, the approximate exchange rate at December 31, 2021.

*2 Figures on and after 2018 represent figures in the continued operation (Pharmaceuticals) excluding the discontinued operation (Bio-chemicals).

*3 Profit attributable to owners of parent per share is based upon the weighted average number of shares of common stock outstanding during each year.

*4 EBITDA = Profit before tax + Interest expenses + Depreciation and amortization (+ Amortization of goodwill)

*5 Under J-GAAP, consolidated payout ratios are calculated using net income before the deduction of amortization of the goodwill that resulted from the reverse acquisition in April 2008 (Kirin Pharma share transfer). The figure on 2021 is calculated using "Core profit" (("Profit attributable to owners of parent" – "Other income and expenses" (excluding impact from applicable taxes)) / average number of shares during fiscal year)

Management's Discussion & Analysis

Figures presented in these materials have been rounded.

Subsidiaries Included in the Scope of Consolidation

The number of consolidated subsidiaries in the Kyowa Kirin Group stood at 35 as of December 31, 2021. Effective April 1, 2021, Kyowa Kirin Pharmaceutical Development, Inc. and Kyowa Kirin Pharmaceutical Research, Inc. were dissolved after being merged into Kyowa Kirin, Inc.

Income

(Billions of yen)

	2020/12	**2021/12**	Change
Revenue	¥318.4	**¥352.2**	¥33.9
Core Operating Profit	60.0	**65.7**	5.7
Profit attributable to owners of parent	47.0	**52.3**	5.3

Revenue and Core Operating Profit

Revenue increased year on year due to steady growth for global strategic products in North America and EMEA, offsetting lower revenue in Japan. The positive impact on revenue from forex factors was ¥9.0 billion.

Core operating profit rose, despite increases in selling, general and administrative expenses and research and development expenses, reflecting higher gross profit from an increase in overseas revenue, as well as a rise in the share of profit of investments accounted for using equity method. The positive impact on core operating profit from forex factors was ¥2.5 billion.

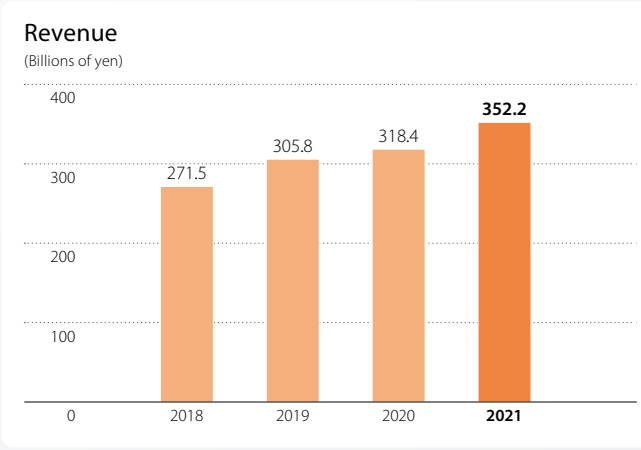
Profit Attributable to Owners of Parent

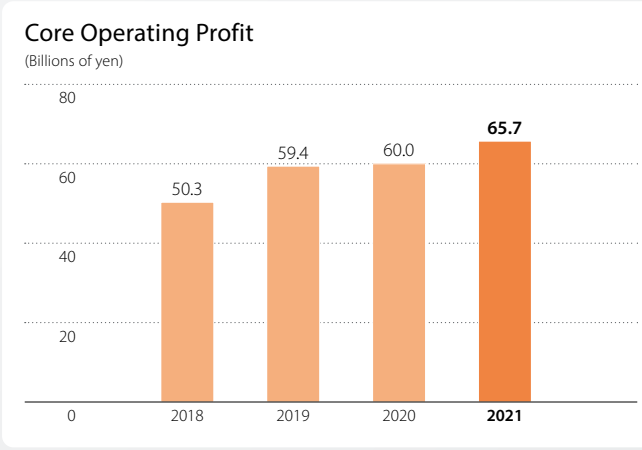
Profit attributable to owners of parent increased as a result of a decline in other expenses and an increase in core operating profit, despite a rise in income tax expenses.

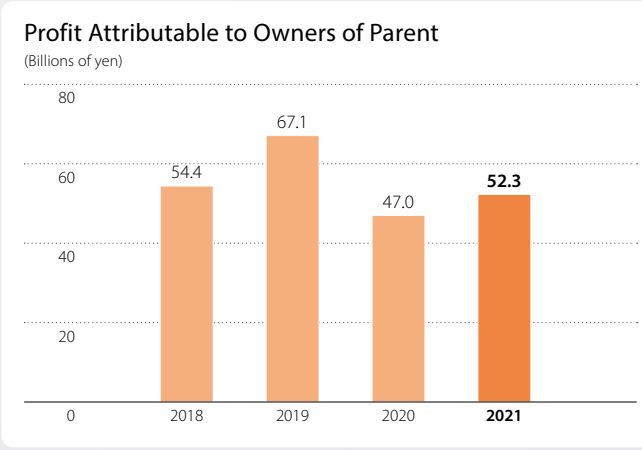
Revenue by Regional Controlling Company

(Billions of yen)

	2020/12	**2021/12**	Change
Japan	¥159.9	**¥156.9**	¥ (3.1)
North America	59.9	**78.8**	18.9
EMEA	48.4	**56.1**	7.7
Asia/Oceania	25.9	**28.4**	2.5
Others	24.2	**32.1**	7.9
Total consolidated revenue	¥318.4	**¥352.2**	¥33.9







Japan

Revenue in Japan decreased year on year due to the expiration of co-marketing agreements for some products and the impact of reductions in NHI drug prices implemented in April 2020 and April 2021, outweighing growth in sales of new product franchises such as Crysvita, a treatment for FGF23-related diseases.

- Revenue from renal anemia treatment Darbepoetin Alfa Injection Syringe (KKF) decreased due to market penetration of rival products.
- G-Lasta, an agent for decreasing the incidence of febrile neutropenia, registered firm growth in revenue.
- Revenue from Nouriast, an antiparkinsonian agent, decreased due to market penetration of rival products.
- Crysvita, a treatment for FGF23-related diseases, continued to steadily gain ground in the market after launching in 2019.
- Revenue from Asacol, an ulcerative colitis treatment drug, and from Minirinmelt and Desmopressin, both treatments for central diabetes insipidus, decreased after the Company discontinued sales of Asacol on March 31, 2020 and Minirinmelt and Desmopressin on April 27, 2020.

North America

Revenue in North America increased year on year due to steady growth for global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily since launch in 2018. The additional indication of tumor induced osteomalacia was approved in June 2020.
- Poteligeo, an anticancer agent, registered firm growth in revenue.
- Revenue from Nourianz, an antiparkinsonian agent, has been growing since launch in October 2019.

EMEA

Revenue in EMEA increased year on year, supported by steady growth for global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily, reflecting growth in the number of markets since launch in 2018. Approval for sale with the extended indication for older adolescents and adults was acquired in September 2020.
- Since launching in Germany in June 2020, anticancer agent Poteligeo has been steadily gaining ground in the market, supported by growth in the number of countries where it is available.
- Revenue from Abstral, a treatment for cancer pain, decreased year on year, due mainly to the market penetration of generics and shipping schedule adjustments.

Asia/Oceania

Revenue in Asia/Oceania increased year on year.

- Revenue from Regpara, a treatment for secondary hyperparathyroidism, declined after it became subject to China's centralized governmental purchasing system* in October 2021.

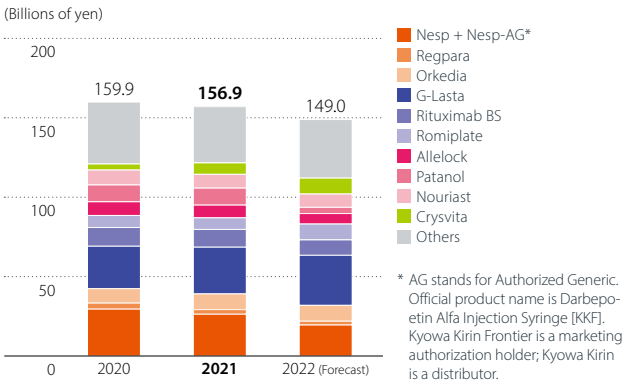
* Pharmaceutical purchasing program (volume-based procurement; VBP) introduced by China in 2018 to reduce national healthcare expenditure. Around 2–5 companies are typically contracted to supply a pharmaceutical product after a bidding process, but drug prices decline significantly.

Others

Revenue from Others increased year on year due to higher revenue from technology out-licensing.

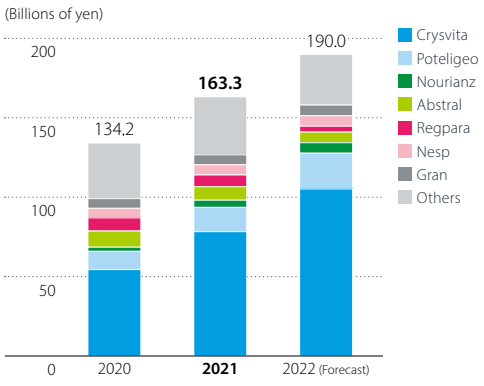
- The increase for technology out-licensing reflected the conclusion of an agreement with Amgen Inc. to jointly develop and commercialize KHK4083, an anti-OX40 fully human monoclonal antibody for the treatment of autoimmune disease atopic dermatitis, the conclusion of an agreement to grant Aevi Genomic Medicine, LLC. (now Avalo Therapeutics, Inc.) the rights to develop, manufacture and commercialize a human anti-LIGHT monoclonal antibody for all indications worldwide, and an increase in royalty income from AstraZeneca in relation to benralizumab.

Revenue of Major Items (Japan)

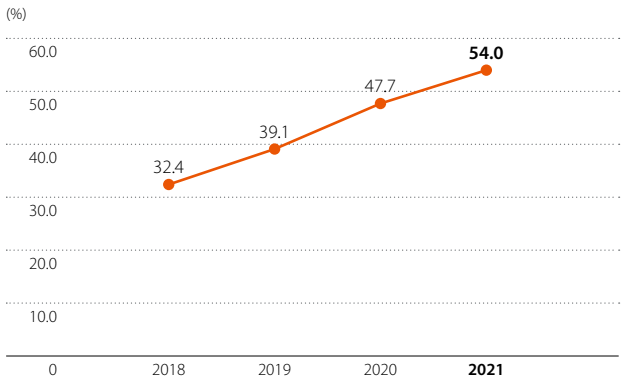


* AG stands for Authorized Generic. Official product name is Darbepoetin Alfa Injection Syringe [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

Revenue of Major Items (North America, EMEA, and Asia/Oceania)



Overseas Revenue Ratio



Cash Flow

Cash and cash equivalents as of December 31, 2021 totaled ¥335.1 billion, an increase of ¥48.1 billion from ¥287.0 billion as of December 31, 2020. The main contributing factors affecting cash flow during FY2021 were as follows:

- Net cash provided by operating activities was ¥86.5 billion, compared with net cash provided of ¥39.5 billion in the previous fiscal year. Major inflows included decrease in contract liabilities of ¥38.8 billion, which included proceeds of US$400 million from an upfront payment received from Amgen Inc. based on an agreement for the joint development and commercialization of KHK4083, in addition to profit before tax of ¥60.1 billion and depreciation and amortization of ¥19.5 billion. Major outflows included income taxes paid of ¥14.8 billion.
- Net cash used in investing activities was ¥11.4 billion, compared with net cash provided of ¥252.6 billion in the previous fiscal year. Major outflows included ¥13.2 billion for purchase of intangible assets and ¥6.5 billion for purchase of property, plant and equipment. Major inflows included proceeds of ¥5.1 billion from sale of investments accounted for using equity method and proceeds of ¥1.9 billion from sale of investment securities.
- Net cash used in financing activities was ¥28.4 billion, compared with net cash used of ¥26.0 billion in the previous fiscal year. Major outflows included dividends paid of ¥24.2 billion.

Financial Position

Assets

Assets as of December 31, 2021 totaled ¥921.9 billion, an increase of ¥120.6 billion compared with the end of the previous fiscal year.

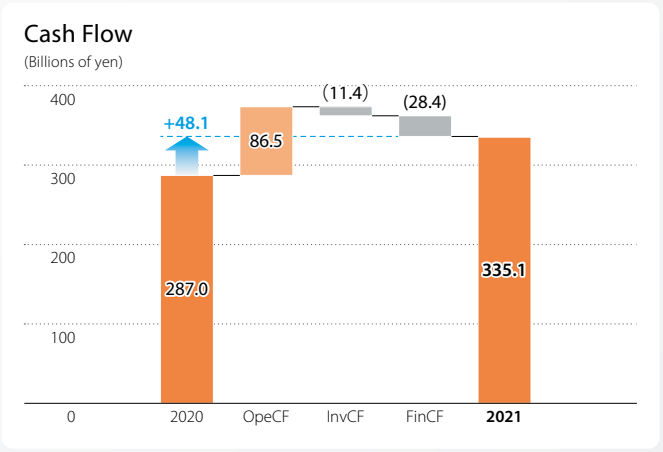
- Non-current assets increased by ¥44.8 billion to ¥403.6 billion, with downward pressure from the impairment of marketing rights and the sale of investment securities being more than offset by factors such as a rise in deferred taxes and an increase in bonds payable by subsidiaries and associates following a shift from accounting for bonds of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. using the equity method.
- Current assets increased by ¥75.7 billion to ¥518.2 billion, despite a decline in assets held for sale (shares of Hitachi Chemical Diagnostics Systems Co., Ltd.) The increase in current assets mainly reflected a rise in cash and cash equivalents due to proceeds from the sale of assets held for sale and proceeds from an upfront payment received from Amgen Inc. based on an agreement for the joint development and commercialization of KHK4083.

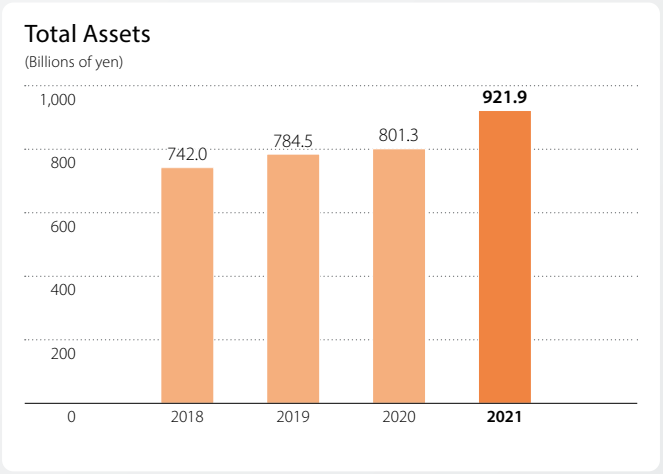
Liabilities

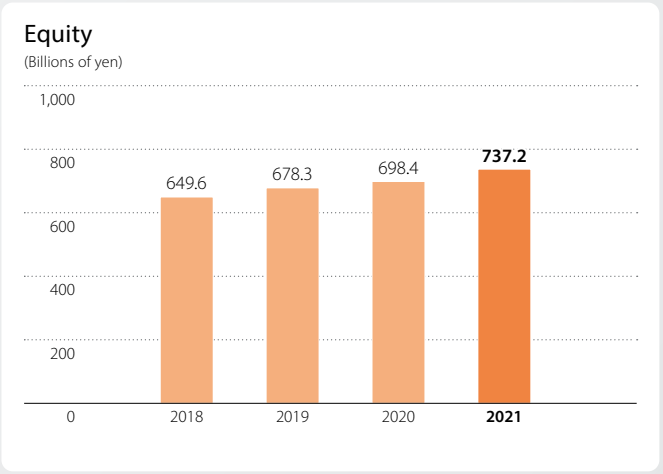
Liabilities as of December 31, 2021 totaled ¥184.7 billion, an increase of ¥81.8 billion from the end of the previous fiscal year, due mainly to an increase in contract liabilities accompanying the conclusion of an agreement with Amgen Inc., and the recording of liabilities from the application of the equity method for FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. following a shift from accounting for bonds payable by subsidiaries and associates using the equity method.

Equity

Equity as of December 31, 2021 totaled ¥737.2 billion, an increase of ¥38.8 billion from the end of the previous fiscal year, mainly reflecting the booking of profit attributable to owners of parent and an increase in exchange differences on translation of foreign operations resulting from the impact of exchange rates, outweighing decreases from the payment of dividends and other factors. As a result, the ratio of equity attributable to owners of parent to total assets was 80.0%, a decrease of 7.2 percentage points from the end of the previous fiscal year.







R&D Expenses

R&D expenses for the fiscal year ended December 31, 2021 totaled ¥57.7 billion, an increase of 10.3% from the previous fiscal year. The ratio of R&D expenses to sales for the year was 16.4%.

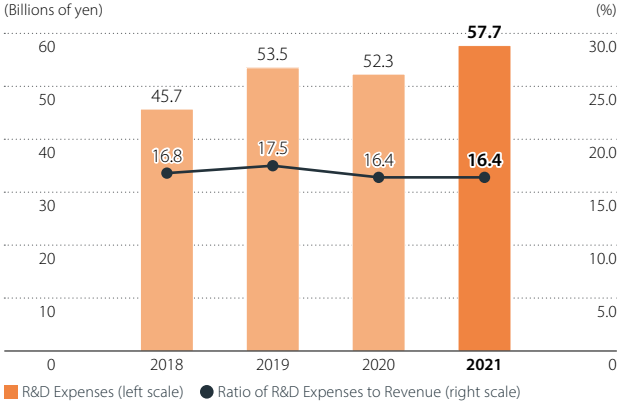
Capital Expenditure and Investments in Intangible Assets

As a basic policy, Kyowa Kirin implements capital expenditure strategically, taking into account the balance with depreciation. Capital expenditure and investments in intangible assets for the fiscal year ended December 31, 2021 totaled ¥22.3 billion, a decrease of ¥12.4 billion (35.8%) compared with the previous fiscal year. Depreciation and amortization was ¥19.5 billion, a decrease of ¥1.0 billion (4.7%).

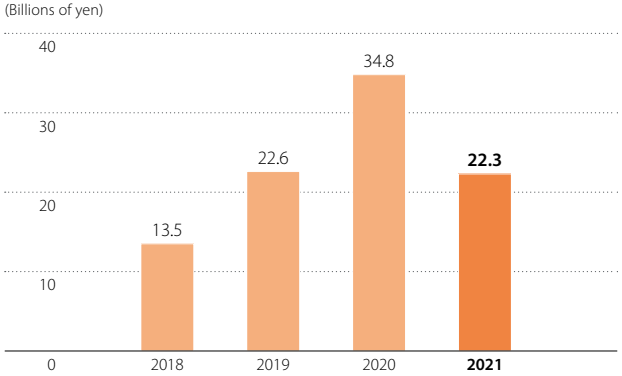
Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2021 was ¥97.43, up from ¥87.56 in the previous fiscal year. Equity attributable to owners of parent per share was ¥1,371.90, compared with ¥1,300.12 in the previous fiscal year.

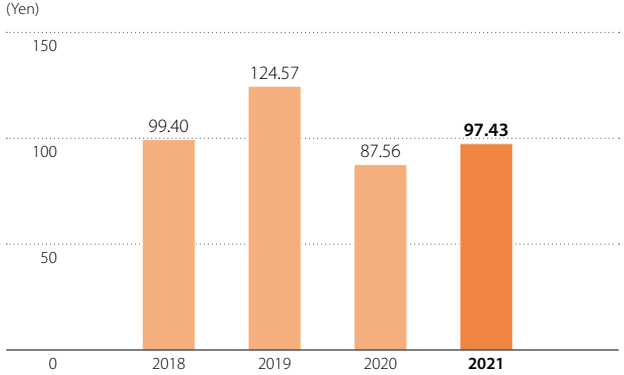
R&D Expenses



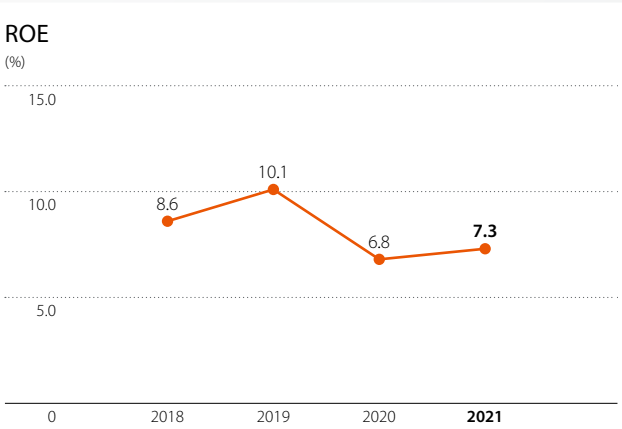
Capital Expenditure and Investments in Intangible Assets



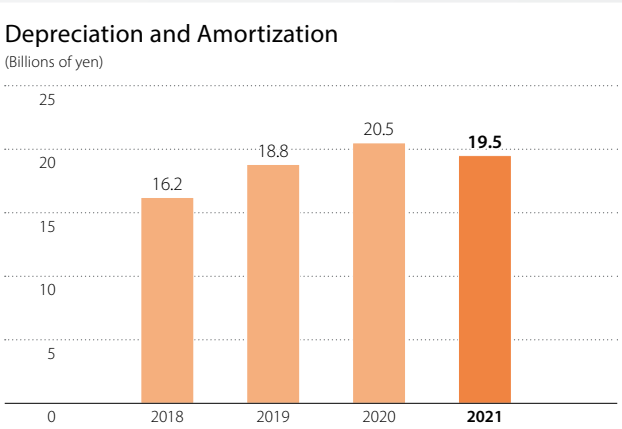
Profit Attributable to Owners of Parent per Share



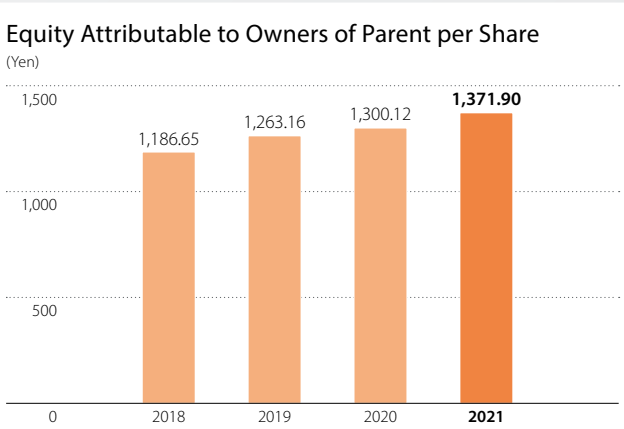
ROE



Depreciation and Amortization



Equity Attributable to Owners of Parent per Share



Outlook for FY2022

For fiscal 2022, ending December 31, 2022, the Company forecasts revenue of ¥380.0 billion (up 7.9% year on year), core operating profit of ¥67.0 billion (up 2.0%), profit before tax of ¥66.0 billion (up 9.9%), and profit attributable to owners of parent of ¥53.0 billion (up 1.2%).

- Although we anticipate an impact from factors such as a reduction in NHI drug prices scheduled for April 2022 in Japan, we forecast revenues will rise year on year due to growth for global strategic products, primarily Crysvita, and an increase in licensing revenue. In addition to increases in selling, general and administrative expenses related to proactive investments in human resources and in our IT/digital platform aimed at maximizing the value of global strategic products and rapidly establishing competitive global business bases, we are budgeting for an increase in spending on research and development related to progress in late-stage development projects for next-generation strategic products such as KHK4083. However, we expect higher overseas revenue to lift core operating profit year on year.
- We forecast an increase in profit before tax, reflecting a decline in other expenses and an increase in core operating profit.
- We see profit attributable to owners of parent increasing year on year, despite an expected increase in income tax expense.
- Although profit before tax is projected to rise year on year, we forecast cash flow from operating activities will decline year on year due to the impact of changes in contract liabilities, including the absence of proceeds of US$400 million booked in the previous fiscal year from an upfront payment received from Amgen Inc. based on an agreement for the joint development and commercialization of KHK4083.
- In cash flow from investing activities, we forecast an increase in net cash used compared with the current fiscal year, mainly reflecting an expected increase in cash used for the purchase of property, plant and equipment and intangible assets. We will use a flexible approach when evaluating and making investments related to strategic partnering, M&A and other strategic investments for acquiring drug discovery technologies and pipeline drugs.
- In cash flow from financing activities, we forecast net cash used will be the same level as in the current fiscal year. We will take a flexible stance on the purchase of treasury shares, funding procurement and other financing activities, while taking into account economic conditions and the funding environment.

Based on the above, we forecast cash and cash equivalents as of the end of fiscal 2022 will be largely unchanged from the level at the end of fiscal 2021.

Profit Distribution

Returning profits to shareholders is one of Kyowa Kirin's key management priorities.

The basis of the Company's policy regarding the distribution of profits is to pay stable dividends while taking into account a range of factors, including consolidated results and the dividend payout ratio for each fiscal year, while also ensuring sufficient retained earnings for future business development and other purposes. We plan to improve capital efficiency with regards to the purchase of treasury shares by taking a flexible approach while considering the share price and other factors. The Company considers it a top priority to use internal reserves for investments for future growth (R&D investments, strategic investments and capital expenditures) in order to achieve sustainable growth from fiscal 2025 and maximize corporate value.

Regarding dividend policy, the Company's target dividend payout ratio in the FY2021-2025 Medium Term Business Plan is 40% based on core EPS. We aim to ensure a stable and sustained increase in dividends (continuous increase of dividend payments) in line with medium- to long-term growth in profits.

In line with the above policy, the Company paid an annual dividend from surplus of ¥46.00 per share for FY2021, an increase of ¥2.00 from the previous fiscal year and the fifth consecutive year of increase. The Company plans to raise the dividend for a sixth consecutive year in FY2022 to ¥48.00 per share.

Outlook for FY2022

(Billions of yen)

	2021/12	2022/12 (Outlook)	Year-on-year change
Revenue	352.2	380.0	27.8
Core Operating Profit	65.7	67.0	1.3
Profit before tax	60.1	66.0	5.9
Profit Attributable to Owners of Parent	52.3	53.0	0.7

* Note: These forecasts assume average exchange rates of ¥110/US$, ¥150/British pound and ¥17.1/Chinese Yuan

	2021/12	2022/12 (Outlook)	Calculation method
ROE	7.3%	7.1%	Profit / Average beginning and ending equity
Revenue growth ratio	10.6%	9.3%	Revenue / Revenue for the previous fiscal year
R&D expense ratio	16.4%	18.4%	Research and development expenses / Revenue
Core operating profit ratio	18.6%	17.6%	Core operating profit / Revenue

(Yen)

	2021/12	2022/12 (Outlook)
Dividend per share (Second quarter-end)	23	24
Dividend per share (Fiscal year-end)	23	24
Dividend per share (Annual)	46	48
Dividend payout ratio*	43.2%	47.9%

* The dividend payout ratio is based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting "other income," "other expenses" and the related "income tax expense" from "profit") by the average number of shares during the period).

Risk Factors

This section describes principal risks identified by the Kyowa Kirin Group as of December 31, 2021. However, the Group may face other unforeseen risks caused by changes in internal and external conditions, and risks not described here may have a negative impact on the Group's business performance and financial position.
The Group defines risks as factors that could have an uncertain impact on business targets, including both threats and opportunities.

Risks Related to Maximizing the Value of Global Strategic Products

▸ Details of risks and expected main impacts

The Kyowa Kirin Group is working to maximize the value of three drugs that have been positioned as global strategic products – Crysvita, a treatment for X-linked hypophosphatemia, Poteligeo, an anticancer agent, and Nourianz (product name in Japan: Nouriast), an antiparkinsonian agent. However, delays to sales area expansion caused by setbacks in market launch preparations, slow progress with market penetration due to difficulties in identifying potential patients, sharply lower-than-expected sales due to a shortfall in projected product prices in new markets, and impediments to stable supplies caused by quality issues, manufacturing problems and other issues, may prevent the Group from attaining its business targets.

▸ Key mitigation measures

To maximize the value of global strategic products, the Group is implementing initiatives to spur market uptake and expanding its business reach, centered on the US and Europe. In addition to a global management framework that facilitates seamless cooperation between functions (divisions) and regions (affiliates) on a global level, the Group has appointed personnel to take responsibility for each global strategic product. This person leads a cross-function/region team that works together to draft and execute strategies to maximize the value of each product. Regarding issues with quality and manufacturing, key mitigation measures are outlined in the Risks Related to Product Quality and Risks Related to Production and Stable Supply sections below.

Risks Related to R&D

▸ Details of risks and expected main impacts

In its R&D, the Group pursues the ongoing creation of groundbreaking pharmaceutical products and has established the following strategies centered on technology, disease, and open innovation.

(1) In addition to its ongoing quest to drive advances in antibody technologies, the Group will build a platform for creating breakthrough drugs by making full use of diverse modalities.
(2) The Group will continue to provide "Only-one value" drugs to address diseases that currently have no effective treatment while drawing on achievements cultivated to date in disease science (in the areas of nephrology, oncology, immunology and allergies, and the central nervous system).
(3) The Group will continue to incorporate external innovation through advanced open innovation activities, fusing collaborative research activities with academia, startups, and other partners (information gathering in the San Diego area, etc.) with early access to information by means of venture capital fund investments.

However, in the process of developing new drugs over long periods of time, there may be cases where R&D has to be abandoned, for example if expected efficacy is not confirmed or for safety and other reasons, which may prevent the Group from expanding its drug pipeline and undermining growth potential and profitability.

▸ Key mitigation measures

The Group is actively stepping up investment in R&D (aiming for an R&D expense ratio of 18–20%) to identify the next global drug candidates and take other steps to reinforce its pipeline of new drugs to support future growth. In addition, to complement proprietary research, the Group is also focusing on open innovation activities involving partners from across industry, government, and academia, including active strategic partnering (in-licensing, tie-ups, etc.) to acquire platform technologies and pipeline assets. For instance, since 2020, the Group has been collaborating with Axcelead Drug Discovery Partners Inc., a drug discovery solutions provider formed by the spinout of Takeda Pharmaceutical Company Limited's drug discovery platform business. The aim of the tie-up is to combine Axcelead's long-established, extensive technologies and expertise in small-molecule drug discovery with the Group's own innovative drug discovery technologies, thereby building a small-molecule drug discovery platform and using this technology to broaden the R&D pipeline with groundbreaking new compounds. The Group is also extending its R&D alliance with InveniAI LLC, a US company providing AI and machine learning applications, identifying, assessing, and optimizing novel drug discovery targets that complement the Group's proprietary next-generation antibody technologies.

Risks Related to Healthcare Cost-Control Policies

▸ Details of risks and expected main impacts

The trend toward tighter control of healthcare costs is increasing in Japan and elsewhere. Efforts to reform healthcare systems in various countries involve reducing prices of branded drugs and encouraging wider use of generic drugs. These trends may have a negative impact on the Group's business performance and financial position. In this context, while being innovative is important to the successful reception of a new drug, delays to the development of practical, groundbreaking new drugs may undermine the Group's growth potential and profitability.

▸ Key mitigation measures

The Kyowa Kirin Group closely monitors healthcare policy trends in each country while also forecasting post-launch pricing for development compounds and evaluating their impact on revenue. To deliver life-changing drugs that meet the needs of patients, the Group is also exploring the formulation of strategic data packages that highlight the scientific basis for the value of such drugs.

Risks Related to Parent and Group Company Management

▸ Details of risks and expected main impacts

For the Group's business as a Global Specialty Pharmaceutical Company to grow, robust risk management for Kyowa Kirin and its Group companies is management's top priority. Since 2020, the Group has been working to enhance governance, and launched an improvement plan with three key objectives: creating a strong production and quality assurance platform, improving risk management, and reforming the corporate culture. In the event that these measures are not fully effective, trust in the Company as a pharmaceutical manufacturer may be eroded if production, sales and other business activities are restricted or halted due to emerging risks.

▸ Key mitigation measures

Improving risk management aims to achieve Group-wide risk management that can anticipate the future and take preventative measures. To this end, the Group holds workshops for all executives and managers at the head office as well as workshops with overseas regional head offices, stages ongoing crisis and business continuity plan (BCP) drills across regions in Japan and overseas, and deliberates on material issues (materiality) that are both risks the Group needs to address over the medium and long term as well as opportunities. Through these actions, the Group is working to heighten its ability to respond to new and potential risks. Please refer to Risks Related to Product Quality for details about how Kyowa Kirin is building a robust quality assurance system and Risks Related to Human Resources for details about corporate culture reforms.

Risks Related to Product Quality

▸ Details of risks and expected main impacts

Pharmaceutical manufacturing requires facilities (hard assets) and procedures and people (soft assets) that are compatible with good manufacturing practice (GMP).

Should a GMP inspection by a national authority or an internal audit find a serious GMP issue, the regulatory authority may issue instructions for production or shipments to be suspended. In addition, if for any reason there are any concerns about the safety or quality of the product with regard to raw materials or manufacturing processes used to make the product, these may give rise to a suspension of shipments or product recall.

▸ Key mitigation measures

The Group's quality assurance functions are centered on the Global QA Head, who reports directly to the President and guides quality assurance activities in each region. Specifically, the Global Quality Assurance Committee, regular and ad hoc Global Product Council and other quality assurance bodies discuss critical quality-related issues reported by key regional subsidiaries, evaluate quality performance at newly selected manufacturing sites, regularly assess product quality, review the activities of global taskforces established to address specific issues, and monitor issues identified in audits and progress with related response measures. The Group has also established a global, independent specialist audit unit to reinforce product quality audits within the Group and at contractors. In addition, the Group is introducing an electronic Quality Management System (eQMS) to appropriately manage and utilize large volumes of quality assurance information on a global level and to drive continuous improvements in processes and reliability. With eQMS, key quality management processes (education and training, document management, deviation, complaints, corrective and preventative actions, modifications, change control, audits, etc.) are all managed electronically.

Risks Related to Production and Stable Supply

▸ Details of risks and expected main impacts

In cases where detailed, accurate demand forecasts in various regions are impossible; where it is impossible to maintain supply capacity with the Group's proprietary plants or through cooperation with contract manufacturers and other suppliers; where market supply and demand fluctuates significantly due to the supply difficulties of other companies; or in other cases, stable supplies of the Group's products could be impeded, and resulting factors such as delays in drug launch schedules or adjustments of product shipments could erode trust in Kyowa Kirin as a pharmaceutical company or depress revenues, among other things.

▸ Key mitigation measures

The Group is implementing sales and operations planning (S&OP) to optimize the entire supply chain. S&OP is being used to increase the accuracy of demand forecasting by rapidly identifying changes in product sales and needs, and to achieve a supply-demand balance and enable quick adjustments in line with business plans. The Group has visualized demand for global strategic products using a supply-demand planning system. In addition, to respond to spikes in demand and tight supply-demand conditions, the Group is expanding its network of contractors, investing in Group plants, rolling out digital technology to enhance manufacturing operational efficiency, and increasing headcount and upgrading training systems in the production and quality assurance divisions.

Risks Related to the Management of Suppliers and Contractors

▸ Details of risks and expected main impacts

The Group enters into alliances with other companies, in the form of joint development projects, joint marketing, technology partnerships and establishing joint ventures, and it also outsources operations related to the supply of raw materials for pharmaceutical products, production, logistics and marketing to other domestic and overseas suppliers. However, if the alliances and outsourcing contracts fail to deliver the expected results or are dissolved due to issues related to human rights, legal compliance, the environment, information security, or if there are quality issues with contracted deliverables, the Group could face difficulty securing stable supplies of its products or issues in logistics and sales, which may erode trust in Kyowa Kirin as a pharmaceutical company, lower revenues, or lead to delays in new drug applications.

▸ Key mitigation measures

The Group is seeking to conduct open, fair CSR-based procurement in line with the Kyowa Kirin Group Procurement Policy, which states its commitment to pursue CSR procurement together with suppliers to ensure stable supplies of high-quality products. In addition, the Supplier Code of Conduct sums up the seven areas where the Group calls for understanding and cooperation from suppliers: relationships with society, relationships with employees, compliance with rules, respect for human rights, environmental preservation, information management, and risk management. Contracts with suppliers carry a CSR clause, which includes compliance with the Code of Conduct, and the Group carries out CSR questionnaires to confirm compliance with the Code, publishing the results. The Group also obtains risk and credit background data from external organizations and conducts supplier assessments based on objective information. The Group will continue to obtain similar information in the course of transactions as needed, and confirm with a supplier when there is any cause for concern. In addition, the Group promptly shares the risk information it obtained with relevant divisions and works together to mitigate risk, including requesting corrective action from suppliers or considering changing suppliers, as needed.

Risks Related to Information Security

▸ Details of risks and expected main impacts

As the Group utilizes a variety of information systems, confidential information may be leaked outside the Company or systems may be rendered inoperable in the event of unauthorized system access or following a cyberattack. In addition, cyberattacks on servers at suppliers could have a negative impact on the Group, such as unauthorized access to the Group's confidential information or personal data, interruption to the Group's business activities, or brand damage. As explained in key mitigation measures for Risks Related to Pandemics, the move to home working is improving productivity, but the number of employees using home communication environments or working alone is rising, which increases the risk of surveillance, cyberattacks and email errors that may lead to information leaks.

▸ Key mitigation measures

The Group is taking steps to upgrade information security, including technical measures to guard against cybersecurity threats that are becoming more diverse and more sophisticated each year, as well as developing playbooks that include information such as the recommended initial response flow and procedural steps in the event of a cyber incident. The Group is also working to mitigate risks at suppliers, including verifying security countermeasures. In addition, to be better prepared to mount a rapid response and minimize damage in the event of an incident, the Group is conducting crisis drills in each region to deal with ransomware and other cyberattacks. The Group is also educating employees in information security, conducting ongoing drills on handling targeted email attacks, and raising awareness by disseminating information and precautions on preventing computer viruses updated to reflect the latest cyberattack methods, both in writing and on a dedicated cybersecurity website.

Risks Related to Compliance

▸ Details of risks and expected main impacts

The Group is required to comply with a range of laws and regulations governing pharmaceutical R&D, manufacturing, sales, imports and exports. In addition, pharmaceutical companies must strictly adhere to regulations in each country and voluntary industrywide codes regarding pharmaceutical promotion. Failure to comply with these laws, regulations and voluntary codes could result in sanctions that delay or suspend the development of new drugs, or restrict or suspend production, sales and other business activities, which may erode trust in Kyowa Kirin as a pharmaceutical company.

▸ Key mitigation measures

In the Kyowa Kirin Group, compliance is not restricted to legal compliance. The Kyowa Kirin Group Code of Conduct stipulates general actions that every executive and employee must take to quickly identify and correctly gauge the needs of society and to act ethically. In addition, the Group is establishing systems and conducting continuous training to ensure compliance with laws and regulations and voluntary codes. To strengthen compliance, each Regional CSR Committee, which convene on a quarterly basis, and the Group CSR Committee, which meets annually, promote continuous improvement by discussing compliance status and progress made with measures to address important issues. In addition, the Group has set up a whistleblowing hotline to prevent or quickly detect and rectify actions that violate the Code of Conduct or that significantly damage the brand value of the Kyowa Kirin Group. Furthermore, the Group conducts an annual employee compliance awareness survey to identify potential risks, while working to mitigate risks in the early stages by confirming the facts of survey responses and responding

accordingly. Survey results are also reported to the CSR Committee and Board of Directors. The Group also launched a Group compliance enhancement project in 2021. Based on the various Kyowa Kirin Group Policies that supplement the Code of Conduct, the project seeks to assess the status of efforts such as the formulation of relevant policies and procedures, education and training, and monitoring. Based on the assessment results, the Group creates a roadmap for improvement and implements measures accordingly, further raising its compliance level.

Risks Related to Human Resources

▸ Details of risks and expected main impacts

The Group is working to embed its global management system to encourage individuals from diverse backgrounds to demonstrate their abilities and engage in business activities in Japan and overseas. However, if the Group is unable to develop and hire the personnel who will be responsible for its global management system, this may hinder the continuation of its business activities or its sustainable growth.

▸ Key mitigation measures

The Group believes people are the source of innovation. In line with that thinking, the Group develops and implements human resources training plans designed to maximize the potential of its diverse workforce to cultivate personnel who are motivated to drive change and create new value. The Group also formulated a new Diversity, Equity, and Inclusion (DE&I) Statement, shared worldwide, and is moving forward with efforts to realize the strengths of teams that shine with diverse personalities. The Group is reinforcing the global human resources management framework to ensure adequate staffing, creating succession planning for each global key position and nominating next-generation candidates regardless of race, nationality, gender, or age. Going forward, the Group will strategically develop human resources to expand the pool of potential nominees, after clarifying the requirements for leadership positions and designing separate training programs for each position to be filled. In Japan, the Group will identify shortfalls in current staffing with a view to the ideal future business scale and organizational structure. The Group will also provide every employee with opportunities to draw out their maximum potential. The Group set up talent review meetings in all divisions to deliberate on staff rotation and recruitment, and is formulating and implementing appropriate plans. In addition, to cultivate managers who can lead the next generation, the Group is selecting candidates and pursuing training measures that combine assessments, attendance at nominee training, early selection, and tough assignments such as overseas postings. With regard to these various personnel initiatives, as part of its improvement plan, the Group established a Human Resources Development Committee. With the participation of executives other than those in charge of human resources, this committee thoroughly discusses ways of making initiatives even more effective.

In addition, to foster the corporate culture it aspires to, the Group has established Key Behavior "Overcome Barriers" (KABEGOE in Japanese). The Group is implementing activities, such as dialogues with the President and other executives and group work, to empower all employees to overcome the barriers that divide them—all the difficulties and new challenges they face. Through employee awareness and corporate culture surveys, the Group monitors the extent to which initiatives to transform the corporate culture are gaining acceptance and taking root.

Risks Related to Pandemics

▸ Details of risks and expected main impacts

The emergence or re-emergence regionally of new cases of COVID-19 or other infectious diseases or global pandemics could force the Group's head office, plants, research laboratories and other business sites to close or cease business activities due to onsite infection clusters, or raw material suppliers could halt supplies and logistics may be affected. Disruption at medical facilities and other issues could prevent the Group from ensuring stable supplies of products or collecting product safety data, or delay in the provision of product information to medical professionals and progress with clinical studies. In addition, any impact on government authorities in each country could slow down new drug approvals and price negotiations, delaying the launch of new products. Under those conditions, the Group's business performance and financial position may be adversely affected.

▸ Key mitigation measures

Reducing the risk of infection is the first priority in dealing with the global COVID-19 pandemic. To this end, the Group implemented remote working as the main mode of work, including working from home, and actively introduced web meeting tools for internal and external communication to enable employees to continue their duties. At the same time, the Group is taking every effort to ensure the safety of employees that need to attend work, including those in the production, R&D, and sales divisions, such as temperature checks, face masks, social distancing, divided indoor spaces and ventilation. The Group has also made careful preparations to prevent the spread of infection in the event that an employee becomes infected and for other scenarios. Home working is also the main mode of work at the Group's overseas businesses, but online training is being conducted to prepare for the restart of normal business activities. In terms of sales activities as well, the Group is working to create optimal customer contact points that combine in-person and digital approaches. Considering efforts to make effective use of working from home as a critical element of working style reforms, the Group set a global policy for a hybrid working model to encourage both innovation and employee well-being. The Group will boost productivity by expanding the scope of the new working styles and stepping up the pace of digitizing tasks and achieving operational excellence, while carefully tracking new case levels in each region.

Risks Related to Natural Disasters

▸ Details of risks and expected main impacts

Natural disasters such as earthquakes and typhoons in regions worldwide could lead to the closure of the Group's head office, plants, research laboratories and other business sites or halt business activities, potentially impacting drug discovery or clinical development, stable supplies of products, collection of product safety data, and the provision of product information, which may have a negative impact on the Group's business performance and financial position.

▸ Key mitigation measures

The Group has developed a coordinated disaster prevention plan with its business sites to ensure the safety of employees and their families in the event of a disaster. Based on the plan, the Group regularly conducts employee safety confirmation drills and safety equipment upgrades/checks. The Group has also developed a Business Continuity Plan (BCP) to continue supplies of pharmaceutical products, safety monitoring activities and the provision of product information when normal business activities are disrupted. The Group conducts BCP drills simulating a range of scenarios, including super typhoons, a massive earthquake directly under Tokyo, and plant fires. The Group is working to identify issues through such drills and continuously improve BCP. In 2021, the Group established global, all-hazard BCP guidelines and is working to enhance the business continuity framework in each region.

Risks Related to Climate Change

▸ Details of risks and expected main impacts

Flood damage stemming from abnormal weather patterns brought about by climate change may affect all of the Group's business activities, including stable supplies of its products and research activities. In addition, in the future, Kyowa Kirin may face additional costs from the introduction of a carbon tax or to respond to tighter environmental regulations, or fail to attain its greenhouse gas reduction targets, which may undermine the Group's brand value.

▸ Key mitigation measures

In addition to the impact on business activities, the Group considers the response to climate change (prevention of global warming) to be critical to bringing about a sustainable society. The Group drafted a roadmap for reducing greenhouse gas emissions over the medium to long term, and is moving forward with an array of initiatives across the Group. In the medium term, the Group aims to cut emissions of greenhouse gases by focusing on energy-saving measures and expanding the use of renewable energy. In 2020, the Group selected Aqua Premium* to provide 75% of power at its Takasaki Plant. Aqua Premium is a 100% hydropower electricity supply service that generates zero CO_2 emissions. In 2021, the Group's head office switched 100% of its electric power to renewable energy. The Group has also expressed support for the Task Force on Climate-related Financial Disclosures (TCFD) recommendations. It is identifying the risks and opportunities that climate change poses to its businesses and its impacts, and is make disclosure based on the four thematic areas recommended by the TCFD: governance, strategy, risk management, and metrics and targets.

* Electricity payment plan provided by Tokyo Electric Power Company Energy Partner Inc.

Corporate Data

Corporate Data (As of December 31, 2021)

Kyowa Kirin Co., Ltd.

Head Office
1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan
Tel: 81-3-5205-7200
Fax: 81-3-5205-7182
URL: https://www.kyowakirin.com/

Number of Employees
Consolidated: 5,752

Date of Foundation
July 1, 1949

Paid-in Capital
¥26,745 million

Principal Plants

Japan
Takasaki Plant (Takasaki City, Gunma)
Ube Plant (Ube City, Yamaguchi)

Overseas
Kyowa Kirin China Pharmaceutical Co., Ltd.

R&D Network

Japan
Tokyo Research Park (Machida City, Tokyo)
Fuji Research Park (Sunto-gun, Shizuoka)
CMC R&D Center (Sunto-gun, Shizuoka)
Bio Process Research and Development Laboratories (Takasaki City, Gunma)

Overseas
Kyowa Kirin, Inc.
Kyowa Kirin China Pharmaceutical Co., Ltd.
Kyowa Kirin Korea Co., Ltd.

Network (As of December 31, 2021)

Name of Company	Proportion of Voting Rights Held	Share Capital (1,000)	Principal Business
Japan			
Kyowa Kirin Frontier Co., Ltd.	100%	¥100,000	Manufacturing and sales of pharmaceuticals
Kyowa Kirin Plus Co., Ltd.	100%	¥112,500	Insurance, wholesale and retail
Kyowa Medical Promotion Co., Ltd.	100%	¥50,000	Promotion and sales of pharmaceuticals
North America			
Kyowa Kirin USA Holdings, Inc.	100%	US $76,300	Supervision and management of specific subsidiaries (U.S.A.)
Kyowa Kirin, Inc.	100%	US $0.2	R&D and sales of pharmaceuticals (U.S.A.)
Kyowa Kirin Canada, Inc.	100%	CA $0.1	Sales of pharmaceuticals (Canada)
BioWa, Inc.	100%	US $10,000	Out-licensing of antibody technology (U.S.A.)
EMEA			
Kyowa Kirin International plc	100%	£13,849	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Pharmaceutical Development Limited	100%	£501	Development of pharmaceuticals (U.K.)
Kyowa Kirin Limited	100%	£6,952	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Ireland Limited	100%	€0.1	Sales of pharmaceuticals (Ireland)
Kyowa Kirin Pharma SAS	100%	€1,241	Sales of pharmaceuticals (France)
Kyowa Kirin Farmacéutica, S.L.U.	100%	€216	Sales of pharmaceuticals (Spain)
Kyowa Kirin GmbH	100%	€51	Sales of pharmaceuticals (Germany)
Kyowa Kirin Holdings B.V.	100%	€111	Sales, licensing-in and licensing-out of pharmaceuticals (Netherlands)
Kyowa Kirin Pharma B.V.	100%	€18	Sales of pharmaceuticals (Netherlands)
Kyowa Kirin S.r.l.	100%	€10	Sales of pharmaceuticals (Italy)
Kyowa Kirin AB	100%	SEK 200	Sales of pharmaceuticals (Sweden)
Archimedes Pharma Limited	100%	£543	Supervision and management of specific subsidiaries (U.K.)
Kyowa Kirin Services Ltd	100%	£0.3	Sales and development of pharmaceuticals (U.K.)
Archimedes Pharma UK Limited	100%	£78	Sales of pharmaceuticals (U.K.)
Kyowa Kirin Sàrl	100%	CHF 20	Sales of pharmaceuticals (Switzerland)
Kyowa Kirin Austria GmbH	100%	€35	Sales of pharmaceuticals (Austria)
Kyowa Kirin Farmaceutica, Unipessoal Lda.	100%	€5	Sales of pharmaceuticals (Portugal)
Kyowa Kirin Pharma s.r.o.	100%	CZK 100	Sales of pharmaceuticals (Czech Republic)
Kyowa Kirin Pharma S.R.L.	100%	RON 10	Sales of pharmaceuticals (Romania)
Kyowa Kirin Pharma FZ-LLC.	100%	AED 50	Sales of pharmaceuticals (UAE)
Asia-Pacific			
Kyowa Kirin Asia Pacific Pte. Ltd.	100%	SGD 123,045	Supervision and management of specific subsidiaries and sales pharmaceuticals (Singapore)
Kyowa Kirin China Pharmaceutical Co., Ltd.	100%	US$ 29,800	Manufacturing and sales of pharmaceuticals (China)
Kyowa Kirin Korea Co., Ltd.	100%	KRW 2,200,000	Sales of pharmaceuticals (Korea)
Kyowa Kirin (Taiwan) Co., Ltd.	100%	TW $262,450	Sales of pharmaceuticals (Taiwan)
Kyowa Kirin (Hong Kong) Co., Ltd.	100%	HK $6,000	Sales of pharmaceuticals (Hong Kong)
Kyowa Kirin (Thailand) Co., Ltd.	100%	THB 100,000	Sales of pharmaceuticals (Thailand)
Kyowa Kirin (Malaysia) Sdn. Bhd.	100%	RM 1,000	Sales of pharmaceuticals (Malaysia)
Kyowa Kirin Australia Pty Ltd	100%	AU $ 5,000	Sales of pharmaceuticals (Australia)
Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceuticals

Note: All of the companies are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

Investor Information (As of December 31, 2021)

Stock Listing
Tokyo

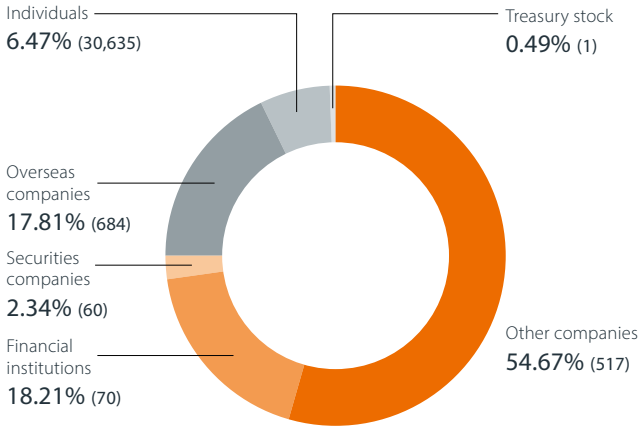
Securities Code
4151

Transfer Agent of Common Stock
Sumitomo Mitsui Trust Bank, Limited
1-4-1, Marunouchi, Chiyoda-ku, Tokyo
100-8233, Japan
http://www.smtb.jp/personal/agency/index.html

Number of Shares of Common Stock
Authorized: 987,900,000
Issued: 540,000,000

Number of Shareholders
31,967

Shareholding by Type of Investor (Number)



Principal Shareholders

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	53.75
The Master Trust Bank of Japan, Ltd. (Trust account)	56,174	10.45
Custody Bank of Japan, Ltd. (Trust account)	20,312	3.78
State Street Bank & Trust Company 505223	7,639	1.42
SMBC Nikko Securities Inc.	5,363	1.00
Custody Bank of Japan, Ltd. (Securities investment trust account)	4,954	0.92
State Street Bank West Client-Treaty 505234	4,894	0.91
JP Morgan Chase Bank 385780	4,041	0.75
State Street Bank & Trust Company 505103	3,457	0.64
JP Morgan Chase Bank 385781	3,317	0.62

Stock Price and Trading Volume

Total Shareholder Return (TSR)

	Past 4 years	Past 3 years	Past 2 years	Past 1 year	Current year
Kyowa Kirin Co., Ltd.	**136.5%**	**132.4%**	**165.7%**	**183.3%**	**206.0%**
TOPIX Total Return Index	122.2%	102.7%	121.3%	130.3%	146.9%