

### Annual Report 2019

For the year ended December 31, 2019

## ONE KYOWA KIRIN

Kyowa Kirin Co., Ltd.

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#### **Editorial Policy**

We have published this integrated report to help investors understand the Kyowa Kirin Group's values, management vision, strengths, operating conditions and future vision, referencing the IIRC International Integrated Reporting Framework and Guidance for Collaborative Value Creation released by Japan's Ministry of Economy, Trade and Industry.

We launched Nourianz in the US in 2019, achieving one of the goals in our Mid-term Business Plan – deliver global strategic products to patients worldwide. We are steadily transforming Kyowa Kirin into a Global Specialty Pharmaceutical Company (GSP). I look forward to your continued support as we drive the Group's growth on the global stage.





Concerning the Scope of This Report

The scope of this report is Kyowa Kirin Co., Ltd. and its consolidated subsidiaries in Japan and overseas, and certain non-consolidated subsidiaries and affiliates are mentioned in a part of the report. Environmental data is annotated for the convenience of readers. The reporting period includes calendar year 2019, and 2020 in part.

#### Performance Forecasts

Forecasts contained in this report are assumptions based on reasonable judgments and information available at the time. Actual results may differ significantly due to a variety of factors.

#### **Company Names**

In this report, group companies are abbreviated as follows: Kyowa Kirin Co., Ltd. (Kyowa Kirin).

#### Numerical Data

The sum of the breakdown may not equal the total due to rounding.

## Moving to a One Kyowa Kirin structure to drive the next leap forward

We have implemented our new One Kyowa Kirin structure since April 2019. One Kyowa Kirin is a matrix management structure combining a regional organization based on four regions – Japan, EMEA (Europe/Middle East/Africa), North America, and Asia/Oceania – and a functional organization based on the functions needed by a pharmaceutical company.

The new structure will allow us to accurately and rapidly respond to region-specific and global issues, while also supporting greater efficiency across all areas of the Group's operations. We will accelerate our globalization under this One Kyowa Kirin structure.

# North America **BANE EMEA**Japan **Asia/Oceania Asia/Oceania**

## Business Restructuring

#### Channeling management resources into the pharmaceutical business

Kyowa Kirin transferred 95% of its shares in Kyowa Hakko Bio Co., Ltd. to parent company Kirin Holdings Company, Limited on April 24, 2019. We made the decision to transfer the shares, as we believe Kyowa Hakko Bio will be able to continue growing and maximizing corporate value as a direct subsidiary of Kirin Holdings, which is enhancing its presence in the health science domain. The move will also allow Kyowa Kirin to concentrate its resources on new drug development in the pharmaceutical business, helping to accelerate its transition to a Global Specialty Pharmaceutical Company.



#### MANAGEMENT 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.



#### **Commitment to Life**

Work for the most precious presence on this planet. Create value for patients, caregivers, healthcare professionals, and customer.



Teamwork/Wa

One for all, all for one. Work in diverse teams and respect each other. Go beyond boundaries and collaborate with stakeholders.



Integrity

Do the right things. Be sincere and ethical consistently. Make a better world through good business practices.

## Innovation

Transform lives with passion and excitement. Challenge the status quo in all of our work.

The Kyowa Kirin Group has world-class research and development capabilities in the field of biopharmaceuticals. To strengthen those capabilities, we continue to actively invest in research and development in line with our firm commitment to innovation. Led by our research centers in Japan and San Diego in the US, we are driving forward research efforts on a global scale in search of new drug candidates Four Major Modalities
Next Generation
Therapeutic Antibodies

## Nucleic Acid Drugs Nucleic acid function-enhancing

 Nucleic acid function-enhancing technology nanoparticles
 DDS technology using lipid

**Establishment of** 

New Technology

Our Core Strengths Established by R&D and Production of Biopharmaceuticals

**Development of** 

- Destain (antihadu anginagring technology
- Excellence in analysis and co
- of carbohydrates
- lechnology in cell culture and control
- Technology for manufacturing
- of biologics

New Small Molecule Drugs

Immune activating antibody

Cell/tissue specific antibody

**Further Evolution of** 

**Existing Technology** 

 Integrated approach with science of biologics
 Precise drug design and synthesis based on structural analysis of target molecule Regenerative Therapeutics

 Technology in control of cell differentiation and others



## Teamwork/Wa\*

One for all, all for one. Work in diverse teams and respect each other. Go beyond boundaries and collaborate with stakeholders.

One of our strengths as a Group is to shrink distances between divisions and affiliates worldwide to achieve seamless cooperation. We will continue to take on new challenges by harnessing that strength to support a high level of teamwork. We will also create new value by working closely with all stakeholders, including patients and their families and medical professionals. \* Harmony and loop among people

1 <sup>NO</sup>POVERTY **Ř∵ŘŤ**ŤŤ

> 12 RESPONSIBLE CONSUMPTION AND PRODUCTION

> > 9 INDUSTRY, INNOVATION AND INFRASTRUCTURE

AND STRONG

15 UFF OR LAND 07

## Integrity

14 UFE BELOW WATER

6

8 DECENT WORK AND ECONOMIC GROWTH

6 CLEAN WATER AND SANITATION

•

17 PARTNERSHIPS FOR THE GOALS

13 CLIMATE ACTION

4 QUALITY EDUCATION

2 ZERO HUNGER

#### Do the right things. Be sincere and ethical consistently. Make a better world through good business practices.

5 EQUALITY

**3** GOOD HEALTH AND WELL-BEING 10 REDUCED INEQUALITIES

Initiatives are being implemented worldwide to realize the Sustainable Development Goals (SDGs). As a company, we have a social responsibility to also address SDG-related issues as part of our business activities. Specifically, we are working to tackle social issues that have a direct connection to our business – developing innovative new drugs for conditions with unmet medical needs, contributing to the economics of healthcare by reducing medical costs, improving quality of life (QOL), and contributing to the field of pre-symptomatic treatment, such as preventative healthcare.

08

Kirin

Co., Ltd.

ORIGIN

## A History of Creating Value

Formed in October 2008 through a merger between Kyowa Hakko Kogyo Co., Ltd. and Kirin Pharma Company, Limited, Kyowa Kirin is an R&D-based pharmaceutical company with state-of-the-art antibody technologies. Challenging the new possibilities as one of Japan's leading life-science companies, we are striving to contribute to the health and well-being of people around the world by creating new value.

#### Open Innovatior

### 1988

Supported the establishment of the La Jolla Institute for Immunology in the US; Kyowa Kirin continues to collaborate with the institute, which helped discover KHK4083

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Technological

Innovation

Technology established

to produce a wide range

of fully human antibod-

ies, just as the human body does, using mice Birth of a company business structure

> Kyowa Hakko Kirin Co., Ltd. starts operations

2008



#### Successfully isolated mitomycin C and started 1949 commercial production Kyowa Hakko as an anticancer drug Kyowa Hakko Kogyo Co., Ltd. Kyowa Kirin established as a secondary company of Kyowa Sangyo Co., Ltd. as part of restructuring plans 1885 Japan Brewery Company founded, forerunner company of Kirin Brewery First for Japan 1951 First volume production of streptomycin in Japan using technology from US drug firm Merck & Co., helping to eliminate tuberculosis in Japan R&D Division established at head office, marking the 1907 Group's full-scale move into the Kirin Brewery Co., Ltd. pharmaceuticals business. established Research Institute for Production Development starts active research efforts to commercialize erythropoietin DENTITY

1956

## **INTEGRATION**

Kirin Pharma Co., Ltd.

move to a holding

company structure

established in conjunc-

tion with Kirin Brewery's

#### Introduction > A History of Creating Value

iopharmaceutical

iopharmaceutica

2010

Started realigning production sites to upgrade aging facilities, tackle location

issues, raise GMP levels and improve cost competitive-

ness; completed 2017

2010

investigational antibodies completed at the Bio

Process Research and Development Laboratories

One of Japan's leading facilities for producing

### 2013

Nouriast tablets 20 mg, a novel antiparkinsonian agent, launched in Japan

Establishing

Biopharmaceutical

2014

Archimedes

2016 Completed construction of new biopharmaceutical API manufac-

turing facility at the Takasaki Plant,

boosting production capacity

Acquired UK company Archimedes Pharma Ltd., making it

a subsidiary

#### 2012

Poteligeo, an anticancer agent, launched in Japan; first drug based on POTEL-LIGENT technology

### 2012

Established Fujifilm Kyowa Kirin Biologics Co., Ltd., a joint-venture with FUJIFILM Corporation, to develop, make and sell biosimilars

## Kvowa Kirin Fuiifilm Joint venture with shared strengths

2011 Acquired UK company ProStrakan Group plc., making it a subsidiary (now Kyowa Kirin International plc.)

## ProStrakan

CONSOLIDATION



### 2013

Signed agreement with US firm Ultragenyx Pharmaceutical Inc. to develop and commercialize burosumab (KRN23), a fully human antibody against fibroblast growth factor 23 (FGF23)

 $\sim$ 

CHALLENGE

#### 2017

Kvowa Kirin Frontier Co., I td. established to secure domestic marketing approval for authorized version of flagship product Nesp

#### **Building the One Kyowa Kirin structure**

2019

- Launched our third global strate-



## **(Syowa KIRIN**

### 2018

Launched two global strategic products - XLH treatment Crysvita in the US and Europe and anticancer\* treatment Poteligeo in the US. Also started sales of biosimilar product Hulio. \* Relaspsed or refractory mycosis fungoides or Sézarv syndrome



**POTELIGEO**<sup>®</sup> (mogamulizumab)



## **Our Approach to Research and Development**

#### Targeting resources on four key categories, backed by antibody technology

Leveraging cutting-edge biotechnology anchored by antibody technology, Kyowa Kirin is focusing research and development efforts on four key areas – nephrology, oncology, immunology and allergy, and the central nervous system – to create new medical value and speed up the drug discovery process.



#### A strong pipeline from technology-driven drug discovery

Drawing on research and development capabilities and production technology from earlier work in biopharmaceuticals, coupled with maximum use of open innovation, we are deploying new drug discovery activities in four modalities – therapeutic antibodies, small molecule drugs, therapeutic nucleic acids and regenerative medicine. We call our unique approach technology-driven drug discovery.



\*List includes existing approved products targeting for additional indications and new markets.

### **Message from President**

Stepping up efforts to become a Global Specialty Pharmaceutical Company (GSP) anchored by the new One Kyowa Kirin structure

> Masashi Miyamoto, Ph.D. Executive Director of the Board.

President and Chief Executive Officer

#### Implementing the One Kyowa Kirin structure

Under the FY2016-2020 Mid-term Business Plan, the whole Group has been working to transform Kyowa Kirin into a Global Specialty Pharmaceutical Company (GSP) with capabilities in all areas of the pharmaceutical value chain – from drug discovery and development to manufacturing and sales.

To accelerate that process, we introduced a new management structure called One Kyowa Kirin in April 2019. One Kyowa Kirin is a matrix management structure combining a regional organization based on four regions – Japan, EMEA (Europe/Middle East/Africa), North America, and Asia/Oceania – and an international functional organization.

Region Heads, the top managers for each region, have the authority to implement flexible marketing campaigns tailored to market trends in their region, while Global Function Heads have the authority to implement global initiatives across all four regions based on clear, global standards in their area of responsibility, such as research and development, pharmacovigilance and quality assurance. The new structure will allow us to accurately and rapidly respond to region-specific and global issues, while also supporting greater efficiency in all areas of the Group's operations.

By clearly defining the roles and responsibilities of each Region Head and Global Function Head and promoting close communication between them, we aim to reinforce global corporate governance to ensure Kyowa Kirin makes the leap overseas as a GSP.

#### **Business restructuring and investment plans**

On April 24, 2019, we transferred 95% of our shares in Kyowa Hakko Bio to Kirin Holdings, our parent company. Within the Company, we have discussed our vision for Kyowa Hakko Bio for some time now. However, following the parent company's decision to launch and develop "Health Science Domain," we believe Kyowa Hakko Bio is well-placed to use its strengths to be the main player developing that business. We therefore decided to transfer our shares in the company to Kirin Holdings to promote effective use of management resources and accelerate business development, which will support Kyowa Hakko Bio's sustained growth and maximize its corporate value. The transfer of Kyowa Hakko Bio to Kirin Holdings also allows us to concentrate management resources on new drug development in our pharmaceuticals business.

The cash from the sale of the subsidiary has lifted Kyowa Kirin's cash on hand (cash and deposits plus loans receivable from parent company) to around ¥300 billion as of the end of 2019. We plan to use those funds to reinforce research and development capabilities and invest for the future growth to become an organization capable of consistently creating new medicines. Our pipeline includes a number of mid- and late-stage development compounds such as RTA 402, KHK4083 and KW-6356 that are progressing well, but we still need to strengthen our pipeline for the next decade and further into the future. For that longer timeframe, we will consider in-licensing to help us build a pipeline that will drive the Group's growth for many years to come. We are also looking at acquiring development compounds that have potential sales synergies with our global strategic products (Crysvita, Poteligeo and Nouriast/Nourianz). And to ensure we remain competitive in the global market, we need to reinforce and enhance drug discovery technologies as our platform for finding new drugs. With that in mind, we plan to actively acquire and introduce technologies from other companies to support our own efforts in technology development.

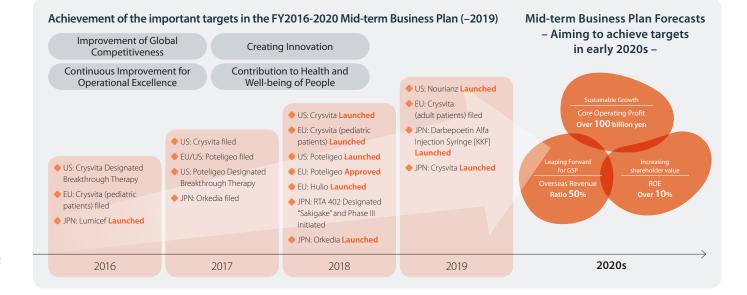
#### FY2019 results and FY2020 outlook

I'm pleased to report that the pharmaceuticals business had an excellent year in FY2019, with revenue and core operating profit both rising year on year.

Revenue in Japan faced considerable headwinds, such as drug price revisions and the impact of generics and rival products, as well as the transition to an authorized version of Nesp. Despite that, revenue increased year on year, supported by higher sales of G-Lasta, Romiplate and other products. Overseas revenue also rose year on year, driven by sales of global strategic products Crysvita and Poteligeo, both launched in 2018, and strong sales of Regpara in China and Neulasta in the Middle East.

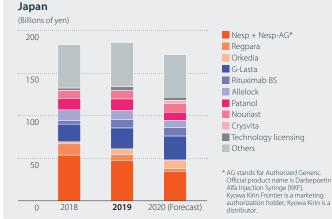
Selling, general and administrative expenses and research and development costs increased, but core operating profit rose 18% year on year, reflecting an increase in gross profit on higher revenue and earnings improvement at biosimilar business Fujifilm Kyowa Kirin Biologics.

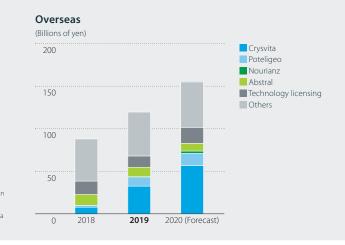
For FY2020, we see revenue rising 7% and core operating profit increasing 10% year on year, supported by continued growth overseas.





**Pharmaceuticals Business** 







Staying true to our roots as a unique pharmaceutical company

#### **Raising global competitiveness**

The Kyowa Kirin Group's strengths are its proprietary drug discovery capabilities and its unique pipeline. The global launch of Crysvita, Poteligeo and Nouriast/Nourianz, all developed in-house, underscore our strengths in drug discovery, and the success of those products has given us even greater confidence. Crysvita and Poteligeo are both used in niche treatment fields – areas we have been targeting for many years but that have been relatively neglected by other pharmaceutical companies. While some disorders are rare, there are still many people suffering from the impact of those illnesses. In markets large or small, we are fully committed to helping as many patients as possible. By staying true to that principle, we aim to stand out as a unique pharmaceutical company in the crowded global pharmaceutical industry. Overseas revenue reached ¥119.6 billion in FY2019. We aim to keep growing revenue overseas and expand our business globally. However, as we grow, we need to ensure the things that make Kyowa Kirin unique are not diluted. When other companies hesitate, we have to take the initiative and pursue all the possibilities of new drug development to become a company that shines on the global stage.

#### **Creating innovation**

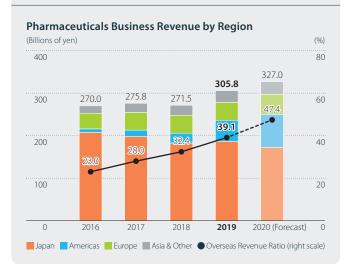
To continue creating groundbreaking new drugs, we need to give researchers time and space to explore new ideas and approaches, while backing them up with sufficient management resources. Over the last decade, we have prioritized investment in the development section and carefully selected drug discovery projects in the research section with the overarching aim of launching global products. That is one of the reasons why our pipeline now lacks early-stage development compounds. Going forward, senior management will support the promising new targets missed by other companies and projects that researchers are committed to and passionate about. We will allocate management resources to those projects whenever possible.

We believe a diverse workforce plays a major role in driving innovation. As our business has expanded worldwide, many overseas employees have joined our Group. These new members have brought with them different ideas, experiences and perspectives that are energizing our existing workforce. We aim to cultivate a corporate culture that offers opportunities for everybody to excel – regardless of background – to drive a steady stream of innovative new ideas.

#### Building a robust quality assurance structure

As already disclosed in 2019, we conducted a voluntary recall of anticancer treatment "Mitomycin Kyowa for injection" after discovering issues in the aseptic manufacturing processes of the active pharmaceutical ingredient (API) "Mitomycin-C" at Kyowa Hakko Bio's Hofu Plant. We would like to take this opportunity to apologize for the incident, which was the result of insufficient monitoring and supervision by Kyowa Kirin as a marketing authorization holder of the drug and a Group company of Kyowa Hakko Bio. In addition to conducting a thorough investigation into the issues with mitomycin-C and the causes of the incident, we are

#### Overseas revenue increased steadily



prioritizing efforts to build a more robust manufacturing and quality assurance system and working across the Group to prevent any reoccurrence. At the same time, we are devoting ourselves to reforming Kyowa Kirin's corporate culture to improve risk management and ensure compliance awareness reaches all corners of the Group.

#### Governance

#### Improving the effectiveness of the Board of Directors

We believe improving the effectiveness of the Board of Directors is a vital part of strengthening corporate governance. To ensure members of the board are fulfilling the expectations of shareholders and investors, we conduct an annual review with an outside expert to identify any issues in the board and board members' roles. Issues that emerged from the latest review included a lack of information provided to the board and insufficient time for discussion. Due to the large number of topics discussed by the board, we found that board members did not have enough information or discussion time for critical matters that affect earnings, such as R&D strategy and business alliances. In FY2019, that prompted us to review the process for deciding which matters are discussed by the board in order to narrow its focus to key topics, allowing for more information and time for critical matters. That change has led to more dynamic and effective discussions during board meetings. In FY2020 and beyond, we will continue to identify any problems and implement necessary improvements.

#### Dialogue with stakeholders

To build closer links with stakeholders, we are increasing opportunities for dialogue to give them a deeper understanding of the Group's strengths, organization and strategy. In particular, given the growing trend towards ESG investing in capital markets, we have put greater emphasis on environmental, social and governance factors in our engagement with stakeholders. We use our website and this annual report to disclose the Group's active efforts in the environmental and social spheres – an approach that has been welcomed by stakeholders. With governance, we receive a lot of input and questions about Kyowa Kirin's relationship with parent

company Kirin Holdings. To allay any concerns, we allocate substantial time to explain to shareholders and investors that Kyowa Kirin retains its independence and has firm control over minority interests and profits. We're also careful to emphasize that there are no business transactions with the parent company that are detrimental to the interests of shareholders. For example, to ensure the highest levels of integrity in discussions about transferring subsidiary Kyowa Hakko Bio to Kirin Holdings in 2019, we conducted board meetings that excluded any director or auditor who concurrently serve as senior managements of the parent company. We also carried out a detailed assessment of Kyowa Hakko Bio's corporate value, drawing on the objective input of outside directors, to arrive at a fair and reasonable sale price for the company. While some of the cash received from the sale was loaned back to the parent company at a slightly higher interest rate than market rates offered by the banks, we have made sure that those funds can be accessed rapidly if needed to acquire pipeline drugs or other companies. Protecting minority interests and preventing conflicts of interest are important principles for listed companies, so we intend to keep a close eye on such matters and ensure transparent governance at all times.

#### **Management vision**

FY2020 is the final year of our Mid-term Business Plan. It will be a crucial time to lay the foundations for our next Mid-term Business plan. Specifically, we will harness the Group's unique strengths and its diverse personnel, which I talked about earlier, to reinforce our business from both an offensive and defensive perspective. Looking further ahead, we will strive to achieve the Sustainable Development Goals (SDGs), and in line with our management philosophy, work tirelessly and fearlessly to realize our shared vision for Kyowa Kirin: a Japan-based Global Specialty Pharmaceutical Company contributing to human health and wellbeing worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies in the core therapeutic areas of oncology, nephrology, central nervous system and immunology.

I hope we can count on your continued support and understanding as we work to make that vision a reality.



## Working tirelessly and fearlessly to realize our management vision

## Message from the Executive Vice President



**Compliance and** risk management are vital elements supporting Kyowa Kirin's transformation into a global company

#### Yutaka Osawa

Executive Director of the Board, **Executive Vice President** 

#### **Rigorous compliance**

Kyowa Kirin is rapidly expanding its business overseas to achieve its goal of becoming a GSP. Speed is the key to growing businesses on the global stage. Kyowa Kirin is no exception and we have to make decisions more rapidly than ever before to develop our business. However, we must not neglect compliance, which anchors all of our business activities. Once a company loses trust due to a legal violation or misstep in its business, it's hard to get it back. That loss of trust can become a major obstacle to growth. That's why we have positioned compliance as one of our priority management issues and are working to ensure our employees rigorously comply with all rules and regulations.

The Group has offices in different markets worldwide, each with their own business customs and regulations. In addition, there are inconsistences in compliance awareness between different regions. We first have to raise awareness about compliance across all of our global sites. To support that, we have formulated the Kyowa Kirin Group Code of Conduct to create a culture of specific behaviors that employees must follow. Despite those efforts, we discovered a large number of long-term issues with manufacturing processes at a Group company Kyowa Hakko Bio in 2019. We regret to say that Integrity, one of our core values, had not taken hold deep enough in the Group. On behalf of the Company,

#### Positioning of the Kyowa Kirin Group Code of Conduct

We have developed the Kyowa Kirin Group Code of Conduct to clarify specific actions and behavior that all executives and employees must follow in order to realize our management philosophy.



I would like to apologize to all our stakeholders about this lapse. Management is now prioritizing efforts to build a more robust quality assurance system and our entire workforce is actively engaged in activities to prevent any reoccurrence. We will also focus on overhauling our corporate culture. Specifically, we will use the core value of Integrity to anchor compliance and draw on our concept of Teamwork/Wa, which is designed to encourage managers and colleagues to talk to each other about any issue – however small – instead of dealing with it themselves.

Reinforcing compliance is a never-ending job. On a daily basis, every one of our employees needs to ask themselves if they are doing the right thing, while also pushing themselves to raise their game in response to changing conditions. Going forward, we will continue to actively discuss compliance issues and exchange information with all our compliance leaders worldwide, with feedback from them used to develop and implement training programs.

#### Reinforcing risk management

The overseas revenue ratio reached 39.1% in FY2019, driven by strong sales of new global strategic products. Kyowa Kirin's rapid transformation into a global company is also leading to increased risk exposure. One area we are watching closely is the risk of disruption to supplies of our products. In the past, our business was focused on Japan, which is a relatively small market with low volatility in demand. That made it quite easy to control production to avoid any serious shortages of products. However, as the overseas revenue ratio rises, we have to develop more detailed and accurate demand forecasts for each region to ensure reliable supplies of our medicines worldwide. Those forecasts are based on information gathered by our staff who deal directly with frontline medical professionals in each region. They rapidly identify sales trends for each product and any changes in frontline needs, then relay the data back to head office in real time. We also draw on insights from key opinion leaders – medical professionals who have expert knowledge about

the market potential of our products – and use scientific analysis to improve the accuracy of forecasting. We are also increasing the responsiveness of procurement, logistics, manufacturing and other functions and optimizing the entire supply chain to create a system that adapts to large fluctuations in supply and demand.

In addition to that, we constantly monitor and evaluate the level of risks related to research and development, regulatory environment, investment and other areas. In our business, there are many risks that can be identified with the help of an outside perspective. In particular, outside directors on the Board of Directors help to highlight risks that inside directors with a long track record experience in the pharmaceutical industry could potentially overlook. In that sense, outside directors with specialist knowledge in various fields can play an extremely important role in risk management. In some cases, employees who join Kyowa Kirin from competitors or other industries also provide detailed insights about risks in our frontline operations, as well as ideas about how to mitigate those risks.

Drawing on those and other perspectives, we aim to build the foundations for a robust organization that is resilient to a wide range of risks.

#### A final word for stakeholders

Developing new drugs can take a very long time and requires immense patience during the multistep development process. Some researchers devote their lives to developing a single drug and overcoming hurdles that stand in the way of success. Even then, many drugs never make it to market. Despite that, we know there are many patients out there who are waiting for new treatments to be developed by us. What motivates us is a desire to contribute to the health and well-being of those patients – something I want stakeholders to share with us. I hope our stakeholders will continue to support the Kyowa Kirin Group from a long-term perspective. I look forward to working with you as partners creating value for society.



## Building the foundations for risk-resilient organization

## **CSV** Management

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 by addressing social issues.

#### **CSV** Materiality

In practicing its CSV management, we identified issues that need to be tackled with top priority as CSV material issues (materiality) in view of their impacts on social sustainability and our business, and in reference to ISO 26000 and other guidelines. CSV materiality is also consolidated into our FY2016-2020 Mid-term Business Plan. The four health and environmental issues that are also important to the Kirin Group included in the identified 20 CSV material issues are shared as targets by the Kirin Group's CSV Commitment. In other words, the Kyowa Kirin Group is working together in response to the needs or demands of society as the Kirin Group.

#### Recognizing society's demands on Kyowa Kirin

We are working to understand and recognize society's demands on the Kyowa Kirin Group by referencing the Sustainable Development Goals (SDGs), which are being promoted as an international framework for social issues. Goal 3 of the SDGs, "Good health and well-being," is consistent with the main aim of our management philosophy, "Contribute to the health and well-being of people around the world." We have therefore positioned Goal 3 as the core issue for the Group. We have also designated a number of issues related to other SDGs that we think should be tackled through our business activities. By working to solve those CSV material issues, we aim to help achieve the SDGs.

#### **Promotion framework**

The Group CSR Committee meets every quarter to promote the Group's CSR activities, centered on CSV materiality. The committee is chaired by the Company's Executive Vice President and the committee consists of directors in departments and presidents of affiliates. The committee discusses all key matters related to the Group's CSR strategy and action plans, including risk management and compliance, and monitors progress with implementation. Details of discussions and critical reports are passed on to the Board of Directors.

CSV Materiality	Kyowa Kirin Group's target SDGs	
Foster corporate culture in line with the Core Values     Promote compliance     Strengthen risk management     Strengthen organizational governance system	(Organizational Governance)	
• Respect human rights	(Human Rights)	Consistent with our management philosophy
Ensure employee safety     Promote employee health     Promote diversity of employee and work style     Develop employee competencies	(Labor Practices)	3 MARTINIAN JANA AND AND AND AND AND AND AND AND AND
<ul><li>Prevent global warming</li><li>Preserve water resources</li></ul>	(Environment)	6 minuter <b>7 minuter</b> <b>13 minuter</b> <b>15 minute</b>
Prevent bribery     Ensure transparency in relationships with medical institutions     Provide appropriate pharmaceutical information     Ensure reliability in clinical research	(Fair Operating Practices)	16 fride.user entities 
Create new products and services centered on leading-edge technology     Provide high-quality and safe products and services     Ensure stable supply of products and services	(Consumer Issues)	3 MOMENTARY -W
Contribute to communities     Contribute to advances in life sciences	(Community Involvement and Development)	4 marin

#### **Group CSR Committee**

Committee members					
Chairperson Executive Vice President					
General member Directors in departments and President of Kyowa Kirin plus					
Observer	Company Auditors and Internal Audit Department				
Secretariat	CSR Management Dept.				

#### Main topics in 2019

Meeting date	Topics		
23 January	<ul> <li>Key CSV issues in 2019 • Trends in cyberattacks and countermeasures</li> <li>Revisions to or abolition of Group Policies</li> <li>Reviewed information on business risk and other risks disclosed in Securities reports</li> </ul>		
19 April         • Results of 2018 environmental performance evaluation           • Improved the effectiveness of the whistle-blower system         • Launched Mirai Port brand content			
17 July	Contractor management • Guidelines related to sales data provision activities     Results of compliance survey about awareness of human rights		
15 October	Results of employee engagement survey     Reviewed information on business risk and other risks disclosed in Securities reports     Environmental and health and safety action plans and goals		

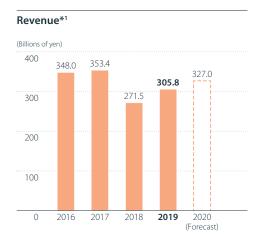
At every meeting, the committee monitors progress with risk management and CSV materiality, which is reflected in annual business plans in each department and affiliate.

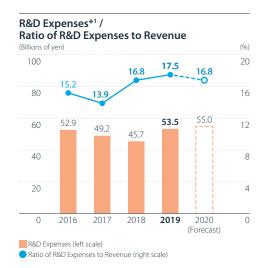
#### Key performance indicators, outcomes and initiatives

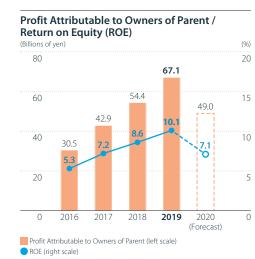
CSV material issues are selected and managed through the following process. The Group works to tackle the issues to meet certain performance targets.

STEP 1	List issues to be deliberated as CSV initiatives accord-		CSV Materiality	Key performance indicators for 2019	Key outcomes and initiatives
Listing of issues	ing to international guidelines, such as ISO26000.		<ul> <li>Foster corporate culture in line with the Core Values</li> </ul>	Promoting our management philosophy, values and Code of Conduct: Employee awareness survey to gauge level of understanding (1) "Good understanding of management philosophy" (2) "Good understanding of values" (3) "Understanding of Code of Conduct content"	(1) 81% (2) 79% (3) 87%
STEP 2	Prioritize the listed issues from the perspective of impact on social sustainability and our business, and	Organizational Governance	<ul> <li>Promote compliance</li> <li>Strengthen risk management</li> <li>Strengthen organizational governance</li> </ul>	Whistle-blower system (1) Number of whistle-blower reports (2) Awareness of whistle-blower system at overseas subsidiaries	(1) 27 (2) 97% P51
Assessment of impact on social sustainability and business	formulate a materiality matrix.		system	Established incident reporting system	Establishing a global incident reporting system
				Appraisal by external ESG evaluation body	P46
business		Human Rights	Respect human rights	Human rights due diligence implemented across the entire Kyowa Kirin Group	Implementing initiatives to address issues in each department
STEP 3	In the materiality matrix, identify issues that need to be addressed with priority under the Mid-term			Number of accidents requiring time off work	1 P20
Identification of materiality (material issues)	Business Plan as our CSV materiality.	Labor Practices	<ul> <li>Ensure employee safety</li> <li>Promote employee health</li> <li>Promote diversity of employee and work style</li> </ul>	Frequency of accidents resulting in injury or death	Please refer to the Company's website for details of promotion of safe driving 1.2% https://www.kyowakirin.com/sustainability/human_rights_ labor_practices/workplace_safety/index.html
			<ul> <li>Develop employee competencies</li> </ul>	Ratio of female managers	9.7% P20 P39
STEP 4	Finalize the materiality by obtaining the approval of the Group CSR Committee after hearing from			Ratio of employees with disabilities	2.59% P20
Confirmation of validity and finalization	executives and discussions with relevant divisions.			CO: (1) CO, emissions (2) Per-unit energy consumption	(1) 52 thousand tons P20 P37 (2) Reduced by 5.1% from previous year
	Incorporate the materiality into the business man-	Environment	<ul> <li>Prevent global warming</li> <li>Preserve water resources</li> </ul>	Water (1) Water usage (2) Per-unit water consumption	(1) 2.2 million m <sup>3</sup> (2) Reduced by 3.9% from previous year
STEP 5	agement plan for the relevant fiscal year. Arrange for the Group CSR Committee to monitor updates on			Final disposal rate for industrial waste	0.091% P20
and assessment	progress and changes in social requirements and			Number of environmental accidents (crisis level 1 or higher)	0
	Review the plan for necessary adjustments.	Fair Operating Practices	Prevent bribery     Ensure transparency in relationships     with medical institutions     Provide appropriate pharmaceutical     information     Ensure reliability in clinical research	Initiatives implemented in line with group policies	P51
	Materiality		<ul> <li>Create new products and services centered on leading-edge technology</li> </ul>	Become a Global Specialty Pharmaceutical Company (GSP) by supplying new proprietary medicines to patients worldwide	P11 P23
	ocial su stainability	Consumer Issues	<ul> <li>Provide high-quality and safe products and services</li> <li>Ensure stable supply of products and services</li> </ul>	Established Group quality assurance system including management of contract manufacturers	P36
	Impact on the Group's business	Community Involvement and Development	<ul> <li>Contribute to communities</li> <li>Contribute to advances in life sciences</li> </ul>	Implemented initiatives in line with the Community Involvement Activities Policy and measures to "support the development of the life sciences field"	Implementing initiatives to support communities Making donations that comply with regulations, industry rules and internal regulations

## **Financial Highlights**

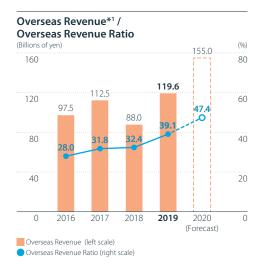


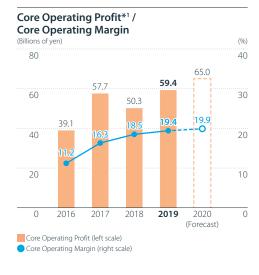




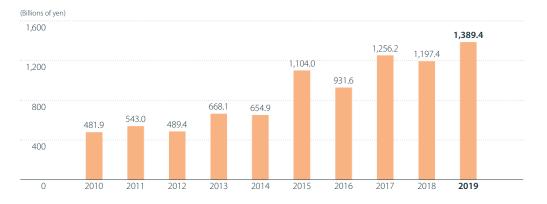
#### Cash Dividends / Payout Ratio







#### **Market Capitalization**

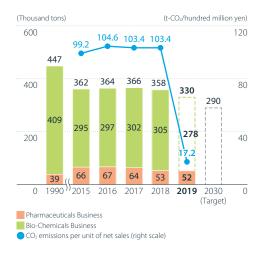


\*1 Revenue, Overseas revenue, R&D expenses and Core Operating Profit on and after 2018 represent figures in the continued operation (Pharmaceuticals) excluding the discontinued operation (Bio-chemicals).

## **ESG Highlights**



#### CO<sub>2</sub> Emissions \*1,2,3

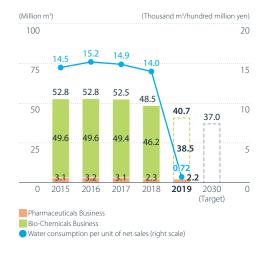


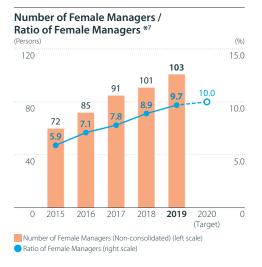
#### Number of Employees / **Ratio of Overseas Employees**

(Persons)	(%)
10,000	50.0



#### Water Use \*1,2,3





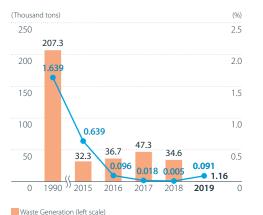
#### \*1 It covers plants and research laboratories around the world. Figures for 2018 and prior are for Pharmaceuticals and Bio-Chemicals, and those for 2019 are for Pharmaceuticals only. The dotted line in the 2019 bar graph shows the Bio-Chemicals business.

\*2 The targets for 2030 are the sum of the Pharmaceuticals Business and the Bio-Chemicals business.

\*3 Net Sales used for calculating per-unit data for 2015 are based on J-GAAP and after 2016 on IFRS.

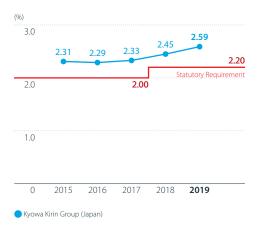
\*4 It covers plants and research laboratories in Japan. Figures for 2018 and prior are for Pharmaceuticals and Bio-Chemicals, and those for 2019 are for Pharmaceuticals only.

#### Waste Generation \*4

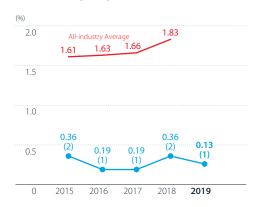


Final Disposal Rate (right scale)

#### Ratio of Workers with Disabilities \*8



#### Accident Frequency Rate \*5,6



#### Accident Frequency Rate

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

#### Number of Directors



Number of Internal Directors Number of Independent Outside Directors

\*5 The plants and research laboratories in Japan of Kyowa Kirin, Kyowa Medex (excluded in 2018 due to deconsolidation), Kyowa Hakko Bio and Kyowa Pharma Chemical are covered until 2018. In 2019 all locations are covered

\*6 The rates indicate the number of casualties from fatal lost-time accidents per million working hours.

\*7 Calculated based on the new criteria from 2015.

\*8 As of June each year.

## Pipeline (As of December 31, 2019)

Category	Type*1	Code Name	Area of Study	Country or Region of Development	Development Phase			
Category	Type	(Generic Name)		Country of Region of Development	Phase I	Phase II	Phase III	Filed
	0	KRN321 (darbepoetin alfa)	Renal anemia (on dialysis)	China				
		KHK7580 (evocalcet)	Secondary hyperparathyroidism	China / Korea / Taiwan / Hong Kong				
Nephrology		RTA 402 (bardoxolone methyl)	Diabetic kidney disease	Japan				
	0	KW-3357 (antithrombin gamma)	Preeclampsia	Japan				
		KHK7791 (Tenapanor)	Hyperphosphatemia Under Maintenance Dialysis	Japan				
		KW-0761 (mogamulizumab)	Adult T-cell Leukemia/Lymphoma	U.S.A. / Europe / Others				
		KHK2375 (Entinostat)	Breast Cancer	Japan				
On ealers	0	KRN125 (Pegfilgrastim)	Mobilization of Hematopoietic stem cell into Peripheral blood	Japan				
Oncology		КНК2455	Solid Tumor	U.S.A.				
			Urothelial carcinoma	U.S.A.				
		ME-401	B-cell malignancies	Japan				
			Psoriasis	Korea / Malaysia / China / Macau				
	•		Axial Spondyloarthritis (axSpA)	Japan				
		KHK4827 (Brodalumab)	Systemic Sclerosis	Japan				
			Palmoplantar Pustulosis	Japan				
Immunology / Allergy				U.S.A. / Europe / Others				
		КНК4083	Ulcerative Colitis	Japan				
			Atopic Dermatitis	Japan / U.S.A. / Europe				
	•	ASKP1240 (Bleselumab)	Recurrence of Focal Segmental Glomerulosclerosis (FSGS) in <i>de novo</i> kidney transplant recipients	U.S.A.			I	

\*1 •: Antibody O: Protein No mark : Small molecule

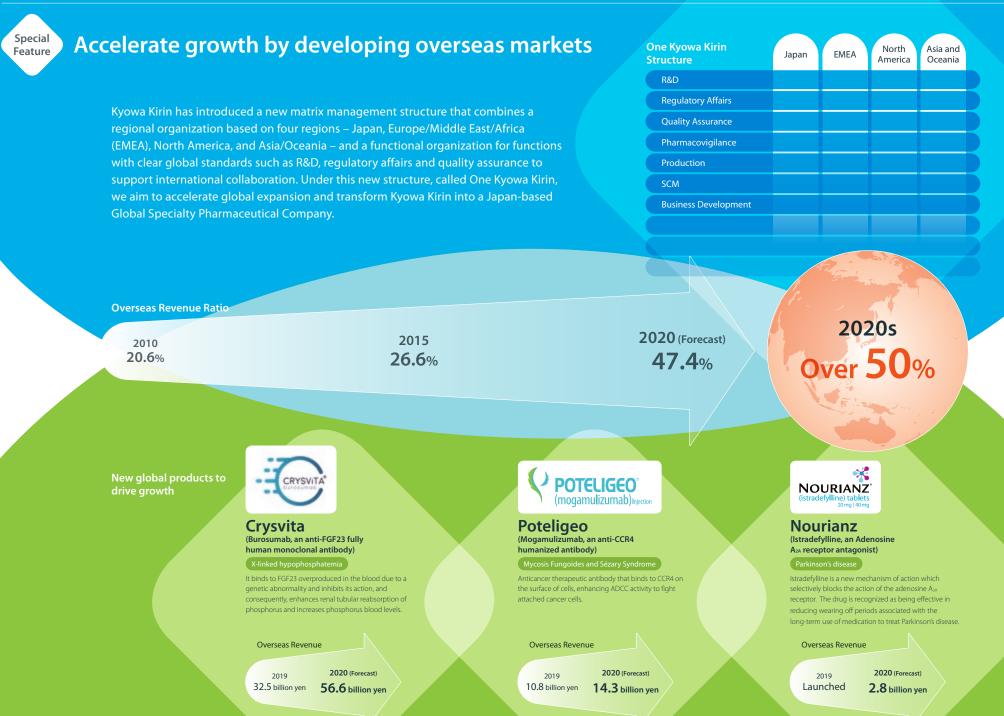
Category	Type*1	Code Name	Area of Study	Country or Region of Development	Development Phase			
Category	Type	(Generic Name)		Country of Region of Development	Phase I	Phase II	Phase III	Filed
Control		KW-6002 (istradefylline)	Parkinson's disease	Europe				
Central Nervous		KW-0761 (mogamulizumab)	HTLV-1 associated myelopathy	Japan				
System		KW-6356	Parkinson's disease	Japan			l	
		KHK6640	Alzheimer's disease	Europe / Japan				
	•	KRN23 (burosumab)	X-linked hypophosphatemia	Taiwan / Switzerland / Kuwait / Saudi Arabia / China / Hong Kong / Singapore				
			X-linked hypophosphatemia in adult patients	Europe				
			FGF23-Related Hypophosphatemic Rickets and Osteomalacia	Korea				
			Tumor-induced osteomalacia	U.S.A.				
			Tumor-induced osteomalacia / Epidermal nevus syndrome	Japan / Korea / U.S.A.			l	
Other		AMG531 (romiplostim)	Aplastic anemia who have had an inadequate response to conven-	Taiwan				
			tional therapy	Korea				
	0		Idiopathic (immune) thrombocytopenic purpura	China				
			Aplastic anemia who were previously untreated with immunosuppressive therapy	Japan / Korea / Taiwan				
	0	KW-3357 (antithrombin gamma)	Disseminated intravascular coagulation, congenital antithrombin deficiency	Europe				

\*1 •: Antibody O: Protein No mark : Small molecule

Glossary			
Phase IStudies in small numbers of healthy people (patients in some cases) to 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.		

 $\bigtriangleup$ 

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



Special Accelerate Growth by Developing Overseas Market

EMEA Region Head President, Kyowa Kirin International plc Abdul Mullick, Ph.D. НОТ ТОРІС

## Kyowa Kirin Value Days -We don't just make medicine, we make people smile

Kyowa Kirin's Core Values sit at the heart of our transformation to a Japan-based GSP so we continually strive to bring these to life for all our EMEA colleagues so that they are more than just words on a piece of paper.

The business launched an inspirational project in 2019, named "Values Days", during which each affiliate, alongside the main UK offices, organized events in which staff participated in various ways to give back to the communities we serve. Events ranged from decorating paediatric infusion rooms to creating artwork for a cancer charity and directly engaging with patients to better understand their burden of disease.

After a successful launch in 2019 it is planned that these and other ongoing events will maintain the long-term connection to Kyowa Kirin Values for its EMEA team in order that we continue to "Leap forward to make people smile".



#### Message from Region Head

## We will continue to grow our EMEA business by ongoing launches of our global products

With a sharp focus on treatments for rare diseases, built on the strong, profitable foundation provided by our long-established supportive care franchise, Kyowa Kirin's EMEA (Europe, Middle East and Africa) business is well-placed to strengthen Kyowa Kirin's ambitions to be a Japan-based Global Specialty Pharmaceutical company (GSP).

By the end of 2019 we had successfully launched Crysvita (for the treatment of X-linked hypophosphatemia) in 15 countries in EMEA and we had embarked on pre-launch preparations for Poteligeo (for the treatment of mycosis fungoides and Sezary syndrome) after receiving approval from the European Medicines Agency (EMA). We also filed Crysvita for the adult indication as well as Istradefylline (an add-on treatment to levodopa/carbidopa in adults with Parkinson's disease) with the EMA.

We have a strong geographic footprint across more than 20 markets in Europe and the Middle East. Our in-market teams, based in nine dedicated offices, focus on overcoming the challenges of heterogeneous and complex healthcare systems to meet the needs of patients, clinicians and payers in each of these markets in order to ensure that our medicines are made available to those whose lives may be improved by these treatments.

We will continue to grow our EMEA business by ongoing launches of our global products and continuing to strengthen how we work as one Kyowa Kirin.

Kyowa Kirin EMEA has a dedicated and growing team of more than 700 people who are committed to our mission of leaping forward to make people smile around the world. I am confident that through their continued dedication and hard work, we will continue to improve the lives of patients across the EMEA, building our business as we do so; good medicine = good business. eature Accelerate Growth by Developing Overseas Markets

#### Message from Region Head

## We will continue to do this work with great determination, integrity, and empathy – making a strong contribution to Kyowa Kirin worldwide.

Last year (2019) was a year of big changes for Kyowa Kirin North America. We formally combined our research capabilities in La Jolla, CA with the Development, Regulatory and Commercial capabilities centered in Princeton, NJ and Bedminster, NJ under one regional management structure. The result is an integrated organization with complete capabilities to research, develop and deliver first-in-class medicines to meet the needs of patients.

Currently, North America is the fastest growing region in terms of revenue for Kyowa Kirin worldwide. We are very pleased with the performance of both Poteligeo and Crysvita. Both medicines are making a big difference in the lives of patients with rare forms of cancer and X-linked hypophosphatemia (XLH). In the third quarter, we also received FDA approval for Nourianz. This marked the third U.S. product approval within the last two years for medicines with novel mechanisms of action and differentiated product profiles – a particularly impressive record of achievement by our Development and Regulatory teams.

The rapid succession of FDA approvals and subsequent commercial launches creates exciting challenges. Put simply, we have more physicians to meet and more patients to serve. In response, we have rapidly expanded our Commercial organization, adding more than 60 people in customer-facing teams and expanding the functions that support the field.

We anticipate another busy year in 2020, as the launches proceed and programs in our pipeline continue to advance. We expect to publish new data to help health care providers and payers understand our products and the value they offer. We are also working on new programs to engage patient communities. Internally, we aim to drive more cross-functional collaboration between teams and build "shared services" in Finance, Legal and Human Resources to benefit all employees. We have also begun to build out our North America supply chain team to ensure optimal manufacturing, tracking and delivery of our products to patients.

The North America business is filled with talented people, working hard, to get patients the medicines they need. We will continue to do this work with great determination, integrity, and empathy – making a strong contribution to Kyowa Kirin worldwide.

## North America

HOT TOPIC

## Working with Patient Communities

Kyowa Kirin emphasizes its commitment to life, and to patients, as one of the core values underpinning our global business. In North America, we are working to realize this commitment by growing a new function dedicated to patient advocacy and community engagement.

Advocacy organizations play an important role in our region, where patients bear a lot of personal responsibility for making their own health care choices. Advocacy groups typically collaborate with multiple corporate partners, researchers and health care institutions to improve patient care through educational programs, supportive resources and research projects. Through this work, advocates become leading voices and experts with a broad view of the issues affecting patients.

Our new advocacy function is committed to working with advocacy organizations in three ways:

- Conducting research to learn from patients and their experiences;

- Sharing information about our medicines and clinical trials to inform patients and their caregivers; and

- Collaborating on initiatives to improve patient care and outcomes.

North America Region Head

**Gary Zieziula** 

President, Kyowa Kirin USA Holdings, Inc.

We believe supporting advocates and connecting with the Parkinson's disease, Cutaneous T-Cell Lymphoma and rare disease communities will make us a better corporate citizen - and we look forward to sharing what we learn with Kyowa Kirin colleagues worldwide.



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cial Accelerate Growth by Developing Overseas Markets

## Asia and Oceania

Asia and Oceania Region Head President, Kyowa Kirin Asia Pacific Pte. Ltd.

Tan Boon Heon, Ph.D.

made significant contributions to Kyowa Kirin's growth over the past year. This was Kyowa Kirin Asia Pacific's inaugural year hosting the award ceremony. The winners were invited to Singapore for a tour of the city and a night of festivities to celebrate their achievements. By recognizing outstanding talent, we hope to motivate performance among employees and emphasize the importance of Kyowa Kirin's core values as we grow as One Kyowa Kirin.

#### Message from Region Head

## Established Brands and New Product Launches Sustain Rapid Growth in the Asia/Oceania

2019 was a great year for Team Asia Pacific. We achieved over US\$200M in revenue and contributed approximately half of that in consolidated operating profit to the group, bringing our business in Asia Pacific to a new record high. Our established brands in the areas of nephrology and hematology/oncology, like Nesp/Espo, Gran/Neulasta, Regpara, and Romiplate, continue to maintain or strengthen their strong and profitable positions. We successfully launched Lumicef (for the treatment of plaque psoriasis) in Taiwan, Thailand and Hong Kong, and are progressively expanding this franchise to other markets in Asia. In China, we implemented a co-promotion partnership for Regpara which has extended our reach to more customers, and are on track with our regulatory activities to launch at least four new brands over the next three years, including two of which have been granted expedited review.

Awards Ceremony for Excellent Performers HOT TOPIC

Innovation, Teamwork/Wa and Integrity underpin what we do at Kyowa Kirin. The winners of the Asia Excellent Performer Award embody each of these core values and are selected from our affiliates across the region. The award is given to medical representatives and corporate staff who have outperformed in their roles and



The future has never been brighter in this region where the pharmaceutical market is expected to grow to a size comparable to that of the US over the next ten years. Home to more than half of the world's population, the Asia Pacific is growing at a rapid pace, with unparalleled demand for access to better medical care and healthcare innovations. Consequently, healthcare reforms are making innovative drugs more accessible across the region. This bodes well for our ongoing efforts to register and launch new innovative products in our pipeline, including Crysvita (for the treatment of X-linked hypophosphatemia) and Poteligeo (for the treatment of mycosis fungoides and Sézary syndrome). Among the key markets we expect to launch these products is Australia, where we welcomed the first colleague of the newly established Kyowa Kirin Australia affiliate in August 2019.

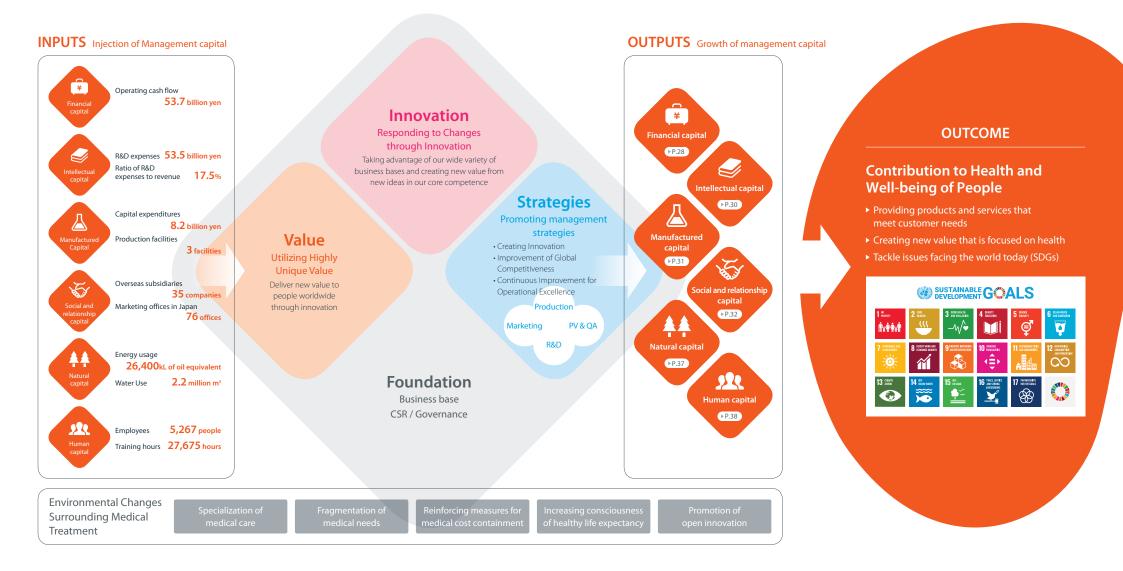
Since the implementation of "One Kyowa Kirin" structure in April 2019, Kyowa Kirin Asia Pacific has launched various initiatives to transform the Asia Pacific region, in line with our mission to be a global specialty pharmaceutical company. In this short period, we established the modus operandi for planning and day-to-day operations, began the process to transform life cycle management and accelerate products to market, and improved the governance and risk management infrastructure to support our business expansion. The key to our success has been our ability to attract and retain a team of talented individuals who approach challenges and opportunities with an entrepreneurial spirit that reflects our newly minted organization, and a commitment to our values of Innovation, Teamwork/Wa and Integrity. Together, we will create the conditions for

memorable work experiences and rewarding careers in Kyowa Kirin, even as we create shared value for the benefit of our customers, shareholders and other stakeholders.

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## **Value Creation Process**

The Kyowa Kirin Group will continue to contribute strongly to the health and well-being of people around the world with innovation on our foundation utilizing state-of-the-art biotechnology to constantly respond to changes and rolling out products and services that meet true customer needs and have unique high value.



## Creating and Strengthening Financial Capital

Targeting long-term growth in ROE by maximizing the value of global strategic products and actively investing in value creation





## What are the targets in the current business plan?

The Kyowa Kirin Group has selected return-on-equity (ROE) as a key performance indicator to increase corporate value over the medium to long term. Under our Mid-term Business Plan, we are targeting ROE of 10% or higher in the early 2020s, so that returns are consistently above the cost of shareholders' equity. To achieve that goal, we aim to increase the overseas revenue ratio to 50% and generate core operating profit of ¥100 billion or more – which are key targets for transforming Kyowa Kirin into a Global Specialty Pharmaceutical Company (GSP) – by focusing on maximizing the value of our global strategic products (Crysvita, Poteligeo and Nouriast/Nourianz) to drive growth.



## QUESTION 2

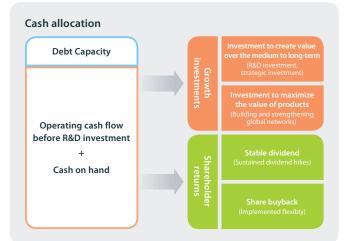
#### How do you plan to support the Group's Medium- to long-term growth?

Our first aim is to lift ROE to 10% or higher in the early part of this decade. The next step is to ensure ROE remains at that level and then raise it further over the medium and long term. To achieve that, we have to continue creating new global products. As of the end of 2019, the Group had roughly 300 billion yen in cash on hand (cash and deposits plus loans receivable from the parent company), which has come from operating cash flow and the sale of the biochemical business to channel management resources into new drug development in the pharmaceutical business. Cash on hand will be allocated to "growth investments" as a matter of priority to support the ongoing creation of next-generation global products. We aim to increase corporate value over the medium and long term by stepping up investment to drive value creation in the pharmaceutical business.

## **3** Please tells us about the growth investments.

As a research and development-focused pharmaceutical company, Kyowa Kirin's overriding mission (social value) is to consistently create revolutionary new medicines that address unmet medical needs. Through that process, we can sustainably generate corporate value (economic value). Kyowa Kirin is one of the leading research and development companies worldwide in the field of biopharmaceuticals. To further enhance the Group's ability to innovate in order to support sustained growth, we plan to step up investment in R&D by allocating 20% of revenue to R&D expenses. With overseas revenue likely to rise, we expect to have scope to invest even more aggressively. The Group's growth investments can be divided into two categories – investment to create value over the medium to long-term (R&D investment, strategic investment), and investment to maximize the value of products (building and strengthening global networks). In the first category, we will consistently invest in R&D to create proprietary products, including strengthening drug discovery platforms and technologies to support innovation over the long term and enhancing drug discovery modalities. The aim is to continue creating a pipeline of early-stage development drugs that can support growth well into the future. We will also aggressively invest in propriety R&D to reinforce and expand our pipeline of next-generation drugs, such as KHK4083 and other promising candidates for the next phase of global products.

Together with our proprietary drug discovery efforts, we will actively consider strategic investments. We of course intend to collaborate with a wide range of different partners in industry, government and academia through open innovation drug discovery and by utilizing strategic partnerings (in-licensing, tie-ups, etc.) to acquire fundamental technologies and pipeline drugs, but to accelerate the Group's growth in the future, we also need to consider strategic growth investments such as M&A deals. As part of that approach, the Strategic Investment Review



Committee, led by CEO Masashi Miyamoto, meets twice monthly to discuss potential investment opportunities. With strategic investment deals becoming even larger in the pharmaceutical sector, we have put in place commitment lines and other means of flexibly accessing funds to bolster the Group's cash reserves when the time arises.

In the second category, we will channel investment into upgrading and expanding the Group's global network to increase revenue and maximize value from our global strategic products. In particular, we will focus on further upgrading and strengthening our robust manufacturing and quality assurance systems to ensure stable supplies of high-quality pharmaceuticals worldwide.

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

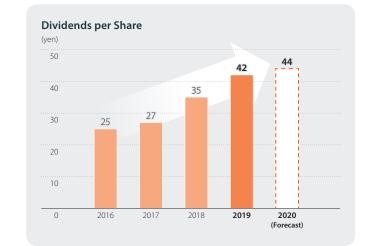
## 4 What is Kyowa Kirin's stance on shareholder returns?

Our priorities for cash allocation are growth investments, paying stable dividends, and share buybacks, in that order.

Targeting our consolidated dividend payout ratio of 40% in the current Mid-term Business Plan, we aim to steadily increase returns for investors by raising the dividend in line with profit growth over the medium and long term. Based on that policy, we paid a dividend of ¥42.00 per share for FY2019, a hike of ¥7.00 and the third consecutive year of increases. We plan to raise the dividend again in FY2020, by ¥2.00 per share to ¥44.00.

While our first priority for allocation of funds is growth investments, opportunities are likely to be thin on the ground when there is considerable uncertainty. When those conditions arise, we will flexibly consider buying back shares in order to improve capital efficiency, while taking into account prevailing market conditions. In February 2019, we repurchased 10,700,000 shares (worth ¥22.6 billion) and retired 36,480,000 shares (equivalent to 6.33% of total shares outstanding before the retirement).

Going forward, we intend to continue increasing shareholder returns, supported by sustained growth in profits.



#### **Dividends per Share/Payout Ratio/ROE**

	FY		Annual dividend		Payout	ROE	
		Interim dividend Year-end			Ratio		
20	016	12.50 yen	12.50 yen	25.00 yen	44.9%	5.3%	
20	017	12.50 yen	14.50 yen	27.00 yen	34.4%	7.2%	
20	018	15.00 yen	20.00 yen	35.00 yen	35.2%	8.6%	
20	019	20.00 yen	22.00 yen	42.00 yen	33.7%	10.1%	
20	020 (Forecast)	22.00 yen	22.00 yen	44.00 yen	48.2%	7.1%	

## Creating and Strengthening Intellectual Capital

## Research and Development

Driving forward R&D to continue creating global products

#### Progress in FY201

## Global Products Marketing and Efforts to Maximize Value of Existing Products Are Gathering Pace

In 2019, our tireless activities to strive for new solutions in areas of high unmet medical needs worldwide reached to obtain approvals for burosumab (marketed as Crysvita) in Japan and istradefylline (marketed as Nourianz) in the US. We also received approval for an additional indication for existing product romiplostim (marketed as Romiplate) in Japan. The efforts for creating new values to address unmet medical needs in Asia have also been active, as shown by brodalumab (marketed as Lumicef in Japan) and burosumab filed for new drug application in China, South Korea and other countries/regions.

Regarding the development pipeline, we initiated a phase II clinical trial of Tenapanor (KHK7791) in Japan and achieved good progress with several other clinical trials – a phase III trial of RTA 402 in Japan, a global phase II trial of KHK4083, a phase II trial of KW-6356 in Japan, and phase I/II trials of ME-401 in Japan. Meanwhile, strategic conduct of late-phase trials have been ongoing to expand indications of brodalumab, pegfilgrastim (marketed as G-Lasta in Japan), romiplostim and antithrombin gamma (marketed as Acoalan in Japan) to maximize the value of existing products.

For continuous breakthrough innovation, "technology-driven drug discovery," research projects of next generation antibodies using competitive and novel technology, as well as those of small molecules using a unique drug delivery system proceeded to the stage very close to start clinical development.

#### ioals for FY2020

## Aiming to Create a Steady Stream of Absolute Unique Novel Global Products

In 2020, the final year of Kyowa Kirin's five-year Mid-term Business Plan, our focus is placed on maximizing the value of products launched so far. In the Asia-Pacific region, where further market growth is expected, we will reinforce our research and development framework to obtain the marketing approval for new drugs, as well as indication expansion of the products such as burosumab, brodalumab and romiplostim. We will also push ahead with late-stage studies of evocalcet (marketed as Orkedia in Japan) and other products while optimizing the development system in Asia. In parallel, we will conduct meticulous clinical development of KHK4083, KW-6356, and KHK2455 etc. using the cross-regional drug development platform, virtual Global Development Organization (vGDO) with the utmost effort to produce the next global products.

To continuously fill the development pipeline in a timely manner, collective efforts will be made by the diverse talents in R&D sharing the keyword "Only One Value", which stands for to pursue absolute unique and competitive values that only Kyowa Kirin can generate. We will continuously drive innovation by making open innovation activities to have access to new technologies or intellectual properties, in addition to fruitful in-house R&D activities at our research laboratories in the US and Japan. To accomplish breakthrough values, constant pursuit of innovation by young talents is indispensable. All staff in R&D will keep challenging boldly.



## Individuality spurs innovation

There are diseases in the world that are yet to be adequately treated, and patients are waiting for new drugs and treatment options. We keep this fact in mind and will take on the challenge in providing solutions for the patients' needs.

It is not easy to continuously drive innovation, but we are confident of being able to work this out, because we are an exquisite team of excellent individuals with diverse backgrounds. The sprouts of new scientific discoveries are born and growing out every day around the world. By opening our eyes to the world, we will actively collaborate and drive open innovation with a wide range of external partners. Under the R&D's key phrase – "Provide Only One Value to Patients with Our Dream", we pursue innovative drugs based on medical needs in four key categories – nephrology, oncology, immunology and allergy, and central nervous system – as well as breakthrough technologies that will lead to create new valuable series of pipeline. Every challenge brings us exciting days.

Intellectual sparring among our group of excellent individuals spurs innovation, while the mutual support and stimulation that comes out of the process brings the team closer together, helping to drive the creation of "Only One Value". Every person in R&D is committed to providing new value to patients by putting our core value of innovation into practice.



In Kyowa Kirin, we paint in the blank left eye of a daruma doll when a new drug application is filed. The other eye is filled in when the approval is obtained. The number of daruma dolls is increasing in our office as late-stage pipeline drugs progress steadily. We send the dolls to overseas partners involved in the drug development of global products to share the success and create a sense of unity.



## Creating and Strengthening Manufactured Capital

## Production

Stepping up efforts to boost productivity and improve competitiveness

#### Progress in FY201

#### LCM\* and measures to raise productivity

The pharmaceutical industry in Japan continues to face pressure from policies designed to control healthcare expenditure, which means pharmaceutical companies need to further increase the competitiveness of their products and raise productivity. The Production Department is testing new approaches aimed at developing easier-to-use drug formulations for post-launch products and for new drugs under development.

In biopharmaceutical API manufacturing, the division has established a new approach for reliably creating production cells used to secrete antibodies at high concentrations. The technology, which will help to reduce production costs, is progressively being introduced into manufacturing processes. The division is also looking into gradually applying continuous production technology to small-molecule drug manufacturing and biopharmaceutical API manufacturing processes to increase productivity. \*Life Cycle Management: Refers to measures designed to continuously improve pharmaceutical products

#### Goals for FY2020

## Build systems to ensure stable supplies of high-quality pharmaceuticals to patients worldwide

In line with plans to increase output, each of the Group's plants will implement the following measures to reinforce production system stability.

- Build a new quality control center at the Takasaki site to create a worldleading analysis environment
- Actively introduce automation technology to increase production capacity at
   each plant
- Install new IT and digital systems to improve data integrity and increase manufacturing efficiency
- Create a framework that allows global products to be manufactured at multiple plants to reinforce the Business Continuity Plan (BCP)

 Increase personnel at plants and upgrade training systems to support robust frontline operations

Building on progress in FY2018, we intend to apply for manufacturing and sales approval for several products in various countries. We will prepare applications to avoid delays in development plans and progressively audit by each country's regulatory authority to prepare for pre-approval inspections and regular postapproval inspections. Through the audits experience, we will improve the quality levels even further.

### Ube Seminars – Understanding the entire Ube Plant

Putting our values into practice

Teamwork/Wa

The Ube Plant runs seminars (Ube Seminars) throughout the year to provide onsite staff with various training modules.

Modules on GMP and environmental safety are aimed at all staff, while optional modules include skills training (manufacturing technology, quality control, engineering, system, etc.) and awareness training courses. The plant provided 46 modules in FY2019, half of which (23) were optional courses.

The Ube Seminars are designed to raise staff skill levels as part of moves to transform the Ube Plant into one of the Group's core plants. Modeled on the Hagiwara School training program run by the Takasaki Plant, the Ube Seminars were launched in 2016 and gained traction from 2017. FY2019 was the program's third year and the seminars are now an established activity at the Ube Plant.

Onsite staff mainly run the courses, but the program relies on support from across the Production Division, with personnel from head office, the Takasaki Plant, the CMC R&D Center and other Group facilities also invited to take part as instructors.

One of the objectives of the Ube Seminars is to give staff an understanding of the entire Ube Plant through optional modules that provide a different perspective to OJT training. The aim is to encourage staff to take a deeper interest in their work by thinking about how their roles fit into the larger picture and what impact they have in the workplace, rather than just doing their jobs in isolation.

To encourage greater participation in the optional learning modules, the Ube Plant's training committee develops annual plans for Ube Seminar study themes from two perspectives: courses that each department wants to lead, and courses that each department wants other departments to lead.

Thanks to that approach, more than 90% of staff at the plant take part in at least one optional training module each year (FY2018 and FY2019). Meanwhile, a survey of course participants shows a relatively high level of understanding and satisfaction with the courses.

Going forward, we will continue to develop interesting course content that appeals to plant staff and gives them insights into the entire Ube Plant, so that they can see the relevance of their own roles. We will also use the seminars to promote the values in our Teamwork/Wa concept.



An Ube Seminar class

## Creating and Strengthening Social and Relationship Capital

## Supply Chain Management (SCM)

Supporting One Kyowa Kirin by reliably supplying high-quality pharmaceutical products

#### Progress in FY201

#### Global SCM system gains momentum

Supplies of global strategic products Crysvita and Poteligeo were increased further in 2019 after they were launched in the West in 2018. We plan to boost distribution volumes further as sales areas expand and the number of items in each product line increases. To respond to these major changes, we worked closely with teams in Japan, North America, EMEA and Asia/Oceania under the One Kyowa Kirin structure to start up a global SCM system that ensures reliable supplies of high-quality products to patients worldwide. Our global SCM system integrates and manages supply chains optimized for each region from a global standpoint, ensuring supply and demand for our products worldwide is controlled independently from production and sales.

#### Goals for FY2020

#### Reinforcing SCM function by building robust global S&OP

Sales of Crysvita and Poteligeo are growing steadily and our third global strategic product Nourianz was launched in the US in October 2019. We therefore expect further growth in distribution volumes. To prepare for that growth in 2020, we will reinforce our global SCM system, which was overhauled in 2019. Our aim is to create a robust organization capable of rapidly supplying the necessary volume of products to patients worldwide whenever they need them. To achieve that, we first plan to introduce a system that allows us to visualize global inventories. We will also step up efforts in sales and operations planning (S&OP), which will enable us to rapidly respond to changes in supply and demand from the viewpoint of profitability based on our business plans.

### Teamwork / Wa across four regions

Our mission in the SCM team is to ensure patients and the stakeholders that support those patients continue to receive reliable supplies of new drugs, which the whole company has worked hard to develop. Launching products worldwide requires more than just increasing volumes to supply more markets. The number of manufacturing and logistics sites also increases, as does the number of parties involved in distribution, including contractors, resulting in a highly complex supply chain. Under the leadership of the Global SCM Head, we have been collaborating with teams in other regions to create a new system that realizes ideal global supply chain operations. We also launched a new process called sales and operations planning (S&OP) that optimizes the entire supply chain. Using S&OP, we actively gather and share information from manufacturing, inventory management, sales and other business departments, allowing us to rapidly make the right decisions from a global perspective. Building frameworks and systems is crucial to creating optimal SCM, but teamwork is essential to get the most out of those physical assets. The SCM team holds regular global SCM meetings to share and discuss issues in four regions – Japan, North America, Europe and Asia/Oceania. Using that information, we develop strategies and action plans to optimize the supply chain. The meetings are attended by people who live and work in different environments and who have diverse backgrounds, leading to lively discussions. The dynamic nature of the discussions results in ideal solutions.

Putting our values into practice

Teamwork/Wa

Going forward, the SCM team will continue to pursue the highest levels of teamwork to appropriately manage the Group's increasingly complex supply chains.



Global SCM meeting attended by SCM leaders from the four regions

Delivering products to patients worldwide

## **Operations in Japan**

Working to promote the usage of new drugs and contributing to community healthcare

#### Progress in FY201

Contributing to healthcare by promoting market penetration of new drugs In June last year, Kyowa Kirin received approval for Romiplate for the treatment of aplastic anemia (AA) in patients with an inadequate response to conventional therapy. In August, our subsidiary Kyowa Kirin Frontier launched Darbepoetin Alfa Injection Syringe [KKF], an authorized version\*1 of our flagship product Nesp. Since its launch, Nesp has been adopted by many medical institutions due to its superior clinical efficacy and safety for the treatment of renal anemia for all stages from pre-dialysis to dialysis. Like Rituximab-BS, we are promoting market penetration to help curb rising medical costs and satisfy patients' needs. In December, we launched Crysvita in Japan following its release in the US and Europe. Crysvita was discovered by Kyowa Kirin and is the first monoclonal antibody drug targeting fibroblast growth factor 23 (FGF23). Patients and medical professionals in Japan have been waiting for the launch of Crysvita for some time. We will work to deliver the drug to patients as soon as possible and actively promote awareness of the condition. During the fiscal year, we also launched Haruropi Tape, a transdermal patch treatment for Parkinson's disease. Together with our flagship drug Nouriast,

Haruropi Tape will offer another treatment option to patients with Parkinson's. Meanwhile, Orkedia received approval for the treatment of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or experience relapse after parathyroidectomy.

\*1 Generic versions of branded drugs manufactured and marketed under license from the pharmaceutical company that holds the patent, using the same ingredients and manufacturing methods.

#### Goals for FY2020

#### Promoting and reinforcing our category strategy

In 2020, we will continue to focus on new drugs and existing drugs that obtained additional indications in the four treatment categories where we already have a strong position – nephrology, oncology, immunology and allergy, and the central nervous system (CNS). In the nephrology category, we plan to launch daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) for the treatment of patients with renal anemia. Daprodustat has been developed as an alternative orally-available treatment option that avoids the administration

burdens and refrigerated transport/storage requirements of injectable erythropoiesis-stimulating agents (ESA). Along with Darbepoetin [KKF], daprodustat will provide more treatment options to patients suffering from renal anemia. In the oncology category, we plan to add the indication of opioid analgesic naïve pain relief for Fentos Tape. By providing appropriate product information, we hope to make a further contribution to quality of life for patients suffering from cancer pain or chronic pain.

Going forward, we will continue to support healthcare provision by promoting the uptake of new medicines through the provision of information relevant to the changing healthcare environment and medical practitioners' needs. At the same time, medical representatives (MR) and regional liaison officers\*<sup>2</sup> will work together to actively support policies aimed at tackling healthcare issues in each community, such as measures to halt the increasing severity of lifestyle-related diseases\*<sup>3</sup>.

\*2 Staff with medical management consultant qualifications who meet with diverse stakeholders and support the implementation of solutions developed by MRs to address community healthcare issues. \*3 A wide-ranging Ministry of Health, Labour and Welfare project to tackle lifestyle-related diseases, aimed at

Putting our values into practice

Integrity

prolonging healthy life expectancy and moderating national healthcare expenses.

### Helping to solve community healthcare issues through our business activities

To realize its goal of extending healthy life expectancy, the government is promoting measures in each region to prevent major lifestyle-related diseases and stop them becoming more severe. However, the extent and impact of those measures has not necessarily been consistent in each region. Against that backdrop, we have reformed our organizational structure to ensure we make more effective contributions to community healthcare issues. Specifically, to respond more rapidly to changes in the healthcare environment in each region, we have created a new sales structure aligned to secondary medical areas, and we have deployed regional liaison officers to coordinate with local government officials and a broad range of other stakeholders in each community, as well as healthcare professionals.

Among lifestyle-related diseases, the government is focusing in particular on a range of policies to prevent progression in diabetes, which is one of the main conditions that lead to dialysis treatment. In addition to promoting market penetration of new drugs, we are actively implementing a number of approaches in line with local policies to help each region tackle healthcare issues, such as raising awareness of health conditions, supporting efforts to promote screening, and creating opportunities for medical specialists, primary care doctors and other professions to work more closely together. When needed, we also sign partnership agreements with local governments to implement joint public-private healthcare activities. On December 1, 2017, we signed an agreement with the Japan Association for Diabetes Education and Care\*<sup>4</sup> to cooperate on early detection of diabetic renal disease. In May 2019, we concluded an agreement with the Japan Kidney Association\*<sup>5</sup> to work together on raising awareness of kidney disease. Based on those agreements, we are implementing joint measures to ensure early detection of diabetic renal disease and further raise awareness of kidney disease.

\*4 A public interest incorporated association established to tackle diabetes and promote healther lifestyles by: providing correct knowledge about preventing and curing diabetes; offering support for sufferers, their families and people at risk of developing the disease; conducting surveys and research to prevent diabetes and promote healthier lifestyles; and as a member of the International Diabetes Federation, cooperating with partners internationally to eradicate diabetes worldwide.

\*5 An NPO established by the Japanese Society of Nephrology to expand and enhance efforts to fight chronic kidney disease.

#### Initiatives in community healthcare



Activities based on treatment and prevention

CSV management

Creating and Strengthening Social and Relationship Capital

## **Overseas Operations**

Targeting an overseas revenue ratio of 50%, we are expanding overseas business, building a highly productive sales structure and developing human resources to support them.

#### Progress in FY201

#### Record overseas revenue

In FY2019, overseas revenue (excluding technology licensing revenue) totaled ¥106.3 billion, a record-high for Kyowa Kirin.

In EMEA, global strategic product Crysvita expanded its launched countries and the number of them grew up to 15 by the end of FY2019 following its first launch in Germany in April 2018. Sales of Crysvita in EMEA totaled ¥7.4 billion in FY2019, becoming Kyowa Kirin's flagship drug in the market in just the second year since its launch.

In North America, sales of Crysvita were also strong, totaling ¥25.1 billion in FY2019, while sales of Poteligeo, which was released in October 2018, reached ¥10.8 billion. Crysvita and Poteligeo are now driving growth in the North America business. We also launched global strategic product Nourianz in the US (marketed as Nouriast in Japan) in October 2019.

In Asia, we launched Lumicef in Thailand, Taiwan and Hong Kong. The drug is helping increase sales in new categories, in addition to nephrology and oncology

categories, two franchise areas we have worked hard to develop in Asia. In China, Regpara, which was added to the National Essential Drug List (NEDL) in October 2018, recorded sales of ¥5.0 billion in FY2019, representing an increase of over 150% year on year. Regpara's inclusion in the NEDL and our efforts to expand sales channels in China bode well for further growth in sales and penetration in the market.

#### Goals for FY2020

#### Aiming to be a Global Specialty Pharmaceutical Company

We forecast overseas revenue of over ¥130 billion in FY2020 (excluding technology licensing revenue), with the overseas business set to drive the Kyowa Kirin Group's growth.

In EMEA, we aim to maintain and grow sales of existing products, expand sales channels for Crysvita, and make preparations to launch Poteligeo and Istradefylline. To ensure patients benefit through earlier access to our new drugs, we will put in place the necessary business and marketing structures and provide appropriate information about the products and related diseases. We are targeting further growth in markets with the launch of new products.

In North America, we will continue making efforts as we did in FY2019 to increase the market penetration of Crysvita and Poteligeo. We also plan to reinforce our marketing network for Nourianz to ensure its rapid and wide penetration in the market.

In Asia, we aim to leverage our expertise in information provision, gleaned from existing business activities, to establish our presence as a leading company in the nephrology and oncology categories. We will also move into the immunology and allergy category with our new drug Lumicef. In China, we aim to maximize the value of new and existing products by strategically introducing new products that dovetail with the characteristics of our portfolio from our expanding development pipeline.

To achieve the further growth as a Japan-based Global Specialty Pharmaceutical Company, we will put in place a framework to deliver our products to patients worldwide.



### Synergies through global communication

Innovation

Kyowa Kirin is carrying out sales activities in around 40 countries worldwide. We need to formulate sales strategies that take into account not only a just the characteristics of our products but also a whole host of factors, such as different regulations, market conditions, competing products and our internal resources in each country, so that healthcare professionals and patients select our products and consequently that brings the increase the Group's sales. As of the end of 2019, the Kyowa Kirin Group had 35 overseas subsidiaries, each with their own know-how gained through business activities in their respective markets. We aim to bring all that knowledge together to spur innovation that drives our business forward. To support that, we provide regular opportunities for Kyowa Kirin personnel from different countries and regions to share and discuss strategies and challenges.

In May 2019, marketing and pharmacovigilance (PV) teams from across Asia gathered in Tokyo to take part in our Asian Weeks corporate event. At the event, we held marketing meetings about the nephrology and oncology categories – key areas for the Group in Asia – and discussed plans for the launch of new drugs Lumicef and Crysvita. Discussions went beyond simply sharing best practice, and participants were offering solutions from various perspectives for issues faced by each company, resulting in a highly productive event.

In September 2019, we held a global product meeting for all our global function leaders (responsible for sales, marketing, medical affairs, regulatory affairs, R&D, PV, quality assurance, supply chains and other functions) related to global strategic products Crysvita, Poteligeo and Nouriast/Nourianz. The three-day meeting gave them an opportunity to meet counterparts in affiliated organizations and to share and discuss the vision and strategy for maximizing product value and tackle related issues.

We will spur innovation by various channels of communication between regions, organizations and divisions and support Kyowa Kirin's further growth as a GSP.

## Pharmacovigilance (PV)

Patient safety and appropriate use of our medicines is at the core of our business. We carefully evaluate safety data, provide reports to regulatory authorities in each jurisdiction and ensure frontline medical staff have access to the right information

#### Progress in FY20

#### Pharmacovigilance Division established

In FY2019, we received approval for our second global product in several countries in Europe. We also gained approval for our third global product in the US. We are seeing rapid growth in the use of our products worldwide. In response, under the supervision of our global safety committee, our global safety teams are gathering and accurately evaluating safety data from sources worldwide and preparing safety reports to provide information to regulatory authorities in each jurisdiction in a timely manner and ensure frontline medical staff have access to the right information.

In line with our new global management structure "One Kyowa Kirin," which was launched in April 2019, we have created an integrated Quality Management System (QMS) based around PV officers in four regions: Japan, Europe/Middle East/ Africa (EMEA), North America and Asia/Oceania. Under the leadership of the Global Head of PV, we are putting in place a global framework using PV officers to gather, analyze and evaluate all safety data. In Japan, we established a new Pharmacovigilance Division in January 2020 as part of a broader reorganization. The division has global capabilities, supported by a PV Business Management Department, PV Operations Department and PV Medical Department.

#### Goals for FY20

#### Aiming to further reinforce global systems

We plan to continue reinforcing our safety monitoring activities worldwide, while also expanding sales of global products and responding to increasingly stricter standards in each jurisdiction.

Since the second half of 2019, we have been building a global PV framework, under the leadership of the Global Head of PV. The aim is to upgrade compliance functions, operational functions (evaluation and reporting of safety management data), and medical science functions. In particular, we will use the Quality Management System, which integrates all compliance functions worldwide, to establish a structure that allows us to implement global compliance activities. We will also continue to upgrade systems to support risk management activities by collecting safety data from all markets and storing it in our global safety database. To reinforce PV organizations in each of the four regions, we will actively recruit the necessary staff and promote personnel exchanges between each region.

Global PV is also key to strengthening our Business Continuity Plan (BCP). To that end, we are looking at ways of ensuring the global PV organization can continue to operate in the event of a natural disaster that disables our capabilities in Japan.





Together, we will work, learn and grow to create a highly compliant global PV organization, using medical science to add value to our medicines by predicting and preventing adverse reactions and change the lives of our patients for the better.



## Contributing to the safety of patients worldwide



#### Jean-David Rafizadeh-Kabe, MD, JD

All pharmaceutical products have both benefits for patient treatment and risks in the form of potentially adverse reactions. To provide safer pharmaceutical products that give patients even greater peace of mind, we implement timely assessments and reviews of drug benefits and risks and continue to actively provide appropriate information to frontline practitioners, based on safety information collected from sources worldwide.

Global Head of PV

Global PV activities have a very important role to play in ensuring compliance worldwide, but complying with standards and regulations is more than just committing to our core value of integrity – "Do the right things. Be sincere and ethical consistently. Make a better world through good business practices." As employees, we also have to ask ourselves every day: are we acting ethically and doing the right thing for the safety of patients worldwide?

Our global safety teams play a central role in collecting and accurately evaluating safety data from markets around the world. When they face problems evaluating the data, we use the cross-functional capabilities of the global safety committee to discuss any issues. In all cases, patient safety is at the forefront of our thinking.

## Quality Assurance (QA)

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.

#### Progress in FY201

#### Strengthen global systems to improve Quality Assurance

Following the launch of One Kyowa Kirin in 2019, a new Global Quality Assurance framework and plan was launched in April 2019. As shown in the figure below, the Quality Assurance function has been arranged so that the Global QA Head, who reports directly to the President directly guides Quality Assurance activities in each region including Japan, North America, Europe and Asia/Oceania. Also, importantly in September 2019, a new Global GxP Audit & Regulatory Compliance department was launched forming an independent and dedicated global auditing unit. This Global Quality Assurance and management supervision structure has been designed and implemented with the highest priority on patient safety, compliance and customer satisfaction.

In addition, a Global QA Head with deep experience in the bio-pharmaceutical industry has been appointed since February 2019. He is also the Chairman of the Global Quality Assurance Committee, which evaluates the effectiveness of each region's Quality Management Systems and overall performance. He is consistently working with the Regional QA Heads to provide leadership and strategic direction according to our Global Quality Roadmap which contains focused strategic imperatives and actions through 2023.

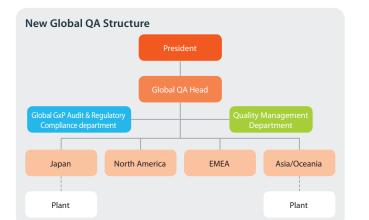
#### Goals for FY20

#### Further strengthen organizational capability

In order to guarantee the quality of global products in each region, we will further strengthen our organizational capabilities in each region in 2020.

Based on the newly established "Kyowa Kirin Group Quality Policy", a project has been started to formulate global policies for each process within our QMS. Based on these policies, we will aim to improve and optimize our processes in full alignment with our global regulators' expectations.

In addition, by effectively utilizing IT technology, we will manage and utilize our expansive quality data to continuously improve our processes and reliability. The electronic Quality Management System (eQMS) initiative is underway and once completed we will electronically manage our key quality management processes (training, document management, corrective and preventative actions, audits, etc.) and move from a largely paper based system to fully electronic/paperless.



#### 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.

- We utilize People, Process, Systems / Technology to conduct reliable and ethical activities in alignment with our compliant and effective GxP quality management system.
- 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.



## Delivering the highest Quality medicines

Vision and executing our Mission:



Global QA contributes to the Kyowa Kirin's business by following our

Head of Global OA

- Our Vision (the what) is to help deliver the highest quality medicines to our patients by designing and implementing a world class Quality Management System (QMS) while embracing our quality, safety and compliance policies.
- Our Mission (the how) is to achieve our goals by executing our Global Quality Roadmap to 2023 which is a set of key initiatives that we aim to achieve over the next 3 to 4 years in order to become a world class organization with respect to Quality and Compliance.

A Quality Culture is really about three things, establishing a clear vision, having a set of agreed upon values that all employees live by, and providing strong leadership. In a healthy quality culture you will find things like science-based approaches to decisions, sound risk management, robust data integrity, compliance, a supportive management structure, an environment of preventing issues before they arise, and a continual improvement mindset.

Our ultimate goal as part of our Global Quality Roadmap is to achieve a competitive advantage and have a world class Quality System and Quality Culture.

# Creating and Strengthening Natural Capital

# Environment

Kyowa Kirin makes dedicated efforts to protect the global environment, which is key to business continuity, while promoting activities that are geared toward realizing a sustainable society.

# **Environmental Management**

The Kyowa Kirin Group makes dedicated efforts to protect the global environment for the next generation. In this regard, the Group takes into consideration the environmental impacts of its products throughout their entire life cycle extending from research and development through production, marketing, use and disposal, as well as across the supply chain based on the Kyowa Kirin Group Environmental Policy.

In practicing CSV management, we position the Kyowa Kirin Group's priority issues as material CSV issues and incorporate them into the Mid-term Business Plan.

Some of the material CSV issues are designated as core issues, as they overlap with the Sustainable Development Goals (SDGs) – create new products and services centered on leading-edge technology, promote employee health, prevent global warming and preserve water resources.

Key matters related to the Group's environmental management activities are discussed and decided by the Group CSR Committee, which is chaired by the Executive Vice President. The results of that process are reported to the Board of Directors.

Daily environmental management activities are conducted in accordance with the ISO 14001 environmental management system. Effective from January 1, 2019, all domestic production and research sites have switched from third-party accreditation of compliance with ISO 14001 to self-declaration.

# Response to Material Issues and Other Countermeasures

To prevent global warming and preserve water resources – two of our material CSV issues – we are reducing CO<sub>2</sub> emissions and cutting back water usage as part of ongoing concrete initiatives to reduce our impact on the environment.

Additionally, to prevent global warming, by 2030 we are aiming to reduce global CO<sub>2</sub> emissions by 20%<sup>\*1</sup> compared with the level in 2015. Production and research sites have also set individual per-unit energy consumption targets and are implementing measures to raise productivity. Similarly, we have set a long-term 2030 goal to reduce worldwide water consumption by 30%<sup>\*1</sup> versus 2015 and established targets to reduce per-unit water consumption at each business site. In FY2019, we cut per-unit energy consumption by 5.1% year on year (global target: reduction of 1% year on year), and per-unit water consumption by 3.9% year on year (global target: reduction of 1% year on year). Our long-term target for reduction in CO<sub>2</sub> emissions is based on the Kirin Group's Science Based Targets (SBS). Together with our long-term target for reducing water consumption, the long-term CO<sub>2</sub> emissions target has also been incorporated into the Kirin Group's CSV Commitment.

In addition to energy-saving initiatives, we are promoting wider use of renewable energy, including the installation of solar panels at the Tokyo Research Park, Fuji Research Park and the Ube and Takasaki plants.

We have also achieved major reductions in CO<sub>2</sub> emissions at the Takasaki Plant by selecting the Aqua Premium\*<sup>2</sup> product from our energy partner, Tokyo Electric Power, since January 1, 2020. Aqua Premium is a 100% hydropower electricity supply service that generates zero CO<sub>2</sub> emissions. The power sourced through the service equates to roughly 75% of all electricity procured for the Takasaki Plant. We estimate the service will enable us to reduce emissions from all the Group's production and research sites by roughly 20%.

\*1 Target for the Kyowa Kirin Group and the Kyowa Hakko Bio Group \*2 Kyowa Kirin is the first pharmaceutical maker in Japan to sign up to the service.

## Task Force on Climate-Related Financial Disclosures (TCFD)

The Kirin Group, of which Kyowa Kirin is a member, has declared its support for the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD). In accordance with the TCFD recommendations, the Kirin Group analyzes different scenarios and evaluates the resilience of business strategy with respect to climate change. In line with the Kirin Group's declaration, Kyowa Kirin will conduct scenario analysis to evaluate the business risks and opportunities associated with climate change, monitor the potential impact and disclose detailed information in accordance with the TCFD recommendations.

# Water Resource Risk Assessments

Kyowa Kirin uses the WRI Aqueduct and WWF-DEG Water Risk Filter assessment tools and data from other surveys to assess the current risk of water shortages, water stress, flooding, water resource contamination and other water-related risks at its manufacturing sites (including overseas sites), as well as prospects for changes in risk levels due to climate change. We have started using the results of those risk assessments to develop a range of responses.

## **Biodiversity Preservation**

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. The Takasaki Plant has entered into a three-party agreement with Gunma Prefecture and Kurabuchi Furusato Public Corporation, under which it engages in Takasaki Water Source Forest Conservation Activities to protect forest areas in Kurabuchi-machi, Takasaki City.

The activities, which have now been running for more than a decade, received an environmental prize from Gunma Prefecture in 2018, recognizing the positive impact on protecting and cultivating the prefecture's abundant woodland areas.

In addition, for the third year running, Kirin Holdings Co., Ltd. has been recognized as a 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 cleaning local streams and rivers and releasing young amago trout into rivers. The Fuji Research Park continues to clean up a nearby river through Shizuoka Prefecture's River Friendship Program in collaboration with local government agencies. The Kyowa Kirin Group is also taking steps to reduce its impact on ecosystems in procurement activities. Specifically, we are introducing internal envelopes, company pamphlets, cardboard product packaging and other items made from FSC® certified paper\*<sup>3</sup> to help protect the world's forests.

Kyowa Kirin complies with the Kirin Group's Guidelines on Access to Genetic Resources when seeking access to raw materials and specimens. Under the guidelines, any profits generated from their use are shared with the local communities that provide them.

Furthermore, to comply with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act), we have put in place an internal committee to conduct proper management.

\*3 Kyowa Kirin has acquired FSC® promotion license (FSC® N003037).



Forest activities to preserve water resources

Gunma Prefecture Environmental Award

# **2** Creating and Strengthening Human Capital

# Talent Management Policy

Considering its employees as the source of innovation, the Kyowa Kirin Group is striving to unleash the full potential of each and every employee to develop individuals and organizations that will tirelessly tackle reform and create new value. The policy clearly defines the relationship between the Group's employees and the companies they work for and our common global approach to developing the capabilities of our personnel. In an effort to fulfill its management philosophy amid the increasingly drastic changes surrounding our business, we believe it to be critically important to recruit and foster people capable of exercising leadership and autonomously taking on the challenge of reform.

It is also imperative to help every one of our employees achieve healthy, fulfilling and high-quality lives and to harness the unique capabilities of employees with diverse backgrounds and offer them opportunities to co-create new value.

# Personnel Development

To consistently foster employees who can support Kyowa Kirin's future as a GSP, we are committed to talent management that harnesses the individual qualities of our people. Based on that goal, we create and implement individual development plans for each employee in a planned and strategic way, including job placements and transfers.

# **Talent Management**

We set up a new Talent Review Council in 2019. Based on our vision for Kyowa Kirin in the future, the council ascertains the Group's current supply-demand gap in personnel and discusses what each division needs to do to provide more opportunities to maximize the capabilities of each employee. The council is also working on cultivating the next generation of business leaders. To train future business leaders, we conduct assessments, training selected personnel, provide promotion opportunities early in their careers, and give them tough assignments, including overseas roles.

Our talent management system integrates a whole host of information about employees, such as performance evaluations, work experience, training course track records, language skills and global work experience.

Under our "One Kyowa Kirin" structure, ensuring the best people are in the right positions worldwide is now increasingly important, and we are promoting Global Mobility Programs to support those efforts.

# 1-on-1 Communication

To accelerate the development of our personnel, we need to encourage them to repeatedly take on new challenges in line with their individual development plans. We also have to provide feedback on their progress. To ensure that process is effective, we are actively promoting 1-on-1 communication between employees and their managers or team leaders to discuss their work and careers.

## Talent Management Policy

Based on our core values of Integrity, Innovation, Teamwork/Wa and the belief that our employees are the source of innovation, we strive to unleash the full potential of each and every employee to develop individuals and organizations that will tirelessly tackle reform and create new value



# Insights from the frontline

Using my specialist skills and experience to support global development



Kyowa Kirin Pharmaceutical Development, Inc. Yu Nakajima

Since joining Kyowa Kirin, I've worked as a data analyst evaluating data from clinical studies. In 2018, I was transferred to Princeton in the US.

At the moment, I'm mainly working on FDA and EMA applications for KW-6002. In the US, we have to respond in a timely manner to inquiries about new drug applications, so I need to work closely with related parties inside and outside the company to ensure a rapid response. With EMA applications, I work with my counterpart in Galashiels in the UK and take part in meetings with the European authorities to progress applications.

We conduct broad discussions with people in various roles inside and outside the company, so sometimes there is a difference of opinion, but I get a real sense of satisfaction when we reach agreement by balancing what they really want with our red lines. Although I try hard to understand people from different backgrounds, I sometimes struggle to make them see my point of view.

As a working woman, I think Kyowa Kirin is a flexible place to work that allows employees to balance their work and private lives, regardless of gender. Kyowa Kirin has put various personnel systems in place, but employees also access them on a routine basis and there is broad understanding among staff about how they should be used. Even if employees enter a new stage in their lives, such as getting married or having children, they have a clear idea of how they can easily adjust their work commitments to suit those changes, creating a working environment where people feel more secure about the future.

Looking ahead, I naturally want to improve my skills as a data analyst, but I also want to use my experience in Princeton to make a contribution, however small, to the globalization of development activities and the Group as a whole. To do that, I want to look beyond my own area of expertise to create a career path where I acquire knowledge in a wide range of other fields.

# Diversity & Inclusion (D&I)

At Kyowa Kirin, we believe workplaces that encourage mutual respect between diverse people and that enable employees to fulfill their potential help to further energize the Group and drive innovation. That's why we are actively implementing D&I initiatives.

# Supporting diverse human resources

Kyowa Kirin is implementing various measures to create working environments for employees with diverse backgrounds, regardless of age, gender, disability and nationality. As our business becomes more global, we are also hiring more non-Japanese employees who have graduated from a university overseas. Those employees are working in a growing number of areas across the Group through personnel transfers and assignments that dovetail with their career goals. To create working environments that spur innovation by harnessing the capabilities of employees from diverse backgrounds, including people with different values and lifestyles, we run Ikuboss management seminars and seminars about unconscious bias to raise awareness about diversity among managers. And because we believe women have a crucial role to play in raising the competitiveness of the whole Group, we offer training programs to prepare female employees for managerial positions and to increase awareness of career planning among younger female staff. We also host Back-to-Work Support Forums to provide employees with support for a smooth return to work after taking childcare leave. Thanks to these and other initiatives, Kyowa Kirin has maintained level 3 Eruboshi accreditation since August 2016, recognizing our efforts to help women develop their careers. Also, as of December 31, 2019, 9.7% of managers at Kyowa Kirin were women, and we aim to increase that to more than 10% in 2020.

# Supporting work-life balance

Kyowa Kirin is making a number of improvements to help employees continue their careers while balancing work and life commitments. Specifically, we offer childcare support, provide information to all employees about nursing care services via the corporate intranet, and run e-learning seminars to give employees aged 40 and older basic knowledge about nursing care.

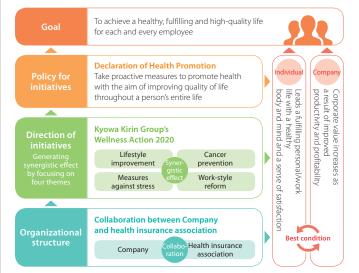
# LGBT

To create workplaces that welcome people with diverse sexual orientations and gender identities, including people from the LGBT community, Kyowa Kirin runs training for senior executives and employees to improve their understanding and raise awareness. We have also revised personnel systems and policies so that same-sex partners can use personnel systems in regions where same-sex partnership is recognized as marriage, and we have set up a hotline to provide advice about sexual orientation and gender identity to all employees seeking more information.

# Health and productivity management

The Kyowa Kirin Group is working to help employees achieve healthy and full lives, in line with the Declaration of Health Promotion announced by the senior management team.

Focusing on a number of key areas, we formulated the Wellness Action 2020 GOALS as KPIs for health and productivity management, aiming to minimize health-related risks and promote a healthy and safe workplace.



# Work and annual leave approaches that support innovation

Kyowa Kirin is offering employees a wider choice of ways to work. The goal is to allow them to independently select the best way of working to suit their situation and the needs of the organization. In 2019, we revised personnel systems to promote independent ways of working, aiming to create a balanced approach to work and annual leave to ensure employees are productive at work and well-rested after annual leave.

To give employees more flexible options about when and where they can work, we have introduced an annual paid leave system that can be used in hourly increments and a superflex system (flexible work with no core hours) for head office staff and certain other employees. Also, in light of growing nursing care needs, employees' parent's homes have been recognized as workplaces under our teleworking system, as well as employees' own homes.
To encourage employees to use their allocations of annual paid leave, we have ended a system that allowed staff to build up blocks of unused leave. We have also established a new Self-Management Leave system designed to ensure employees are in the best condition by helping them take control of their physical and mental health and respond to key life events. The system gives all employees up to 10 days of paid leave per year for illness, childcare, nursing care or other reasons.



# Providing support for employees to quit smoking

Kyowa Kirin is taking the following actions to reduce the ratio of employees who smoke to 5%, which is one of the Wellness Action 2020 Goals:

Promote smart work

Promote measures to enhance work engagement

(1) All employees who smoke and are trying to quit

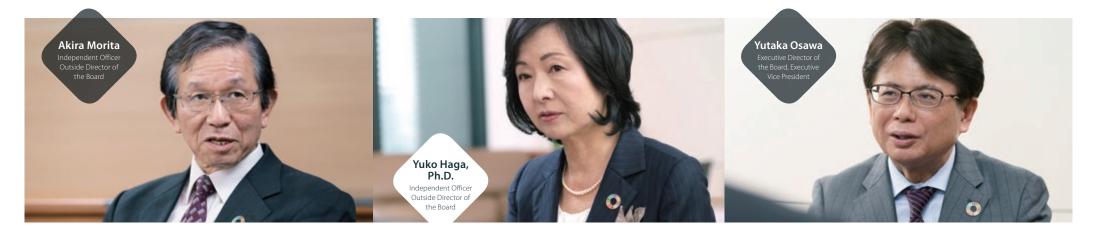
Promote measures to support highly stressed.

individuals and measures to invigorate workplaces

- (2) "Quit smoking" means completely stopping smoking, not just complying with internal rules that prohibit smoking during work hours or at company facilities
- (3) Smoking is the main risk factor for cancer, cardiovascular disease, strokes and other
- conditions; however, nicotine is highly addictive, making it difficult to quit. (4) Organization support all the individuals who are trying to quit smoking
- 4) organization support all the individuals who are trying to quit smoking

We believe all employees, including those who do not smoke, have to be involved in efforts to reduce the employee smoking rate. Respectful communication is also key. As of October 2019, roughly 800 employees were smokers. The organization is providing support by working closely with individual employees who have signed a declaration to stop smoking.

# **Special Roundtable Discussion**



While aiming for sustainable growth, the Kyowa Kirin Group is working to enhance the effectiveness of its Board of Directors. For this report we held a special roundtable discussion—involving Executive Vice President Yutaka Osawa and outside directors of the Board, Mr. Akira Morita and Dr. Yuko Haga on topics that included such Board of Directors initiatives and management strategies.

# Drawing on outside knowledge to enhance Board of Directors' effectiveness

Osawa Compared with other industries, the business structure and processes of the pharmaceutical industry are different, and there are closed aspects. Hence, there is a strong tendency to judge things only by the logic of insiders. For these reasons, however, the industry is unable to keep pace with the major changes that are taking place in the world and society. It's for that very reason that we expect outside directors to provide advice with regard to medium- to long-term strategies and the formulation of policy from external objective and professional perspectives.

Morita I agree. I have gained the strong impression from in-house directors that their attitude is to actively utilize my specialist knowledge of government regulations and drug price revisions in management. I have been participating in the management of the Company as an outside director since March 2019. In the initial stages having only just taken up the post, there were some parts with regard to company-specific terms and business processes that were quite difficult for me to understand. However, everyone in the executive departments kindly took enough time prior to Board of Directors' meetings to politely fill me in on the details until I had a sufficient grasp of them. This support system has been of great help to me in gaining an understanding of the current situation. Haga The high quality of the support system is something that I, too, have sensed strongly. Although there are restrictions on browsing by information attributes, outside directors are able to access the Company's intranet and check the minutes of various meetings held by the executive departments. This system allows us to know the situation inside the Company well. The important role for outside directors is to exchange their specialist perspectives in assessing whether management processes are logical and have validity. With that in mind, I thoroughly analyze the variety of information provided and attend Board of Directors' meetings on every occasion.

Osawa The executive departments are strengthening their support system year by year so that outside directors can demonstrate their knowledge and expertise. Also, we regularly conduct on-site observation and provide opportunities for direct dialogue with employees. This stems from the idea of wanting you to understand the Kyowa Kirin Group from personal experience. Last year, both of you kindly participated in on-site observation on a number of occasions. What kind of impression do you gain from them?

Haga All the employees I met were energetically applying themselves to their tasks, and the fact that there were many women in important positions also left an impression on me. Many young employees possess the desire to put their skills to

the test overseas, and I feel that this tendency is very encouraging for a company that is accelerating its global expansion. By actually going to the workplace frontlines I noticed many things, such as the atmosphere within the Company and specific business flows.

Morita During the on-site observation, I had many opportunities to interact with researchers engaged in development and was very impressed with their passionate attitude toward research. On the other hand, there are concerns that their attention is focused only on the world of research, and whether they have ended up blind to the world outside the department and outside the Company. The seeds of drugs are often found in unexpected places. I want all employees to engage in their tasks with a broader perspective.

Osawa I believe that, through the on-site observation, you were able to gain an understanding of our culture, strengths and issues through first-hand experience. If, besides desktop raw data, you have no understanding of the raw activities that actually take place in the field, you cannot make appropriate business decisions. To enable the outside directors to benefit from their more active participation, we want to conduct these on-site observation on an ongoing basis in the years to come.

# Evaluation of and expectations from new global system

Morita I recognize that the Group's target of a "One Kyowa Kirin Matrix System," which would be difficult to put in place in a short space of time, is a very challenging initiative. However, organizational reform is unavoidable in developing the overseas markets that will be the major drivers of future growth, and all employees must work in unison to build the system. In particular, an extremely important point is to respond flexibly to different governments and the regulations in each country and to take measures. In this regard, I think that the Company can make use of the knowledge that I have been cultivating with regard to international public administration.

Haga Under this system, which is geared toward the making of rapid progress on the global stage, Japanese and non-Japanese personnel from diverse backgrounds are being newly added, and remarkable progress is being made in organizational diversification. In response to this, the Company is focusing on the instilling of Group common values, an initiative that I rate very highly. If diverse personnel who possess common values can join forces and work toward the same vision, they can be expected to achieve unwavering growth, even in a global market where the environment is changing and the future is uncertain.

Osawa You're right. Based on common values, and in the spirit of creating a new company from scratch, top management has to hold a series of daily discussions and optimally allocate personnel, equipment and capital.

# Thoughts about CEO succession planning

Osawa Both of you are also members of the Nomination & Remuneration Consultative Committee. One of the items on the Committee's agenda is CEO succession planning. What are your thoughts on the qualities that the next president will need?

Haga The traits and requirements that we will be looking for in the next CEO are being fully discussed by the Committee. However, as that doesn't mean that the right person for the top position will suddenly emerge, it is important to steadily develop a senior management development program that targets the director candidates for the next term. I want them to acquire the skills and the mindset that will enable them to respond to the future changes in the external environment.

Morita In terms of qualifications, as its scale of activities expands on a global basis, the Company will need not only soundness of judgment but also speedy

decisiveness. Also well placed will be those personnel who can take over the attributes and strengths that the current CEO possesses, such as his personal charm and coordinating abilities.

# Assessments of diversity, personnel strategies

**Osawa** Diversity and personnel strategies are important themes to enable the Company to make a leap forward. How do you rate us on this point?

Haga The Company is now promoting diversity at a rapid rate. However, diversity isn't just about increasing the numbers of one gender or of people from different countries of origin. The essence is to prepare the fertile soil that will readily accept the planting of a wide variety of "thoughts" and lead to new ideas. Fundamental in achieving that is to respect each other's personality and background.

Osawa For a diverse organization to succeed, I also think it's important to bear in mind knowing and understanding one another. Recently, communications between people in different departments and regions have been becoming more active, and I want to increase opportunities for those communications.

Morita With regard to human resource strategies, we should naturally strengthen the development of our in-house personnel but should also encourage the creation of an environment in which mid-career personnel who join the Company from outside can play an active role. Especially since the numbers of overseas human resources are increasing rapidly, I think the challenge is to bring about changes to globally acceptable methods in the recruitment and evaluation systems that have been conducted in Japan up until now.

Osawa I agree. In response to this age of increasing personnel mobility, we are reviewing our personnel evaluation system so that newly added personnel are properly evaluated, and apply themselves to their tasks with a high degree of motivation.

# Meeting stakeholder expectations

Morita With regard to the Company's advanced R&D capabilities and the uniqueness of its antibody technology in the four key categories—nephrology, oncology, immunology/allergy, and central nervous system—I feel that they have been well received by investors. In order not to betray those expectations, we should continue to strengthen our R&D capabilities in the years ahead. Also, not only in Japan, but also in other advanced nations where the populations are aging, the national medical expenses are continuing to increase. As part of this response, a cost-benefit assessment has begun to be introduced that statistically analyzes the effects of drugs and determines appropriate drug prices according to their efficacy. What will increasingly be demanded of pharmaceutical companies in the years to come will be for them to continuously create innovative new drugs that are highly effective for patients.

Haga Kyowa Kirin has the power to create innovative new drugs that other companies cannot easily imitate. Those new drugs can save and improve the lives of patients who are suffering from illnesses. In managing this business that is of high social significance, I would like you to take to heart, without being bound by previous limits, to continue to pursue the provision of new value in the future. This is what stakeholders, including myself as an outside director, expect.

Osawa To create new value, you must not be content with the status quo. Sometimes it's necessary to defy conventional wisdom and overrule precedent. The current position of the Kyowa Kirin Group was established only because of an attitude to face challenges that did not fit the mold. In the years to come, we want our directors to be at the forefront and lead our employees so that we can continue to meet the expectations of our stakeholders. Dr. Haga, Mr. Morita, thank you both for your valuable inputs today.



# **Corporate Governance**

# **Basic Policy on Corporate Governance**

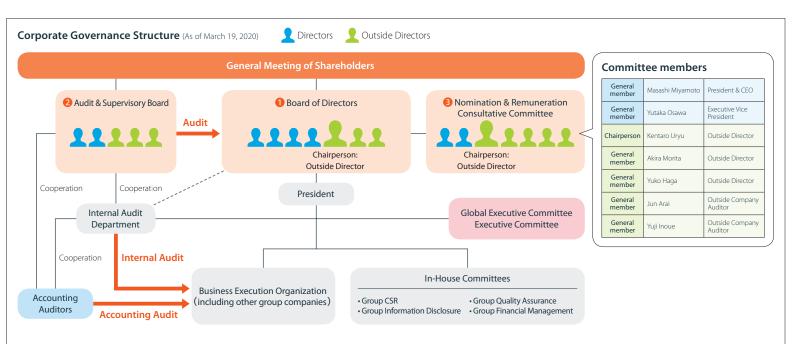
From a management perspective, Kyowa Kirin engages in business activities that include putting in place an appropriate organizational structure and systems while carrying out various measures in an effort to realize its management philosophy of "contributing to the health and well-being of people worldwide by creating new value with the pursuit of advances in life sciences and technology." Also, recognizing the importance of increasing management transparency and strengthening the monitoring and supervisory functions in order to continuously enhance its corporate value, the Company has formulated an overarching policy with the aim of further upgrading and expanding corporate governance.

 Based on its management philosophy and the Mid-Term Business Plan, and as a company responsible for supporting the foundation of society, Kyowa Kirin will enhance its corporate governance to promote its sustainable growth and improve its corporate value over the medium to long term, by ensuring the transparency and fairness of its decision-making processes, establishing speedy and strong decision-making and operating systems and putting in place proper supervisory and monitoring systems. Recognizing that cooperation with stakeholders is indispensable for realizing the goals of its Mid-Term Business Plan and management philosophy, the Company values the viewpoints of its respective

 The Company fulfills its accountability with integrity by promptly disclosing information to shareholders and investors based on the principles of transparency, fairness and continuity, and proactively engaging in constructive dialogue with shareholders and investors.

stakeholders.

• The Company maintains its independence while respecting the group management policy of Kirin Holdings Company, Limited.



## Board of Directors

The Board of Directors makes decisions on matters stipulated by law and the execution of the Group's important operations, which include long-term management visions, mid-term business plans and annual business plans of the Group and key Group companies. The Board is also responsible for monitoring the execution of directors' duties, and for developing appropriate internal control systems across the Group.

The number of directors forming the Board of Directors in the Company should not exceed 10 directors in accordance with its Articles of Incorporation. At least two independent outside board directors are appointed to ensure the knowledge, experience, skills and insights necessary for the Company to grow into a "Global Specialty Pharmaceutical Company," to maintain the diversity of Board members, to establish a generally balanced and highly transparent governance system and to ensure that management is monitored effectively and objectively.

Board of Directors	Number of meetings: 13
Meetings in 2019	Director attendance: 98%
Meetings in 2019	Company auditor attendance: 100%

## 2 Audit & Supervisory Board

The Audit & Supervisory Board has five members, including three outside audit & supervisory board members (two of whom meet criteria for independent auditors). The Audit & Supervisory Board audits directors regarding the execution of their duties, as an independent body that acts for the benefit and on behalf of shareholders, to audit processes necessary to ensure the integrity of management, with an eye to the Group's sustainable growth and the improvement of its corporate value over the medium to long term.

Company auditors will actively express opinions at meetings of the Board of Directors, by making use of their independence and the ability of full-time members to gather information from within the Group, and work to establish a system that ensures effective auditing conducted by individual company auditors.

Board of Company	Number of meetings: 14
Auditors Meetings	Company auditor attendance: 100%
in 2019	Company auditor attenuance. 100%

## Nomination & Remuneration Consultative Committee

The Company has opted to establish the Nomination & Remuneration Consultative Committee in order to supplement the functions of the Board of Directors as its advisory body and create an even more transparent corporate governance system. The majority of Nomination & Remuneration Consultative Committee members are independent outside officers, which is intended to facilitate objective and fair deliberations.

The Nomination & Remuneration Consultative Committee deliberates and decides on proposals for policies regarding the appointment and removal of directors, executive officers and company auditors 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 officers of individual group companies, remuneration systems, levels and amounts for directors, executive officers, company auditors and other officers of individual group companies, and presents the proposals to the Board of Directors.

	Number of meetings: 14
Consultative Committee in 2019	Committee member
consultative committee in 2019	attendance: 100%

# Evaluation of the Effectiveness of the Board of Directors

Based on improvements from the previous fiscal year, the Company regularly evaluates the effectiveness of the Board of Directors in order to identify any priority issues for the next fiscal year.

# Evaluation Method in FY2019

The Company employed the services of an external advisor and conducted a survey in October 2019. While taking into consideration the progress made in implementing improvements from the previous fiscal year, the focus of this survey was directed toward specific issues associated with the Company's growth and matters of concern raised by third parties. Drawing on an analysis of the results of the survey, a review was conducted, and opinions exchanged mainly by directors and company auditors during a meeting in November 2019.

## Survey Scope:

Directors, company auditors and executive officers participating in Board of Directors meetings as observers

## Survey Items:

1. Growth strategies, 2. Global management, 3. Governance systems at listed subsidiaries, 4. Capital policies, 5. Risk management, 6. Remuneration system, 7. Succession planning, 8. Dialogue with shareholders, 9. Discussion topics, 10. Training for directors

### **Evaluation Results**

Survey scores, remarks, comments from external advisors and the results of opinions exchanged confirmed the effectiveness of the Board's activities.

# Actions for the Next Fiscal Year

As part of the 2021 Mid-Term Business Plan formulation process, the Board will set KPIs that take into account the allocation of management resources and capital costs, and deepen discussions about topics such as dialogue with shareholders.

# **Internal Control**

Based on the basic policy of our parent company Kirin Holdings Company, Limited, we have established a "Basic Policy on Internal Control System" to ensure the appropriateness of operations. Under this basic policy, the establishment and operations of the system are confirmed by the Board of Directors, and the main details are made public. Moreover, in accordance with the Group's "Basic Policy on Compliance" and "Basic Policy on Risk Management," the Company promotes compliance in good faith and strives to ensure a system that responds appropriately to risks. With the enforcement of the revised Companies Act of 2015, we are making efforts to revise our basic policies and implement initiatives to strengthen the corporate governance of the Group.

The internal audit unit, in charge of conducting audits on how the internal control system is developed and operated, was subjected to an external assessment by an outside specialized agency in 2017 and was rated as "Generally Conforming" to the International Standards for the Professional Practice of Internal Auditing.

# **CEO Succession Planning**

The Nomination & Remuneration Consultative Committee conducts ongoing discussions about the selection and development of individuals with the capacity to assume the position of CEO and reports its findings to the Board of Directors. All candidates are required to understand and be fully committed to the Company's management philosophy and core values – Commitment to life, Innovation, Teamwork/Wa and Integrity.

In addition to those basic criteria, the Nomination & Remuneration Consultative Committee considers traits that the ideal CEO should have, such as a strong sense of responsibility towards society (patients) and the Company (employees), a firm idea of the values he or she would like to provide to society, or someone who can think beyond national borders and come up with a vision for the company. The committee also looks at the knowledge, skills and experience needed for the role of CEO. The committee then recommends candidates to the Board of Directors based on those attributes and provides recommendations on how candidates can be developed.

# Basic policy on construction of the Internal Control System

1	Compliance framework
2	Information storage and management framework
3	Risk management framework
4	Efficient execution of duties framework
5	Reporting on the execution of duties, and other Group internal control framework
6-10	Company auditor-related framework

# Kyowa Kirin Group Compliance Policy Summary

Relationship with Society	We, as good members of society, will build friendly and ethical relationships with all our stakeholders.
Relationship with Employees	We will respect each member's individuality and endeavor to maintain a friendly workplace environment.
Compliance with Rules	We will behave with integrity and ethically, while complying with rules.
Respect for Human Rights	We will respect human rights and characteristics of all people.
Environmental Preservation	We will actively engage in the preservation of the global environment to safely hand it over to the next generation.
Information Management	We will properly manage information concerning our businesses.

# 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 do this, the Company took close reference from 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 of the Japan Association of Corporate Directors in order to secure the transparency and objectivity of its governance function while exerting proper management oversight.

## Functions of Outside Board Directors and Outside Company Auditors

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 three independent outside board directors who satisfy the separately established "Criteria for Independence of Outside Directors." Independent outside board directors not only actively offer business advice on management issues, supervise the execution of business activities and monitor conflicts of interest, they also play a role in accurately conveying the opinions of stakeholders, including minority shareholders, at meetings of the Board of Directors. In addition, the Company appoints two independent outside company auditors in order to ensure the objectivity and neutrality of audits as well as the soundness of management. In an effort to strengthen the abilities of independent outside officers to gather information, meetings are held between full-time company auditors and non-executive board directors, including independent outside board directors.

## **Executive remuneration**

# (1) Basic policy on executive remuneration

 Remuneration for executives is designed to increase commitment to the Company's further sustainable growth and improvement in corporate value, to attract and retain talent who aspire to help the Company make the leap forward to a Global Specialty Pharmaceutical Company, and to motivate executives to contribute to the Company by fulfilling their respective duties.

# (2) Components of remuneration

Remuneration for executive board directors has three components

 basic fixed compensation, an annual performance-based bonus as a
 near-term incentive, and stock options as a medium- and long-term
 incentive. Remuneration for non-executive directors and company
 auditors is made up of a fixed compensation component only, to
 ensure they fully fulfill their role of supervising the management of the
 Company from an objective and independent standpoint.

# (3) Setting pay levels and the ratio of performance-linked pay

 Pay levels and the ratio of performance-linked remuneration (bonuses and stock options) are discussed and determined by the Nomination & Remuneration Consultative Committee, referencing survey data on executive pay provided by a third-party research organization. Based on executive pay data for listed pharmaceutical companies in Japan, we set pay levels that compare favorably with sector peers when performance targets are achieved. When performance targets are achieved, the ratio of total pay allocated to performance-linked remuneration is roughly 40%.

# (4) Performance-Based Bonus

Bonuses, which are paid as a short-term incentive, have two components that reflect Kyowa Kirin's current shift towards becoming a Global Specialty Pharmaceutical Company supported by rising overseas sales: a portion linked to performance versus annual targets, and another portion linked to achieving targets in the Mid-Term Business Plan. For annual performance targets, we use revenue and profit attributable to owners of parent, and for Mid-Term Business Plan targets, we use core operating profit. The split between the two components of performance-linked remuneration is roughly 50:50.

# Professional Skills of Independent Outside Officers (As of March 19, 2020)

	Kentaro Uryu Outside Director	Akira Morita Outside Director	Yuko Haga Ph.D. Outside Director	Jun Arai Outside Company	Yuji Inoue           Outside Company
				Auditor	Auditor
Corporate management			0	0	0
Global management	0		0	0	0
Finance and accounting				0	0
Legal affairs	0				
Public administration		0			
Healthcare		0	0		

# Executive Remuneration\*1

		Breakdo	wn of Remuneration (Million	ion (Millions of yen)			
Position	Total Remunera- tion (Millions of yen)	Basic Remuneration	Annual Performance- Based Bonus* <sup>2</sup>	û Stock Option*³	Number of Directors and Outside Company Auditors		
Directors (Excluding Outside Directors)	394	231	84	79	5		
Company Auditors (Excluding Outside Company Auditors)	26	26	_	_	3		
Outside Directors	38	38			4		
Outside Company Auditors	51	51	_	_	3		

\*1 Above information includes an Audit & Supervisory Board Member and an Outside Director who retired at the Ordinary General Meeting of Shareholders held last year. \*2 The amount of annual performance-based bonus is the provision for directors' and officers' bonus applicable to the fiscal year.

\*3 The amount of stock option remuneration is the expenses amount for the fiscal year.

# **Executive Training Systems**

Taking into consideration the Company's fiduciary responsibilities and accountability to shareholders, Kyowa Kirin recognizes the importance of providing its executives with the knowledge and information required to realize its management philosophy by building an effective and efficient corporate governance structure and to achieve the sustainable growth of the Group while enhancing corporate value over the medium to long term. In providing its executive with this training and information, Kyowa Kirin is guided by the following policy.

In addition to providing information about business operations, legal affairs, risk management and other relevant matters through the above training courses, the Company held in-house lectures on business ethics in FY2019 to help executives gain the knowledge they need for their roles. Newly appointed outside directors were also taken on tours of the Group's research facilities and plants.

# Policy on Cross-Shareholding

To realize sustainable growth and enhance its corporate value over the medium to long term, the Company uses return on equity (ROE) as one of its key management indicators, and sets medium- and long-term ROE targets. The Company's basic policy for return to shareholders is to distribute dividends constantly at a consolidated payout ratio of around 40% (based on profit before goodwill amortization). The Company may buy back its shares flexibly as necessary, considering the business environment, capital efficiency and any other factors.

If the Company plans to implement a capital transaction that will result in the change of control or significant dilution of share value, the Board of Directors will thoroughly examine the proposed transaction from the viewpoint of protecting its corporate value for all stakeholders and make a reasonable decision.



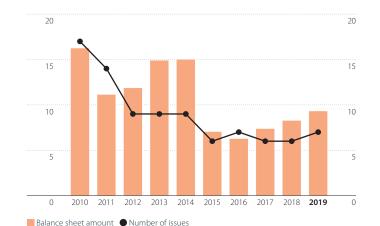
# IR activities focused on dialogue with shareholders

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 strategy, finance, accounting and research and development as well as the three full-time staff that make up the IR Department. 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.

# **Training policy**

- The Company provides the training and information necessary for directors and company auditors to perform their roles and fulfill their responsibilities.
- Upon assuming office, directors and company auditors will receive lectures and training from specialists and relevant departments regarding the Japanese Companies Act, corporate governance, risk management and other relevant matters. Subsequently, training and workshops will continue to be provided as necessary regarding the amendment of relevant laws and regulations as well as business issues.
- Upon assuming office, outside directors and outside company auditors will receive explanations of the Group's businesses, and will participate in observation tours of key sites.

# Comparison Compari



# Status of IR Activities (implemented in FY2019)



46

# We are stepping up engagement with stakeholders to build even stronger relationships.

# Engagement 2

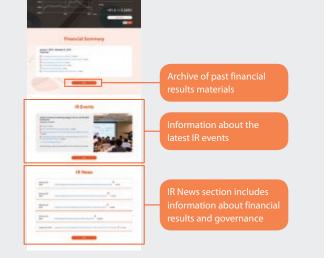
# Comprehensive Information Disclosure

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, available in both Japanese and English, as a tool to ensure immediate and fair disclosure of information.

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

2.563.0 -







# 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. Until the notices are sent by mail, the information is 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. During the General Meeting of Shareholders, a summary of the Company's performance is clearly explained on a screen or via a narration. Shareholders vote on measures after receiving ample explanation.

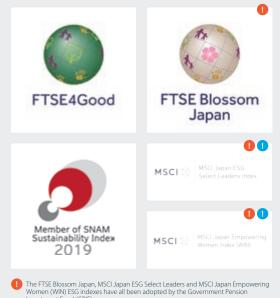


Many people attended the Company's 97th Ordinary General Meeting of Shareholders.



# 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.



Investment Fund (GPIF).
 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 index serves the exclusive property of MSCI. MSCI and the MSCI index names and

logos are trademarks or service marks of MSCI or its affiliates

# Directors



5 2 3

Executive Director of the Board, President and Chief Executive Officer Masashi Miyamoto, Ph.D.\*1

Executive Director of the Board, Executive Vice President 2 Yutaka Osawa\*1

Director of the Board, Senior Managing Executive Officer **Toshifumi Mikayama, Ph.D.** 

Director of the Board

Voriya Yokota

Outside Director of the Board 5 Yuko Haga, Ph.D.\*2

Outside Director of the Board 6 Kentaro Uryu\*2

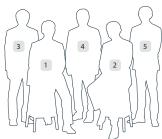
Outside Director of the Board
7 Akira Morita\*2

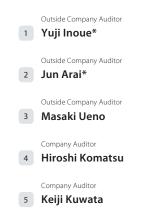
\*1 Concurrently serves as executive officer

\*2 Independent Board Directors

# **Company Auditors**







# **Directors' Profiles**

# Executive Director of the Board, President and Chief Executive Officer

# Masashi Mivamoto, Ph.D.

- Apr. 1985: Joined Kirin Brewery 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,
- Kvowa Hakko Kirin Co., Ltd. Apr. 2017: Executive Director of the Board, Managing Executive Officer, Director, Corporate Strategy & Planning Department,
- Kvowa Hakko Kirin Co., Ltd. Mar. 2018: Executive 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 Executive 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.

## Executive Director of the Board, Executive Vice Presider

#### 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. Kvowa 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: Executive 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, Senior Managing Executive Officer

# Toshifumi Mikavama, Ph.D.

#### Apr. 1983: Joined Kirin Brewery 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. (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

## Noriya Yokota

- Apr. 1984: Joined Kirin Brewery Company, Limited
- Mar. 2006: Managing Director, Kirin Australia Ptv. Ltd.
- Mar. 2011: General Manager, Sendai Plant, Production Division, Kirin Brewery Company, Limited
- Mar. 2014: General Manager, Production Department, Production Division, Kirin Brewery Company, Limited Mar. 2015: Director, Group Personnel & General Affairs, Kirin Holdings Company, Limited
- Executive Officer, General Manager, Personnel & General Affairs Department, Kirin Company, Limited Mar. 2017: Senior Executive Officer, Director, Corporate Strategy, Kirin Holdings Company, Limited
- Director of the Board, Senior Executive Officer, Kirin Company, Limited Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)
- Mar. 2018: Director of the Board, Senior Executive Officer & CFO, Kirin Holdings Company, Limited (to present) Senior Executive Officer, Kirin Company, Limited

#### Reasons for Selection

The Company has judged that Mr. Noriya Yokota 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 tight-knit cooperation with Kirin Group companies which have various business bases aimed at facilitating contributions to the health and well-being of people by providing solutions responding to various medical needs, through the use of our various business bases.

#### Director of the Board (Outside Directo

### Kentaro Uryu

- Apr. 1995: Admitted to Tokyo Bar Association
- Apr. 1995: Joined Tsunematsu Yanase & Sekine Law Firm (presently Nagashima Ohno & Tsunematsu Law Firm)
- Jan. 1996: Joined Matsuo & Kosugi Law Firm
- Feb. 1999: Joined Salomon Smith Barney (presently Citigroup Global Markets Japan Inc.)
- Apr. 2000: Long-term expert, Japan International Cooperation Agency
- Aug.2002: Attorney-at-Law, Managing Partner, Uryu & Itoga Law Firm (to present)
- Aug.2008: CEO, U&I Advisory Service Co., Ltd. (to present)
- Mar. 2015: Outside Company Auditor, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)
- Jun. 2015: Outside Company Auditor, ITOCHU Corporation (to present)
- Mar. 2018: Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (to present)

#### **Reasons for Selection**

The Company has judged that Mr. Kentaro Uryu has continued to apply his experience and high level of insight as a legal professional in the management of the Company since his assumption of office as Outside Company Auditor in March 2015 and as outside Director of the Board in March 2018, and is the right person to fully perform the role of decision making on material matters of management and supervising the execution of operations.

# Director of the Board (Outside Directo

## 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)
- Apr. 2014: Director-General, National Institute of Population and Social Security Research
- Aug.2014: Adjunct Professor, National Graduate Institute for Policy Studies (to present)
- Apr. 2017: Professor, Department of Policy Studies, Tsuda University (to present)
- Apr. 2017: Visiting Professor, Mie University Graduate School of Medicine (to present)
- Apr. 2018: Director-General, Research Institute of Science and Technology for Society, Japan Science & Technology Agency (to present)

Mar. 2019: Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (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 Director

# Yuko Haga, Ph.D.

- Apr. 1989: Senior Consultant, Tokyo Office, Price Waterhouse Consultants
- Apr. 1991: Representative, Haga Management Consulting Office (to present)
- Apr. 2008: Executive Officer, Sompo Japan Healthcare Services Inc.
- 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 (Professor since April 2020)
- Jun. 2017: Board Member, Non Profit Organization Japan Abilities Association (to present)
- Mar. 2019: Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (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.

# **Company Auditors' Profiles**

# Hiroshi Komatsu

Apr. 1986: Joined Kyowa Hakko Kogyo Co., Ltd.

- Feb 2009: CEO 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 experiences or accounter, leading the second second



### Keiji Kuwata

Apr. 1985: Joined Kirin Brewery 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
- 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 Kimi 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.

# Outside Company Audito

### 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 Sekivu 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.). (to present)
- Apr. 2019: Outside Director, Sumitomo Mitsui DS Asset Management Company, Limited (to present)

#### **Reasons for Selection**

The Company has judged that Mr. Jun Arai possesses considerable knowledge in finance and accounting accrued during his long-standing service in charge of the accounting and financial departments at Showa Shell Sekiyu K.K., and experience in corporate management as a Representative Director and President, and will apply this broad-ranging insight to guiding and auditing the Company's overall management.

#### Outside Company Audito

#### Yuji Inoue

- Apr. 1971: Joined Ricoh Company, Ltd.
- Nov. 1985: Managing Director, Ricoh UK Ltd. (London)
- Apr. 1993: General Manager, Finance Department, Finance and Accounting Division, Ricoh Company, Ltd.
- Apr. 1998: General Manager, Finance and Accounting Division, Ricoh Company, Ltd.
- Jun. 1999: Managing Director, General Manager, Sales Division, Ricoh Leasing Co., Ltd.
- Apr. 2000: President, Ricoh Leasing Co., Ltd.
- Jun. 2000: Group Executive Officer, Ricoh Company, Ltd.
- Jun. 2004: Managing Director, Finance Solutions, Ricoh Company, Ltd.
- Jun. 2005: President and Chief Executive Officer, Ricoh Leasing Co., Ltd.
- Jun. 2009: Corporate Auditor (Full-time), Ricoh Company, Ltd.
- Jun. 2014: Outside Corporate Auditor, Infoteria Corporation (presently Asteria Corporation)
- Jun. 2015: Outside Director, ANRITSU CORPORATION
- May 2016: Outside Corporate Auditor, Rvohin Keikaku Co., Ltd. (to present)
- Mar. 2018: Outside Audit & Supervisory Board Member, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.) (to present)

#### **Reasons for Selection**

The Company has judged that Mr. Yuji Inoue possesses a significant level of insight into finance and accounting through his experience in important posts in the accounting and finance division and as a Corporate Auditor in Ricoh Company, Ltd., as well as abundant experience from his service as President and Chief Executive Officer, and in other roles at Ricoh Leasing Co., Ltd., and will apply such insight and experience to the business management and audits of the Company.

# Outside Company Audito

# Masaki Ueno

- Apr. 1998: Joined Kirin Brewery 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
- 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 Hakko Kirin Co., Ltd. (presently 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

#### KYOWA KIRIN Annual Report 2019

# Compliance

The Kyowa Kirin Group recognizes that compliance entails quickly grasping societal demand while engaging in ethical manner. With this in mind, the Group works diligently to build and maintain healthy and positive ties with all stakeholders.

# Promoting Compliance

In order to put our philosophy into practice, we at the Kyowa Kirin Group act in accordance with our Core Values and with high ethical standards and aim to be a corporate group trusted by society. Regarding compliance as the foundation of all our corporate activities, we have established an organizational structure to comply with all laws and ordinances, internal and external guidelines and rules and social norms.

We have also put in place the Kyowa Kirin Group Code of Conduct, which provides guidelines for the overall behavior of executives and employees, and Group Policies that outline codes of conduct for individual areas of business. The Kyowa Kirin Group is committed to promoting compliance by disseminating the Code of Conduct and Group Policies.

The status of promoting compliance and the progress of countermeasures aimed at addressing material issues are deliberated by the Group CSR Committee, which is held on a quarterly basis, and reported to the Board of Directors. The countermeasure are improved continuously through the deliberation and reporting. The Code of Conduct has been translated into the languages of countries in which our sites are located. Every effort is being made to ensure that the Code of Conduct is instilled in all Group employees around the world. Each executive and employee pledges to comply with the Code of Conduct, and the degree of understanding and adherence are monitored through employee awareness surveys. Moreover, the Group conducts various training programs such as a corporate ethics lecture for executives, on-site training, and e-learning to foster a corporate culture that enables executives and employees to adapt flexibly to changes in social norms.

In light of changes in the internal and external environment, we revised the Code of Conduct in December 2019 to set out a clearer commitment to realizing a sustainable society and to clarify the responsibilities of executives and managers.

# **Anti-Bribery Initiatives**

International agencies, such as the United Nations and the Organisation for Economic Co-operation and Development (OECD), are calling for the strengthening of measures aimed at preventing bribery, which is recognized as an impediment to the sustainable development of society including healthy economic growth. For its part, the Kyowa Kirin Group continues to provide its executives and employees with annual training while endeavoring to educate individual departments at high risk to ensure a deeper understanding of the "Kyowa Kirin Group Policy for Anti-Bribery Measures" and "Regulation for Anti-Bribery" by Group companies.

Group companies work diligently to prevent bribery appointing anti-bribery managers and establishing help desks in line with this Policy and Regulation. In addition, we regularly monitor and audit how each Group company complies with the regulations and standards on bribery prevention and revisions to anti-bribery laws in each country, and are reviewing continuously our anti-bribery structure.

# Ethical Promotion Activities

As a business with a deep connection to people's lives and health, the Kyowa Kirin Group conducts ethical promotion activities. We have established the Kyowa Kirin Group Promotion Policy and related regulations to guide our ethical promotion activities. Organizational systems and work processes are run in accordance with the policy and regulations. To deepen understanding and knowledge of ethical promotions, we run ongoing training programs about related laws and other topics for executives and employees.

# Rollout to the Supply Chain (CSR Procurement)

The Kyowa Kirin Group has stipulated the "Kyowa Kirin Group Procurement Policy" which is designed to ensure that we promote the CSR procurement in collaboration with our suppliers so that we will meet the expectations of various stakeholders and adapt to social changes. As a part of efforts to fulfill this policy, we have also published the "CSR Procurement Guidebook" including the "Supplier Code of Conduct" which establishes our fundamental expectations for suppliers. Through these and other means, we are promoting fair, equitable and transparent procurement activities with suppliers.

To ascertain the status of suppliers' CSR activities we conduct questionnaire surveys composed of questions on topics covered by the "Supplier Code of Conduct" such as relationship with society, relationship with employees, compliance with rules, respect for human rights, environmental conservation and information management. To encourage suppliers to make continuous improvements in their CSR activities, we feed back the results of questionnaire surveys and conduct site

visits of suppliers to keep track of their activities. We disclose the results on our website and promote the CSR procurement across the entire supply chain. Also, we periodically hold briefing sessions for suppliers focusing on the CSR procurement. These sessions are designed to introduce and deepen the understanding of the Group's approach toward the CSR procurement including the importance of ensuring compliance across the entire supply chain. Going forward, we will also work to promote the compliance focusing on the human rights of partners including suppliers, environmental conservation and bribery.

# Internal Reporting

The Kyowa Kirin Group has in place a whistle-blowing contact in order to prevent, detect at an early stage and correct acts that contravene 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 mechanism under which a report about a board member is passed directly to a company auditor. The whistle-blowing systems are operated under internal rules that explicitly require informants and those cooperating with related investigations to be protected.

We constantly work to promote wider understanding of the system among employees and how to make reports by providing e-learning modules and group training, supported by regular messages from the CEO on topics such as the importance of the whistleblower system, confidentiality and protecting whistleblowers.

In 2019, there were a total of 27 whistleblowing cases in Japan and overseas.

Outline of relations between the Management Philosophy and Group Policies



In order to secure trust from customers and society, the Kyowa Kirin Group identifies a variety of risks arising during the course of its business activities and addresses them appropriately.

# **Risk Management System**

**Risk Management System** 

To secure the long-term trust of customers and society and continue our business to achieve our management goals, we have implemented risk management in all group company under the Kyowa Kirin Group Risk Management Policy established, referencing international standards such as ISO 31000 and the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In the Kyowa Kirin Group, risk management refers to a set of ongoing activities: identifying and analytically assessing risks that may affect business management, responding to risks, confirming response progress, and making improvements to responses. These activities are carried out based on a strong commitment of the management. Specifically, risk managers responsible for overall risk management in each division work with risk management key persons to select and evaluate risk

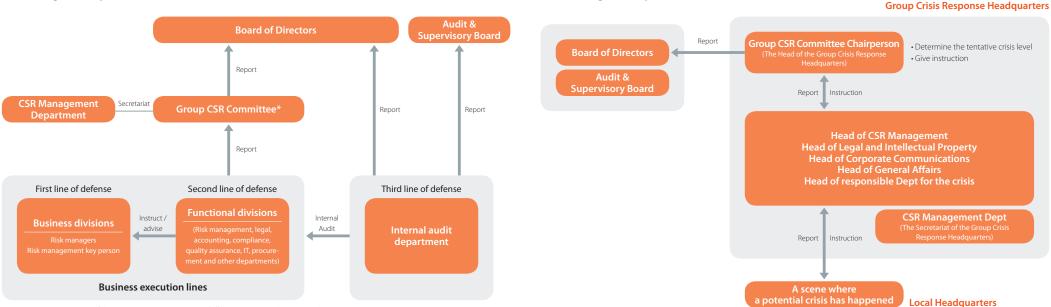
in their divisions, and to take measures, implement and improve measures that address that risk. In addition, the Group CSR Committee secretariat integrates risks in all divisions to create a risk map and identifies material risks for the Group. The material risk control status is confirmed quarterly in the Group CSR Committee, which then reports the status to the Board of Directors.

The Kyowa Kirin Group controls risk by three lines of defense – each business division controls risk in their own operational areas, while each functional division is responsible for providing guidance, advice and risk monitoring in their specialist areas to the relevant business division. Additionally, the internal audit department, which is separate from lines of business execution, conducts audits of risk management and control activities and reports them to the Audit & Supervisory Board and the Board of Directors.

**Crisis Management System** 

# **Crisis Management**

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. We prioritize human life and health and act quickly and appropriately to minimize the impact of the crisis and restore normal business operations as soon as possible. In particular, we believe it is crucial to quickly report any early signs of a crisis to senior managers or the relevant department (called "Bad News Fast"), establish cross-divisional teams to develop an integrated response to the crisis while taking into account the impact on stakeholders, and monitor the implementation of measures to prevent any reoccurrence after the response to the crisis has been completed.



#### \*Group CSR Committee consists of directors in departments, presidents of affiliates and auditors who attend as observers

# **Financial Information**

# 54 Eleven-Year Selected Financial Data

# 55 Management's Discussion & Analysis (MD&A)

We report on the financial condition and management measures of the company during the fiscal year. We also perform an assessment and analysis of corporate performance and refer to forecasts for the next fiscal year.

# 61 Risk Factors

Major risks concerning the performance, financial condition, etc. of the company, which may significantly affect the decisions of investors, are reported.

# 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.

# About adoption of "core operating profit" (IFRS)

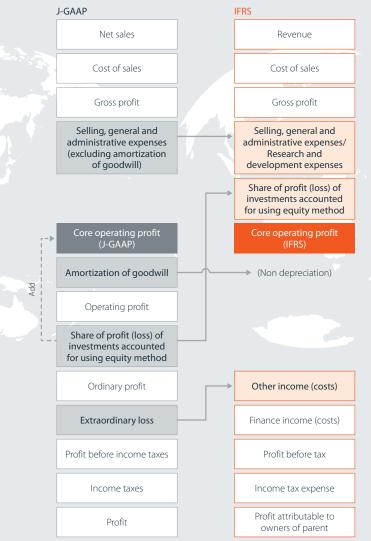
The Group uses "core operating profit" (Japanese GAAP)\*<sup>1</sup> as an indicator of sustainable growth in the five-year Mid-term Business Plan for FY2016 to 2020. After the adoption of IFRS, the Group adopts "core operating profit" (IFRS)\*<sup>2</sup> as an indicator showing recurring profitability from operating activities.

\*1 Operating profit + Amortization of goodwill + Share of profit (loss) of entities accounted for using equity method \*2 Gross profit – Selling, general and administrative expenses – Research and development expenses + Share of profit (loss) of investments accounted for using equity method

# **About 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 of the "Pharmaceuticals business."

# Major differences between IFRS and J-GAAP



# **Eleven-Year Selected Financial Data**

		IFR	S					J-GAAP				IFRS
		(Millions)	of ven)		(Millions of yen)				(Thousands of U.S. dollars*			
For the Year:	2019/12	2018/12	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2011/12	2010/12	2009/12	2019/12
Revenue*2	¥ 305,820	¥ 271,510	¥ 353,380	¥ 347,956	¥ 364,316	¥ 333.446	¥ 340.611	¥ 333,158	¥ 343,722	¥ 413,738	¥ 309,111	\$2,791,602
Gross profit*2	226,200	198,149	224,321	214,592	225,393	205,904	212,761	210,690	197,555	190,979	139,739	2,064,813
Selling, general and administrative expenses (including R&D expenses)*2	170,827	147,745	162,113	163,124	181,628	169,731	160,987	157,785	150,940	145,568	111,496	1,559,354
Core Operating Profit (J-GAAP:Operating profit)*2	59,353	50,306	57,731	39,116	43,765	36,173	51,773	52,905	46,614	45,410	28,243	541,790
Profit attributable to owners of parent	67,084	54,414	42,899	30,450	29,774	15,898	30,078	24,199	25,608	22,197	8,797	612,357
Capital expenditure and investments in intangible assets*2	22,586	13,489	20,714	33,270	20,039	29,487	35,183	27,808	19,697	29,374	25,135	206,168
Depreciation and amortization*2	18,797	16,243	22,032	23,784	23,126	23,885	21,592	20,904	22,833	22,188	17,003	171,580
R&D expenses*2	53,511	45,659	49,216	52,929	51,604	47,737	43,682	44,808	47,961	44,210	34,979	488,465
Cash Flows:												
Net cash provided by operating activities	¥ 53,655	¥ 56,181	¥ 64,902	¥ 66,881	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	¥ 40,634	¥ 64,189	¥ 24,203	\$ 489,778
Net cash provided by (used in) investing activities	(933)	(39,929)	(45,265)	(49,824)	(57,747)	16,805	(77,163)	(98,772)	18,460	(32,373)	(13,246)	(8,517)
Net cash provided by (used in) investing activities	(47,371)	(16,501)	(18,287)	(13,871)	(14,060)	(37,184)	(12,579)	(19,189)	(30,740)	(14,446)	(15,240)	(432,413)
Cash and cash equivalents at the end of the period	20,762	15,867	14,685	13,076	12,784	17.013	19,242	50,334	107,555	79,882	63,745	189,524
At Year-End:	,	,	,	,		,		,	,	,		
Total current assets	¥ 448,610	¥ 385,844	¥ 348,150	¥ 314,999	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	¥ 284,217	¥ 288,852	¥ 276,587	\$4,095,024
Total assets	784,453	741,982	708,295	683,801	720,764	719,135	719,257	679,342	658,873	695,862	695,268	7,160,686
Total current liabilities	87,530	80,459	78,409	88,072	84,823	85,182	85,076	85,774	78,465	102,483	110,080	798,997
Interest-bearing debt	17,185	2,527	2,814	7,000	4.840	4,868	6,207	5,699	6,042	7,515	13,228	156,871
Equity	678,250	649,621	616,028	577,036	614,858	605,368	595,415	555,898	540,023	544,992	540,343	6,191,233
Number of employees	5,267	7,242	7,532	7,465	7,435	7,424	7,152	7,243	7,229	7,484	7,436	0,191,233
Per Share Data:	0,207			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		77121	7,132		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Per share Data: Profit attributable to owners of parent*3	¥ 124.57	(Yer ¥ 99.40	n) ¥ 78.38	¥ 55.65	¥ 54.40	¥ 29.05	¥ 54.95	(Yen) ¥ 44.12	¥ 45.16	¥ 38.96	¥ 15.40	(U.S. dollars*1) \$ 1.137
Equity attributable to owners of parent	1,263.16	¥ 99.40 1,186.65	1,125.56	1,054.48	1,122.80	∓ 29.03 1,105.44	∓ 54.95 1,085.17	∓ 44.12 1,013.61	∓ 45.10 970.16	≠ 56.90 954.58	¥ 13.40 940.79	11.530
Cash dividends	42	35	27	25	25	25	25	20	20	20	15	0.383
	72		2/	25	25	25	23	20	20	20	15	0.505
Common Stock Price Range (Per share):												
High	¥ 2,594	¥ 2,478	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	¥ 953	¥ 1,040	¥ 1,178	\$ 23.68
Low	1,674	1,894	1,515	1,412	1,094	1,006	833	757	628	773	793	15.28
Stock Information (Thousands of shares):												
Number of common stock issued	540,000	576,484	576,484	576,483	576,483	576,483	576,483	576,483	576,483	576,483	576,483	—
Weighted average number of common stock issued	538,542	547,412	547,290	547,224	547,285	547,348	547,391	548,449	567,029	569,711	570,935	
Financial Ratios:		(%, except	EBITDA)					(%, except EBITDA)				
Return on assets (ROA)	8.8	7.5	6.2	4.4	4.1	2.2	4.3	3.6	3.8	3.2	1.3	_
Core operating return on assets (J-GAAP:Operating profit)*2	7.8	6.9	8.3	5.6	6.1	5.0	7.4	7.9	6.9	6.5	4.1	_
Return on equity attributable to owners of parent (ROE)	10.1	8.6	7.2	5.3	4.9	2.7	5.2	4.4	4.7	4.1	1.6	_
Ratio of equity attributable to owners of parent to total assets	86.5	87.6	87.0	84.4	85.2	84.1	82.6	81.7	81.8	78.2	77.1	-
Debt/equity ratio	2.5	0.4	0.2	0.9	0.8	0.8	1.1	1.0	1.1	1.4	2.5	-
Core operating margin (J-GAAP:Operating profit)*2	19.4	18.5	16.3	11.2	12.0	10.8	15.2	15.9	13.6	11.0	9.1	-
EBITDA*2.*4 (Millions of yen)	63,750	83,421	78,220	66,981	78,018	64,101	83,190	78,160	79,864	74,614	45,056	-
Payout ratio*5	33.7	35.2	34.4	44.9	35.1	54.4	34.8	32.8	32.5	36.2	54.3	_

\*1 U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥109.55=U.S.\$1, the approximate exchange rate at December 31, 2019.

\*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 amorization (+ Amoritzation 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).

# Management's Discussion & Analysis (MD&A)

Figures presented as IFRS in these materials have been rounded down to the nearest tenth and ones presented.

# Subsidiaries Included in the Scope of Consolidation

The number of Kyowa Kirin's consolidated subsidiaries stood at 38 as of December 31, 2019. Kyowa Kirin Pharma S.R.L. and Kyowa Kirin Australia Pty Ltd were newly established during the fiscal year under review. As a result, these companies have been included in the Company's scope of consolidation. On April 24, 2019, Kyowa Kirin transferred 95% of its shares in Kyowa Hakko Bio Co., Ltd. to Kirin Holdings Company, Limited. In line with this transfer, a total of 13 companies comprising Kyowa Hakko Bio Co., Ltd. and its subsidiaries have been excluded from the scope of consolidation.

Income		(Billions of yen)	
	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2018	Change
Revenue	305.8	271.5	34.3
Core Operating Profit	59.4	50.3	9.0
Profit attributable to owners of parent	67.1	54.4	12.7

# **Revenue and Core Operating Profit**

The increase in revenue was the result of global strategic products in Europe and the U.S. and new product groups in Japan steadily penetrating into the market and strong sales in Asia, mainly in China, despite the impact of reductions in drug price standards in Japan, etc. The increase in core operating profit was the result of growth in sales of global strategic products and the improved share of profit (loss) of investments accounted for using equity method, despite increases in selling, general and administrative expenses and research and development expenses.

# Profit Attributable to Owners of Parent

The increase in profit attributable to owners of parent was owing to an increase in profit from discontinued operations due to recording of a gain on sale of investments in subsidiaries associated with the transfer of Kyowa Hakko Bio Co., Ltd. shares, despite a decrease in profit from continuing operations resulting from the impairment losses and business restructuring expenses recorded in the fiscal year under review, while there were a gain on sale of investments in subsidiaries associated with the transfer of Kyowa Medex Co., Ltd. (currently Hitachi Chemical Diagnostics Systems Co., Ltd.) shares and a reversal of impairment losses recorded in the previous fiscal year.



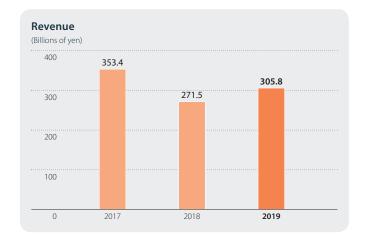
Revenue by geographic region is presented in the table below.

	(Billions	(Millions of U.S. dollars*)	
	2019/12	2018/12	2019/12
Japan	¥186.2	¥183.5	\$1,700
International	¥119.6	¥ 88.0	\$1,092
Americas	49.7	23.0	454
Europe	42.2	42.3	385
Asia	27.6	22.5	252
Others	0.1	0.2	1
Total consolidated revenue	¥305.8	¥271.5	\$2,791

\* U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥109.55=U.S.\$1, the approximate exchange rate at December 31, 2019.

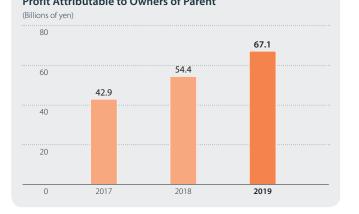
# Performance by Geographic Region Japan

Revenue in Japan increased from the previous fiscal year mainly due to the growth in sales of new product groups, despite various factors including the reduction in drug price standards implemented in April 2018 and October 2019, the impacts of generics and rival products, as well as the impact of switching to Darbepoetin Alfa Injection Syringe [KKF], an authorized generic of Nesp, a renal anemia treatment drug whose patent has expired, following that drug's launch in August 2019.





Profit Attributable to Owners of Parent



• Darbepoetin Alfa Injection Syringe [KKF] achieved steady market penetration in line with rapid progress in switching from a core product Nesp.

 Revenue from long term NHI products such as ALLELOCK, an anti-allergy agent, CONIEL, a hypertension and angina pectoris drug, and Depakene, an anti-epileptic drug, decreased compared to the previous fiscal year due mainly to the impact of the market penetration of generics.

• Revenue from new product ORKEDIA, a treatment for secondary hyperparathyroidism, which was launched in May 2018, increased. Meanwhile, revenue from REGPARA, a treatment for secondary hyperparathyroidism, decreased due to factors such as switching to ORKEDIA and the impact of rival products.

- Firm growth in revenue was also realized for G-Lasta, an agent for decreasing the incidence of febrile neutropenia, ROMIPLATE, a treatment for chronic idiopathic thrombocytopenic purpura, Dovobet, a topical combination drug for psoriasis vulgaris, LUMICEF, a treatment for psoriasis, and Nouriast, an antiparkinsonian agent, among others.
- Rituximab BS [KHK], an anticancer agent, launched in January 2018, has achieved
  market penetration and sales growth as planned.
- In December 2019, HARUROPI, a Parkinson's disease treatment patch, and Crysvita, a treatment for FGF23-related diseases were launched.

# Overseas

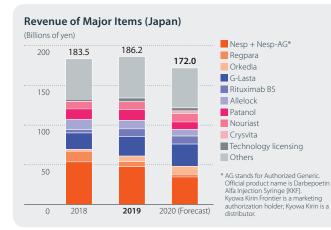
Revenue from international business increased compared to the previous fiscal year due to the steady growth of global strategic products that were launched in 2018.

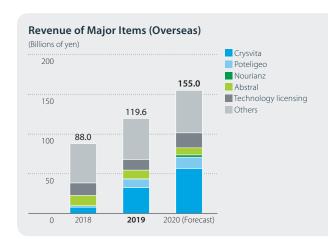
- In the Americas and Europe, sales of Crysvita, a treatment for X-linked hypophosphatemia whose sales commenced in the U.S. and Europe in April 2018, have continued to grow steadily since the product's launch, and the number of patients receiving the drug have also been increasing steadily. Furthermore, in the U.S., Poteligeo, an anticancer agent which was launched in October 2018, has also been penetrating the market favorably, and Nourianz (product name in Japan: Nouriast), an antiparkinsonian agent, were launched in October 2019.
  Revenue from Asia increased from the previous fiscal year, due to the growth of REGPARA for the treatment of secondary hyperparathyroidism particularly in China as well as the start of sales of Neulasta (product name in Japan: G-Lasta), an agent for decreasing the incidence of febrile neutropenia, and other products, from January 2019 in the Middle East.
- Licensing revenue decreased from the previous fiscal year, reflecting the recording of the gain on sales of the Priority Review Voucher in 2018, despite an increase in royalties revenue from AstraZeneca in relation to benralizumab.

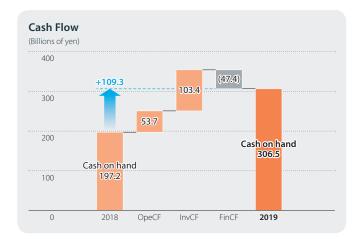
# **Cash Flow**

Cash and cash equivalents as of December 31, 2019 were ¥20.8 billion, an increase of ¥4.9 billion compared to the balance of ¥15.9 billion as of December 31, 2018. The main contributing factors affecting cash flow during the fiscal year under review were as follows:

- Net cash provided by operating activities was ¥53.7 billion, a 4.5% decrease compared to the previous fiscal year. Major inflows included profit before tax from continuing operations of ¥44.5 billion and depreciation and amortization of ¥18.8 billion. Major outflows included income taxes paid of ¥22.7 billion.
- Net cash used in investing activities was ¥0.9 billion, a 97.7% decrease compared to the previous fiscal year. Major inflows included proceeds from sale of investments in subsidiaries associated with the transfer of Kyowa Hakko Bio Co., Ltd. shares of ¥105.1 billion (included in net cash provided by investing activities from discontinued operations) and the collection of loans receivable of ¥24.3 billion. Major outflows included ¥104.4 billion for a net increase in loans receivable from parent, ¥14.2 billion for purchase of intangible assets, and ¥7.0 billion for purchase of property, plant and equipment.
- Net cash used in financing activities was ¥47.4 billion, a 187.1% increase compared to the previous fiscal year. The main outflows included ¥22.6 billion for purchase of treasury shares and dividends paid of ¥21.7 billion.







# Financial Position

# Assets

Assets as of December 31, 2019, were ¥784.5 billion, an increase of ¥42.5 billion compared to the end of the previous fiscal year.

- Non-current assets declined from the end of the previous fiscal year by ¥20.3 billion to ¥335.8 billion, due mainly to Kyowa Hakko Bio Co., Ltd. and its subsidiaries being excluded from the scope of consolidation, despite an increase in property, plant and equipment resulting from the application of IFRS 16 "Leases," etc.
- Current assets increased from the end of the previous fiscal year by ¥62.8 billion to ¥448.6 billion due mainly to an increase in loans receivable from parent as fund management, etc. resulting from the transfer proceeds, etc. of Kyowa Hakko Bio Co., Ltd. despite a decrease due to Kyowa Hakko Bio Co., Ltd. and its subsidiaries being excluded from the scope of consolidation.

## Liabilities

Liabilities as of December 31, 2019, were ¥106.2 billion, an increase of ¥13.8 billion compared to the end of the previous fiscal year, due mainly to an increase in other financial liabilities resulting from the application of IFRS 16 "Leases," despite a decrease due to Kyowa Hakko Bio Co., Ltd. and its subsidiaries being excluded from the scope of consolidation.

# Equity

Equity as of December 31, 2019, was ¥678.2 billion, an increase of ¥28.6 billion compared to the end of the previous fiscal year, due mainly to an increase resulting from the recording of profit attributable to owners of parent, despite a decrease due to a payment of dividends as well as implementation of shareholder return measures such as repurchase and cancellation of treasury shares, etc.

As a result, the ratio of equity attributable to owners of parent to total assets was 86.5%, a decrease of 1.1 percentage points compared to the end of the previous fiscal year.

# FY2016-2020 Mid-term Business Plan Targets

 Sales of global strategic products grew steadily in the US and Europe. The overseas revenue ratio, a key measure of the Company's efforts to leap forward and become a Global Specialty Pharmaceutical Company (GSP), increased to 39.1% in the fiscal year under review, up 6.7 percentage points from 32.4% in the previous fiscal year.

Core operating profit, an important indicator of sustainable growth, came to ¥59.4 billion in fiscal 2019 owing mainly to the upswing in global strategic product sales. This was ¥9.0 billion higher than the ¥50.3 billion recorded in fiscal 2018.
ROE, a benchmark used to evaluate efforts to increase shareholder value, improved to 10.1% in the fiscal year under review, up 1.5 percentage points from 8.6% in the previous fiscal year. This improvement largely reflected the gain on sales of investments in subsidiaries associated with the partial transfer of shares of Kyowa Hakko Bio Co., Ltd.

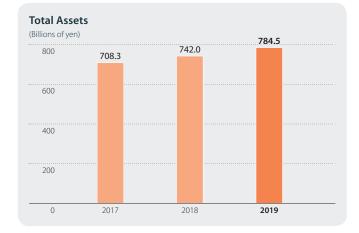
# **Capital Requirements and Financing**

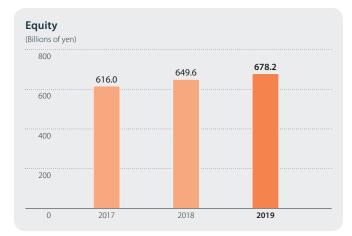
The Group mainly uses funds derived from operating activities to finance its investments.

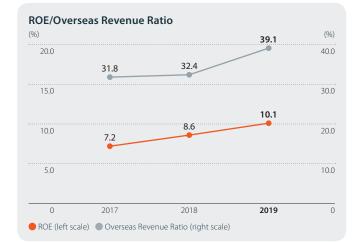
The Kyowa Kirin Group's capital requirements mainly consist of purchases of raw materials for manufacturing products, purchases of goods and supplies, and operating expenses such as manufacturing expenses and selling, general and administrative expenses. Principal operating expenses consist of payroll costs such as wages and bonuses, research and development expenses and promotional expenses. The Kyowa Kirin Group continuously makes capital investments for purposes such as expanding and streamlining production facilities and strengthening research and development capabilities. In addition, strategic investments are made to maximize the development pipeline and product portfolio value inclusive of new candidate substances and product lineup.

When procuring funds to support business activities, Kyowa Kirin leads to secure stable, low-cost capital for the Kyowa Kirin Group. We have implemented a global cash management system (CMS), which we use to support the efficient use of funds and reduction of financing costs through approaches such as capital pooling.

Kyowa Kirin works diligently to upgrade and expand financing methods in a bid to quickly undertake strategic investments. In addition to securing a commitment line of credit, the Company maintains a short-term credit rating sufficient to meet its funding requirements and is able to procure funds through the issuance of domestic commercial paper. Utilizing these and other procurement methods, Kyowa Kirin is in a position to quickly undertake strategic investments that exceed the Group's cash in hand. We are also taking measures to improve our financial strength and increase our creditworthiness while considering the funding environment and other factors.



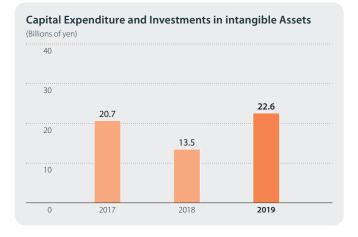




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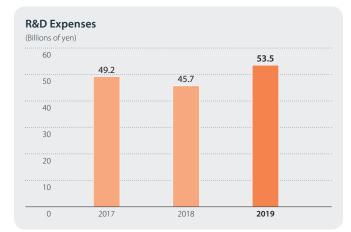
# Capital Expenditure and Investments in Intangible Assets

As a basic policy, Kyowa Kirin implements capital expenditure strategically in consideration of achieving a desirable balance between it and depreciation. Capital expenditure and investments in intangible assets for the fiscal year ended December 31, 2019 stood at ¥22.6 billion, an increase of ¥9.1 billion (67.4%) compared to the previous fiscal year. Depreciation and amortization for the fiscal year amounted to ¥18.8 billion, an increase of ¥2.6 billion (15.7%) compared to the previous fiscal year.



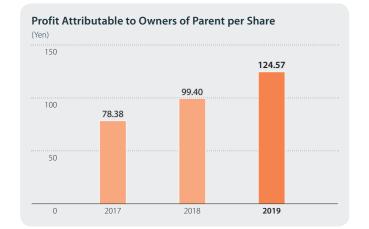
# **R&D** Expenses

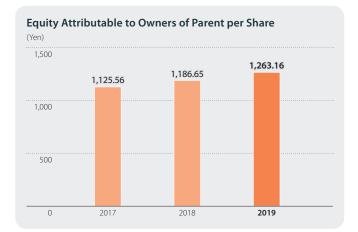
R&D expenses for the fiscal year ended December 31, 2019 stood at ¥53.5 billion, an increase of 17.2% compared to the previous fiscal year, due mainly to increase in the late phase development such as KHK4083, RTA 402 and KW-6356. The ratio of R&D expenses to sales for the year came to 17.5%, an increase of 0.7 percentage points from 16.8% the previous fiscal year.



# Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2019 stood at ¥124.57 compared to ¥99.40 the previous year. Equity attributable to owners of parent per share on December 31, 2019 totaled ¥1,263.16 compared to ¥1,186.65 on December 31, 2018.







# Management Plan

A wide range of healthcare-related needs, including the reduction of medical costs and increased use of generic products, have become issues of universal concern in recent years. At the same time, nations throughout the world continue to await the development of innovative drugs that address unmet medical needs. Against this backdrop, research and development-oriented pharmaceutical companies are being forced to adapt swiftly to changes in their operating environment and to shift their businesses to the world stage.

For its part, the Kyowa Kirin Group is committed to contributing to the health and well-being of people around the world and becoming a Japan-based world-leading R&D-focused life science company by engaging in "Creating Shared Value (CSV)" management that helps boost corporate value. To this end, the Group will continue to rely on innovation as its foundation, utilize state-of-the-art biotechnology to changes and roll out products and services that meet true customer needs and have high unique value. Using cutting-edge biotechnology centered on antibody technology, the Group has made nephrology, oncology, immunology/ allergy and the central nervous system (CNS) the focus of its research and development. By investing resources efficiently, the Group is also working to further speed up the creation of new medical value and drug creation.

During the fiscal year under review, the Kyowa Kirin Group took steps to achieve the four strategic priorities set out in its five-year Mid-term Business Plan announced in January 2016. In specific terms, every effort was made to improve global competitiveness, create innovation, continuously improve operational excellence and contribute to the health and well-being of people. In 2019, the Group expanded sales of Crysvita and POTELIGEO in the West while successfully launching Nourianz (product name in Japan: Nouriast) in the US. Through these means, the Group took its first step toward becoming a Global Specialty Pharmaceutical Company (GSP). Looking ahead, the Group will continue with efforts to achieve its four strategic priorities while maximizing the value of global strategic products and establishing a robust foundation as a GSP.

Under the first strategic priority of improving global competitiveness, the Group will work to further penetrate the market and expand business areas focusing on Europe and the US in order to maximize the value of global strategic products. In addition, the Group will strive vigorously to build a robust production platform, put in place a global standard quality control and assurance structure and systems, and

engage in supply chain management in a bid to deliver a stable supply of high-quality pharmaceuticals worldwide.

Under the second strategic priority of creating innovation, by combining the expertise gained in each of the four categories of nephrology, oncology, immunology/allergy, and CNS, with the cutting-edge technology platforms for drug discovery, the Kyowa Kirin Group will build an attractive development pipeline while focusing especially on efforts to uncover global product candidates that can follow in the footsteps of its three global strategic products. Currently, an international joint phase II clinical trial is under way for the anti-OX40 fully human antibody KHK4083, which was discovered using POTELLIGENT technology that facilitates the production of antibodies with enhanced antibody-dependent cellular cytotoxicity (ADCC) activity, and human antibody-producing technologies, targeting moderate to severe atopic dermatitis. In addition, RTA 402 (generic name: bardoxolone methyl), a small-molecule compound licensed from Reata Pharmaceuticals, Inc., is presently undergoing phase III clinical trials in Japan for the treatment of diabetic kidney disease. RTA 402 has been granted "SAKIGAKE (Priority Review) Designation" by Japan's Ministry of Health, Labour and Welfare.

Under the third strategic priority of continuously improving operational excellence, the Kyowa Kirin Group is working to further entrench its global management structure under the "One Kyowa Kirin" banner on an ongoing basis. In order to maximize the value of global strategic products in Europe, the Middle East, Africa and North America as well as mainstay and new products in the Asia/Pacific region, headquarter companies spearhead efforts to strengthen the governance function in each region. In Japan, the Group will strive to ensure the further penetration of such new products as HARUROPI and Crysvita. At the same time, energies will be directed toward increasing the pace of area strategy implementation with a view to meeting the needs of community health initiatives. Complementing these measures, the Kyowa Kirin Group will endeavor to promote thoroughgoing compliance as well as health-centric business management. While maintaining its focus on providing an environment in which diverse personnel can mutually respect one another while playing an active role, the Group will also emphasize the need to nurture a corporate culture that befits a GSP.

Under the fourth strategic priority of contributing to the health and well-being of people, the Kyowa Kirin Group is working to engage in efforts that involve discovering innovative drugs that satisfy unmet medical needs, uncovering clinical evidence through research, providing additional indications and dosage formulations of products, and also ensuring stable supplies of high-quality products while taking action in response to societal demands for lower medical costs as part of its CSV management.

Group company Kyowa Kirin Frontier Co., Ltd. launched Darbepoetin Alfa Injection Syringe [KKF], an authorized version of our flagship product Nesp in August 2019. In its biosimilars business, which is a joint venture with FUJIFILM Corporation, Mylan N.V., with which Kyowa Kirin maintains a sales alliance relationship, has engaged in the sale of an adalimumab biosimilar of the fully human anti-TNF- $\alpha$  monoclonal antibody in Europe since 2018. In this manner, the Group will continue to manufacture and supply high-quality products that address societal needs.

As announced in October 2019, steps were taken to voluntarily recall the antineoplastic drug, Mitomycin-C Kyowa, as a precautionary measure against deviations in the aseptic manufacturing processes undertaken at the Hofu Plant of Kyowa Hakko Bio Co., Ltd. The decision to implement this recall was based on concerns that the product's sterility could not be guaranteed. Meanwhile, the Group is undertaking a final inspection to confirm the quality of all of its products prior to shipment. Treating this incident with the utmost seriousness, the Group assembled an investigative committee led by third parties to objectively and independently scrutinize the facts and ascertain the root cause.

In addition to uncovering the root cause of the incident, and working in conjunction with Kyowa Hakko Bio, ongoing efforts will be made to identify any and all quality assurance-related issues and to put in place preventive measures. Building on the internal investigation and subsequent discussions, the Group will not only strengthen its manufacturing and quality assurance structure and systems to prevent a recurrence, but also take steps to reinforce the governance function Group-wide. In particular, the Group will (1) build a robust quality assurance system as a top management priority, (2) improve the Group's risk management capabilities, and (3) thoroughly implement the necessary improvement measures to fulfill the Group's responsibility as a manufacturer and marketer of pharmaceuticals while addressing the critical need to reform the Group's corporate culture. Through these means, the Kyowa Kirin Group will redouble its efforts to ensure the quality of its products and prevent a repeat of this incident.

# Outlook for 2020

Consolidated financial earnings forecasts for fiscal 2020 are for revenue of ¥327.0 billion (up 6.9% compared to fiscal 2019), core operating profit of ¥65.0 billion (up 9.5%), profit before tax of ¥63.0 billion (up 41.6%), and profit attributable to owners of parent of ¥49.0 billion (down 27.0%).

In Japan, although we expect to be impacted from such effects as switching to Darbepoetin Alfa Injection Syringe [KKF], an authorized generic of NESP, our core product, and the reduction in drug price standards, revenues are expected to increase compared to fiscal 2019 due to expected growth in the global strategic products Crysvita and Poteligeo, which were launched in the U.S. and Europe in 2018, as well as Nourianz, which was launched in the U.S. in 2019. Moreover, although we expect an increase in selling expenses for expanding revenues and maximizing the value of global strategic products, core operating profit is expected to increase due to growth in overseas revenue.

• A year-on-year increase is forecasted for profit before tax as a result of a decrease in other expenses in addition to an increase in core operating profit.

• A year-on-year decline is forecasted for profit attributable to owners of parent for fiscal 2020 because of the absence of the profit from discontinued operations recorded in fiscal 2019 in connection with the transfer of shares of Kyowa Hakko Bio., Ltd.

• Concerning cash flows from operating activities, net cash provided is expected to be lower in the next fiscal year than fiscal 2019 as the payment of income taxes is expected to be higher, despite higher expected profit before tax compared to fiscal 2019.

Concerning cash flows from investing activities, the Company expects an increase in net cash used compared to fiscal 2019 because of an expected increase in cash used in the purchase of property, plant and equipment, and intangible assets.
Concerning cash flows from financing activities, the Company expects a decrease in net cash used compared to fiscal 2019 in which the purchase of treasury shares was implemented. As regards the purchase of treasury shares and the sourcing of funds, we will continue to remain flexible and act as appropriate for the economic and funding environment.

As a result of the above, cash and cash equivalents as of the end of fiscal 2020 are expected to be at the same level as at the end of fiscal 2019.

# **Profit Distribution**

The Company regards the return of profits to its shareholders as one of its key management priorities.

Our basic policy on profit distribution is to deliver stable dividends, while maintaining fully adequate internal reserves for future business expansion and other developments, and considering factors such as our consolidated results for the respective fiscal years and the dividend payout ratio. We plan to improve our capital efficiency by acting rapidly with regards to purchase of treasury shares. The Company intends to use internal reserve funds for investments required to drive new growth, such as those in research and development, capital expenditures, and our development pipeline's expansion that are expected to contribute to the improvement of our future corporate value.

With respect to the dividend policy, we will aim to achieve a stable and continuous increase in the level of dividend payment according to growth in profits, guided by the consolidated dividend payout ratio of 40% stated in the FY2016-2020 Mid-term Business Plan.

In accordance with the above-mentioned policy, the Board of Directors has resolved to pay a year-end dividend for fiscal 2019 of ¥22 per share. As a result, we increased dividends for the third year in a row. The annual dividend was determined to be ¥42 per share, an increase of ¥7 per share compared to the previous fiscal year, including an interim dividend of ¥20 per share.

For the fiscal year ending December 31, 2020, we expect to pay an annual dividend of ¥44 per share, an increase of ¥2 per share compared to the fiscal year under review, consisting of an interim dividend of ¥22 per share and a year-end dividend of ¥22 per share.

# **Risk Factors**

With respect to the Kyowa Kirin Group's business performance and financial position, the major risks that may significantly affect investors' assessments include, but are not limited to, those described below. The Group recognizes that these risk events may occur and takes steps to prevent the occurrence of those risk events that it can control through its risk management system. At the same time, the Group will do its utmost to respond in the event of the occurrence of these risk events.

\* Items in this section dealing with future events reflect the assessment of the Group at the end of the current consolidated fiscal year (December 31, 2019).

## (1) Risks Associated with R&D Investment

As a pharmaceutical company that discovers new drugs the Group aims to build an attractive development pipeline centered on four major modalities (next-generation therapeutic antibodies, nucleic acid drugs, new small molecule drugs and regenerative therapeutics). As part of its drug discovery and research processes, the Group is also actively incorporating open innovation, which utilizes information and knowledge from outside the Group, and working together with universities, medical institutions, and venture companies to promote joint R&D of new drugs from an early stage. 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 the expected efficacy is not confirmed or for safety and other reasons. In such cases, the Group's future growth and profitability may decline and its business performance and financial position may also be adversely affected.

# (2) Risks Related to Intellectual Property Assets

The Group strictly manages its intellectual property assets and closely monitors infringement by third parties. Nevertheless, in cases where the Group's intellectual property rights are infringed upon, sales revenue of the Group's products or licensing revenue could decline earlier than forecast and the Group's business performance and financial position could be adversely affected. Furthermore, while the Group pays particular attention not to violate the intellectual property rights of others, in cases where the Group is subject to litigation based on allegations of infringement of intellectual property rights, the Group may be required to cease such activities, and pay compensation and/or settlement, and our business activities, business performance and financial position may be adversely affected.

# (3) Risks of Side Effects

Pharmaceutical products undergo strict safety assessments at the development stage and are approved following reviews by the relevant national regulatory authorities. However, following launch, there have been cases whereby previously unknown side effects based on the accumulated drug usage record become apparent. In such cases where unexpected side effects are discovered following launch, the Group's business performance and financial position may be adversely affected.

## (4) Risks Related to Pharmaceutical Regulations

The Group's pharmaceuticals business operates under the pharmaceutical regulatory authorities of the countries in which we operate. In Japan, the Group's business performance and financial position could be adversely affected by trends in the reform of Japan's healthcare system, such as the promotion of generic drugs usage, in addition to price reductions under the public pharmaceutical price system.

As for overseas pressure to suppress medical cost is becoming higher, and in cases where a price reduction cannot be compensated for by an increase in volumes, the Group's business performance and financial position could be adversely affected.

# (5) Legal Regulation Risks

In the course of carrying out its operations in Japan and overseas, the Group must strictly comply with the legal regulations of each of the countries in which it operates. If new product development is delayed or stopped, or manufacturing or sales activities are restricted, because we were unable to observe these legal regulations, this could lead to the Group's credibility being damaged.

In the Group, compliance is not only legal compliance. The "Kyowa Kirin Group Code of Conduct" stipulates the general actions that each and every one of its executives and employees must take to quickly identify the needs of society and to act ethically. To strengthen compliance, the Group CSR Committee, which convenes on a quarterly basis, promotes continuous improvement by discussing the status of compliance and the progress made with measures to address important issues, and reporting to the Board of Directors. We also have in place a whistle-blowing hotline to prevent or else detect and correct at an early stage any acts that would be in violation of the Group Code of Conduct or significantly impair the Group's brand value.

# (6) Risks of Fluctuations to Foreign Exchange Rate

The Group conducts transactions denominated in foreign currencies such as receiving income from overseas sales, licensing-out of technologies overseas, and acquiring raw materials overseas. Therefore, any sudden change in exchange rates could adversely affect the Group's financial position and business performance. Fluctuations to the exchange rate could also affect our ability to be price competitive on products sold in markets shared with overseas competitors.

In addition, the gains and losses, and assets and liabilities of overseas-consolidated subsidiaries converted in local currencies are translated into yen for the preparation of the consolidated financial report. The exchange rate at the time of conversion could have an effect on values following currency conversion.

# (7) Disaster-related and Accident-related Risks

Natural disasters, such as earthquakes and typhoons, pandemics such as influenza, large-scale electrical blackouts, and other events potentially occurring in different locations could result in the suspension of business activities at the Group's headquarters, plants, research facilities or offices. The Group handles substances that are subject to various legal regulations and guidelines, and as a result of natural disasters, etc., these substances could enter the external environment and cause damage to the surrounding area. In cases where serious accident or disaster occurs, it might result in significant damage and negatively impact the Group's position of trust in society. Additionally, the Group's business performance and financial position could be adversely affected. To maintain a stable supply of pharmaceuticals even at times when normal business activities are beset with ongoing difficulties, the Group has formulated a Business Continuity Plan (BCP) that is being continuously improved through BCP training and workshops.

## (8) Litigation-related Risks

A lawsuit filed against the Group concerning our business activities (e.g., side effects of pharmaceutical products, product liability, labor-related problems, fair trade), could have a negative impact on the Group's operating results, financial condition, etc.

# (9) Security and Information Management Risks

As the Group utilizes a variety of information systems, in the event of unauthorized system access or following a cyberattack confidential information may be leaked outside the Company or the system rendered inoperable. As a countermeasure against cybersecurity threats that are becoming more diverse and sophisticated with each passing year, the Group is promoting initiatives to improve its level of information security under a Group information security management system. In addition to technical measures against cybersecurity threats, we are conducting education and training to raise employees' awareness with regard to information security, while promoting continuous improvements to ensure the proper management of information.

# (10) Environmental Risks

The Group ensures thorough compliance with environment-related laws and regulations regarding air, water quality, noise, vibrations, offensive odors, soil contamination, ground subsidence, waste, etc. However, in the event that environmental-preservation problems such as pollution arise, or if a revision in the relevant laws occurs, leading to costs incurred in having to provide compensation to the surrounding areas, fix the environmental damages, or invest in new facilities the Group's business performance and financial position could be adversely affected.

## (11) Risks Related to Alliances with Other Companies

The Group enters into alliances with other companies, in the form of joint developments, joint marketing and the establishment of technology partnerships or joint ventures, and outsources operations relating to the supply of raw materials for pharmaceutical products, production, logistics and marketing to other domestic and overseas suppliers. However, if problems arise and/or the Group fails to achieve results from such alliances or operations outsourcing for any reason, or experiences a contract alteration or alliance termination, the Group's business performance and financial position could be adversely affected. Having stipulated compliance clauses in contracts, the Group demands that its suppliers ensure thorough compliance. Furthermore, the attitudes and actions required of the suppliers that make up the Group's supply chains are stipulated in the "Supplier Code of Conduct" and understood by the suppliers. In addition to conducting questionnaire surveys on the items described in the Supplier Code of Conduct and feeding the results back to suppliers, the Group is working on activities designed to ascertain the actual status of compliance activities and improve the status of those activities.

# (12) Risks Related to Securing and Training Personnel

Based on matrix structure that is organized both by region-Japan, EMEA (Europe, Middle East, Africa), North America and Asia/Oceania-and transregional function, the Group is promoting the establishment of its global management system, "One Kyowa Kirin" 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 adversely affect the continuation of its business activities. Having established the Kyowa Kirin Group Talent Management Policy, the Group has specified the relationship between employees and the Company and a globally common approach to the development of employee skills.

# (13) Risks Related to Stable Supply

In developing its business on a global basis, the Group is advancing the building of a robust production system. However, if technical or legal issues arise in manufacturing or logistical facilities, or stoppages arise in the supply of raw material and fuel, leading to the supply of our products being stopped, delayed, or being insufficient to meet a greater-than-expected growth in demand the Group's business performance and financial position could be adversely affected.

# (14) Risks Related to Competition and Patent Expiration

Revenue could decline as a result of competition between the Group's and other companies' products and/or the entry of generic products following the expiry of the Group's patents. In the event that new product sales do not cover the decrease in sales associated with the expiry of the substance patent for Nesp, the renal anemia treatment that is one of its flagship products, the Group's business performance and financial position could be adversely affected.

# (15) Risks Related to Overseas Business Development

Based on its global management system, the Group is promoting the global development of its business and obtained U.S. approval for two of its global strategic products, Crysvita and Poteligeo, in 2018 and for its Parkinson's disease treatment Nourianz (marketed as Nouriast in Japan) in 2019.

We are aiming to achieve our management goals by maximizing the value of these global strategic products, which are key drivers of growth. However, those goals could be difficult to achieve if the construction of our global management system for overseas business development were not to proceed as planned, if drug prices in newly entered markets and countries were to prove significantly lower than expected, if there were delays in preparations for the launch and expansion of a business area, if sales were not to penetrate a market as expected, if sales were to fall significantly below forecasts or were to differ from expectations due to quality or manufacturing issues.

Developing business overseas carries with it the risks of political instability caused by terrorism or conflicts, uncertain economic conditions, and difficulties resulting from differences in culture and/or customs. If the Group is unable to avoid such risks, the Group's business performance and financial position could be adversely affected.

# (16) Risks Related to Product Quality

Pharmaceutical manufacturing requires equipment and systems that are compatible with good manufacturing process (GMP). Data integrity is a global standard that ensures that records and analytical data relating to manufactured pharmaceuticals are perfectly stored as they are acquired. Accordingly, should a GMP inspection or an internal audit by a national authority find a serious GMP issue, such as a data integrity breach, the regulatory authority may issue instructions for production to be suspended. In addition, if for any reason there are any concerns about the safety or quality of the product with regard to the raw materials used or the manufacturing process, these may give rise to a product recall. For the stable supply of high-quality pharmaceuticals, the Group is advancing ongoing improvements to its global quality assurance system under the guidance of our global guality assurance committee. Specifically, we discuss any major guality issues reported by the companies responsible for regional operations, assess quality standards at newly selected manufacturing sites, conduct regular guality reviews of global products, regularly evaluate the activities of issue-specific global taskforces, and monitor the steps being taken to address any issues highlighted in guality audits.

In 2019, having identified facts that could affect sterility in the manufacturing process of an antiemetic agent (Mitomycin-C) at manufacturing contractor Kyowa Hakko Bio, it was determined that the sterility of Mitomycin injections could not be guaranteed, and the product was voluntarily recalled. With regard to this case, we are not only working with Kyowa Hakko Bio in investigating the cause of this product recall, but are also addressing problems in overall quality control and measures to prevent any recurrence. Furthermore, we are conducting thorough investigations of the facts and of the root cause as a group. To prevent any recurrence, we believe that we should not only strengthen our manufacturing and guality assurance systems, but also work to strengthen the governance of the corporate group. In particular regarding "creation of a strong production and guality assurance system as management's top priority,""improvement of risk management" and "reformation of corporate culture" as priority issues, we will make absolutely sure of product quality control and strive to prevent any recurrence of such incidents by thoroughly implementing the necessary improvement measures to fulfill our responsibilities as a holder of marketing authorization for pharmaceutical products.

# (17) Other Risks

In addition to the above, there are other risks that could adversely affect the Group's business performance and financial position, and they include changes to share prices and interest rates, impairment of fixed assets, etc.

Name of Company

# Network

# (As of December 31, 2019)

63

	Indirectly by the Company		
Japan			
Kyowa Medical Promotion Co., Ltd.	100%	¥50,000	Promotion and sales of pharmaceuticals
Kyowa Kirin plus Co., Ltd.	100%		Insurance, wholesale and retail
Kyowa Kirin Frontier Co., Ltd.	100%		Manufacturing and sales of pharmaceuticals
U.S.A. / Europe			
Kyowa Kirin USA Holdings, Inc.	100%	US \$76,300	Supervision and management of specific subsidiaries U.S.A.)
BioWa, Inc.	100%	US \$10,000	Out-licensing of antibody technology (U.S.A.)
Kyowa Kirin Pharmaceutical Development, Inc.	100%	US \$100	Development of pharmaceuticals (U.S.A.)
Kyowa Kirin Pharmaceutical Research, Inc.	100%	US \$100	Generation of new drug candidate substances and promotion of research alliance (U.S.A.)
Kyowa Kirin, Inc.	100%	US \$0.2	Sales of pharmaceuticals (U.S.A.)
Kyowa Kirin Canada, Inc.	100%	CA \$0.1	Sales of pharmaceuticals (Canada)
Kyowa Kirin International plc	100%	£13,849	Supervision and management of specific subsidiaries (U.K.)
Strakan International S.A.	100%	£9,720	Holding Company (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.I.	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)

Percentage Owned Directly or

Indirectly by

Share Capital (1,000)

Principal Business

Name of Company	Owned Directly or Indirectly by the Company	Share Capital (1,000)	Principal Business
Asia			
Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.	100%	CNY 246,794	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 Asia Pacific Pte. Ltd.	100%	SG \$1,000	Sales of pharmaceuticals and control of business in the Asia and

Percentage

NYOWA NITIT ASIA PACIFIC PLE, ELG.	100%	29 \$1,000	Oceania region excluding Japan (Singapore)
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)
Kyowa Kirin Pharma FZ-LLC.	100%	AED 50	Sales of pharmaceuticals (UAE)
Kyowa Kirin (Thailand) Co., Ltd.	100%	THB 100,000	Sales of pharmaceuticals (Thailand)

Japan (Equity-method affiliate)			
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	¥100,000 Development, manufacturing and sales of biosimilar pharmaceuticals	
Hitachi Chemical Diagnostics Systems Co., Ltd.	33.4%	¥450,000 Manufacturing and sales of diagnostic reagents	

Note: All of the companies are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. and Hitachi Chemical Diagnostics Systems Co., Ltd. which are affiliated companies accounted for using the equity method.

# Investor Information (As of December 31, 2019)

# 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

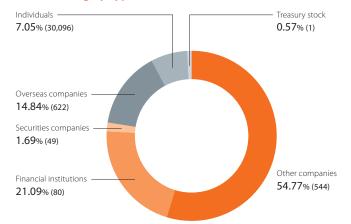
# Number of Shares of Common Stock

Authorized: 987,900,000 Issued: 540,000,000

# Number of Shareholders

31,392

# Shareholding by Type of Investor (Number)



# **Principal Shareholders**

	Number of Shares Held (Thousands)	Percentage of Tota Shares Issued (%)
Kirin Holdings Company, Limited	288,819	53.79
The Master Trust Bank of Japan, Ltd. (Trust Account)	41,567	7.74
Japan Trustee Services Bank, Ltd. (Trust Account)	22,126	4.12
Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.)*	6,809	1.27
Goldman Sachs and Company (Regular account) (Standing Proxy: Goldman Sachs Japan Co., Ltd.)	4,542	0.85
Japan Trustee Services Bank, Ltd. (Trust Account 7)	4,401	0.82
Japan Trustee Services Bank, Ltd. (Trust Account 9)	4,336	0.81
State Street Bank West Client-Treaty 505234 (Standing Proxy: Mizuho, Ltd., Settlement & Clearing Services Division)	4,216	0.79
The Nomura Trust and Banking Co., Ltd. (Trust Account)	4,146	0.77
Japan Trustee Services Bank, Ltd. (Trust Account 5)	4,080	0.76

\* The 6,809 thousand shares held by Mizuho Trust & Banking Co., Ltd. (Retirement Benefit Trust for Mizuho Bank, Ltd.) are the trust assets entrusted by Mizuho Bank for its retirement benefit trust, and voting rights for the shares are retained by Mizuho Bank. Note: The 3,053 thousand shares (0.57%) held by the Company as treasury stock are excluded from the above because treasury stock has no voting rights.

# **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.	1 <b>70.8</b> %	1 <b>46.7</b> %	<b>198.6</b> %	<b>192.7</b> %	240.1%
TOPIX Total Return Index	112.1%	112.4%	137.4%	115.5%	136.4%

# **Corporate Data**

6.5

# Corporate Data (As of December 31, 2019)

# 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: 5,267

Date of Foundation

July 1, 1949

Paid-in Capital ¥26,745 million

# **Principal Plants**

# Japan

Takasaki Plant Ube Plant

# **Overseas**

Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.

# **R&D** Network

# Japan

Tokyo Research Park Fuji Research Park Bio Process Research and Development Laboratories CMC R&D Center

# **Overseas**

Kyowa Kirin Pharmaceutical Development, Inc. (U.S.A.) Kyowa Kirin Pharmaceutical Research, Inc. (U.S.A.) Kyowa Kirin Pharmaceutical Development Limited (U.K.) Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. Kyowa Kirin Korea Co., Ltd.

Noriya Yokota

Outside Director of the Board Kentaro Uryu\*2

Outside Director of the Board Akira Morita\*2

Outside Director of the Board Yuko Haga, Ph.D.\*2

Management M	/lembers	(As of March 19	9, 2020)
management	101110 010	(15 01 14 01 11	, 2020)

# **Board Members Executive Director of** the Board. President and **Chief Executive Officer** Masashi Miyamoto, Ph.D.\*1 **Executive Director of** the Board, Executive

Vice President Yutaka Osawa \*1

Director of the Board, Senior Managing **Executive Officer** Toshifumi Mikayama, Ph.D.

Director of the Board

\*2 Independent Board Directors and Company Auditors

<b>Company Auditors</b>
Company Auditor
Hiroshi Komatsu

**Outside Company Auditor** 

**Outside Company Auditor** 

**Outside Company Auditor** 

\*1 Concurrently serves as

executive officer

**Company Auditor** 

Keiji Kuwata

Jun Arai\*2

Yuji Inoue\*2

Masaki Ueno

Managing Executive Officers Hiroshi Sugitani

Vice President,

Head, Sales & Marketing Division

Kenya Shitara, Ph.D. Director. Legal and Intellectual Property Department

**Executive Officers** 

Wataru Murata Director, Human Resources Department

# Executive Officers

Niro Sakamoto Director, General Affairs Department

> Hiroshi Sonekawa Director, Internal Audit Department

Shin-ichiro Mohri Director, Corporate Strategy & Planning Department

Mitsuo Satoh, Ph.D. Director, Medical Affairs Department

Nagoya Branch

Nobuyuki Tsukahara Director,

> Tomohiro Sudo Director, Corporate Strategy & Planning Department

Takeyoshi Yamashita, Ph.D. Director. Corporate Strategy & Planning Department

## Motohiko Kawaguchi Director, Finance Department

Yasuo Fujii

Director, Business Development Department

## Shin Inoue Director Sales & Marketing Planning Department

Fumihiko Kanai Vice President. Head, Production Division

Koichiro Ishimaru Director, Corporate Social Responsibility Management Department

# Jean-David Rafizadeh-Kabe, MD, JD Vice President, Head, Pharmacovigilance Division

Yoshifumi Torii, Ph.D. Vice President, Head, R&D Division

Hiroki Takamatsu Vice President,

Head, Quality Assurance Division