

Results Presentation Fiscal 2021

Kyowa Kirin Co., Ltd.

The logo for Kyowa Kirin, featuring a stylized 'K' icon followed by the text 'KYOWA KIRIN' in a bold, sans-serif font. The logo is positioned on an orange semi-circular background element in the bottom right corner of the slide.

KYOWA KIRIN

Agenda

Medium Term Business Plan Review - Progress in FY2021
 Medium Term Business Plan Review - Outlook for FY2022
 Shareholders Return
 Commercial Update
 R&D Update

President and Chief Executive Officer **Masashi Miyamoto, Ph.D.**

Q&A

President and Chief Executive Officer **Masashi Miyamoto, Ph.D.**

Executive Officer, Head of Finance **Motohiko Kawaguchi**

Executive Officer, Vice President, Head of R&D **Yoshifumi Torii, Ph.D.**

Executive Officer, Head of Global Product Strategy **Tomohiro Sudo**

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but the actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

This document is used only for the purpose of providing the information to investors. Though it may contain the information concerning pharmaceutical products (including products under development), it is not for the purpose of promotion, advertising, or medical advice.

Medium Term Business Plan Review Progress in FY2021

2021 Review

Provide pharmaceuticals for unmet medical needs

■ Maximize the value of G3B

- ✓ Evolved OKK matrix structure to reinforce global product axis
- ✓ Crysvida: Grew as planned. Started the preparation for the business transition in North America from Ultragenyx
- ✓ Poteligeo: Recovering the growth in the US. Delayed in market launch in EMEA
- ✓ Nourianz: Delayed market penetration in the US due to COVID-19 impact. Not approved by EMA

■ Continue to create groundbreaking new drugs

- ✓ Launched new R&D organization; Candidates developed through Open Innovation activities entered the non-clinical stage
- ✓ Next-generation strategic products development progressed; KHK4083: met the P2b PE^{*1} and entered a strategic alliance, ME-401: met the P2 PE

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

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Expanded the Corporate Culture Reform Initiatives globally
- ✓ Transitioning to the new normal working style through COVID-19
- ✓ Adopted the global DE&I Statement
- ✓ Introduced the Global Talent Management System
- ✓ Re-organized ICT system to support the operational excellence
- ✓ Developed human resources and data infrastructure for driving DX
- ✓ Adopted the revised Corporate Governance Code

Address patient-centric healthcare needs

■ Patient advocacy

- ✓ Launched regional and cross-functional collaboration on patient advocacy activities
- ✓ Implemented the Early Access Program and the Named Patient Program to improve access to medicines

■ Provide value that goes beyond pharmaceuticals

- ✓ Newly established the dedicated team to meet society's medical needs beyond pharmaceuticals

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Improved the accuracy of demand forecast and systematically organized the global production and supply system
- ✓ Raised quality awareness among all employees and fostered trust in stakeholders

■ Help to protect the global environment

- ✓ Disclosed the support for the TCFD declaration and environmental information
- ✓ Expanded the introduction of renewable energy^{*2}; reduced annual CO₂ emissions by approximately 39%
- ✓ Expanded Scope 3 disclosure data

Summary of FY2021 Results

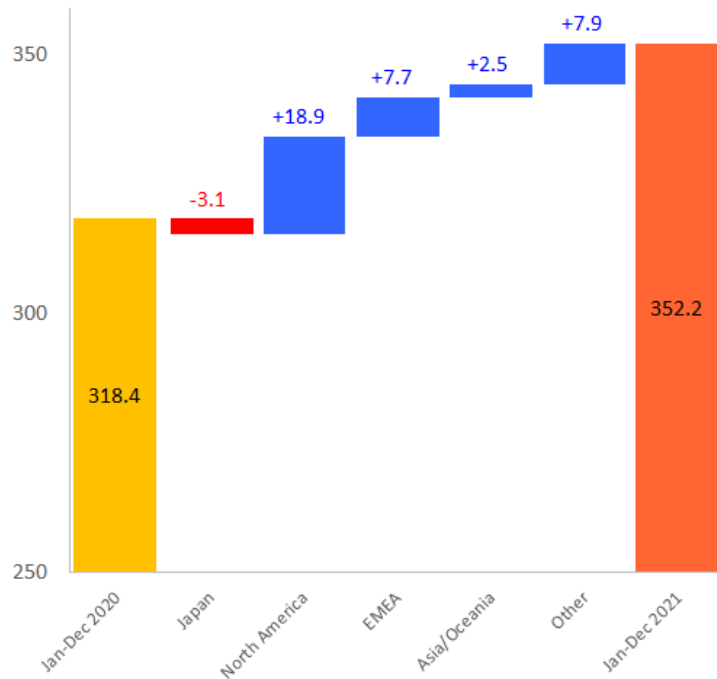
(Billion Yen / Rounded)

| | 2020 Results | 2021 Results | Changes | 2021 Plans | Achieved |
|--|-----------------------|-----------------------|--------------------|-----------------------|-------------|
| Revenue <i>[Overseas Ratio]</i> | 318.4 <i>[48%]</i> | 352.2 <i>[54%]</i> | +33.9 (+11%) | 351.0 <i>[54%]</i> | 100% |
| Gross Profit <i>[Gross Profit Margin]</i> | 237.9 <i>[75%]</i> | 264.4 <i>[75%]</i> | +26.5 (+11%) | 270.0 <i>[77%]</i> | 98% |
| SG&A <i>[SG&A Ratio]</i> | 126.6 <i>[40%]</i> | 145.6 <i>[41%]</i> | +19.0 (+15%) | 141.0 <i>[40%]</i> | 103% |
| R&D <i>[R&D Ratio]</i> | 52.3 <i>[16%]</i> | 57.7 <i>[16%]</i> | +5.4 (+10%) | 65.0 <i>[19%]</i> | 89% |
| Gain/Loss on Equity Method | 1.0 | 4.6 | +3.6 (+374%) | 1.0 | 457% |
| Core Operating Profit <i>[Core OP Margin]</i> | 60.0 <i>[19%]</i> | 65.7 <i>[19%]</i> | +5.7 (+10%) | 65.0 <i>[19%]</i> | 101% |
| Profit | 47.0 | 52.3 | +5.3 (+11%) | 50.0 | 105% |
| Return on Equity | 6.8% | 7.3% | | 7.0% | |
| Dividend Payout Ratio ^{*1} | 50.3% | 43.2% | | 48.5% | |

*1 Figure for FY2020 is based on EPS and figure for FY2021 is based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

FY2020 vs FY2021 -Revenue-

+33.9 billion yen
(incl. forex effect +9.0)



● Japan -3.1

Decrease of Nesp-AG & Nourias (Competitors) etc. and negative impact by NHI price-cut in 2020/2021 were offset by increase of Crysvida, Haruropi, Duvroq (New products) and G-Lasta (Market's recovery & penetration), etc. However, co-promotion termination of Asacol, Minirinmelt and Desmopressin was not offset and total revenue in Japan decreased.

● North America +18.9 (incl. forex effect +1.9)

All three global strategic brands were increased. Crysvida grew robustly and Poteligeo sees a recovery trend since Q2. Norianz is firmly penetrating to the market. In Q4, received US\$13.5M upfront regarding license-out of Sancuso.

● EMEA +7.7 (incl. forex effect +5.0)

Crysvida maintained steady growth supported by farther launches and label expansion to adult. Poteligeo, that started to deploy in Europe from June 2020, increased with market penetration and geographical expansion. On the other hand, Abstral decreased due to emergence of generic competitors.

● Asia/Oceania +2.5 (incl. forex effect +1.8)

Increased due to the growth of Neulasta, Nesp. Gran and Coniel etc, while Regpara shrunk due to the Chinese national tender system.

● Other +7.9 (incl. forex effect +0.3)

Sales royalties of Fasentra (Benralizumab) increased. Received \$10M upfront regarding license-out of anti-LIGHT antibody. Initiated to recognize deferred revenue of upfront payment from KHK4083 joint development/commercial agreement (\$400M) from July.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

| Item | 2020 Results | 2021 Results | Changes | Reasons | 2021 Plans | Achieved |
|------------------------------|--------------|--------------|--------------|--|------------|----------|
| Nesp + Nesp-AG* ¹ | 29.5 | 26.3 | -3.3 (-11%) | | 23.2 | 113% |
| Nesp | 4.4 | 4.0 | -0.4 (-9%) | Biosimilars' penetration & NHI price-cut | 3.8 | 105% |
| Nesp-AG | 25.2 | 22.3 | -2.9 (-11%) | | 19.4 | 115% |
| Duvroq | 0.6 | 2.6 | +2.0 (+344%) | Launched in Aug 2020 | 4.0 | 64% |
| Regpara | 3.8 | 2.9 | -1.0 (-25%) | Shift to Orkedia | 2.0 | 143% |
| Orkedia | 9.1 | 9.9 | +0.7 (+8%) | Shift from Regpara | 10.4 | 95% |
| G-Lasta | 26.7 | 29.4 | +2.7 (+10%) | Market's recovery & penetration | 29.8 | 98% |
| Poteligeo | 2.1 | 2.0 | -0.1 (-3%) | | 2.0 | 102% |
| Rituximab BS | 11.8 | 11.2 | -0.6 (-5%) | NHI price-cut | 11.5 | 97% |
| Romiplate | 7.6 | 7.3 | -0.3 (-4%) | Supply constraints (Jun 2020-Mar 2021) | 8.7 | 83% |
| Allelock | 8.6 | 8.0 | -0.5 (-6%) | Generics' penetration & NHI price-cut | 6.8 | 118% |
| Patanol | 10.6 | 10.7 | +0.1 (+1%) | | 10.9 | 98% |
| Nourias | 9.4 | 8.7 | -0.7 (-8%) | Competitors' penetration | 9.1 | 95% |
| Haruropi | 0.9 | 3.1 | +2.2 (+243%) | Launched in Dec 2019 | 4.6 | 68% |
| Crysvita | 3.8 | 7.2 | +3.4 (+90%) | Launched in Dec 2019 | 5.5 | 130% |
| Tech-licensing | 2.0 | 1.6 | -0.3 (-18%) | | 2.5 | 67% |

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

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

| Item | 2020 Results | 2021 Results | Changes | Reasons | 2021 | |
|------------------------------------|--------------|--------------|--------------|---|-------|----------|
| | | | | | Plans | Achieved |
| Crysvita | 54.4 | 78.3 | +23.9 (+44%) | [North America] Market penetration & Additional indication (TIO) [EMEA] Geographical expansion & Additional indication (Adult) [Asia/Oceania] Launched in China | 77.2 | 101% |
| North America | 42.4 | 57.7 | +15.3 (+36%) | | | |
| EMEA | 12.0 | 20.6 | +8.6 (+72%) | | | |
| Asia / Oceania | — | 0.0 | +0.0 (—) | | | |
| Poteligeo | 11.5 | 15.3 | +3.7 (+33%) | [North America] Market recovery & penetration [EMEA] Launched in Germany in Jun 2020 & Geographical expansion | 17.3 | 88% |
| North America | 10.8 | 12.7 | +1.8 (+17%) | | | |
| EMEA | 0.7 | 2.6 | +1.9 (+279%) | | | |
| Nourianz | 2.6 | 4.5 | +1.9 (+74%) | Market penetration | 6.7 | 68% |
| Abstral | 10.2 | 8.5 | -1.6 (-16%) | Generic's penetration & Supply constraints | 8.1 | 106% |
| Regpara | 8.3 | 7.4 | -0.9 (-11%) | Listed on Chinese tender list* ¹ in Oct 2021 | 9.3 | 79% |
| Tech-licensing | 17.5 | 24.5 | +6.9 (+40%) | Growth of Fasenra & Upfront revenue of anti-LIGHT antibody & Deferred revenue of KHK4083 upfront | 23.7 | 103% |
| Benralizumab Royalty* ² | 11.0 | 16.8 | +5.8 (+53%) | | | |

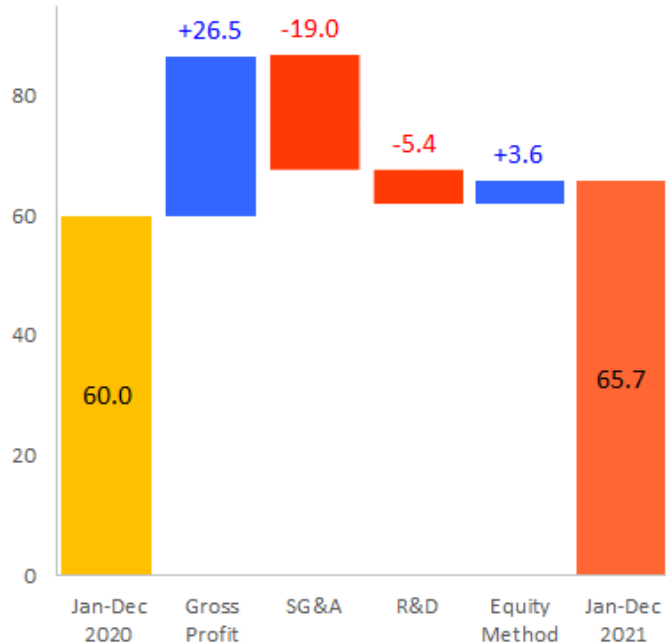
*1 Volume-Based Procurement (VBP) program that has been launched since 2018 for reducing healthcare cost in China. A few companies are selected as a supplier through a tender, while their drug prices dramatically drop down.

*2 Sales royalties of Fasenra, marketed by AstraZeneca (Including our own estimation)

* Revenue from Early Access Program (EAP) are not included in the figures above.

FY2020 vs FY2021 -Core OP-

**+5.7 billion yen
(incl. forex effect +2.5)**



- **Gross Profit +26.5 (incl. forex effect +7.6)**

Increased in conjunction with 33.9B yen rise in revenue. Margin is almost same level as FY2020 (74.7%→75.1%, +0.4%) due to forex impact related to elimination of intercompany profits on inventories (about 2.5B yen) and unplanned losses on disposal/write-off of inventories (about 3.0B yen).

- **SG&A -19.0 (incl. forex effect -4.6)**

Increased by aggressive investment in IT/Digital infrastructure and human resources for the maximization of the global 3 brands (G3B) and the early consolidation of global business foundation, in addition to Crysvita profit sharing expenses for North America. [Sales promotion -8.3 (incl. Crysvita profit sharing expenses for North America -5.9) / Labor -6.6 / Other -4.1]

- **R&D -5.4 (incl. forex effect -0.5)**

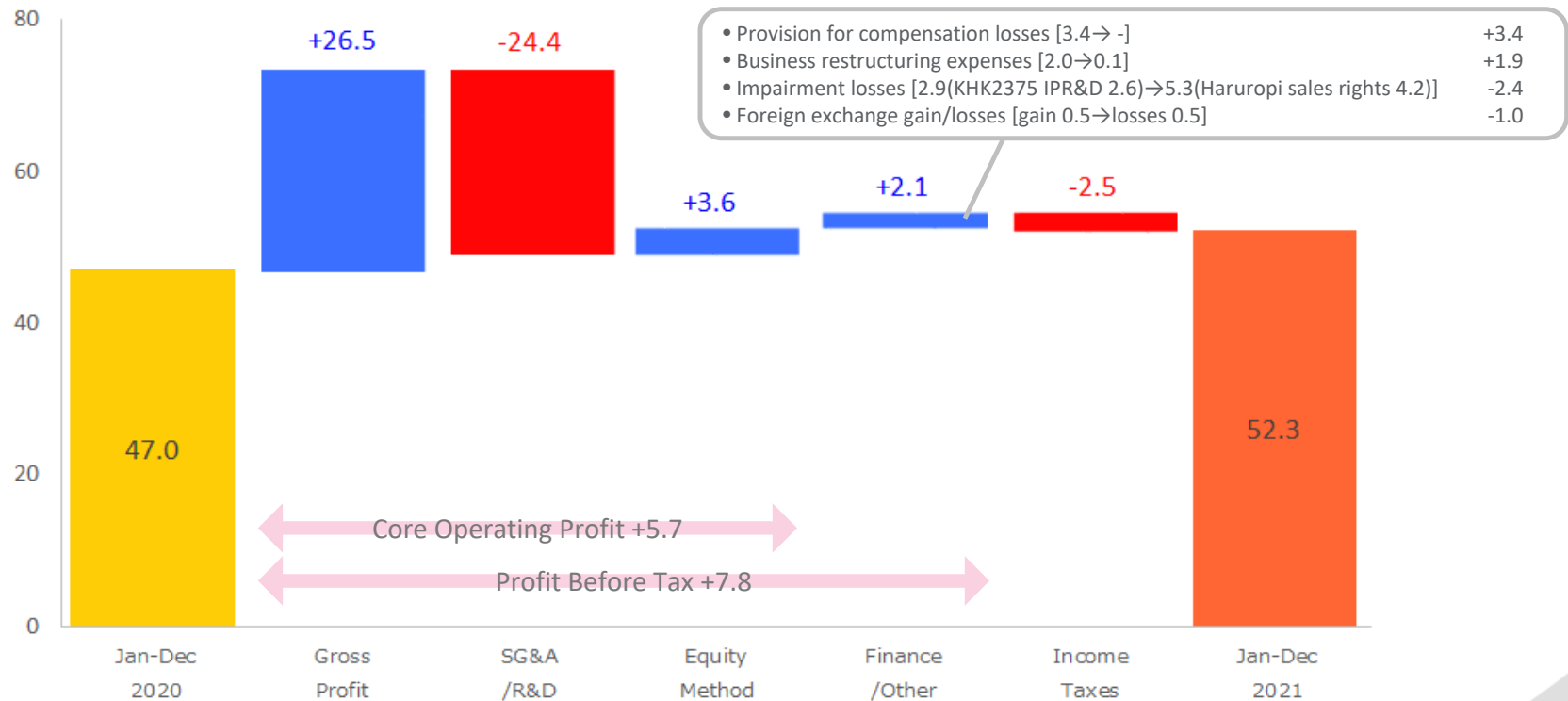
Development cost of ME-401 and KHK7791 increased.

- **Gain/Loss on Equity Method +3.6**

Hulio (FKB327/Adalimumab BS) is steadily increasing. In Q4, recorded additional deferred tax asset due to the betterment of future taxable income forecast.

FY2020 vs FY 2021 -Profit-

Profit (Jan-Dec) +5.3 billion yen



Medium Term Business Plan Review Outlook for FY2022

2022 Goals

Provide pharmaceuticals for unmet medical needs

■ Maximize the value of G3B

For the further market penetration;

- ✓ Steadily implement the Crystiva transition plan in North America and increase launched countries globally
- ✓ Develop approaches that utilize evidence and features of Poteligeo/Nourianz
- ✓ Keep evolving the OKK system through collaboration among regions, functions, and franchises

■ Continue to create groundbreaking new drugs

- ✓ Promote next-generation strategic products development and formulate marketing strategies
- ✓ Expand early-stage development pipeline using Technology axis x Disease biology axis x Open Innovation axis
- ✓ Explore external innovation through the CVC

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

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Continue the Corporate Culture Reform Initiatives globally
- ✓ Spread DE&I throughout the company
- ✓ Operate the Global Talent Management System
- ✓ Develop the strategic IT/digital environment for use
- ✓ Unify global ERP system among overseas subsidiaries
- ✓ Introduce the global budget system to improve the budgeting process
- ✓ Optimize the procurement cost

Address patient-centric healthcare needs

■ Patient advocacy

- ✓ Promote patient advocacy activities
- ✓ Penetrate "Patient Centricity" mindset in the company
- ✓ Develop a drug access policy

■ Provide value that goes beyond pharmaceuticals

- ✓ Take concrete steps to "Provide value that goes beyond pharmaceuticals"

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Enhance the production and storage capacity with global supply perspective
- ✓ Take efforts to prevent counterfeit drugs
- ✓ Complete the installation of eQMA and keep improving its operation
- ✓ Use quality risk management for preventive quality assurance
- ✓ Establish a "quality culture"

■ Help to protect the global environment

- ✓ Reduce CO₂ emissions through the expanding the renewable energy and progress in the solar power introduction plan

Summary of FY2022 Plans

(Billion Yen / Rounded)

| | 2020 Results | 2021 Results | 2022 Plans | Changes |
|--|-----------------------|-----------------------|-----------------------|-------------------|
| Revenue <i>[Overseas Ratio]</i> | 318.4 <i>[48%]</i> | 352.2 <i>[54%]</i> | 380.0 <i>[59%]</i> | +27.8 (+8%) |
| Gross Profit <i>[Gross Profit Margin]</i> | 237.9 <i>[75%]</i> | 264.4 <i>[75%]</i> | 298.0 <i>[78%]</i> | +33.6 (+13%) |
| SG&A <i>[S&G Ratio]</i> | 126.6 <i>[40%]</i> | 145.6 <i>[41%]</i> | 164.0 <i>[43%]</i> | +18.4 (+13%) |
| R&D <i>[R&D Ratio]</i> | 52.3 <i>[16%]</i> | 57.7 <i>[16%]</i> | 70.0 <i>[18%]</i> | +12.3 (+21%) |
| Gain/Loss on Equity Method | 1.0 | 4.6 | 3.0 | -1.6 (-34%) |
| Core Operating Profit <i>[Core OP Margin]</i> | 60.0 <i>[19%]</i> | 65.7 <i>[19%]</i> | 67.0 <i>[18%]</i> | +1.3 (+2%) |
| Profit | 47.0 | 52.3 | 53.0 | +0.7 (+1%) |
| Return on Equity | 6.8% | 7.3% | 7.1% | |
| Dividend Payout Ratio* | 50.3% | 43.2% | 47.9% | |

* Figure for FY2020 is based on EPS and figures for FY2021/FY2022 are based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

FY2022 Plans of Major Items (Japan)

(Billion Yen / Rounded)

| Item | 2020 Results | 2021 Results | 2022 Plans | Changes | Reasons |
|------------------|--------------|--------------|------------|--------------|---|
| Nesp + Nesp-AG*1 | 29.5 | 26.3 | 19.5 | -6.8 (-26%) | Penetration of biosimilars/HIF-PHIs & NHI price-cut |
| Nesp | 4.4 | 4.0 | 3.1 | -0.9 (-23%) | |
| Nesp-AG | 25.2 | 22.3 | 16.4 | -5.8 (-26%) | |
| Duvroq | 0.6 | 2.6 | 5.5 | +3.0 (+116%) | Market penetration (Launched in Aug 2020) |
| Regpara | 3.8 | 2.9 | 2.4 | -0.4 (-15%) | Shift to Orkedia |
| Orkedia | 9.1 | 9.9 | 10.0 | +0.2 (+2%) | Shift from Regpara |
| G-Lasta | 26.7 | 29.4 | 31.5 | +2.1 (+7%) | Market's recovery & penetration |
| Poteligeo | 2.1 | 2.0 | 1.9 | -0.1 (-3%) | |
| Rituximab BS | 11.8 | 11.2 | 9.7 | -1.5 (-13%) | NHI price-cut |
| Romiplate | 7.6 | 7.3 | 10.0 | +2.7 (+38%) | Recovery from supply constraints & Market penetration |
| Allelock | 8.6 | 8.0 | 6.6 | -1.4 (-18%) | NHI price-cut & Generics' penetration |
| Patanol | 10.6 | 10.7 | 3.9 | -6.8 (-63%) | NHI price-cut & Generics' penetration |
| Nouriastr | 9.4 | 8.7 | 8.4 | -0.3 (-3%) | Competitors' penetration |
| Haruropi | 0.9 | 3.1 | 5.5 | +2.4 (+78%) | Market penetration (Launched in Dec 2019) |
| Crysvita | 3.8 | 7.2 | 10.0 | +2.8 (+40%) | Market penetration (Launched in Dec 2019) |
| Tech-licensing | 2.0 | 1.6 | 1.0 | -0.7 (-41%) | |

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

FY2022 Plans of Major Items (ex-Japan)

(Billion Yen / Rounded)

| Item | 2020 Results | 2021 Results | 2022 Plans | Changes | Reasons |
|------------------------------------|--------------|--------------|------------|--------------|---|
| Crysvita | 54.4 | 78.3 | 105.2 | +26.9 (+34%) | Market penetration & Geographical expansion |
| North America | 42.4 | 57.7 | | | |
| EMEA | 12.0 | 20.6 | | | |
| Asia / Oceania | — | 0.0 | | | |
| Poteligeo | 11.5 | 15.3 | 22.5 | +7.3 (+48%) | Market penetration & Geographical expansion |
| North America | 10.8 | 12.7 | 15.0 | +2.3 (+18%) | |
| EMEA | 0.7 | 2.6 | 7.6 | +5.0 (+192%) | |
| Nourianz | 2.6 | 4.5 | 6.6 | +2.1 (+46%) | Market penetration |
| Abstral | 10.2 | 8.5 | 6.7 | -1.8 (-21%) | Generic's penetration |
| Regpara | 8.3 | 7.4 | 3.7 | -3.7 (-49%) | Listed on Chinese tender list* ¹ in Oct 2021 |
| Tech-licensing | 17.5 | 24.5 | 34.3 | +9.8 (+40%) | Growth of Fasenra & Deferred revenue of KHK4083 upfront (6→12months worth) |
| Benralizumab Royalty* ² | 11.0 | 16.8 | | | |

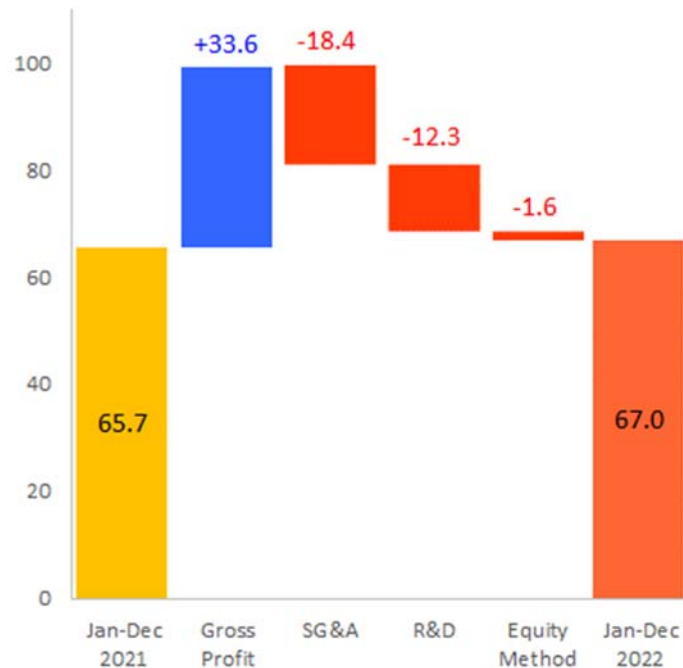
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*2 Sales royalties of Fasenra, marketed by AstraZeneca (Including our own estimation)

* Revenue from Early Access Program (EAP) are not included in the figures above.

FY2021 vs FY2022 -Core OP-

Core OP +1.3 billion yen



● Gross Profit +33.6

Due mainly to 27.8B yen rise in revenue (Japan-7.9, North America+22.1, EMEA+6.4, Asia/Oceania-1.8, Other+8.9) and absence of FY2021's negative factor on COGS. Margin is expected to improve by 3.4% (75.1%→78.4%).

● SG&A -18.4

Due to transient investment for preparation toward self-commercialization of Crysvita in North America starting from spring FY2023, in addition to growing Crysvita's profit sharing expenses. Will continue our aggressive investment in IT/Digital infrastructure and human resources for the maximization of the global 3 brands (G3B) and early consolidation of the global business base.

[Main factor of increase]

- Crysvita profit sharing expenses for North America
- Expenses for building a self-commercialization structure for Crysvita in North America (HR, Activities, IT, etc.) [approx. 5.0B yen]
- Human resources (mainly for global functions) [approx. 4.5B yen]
- IT/Digital (Global ERP, Global budget system, Global quality management system, Sales supporting system in Japan, Global IT help desk, Cyber security enhancement, etc.) [approx. 2.0B yen]
- Launch readiness for next generation strategic products [approx. 1.5B yen]

● R&D -12.3

Due to the late phase development costs of next generation strategic products centered on KHK4083.

● Gain/Loss on Equity Method -1.6

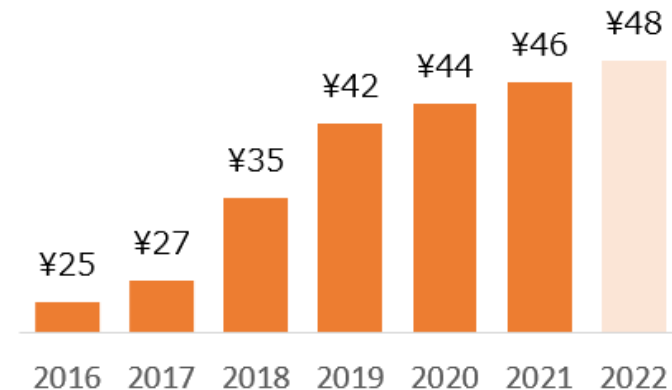
Due to the rebound from last year's positive deferred tax impact, while Hulio (FKB327 /Adalimumab BS) grows.

Shareholders Return

Shareholders Return

- ✓ FY2021 dividend is **46** yen, and FY2022 to be **48** yen (plan)
- ✓ Plans **6-year consecutive rises** since FY2017

| Year | Dividend (yen) | | Payout Ratio ^{*1} | Return on Equity | |
|--------------------|----------------|----------|----------------------------|------------------|-------|
| | Interim | Year-end | | | |
| 2016 | 12.50 | 12.50 | 25.00 | 44.9% | 5.3% |
| 2017 | 12.50 | 14.50 | 27.00 | 34.4% | 7.2% |
| 2018 | 15.00 | 20.00 | 35.00 | 35.2% | 8.6% |
| 2019 ^{*2} | 20.00 | 22.00 | 42.00 | 33.7% | 10.1% |
| 2020 | 22.00 | 22.00 | 44.00 | 50.3% | 6.8% |
| 2021 ^{*3} | 23.00 | 23.00 | 46.00 | 43.2% | 7.3% |
| 2022 (Plan) | 24.00 | 24.00 | 48.00 | 47.9% | 7.1% |

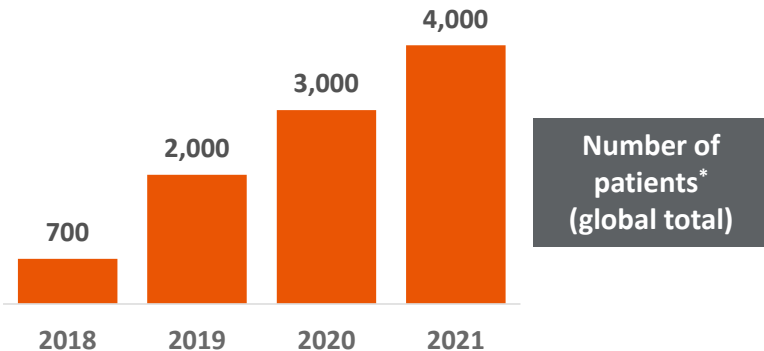
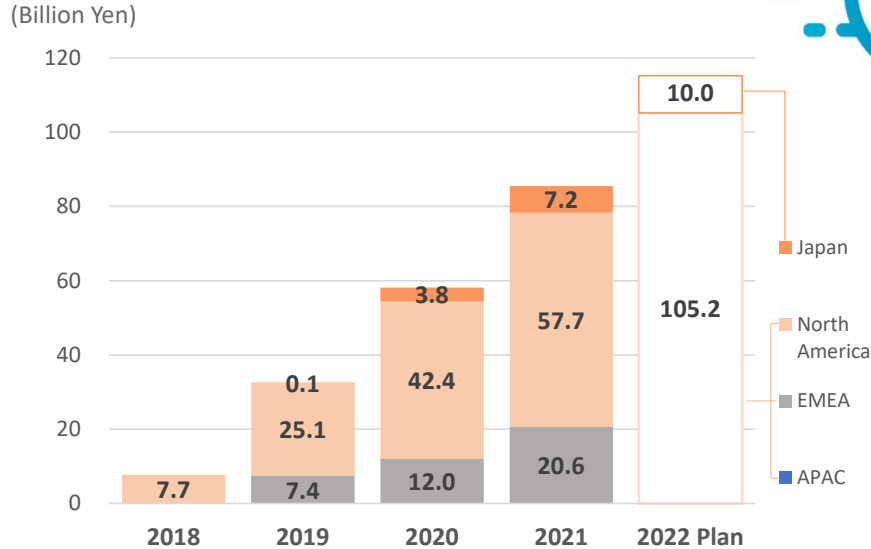


*1 FY2021/2022 figures are payout ratios against the Core EPS that is calculated based on the Core Earnings (= Profit - Other income/losses - Related income taxes)

*2 Repurchase of 10.7M own shares (¥22.6B) executed on February 6, 2019. Total return ratio for FY2019 is 67.3%.

*3 Year-end dividend of 23 yen/share will be submitted to the 99th Ordinary General Meeting of Shareholders to be held on March 25, 2022.

Commercial Update



2021 Review & 2022 Key Actions

2021

- Steady progress in patient discovery and expansion of markets and indications.
- Achieved the plan with strong growth in Japan, North America, and EMEA.

2022

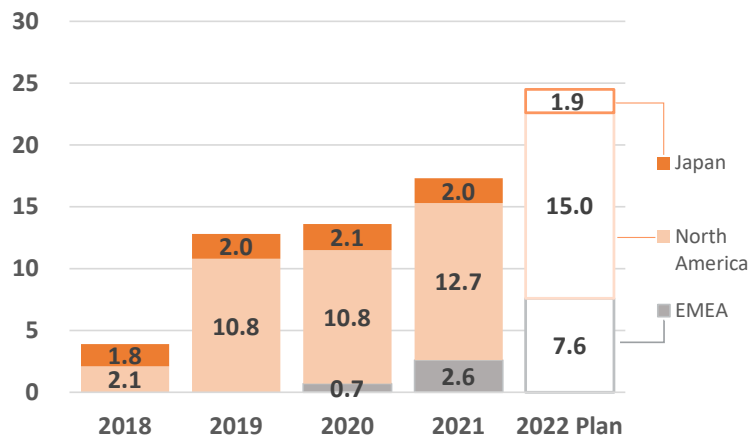
- North America : Begin full-scale preparations for sales transfer in 2023.
- EMEA : Continue to focus on expansion of market countries and indications. TIO review to be completed.

Launched Countries/Regions (XLH) as of December 31, 2021

Excluding South America
Underlines: Pediatric and Adult /Bolded types: New launches in Q4 2021

- 2018 USA , Canada, Germany, Netherland, Luxembourg
- 2019 England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, **Bahrain**
- 2020 Scotland, Oman, Kuwait, Qatar, Romania, Slovenia, France, Finland, Estonia, Spain
- 2021 Ireland, Hungary, Belgium, Saudi Arabia, Hong Kong, China, **Singapore**

(Billion Yen)



2021 Review & 2022 Key Actions

2021

- North America: In addition to mitigating COVID-19 impacts, achieved the target through campaign focused on patients with blood burden.
- EMEA: Below the target due to tough price negotiation for reimbursement under COVID-19.

2022

- Continued to negotiate for reimbursement and take actions to drive growth by using evidence such as blood burden clinical data.

Launched Countries as of December 31, 2021

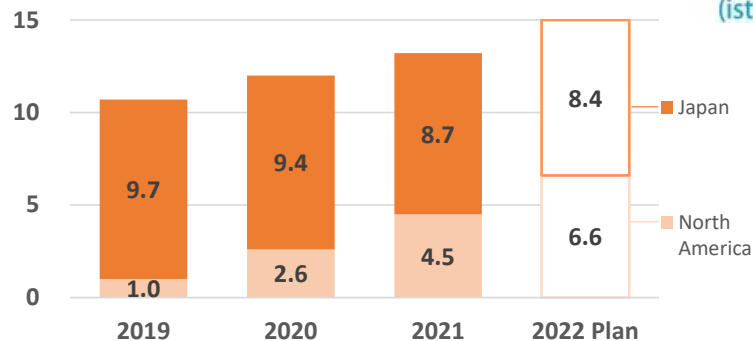
Bolded types: New launches in Q4 2021

Japan, USA, Germany, Austria, Luxembourg, Italy, Scotland, Netherlands, Belgium, Slovenia, Denmark, Spain, **Norway**

(Billion Yen)



NOURIANZ
(istradefylline) tablets



2021 Review & 2022 Key Actions

2021

- North America: Steady Growth, while below the plan. Started approach to re-targeted potential prescribers for further growth.
- EMEA: Received negative opinion from CHMP in Nov. Decided the discontinuation of development in EMEA.

2022

- North America: Ensure targeting to potential prescribers and get their deeper understanding of drug's features such as safety and mode of action.

Launched Countries as of December 31, 2021

Japan, USA

R&D Update

Upcoming Events: Next-generation Strategic Products

Underlined: Completed events from Jan 1 to Nov 1, 2021

✓: Completed events from Nov 2, 2021, to Feb 7, 2022

| Code Generic name | H1 2021 | H2 2021 | H1 2022 | H2 2022 |
|-------------------------------|---|---|--|--|
| KHK4083/ AMG 451 | <u>Atopic dermatitis P2b topline data</u> | <u>Atopic dermatitis P2b topline data</u> | Atopic dermatitis P3 FPI | |
| KW-6356 | | | Parkinson's disease P3 FPI | Parkinson's disease P2b detailed data |
| ME-401 Zandelisib | FL (3L+, mono) <u>P2 LPI</u> MZL (3L+, mono) <u>P2 FPI</u> | FL (3L+, mono) P2 topline data ✓ FL/MZL (2L+, combo) <u>P3 FPI</u> | FL (3L+, mono) P2 detailed data* CLL (2L+ combo) P2 FPI | |
| RTA 402 Bardoxolone methyl | ADPKD <u>P3 FPI (JP)</u> | Alport syndrome <u>MA (JP)</u> | DKD P3 LPO | |
| KHK7791 Tenapanor | Hyperphosphatemia under maintenance dialysis <u>P3 FPI (JP)</u> | Hyperphosphatemia under maintenance dialysis P3 topline data ✓ | Hyperphosphatemia under maintenance dialysis Submission (JP) | |

*: a more complete report of the P2 TIDAL data reported on Nov. 30, 2021, to be provided; FPI: first patient in; LPI: last patient in; LPO: last patient out; FL: follicular lymphoma; MZL: marginal zone lymphoma; iNHL: indolent B-cell non-Hodgkin lymphoma; CLL: chronic lymphocytic leukemia; ADPKD: autosomal dominant polycystic kidney disease; DKD: diabetic kidney disease; MA: marketing application

Update 1: Zandelisib Global Ph2 TIDAL Study Topline Data

Phase 2 study (TIDAL) in patients with r/r FL

Overall Response Rate (ORR)

95% CI (59.8, 79.5)

70.3%

Complete Response Rate (CR)

95% CI (25.4, 45.9)

35.2%

Duration of Response:

Insufficiently mature to estimate final DOR: with median follow-up time for response of 8.4 months, median DOR had not been reached

N=91 in the primary efficacy population for the evaluation of ORR and DOR.



Discontinuation Rate Due to Any Drug Related Adverse Event

9.9%

Adverse Events of Special Interest (Grade ≥3)

- 1.7% ALT/AST Elevation
- 1.7% Colitis
- 5.0% Diarrhea
- 2.5% Mucositis
- 0.8% Pneumonitis
- 3.3% Rash

≤ 5% each

Median Follow-up of 9.4 Months (0.8-24)

N=121 in the total study population for the evaluation of safety.

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

Update 2: Bardoxolone Methyl (RTA 402)

- **Regulatory review for Alport syndrome will continue after Q1 2022 in Japan**
 - ✓ FDA Cardiovascular and Renal Drugs Advisory Committee voted no on bardoxolone methyl's efficacy and risk-benefit for Alport syndrome in the US.
 - ✓ Kyowa Kirin is addressing the PMDA's review in Japan, considering Reata's policy.

- **LPO of the phase 3 study for DKD is expected to be in H2 2022 in Japan**
 - ✓ PMDA pointed out the importance of long-term data in discussions with Kyowa Kirin.
 - ✓ Kyowa Kirin decided on a 6-month study extension to obtain 3-year or longer data for more patients.

Update 3: Next-generation Strategic Products

As of Feb 7, 2022

| | Country / region*1 | Indication*2 | Approval year*3 | Total addressable market*4 | No. of patients*5 |
|-----------------------------|--------------------|---|---------------------|----------------------------|-------------------|
| KHK4083/ AMG 451 | NA/EU/JP | Atopic dermatitis | 2025/2026 | ★★★ | 16,000K |
| KW-6356 | NA/EU/JP | Parkinson's disease | 2026 | ★★★ | 3,500K |
| ME-401 | NA/EU/JP | Follicular lymphoma Marginal zone lymphoma | 2023 | ★★★ | ~800K |
| RTA 402 | JP/Asia | Alport syndrome Diabetic kidney disease Autosomal dominant polycystic kidney disease (ADPKD) | TBD 2024 2025 | ★★★ | 2,500K~ |
| KHK7791 | JP | Hyperphosphatemia under maintenance dialysis | 2023 | ★☆☆ | 250K |

*1 Countries or regions where Kyowa Kirin currently has marketing rights and will launch products (or will conduct marketing activities); products may not be launched in all countries or regions shown in the table

*2 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities

*3 Expected year of first approval

*4 Expected total addressable market, which is the sum of all products for the indications shown in *2, in all countries or regions defined in *1, not projected sales or the Company's targets; ★ = less than ¥50bn, ★★ = ¥50-100bn, ★★★ = Over ¥100bn

*5 Total number of estimated patients in all countries or regions defined in *1.

*6 The size of the total addressable market and patient numbers are based on our estimates

Appendix

FOREX Information

FY2021 Average FOREX Rate

(Yen)

| Currency | 2020 Results | 2021 Results | Change | 2022 Plans |
|----------|--------------|--------------|--------|------------|
| USD/JPY | 107 | 109 | +2 | 110 |
| GBP/JPY | 137 | 150 | +13 | 150 |

FY2021 FOREX Impacts (YoY)

(Billion yen)

| Currency | Revenue | Core OP |
|----------|---------|---------|
| USD/JPY | +2.0 | +0.6 |
| GBP/JPY | +5.0 | +1.0 |

FY2022 FOREX Sensitivity

(Billion yen)

| Currency | Changes | Revenue | Core OP |
|----------|---------|---------|---------|
| USD/JPY | +1 yen | +1.1 | +0.3 |
| GBP/JPY | +1 yen | +0.4 | +0.1 |

Crysvita - Collaboration with Ultragenyx -

| Territories | Economic terms |
|--------------------------|---|
| U.S. & Canada | <ul style="list-style-type: none"> • Kyowa Kirin books sales • 50/50 profit share for 5 years from the U.S. launch • After 5 years, Kyowa Kirin pays tiered sales royalties in mid-high 20% range to Ultragenyx • Supply price: 35% of net sales through 2022, 30% thereafter |
| Europe | <ul style="list-style-type: none"> • Kyowa Kirin books sales • Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx <p>*Ultragenyx have sold a royalty right on/after 2020 to Royalty Pharma</p> |
| Latin America | <ul style="list-style-type: none"> • Ultragenyx books sales • Kyowa Kirin receives low single-digit sales royalties from Ultragenyx • Supply price: 35% of net sales through 2022, 30% thereafter |
| Turkey | <ul style="list-style-type: none"> • Ultragenyx books sales • Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx |
| Asia & Others | <ul style="list-style-type: none"> • Kyowa Kirin books sales |

* Kyowa Kirin supplies commercial products in all territories.

KHK4083/AMG 451 - Collaboration with Amgen -

| | US | Europe and Asia (ex. JP) | JP |
|-------------------|---|--|--|
| Development | <ul style="list-style-type: none"> • Amgen leads development • Share development cost | <ul style="list-style-type: none"> • Amgen leads development • Share development cost | <ul style="list-style-type: none"> • Kyowa Kirin leads development |
| Commercialization | <ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin co-promotes and shares promotion cost | <ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin has opt-in rights for co-promotion | <ul style="list-style-type: none"> • Kyowa Kirin commercializes and books sales |
| Sales Royalties | <ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin | <ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin | |
| Commercial supply | <ul style="list-style-type: none"> • Amgen supplies | <ul style="list-style-type: none"> • Amgen supplies | <ul style="list-style-type: none"> • Kyowa Kirin supplies |

Amgen makes a \$400 million up-front payment (done) and future contingent milestone payments potentially worth up to an additional \$850 million, as well as royalty payments on future global sales, to Kyowa Kirin.

Development Plan of Next-generation Strategic Products

T : Topline data

D : Detailed data

As of Feb 7, 2022

| Code generic name | Target disease | 2021 | 2022 | 2023 | 2024 | + |
|----------------------------------|--|-----------------------|---------------------|------|------|---|
| KHK4083/ AMG 451 | Atopic dermatitis | P2b T D | | | | |
| | | P3 | | | | |
| KW-6356 | Parkinson's disease | P2b | D | | | |
| | | P3 | | | | |
| ME-401 Zandelisib | FL (mono, 3L+) | P2 | T D** | | | |
| | MZL (mono, 3L+) | P2 | | | | |
| | FL/MZL (combo, 2L+) | P3 | | | | |
| | iNHL (mono, 3L+)* | P2 | T | | | |
| | CLL (combo, 2L+) | P2 | | | | |
| RTA 402 Bardoxolone methyl | Alport syndrome | | MA* | | | |
| | Diabetic kidney disease | P3 | | | | |
| | ADPKD | P3 | | | | |
| KHK7791 Tenapanor | Hyperphosphatemia under maintenance dialysis | P3 | | | | |
| | | P3 | | MA* | | |
| | | P3 | | | | |
| | | P3 | | | | |

*: Japan; **: a more complete report of the P2 TIDAL data reported on Nov. 30, 2021, to be provided; MA: marketing application; FL: follicular lymphoma; MZL: marginal zone lymphoma; iNHL: indolent B-cell non-Hodgkin's lymphoma; CLL: chronic lymphocytic leukemia; ADPKD: autosomal dominant polycystic kidney disease; 3L: third-line or later therapy; 2L: second-line or later therapy

Estimated Patient Numbers

| Disease | Country/ Region | Incidence | Prevalence* | Reference |
|----------------|--------------------|------------|-----------------------------|---|
| ATL | JP | 1,150 / y | | Survey and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report (Yamaguchi, 2010) |
| PTCL | JP | | 2,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| CTCL | JP | | 2,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| CTCL | US | 1,500 / y | | SEER Data (2001-2007) |
| XLH | JP | 1:20,000 | Adult: 5,000 Ped: 1,000 | Estimate based on reported prevalence of 1 in 20,000 people; Nationwide survey of fibroblast growth factor 23 (FGF23)-related hypophosphatemic diseases in Japan: prevalence, biochemical data and treatment. (Endo I et al., Endocr J., 2015) |
| XLH | EU | 1:20,000 | Adult: 12,000 Ped: 3,000 | Estimate based on reported prevalence of 1 in 20,000 people |
| XLH | US | 1:20,000 | Adult: 12,000 Ped: 3,000 | Estimate based on reported prevalence of 1 in 20,000 people; New perspectives on the biology and treatment of X-linked hypophosphatemic rickets. (Carpenter TO, Pediatr Clin North Am., 1997) |
| TIO | JP | | 30 | 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms |
| TIO | US | | 500-1,000 | Survey by Ultragenyx Pharmaceutical |
| AD | JP, NA, EU | | 30,000,000 | Study by Decision Resources |
| PD | JP | | 162,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| PD | US | 60,000 / y | ~1,000,000 | Cited from Parkinson's Foundation https://www.parkinson.org/Understanding-Parkinsons/Statistics Accessed February 7, 2022. |
| FL | US | 15,000 / y | | Cited from Cancer.net https://www.cancer.net/ Accessed February 7, 2022. |
| FL | JP | 6,750 / y | | Cited from Cancer Registry and Statistics. Cancer Information Service, National Cancer Center, Japan (Ministry of Health, Labour and Welfare, National Cancer Registry) and Epidemiology of malignant lymphoma and recent progress in research on adult T-cell leukemia/lymphoma in Japan (Miyoshi H et al., Int J Hematol, 2018) |
| MZL | US | 6,000 / y | | Cited from Lymphoma.org https://lymphoma.org/ Accessed February 7, 2022. |
| MZL | JP | 1,060 / y | | Cited from Cancer Registry and Statistics. Cancer Information Service, National Cancer Center, Japan (Ministry of Health, Labour and Welfare, National Cancer Registry) and Epidemiology of malignant lymphoma and recent progress in research on adult T-cell leukemia/lymphoma in Japan (Miyoshi H et al., Int J Hematol, 2018) |
| AS | JP | | 1,200 | Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/4348 Accessed February 7, 2022. |
| ADPKD | JP | | 31,000 | Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/295 Accessed February 7, 2022. |
| CKD | JP | | 13,300,000 | Japanese Society of Nephrology, Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease (2012) |
| CKD (Dialysis) | JP | 40,885 / y | 344,640 | The Japanese Society for Dialysis Therapy, An Overview of Regular Dialysis Treatment in Japan (As of 31 December 2019) |

List of Acronyms

| | |
|--------|--|
| AD | Atopic Dermatitis |
| ADPKD | Autosomal Dominant Polycystic Kidney Disease |
| AG | Authorized Generic |
| AS | Alport Syndrome |
| ATL | Adult T-Cell Leukemia/Lymphoma |
| BS | Biosimilar |
| CKD | Chronic Kidney Disease |
| DKD | Diabetic Kidney Disease |
| FL | Follicular Lymphoma |
| iB-NHL | Indolent B-cell Non-Hodgkin Lymphoma |
| MZL | Marginal Zone Lymphoma |
| PD | Parkinson's Disease |
| PTCL | Peripheral T-Cell Lymphoma |
| TIO | Tumor Induced Osteomalacia |
| XLH | X-linked Hypophosphatemia |



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