Results Presentation Fiscal 2022 First Quarter





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Managing Executive Officer, Head of Finance Motohiko Kawaguchi

Commercial Update

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

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

News Flow in 2022

Managing Executive Officer, Head of Strategy Division Takeyoshi Yamashita, Ph.D.

Q&A

Managing Executive Officer, Head of Strategy Division Takeyoshi Yamashita, Ph.D. Managing Executive Officer, Head of Finance Motohiko Kawaguchi

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

Executive Officer, Head of Global Product Strategy, Strategy Division 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.



Financial Review



Summary of Q1 Results

(Billion Yen / Rounded)

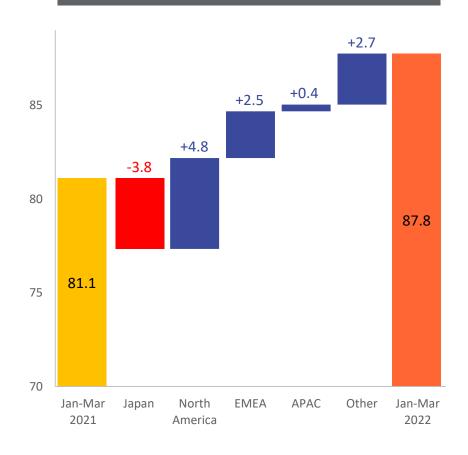
| | 2021Q1 Results | 2022Q1 Results | Changes | 2022 Plans | Progresses |
|--|-------------------|-------------------|--------------|----------------|------------|
| Revenue [Overseas Ratio] | 81.1 [50%] | 87.8 [58%] | +6.6 (+8%) | 380.0 [59%] | 23% |
| Gross Profit [Gross Profit Margin] | 58.7 [72%] | 65.6 [75%] | +6.9 (+12%) | 298.0 [78%] | 22% |
| SG&A [SG&A Ratio] | 31.7 [39%] | 36.1 [41%] | +4.4 (+14%) | 164.0 [43%] | 22% |
| R&D [R&D Ratio] | 12.2 [15%] | 13.6 [16%] | +1.4 (+12%) | 70.0 [18%] | 19% |
| Gain/Loss on Equity Method | 0.6 | 1.4 | +0.8 (+126%) | 3.0 | 48% |
| Core Operating Profit [Core OP Margin] | 15.5 [19%] | 17.3 [20%] | +1.8 (+12%) | 67.0 [18%] | 26% |
| Profit | 12.9 | 16.0 | +3.1 (+24%) | 53.0 | 30% |

^{*} We do not anticipate any direct impact to our business due to Russia/Ukraine conflict for a while, since we have not been operated in / purchased raw materials from those region.



YoY Analysis -Revenue-

+6.6 billion yen (incl. forex effect +3.6)



Japan -3.8

Although new products such as Duvroq and Crysvita increased, revenue in Japan decreased by JPY3.8B due mainly to negative impact by NHI price-cut in April 2021 and shrink in Patanol for which generic products entered the market last December.

North America +4.8 (incl. forex effect +1.6)

Revenue in North America region increased by JPY4.8B with the growth of Crysvita, Poteligeo, and Nourianz.

● EMEA +2.5 (incl. forex effect +1.0)

Growth of Crysvita and Poteligeo contributed to the JPY2.5B increase in EMEA region, although Abstral fell due to generic products' penetration.

● APAC +0.4 (incl. forex effect +0.5)

APAC revenue increased by JPY0.4B with the growth of Gran, Neulasta, Nesp, etc, while Regpara was down due to the Chinese national tender system.

Other +2.7 (incl. forex effect +0.5)

JPY2.7B growth in the other revenue was contributed by the royalties of Fasenra (Benralizumab) and deferred revenue of USD400M upfront payment from KHK4083 partnership that was initiated from last July.



Revenue of Major Items (Japan)

(Billion Yen / Rounded)

| Item | 2021Q1 Results | 2022Q1 Results | Changes | Reasons | 2022 Plans | Progresses |
|------------------|-------------------|-------------------|--------------|--|---------------|------------|
| Nesp + Nesp-AG*1 | 6.5 | 5.2 | -1.2 (-19%) | | 19.5 | 27% |
| Nesp | 1.0 | 0.8 | -0.1 (-13%) | NHI price-cut & Biosimilars' penetration | 3.1 | 27% |
| Nesp-AG | 5.5 | 4.4 | -1.1 (-20%) | · | 16.4 | 27% |
| Duvroq | 0.2 | 1.1 | +0.9 (+570%) | Market penetration (Launched in Aug 2020) | 5.5 | 20% |
| Regpara | 0.7 | 0.5 | -0.2 (-23%) | | 2.4 | 21% |
| Orkedia | 2.1 | 2.2 | +0.1 (+5%) | | 10.0 | 22% |
| G-Lasta | 6.6 | 7.1 | +0.5 (+8%) | Market's recovery & penetration | 31.5 | 23% |
| Poteligeo | 0.5 | 0.5 | -0.0 (-1%) | | 1.9 | 24% |
| Rituximab BS | 2.6 | 2.5 | -0.1 (-4%) | NHI price-cut | 9.7 | 26% |
| Romiplate | 1.5 | 2.2 | +0.7 (+44%) | Recovery from supply constraints since Jun 2020 through Mar 2021 | 10.0 | 22% |
| Allelock | 2.9 | 2.4 | - 0.5(-17%) | Generics' penetration & NHI price-cut | 6.6 | 37% |
| Patanol | 6.5 | 1.8 | -4.7 (-72%) | Generics entered in Dec 2021 | 3.9 | 47% |
| Nouriast | 1.9 | 1.8 | -0.1 (-7%) | | 8.4 | 21% |
| Haruropi | 0.6 | 0.8 | +0.2 (+38%) | Market penetration (Launched in Dec 2019) | 5.5 | 14% |
| Crysvita | 1.5 | 2.0 | +0.5 (+31%) | Market penetration (Launched in Dec 2019) | 10.0 | 19% |
| Tech-licensing | 0.6 | 0.1 | -0.5 (-81%) | Deferred process of FKB*2-related upfront revenue completed | 1.0 | 12% |

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

^{*2} FKB stands for Fujifilm Kyowa Kirin Biologics Co., Ltd.



Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

| ltem | 2021Q1 Results | 2022Q1 Results | Changes | Reasons | 2022 Plans | Progresses |
|------------------------|-------------------|-------------------|-------------|---|---------------|------------|
| Crysvita | 16.3 | 22.2 | +6.0 (+37%) | | 105.2 | 21% |
| North America | 11.7 | 15.8 | +4.1 (+35%) | [North America] Market penetration [EMEA] Geographical expansion | | |
| EMEA | 4.5 | 6.3 | +1.8 (+40%) | & Additional indication (Adult) [APAC] Launched in China | | |
| APAC | - | 0.0 | +0.0 (—) | [] | | |
| Poteligeo | 3.2 | 4.2 | +1.1 (+34%) | [North America] Market penetration | 22.5 | 19% |
| North America | 2.6 | 3.3 | +0.7 (+27%) | [EMEA] Geographical expansion | 15.0 | 22% |
| EMEA | 0.6 | 0.9 | +0.4 (+67%) | & Market penetration | 7.6 | 12% |
| Nourianz | 1.0 | 1.1 | +0.2 (+19%) | Market penetration | 6.6 | 17% |
| Abstral | 1.8 | 1.4 | -0.4 (-22%) | Generic's penetration | 6.7 | 21% |
| Regpara | 2.2 | 1.0 | -1.3 (-56%) | Listed on Chinese tender list*1 in Oct 2021 | 3.7 | 26% |
| Tech-licensing | 4.9 | 7.7 | +2.7 (+55%) | Deferred revenue of KHK4083 upfront payment | 34.3 | 22% |
| Benralizumab Royalty*2 | 3.8 | 4.7 | +0.9 (+24%) | (July 2021-) & Growth of Fasenra | | |

^{*1} Volume-Based Procurement (VBP) program that has been introduced 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 which has been marketed by AstraZeneca, including our own estimation.

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



YoY Analysis -Core OP-

+1.8 billion yen (incl. forex effect +1.2)



• Gross Profit +6.9 (incl. forex effect +3.3)

Increased in conjunction with JPY6.6B rise in revenue. Margin improved by 2.4% (72.4%→74.7%) because there was a big negative impact related to elimination of intercompany profits on inventories last year.

● SG&A -4.4 (incl. forex effect -1.7)

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.

[Labor -2.6 / Sales promotion -1.8 (incl. Crysvita profit sharing expenses -1.4) / Depreciation & Amortization +0.2 / Other -0.2]

■ R&D -1.4 (incl. forex effect -0.5)

Clinical study cost of ME-401 and KHK4083/AMG 451, etc. increased.

Gain/Loss on Equity Method +0.8

FKB recorded additional deferred tax asset.

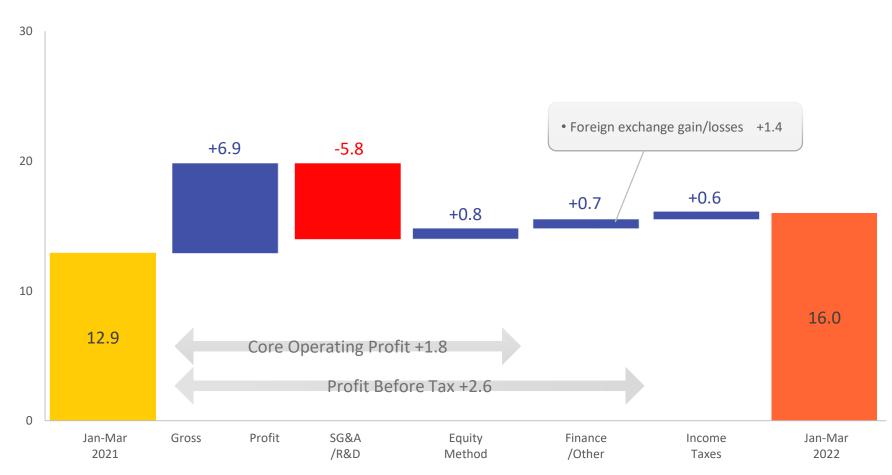
*FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.



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YoY Analysis -Profit-

Profit (Jan-Mar) +3.1 billion yen

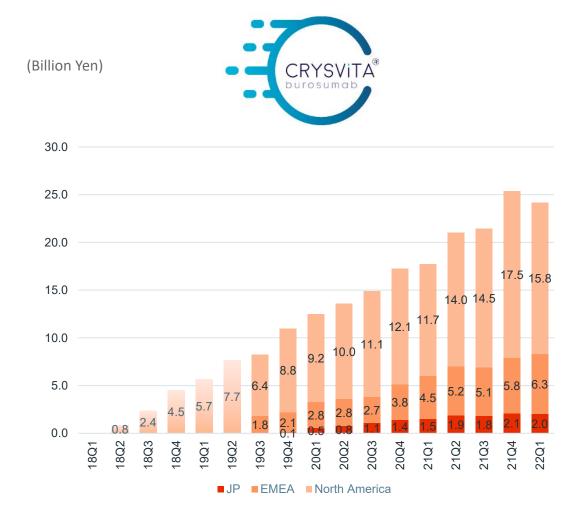




Commercial Update



Crysvita



st Excludes EAP patients and patients who have not started reimbursement process

2022 Key Actions & 2022 Q1 Topics

Key Actions

- North America: Initiate full-scale preparations for transfer of commercialization in spring 2023.
- EMEA: Continue to focus on geographical & indication expansion. TIO review to be completed.

Q1 Topics

- North America: Negative impact from year-end load-up purchase by wholesalers. Preparations for the transfer are proceeding as planned.
- EMEA: Launched in Portugal for Peds, in France and Israel for Adults.
- Japan: Revenue is going as planned.

Launched Countries/ Regions as of March 31, 2022

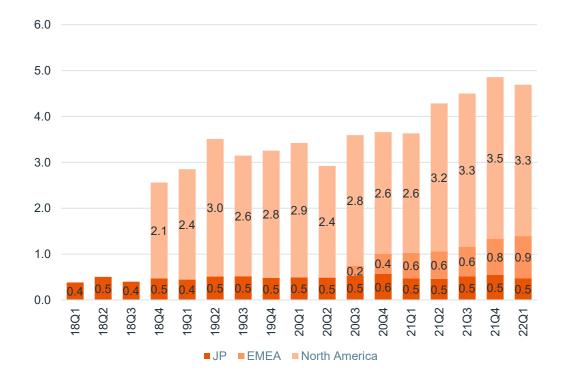
Excluding South America
Underlines: Pediatric and Adult /Bolded types: New launches in Q1 2022

- 2018 USA, Germany, Netherland, Luxembourg
- 2019 <u>Canada</u>, England, Wales, Northern Ireland, Slovakia, Sweden, <u>Israel</u>, <u>UAE</u>, Czech, Denmark, Italy, <u>Japan</u>, Norway, <u>Bahrain</u>, <u>Australia</u>
- 2020 Scotland, <u>Oman</u>, <u>Kuwait</u>, <u>Qatar</u>, Romania, Slovenia, <u>France</u>, Finland, Estonia, Spain
- 2021 Ireland, Hungary, Belgium, Saudi Arabia, Hong Kong, China, Singapore
- 2022 Portugal



Poteligeo





^{*} Excludes EAP patients and patients who have not started reimbursement process

2022 Key Actions & 2022 Q1 Topics

Key Actions

- EMEA: Continue to talk with payers to ensure reimbursement and patient access to product.
- US/EMEA: Work with Healthcare professionals to gather and share evidence such as clinical data in association of blood tumor burden to help understand better use of Poteligeo.

Q1 Topics

●EMEA: While reimbursement negotiations have been difficult and promotional activities have been restricted due to the COVID-19 pandemic, Poteligeo is growing steadily; Reimbursement agreed in France. Launch expected in Q2.

Launched Countries/ Regions as of March 31, 2022

Bolded types: New launches in Q1 2022

2012 Japan

2018 USA

2020 Germany, Austria, Luxembourg

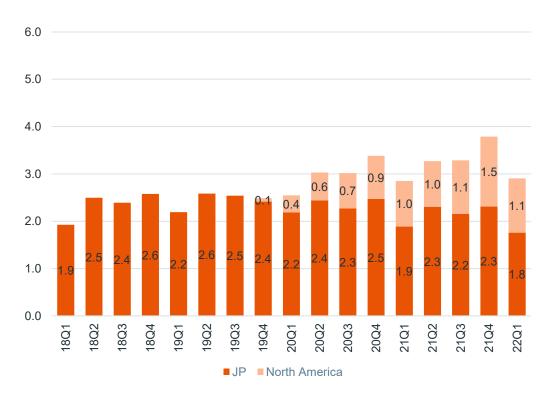
2021 Italy, Scotland, Netherland, Belgium, Slovenia, Denmark, Spain, Finland

2022 Sweden, Saudi Arabia, Slovakia, England, Wales, Northern Ireland



Nourianz





2022 Key Actions & 2022 Q1 Topics

Key Actions

 North America: Focus on approaching potential prescribers and get their deeper understanding of the features of Nourianz such as safety, convenience, and novel mode of action.

Q1 Topics

 North America: Increase in patients' out-of-pocket costs due to annual reset of Medicare and year-end load-up by pharmacies caused negative impacts; Actively holding lectures for HCPs/patients; F2F communication with HCPs on the rise; Advertisement/promotion via paid digital media.

Launched Countries/ Regions as of March 31, 2022

2013 Japan2019 USA



R&D Update



Upcoming Events: Next-generation Strategic Products

| Code Generic Name | Event | Time Expected | Month Completed |
|------------------------------|--|--------------------------------|------------------------|
| KHK4083/AMG 451 rocatinlimab | Atopic dermatitis P3 FPI | Mid-2022 | |
| KW-6356 | Parkinson's disease P3 FPI Parkinson's disease P2b detailed data | H2 2022 H2 2022 | |
| ME-401 zandelisib | CLL (combo, 2L+) P2 FPI FL (mono, 3L+) P2 detailed data* iB-NHL (mono, 3L+) P2 topline data (JP) | H1 2022 Mid-2022 H2 2022 | |
| RTA 402 bardoxolone methyl | Diabetic kidney disease P3 LPO | H2 2022 | |
| KHK7791 tenapanor | Hyperphosphatemia under maintenance dialysis submission (JP) | H2 2022 | |

^{*:} a more complete report of the P2 TIDAL data reported on Nov. 30, 2021, to be provided; FPI: first patient in; LPO: last patient out; CLL: chronic lymphocytic leukemia; FL: follicular lymphoma; iB-NHL: indolent B-cell non-Hodgkin's lymphoma



Update: Zandelisib US development plan

External Environment

- Several PI3K inhibitors have received accelerated approvals from the FDA based on data from single-arm studies in blood cancers.
- Around the end of 2021, several companies made a decision to withdraw their PI3K inhibitor indications/applications that had been marketed/applied for accelerated approvals following discussions with the FDA.
- Discussions at the FDA's Oncology Drug Advisory Committee in April 2022 concluded that randomized controlled trials should be conducted to assess the risk-benefit of the class of drugs in blood cancers.

Development Plan

- Kyowa Kirin and MEI Pharma were seeking accelerated approval of zandelisib using Phase 2 (TIDAL) study data in a single-arm design, similar to the preceding PI3K inhibitors.
- In March 2022, the FDA indicated that it does not recommend approval based solely on single-arm TIDAL data, so the companies will focus on the ongoing Phase 3 (COASTAL) study, which is a randomized controlled trial. In parallel, discussions with the FDA will continue.



News Flow in 2022



Year-to-date Key News Flow

AS of May 10, 2022

| Category | Pub date | Region | Headline |
|----------|----------|--------|----------|
| | | | |
| | | | |

| ESG | Jan 11 | Japan | Introduction of Renewable Energy "Aqua Premium" for its Fuji Research Park and CMC R&D Center |
|-----|--------|--------|--|
| LCM | Jan 31 | Japan | NDA submission of Topical Ophthalmic Mitomycin C Agent |
| ESG | Feb 3 | Global | Formulation of Global DE&I Statement |
| LCM | Feb 25 | Japan | Approval for Partial Change of Approved Indication of G-Lasta (for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogenic Blood Stem Cell Transplantation) |
| ESG | Mar 9 | Japan | Selection for "Health & Productivity Stock" for the First Time |
| LCM | Mar 23 | Japan | Approval for Partial Change of Approved Indication of Hysron Tablets 5 |
| R&D | Mar 31 | Global | Regulatory Update on Zandelisib Following Meeting with the FDA |
| LCM | Apr 4 | Japan | Publication of Safety Data from a Clinical Trial of Automated Injection Device of G-Lasta |
| | | | |

Updates after the previous earnings announcement



Appendix



FOREX Information

Average FOREX Rates (yen)

USD/JPY

GBP/JPY

| 2021Q1 | 2022Q1 | Changes | 2022 Plans |
|--------|--------|---------|------------|
| 105 | 114 | +9 | 110 |
| 143 | 154 | +11 | 150 |

Q1 YoY FOREX Impacts (billion yen)

USD/JPY

GBP/JPY

| Revenue | e Core OP |
|---------|-----------|
| +2.0 | +0.6 |
| +1.0 | +0.2 |

FY2022 FOREX Sensitivities (billion yen)

USD/JPY

GBP/JPY

| Changes | Revenue | Core OP |
|---------|---------|---------|
| +1 yen | +1.1 | +0.3 |
| +1 yen | +0.4 | +0.1 |



Crysvita - Collaboration with Ultragenyx -

| | Economic Terms |
|---------------|---|
| US & Canada | 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 | Kyowa Kirin books sales Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx *Ultragenyx has sold a royalty right from 2020 onwards to Royalty Pharma |
| Latin America | Ultragenyx books sales Kyowa Kirin receives low single-digit sales royalties from Ultragenyx Supply price: 35% of net sales through 2022, 30% thereafter |
| Turkey | Ultragenyx books sales Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx |
| Asia & Others | Kyowa Kirin books sales |

^{*} Kyowa Kirin supplies commercial products in all territories.



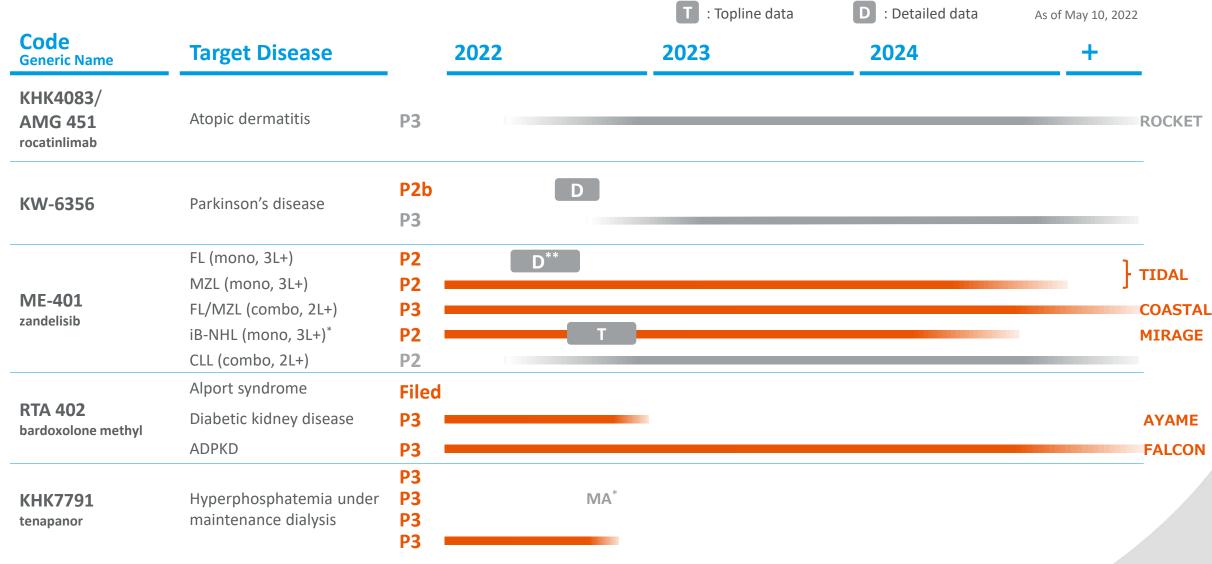
KHK4083/AMG 451 - Collaboration with Amgen -

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

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



^{*:} 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; iB-NHL: 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) |
| OTO! | JP | | 2,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| CTCL | US | 1,500 / y | | SEER Data (2001-2007) |
| | 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 |
| US | 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 |
| DD | 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. |
| | 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) |
| | 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) |
| Kvowa Kirii | n Co. Ltd | | *Provalence renres | sents the estimated patient number per the entire population of each country or region |

^{*}Prevalence represents the estimated patient number per the entire population of each country or region.



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

CLL Chronic Lymphocytic Leukemia

DKD Diabetic Kidney Disease

FL Follicular Lymphoma

iB-NHL Indolent B-cell Non-Hodgkin's Lymphoma

LCM Lifecycle Management

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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