# Results Presentation
# Fiscal 2019

Kyowa Kirin Co., Ltd.

# Agenda

FY2019 Financial Review ＆ FY2020 Forecasts
Shareholder Returns Plan
R&D Review
Business Topics

President and Chief Executive Officer Masashi Miyamoto, Ph.D

Q&A

President and Chief Executive Officer Masashi Miyamoto, Ph.D
Executive Officer, Head of R&D Division Mitsuo Satoh, Ph.D
Executive Officer, Head of Finance Dept Motohiko Kawaguchi

*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.*

# FY2019 Financial Review

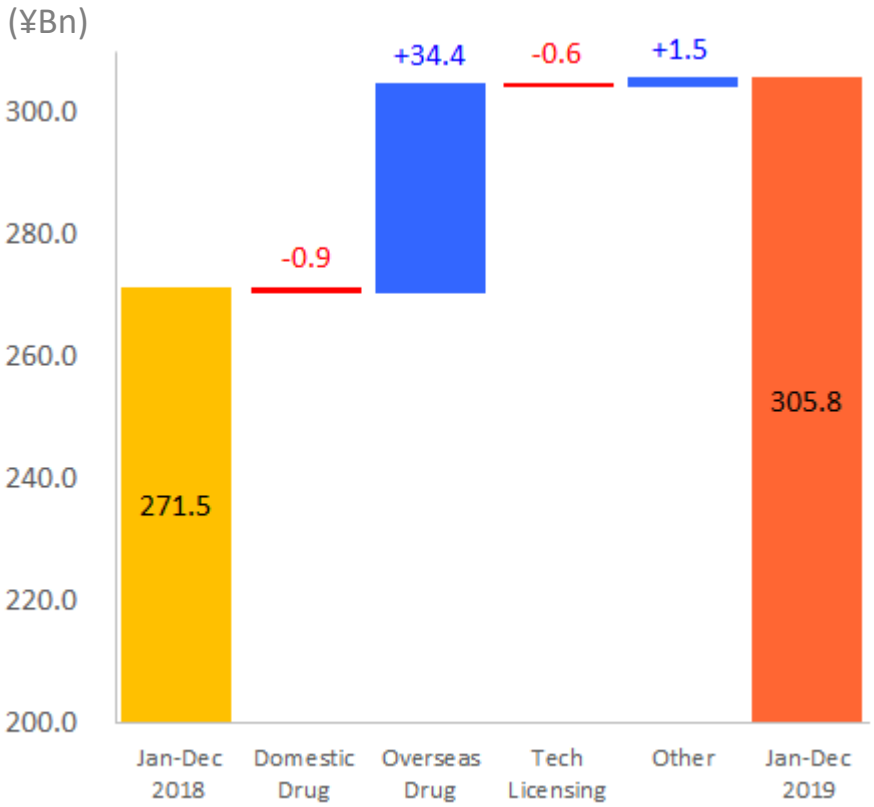
# Summary of FY2019 Results

( Billion Yen / Rounded )

| | 2018 Results | 2019 Results | Changes | 2019 Plan | Progress |
|---|---|---|---|---|---|
| Revenue *[Overseas Ratio]* | 271.5 *[32%]* | 305.8 *[39%]* | +34.3 (+13%) | 305.0 *[39%]* | 100% |
| Gross Profit *[Gross Profit margin]* | 198.1 *[73%]* | 226.2 *[74%]* | +28.1 (+14%) | 224.0 *[73%]* | 101% |
| Core OP *[Core OP margin]* | 50.3 *[19%]* | 59.4 *[19%]* | +9.0 (+18%) | 53.0 *[17%]* | 112% |
| Profit from continued operation | 49.2 | 37.7 | -11.6 (-23%) | 37.0 | 102% |
| Profit from discontinued operation | 5.2 | 29.4 | +24.2 (+467%) | 31.0 | 95% |
| Profit | 54.4 | 67.1 | +12.7 (+23%) | 68.0 | 99% |

# YoY Analysis -Revenue-

**+34.3 billion yen**
**(incl. forex effect -4.9)**




## ● Domestic Drug -0.9

- Rituximab BS (Launched in 2018), G-Lasta (Market expansion), and Romiplate (Additional indication) made strong growth, however they could not cover the impact of NHI price cut and the shrink of Nesp (Nesp-AG launched), Regpara/Orkedia (A competitor's penetration), and other long-listed products.

## ● Overseas Drug +34.4 (incl. forex effect -4.6)

- **EU/US:** Crysvita and Poteligeo, launched in 2018, are strongly penetrated into the market.
- **Asia:** Regpara recorded favorable sales mainly in China. Neulasta/Peglasta also increased due to the newly launch in Middle Eastern countries.

## ● Tech Licensing -0.6 (incl. forex effect -0.3)

- Increased Benralizumab sales royalties were not able to offset the absence of a gain on sale of Priority Review Voucher (US$80.6M × 50%) recorded in 2018.

## ● Other +1.5

- Increase in the sales of FKB327 (Hulio) API.

# Revenue of Major Items (Japan)

( Billion yen / Rounded )

| Item | 2018 Results | 2019 Results | Changes | Reason | 2020 Plan | Changes |
|---|---|---|---|---|---|---|
| Nesp + Nesp-AG* | 53.7 | 47.6 | -6.1 (-11%) | | 34.7 | -27% |
| Nesp | 53.7 | 33.6 | -20.1 (-37%) | Nesp-AG launched in Aug 2019 | 4.0 | -88% |
| Nesp-AG | – | 14.0 | +14.0 | | 30.7 | +119% |
| Regpara | 13.3 | 6.5 | -6.8 (-51%) | A competitor's penetration & switch to Orkedia | 3.2 | -51% |
| Orkedia | 2.4 | 6.9 | +4.5 (+190%) | Launched in May 2018 | 10.1 | +45% |
| G-Lasta | 20.7 | 24.6 | +3.9 (+19%) | Market expansion & Steady market penetration | 28.1 | +14% |
| Rituximab BS | 4.3 | 9.7 | +5.4 (+125%) | Launched in Jan 2018 | 10.1 | +5% |
| Allelock | 12.6 | 10.8 | -1.8 (-14%) | Generic drugs' market penetration | 8.3 | -23% |
| Patanol | 13.4 | 13.6 | +0.2 (+1%) | | 9.5 | -30% |
| Nouriast | 9.4 | 9.7 | +0.3 (+4%) | | 10.5 | +8% |
| Crysvita | – | 0.1 | +0.1 | Launched in Dec 2019 | 3.5 | +5,138% |
| Technology licensing | 2.7 | 4.6 | +1.9 (+68%) | | 3.7 | -20% |

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

# Revenue of Major Items (Overseas)

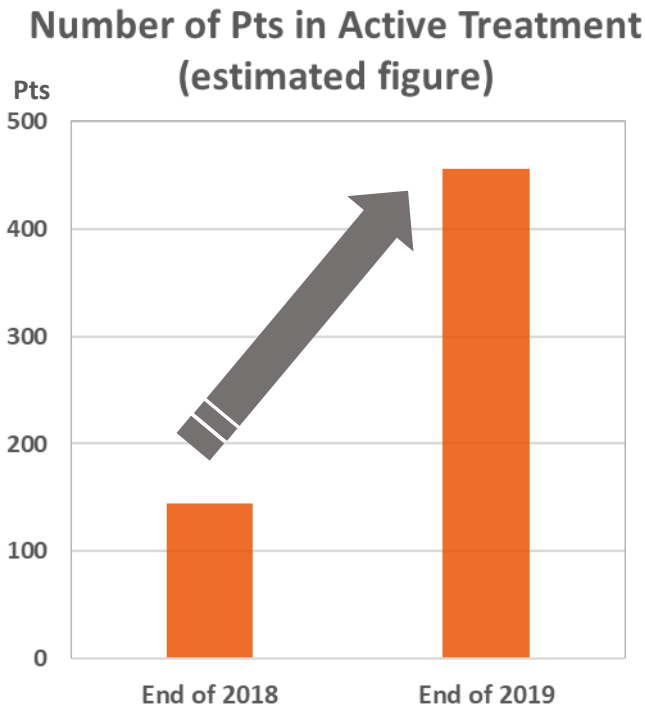
( Billion yen / Rounded )

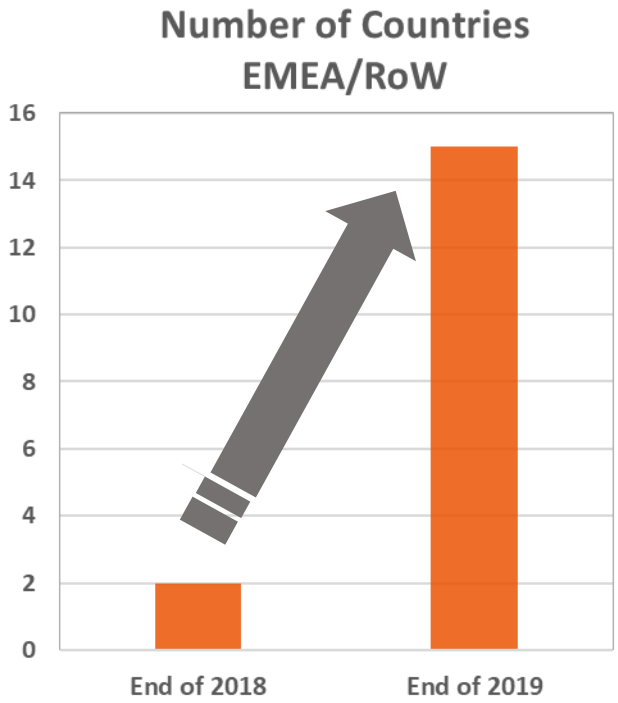
| Item | 2018 Results | 2019 Results | Changes | Reason | 2020 Plan | Changes |
|---|---|---|---|---|---|---|
| Crysvita*1 | 7.7 | 32.5 | +24.8 (+321%) | Launched in Apr 2018 | 56.6 | +74% |
| North America | | 25.1 | | | | |
| Europe & others | | 7.4 | | | | |
| Poteligeo | 2.1 | 10.8 | +8.7 (+416%) | Launched in Oct 2018 | 14.3 | +32% |
| Nourianz | – | 0.1 | +0.1 | Launched in Oct 2019 | 2.8 | +3,962% |
| Abstral | 12.8 | 11.2 | -1.5 (-12%) | Preparation for Brexit | 9.0 | -20% |
| Technology licensing | 15.8 | 13.3 | -2.5 (-16%) | Crysvita PRV*3 in 2018 | 18.8 | +41% |
| Benralizumab Royalty*2 | 3.3 | 8.9 | +5.6 (+170%) | Launched in 2018 | | |

*1 -In January, sales started in England at the list price of GBP2,992 per 10mg vial.
-Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).
-Launched countries as of December 31, 2019 (excluding South America):
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain
*2 Sales royalties of “Fasenra” marketed by AstraZeneca. Includes our own estimation.
*3 PRV = Priority Review Voucher

# Crysvita (EMEA/RoW)

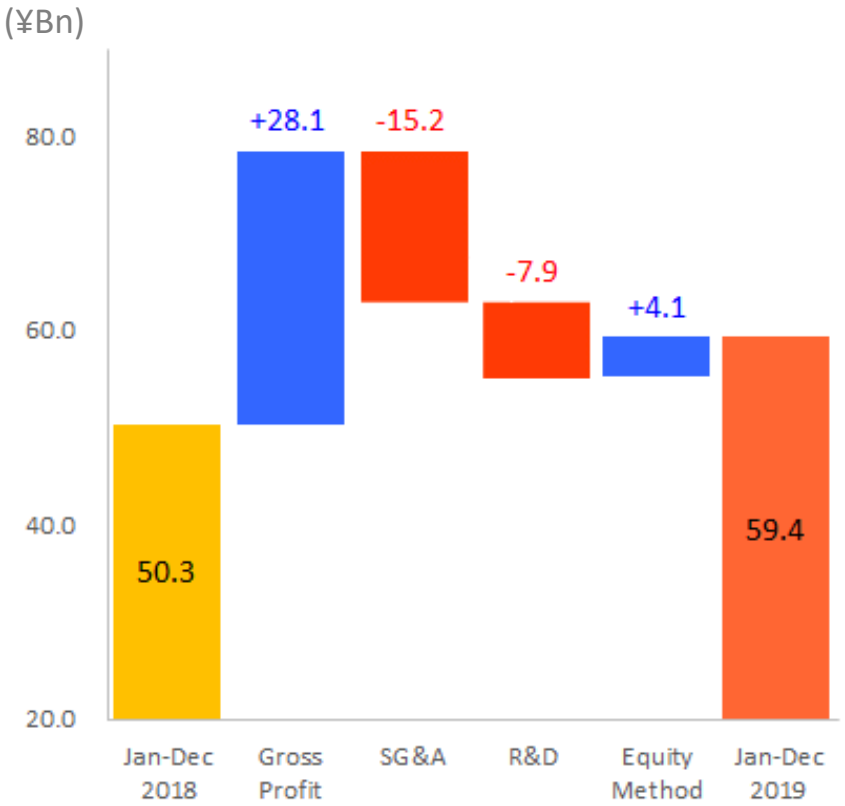
## Successful Market Penetration in EMEA/RoW for the 2nd Year



# YoY Analysis -Core OP-

**+9.0 billion yen**
**(incl. forex effect -1.0)**




- **Gross Profit +28.1 (incl. forex effect -3.9)**
  - Increased in conjunction with the rise in the revenue. Gross profit margin up by 1 point, from 73% to 74%.

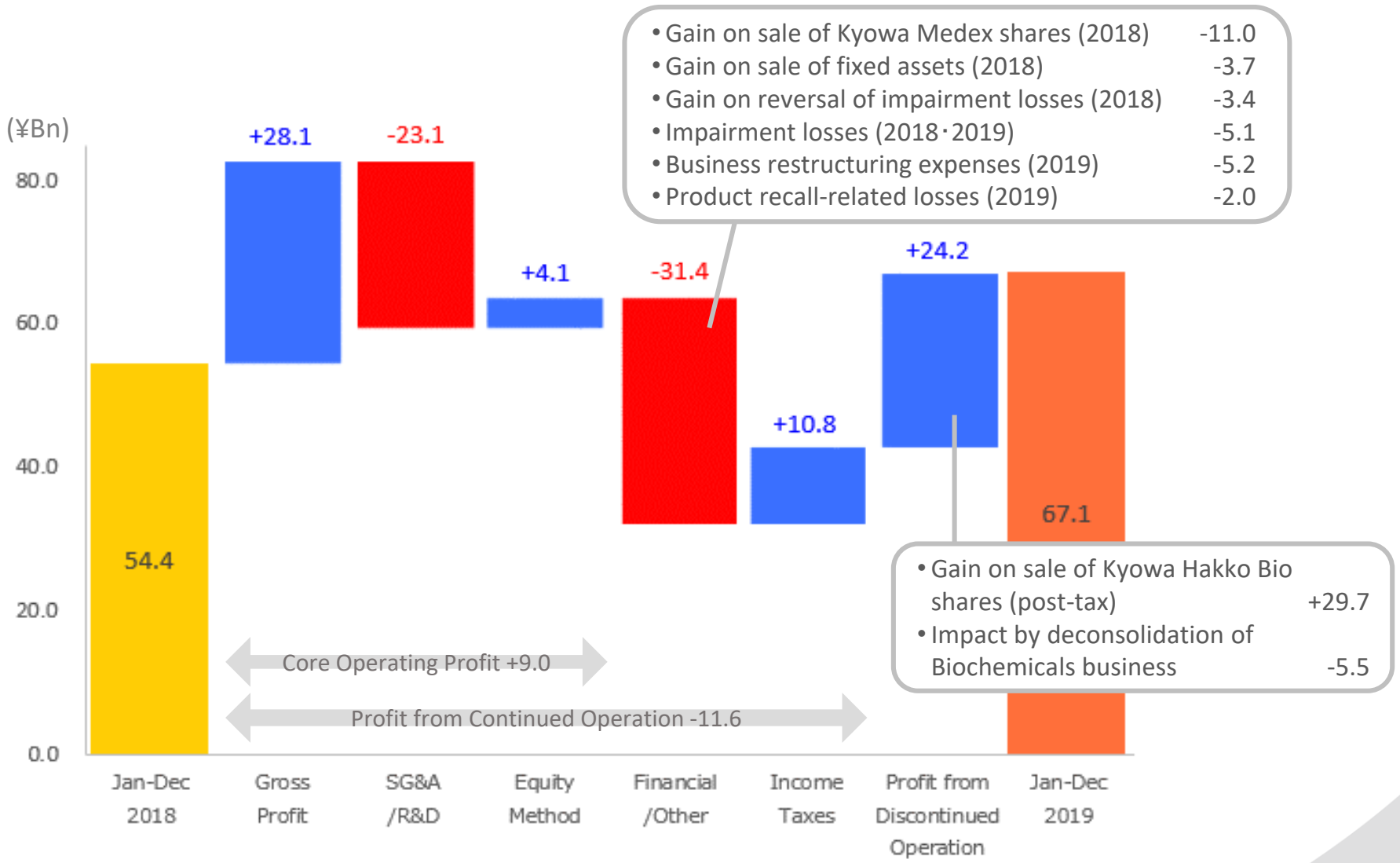
- **SG&A -15.2 (incl. forex effect +2.4)**
  - Increased selling and launch readiness expenses in the EU/US, including Crysvita's profit sharing expenses in North America.

- **R&D -7.9 (incl. forex effect +0.5)**
  - **Negative:** KHK4083 (P2 initiated in Oct 2018), RTA402 (P3 initiated in May 2018), KW-6356 (P2 initiated in Nov 2018), KHK7791 (P2 initiated in Mar 2019), etc.

- **Gain/Loss on Equity Method +4.1**
  - Newly recognized deferred tax asset based on the future taxable income ($4.6Bn).

# YoY Analysis -Profit-

## Profit (Jan-Dec) +12.7 billion yen



# P/L Impact from the Quality Control Issue (Recall of Mitomycin)

| | Amount | Notes |
|---|---|---|
| Cost of Goods Sold | ¥2.0 Bn | Mainly stock disposal |
| Impact to Core OP | -¥2.0 Bn | |
| Other Expenses (Provision for Product Recall-related Losses) | ¥2.0 Bn | Including losses not yet determined |
| Impact to Pre-tax Profit | -¥4.0 Bn | |

**Recognized as Losses in FY2019**

# FY2020 Forecasts

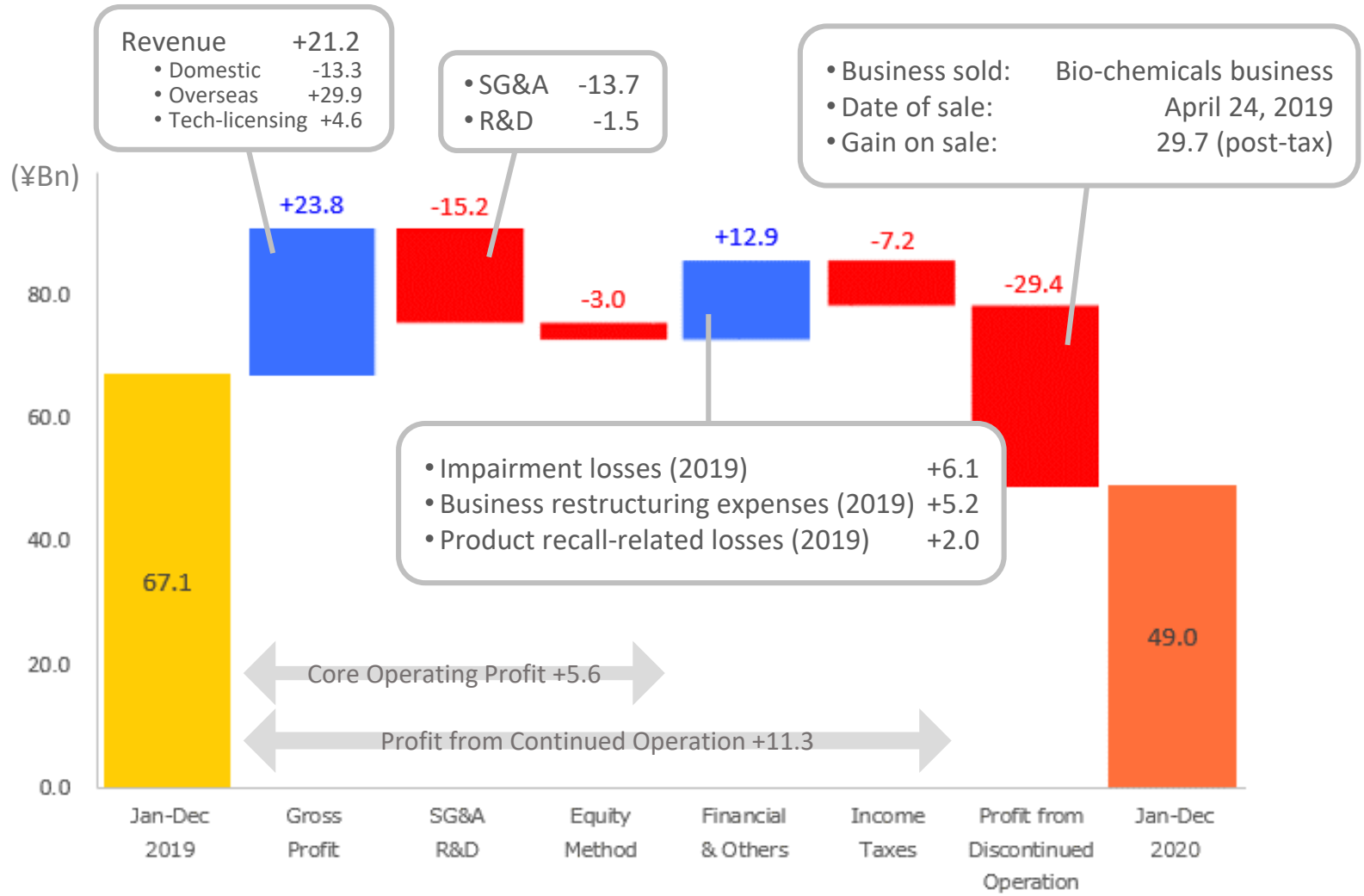
# Summary of FY2020 Forecasts

( Billion Yen / Rounded )

| | 2019 Results | 2020 Forecasts | Changes |
|---|---|---|---|
| Revenue *[Overseas Ratio]* | 305.8 *[39%]* | 327.0 *[47%]* | +21.2 (+7%) |
| Gross Profit *[Gross Profit margin]* | 226.2 *[74%]* | 250.0 *[76%]* | +23.8 (+11%) |
| Core OP *[Core OP margin]* | 59.4 *[19%]* | 65.0 *[20%]* | +5.6 (+10%) |
| Profit from continued operation | 37.7 | 49.0 | +11.3 (+30%) |
| Profit from discontinued operation | 29.4 | – | -29.4 (-100%) |
| Profit | 67.1 | 49.0 | -18.1 (-27%) |

# 2019 Results vs 2020 Forecasts

## Profit (Jan-Dec) -18.1 billion yen



# Shareholder Returns Plan

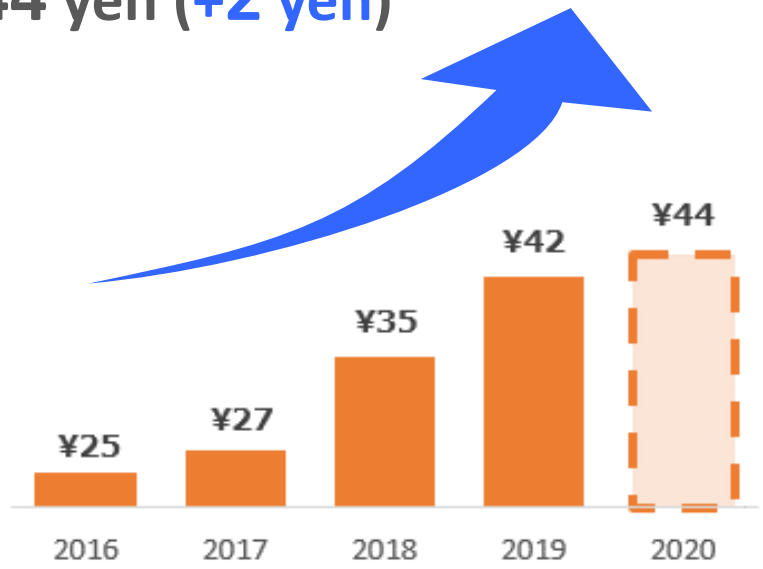
# Shareholder Returns Plan

- FY2019 dividends determined to be 42 yen (+7 yen)
- FY2020 dividends planned to be 44 yen (+2 yen)

| Year | Dividend (yen) | | | Payout Ratio | 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 | 20.00 | 22.00 | 42.00 | 33.7% | 10.1% |
| 2020(Plan) | 22.00 | 22.00 | 44.00 | 48.2% | 7.1% |

* Repurchase of 10.7M own shares (¥22.6B) executed on February 6, 2019.

Total Return Ratio 67.3%*




## Aiming continued escalation in dividends based on a payout ratio of 40%

**[Basic policy for profit allocation]**

**Along with working to enhance retained earnings, such as preparing for future business developments, provide a stable dividend while comprehensively considering factors including the consolidated business results and dividend payout ratio.**

- **Stock Repurchase** Flexibly acquire treasury stock based on the market environment and financial situation.
- **Retained Earnings** Allocate to investments that will lead to new growth, such as R&D, capital investments and development pipeline enhancements which will contribute to increased corporate value in the future..
- **Dividend** Based on the consolidated dividend payout ratio of 40% set forth in the Mid-term Business Plan, aim to stably and continually increase the dividend level in accordance with the growth in profits.

# R&D Review

# Key Development Updates in 19Q4

- Acceptance of the application for the expanded use of KRN23 for adult XLH in Europe (November)
- Initiation of the phase 3 study of KW-3357 for the treatment of preeclampsia in Japan (November)
- Partial change approval of KHK7580 for hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism in Japan (December)
- Application for partial change approval of KHK4827 for axial spondyloarthritis in Japan (December)
- Submission of supplemental biologics license application of KRN23 for tumor-induced osteomalacia in the U.S. (December)

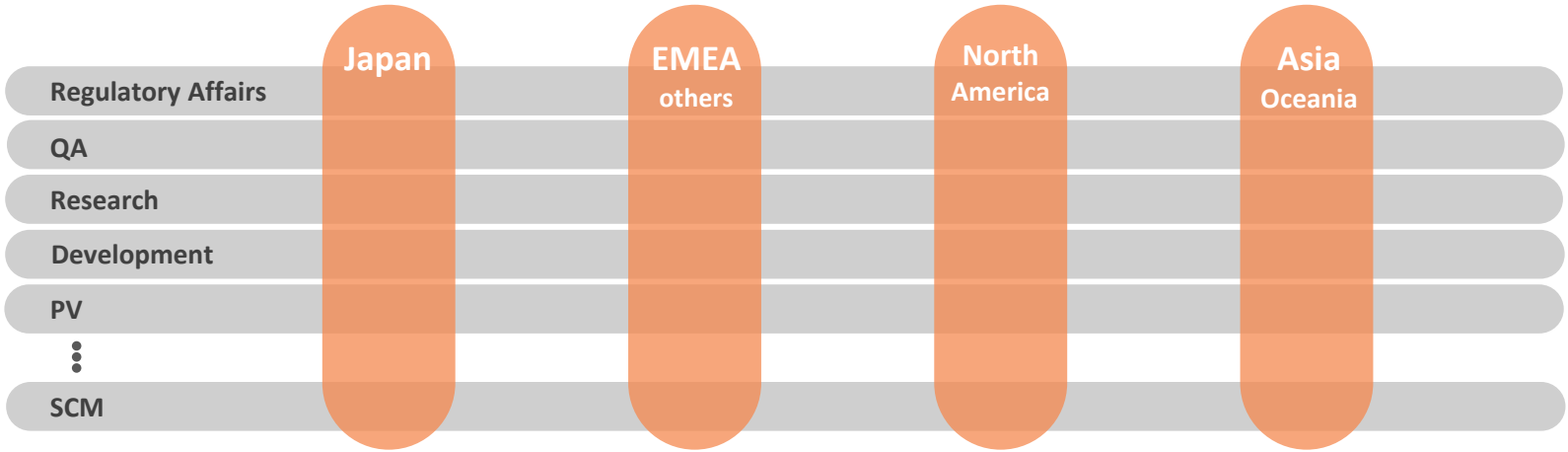
# Key Development Updates after December

- **Acceptance of the marketing authorization application for approval of KW-6002 for Parkinson's disease in Europe (January)**

# Business Topics

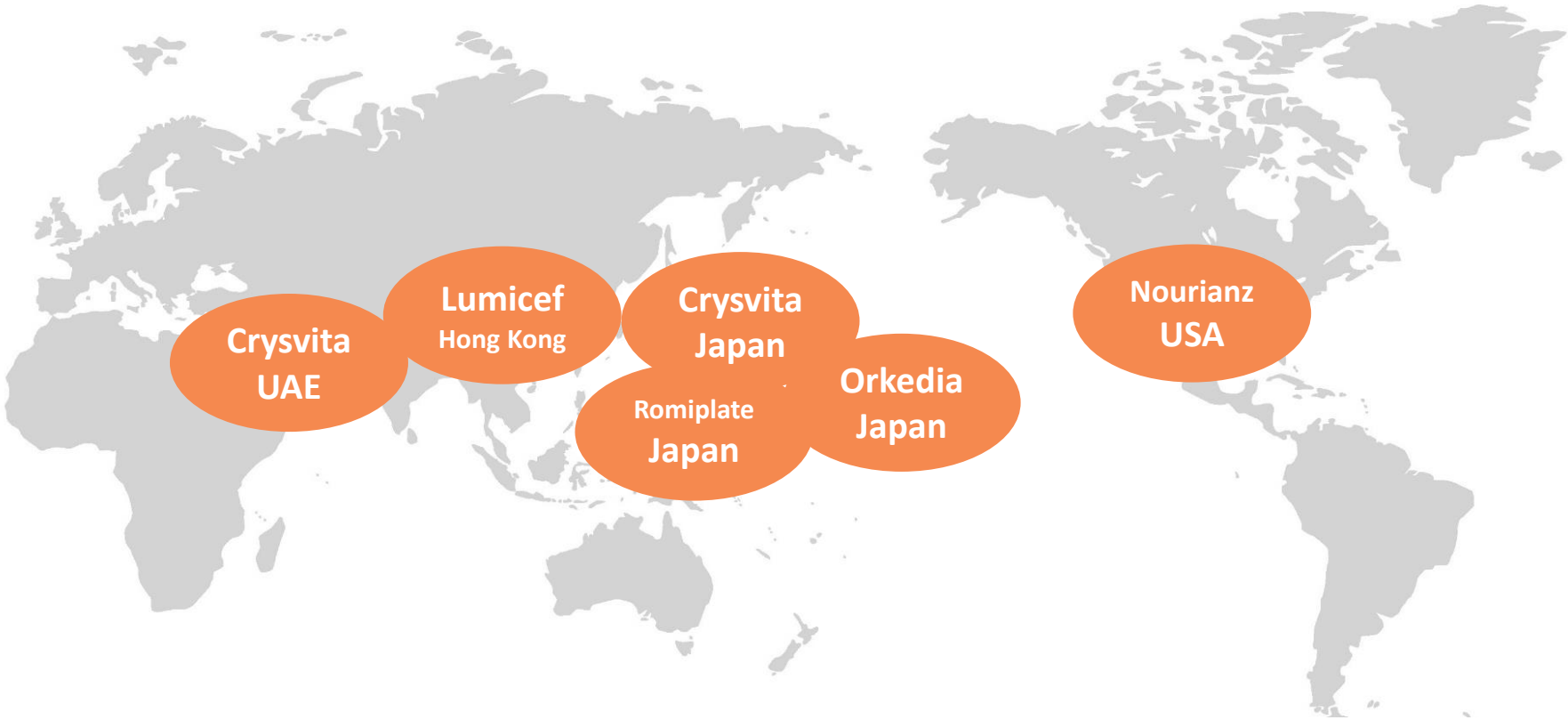
# “One Kyowa Kirin” Organization

## Global Management System from April 2019


Functions × Regions = Global Matrix Organization

# All Products Kyowa Kirin Received MA in 2019 (incl. additional indication)




**Making further leaps as a Global Pharmaceutical Company**

# Appendix

# FOREX Information

## Average FOREX Rate

(Yen)

| Currency | 2018 Results | 2019 Results | Changes | 2020 Plan |
|---|---|---|---|---|
| USD/JPY | 110 | 109 | -1 | 105 |
| GBP/JPY | 148 | 140 | -8 | 130 |

## FY2019 FOREX Impact (YoY)

(Billion yen)

| Currency | Revenue | Core OP |
|---|---|---|
| USD/JPY | -0.9 | -0.1 |
| GBP/JPY | -2.8 | +0.1 |

## FY2020 Currency Fluctuation Sensitivity

(Billion yen)

| Currency | Changes | Revenue | Core OP |
|---|---|---|---|
| USD/JPY | +1 yen | -0.75 | -0.35 |
| GBP/JPY | +1 yen | -0.34 | -0.03 |

# Key progress in development (2019)

Note: Listed events were completed between January 1st, 2019 and December 31st, 2019.

| Month | Generic name Code | Indication | Country/region | Event |
|---|---|---|---|---|
| Jan. | Burosumab KRN23 | FGF23-related hypophosphatemic rickets and osteomalacia | JP | Filed |
| Feb. | Tenapanor KHK7791 | Hyperphosphatemia under maintenance dialysis | JP | Initiated phase 2 study |
| Apr. | Istradefylline KW-6002 | Parkinson's disease | US | Accepted resubmission |
| Apr. | Evocalcet KHK7580 | Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism | JP | Filed additional indications |
| May | Brodalumab KHK4827 | Systemic sclerosis | JP | Initiated phase 3 study |
| Jun. | Romiplostim AMG531 | Aplastic anemia in patients with inadequate response to conventional therapy | JP | Approved additional indication |
| Aug. | Brodalumab KHK4827 | Palmoplantar Pustulosis | JP | Initiated phase 3 study |
| Aug. | Istradefylline KW-6002 | Parkinson's disease | US | Approved |
| Sep. | Burosumab KRN23 | FGF23-related hypophosphatemic rickets and osteomalacia | JP | Approved |
| Nov. | Burosumab KRN23 | Adult XLH | EU | Filed additional indication |
| Nov. | Antithrombin gamma KW-3357 | Preeclampsia | JP | Initiated phase 3 study |
| Dec. | Evocalcet KHK7580 | Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism | JP | Approved additional indications |
| Dec. | Brodalumab KHK4827 | Axial spondyloarthritis | JP | Filed additional indications |
| Dec. | Burosumab KRN23 | Tumor-induced osteomalacia | US | Filed additional indications |

# Submission plan of major pipeline

As of December 31st, 2019

| Generic name Code | Indication | Country/region | 2019 | 2020 | 2021~ |
|---|---|---|---|---|---|
| Burosumab[1] KRN23 | XLH (adult) | EU | Filed | + | |
| Burosumab KRN23 | XLH[2] | JP | Filed | + | |
| Burosumab KRN23 | XLH[2] | AS | Filed[3] | + | |
| Burosumab KRN23 | Tumor-induced osteomalacia | US | Submission | + | |
| Evocalcet KHK7580 | PHPT | JP | Filed | + | |
| Istradefylline KW-6002 | Parkinson's disease | US | Filed | + | |
| Istradefylline KW-6002 | Parkinson's disease | EU | Submission | | + |
| Romiplostim AMG531 | Aplastic anemia | JP | + | | |
| Romiplostim AMG531 | Aplastic anemia | TW | Filed | + | |
| Romiplostim AMG531 | ITP | CN | Filed | | + |
| Brodalumab KHK4827 | Psoriasis | AS | Filed[3] | + | |
| Brodalumab KHK4827 | Axial spondyloarthritis | JP | Filed | + | |
| Mogamulizumab KW-0761 | HAM | JP | Phase 3 | Submission / + | |

[1] Jointly developed with Ultragenyx
[2] Filed/approved indications are FGF23-related hypophosphatemic rickets and osteomalacia in JP and KR
[3] Korea and China
AS: Asia, CN: China, EU: Europe, JP: Japan, US: United States, TW: Taiwan

+ Estimated time of regulatory decisions
Completed
On going
Planned

# Development plan of major pipeline

As of December 31st, 2019

| Generic name Code | Indication | Country/region | 2019 | 2020 | 2021~ |
|---|---|---|---|---|---|
| Bardoxolone methyl RTA 402 | Diabetic Kidney disease | JP | Phase 3 | | |
| Bleselumab[1] ASKP1240 | Recurrence of FSGS in *de novo* kidney transplant | US | Phase 2 | | |
| Entinostat KHK2375 | Breast cancer | JP | Phase 2 | | |
| Evocalcet KHK7580 | SHPT | AS | FPI | Phase 3 | |
| KHK4083 | Atopic dermatitis | JP US EU | Phase 2 | | Phase 3 |
| KW-6356 | Parkinson's disease | JP | Phase 2 | | Phase 3 |
| Tenapanor KHK7791 | Hyperphosphatemia under maintenance dialysis | JP | FPI | Phase 2 | Phase 3 |
| Brodalumab KHK4827 | Systemic sclerosis | JP | FPI | Phase 3 | |
| Brodalumab KHK4827 | Palmoplantar Pustulosis | JP | | FPI Phase 3 | |
| Romiplostim AMG531 | Aplastic anemia[2] | JP AS | FPI | Phase 2/3 | |
| Pegfilgrastim KRN125 | Mobilization of HSCs into peripheral blood | JP | FPI | Phase 2 | |
| Antithrombin gamma KW-3357 | Preeclampsia | JP | | FPI Phase 3 | |

[1] Jointly developed with Astellas

[2] Aplastic anemia who were previously untreated with immunosuppressive therapy

AS: Asia, EU: Europe, JP: Japan, US: United States

Completed
On going
Planned

# Estimated annual incidence/prevalence

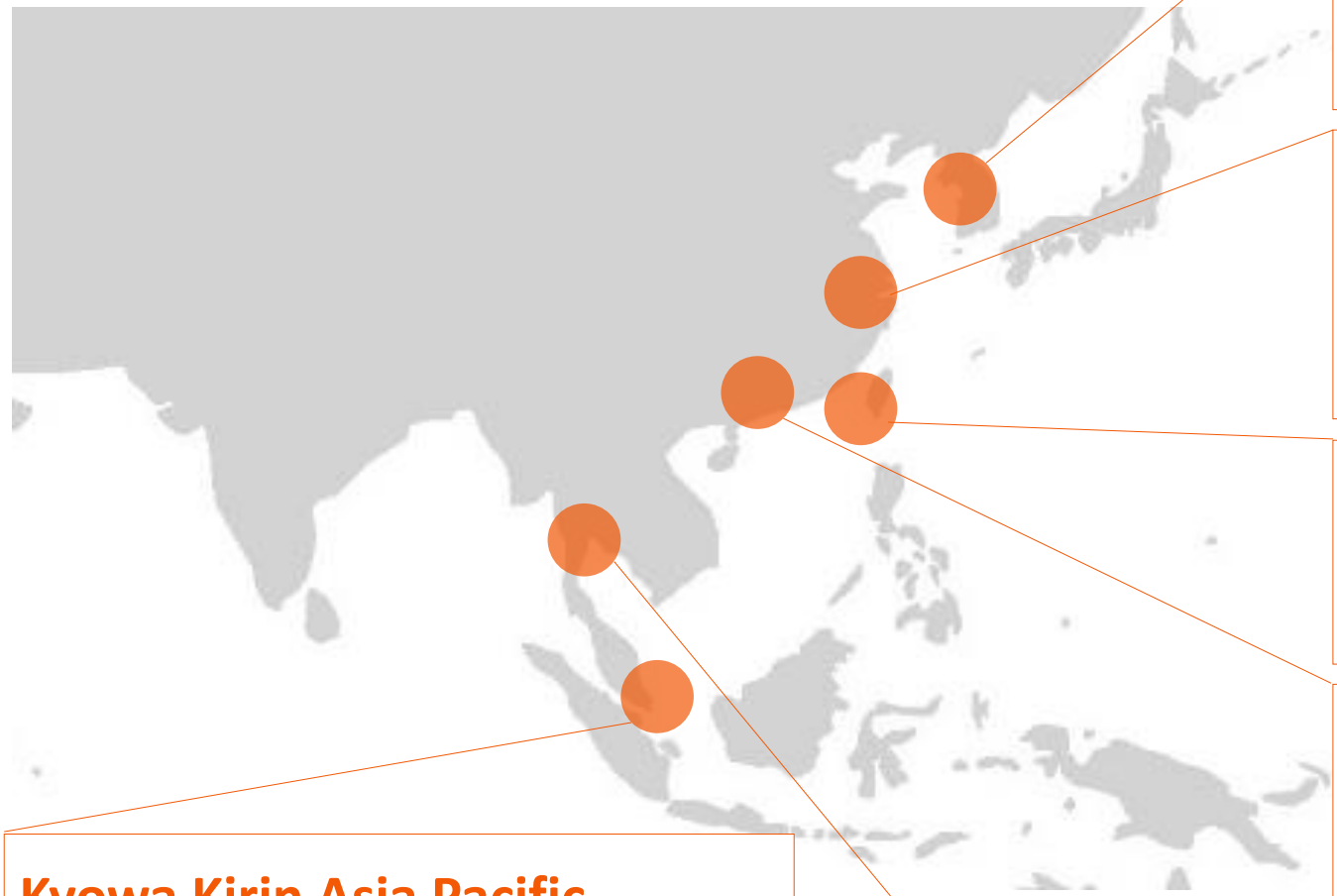
| Disease | Country /region | Estimated # of Incidence (i) or Prevalence (p) | Source |
|---|---|---|---|
| ATL | Japan | i: 1,150 per year<br>p: 2,000 | i: Survey and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report (Yamaguchi, 2010)<br>p: Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| ATL | U.S. | i: 180 per year | US Lymphoid Malignancy Statistics by World Health Organization Subtypes (Lauren R et al., CA Cancer J Clin., 2016) |
| PTCL | Japan | p: 1,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| CTCL | Japan | p: 2,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| CTCL | U.S. | i: 1,500 per year | SEER Data (2001-2007) |
| XLH | Japan | p: 5,000 (adult), 1,000 (ped.) | 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 | Europe | p: 12,000 (adult), 3,000 (ped.) | Estimate based on reported prevalence of 1 in 20,000 people |
| XLH | U.S. | p: 12,000 (adult), 3,000 (ped.) | 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/ENS | Japan | p: 30 (TIO) | 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms |
| TIO/ENS | U.S. | p: 500 - 1,000 | Survey by Ultragenyx Pharmaceutical |
| PD | Japan | p: 162,000 | Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification) |
| PD | U.S. | p: more than 570,000 | Study by Decision Resources |
| AD | U.S. | p: 9,000,000 - 17,000,000 | Studies by Decision Resources and Global Data |
| CKD | Japan | p: 13,300,000 | Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease (2012) |
| AA | Japan | i: 1,000 per year | Cited from the website of Japan Intractable Diseases Information Center (as of July, 2019)<br>http://www.nanbyou.or.jp/entry/106 |
| HAM | Japan | i: 30 per year<br>p: 3,000 - 3,600 | HTLV-1 associated myelopathy (HAM) practice guideline 2019 |

# Crysvita - Collaboration with Ultragenyx -

| | Kyowa Kirin Group | Ultragenyx |
|---|---|---|
| U.S.A /Canada | ● Books sales<br>● For first 5 years, splits profits in half<br>● After 5 years, pays mid to high 20% range sales royalty | ● For first 5 years, splits profits in half<br>● After 5 years, receives mid to high 20% range sales royalty from Kyowa Kirin International (KKI) |
| Europe | ● Books sales<br>● Pay up to 10% sales royalty to Ultragenyx | ● Receives up to 10% sales royalty from KKI |
| Latin America | ● Receives low single-digit sales royalty from Ultragenyx | ● Books sales<br>● Pays low single-digit sales royalty to Kyowa Kirin |
| Turkey | ● Receives up to 20% sales royalty from Ultragenyx<br>● Retains an option to take over commercialization rights after a certain period | ● Books sales<br>● Pays up to 20% sales royalty to KKI |
| Japan/Asia /ROW | ● Books sales | |

* Kyowa Kirin supplies commercial products in all regions.

# Business Expansion in Asia



## Kyowa Kirin Korea
Revenue in 2019：7.2 B JPY
Main Products：Neulasta, Nesp, Grasin

## Kyowa Hakko Kirin China Pharmaceutical
Revenue in 2019：8.7 B JPY
Main Products：Regpara, Gran, Coniel

## Kyowa Kirin Taiwan
Revenue in 2019 ：4.2 B JPY
Main Products ：Nesp, Gran, Regpara

## Kyowa Kirin (Hong Kong)
Revenue in 2019 ：1.6 B JPY
Main Products ：Nesp, Regpara, Romiplate

## Kyowa Kirin Asia Pacific
Asia/Pacific Regional Control Function
President：Tan Boon Heon (March, 2020-)
Revenue in 2019 ：0.6 B JPY
Main Products ： Nesp, Regpara

## Kyowa Kirin (Thailand)
Revenue in 2019 ：0.9 B JPY
Main Products ：Regpara, Nesp

# List of acronyms

| | |
|---|---|
| AA | Aplastic Anemia |
| AD | Atopic Dermatitis |
| ATL | Adult T-Cell Leukemia/Lymphoma |
| BS | Biosimilar |
| CKD | Chronic Kidney Disease |
| CTCL | Cutaneous T-Cell Lymphoma |
| DKD | Diabetic Kidney Disease |
| ENS | Epidermal Nevus Syndrome |
| FSGS | Focal Segmental Glomerulosclerosis |
| HAM | HTLV-1 Associated Myelopathy |
| HSC | Hematopoietic Stem Cell |
| ITP | Idiopathic (immune) Thrombocytopenic Purpura |
| PD | Parkinson’s Disease |
| PHPT | Primary Hyperparathyroidism |
| PTCL | Peripheral T-Cell Lymphoma |
| SHPT | Secondary Hyperparathyroidism |
| TIO | Tumor Induced Osteomalacia |
| XLH | X-linked Hypophosphatemia |

# Revision History

| | | |
|---|---|---|
| Feb. 19, 2020 | P10 | Core Operating Profit / forex effect / -0.4 billion yen -> **-1.0** billion yen<br>Gross Profit / forex effect / -3.4 billion yen -> **-3.9** billion yen |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