Results Presentation
Fiscal 2020 Third Quarter

Kyowa Kirin Co., Ltd.

Agenda

Financial Review

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R&D Review

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Business Topics

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Q&A

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

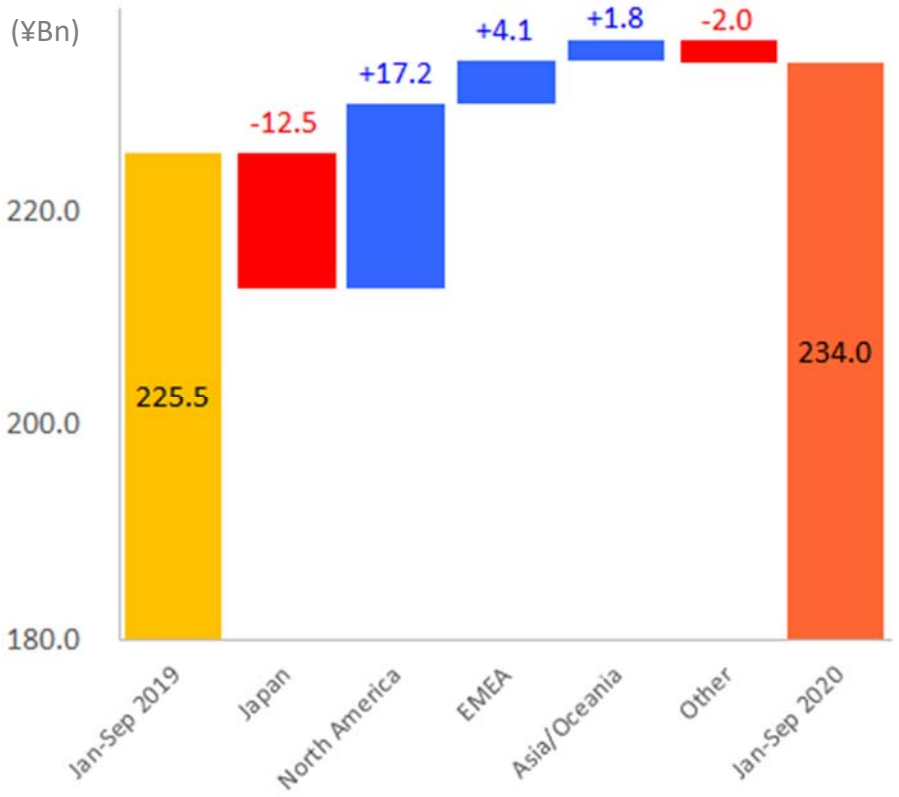
Summary of Q3 Results

(Billion Yen / Rounded)

	2019Q3 Results	2020Q3 Results	Changes	2020 New Plan	Progress
Revenue *[Overseas Ratio]*	225.5 *[39%]*	234.0 *[47%]*	+8.5 (+4%)	313.0 *[47%]*	75%
Gross Profit *[Gross Profit margin]*	168.4 *[75%]*	175.4 *[75%]*	+7.0 (+4%)	236.0 *[75%]*	74%
Core OP *[Core OP margin]*	45.8 *[20%]*	50.7 *[22%]*	+4.9 (+11%)	60.0 *[19%]*	84%
Profit from continued operation	26.9	37.5	+10.6 (+39%)	44.0	85%
Profit from discontinued operation	29.4	—	-29.4 (-100%)	—	—
Profit	56.3	37.5	-18.8 (-33%)	44.0	85%

YoY Analysis -Revenue-

+8.5 billion yen
(incl. forex effect -2.0)



● Japan -12.5

- In addition to newly-launched Crysvita, Romiplate (Additional indication), Rituximab BS and G-Lasta made strong growth. However, they could not cover the impact such as the shrink of Nesp (Shift to Nesp-AG) and Patanol/Allelock (Lower pollen and COVID-19*) and NHI price-cut applied on Oct 2019 and Apr 2020.

*Voluntary ban on doctor's visit/outing or wearing a mask etc.

● North America +17.2 (incl. forex effect -0.3)

- Sales of Crysvita and Nourianz increased. Poteligeo was at the same level as 2019 due to the COVID-19 pandemic.

● EMEA +4.1 (incl. forex effect -1.0)

- Crysvita went up. Poteligeo was launched in Germany.

● Asia/Oceania +1.8 (incl. forex effect -0.6)

- Regpara maintained favorable sales in China.

● Other -2.0 (incl. forex effect -0.1)

- Benralizumab's sales royalties made steady growth, but other milestone revenue decreased.

Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2019Q3 Results	2020Q3 Results	Changes	Reason	2020 New Plan	Progress
Nesp + Nesp-AG*	37.6	21.9	-15.6 (-42%)	Nesp-AG launched in Aug 2019 and Biosimilars' penetration	28.9	76%
Nesp	32.0	3.3	-28.7 (-90%)		4.6	72%
Nesp-AG	5.6	18.6	+13.0 (+232%)		24.4	76%
Duvroq	–	0.5	+0.5	Launched in Aug 2020		
Regpara	5.2	2.9	-2.4 (-45%)	Switch to Orkedia	3.3	87%
Orkedia	4.8	6.6	+1.7 (+35%)	Steady market penetration	9.5	69%
G-Lasta	18.3	19.6	+1.2 (+7%)	Market expansion	27.6	71%
Poteligeo	1.5	1.5	+0.0 (+2%)		2.0	76%
Rituximab BS	6.8	8.6	+1.8 (+27%)	Steady market penetration	11.4	75%
Romiplate	3.0	5.8	+2.8 (+94%)	Indication added in Jun 2019	7.4	79%
Allelock	8.5	6.5	-1.9 (-23%)	Lower pollen in the air and COVID-19 (Voluntary ban on doctor visit/outing or wearing a mask etc.)	8.3	79%
Patanol	11.7	8.7	-2.9 (-25%)		9.8	89%
Nouriast	7.3	6.9	-0.4 (-6%)	COVID-19 (Voluntary ban on doctor visit)	9.9	70%
Haruropi	–	0.4	+0.4	Launched in Dec 2019	1.1	38%
Crysvita	–	2.4	+2.4	Launched in Dec 2019	3.5	68%
Technology licensing	3.7	1.6	-2.1 (-56%)	Absence of FKB-related one-off revenue	3.5	46%

* 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	2019Q3 Results	2020Q3 Results	Changes	Reason	2020 New Plan	Progress
Crysvita*1	21.6	38.5	+16.9 (+79%)	Steady market penetration	51.1	75%
North America	16.3	30.3	+14.0 (+86%)			
EMEA	5.3	8.3	+3.0 (+56%)			
Poteligeo*2	8.0	8.4	+0.4 (+5%)	Launched in Jun 2020 and COVID-19 (Extended treatment interval)	10.0	85%
Nourianz	–	1.7	+1.7	Launched in Oct 2019	2.6	65%
Abstral	8.3	7.6	-0.7 (-8%)	Generic drugs launched	9.7	79%
Regpara	3.8	6.1	+2.3 (+60%)	Listed on Chinese NEDL*3 in Oct 2018	7.4	82%
Technology licensing	7.9	10.9	+3.0 (+38%)		18.3	60%
Benralizumab Royalty*4	6.1	8.3	+2.2 (+37%)	Launched in 2018		

*1 Launched countries as of September 30, 2020 (excluding South America):
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain Scotland, Oman, Kuwait, Qatar, Romania, Slovenia

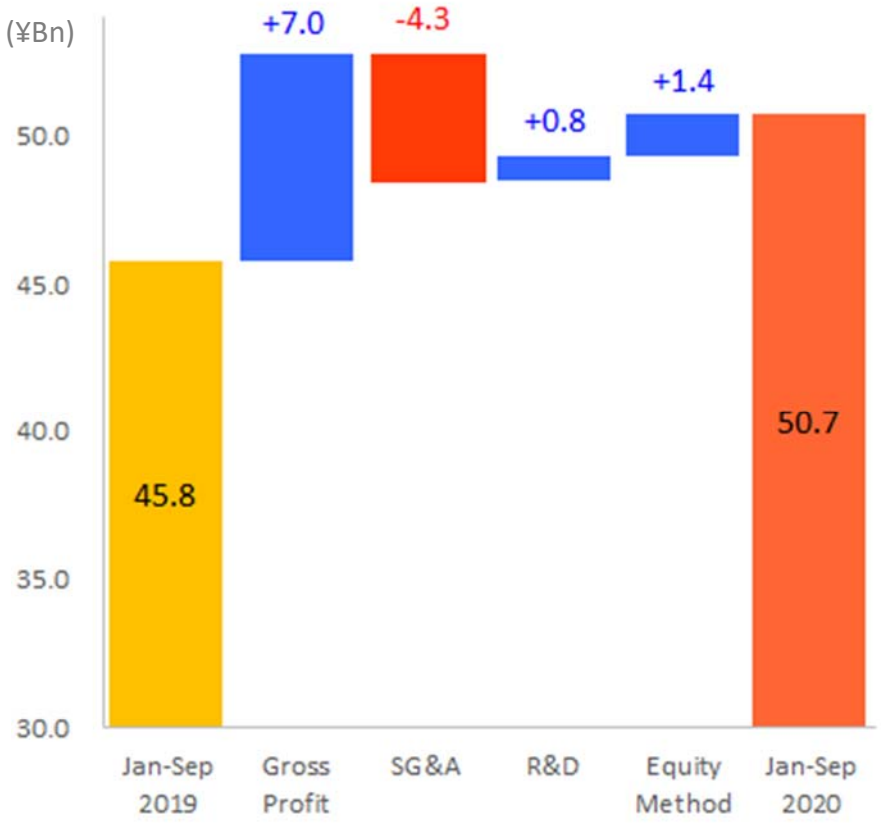
*2 Launched countries as of September 30, 2020:
USA, Germany, Austria, Luxembourg

*3 National Essential Drug List

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

YoY Analysis -Core OP-

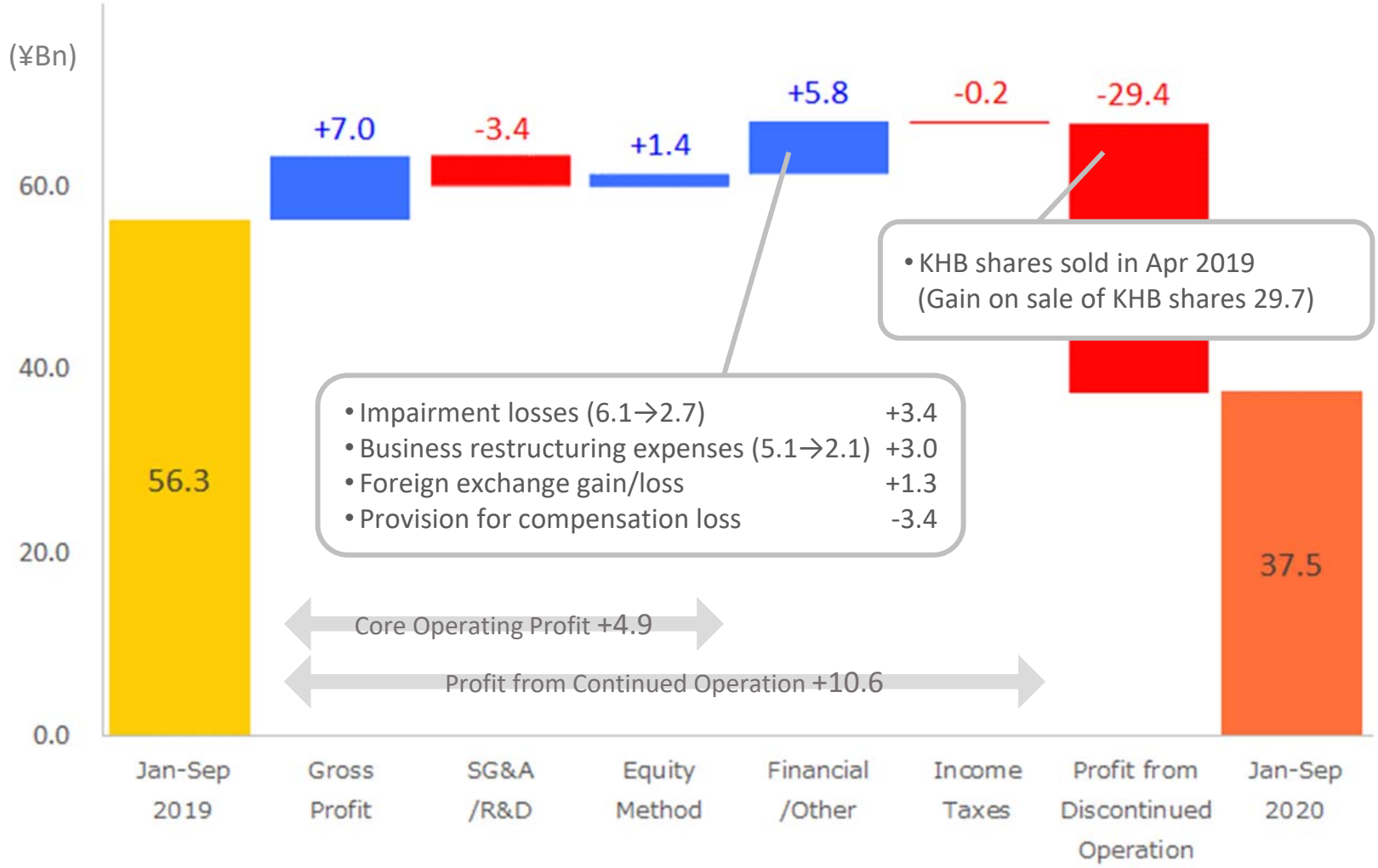
+4.9 billion yen
(incl. forex effect -0.9)



- **Gross Profit +7.0 (incl. forex effect -1.7)**
  - Increased in conjunction with the rise in revenue.
- **SG&A -4.3 (incl. forex effect +0.7)**
  - Increased selling and launch readiness expenses in the EU/US, including Crysvita's profit sharing expenses in North America.
- **R&D +0.8 (incl. forex effect +0.1)**
- **Gain/Loss on Equity Method +1.4**
  - Sales of Hulio (FKB327, Adalimumab BS) increased and development cost of FKB238 (Bevacizumab BS) decreased.

YoY Analysis -Profit-

Profit (Jan-Sep) -18.8 billion yen



R&D Review

Key Development Updates in 20Q3

- **Approval of KRN23 for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Korea (September)**

- **Approval of KRN23 for the treatment of adult XLH in Europe (September)**

- **Discontinuation of the development of KW-0761 for the treatment of adult T-cell leukemia/lymphoma in the U.S. and Europe**

- **Results of the phase 3 study of KW-0761 for the treatment of HTLV-1 associated myelopathy in Japan:**

  There was no significant difference in the primary endpoint

Key Development Updates after September

- Initiation of the pivotal phase 2 study of ME-401 for the treatment of indolent B-cell non-Hodgkin's lymphoma in Japan (October)
- Announcement of the positive phase 2b results for KW-6356 in patients with Parkinson's disease in Japan (October)
- Presentation of phase 2 study data on KHK7791 for the treatment of hemodialysis patients with hyperphosphatemia in Japan at ASN (October)
- Initiation of an innovative collaboration with Axcelead in small-molecule drug development in Japan (October)

Business Topics

Key Business Topics in 20Q3

- **Launch of Duvroq for Patients with Renal Anemia due to Chronic Kidney Disease (August)**

- **Centus Biotherapeutics* received European Marketing Authorization for Equidancent, biosimilar Avastin (September)**

- **Provision for the payment responding to the compensation request by Kirin Holdings Company, Limited.**

*Centus Biotherapeutics: Established in 2015 as a joint venture between Fujifilm Kyowa Kirin Biologics and AstraZeneca. Fujifilm Kyowa Kirin Biologics has granted an exclusive license to Centus for the development, manufacture, and commercialization of Equidacent on a worldwide basis.

Launch of Duvroq for Patients with Renal Anemia due to Chronic Kidney Disease (August)

- Launched Duvroq, an oral HIF-PH* inhibitor for the treatment of renal anemia due to chronic kidney disease (CKD), as the second group in the class for patients on dialysis, and as the first group in the class that can be used for the patients not on dialysis.
- At the end of September, the Japanese Society of Nephrology, in collaboration with the Japanese Society for Dialysis Therapy, announced the recommendation for appropriate use of HIF-PH inhibitors.
- Currently informing healthcare professionals with the drug information for appropriate use of Duvroq, especially prioritizing the safety.

*HIF-PH：Hypoxia Inducible Factor-Prolyl Hydroxylase

Product Portfolio in Nephrology Area

*Under development

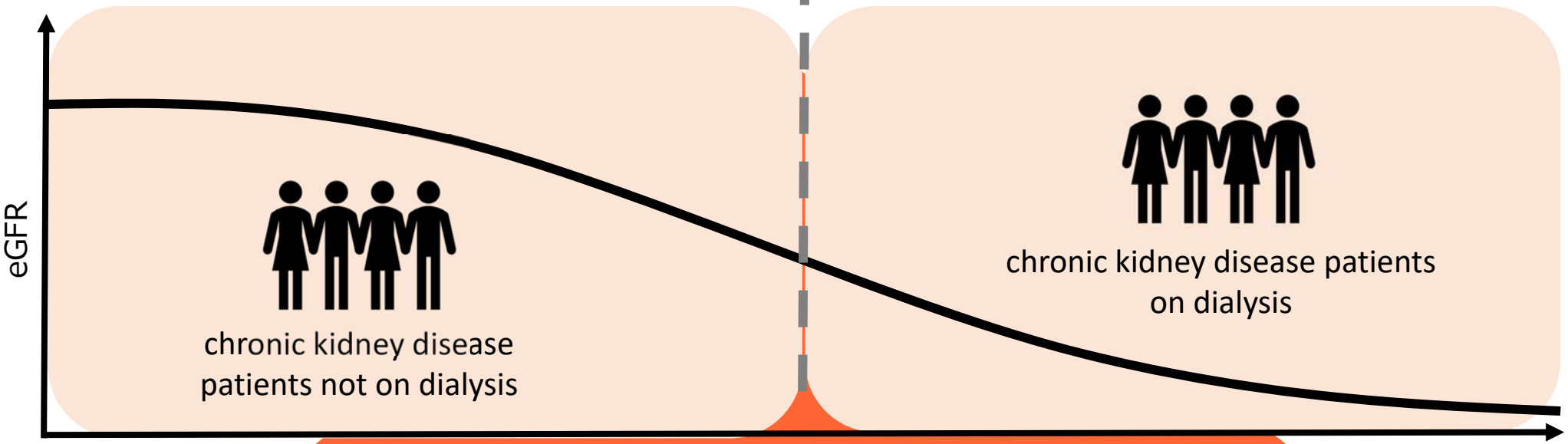
Diabetic Kidney Disease
RTA 402 *

Hyperphosphatemia
KHK7791 *

Hypertension・Diabetes
Coniel・Coversyl・Onglyza

CKD-MBD
Regpara・Orkedia・Rocaltrol・Phosblock

Renal Anemia：Espo・Nesp・Darbepoetin Alfa「KKF」・Duvroq



MR activities　Seminars　Digital detailing　Webinars

Appendix

FOREX Information

Average FOREX Rate

(Yen)

Currency	2019Q3 Results	2020Q3 Results	Changes	2020 New Plan
USD/JPY	109	108	-1	108
GBP/JPY	140	137	-3	135

2020Q3 FOREX Impact

(Billion yen)

Currency	Revenue	Core OP
USD/JPY	-0.4	-0.2
GBP/JPY	-1.0	-0.3

FY2020 Currency Fluctuation Sensitivity (New Plan)

(Billion yen)

Currency	Changes	Revenue	Core OP
USD/JPY	+1 yen	-0.8	-0.4
GBP/JPY	+1 yen	-0.3	-0.0

Key progress in development (2020 Q3)

Note: Listed events were completed between January 1st, 2020 and September 30th, 2020.

Month	Generic name Code	Indication	Country/region	Event
Jan.	Istradefylline KW-6002	Parkinson's disease	EU	Accepted MAA
Feb.	Pegfilgrastim KRN125	Chemotherapy induced febrile neutropenia	JP	Initiated phase 1 study
Feb.	Burosumab KRN23	Tumor-induced osteomalacia	US	Accepted sBLA submission & priority review designation
May	ME-401	follicular lymphoma and other B-cell malignancies	US	Presented phase 1b data at ASCO
Jun.	Tenapanor KHK7791	Hemodialysis patients with hyperphosphatemia	JP	Presented phase 2 data at ERA-EDTA
Jun.	Burosumab KRN23	Tumor Induced osteomalacia	US	Approved sBLA
Jul.	Burosumab KRN23	Adult XLH	EU	Received positive CHMP opinion
Sep.	Burosumab KRN23	Adult XLH	EU	Approved expanded MAA

[1] Filed indication is an adjunctive treatment to levodopa-based regimens in adult patients with Parkinson's disease experiencing "OFF" time

Submission plan of major pipeline

As of September 30th, 2020

Generic name Code	Indication	Country/region	2020 H1	2020 H2	2021
Brodalumab KHK4827	Psoriasis	CN	+		
Brodalumab KHK4827	Psoriasis	AS		+[5]	
Brodalumab KHK4827	Axial spondyloarthritis	JP		+	
Brodalumab KHK4827	Psoriatic arthritis	TW	Filed	+	
Burosumab[1] KRN23	XLH (adult)	EU		+	
Burosumab KRN23	XLH[2]	AS	+[4]	Filed[6]/ +[7]	
Burosumab[1] KRN23	Tumor-induced osteomalacia	US	+		
Istradefylline KW-6002	Parkinson's disease	EU			+
Romiplostim AMG531	Aplastic anemia[3]	TW		+	
Romiplostim AMG531	ITP	CN			+

[1] Jointly developed with Ultragenyx
[2] Approved indications are FGF23-related hypophosphatemic rickets and osteomalacia in Korea
[3] Aplastic anemia in patients who have had an inadequate response to conventional therapy
[4] Hong Kong
[5] Macau
[6] Australia
[7] Korea and Taiwan
AS: Asia, CN: China, EU: Europe, JP: Japan, US: United States, TW: Taiwan

+ Estimated time of regulatory decisions
Completed
Planned

Development plan of major pipeline

As of September 30th, 2020

Generic name Code	Indication	Country/region	2020	2021	2022~
Bardoxolone methyl RTA 402	Diabetic Kidney disease	JP	Phase 3		
Bleselumab[1] ASKP1240	Recurrence of FSGS in *de novo* kidney transplant	US	Phase 2		Phase 3
Entinostat KHK2375	Breast cancer	JP	Phase 2		
Evocalcet KHK7580	SHPT	AS	Phase 3		
KHK4083	Atopic dermatitis	JP US EU	Phase 2		Phase 3
KW-6356	Parkinson's disease	JP	Phase 2		Phase 3
Tenapanor KHK7791	Hemodialysis patients with hyperphosphatemia	JP	Phase 2		Phase 3
Zandelisib ME-401	Follicular lymphoma	US EU etc	Phase 2		
Antithrombin gamma KW-3357	Preeclampsia	JP	Phase 3		
Brodalumab KHK4827	Systemic sclerosis	JP	Phase 3		
Brodalumab KHK4827	Palmoplantar Pustulosis	JP	Phase 3		
Mogamulizumab KW-0761	HAM	JP	Phase 3		
Pegfilgrastim KRN125	Mobilization of HSCs into peripheral blood	JP	Phase 2		
Romiplostim AMG531	Aplastic anemia[2]	JP AS	Phase 2/3		

[1] Jointly developed with Astellas
[2] Aplastic anemia who were previously untreated with immunosuppressive therapy
AS: Asia, EU: Europe, JP: Japan, US: United States, etc: others

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 p: 2,000	i: Survey and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report (Yamaguchi, 2010); 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 http://www.nanbyou.or.jp/entry/106 Accessed July 29, 2020.
ITP	Japan	i: 3,000 per year	Cited from the website of Japan Intractable Diseases Information Center http://www.nanbyou.or.jp/entry/157 Accessed July 29, 2020.
HAM	Japan	i: 30 per year p: 3,000 - 3,600	HTLV-1 associated myelopathy (HAM) practice guideline 2019
FL	U.S.	i: 15,000 per year	Cited from Cancer.net https://www.cancer.net/ Accessed July 29, 2020.
FL	Japan	p: 6,750	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	U.S.	i: 6,000 per year	Cited from Cancer.net https://www.cancer.net/ Accessed October xx, 2020.
MZL	Japan	p: 1,060	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)

Crysvita - Collaboration with Ultragenyx -

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

* Kyowa Kirin supplies commercial products in all regions.

List of acronyms

AA	Aplastic Anemia
AD	Atopic Dermatitis
AG	Authorized Generic
ATL	Adult T-Cell Leukemia/Lymphoma
BS	Biosimilar
CKD	Chronic Kidney Disease
CKD-MBD	Chronic Kidney Disease-Mineral and Bone Disorder
DKD	Diabetic Kidney Disease
ENS	Epidermal Nevus Syndrome
FL	Follicular Lymphoma
FSGS	Focal Segmental Glomerulosclerosis
HAM	HTLV-1 Associated Myelopathy
ITP	Idiopathic Thrombocytopenic Purpura
MBD	Mineral and Bone Disorder
MZL	Marginal Zone Lymphoma
PD	Parkinson’s Disease
PHPT	Primary Hyperparathyroidism
PTCL	Peripheral T-Cell Lymphoma
SHPT	Secondary Hyperparathyroidism
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

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