

Results Presentation

Fiscal 2020 First 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.

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Financial Review

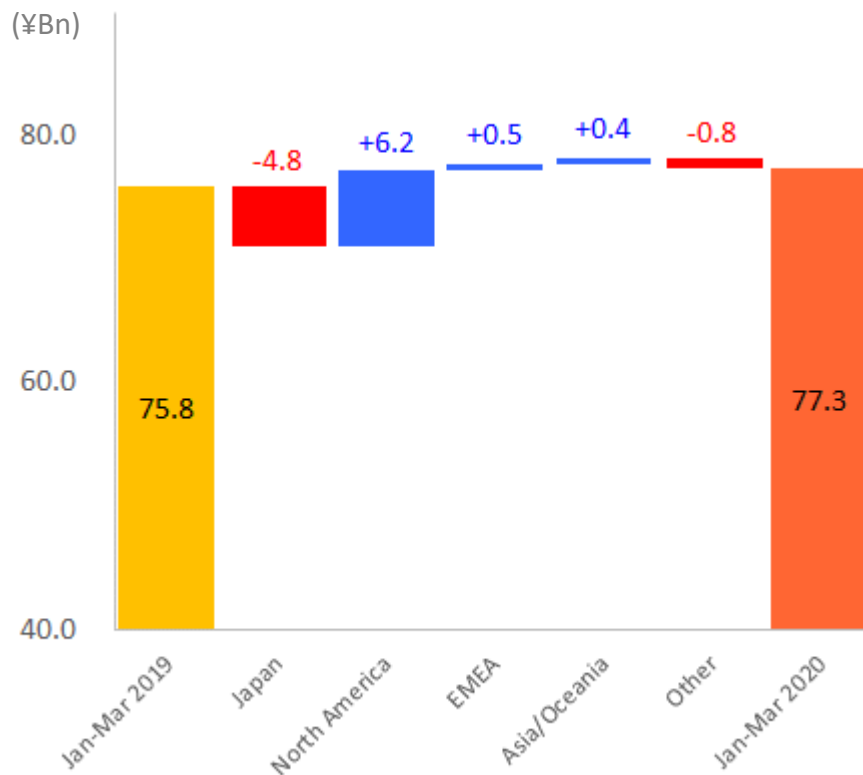
Summary of FY2020 Results

(Billion Yen / Rounded)

	2019Q1 Results	2020Q1 Results	Changes	2020 Plan	Progress
Revenue <i>[Overseas Ratio]</i>	75.8 <i>[36%]</i>	77.3 <i>[44%]</i>	+1.5 (+2%)	327.0 <i>[47%]</i>	24%
Gross Profit <i>[Gross Profit margin]</i>	56.1 <i>[74%]</i>	57.9 <i>[75%]</i>	+1.8 (+3%)	250.0 <i>[76%]</i>	23%
Core OP <i>[Core OP margin]</i>	17.3 <i>[23%]</i>	16.8 <i>[22%]</i>	-0.6 (-3%)	65.0 <i>[20%]</i>	26%
Profit from continued operation	9.3	13.8	+4.5 (+49%)	49.0	28%
Profit from discontinued operation	-1.2	—	+1.2 (-100%)	—	—
Profit	8.1	13.8	+5.7 (+71%)	49.0	28%

YoY Analysis -Revenue-

**+1.5 billion yen
(incl. forex effect -0.1)**



● Japan -4.8

- Romiplate (Additional indication), G-Lasta and Rituximab BS 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 since Oct 2019.

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

● North America +6.2

- Sales of Crysvida, Poteligeo and Nourianz increased.

● EMEA +0.5

- Crysvida went up but Abstral shrunk (Patent lapsed).

● Asia/Oceania +0.4 (incl. forex effect -0.1)

- Regpara maintained favorable sales in China.

● Other -0.8

- Benralizumab - Sales royalties increased but there was more negative impact due to the absence of revenue from the license-out of Asian rights in 2019.

Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2019Q1 Results	2020Q1 Results	Changes	Reason	2020 Plan	Progress
Nesp + Nesp-AG*	11.8	7.4	-4.4 (-37%)		34.7	21%
Nesp	11.8	1.2	-10.6 (-90%)	Nesp-AG launched in Aug 2019	4.0	29%
Nesp-AG	—	6.3	+6.3		30.7	20%
Regpara	1.8	1.0	-0.9 (-48%)	Switch to Orkedia	3.2	30%
Orkedia	1.2	2.0	+0.7 (+61%)	Steady market penetration	10.1	19%
G-Lasta	5.3	6.1	+0.9 (+17%)	Market expansion	28.1	22%
Poteligeo	0.4	0.5	+0.0 (+10%)		2.0	24%
Rituximab BS	1.8	2.6	+0.7 (+40%)	Steady market penetration	10.1	25%
Romiplate	0.8	2.0	+1.2 (+158%)	Indication added in Jun 2019	7.2	28%
Allelock	4.0	3.0	-1.0 (-24%)	Lower pollen in the air and COVID-19 (Voluntary ban on doctor's visit/outing or wearing a mask etc.)	8.3	37%
Patanol	8.5	5.9	-2.6 (-31%)		9.5	62%
Nourias	2.2	2.2	-0.0 (-0%)		10.5	21%
Haruropi	—	0.1	+0.1	Launched in Dec 2019	1.9	5%
Crysvita	—	0.5	+0.5	Launched in Dec 2019	3.5	15%
Technology licensing	0.9	0.3	-0.6 (-66%)		3.7	9%

* 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	2019Q1 Results	2020Q1 Results	Changes	Reason	2020 Plan	Progress
Crysvita*¹	5.7	12.0	+6.3 (+110%)	Steady market penetration	56.6	21%
North America		9.2				
EMEA		2.8				
Poteligeo	2.4	2.9	+0.5 (+22%)	Launched in Oct 2018	14.3	20%
Nourianz	—	0.4	+0.4	Launched in Oct 2019	2.8	13%
Abstral	3.1	2.8	-0.3 (-11%)	Patent lapsed	9.0	31%
Regpara	1.1	1.7	+0.6 (+49%)	Listed on Chinese NEDL*² in Oct 2018	7.3	23%
Technology licensing	3.2	3.1	-0.1 (-4%)		18.8	17%
Benralizumab Royalty* ³	2.0	2.7	+0.7 (+34%)	Launched in 2018		

*1 Launched countries as of March 31, 2020 (excluding South America):

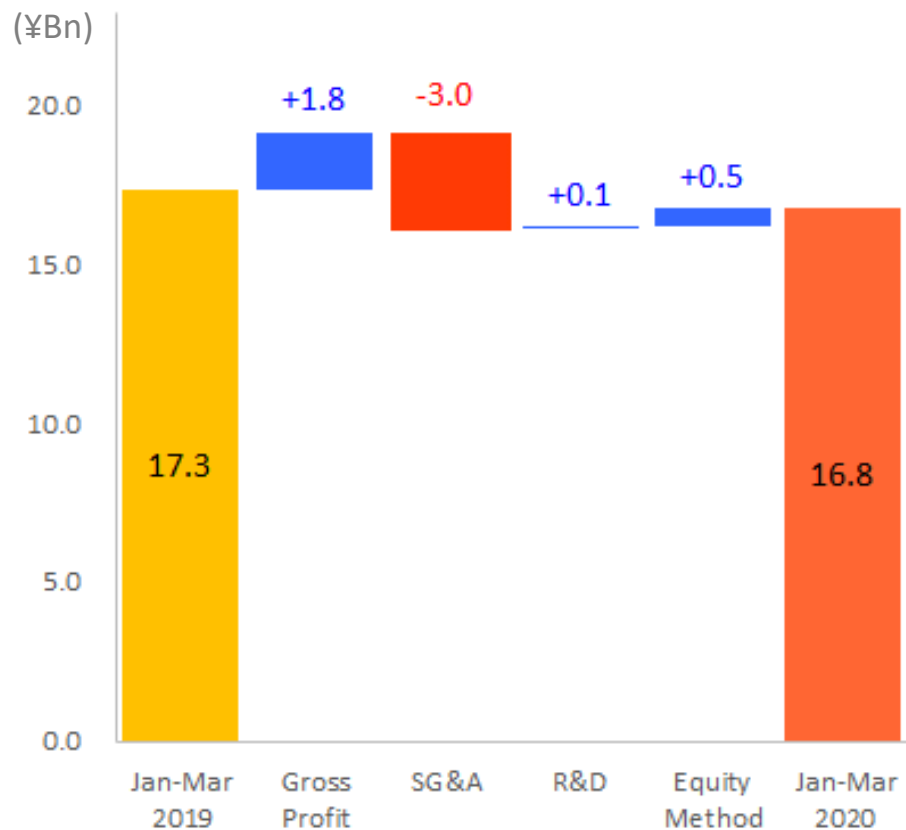
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain

*2 National Essential Drug List

*3 Sales royalties of Fasenera, marketed by AstraZeneca. Includes our own estimation.

YoY Analysis -Core OP-

**-0.6 billion yen
(incl. forex effect -0.1)**



- **Gross Profit +1.8 (incl. forex effect -0.1)**

- Increased in conjunction with the rise in revenue.
Gross profit margin up by 1 point, from 74% to 75%.

- **SG&A -3.0 (incl. forex effect +0.1)**

- Increased selling and launch readiness expenses in the EU/US, including Crysvida's profit sharing expenses in North America.

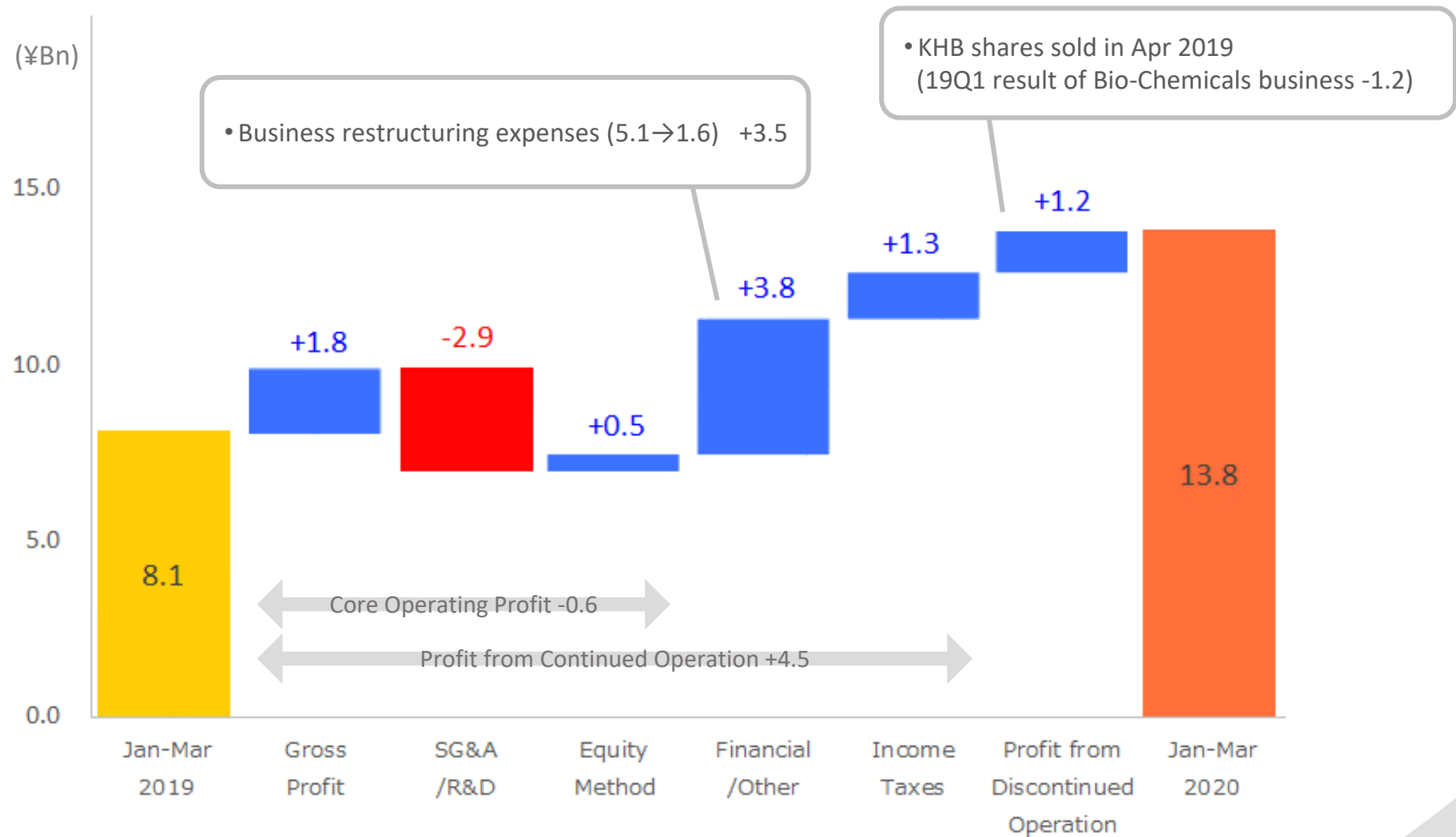
- **R&D +0.1 (incl. forex effect +0.0)**

- **Gain/Loss on Equity Method +0.5**

- Sales of Hulio increased.

YoY Analysis -Profit-

Profit (Jan-Mar) +5.7 billion yen



R&D Review

Key Development Updates in 20Q1

- **Acceptance of marketing authorization application for approval of KW-6002 for Parkinson's disease¹ in Europe (January)**
- **Application for marketing authorization of KHK4827 for axial spondyloarthritis and psoriatic arthritis in Taiwan (February)**
- **Initiation of the phase 1 study of automated injection device of KRN125 in Japan (February)**
- **Acceptance and priority review designation of supplemental biologics license application of KRN23 for tumor-induced osteomalacia in the U.S. (February)**

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

Business Topics

Business Topics after April

- **A Global partnership with MEI Pharma on Global license, Development, and Commercialization for ME-401 (April)**
- **Impacts of COVID-19**
 - No impact has been reported regarding procurement and the product supply.
 - In order to take required actions in a timely manner, we will keep monitoring the changes that would affect our clinical trials, regulatory reviews, and sales: that includes the situations of our supply chains, updated access restrictions of the medical institutions, the change in patient behaviors, and operational changes of the healthcare authorities.

Appendix

FOREX Information

Average FOREX Rate

(Yen)

Currency	2019Q1 Results	2020Q1 Results	Changes	2020 Plan
USD/JPY	110	110	—	105
GBP/JPY	143	143	—	130

2020Q1 FOREX Impact (YoY)

(Billion yen)

Currency	Revenue	Core OP
USD/JPY	—	—
GBP/JPY	—	—

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 (2020 Q1)

Note: Listed events were completed between January 1st, 2020 and March 31st, 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

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

Submission plan of major pipeline

As of March 31st, 2020

Generic name Code	Indication	Country/region	2020 H1	2020 H2	2021
Brodalumab KHK4827	Psoriasis	CN		+	
Brodalumab KHK4827	Psoriasis	AS	+	+	
Brodalumab KHK4827	Axial spondyloarthritis	JP		+	
Brodalumab KHK4827	Axial spondyloarthritis Psoriatic arthritis	TW	Filed	+	
Burosumab ¹ KRN23	XLH (adult)	EU		+	
Burosumab KRN23	XLH ²	AS		+	
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 Filed/approved indications are FGF23-related hypophosphatemic rickets and osteomalacia in KR

³ Aplastic anemia in patients who have had an inadequate response to conventional therapy

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 March 31st, 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 <i>de novo</i> 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	Hyperphosphatemia under maintenance dialysis	JP	Phase 2	Phase 3	
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



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 (as of July, 2019) http://www.nanbyou.or.jp/entry/106
HAM	Japan	i: 30 per year 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	<ul style="list-style-type: none"> ● Books sales ● For first 5 years, splits profits in half ● After 5 years, pays mid to high 20% range sales royalty 	<ul style="list-style-type: none"> ● For first 5 years, splits profits in half ● After 5 years, receives mid to high 20% range sales royalty
Europe	<ul style="list-style-type: none"> ● Books sales ● Pay up to 10% sales royalty to Ultragenyx 	<ul style="list-style-type: none"> ● Receives up to 10% sales royalty
Latin America	<ul style="list-style-type: none"> ● Receives low single-digit sales royalty from Ultragenyx 	<ul style="list-style-type: none"> ● Books sales ● Pays low single-digit sales royalty
Turkey	<ul style="list-style-type: none"> ● Receives up to 20% sales royalty from Ultragenyx ● Retains an option to take over commercialization rights after a certain period 	<ul style="list-style-type: none"> ● Books sales ● Pays up to 20% sales royalty
Japan/Asia /ROW	<ul style="list-style-type: none"> ● Books sales 	

* Kyowa Kirin supplies commercial products in all regions.

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



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