Results Presentation Fiscal 2020





Agenda

FY2020 Financial Review & FY2021 Plan Shareholder Return 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 Finance Motohiko Kawaguchi
Executive Officer, Vice President, Head of R&D Yoshifumi Torii, Ph.D.

Executive Officer, Head of Strategic Product Planning 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.



FY2020 Financial Review & FY2021 Plan



Summary of Result & Plan

(Billion Yen / Rounded)

		2019 Result	2020 Result	Change	2020 Plan	Progress	2021 Plan	Change
	Revenue [Overseas Ratio]	305.8 [39%]	318.4	+12.5 (+4%)	313.0 [47%]	102%	351.0 [54%]	+32.6 (+10%)
	Gross Profit [Pross Profit Margin]	226.2 [74%]	237.9 [75%]	+11.7 (+5%)	236.0 [75%]	101%	270.0 [77%]	+32.1 (+13%)
	Core OP [Core OP Margin]	59.4 [19%]	60.0 [19%]	+0.6 (+1%)	60.0 [19%]	100%	65.0 [19%]	+5.0 (+8%)
	Profit from continued operation	37.7	47.0	+9.4 (+25%)	44.0	107%		
(Profit from discontinued operation	29.4	_	-29.4 (-)	_	_		
	Profit	67.1	47.0	-20.1 (-30%)	44.0	107%	50.0	+3.0 (-6%)



FY2019 vs FY2020 -Revenue-

+12.5 billion yen (incl. forex effect -2.9)



• Japan -14.8

In addition to newly-launched Crysvita, Romiplate (Additional indication), Rituximab BS (Penetration) and G-Lasta (Expanded market) made strong growth. However, Nesp (Shift to Nesp-AG) and Patanol/Allelock (Lower pollen) were down greatly. In addition, there were negative impact by NHI price-cut applied on Oct 2019 & Apr 2020 and the pandemic.

- North America +20.9 (incl. forex effect -0.9)
 Crysvita (launched in 2018) maintained a steady growth. Nourianz (launched in 2019) was also up. Poteligeo was at the same level as 2019 due to the pandemic.
- EMEA +5.5 (incl. forex effect -1.1)
 Crysvita (launched in 2018) maintained steady growth (including EAP revenue; label expanded to adolescent & adult in Sep). Poteligeo increased after its launch in Germany etc. On the other hand, Abstral was down due to emergence of generics.
- Asia/Oceania +2.7 (incl. forex effect -0.5)
 Regpara kept growing in China.
- Other -1.8 (incl. forex effect -0.4)
 - Sales royalties of Fasenra (Benralizumab) made steady growth, but revenue from FKB, contracted manufacturing, and exports etc shrank.



Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2019 Result	2020 Result	Change	Reason	2021 Plan	Change	Reason
Nesp + Nesp-AG*	47.6	29.5	-18.1 (-38%)		23.2	-6.3 (-21%)	
Nesp	33.6	4.4	-29.3 (-87%)	Nesp-AG launched in Aug 2019 and Biosimilars' penetration	3.8	-0.6 (-13%)	Biosimilars' penetration and NHI price-cut
Nesp-AG	14.0	25.4	+11.2 (+80%)		19.4	-5.8 (-23%)	
Duvroq	_	0.6	+0.6 (-)	Launched in Aug 2020	4.0	+3.4 (+593%)	Market penetration
Regpara	6.5	3.8	-2.7 (-41%)	Switch to Orkedia	2.0	-1.8 (-48%)	Switch to Orkedia
Orkedia	6.9	9.1	+2.2 (+31%)	Steady market penetration	10.4	+1.3 (+14%)	Switch from Regpara
G-Lasta	24.6	26.7	+2.1 (+8%)	Market expansion	29.8	+3.1 (+12%)	Market expansion
Poteligeo	2.0	2.1	+0.1 (+6%)		2.0	-0.1 (-5%)	
Rituximab BS	9.7	11.8	+2.1 (+22%)	Market penetration	11.5	-0.3 (-2%)	NHI price-cut
Romiplate	4.9	7.6	+2.8 (+57%)	Indication expanded in Jun 2019	8.7	+1.1 (+15%)	Market penetration
Allelock	10.8	8.6	-2.2 (-21%)	Lower pollen and COVID-19	6.8	-1.8 (-21%)	Competitors
Patanol	13.6	10.6	-3.0 (-22%)	Lower pollen and COVID-19	10.9	+0.3 (+3%)	
Nouriast	9.7	9.4	-0.4 (-4%)	COVID-19 and competitors	9.1	-0.3 (-3%)	Competitors
Haruropi	0.1	0.9	+0.8 (+878%)	Launched in Dec 2019	4.6	+3.6 (+402%)	Market penetration
Crysvita	0.1	3.8	+37 (一)	Launched in Dec 2019	5.5	+1.7 (+46%)	Market penetration
Tech-licensing	4.6	2.0	-2.6 (-57%)	FKB	2.5	+0.5 (+23%)	

^{*} 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.



Revenue of Major Items (Overseas)

(Billion Yen / Rounded)

Item	2019 Result	2020 Result	Change	Reason	2021 Plan	Change	Reason
Crysvita*1	32.5	54.4	+21.9 (+67%)		77.2	+22.8 (+42%)	
North America	25.1	42.4	+17.3 (+69%)	Market penetration and expanded indication (TIO in US & Adult in EU)			Market penetration and market expansion
EMEA	7.4	12.0	+4.6 (+61%)				
Poteligeo*2	10.8	11.5	+0.7 (+7%)	Launched in Germany in Jun 2020	17.3	+5.8 (+50%)	Market penetration and market expansion
Nourianz	0.1	2.6	+2.5 (一)	Launched in Oct 2019	6.7	+4.1 (+158%)	Market penetration
Abstral	11.2	10.2	-1.0 (-9%)	Generic's emergence	8.1	-2.1 (-21%)	Generic's penetration
Regpara	5.0	8.3	+3.3 (+66%)	Listed on Chinese NEDL*3 in Oct 2018	9.3	+1.0 (+12%)	Growth in China
Tech-licensing	13.3	17.5	+4.2 (+32%)		23.7	+6.2 (+35%)	
Benralizumab Royalty* ⁴	8.9	11.0	+2.1 (+24%)	Growth of Benralizumab etc			Growth of Benralizumab etc

^{*1} Launched countries as of December 31, 2020 (excluding South America):

USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Norway, Bahrain, Scotland, Oman, Kuwait, Qatar, Romania, Slovenia, France, Spain

^{*2} Launched countries as of December 31, 2020:

USA, Germany, Austria, Luxembourg

^{*3} National Essential Drug List

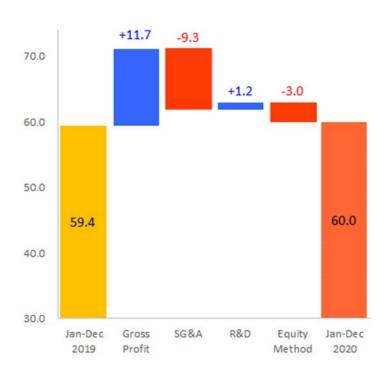
^{*4} Sales royalties of Fasenra, marketed by AstraZeneca (Including our own estimation)

^{*5} Revenue from Early Access Program (EAP) are not included in revenue of major items above.



FY2019 vs FY2020 -Core OP-

+0.6 billion yen (incl. forex effect -1.3)



• Gross Profit +11.7 (incl. forex effect -2.6)

• Increased in conjunction with 12.5B yen rise in revenue. Gross profit margin made 1 point improvement from 74% to 75%.

■ SG&A -9.3 (incl. forex effect +1.0)

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

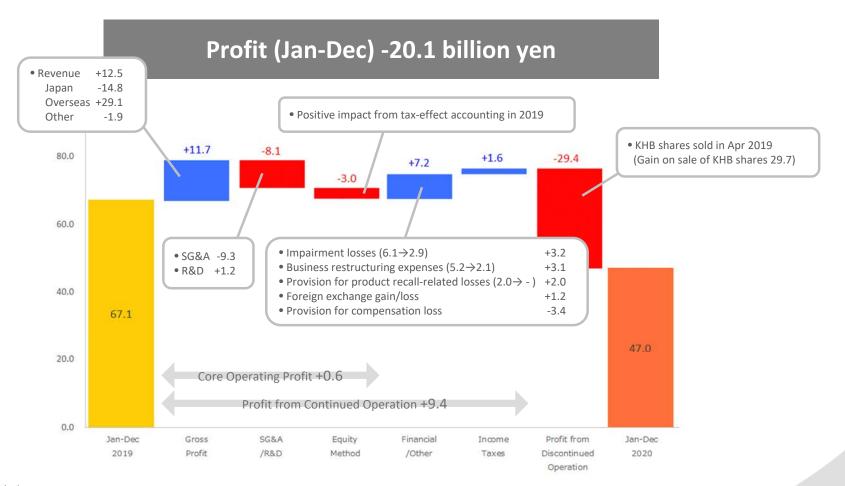
■ R&D +1.2 (incl. forex effect +0.3)

Gain/Loss on Equity Method -3.0

Sales of Hulio (FKB327, Adalimumab BS) increased. However, there was one-time
positive impact related to tax-effect accounting (recognition of differed tax
assets based on future taxable income) in 2019.



FY2019 vs FY2020 -Profit-





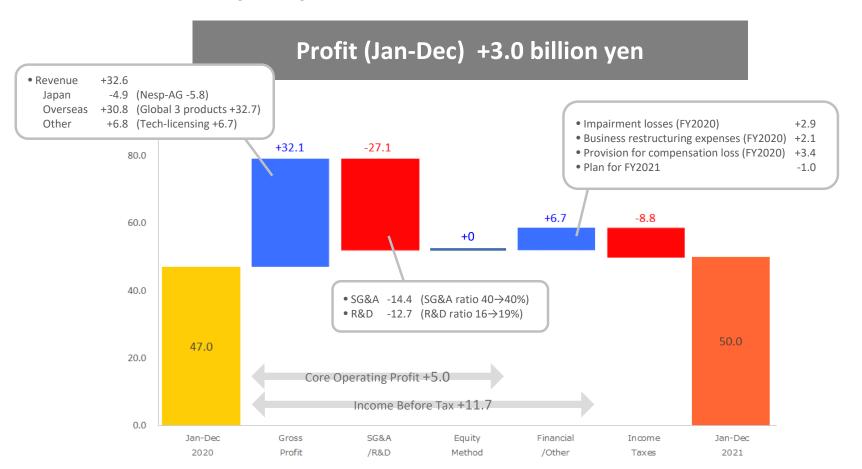
FY2021 Plan

(Billion Yen / Rounded)

	2019 Result	2020 Result	2021 Plan	Change
Revenue [Overseas Ratio]	305.8 [39%]	318.4 [48%]	351.0 [54%]	+32.6 (+10%)
Gross Profit [Gross Profit Margin]	226.2 [74%]	237.9 [75%]	270.0 [77%]	+32.1 (+13%)
SG&A [S&G Ratio]	117.3 [38%]	126.6 [40%]	141.0 [40%]	+14.4 (+11%)
R&D [R&D Ratio]	53.5 [17%]	52.3 <i>[16%]</i>	65.0 [19%]	+12.7 (+24%)
Gain/Loss on Equity Method	4.0	1.0	1.0	+0.0 (+4%)
Core Operating Profit [Core OP Margin]	59.4 [19%]	60.0 [19%]	65.0 [19%]	+5.0 (+8%)
Profit	37.7 (Only Continued Business)	47.0	50.0	+3.0 (+6%)



FY2020 vs FY2021 (Plan) -Profit-





Shareholder Return Plan



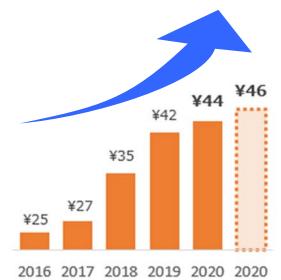
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Shareholder Return Plan

- ✓ FY2020 dividend to be 44 yen, and FY2021 planned to be 46 yen
- **✓ Consecutive up** during FY16-20 term aiming "Leap forward to GSP"
- ✓ **5yr average payout ratio is 39.7**% (against the policy to make it approx. 40%)

Voor	D	ividend (yei	Payout	Return on	
Year	Interim	Year-end		Ratio*1	Equity
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 (Plan)	23.00	23.00	46.00	48.5%	7.0%

^{*1} Payout ratio for 2021 is the one based on the core earnings (Profit - Other income/loss - Income tax related to the other income/loss)



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



R&D Review



Key Development Updates in 20Q4

- 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)
- Marketing authorization application of KRN23 for TIO in China (October)
- Approval of marketing authorization of KHK4827 for psoriasis in Malaysia (November) and partial change approval for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis in Japan (November)
- Completion of phase 1 study of automated injection device of KRN125 (G-lasta®) in Japan
 To be filed during 21Q3 in collaboration with Terumo Corporation
- Initiation of an innovative collaboration with Axcelead in small-molecule drug development in Japan (October)
- Initiation of an AI-powered novel target discovery collaboration with InveniAI (December)



Key Development Updates after December

- Initiation of the phase 3 study of RTA 402 for autosomal dominant polycystic kidney disease in Japan (January)
- Approval of marketing authorization of KRN23 for XLH in China (January)
- Marketing authorization application of KRN23 for TIO in Europe (January)



Business Topics



Key Business Updates in 20Q4 and in January 2021

- Started construction on the New Quality Building (biopharmaceutical analysis facility) at the Takasaki Plant in Japan (October 2020)
- Approval for Partial Change of Rituximab Biosimilar for the treatment of acquired thrombotic thrombocytopenic purpura in Japan (November 2020)
- Crysvita® has become available to be reimbursed as a self-injection formulation in Japan (December 2020)
- Approval of Dovobet® Foam for Psoriasis Vulgaris in Japan (January 2021)



Appendix



FOREX Information

Average FOREX Rate

(Yen)

Currency	2019 Results	2020 Results	Change	2021 Plan
USD/JPY	109	107	-2	105
GBP/JPY	140	137	-3	140

FY2020 FOREX Impact (YoY)

(Billion yen)

Currency	Revenue	Core OP
USD/JPY	-1.3	-0.7
GBP/JPY	-1.1	-0.3

FY2021 Currency Fluctuation Sensitivity

(Billion yen)

Currency	Changes	Revenue	Core OP
USD/JPY	+1 yen	-0.9	-0.5
GBP/JPY	+1 yen	-0.4	-0.1



Key Progress in Development (2020)

Note: Listed events were completed between January 1st, 2020 and December 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	NA	Accepted sBLA submission & priority review designation
May	Zandelisib	ME-401	follicular lymphoma and other B-cell malignancies	NA	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	NA	Approved sBLA
Jul.	Burosumab	KRN23	Adult XLH	EU	Received positive CHMP opinion
Sep.	Burosumab	KRN23	Adult XLH	EU	Approved expanded MAA
Oct.	Zandelisib	ME-401	Indolent B-cell non-Hodgkin's Lymphoma	JP	Initiated phase 2 study
Oct.	-	KW-6356	Parkinson's disease	JP	Met phase 2b primary endpoint
Oct.	Tenapanor	KHK7791	Hemodialysis patients with hyperphosphatemia	JP	Presented phase 2 data at ASN
Nov.	Brodalumab	KHK4827	Ankylosing spondylitis and Non-radiographic axial spondyloarthritis	JP	Approved partial change

¹ Filed indication is an adjunctive treatment to levodopa-based regimens in adult patients with Parkinson's disease experiencing "OFF" time EU: Europe, JP: Japan, NA: North America



Submission Plan of Major Pipeline

As of December 31st, 2020

						AS OT D	ecember 31 st , 2020
Generic name	Code	Indication	Country/region	2020 H1	2020 H2	2021H1	2021H2
Brodalumab	KHK4827	Psoriasis	CN	+			
Brodalumab	KHK4827	Psoriasis	AS		+5		
Brodalumab	KHK4827	Ankylosing spondylitis, non- radiographic 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	NA EU CN	+	Filed ⁸	Submission ⁹	
Istradefylline	KW-6002	Parkinson's disease	EU			+	
Romiplostim	AMG531	Aplastic anemia ³	TW		+		
Romiplostim	AMG531	ITP	CN			+	
Darbepoietin alfa	KRN321	Renal anemia on hemodialysis	CN	+			
Pegfilgrastim	KRN125	Mobilization of HSCs into peripheral blood	JP			Submission	
Pegfilgrastim	KRN125	Chemotherapy-induced febrile neutropenia	JP				Submission ¹⁰
Bardoxolone methyl	RTA 402	Alport syndrome	JP			Submi	ssion

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, China; ⁸ China; ⁹ Europe; ¹⁰ Automated injection device

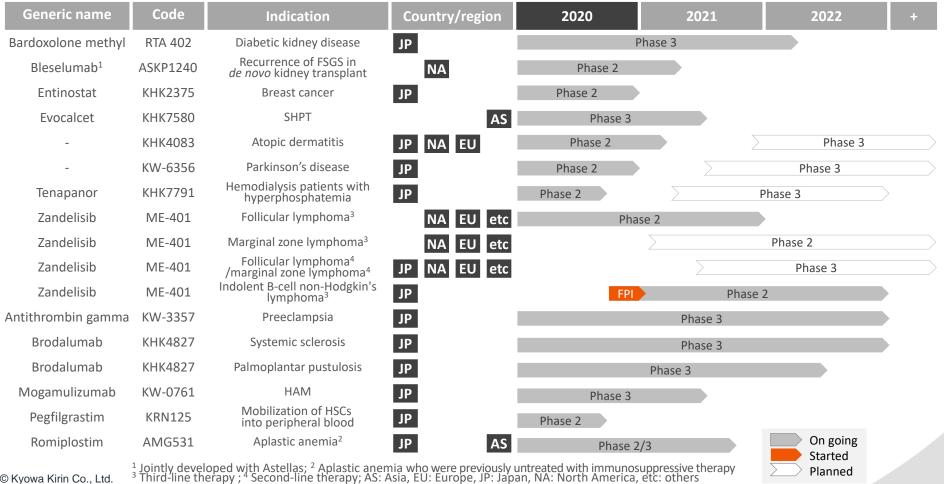
AS: Asia, CN: China, EU: Europe, JP: Japan, NA: North America, TW: Taiwan

+ Estimated time of regulatory decisions
Completed
Planned



Development Plan of Major Pipeline

As of December 31st, 2020





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)
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 https://www.nanbyou.or.jp/entry/106 Accessed January 29, 2021.
ITP	Japan	i: 3,000 per year p: 20,000	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/157 Accessed January 29, 2021.
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 January 29, 2021.
FL	Japan	i: 6,750 per year	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 Lymphoma.org https://lymphoma.org/ Accessed January 29, 2021.
MZL	Japan	i: 1,060 per year	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 salesPay up to 10% sales royalty to Ultragenyx	• Receives up to 10% sales royalty
Latin America	 Receives low single-digit sales royalty from Ultragenyx 	Books salesPays 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 salesPays 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



Kyowa Kirin Co., Ltd.
Corporate Communications Dept., IR Group +81-3-5205-7206 / ir@kyowakirin.com