

Results Presentation

Fiscal 2021 Third Quarter

Kyowa Kirin Co., Ltd.

The logo for Kyowa Kirin, featuring a stylized 'K' icon followed by the text 'KYOWA KIRIN' in a bold, sans-serif font. The logo is positioned on an orange semi-circular background element in the bottom right corner of the slide.

KYOWA KIRIN

Agenda

Financial Review

Executive Officer, Finance **Motohiko Kawaguchi**

Commercial Update

Managing Executive Officer, Corporate Strategy & Planning **Takeyoshi Yamashita, Ph.D.**

R&D Update

Executive Officer, Vice President, R&D **Yoshifumi Torii, Ph.D.**

Q&A

Managing Executive Officer, Corporate Strategy & Planning **Takeyoshi Yamashita, Ph.D.**

Executive Officer, Finance **Motohiko Kawaguchi**

Executive Officer, Vice President, R&D **Yoshifumi Torii, Ph.D.**

Executive Officer, Global Product Strategy **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

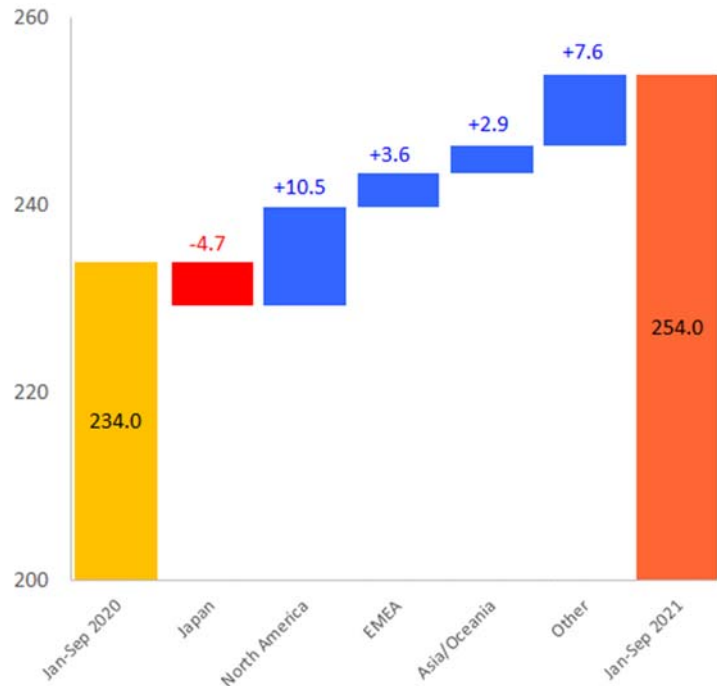
Summary of Q3 Results

(Billion Yen / Rounded)

	2020Q3 Results	2021Q3 Results	Changes	2021 Plans	Progresses
Revenue <i>[Overseas Ratio]</i>	234.0 <i>[47%]</i>	254.0 <i>[53%]</i>	+20.0 (+9%)	351.0 <i>[54%]</i>	72%
Gross Profit <i>[Gross Profit Margin]</i>	175.4 <i>[75%]</i>	189.9 <i>[75%]</i>	+14.5 (+8%)	270.0 <i>[77%]</i>	70%
SG&A <i>[SG&A Ratio]</i>	88.1 <i>[38%]</i>	104.1 <i>[41%]</i>	+16.0 (+18%)	141.0 <i>[40%]</i>	74%
R&D <i>[R&D Ratio]</i>	37.0 <i>[16%]</i>	40.2 <i>[16%]</i>	+3.2 (+9%)	65.0 <i>[19%]</i>	62%
Gain/Loss on Equity Method	0.5	1.3	+0.8 (+163)	1.0	130%
Core Operating Profit <i>[Core OP Margin]</i>	50.7 <i>[22%]</i>	46.8 <i>[18%]</i>	-3.9 (-8%)	65.0 <i>[19%]</i>	72%
Profit	37.5	32.9	-4.6 (-12%)	50.0	66%

YoY Analysis -Revenue-

**+20.0 billion yen
(incl. forex effect +4.6)**



● Japan -4.7

Crysvita, Haruropi, Duvroq (New products), G-Lasta (Market's expansion & recovery) and Patanol (Higher pollen) and increased. However, Nesp-AG (Competitors) and Romiplate (Supply constraints) were down. In addition, there were negative impacts by NHI price-cut applied in April 2020 & April 2021 and co-promotion termination of Asacol, Minirinmelt and Desmopressin.

● North America +10.5 (incl. forex effect +0.0)

Crysvita, Poteligeo, and Nourianz increased. Crysvita was growing favorably and Poteligeo sees the continued market recovery from the Covid pandemic since Q2. Nourianz is steadily penetrating to the market.

● EMEA +3.6 (incl. forex effect +3.2)

Crysvita maintained steady growth supported by farther launches and label expansion to adult. Poteligeo increased after its first launch in Germany in June 2020. On the other hand, Abstral decreased due to emergence of generics and supply constraints.

● Asia/Oceania +2.9 (incl. forex effect +1.3)

China business increased centered on Regpara.

● Other +7.6 (incl. forex effect -0.1)

Sales royalties of Fasenra (Benralizumab) increased. Received US\$10M upfront payment regarding license-out of anti-LIGHT antibody. Initiated to recognize deferred revenue of upfront payment from KHK4083 joint development/commercial agreement (US\$400M) from July.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2020Q3 Results	2021Q3 Results	Changes	Reasons	2021 Plans	Progresses
Nesp + Nesp-AG* ¹	21.9	19.6	-2.3 (-11%)		23.2	84%
Nesp	3.3	2.9	-0.4 (-12%)	Biosimilars' penetration & NHI price-cut	3.8	77%
Nesp-AG	18.6	16.7	-2.0 (-11%)		19.4	86%
Duvroq	0.5	1.4	+0.9 (+187%)	Launched in Aug 2020	4.0	34%
Regpara	2.9	2.1	-0.7 (-25%)		2.0	107%
Orkedia	6.6	7.1	+0.6 (+9%)		10.4	69%
G-Lasta	19.6	21.2	+1.6 (+8%)	Market's expansion & recovery	29.8	71%
Poteligeo	1.5	1.5	-0.0 (-3%)		2.0	74%
Rituximab BS	8.6	8.1	-0.5 (-6%)	Covid-19	11.5	70%
Romiplate	5.8	4.9	-0.9 (-16%)	Supply constraints (2020.6-2021.3)	8.7	56%
Allelock	6.5	6.3	-0.3 (-4%)		6.8	92%
Patanol	8.7	9.2	+0.5 (+6%)	Higher pollen	10.9	84%
Nourias	6.9	6.4	-0.5 (-8%)	Competitors' penetration	9.1	70%
Haruropi	0.4	2.2	+1.7 (+418%)	Launched in Dec 2019	4.6	47%
Crysvita	2.4	5.1	+2.7 (+113%)	Launched in Dec 2019	5.5	93%
Tech-licensing	1.6	1.5	-0.2 (-10%)		2.5	59%

*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.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2020Q3 Results	2021Q3 Results	Changes	Reasons	2021 Progresses	
					2021 Plans	Progresses
Crysvita	38.5	55.1	+16.5 (+43%)	[North America] Market penetration & Expanded indication (TIO) [EMEA] Farther launches & Expanded indication (Adult) [Asia/Oceania] Launched in China	77.2	71%
North America	30.3	40.3	+10.0 (+33%)			
EMEA	8.3	14.8	+6.5 (+79%)			
Asia / Oceania	—	0.0	+0.0 (—)			
Poteligeo	8.4	11.0	+2.5 (+30%)	[North America] Signs of market recovery [EMEA] Launched in Germany in Jun 2020 & Farther launches	17.3	63%
North America	8.2	9.2	+1.0 (+12%)			
EMEA	0.2	1.8	+1.6 (+651%)			
Nourianz	1.7	3.1	+1.4 (+80%)	Market penetration	6.7	46%
Abstral	7.6	6.3	-1.4 (-18%)	Generic's penetration & Supply constraints	8.1	78%
Regpara	6.1	6.7	+0.6 (+11%)	Listed on Chinese NEDL* ¹ in Oct 2018	9.3	72%
Tech-licensing	10.9	16.4	+5.5 (+50%)	Growth of Fasenra & Upfront revenue of anti-LIGHT antibody & Deferred revenue of KHK4083 upfront	23.7	69%
Benralizumab Royalty* ²	8.3	11.7	+3.4 (+41%)			

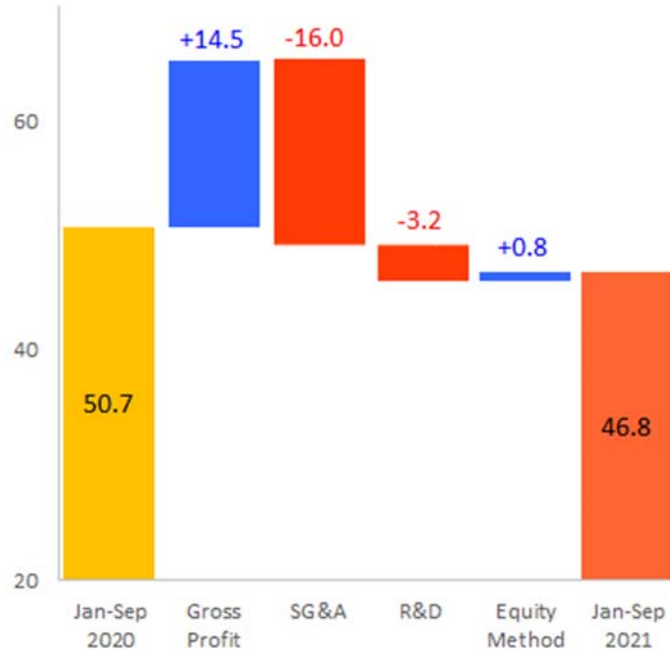
*1 National Essential Drug List

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

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

YoY Analysis -Core OP-

**-3.9 billion yen
(incl. forex effect +1.1)**



- **Gross Profit +14.5 (incl. forex effect +3.7)**

- Increased in conjunction with 20.0B yen rise in revenue.

- **SG&A -16.0 (incl. forex effect -2.4)**

- Increased for the maximization of “Global Strategic 3 Brands” (G3B) and the early consolidation of global business foundation. [Sales promotion -6.0 (incl. Crysivita’s profit sharing expenses in North America) / Labor -4.8 / Other -5.2]

- **R&D -3.2 (incl. forex effect -0.1)**

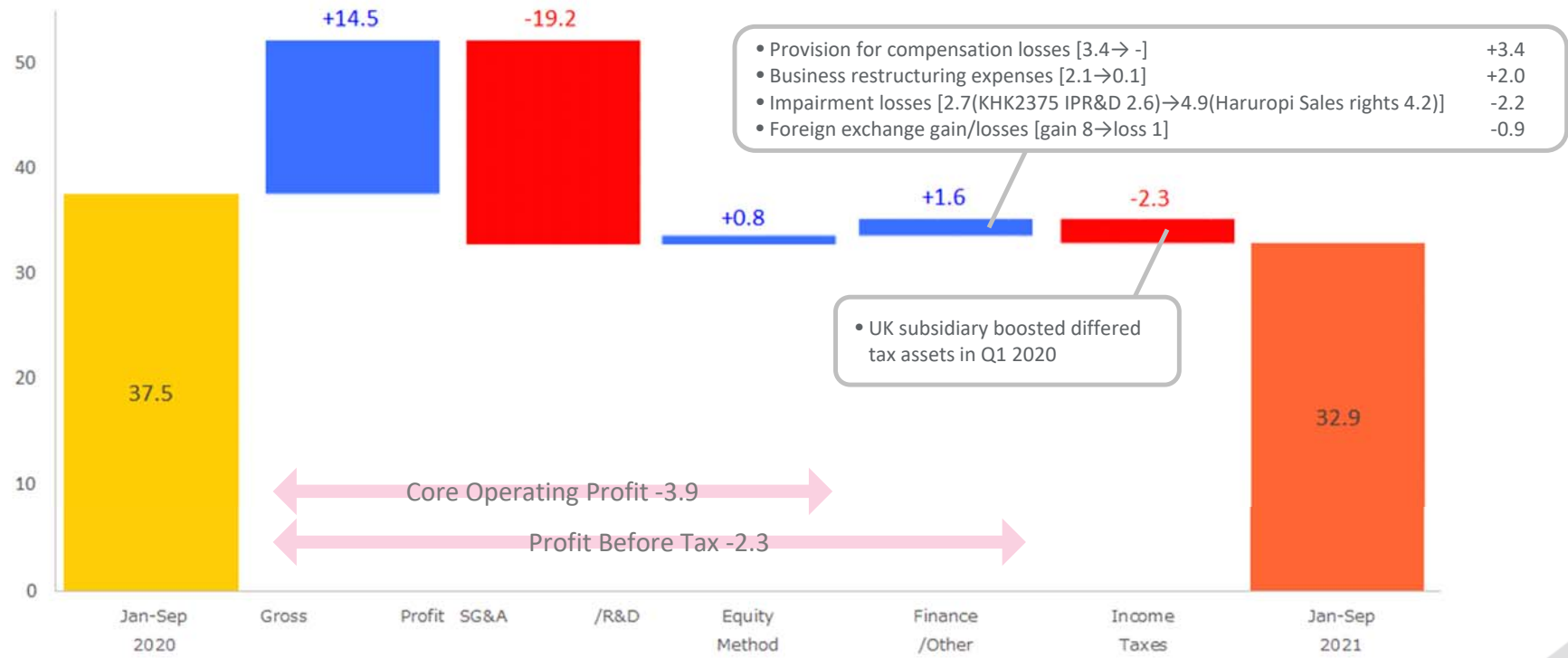
- Development cost of ME-401 and KHK7791 increased..

- **Gain/Loss on Equity Method +0.8**

- Sales of Hulio (FKB327/Adalimumab BS) increased.

YoY Analysis -Profit-

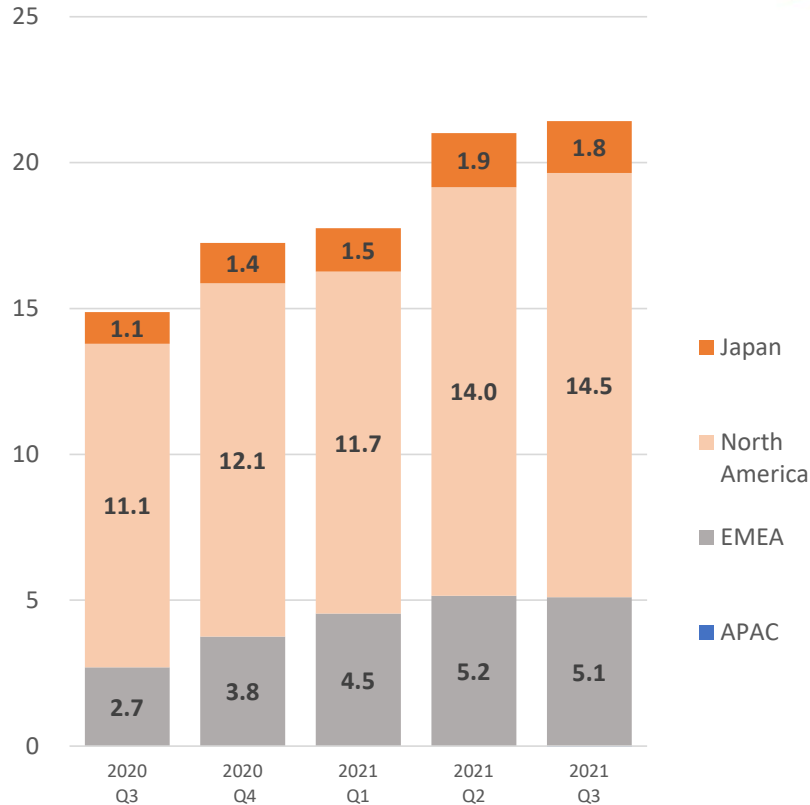
Profit (Jan-Sep) -4.6 billion yen



Commercial Update



(Billion Yen)



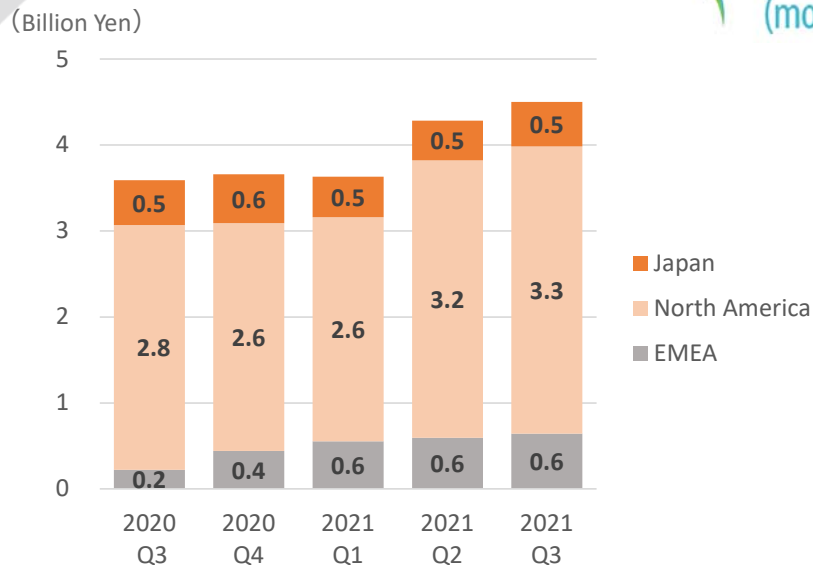
Topics

- North America: Steady progress in identifying new cases.
- EMEA: Market expansion in adults is driving the growth. In some countries where reimbursement negotiations are underway, the number of patients administered is increasing due to EAP.
- APAC: China - launched for XLH (pediatric and adult) and TIO indications (July)

Launched Countries/Regions (XLH) as of September 30, 2021 Excluding South America Underlines: Pediatric and Adult Bolded types: New launches in Q3 2021

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, France, Finland, Estonia, Spain, Ireland, Hungary, Belgium, Saudi Arabia, Hong Kong, **China**

*Early Access Program : Not included in the graph on the left side



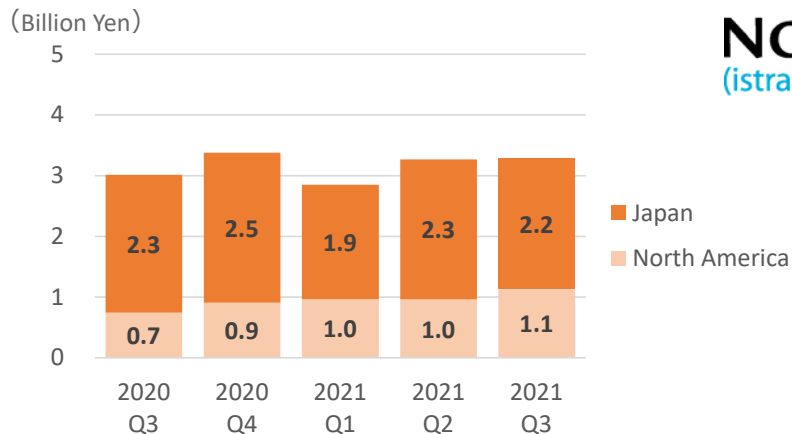
Topics

- America: Started new promotional campaign for MF/SS patients with blood tumor.
- EMEA: Launched in Spain (July), approved in Switzerland (September).

Launched Countries as of September 30, 2021

Bolded types: New launches in Q3 2021

Japan, USA, Germany, Austria, Luxembourg, Italy, Scotland, Netherlands, Belgium, Slovenia, Denmark, **Spain**



Topics

- North America: HCP-targeting and other market penetration measures are being implemented.
- Europe: MAA (Marketing Authorization Application) under re-examination by the Committee for Medicinal Products for Human Use (CHMP).

Launched Countries as of September 30, 2021

Japan, USA

R&D Update

Upcoming Events: Next-generation Strategic Products

✓ : Completed events from Jan 1 to Aug 3, 2021

✓ : Completed events from Aug 4 to Nov 1, 2021

Code generic name	Target disease	H1 2021	H2 2021	H1 2022
KHK4083/AMG 451	Atopic dermatitis	P2b topline data ✓	P2b detailed data ✓	P3 FPI
KW-6356	Parkinson's disease			P2b detailed data P3 FPI
ME-401 Zandelisib	FL (3L, mono)	P2 LPI ✓	P2 topline data	
	MZL (3L, mono)	P2 FPI ✓		
	FL/MZL (2L, combo)		P3 FPI ✓	
RTA 402 Bardoxolone methyl	Alport syndrome		MA (JP) ✓	* (JP)
	DKD			
	ADPKD	P3 FPI (JP) ✓		
KHK7791 Tenapanor	Hyperphosphatemia under maintenance dialysis	P3 FPI (JP) ✓		

* Anticipated timing of regulatory decision; FPI: first patient in; LPI: last patient in; FL: follicular lymphoma; MZL: marginal zone lymphoma; ADPKD: autosomal dominant polycystic kidney disease; DKD: diabetic kidney disease; MA: marketing application

Appendix

FOREX Information

Average FOREX Rate

(Yen)

Currency	2020Q3 Results	2021Q3 Results	Change	2021 Plans
USD/JPY	108	108	—	105
GBP/JPY	137	149	+12	140

2021Q3 FOREX Impacts (YoY)

(Billion yen)

Currency	Revenue	Core OP
USD/JPY	-0.1	-0.2
GBP/JPY	+3.2	+0.6

FY2021 FOREX Sensitivity

(Billion yen)

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

Crysvita - Collaboration with Ultragenyx -

Territories	Economic terms
U.S. & Canada	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Kyowa Kirin books sales • Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx <p>*Ultragenyx have sold a royalty right on/after 2020 to Royalty Pharma</p>
Latin America	<ul style="list-style-type: none"> • Ultragenyx books sales • Kyowa Kirin receives low single-digit sales royalties from Ultragenyx • Supply price: 35% of net sales through 2022, 30% thereafter
Turkey	<ul style="list-style-type: none"> • Ultragenyx books sales • Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx
Asia & Others	<ul style="list-style-type: none"> • Kyowa Kirin books sales

* Kyowa Kirin supplies commercial products in all territories.

KHK4083 - Collaboration with Amgen -

	US	Europe and Asia (ex. JP)	JP
Development	<ul style="list-style-type: none"> • Amgen leads development • Share development cost 	<ul style="list-style-type: none"> • Amgen leads development • Share development cost 	<ul style="list-style-type: none"> • Kyowa Kirin leads development
Commercialization	<ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin co-promotes and shares cost 	<ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin has opt-in rights for co-promotion 	<ul style="list-style-type: none"> • Kyowa Kirin commercializes and books sales
Sales Royalties	<ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin 	<ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin 	
Commercial supply	<ul style="list-style-type: none"> • Amgen supplies 	<ul style="list-style-type: none"> • Amgen supplies 	<ul style="list-style-type: none"> • Kyowa Kirin supplies

Amgen will make 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

T : Topline data

D : Detailed data

As of Nov 1st, 2021

Code generic name	Target disease	2021	2022	2023	+
KHK4083/AMG451	Atopic dermatitis	P2b T D			
		P3			
KW-6356	Parkinson's disease	P2b	D		
		P3			
ME-401 Zandelisib	FL (mono, 3L)	P2	T		
	MZL (mono, 3L)	P2			
	FL/MZL (combo, 2L)	P3			
	iB-NHL (mono, 3L) ¹	P2			
RTA 402 Bardoxolone methyl	Alport syndrome		MA ¹	*2	
	Diabetic kidney disease	P3			
	ADPKD	P3			
KHK7791 Tenapanor	Hyperphosphatemia under maintenance dialysis	P3			
		P3			
		P3			
		P3			

¹ Japan; ² Anticipated timing of regulatory decision; MA: marketing application; FL: follicular lymphoma; MZL: marginal zone lymphoma; iB-NHL: indolent B-cell non-Hodgkin's lymphoma; ADPKD: autosomal dominant polycystic kidney disease; 3L: third-line therapy; 2L: second-line 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)
CTCL	JP		2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
CTCL	US	1,500 / y		SEER Data (2001-2007)
XLH	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
XLH	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
PD	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 October 13, 2021.
FL	US	15,000 / y		Cited from Cancer.net https://www.cancer.net/ Accessed October 13, 2021.
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)
MZL	US	6,000 / y		Cited from Lymphoma.org https://lymphoma.org/ Accessed October 13, 2021.
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 October 13, 2021.
ADPKD	JP		31,000	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/295 Accessed October 13, 2021.
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)

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
DKD	Diabetic Kidney Disease
FL	Follicular Lymphoma
iB-NHL	Indolent B-cell Non-Hodgkin Lymphoma
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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