

Results Presentation

Fiscal 2021 First Quarter

Kyowa Kirin Co., Ltd.

The logo for Kyowa Kirin, featuring a stylized 'K' inside a circle followed by the text 'YOWA 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, Head of Finance **Motohiko Kawaguchi**

Commercial Update

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

R&D Update

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

Q&A

Executive Officer, Head of Finance **Motohiko Kawaguchi**

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

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

Executive Officer, Head of 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.

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Financial Review

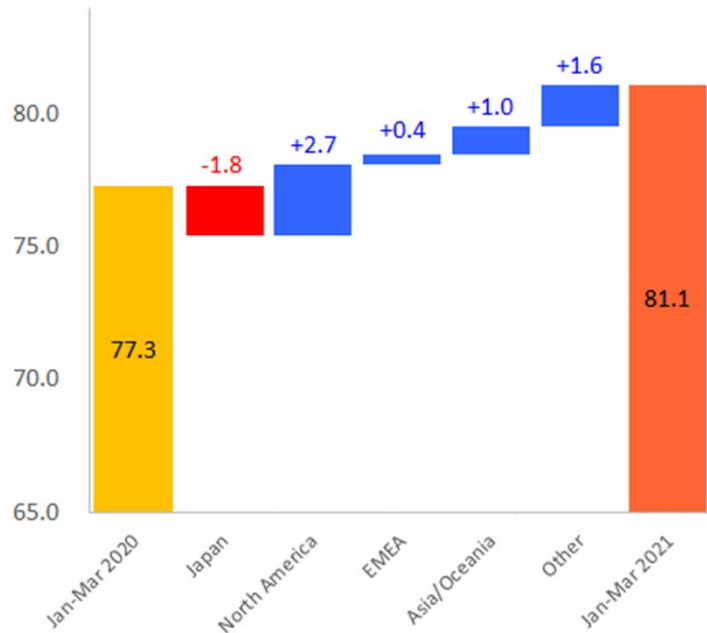
Summary of Q1 Results

(Billion Yen / Rounded)

	2020Q1 Results	2021Q1 Results	Changes	2021 Plans	Progresses
Revenue <i>[Overseas Ratio]</i>	77.3 <i>[44%]</i>	81.1 <i>[50%]</i>	+3.8 (+5%)	351.0 <i>[54%]</i>	23%
Gross Profit <i>[Gross Profit Margin]</i>	57.9 <i>[75%]</i>	58.7 <i>[72%]</i>	+0.8 (+1%)	270.0 <i>[77%]</i>	22%
SG&A <i>[SG&A Ratio]</i>	29.7 <i>[38%]</i>	31.7 <i>[39%]</i>	+1.9 (+7%)	141.0 <i>[40%]</i>	22%
R&D <i>[R&D Ratio]</i>	11.8 <i>[15%]</i>	12.2 <i>[15%]</i>	+0.4 (+3%)	65.0 <i>[19%]</i>	19%
Gain/Loss on Equity Method	4	6	+0.3 (+66%)	1.0	64%
Core Operating Profit <i>[Core OP Margin]</i>	16.8 <i>[22%]</i>	15.5 <i>[19%]</i>	-1.2 (-7%)	65.0 <i>[19%]</i>	24%
Profit	13.8	12.9	-0.9 (-7%)	50.0	26%

YoY Analysis -Revenue-

+3.8 billion yen
(incl. forex effect -0.9)



● Japan -1.8

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

● North America +2.7 (incl. forex effect -0.8)

Crysvita maintained a steady growth. Nourianz, launched in 2019, was also up. Poteligeo was at the same level as 2020 due to the pandemic.

● EMEA +0.4

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 was decreased due to emergence of generics and supply constraints.

● Asia/Oceania +1.0 (incl. forex effect +0.1)

Regpara favorably keeps growing in China.

● Other +1.6 (incl. forex effect -0.2)

- Sales royalties of Fasenna (Benralizumab) made steady growth. In addition, we received US\$10M upfront payment from Aevi Genomic Medicine regarding license-out of anti-LIGHT antibody.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2020Q1 Results	2021Q1 Results	Changes	Reasons	2021 Plans	Progresses
Nesp + Nesp-AG* ¹	7.4	6.5	-1.0 (-13%)		23.2	28%
Nesp	1.2	1.0	-0.2 (-19%)	Biosimilars' penetration	3.8	25%
Nesp-AG	6.3	5.5	-0.7 (-12%)		19.4	28%
Duvroq	—	0.2	+0.2 (—)	Launched in Aug 2020	4.0	4%
Regpara	1.0	0.7	-0.3 (-31%)		2.0	33%
Orkedia	2.0	2.1	+0.1 (+7%)		10.4	20%
G-Lasta	6.1	6.6	+0.5 (+8%)	Market's expansion & recovery	29.8	22%
Poteligeo	0.5	0.5	-0.0 (-3%)		2.0	24%
Rituximab BS	2.6	2.6	+0.1 (+2%)		11.5	23%
Romiplate	2.0	1.5	-0.5 (-24%)	Supply constraints (2020.6-2021.3)	8.7	17%
Allelock	3.0	2.9	-0.1 (-4%)		6.8	43%
Patanol	5.9	6.5	+0.6 (+11%)	Higher pollen	10.9	60%
Nourias	2.2	1.9	-0.3 (-14%)	Competitors' penetration	9.1	21%
Haruropi	0.1	0.6	+0.5 (+504%)	Launched in Dec 2019	4.6	12%
Crysvita	0.5	1.5	+1.0 (+182%)	Launched in Dec 2019	5.5	27%
Tech-licensing	0.3	0.6	+0.3 (+90%)		2.5	24%

*1 AG stands for Authorized Generic. Official product name is Darbeapoetin 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	2020Q1 Results	2021Q1 Results	Changes	Reasons	2021 Progresses	
					2021 Plans	Progresses
Crysvita	12.0	16.3	+4.3 (+36%)	[North America] Market penetration & Expanded indication (TIO) [EMEA] Farther launches & Expanded indication (Adult)	77.2	21%
North America	9.2	11.7	+2.5 (+28%)			
EMEA	2.8	4.5	+1.8 (+64%)			
Poteligeo	2.9	3.2	+0.2 (+8%)	[North America] COVID-19 [EMEA] Launched in Germany in Jun 2020 & Farther launches	17.3	18%
North America	2.9	2.6	-0.3 (-11%)			
EMEA	—	0.6	+0.6 (—)			
Nourianz	0.4	1.0	+0.6 (+168%)	Market penetration	6.7	14%
Abstral	2.8	1.8	-1.0 (-35%)	Generic's penetration & Supply constraints	8.1	22%
Regpara	1.7	2.2	+0.5 (+31%)	Listed on Chinese NEDL* ¹ in Oct 2018	9.3	24%
Tech-licensing	3.1	4.9	+1.8 (+59%)	Growth of Fasenra & Upfront revenue of anti-LIGHT antibody license-out	23.7	21%
Benralizumab Royalty* ²	2.7	3.8	+1.1 (+40%)			

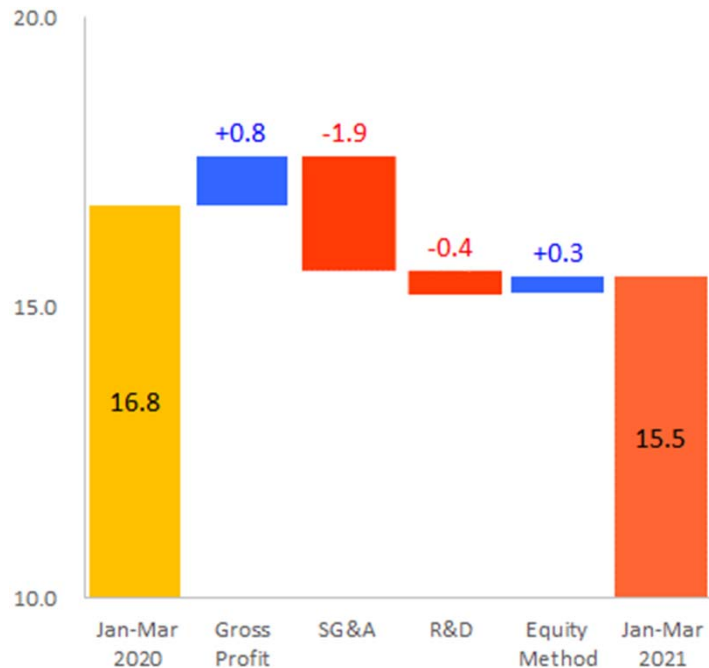
*1 National Essential Drug List

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

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

YoY Analysis -Core OP-

**-1.2 billion yen
(incl. forex effect -0.4)**



- **Gross Profit +0.8 (incl. forex effect -0.9)**
 - Despite the revenue was up by 3.8B yen, it resulted in 0.8B increase due to the elimination of intercompany profits on inventories, etc.

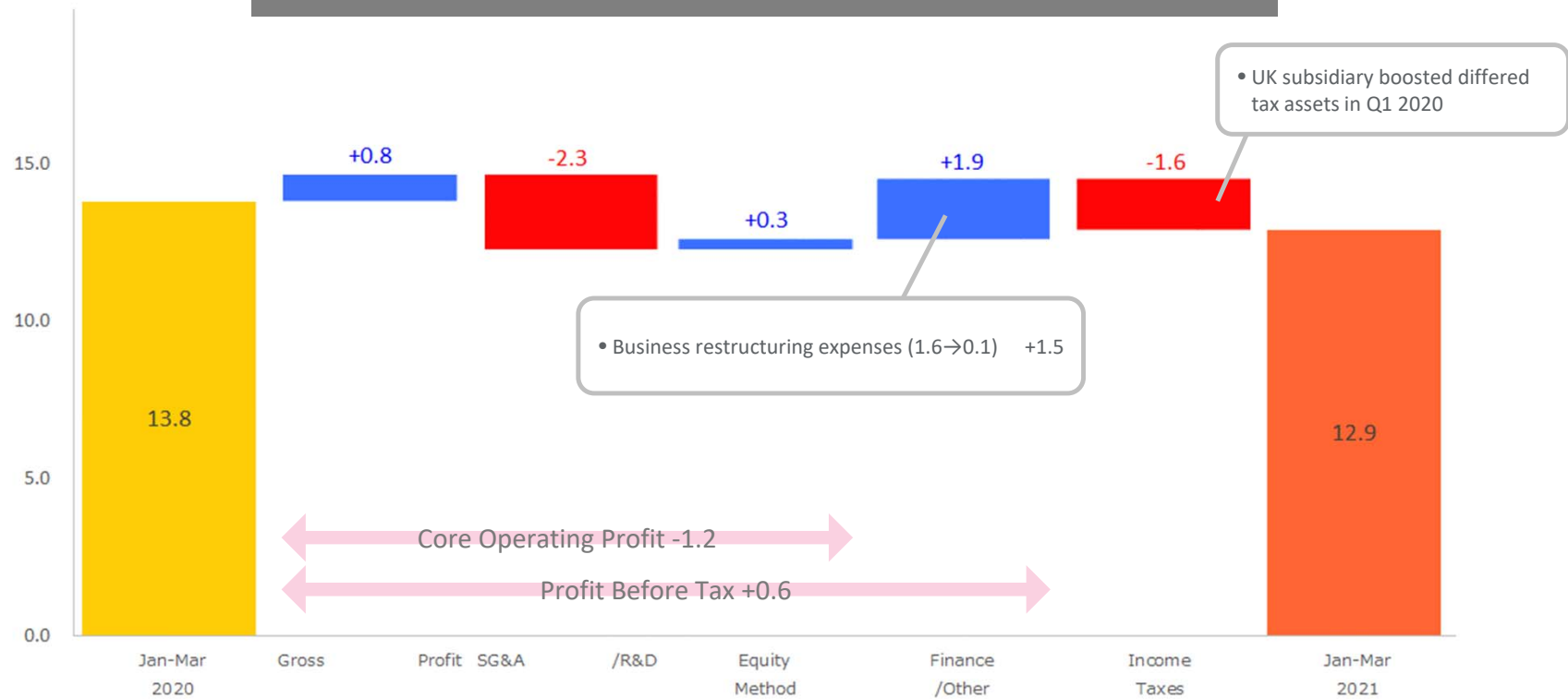
- **SG&A -1.9 (incl. forex effect +0.3)**
 - Increased selling and launch readiness expenses in the EU/US market, including Crysvita’s profit sharing expenses in North America.

- **R&D -0.4 (incl. forex effect +0.2)**

- **Gain/Loss on Equity Method +0.3**
 - Sales of Hulio (FKB327, Adalimumab BS) increased.

YoY Analysis -Profit-

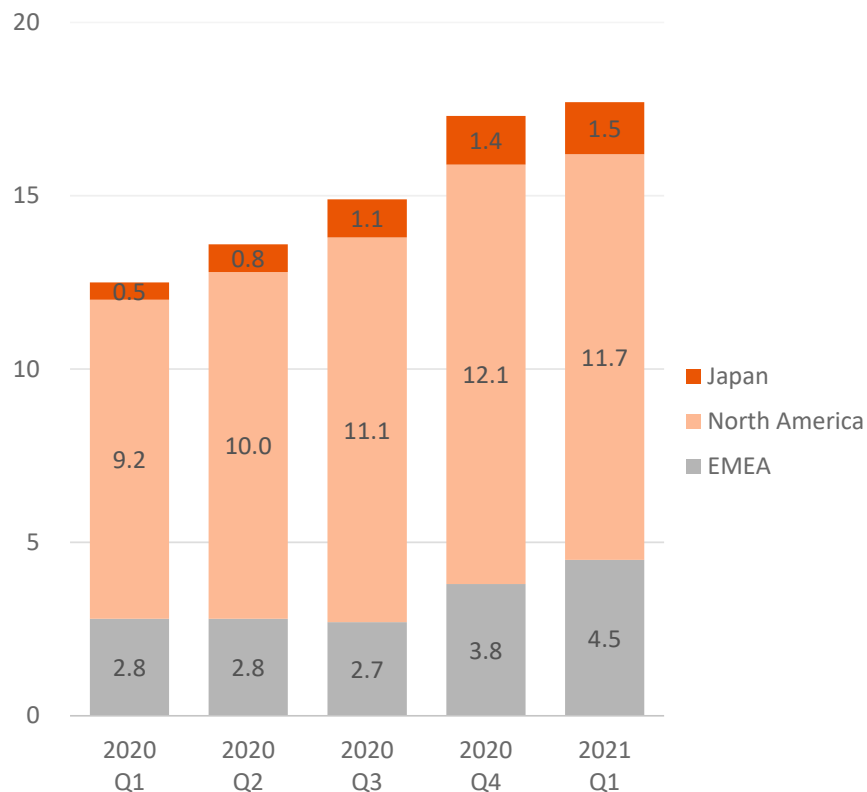
Profit (Jan-Mar) -0.9 billion yen



Commercial Update



(Billion Yen)

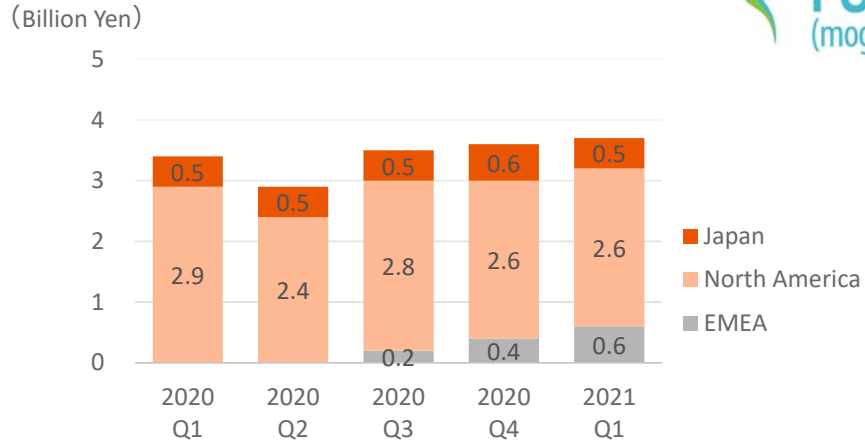


Topics

- Steady sales in Japan, North America, and EMEA even under the influence of COVID-19.
- In EMEA, indications for adult were expanded in Luxembourg, Oman, Kuwait, and Qatar during the Q1 period.
- Sales in Germany are steadily increasing due to the expansion of the indication to adults.
- In China, following the approval for XLH in January, approved for TIO in March.

Launched Countries/Regions (XLH) as of March 31, 2021 Excluding South America Underlines: Pediatric and Adult

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

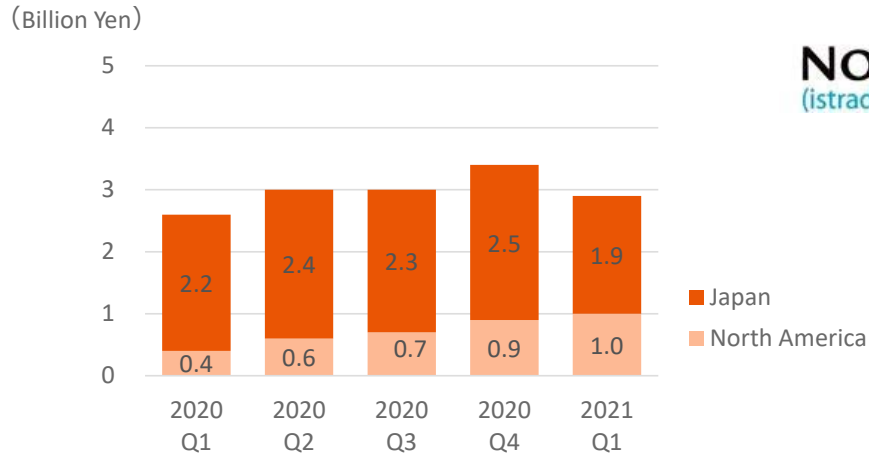


Topics

- Approved in Australia (Jan)
- Application for marketing authorization in Kuwait (Feb)
- Application for marketing authorization in Canada (March)

Launched Countries as of March 31, 2021

Japan, USA, Germany, Austria, Luxembourg, Italy



Topics

- Gradual improvement in call activity in North America impacted by COVID-19
- Ongoing review by EMA in Europe

Launched Countries as of March 31, 2021

Japan, USA

R&D Update

Upcoming events: our Next-generation Strategic Products

✓ : Completed events from Jan 1 to May 6, 2021

Code generic name	Target disease	H1 2021	Mid-2021*1	H2 2021
KHK4083	Atopic dermatitis	P2b topline data ✓		P2b detailed data
KW-6356	Parkinson's disease			P2b detailed data
ME-401 Zandelisib	FL (3L, mono)	P2 LPI ✓		P2 topline data
	FL/MZL (2L, combo)		P3 FPI	
RTA 402 Bardoxolone methyl	Alport syndrome		MA (JP)	
	DKD			
	ADPKD	P3 FPI (JP) ✓		
KHK7791 Tenapanor	Hyperphosphatemia under maintenance dialysis	P3 FPI (JP) ✓		

*1 Events anticipated to be achieved around the end of the H1 2021 at present;

FPI: first patient in; LPI: last patient in; FL: follicular lymphoma; MZL: marginal zone lymphoma; ADPKD: autosomal dominant polycystic kidney disease; MA: marketing application

Appendix

FOREX Information

Average FOREX Rate

(Yen)

Currency	2020Q1 Results	2021Q1 Results	Change	2021 Plans
USD/JPY	110	105	-5	105
GBP/JPY	143	143	—	140

2021Q1 FOREX Impacts (YoY)

(Billion yen)

Currency	Revenue	Core OP
USD/JPY	-1.0	-0.5
GBP/JPY	—	—

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 has 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.

Development Plan of Next-generation Strategic Products

T : Topline data

D : Detailed data

As of May 6th, 2021

Code generic name	Target disease	2021	2022	2023	+
KHK4083	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)	P2			
RTA 402 Bardoxolone methyl	Alport syndrome		MA ¹		
	Diabetic kidney disease	P3			
	ADPKD	P3			
KHK7791 Tenapanor	Hyperphosphatemia under maintenance dialysis	P3			
		P3			
		P3			
		P3			

¹ Japan; 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, EU5		16,000,000	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 April 15, 2021.
FL	US	15,000 / y		Cited from Cancer.net https://www.cancer.net/ Accessed January 29, 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 January 29, 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 April 15, 2021.
ADPKD	JP		31,000	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/295 Accessed April 15, 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

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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