

Results Presentation

Fiscal 2022 Third Quarter

協和キリン株式会社



KYOWA KIRIN

Agenda

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

Commercial Update

Executive Officer, Head of Global Product Strategy **Tomohiro Sudo**

R&D Update

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

News Flow in 2022

Managing Executive Officer, Head of Strategy **Takeyoshi Yamashita, Ph.D.**

Q&A

Managing Executive Officer, Head of Strategy **Takeyoshi Yamashita, Ph.D.**

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

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

Executive Officer, Head of Global Product Strategy **Tomohiro Sudo**

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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

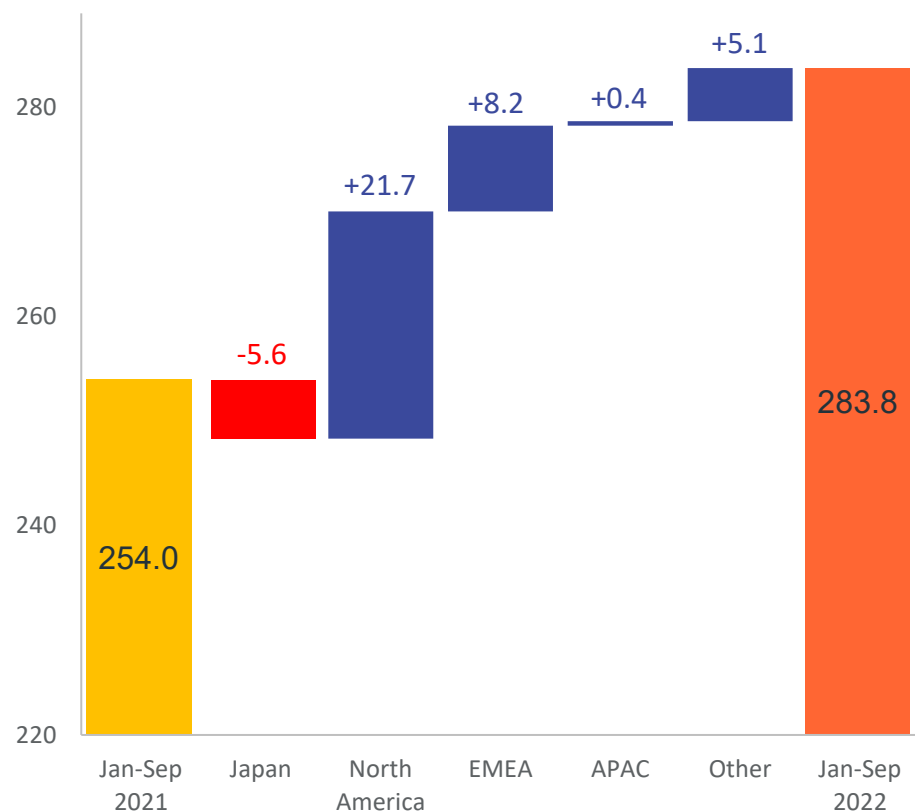
Summary of Q3 Results

(Billion Yen / Rounded)

	2021Q3 Results	2022Q3 Results	Changes	2022 Revised Plans	Progresses
Revenue <i>[Overseas Ratio]</i>	254.0 <i>[53%]</i>	283.8 <i>[61%]</i>	+29.8 (+12%)	400.0 <i>[62%]</i>	71%
Gross Profit <i>[Gross Profit Margin]</i>	189.9 <i>[75%]</i>	219.6 <i>[77%]</i>	+29.8 (+16%)	312.0 <i>[78%]</i>	70%
SG&A <i>[SG&A Ratio]</i>	104.1 <i>[41%]</i>	117.3 <i>[41%]</i>	+13.2 (+13%)	172.0 <i>[43%]</i>	68%
R&D <i>[R&D Ratio]</i>	40.2 <i>[16%]</i>	44.1 <i>[16%]</i>	+3.9 (+10%)	67.0 <i>[17%]</i>	66%
Gain/Loss on Equity Method	1.3	2.6	+1.3 (+103%)	4.0	66%
Core Operating Profit <i>[Core OP Margin]</i>	46.8 <i>[18%]</i>	60.9 <i>[21%]</i>	+14.0 (+30%)	77.0 <i>[19%]</i>	79%
Profit	32.9	49.2	+16.3 (+50%)	63.0	78%

YoY Analysis -Revenue-

+29.8 billion yen
(incl. forex effect +18.7)



● Japan -5.6

Although Duvroq, Romiplate, G-Lasta, and Crysvita increased, revenue in Japan region decreased by 5% due mainly to negative impact by NHI price-cut in April 2021 & April 2022 and shrink in Patanol for which generic products entered the market last December.

● North America +21.7 (incl. forex effect +10.7)

Revenue in North America region increased by 40% with the growth of Crysvita, Poteligeo, and Nouriaz.

● EMEA +8.2 (incl. forex effect +3.4)

Growth of Crysvita and Poteligeo contributed to the 21% increase in EMEA region, although Abstral fell due to generic products' penetration.

● APAC +0.4 (incl. forex effect +2.2)

APAC revenue increased by 2% with the growth of Gran, Nesp, Neulasta, etc, while Regpara was down due to the Chinese national tender system.

● Other +5.1 (incl. forex effect +2.5)

22% growth in the other revenue was due to the deferred revenue of USD400M upfront payment from KHK4083 partnership, that was initiated from last July, and royalties of growing Fasenna (Benralizumab).

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2021Q3 Results	2022Q3 Results	Changes	Reasons	2022 Rev. Plans	Progresses
Nesp + Nesp-AG ¹	19.6	15.7	-3.9 (-20%)	NHI price-cut & Biosimilars' penetration	20.7	76%
Nesp	2.9	2.5	-0.4 (-14%)		3.3	76%
Nesp-AG	16.7	13.2	-3.5 (-21%)		17.4	76%
Duvroq	1.4	4.4	+3.1 (+226%)	Market penetration (Launched in Aug 2020)	5.9	75%
Regpara	2.1	1.7	-0.5 (-23%)		2.0	83%
Orkedia	7.1	7.5	+0.4 (+5%)		10.4	72%
G-Lasta	21.2	22.7	+1.5 (+7%)	Market's recovery & penetration	31.5	72%
Poteligeo	1.5	1.5	+0.0 (+0%)		2.0	73%
Rituximab BS	8.1	7.6	-0.5 (-6%)	NHI price-cut	10.3	73%
Romiplate	4.9	7.5	+2.6 (+53%)	Recovery from supply constraints from Jun 2020 through Mar 2021	10.0	75%
Allelock	6.3	4.8	- 1.5(-24%)	Generics' penetration & NHI price-cut	5.6	85%
Patanol	9.2	2.4	- 6.8(-74%)	Generics entered in Dec 2021	3.0	81%
Nourias	6.4	5.9	-0.5 (-8%)	Competitors' penetration	8.1	72%
Haruropi	2.2	2.8	+0.6 (+29%)	Market penetration (Launched in Dec 2019)	4.1	68%
Crysvita	5.1	6.4	+1.3 (+24%)	Market penetration (Launched in Dec 2019)	9.2	69%
Tech-licensing	1.5	0.5	-0.9 (-63%)	Deferred process of FKB ² -related upfront revenue completed	0.9	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.

2 FKB stands for Fujifilm Kyowa Kirin Biologics Co., Ltd.

Revenue of Major Items (ex-Japan)

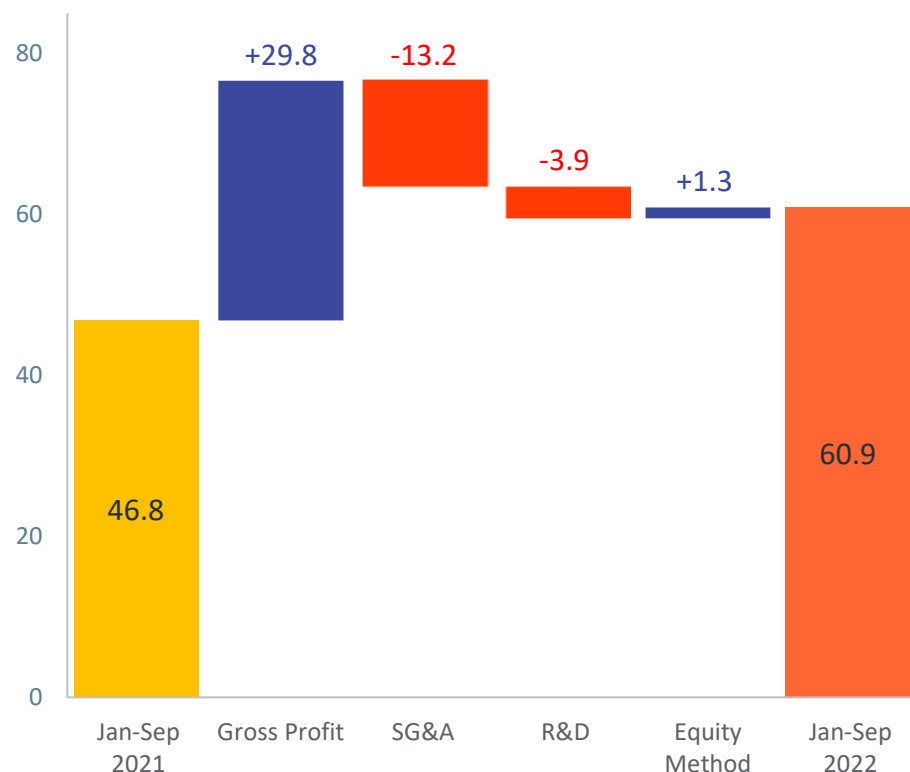
(Billion Yen / Rounded)

Item	2021Q3 Results	2022Q3 Results	Changes	Reasons	2022 Rev. Plans	Progresses
Crysvita	55.1	78.7	+23.7 (+43%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication (Adult/TIO) [APAC] Launched in China	116.2	68%
North America	40.3	57.4	+17.1 (+42%)			
EMEA	14.8	21.2	+6.5 (+44%)			
APAC	0.0	0.1	+0.1 (-)			
Poteligeo	11.0	16.1	+5.1 (+47%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration	23.6	68%
North America	9.2	12.6	+3.4 (+37%)			
EMEA	1.8	3.5	+1.7 (+96%)			
Nourianz	3.1	4.5	+1.4 (+46%)	Market penetration	6.1	73%
Abstral	6.3	5.4	-0.9 (-14%)	Generic's penetration	7.2	74%
Regpara	6.7	2.9	-3.8 (-57%)	Listed on Chinese tender list ¹ in Oct 2021	3.8	77%
Tech-licensing	16.4	23.3	+6.8 (+42%)	Deferred revenue of KHK4083 upfront payment (July 2021-) & Growth of Fasentra	35.0	67%
Benralizumab Royalty ²	11.7	15.4	+3.6 (+31%)			

- 1 Volume-Based Procurement (VBP) program that has been introduced since 2018 for reducing healthcare cost in China. A few companies are selected as a supplier through a tender, while their drug prices dramatically drop down.
 - 2 Sales royalties of Fasentra which has been marketed by AstraZeneca, including our own estimation.
- * Revenue from Early Access Program (EAP) are not included in the figures above.

YoY Analysis -Core OP-

**+14.0 billion yen
(incl. forex effect +6.7)**



- **Gross Profit +29.8 (incl. forex effect +16.6)**

Increased in conjunction with JPY29.8B rise in revenue. Margin improved by 2% (75%→77%) because there was a big negative impact related to elimination of intercompany profits on inventories last year.

- **SG&A -13.2 (incl. forex effect -7.4)**

Increased by aggressive investment in IT/Digital infrastructure and human resources for the maximization of the global 3 brands (G3B) and the early consolidation of global business foundation, in addition to Crysvita profit sharing expenses for North America.
[Labor -7.7 / Sales promotion -5.3 (incl. Crysvita profit sharing expenses -6.3) / Depreciation & Amortization +0.4 / Other -0.5]

- **R&D -3.9 (incl. forex effect -2.6)**

Clinical study costs of KHK4083 and ME-401 increased.

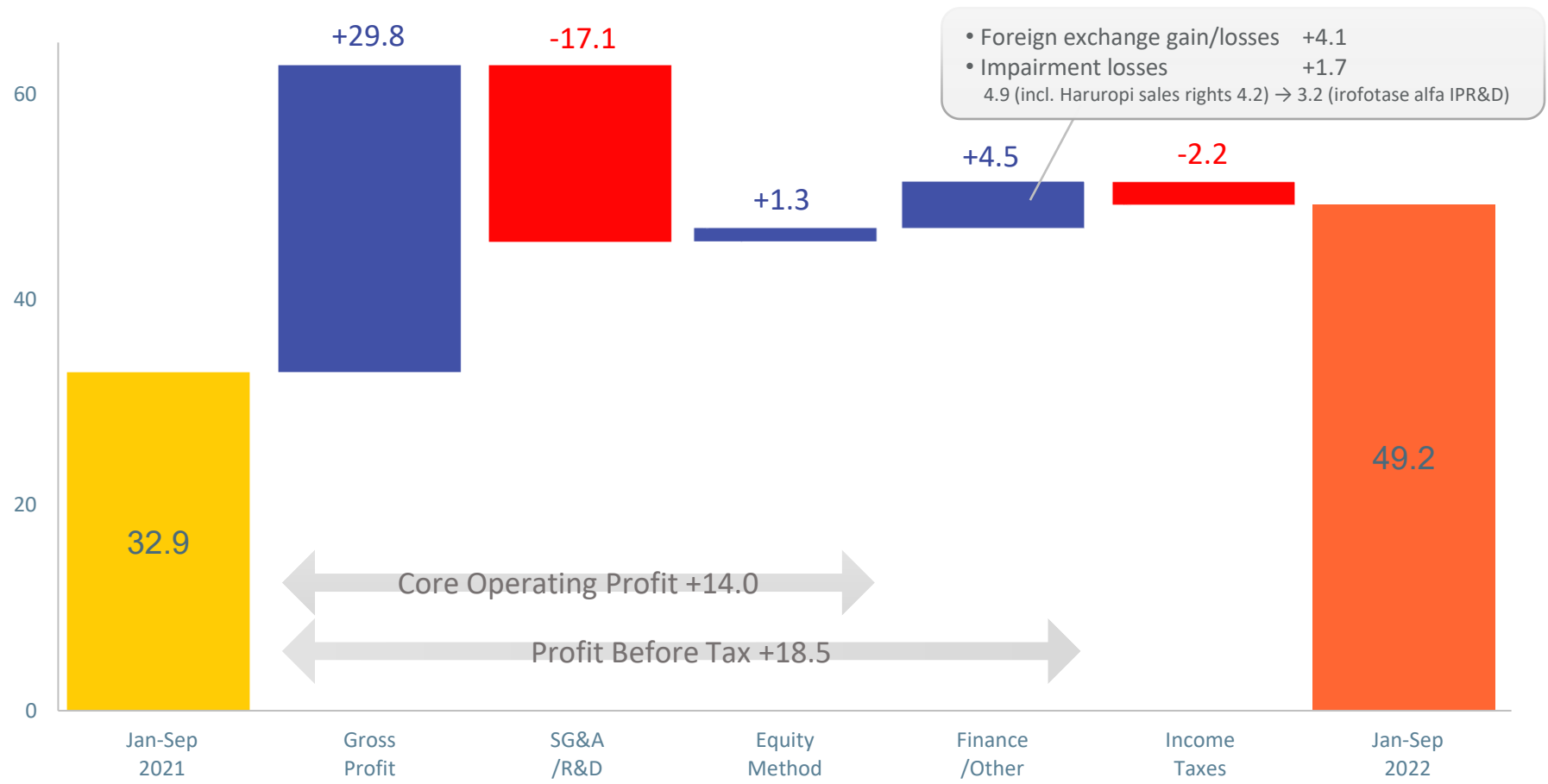
- **Gain/Loss on Equity Method +1.3**

FKB recorded additional deferred tax asset.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

YoY Analysis -Profit-

Profit (Jan-Sep) +16.3 billion yen

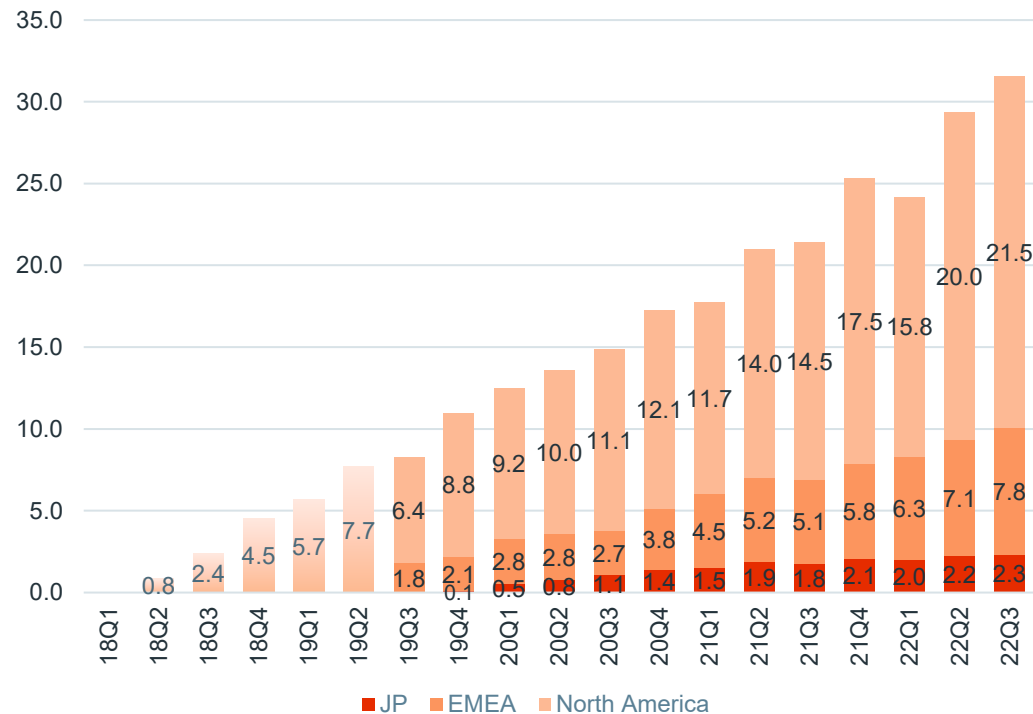


Commercial Update

Crysvita



(Billion Yen)



* Excludes EAP patients and patients who have not started reimbursement process

2022 Key Actions & Q3 Topics

2022 Key Actions

- North America: Initiate full-scale preparation for transfer of commercialization planned in spring 2023.
- EMEA: Continue to focus on geographical & indication expansion. TIO review completed.

Q3 Topics

- North America: Amended the contract with Ultragenyx for specifying the transition scheme. Finalize training of field personnel to start customer outreach in Q4.
- EMEA: Received additional approval for TIO indication from the European Commission and started commercialization.
- Japan: Dedicated personnel is assigned to each branch.

Launched Countries/Regions as of Sep 30, 2022

Excluding Latin America

Underlines: Pediatric and Adult / Bolded types: New launches in Q3 2022

- 2018 USA , Germany, Netherland, Luxembourg
- 2019 Canada, England, Wales, Northern Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain, Austria
- 2020 Scotland, Oman, Kuwait, Qatar, Romania, Slovenia, France, Finland, Estonia, Spain
- 2021 Ireland, Hungary, Belgium, Saudi Arabia, Hong Kong, China, Singapore
- 2022 Portugal, Latvia, **Thailand**

Crysvita - Agreement for Transition Scheme Change -

Economic Terms

US & Canada

- 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

- **No change in the above economic terms. From April 27, 2023, Kyowa Kirin will conduct promotional activities in the US & Canada, and pay sales royalties to Ultragenyx (and book them as COGs) as planned.**

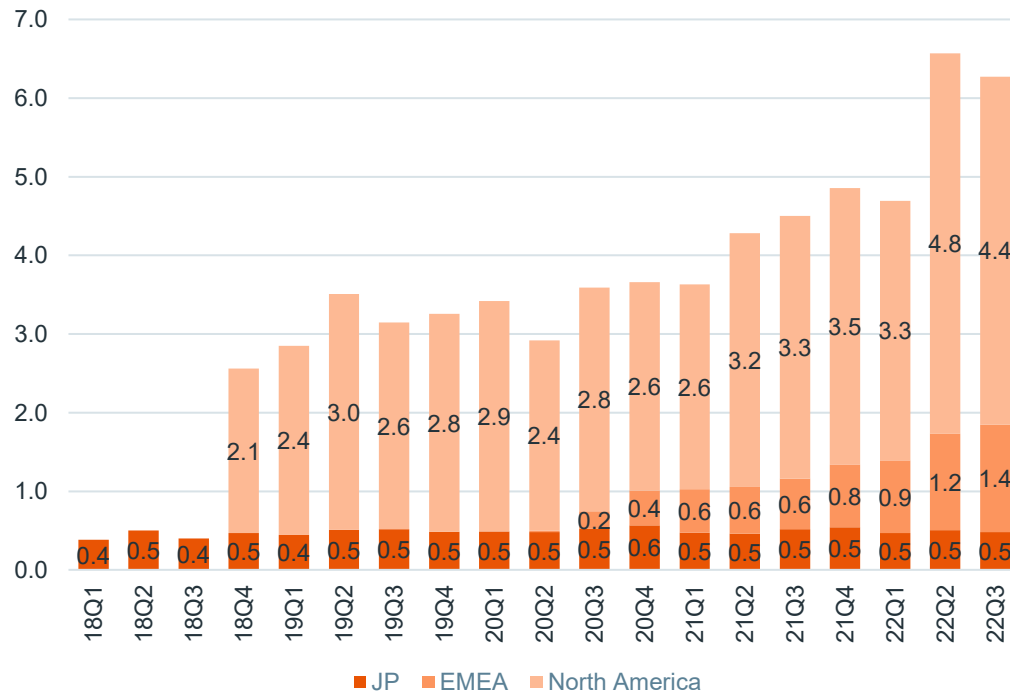
[Key Changes]

- **For one year from April 27, 2023 to April 26, 2024, Kyowa Kirin will receive field support from Ultragenyx for its promotional activities, and both companies will work together to complete the transition smoothly.**
- **The support costs incurred by Ultragenyx will be shared by both companies properly.**

Poteligeo



(Billion Yen)



* Excludes EAP patients and patients who have not started reimbursement process

2022 Key Actions & Q3 Topics

2022 Key Actions

- EMEA: Continue to talk with payers to ensure reimbursement and patient access to product.
- US/EMEA: Work with HCPs to gather and share evidence such as clinical data in association of blood tumor burden to help understand better use of Poteligeo.

Q3 Topics

- US: Steady market penetration due to continued evidence-based promotion.
- EMEA: Newly launched in UAE. Sales increased YoY due to increase in launched countries.
- APAC: Received approval in Korea.

Launched Countries/Regions as of Sep 30, 2022

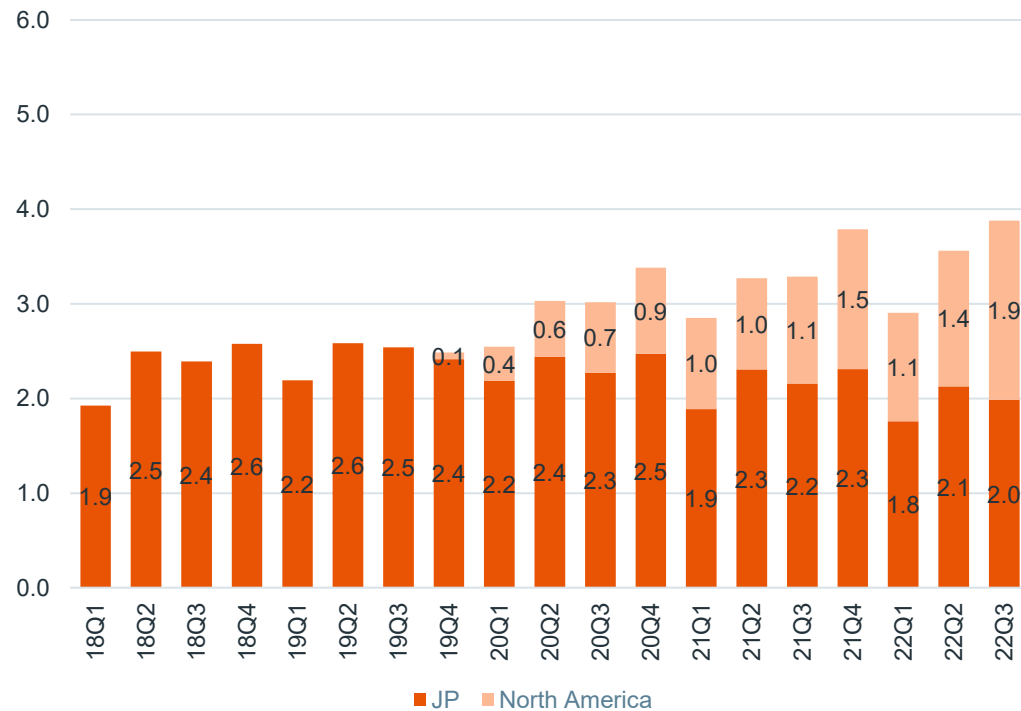
Bolded types: New launches in Q3 2022

- 2012 Japan
- 2018 USA
- 2020 Germany, Austria, Luxembourg
- 2021 Italy, Scotland, Netherland, Belgium, Slovenia, Denmark, Spain, Finland
- 2022 Sweden, Saudi Arabia, Slovakia, England, Wales, Northern Ireland, France, Czech, **UAE**

Nourianz



(Billion Yen)



2022 Key Actions & Q3 Topics

2022 Key Actions

- North America: Focus on approaching potential prescribers and get their deeper understanding of the features of Nourianz such as safety, convenience, and novel mode of action.

Q3 Topics

- North America: In challenging environment of the branded PD drug market, sales increased YoY. Continuing promotional activities to HCPs/patients, appealing Nourianz’s features by utilizing digital tools and leaflets.

Launched Countries/Regions as of Sep 30, 2022

- 2013 Japan
- 2019 USA

R&D Update

Upcoming Events: Next-generation Strategic Products

✓ : Completed events from Aug 5, 2022, to Nov 4, 2022.

Code Generic Name	Event	Time Expected	Month Completed
KHK4083/AMG 451 rocatinlimab	Atopic dermatitis P3 restart	End of 2022 - Beginning of 2023	
ME-401 zandelisib	iB-NHL (mono, 3L+) P2 topline data (JP) CLL (combo, 2L+) P2 FPI	H2 2022 H2 2022	
RTA 402 bardoxione methyl	Diabetic kidney disease P3 LPO Diabetic kidney disease P3 topline data	H2 2022 H1 2023	
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis submission (JP) ✓	H2 2022	Oct. 2022

FPI: first patient in; LPO: last patient out; CLL: chronic lymphocytic leukemia; iB-NHL: indolent B-cell non-Hodgkin lymphoma

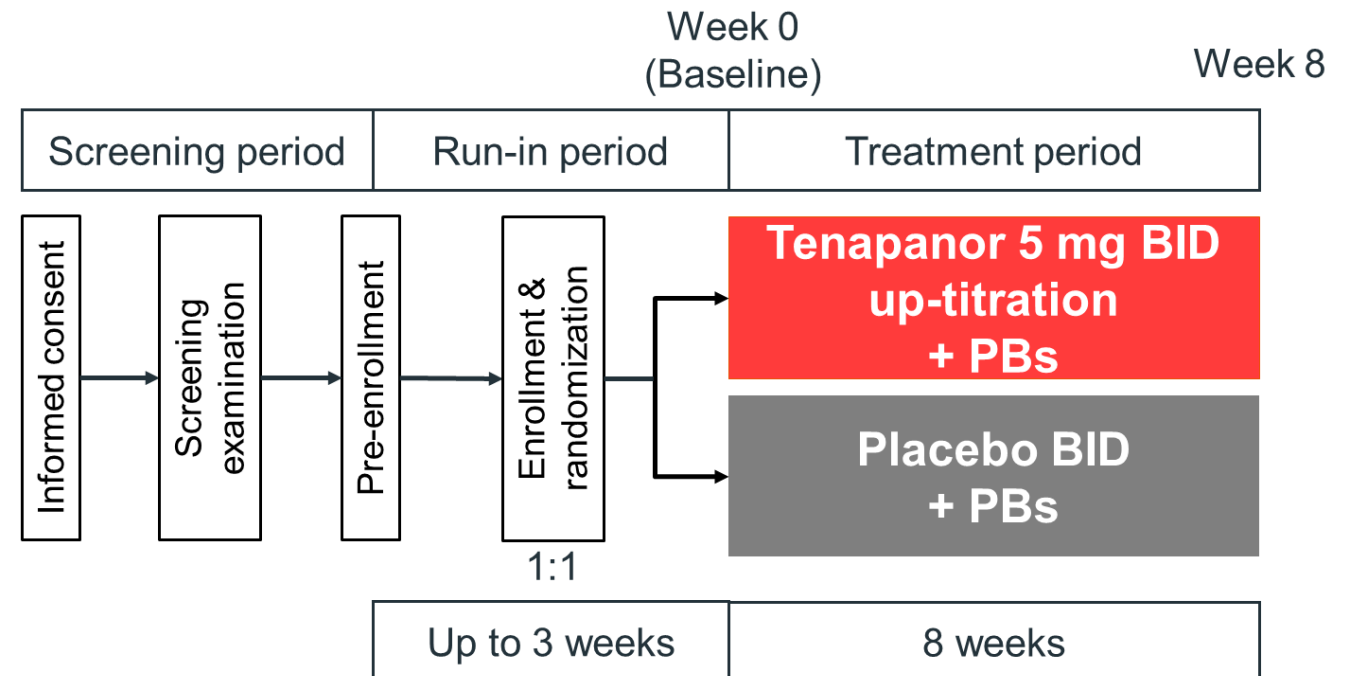
Tenapanor: Phase 3 Study (Combination therapy with PBs) – Study Design

ASN 2022

ClinicalTrials.gov Identifier: NCT04766398

■ A study of tenapanor combination with PBs for Japanese hemodialysis patients with hyperphosphatemia who have poor phosphorus control with existing PBs

■ **Subjects:**
Hyperphosphatemia patients receiving existing PBs and showing sP levels of 6.1-9.9 mg/dL



■ **Primary endpoint:** Change in sP levels from baseline to week 8 after the start of tenapanor

Tenapanor: Phase 3 Study (combination therapy with PBs) – Results

ASN 2022

ClinicalTrials.gov Identifier: NCT04766398

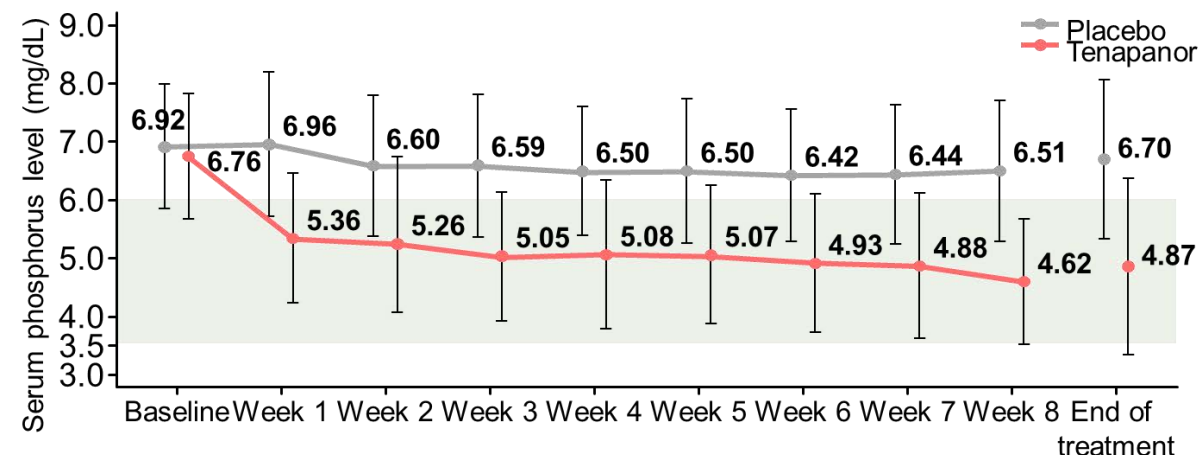
Primary endpoint

	Placebo (n=83)	Tenapanor (n=81)
Change in serum phosphorus level from baseline to week 8, mg/dL		
Mean (95% CI)	-0.24 (-0.52, 0.04)	-2.00 (-2.28, -1.72)
Difference (95% CI)	-1.76 (-2.16, -1.37)	
p-value	<0.0001	

Adverse effects

	Placebo (n=85)	Tenapanor (n=84)
TEAEs		
Total	53 (62.4)	72 (85.7)
Diarrhea		
Severity		
Mild	9 (75.0)	40 (75.5)
Moderate	3 (25.0)	13 (24.5)
Severe	0 (0.0)	0 (0.0)
Discontinuation due to TEAEs		
Total	0 (0.0)	2 (2.4)
Diarrhea	0 (0.0)	0 (0.0)

Mean serum phosphorus levels over time



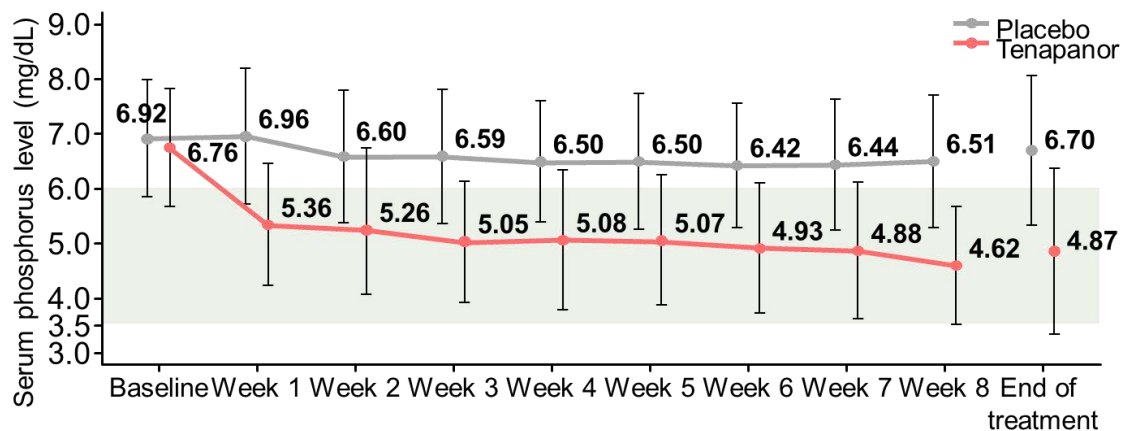
- Addition of Tenapanor to patients who have poor phosphorus control with existing PBs resulted in a statistically significant reduction in sP levels compared to placebo.
- Most diarrheas as predicted adverse effects were mild.

In another study*, tenapanor demonstrated the statistically significant reduction in sP levels as a single therapy as well.

* Subjects: Japanese hemodialysis patients with serum phosphorus levels of 3.5-6.0 mg/dL in a screening period and 6.1-9.9 mg/dL after washout of PBs.

What Kyowa Kirin expects from KHK7791

KHK7791 (tenapanor), a phosphorus absorption inhibitor with a new MOA different from conventional PBs, which inhibits phosphorus absorption from gastrointestinal tracts by inhibiting NHE3 (Na⁺/H⁺ exchange transporter 3)



A decrease in sP concentration was observed in patients who have poor phosphorus control with existing PBs



* This picture is for illustration purposes for an average number of tablets taken for two weeks at week 25-26.

Expecting to reduce pill burden for hyperphosphatemic patients

Kyowa Kirin aims to deliver Life-changing value to hyperphosphatemia treatment

News Flow in 2022

Year-to-date Key News Flow ①

AS of November 4, 2022

Category	Date	Headline
ESG	Jan 11	Introduction of renewable energy “Aqua Premium” for Fuji Research Park and CMC R&D Center
LCM	Jan 31	NDA submission of Topical Ophthalmic Mitomycin C agent (Japan)
LCM	Feb 25	Approval for partial change of approved indication of G-Lasta (Japan) (for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogenic Blood Stem Cell Transplantation)
ESG	Mar 9	Selection as “Health & Productivity Stock” for the first time (Japan)
R&D	Mar 31	Regulatory update on Zandelisib following meeting with the FDA
LCM	Apr 4	Publication of safety data from a clinical trial of automated injection device of G-Lasta (Japan)
SCM	May 17	Construction of a new biopharmaceutical API manufacturing building at Takasaki Plant
R&D	May 18	Joint research agreement with LUCA Science on mitochondrial disease treatment with novel mitochondria modality
R&D	May 31	Achievement of first milestone in research collaboration with InveniAI
LCM	Jun 1	Positive data from Phase 3 study of Lumicef in Systemic Sclerosis (EULAR 2022 Congress)

Year-to-date Key News Flow ②

AS of November 4, 2022

Category	Date	Headline
R&D	Jun 5	New clinical data on Zandelisib (American Society of Clinical Oncology Annual Meeting 2022)
R&D	Jun 10	Clinical data on Zandelisib (European Hematology Association 2022 Hybrid Congress)
LCM	Jun 27	Positive CHMP opinion for use of Crysvita for TIO
R&D	Jul 15	Discontinuation of developing KW-6356
R&D	Jul 19	Data from Phase 1b clinical study of Zandelisib in patients with relapsed or refractory B-cell malignancy (The Lancet Oncology)
LCM	Aug 1	Approval of “G-Lasta Subcutaneous Injection 3.6mg BodyPod” (Japan)
LCM	Aug22	Approval of Crysvita for TIO from European Commission
LCM	Sep7	Positive data from Phase 3 study of Lumicef for Palmoplantar Pustulosis (EADV 2022 Congress)
LCM	Sep15	Application for partial change of approved indication of Lumicef for Palmoplantar Pustulosis (Japan)
R&D	Oct5	Initiated CVC activities and made first investment in a startup company

Updates after the previous earnings announcement

Year-to-date Key News Flow ③

AS of November 4, 2022

Category	Date	Headline
LCM	Oct 17	Application for partial change of approved indication of Lumicef for Palmoplantar Pustulosis (Japan)
R&D	Oct 20	Data from Phase 3 clinical study of Tenapanor Hydrochloride (KHK7791) for hemodialysis patients on dialysis with hyperphosphatemia in Japan (American Society of Nephrology Meeting)
R&D	Oct 28	NDA submission of Tenapanor Hydrochloride (KHK7791) for improvement of hyperphosphatemia in chronic kidney disease patients on dialysis (Japan)
R&D	Nov 4	Final results of TIDAL Phase 2 clinical study FL cohort of Zandelisib, etc. (American Society of Hematology 2022 Annual Meeting)

Updates after the previous earnings announcement

Appendix

Summary of FY2022 Revised Plan

(Billion Yen / Rounded)

	2022 Full Year Original Plans	2022H1 Results	2022H2 Revised Plans	2022 Full Year Revised Plans	Changes
Revenue <i>[Overseas Ratio]</i>	380.0 <i>[59%]</i>	185.3 <i>[59%]</i>	214.7 <i>[65%]</i>	400.0 <i>[62%]</i>	+20.0 (+5%)
Gross Profit <i>[Gross Profit Margin]</i>	298.0 <i>[78%]</i>	141.9 <i>[77%]</i>	170.1 <i>[79%]</i>	312.0 <i>[78%]</i>	+14.0 (+5%)
SG&A <i>[SG&A Ratio]</i>	164.0 <i>[43%]</i>	76.4 <i>[41%]</i>	95.6 <i>[44%]</i>	172.0 <i>[43%]</i>	-8.0 (+5%)
R&D <i>[R&D Ratio]</i>	70.0 <i>[18%]</i>	27.9 <i>[15%]</i>	39.1 <i>[18%]</i>	67.0 <i>[17%]</i>	+3.0 (-4%)
Gain/Loss on Equity Method	3.0	2.4	1.6	4.0	+1.0 (+33%)
Core Operating Profit <i>[Core OP Margin]</i>	67.0 <i>[18%]</i>	39.9 <i>[22%]</i>	37.1 <i>[17%]</i>	77.0 <i>[19%]</i>	+10.0 (+15%)
Profit	53.0	35.0	28.0	63.0	+10.0 (+19%)

FOREX Information

Average FOREX Rates (yen)

	2021Q3	2022Q3	Changes	2022 Rev. Plans
USD/JPY	108	126	+18	128
GBP/JPY	149	160	+11	162

Q3 YoY FOREX Impacts (billion yen)

	Revenue	Core OP
USD/JPY	+12.8	+4.6
GBP/JPY	+3.4	+0.9

FY2022 FOREX Sensitivities (billion yen)

	Changes	Revenue	Core OP
USD/JPY	+1 yen	+1.1	+0.3
GBP/JPY	+1 yen	+0.4	+0.1

Crysvita - Collaboration with Ultragenyx -

Economic Terms

US & Canada

- Kyowa Kirin books sales
 - 50/50 profit share for 5 years from the U.S. launch
 - After 5 years (April 27 2023~), Kyowa Kirin pays tiered sales royalties in mid-high 20% range to Ultragenyx
 - Supply price: 35% of net sales through 2022, 30% thereafter
- *Ultragenyx has sold 30% of a royalty right from April 2023 onwards to OMERS Capital Markets

Europe

- Kyowa Kirin books sales
 - Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx
- *Ultragenyx has sold a royalty right from 2020 onwards to Royalty Pharma

Latin America

- Ultragenyx books sales
- Kyowa Kirin receives low single-digit sales royalties from Ultragenyx
- Supply price: 35% of net sales through 2022, 30% thereafter

Turkey

- Ultragenyx books sales
- Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx

Asia & Others

- Kyowa Kirin books sales

* Kyowa Kirin supplies commercial products in all territories.

KHK4083/AMG 451 - Collaboration with Amgen -

	US	Europe & 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 promotion 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 makes 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 4, 2022

Code Generic Name	Target Disease		2022	2023	2024	+	
KHK4083/AMG 451 rocatinlimab	Atopic dermatitis	P3					ROCKET
ME-401 zandelisib	FL (mono, 3L+)	P2		D**			} TIDAL
	MZL (mono, 3L+)	P2					
	FL/MZL (combo, 2L+)	P3					COASTAL
	iB-NHL (mono, 3L+)*	P2			T		MIRAGE
	CLL (combo, 2L+)	P2					
RTA 402 bardoxolone methyl	Alport syndrome	Filed					
	Diabetic kidney disease	P3			T		AYAME
	ADPKD	P3					FALCON
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis	P3					
		P3			MA*		★
		P3					
		P3					

*: Japan; **: a more complete report of the P2 TIDAL data reported on Nov. 30, 2021; MA: marketing application; ★: Anticipated timing of regulatory decision; FL: follicular lymphoma; MZL: marginal zone lymphoma; iB-NHL: indolent B-cell non-Hodgkin's lymphoma; CLL: chronic lymphocytic leukemia; ADPKD: autosomal dominant polycystic kidney disease; 3L+: third-line or later therapy ; 2L+: second-line or later 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)
	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)
	EU	1:20,000	Adult: 12,000 Ped: 3,000	Estimate based on reported prevalence of 1 in 20,000 people
	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
	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)
	US	60,000 / y	~1,000,000	Cited from Parkinson's Foundation https://www.parkinson.org/Understanding-Parkinsons/Statistics Accessed February 7, 2022.
FL	US	15,000 / y		Cited from Cancer.net https://www.cancer.net/ Accessed February 7, 2022.
	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 February 7, 2022.
	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 February 7, 2022.
ADPKD	JP		31,000	Cited from the website of Japan Intractable Diseases Information Center https://www.nanbyou.or.jp/entry/295 Accessed February 7, 2022.
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
CLL	Chronic Lymphocytic Leukemia
DKD	Diabetic Kidney Disease
FL	Follicular Lymphoma
iB-NHL	Indolent B-cell Non-Hodgkin's Lymphoma
LCM	Lifecycle Management
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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