# Results Presentation Fiscal 2023 First Quarter





# Agenda

**Financial Review** 

Commercial Update

**R&D Update** 

News Flow in 2023

Managing Executive Officer, Head of Finance Motohiko Kawaguchi

Executive Officer, Head of Global Product Strategy Tomohiro Sudo

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

Managing Executive Officer, Head of Strategy Yasuo Fujii

Q&A

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# **Financial Review**



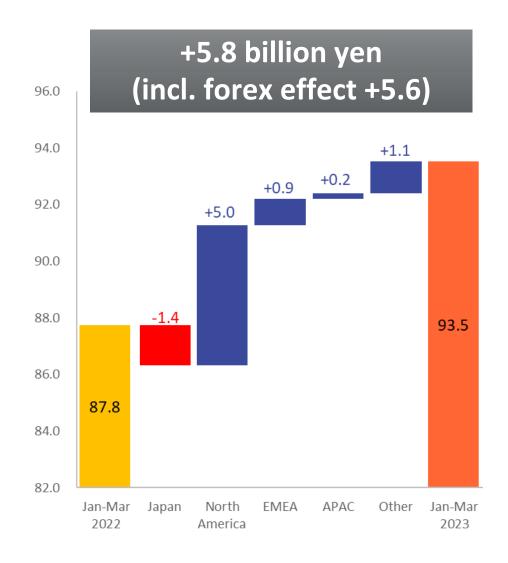
# **Summary of Q1 Results**

(Billion Yen / Rounded)

	2022Q1 Results	2023Q1 Results	Changes	2023 Revised Plans	Progresses
Revenue [Overseas Ratio]	87.8 [58%]	93.5 [63%]	+5.8 (+7%)	426.0 [64%]	22%
Gross Profit [Gross Profit Margin]	65.6 [75%]	74.6 [80%]	+9.0 (+14%)	326.0 [77%]	23%
SG&A [SG&A Ratio]	36.1 [41%]	41.8 [45%]	+5.7 (+16%)	162.0 [38%]	26%
R&D [R&D Ratio]	13.6 [16%]	16.6 [18%]	+3.0 (+22%)	79.0 [19%]	21%
Gain/Loss on Equity Method	1.4	0.8	-0.6 (-44%)	3.0	27%
Core Operating Profit [Core OP Margin]	17.3 [20%]	17.0 [18%]	-0.4 (-2%)	88.0 [21%]	19%
Profit	16.0	12.8	-3.3 (-20%)	<sup>76.0→</sup> 70.0	18%



# YoY Analysis -Revenue-



### Japan -1.4

Although Duvroq, Romiplate, and Crysvita increased, revenue in Japan region decreased by 4% due mainly to negative impact by NHI price-cut in April 2022 and shrink in Nesp-AG and Allelock affected by competitive products.

### North America +5.0 (incl. forex effect +3.5)

Revenue in North America region increased by 24% with the growth of Crysvita(+19%), Poteligeo(+31%), and Nourianz(+46%).

### ● EMEA +0.9 (incl. forex effect +0.7)

Revenue in EMEA region increased by 6% with the growth of Crysvita(+27%), and Poteligeo(+60%).

### ● APAC +0.2 (incl. forex effect +0.5)

APAC revenue increased by 3% with the growth of Crysvita, and Nesp, while Gran was down due to the Chinese national tender system.

### Other +1.1 (incl. forex effect +0.9)

12% growth in the other revenue was due to the royalties of growing Fasenra (Benralizumab).



# Revenue of Major Items (Japan)

(Billion Yen / Rounded)

ltem	2022Q1 Results	2023Q1 Results	Changes	Reasons	2023 Plans	Progresses
Nesp + Nesp-AG <sup>1</sup>	5.2	4.2	-1.0 (-20%)		16.6	25%
Nesp	0.8	0.8	-0.1 (-9%)	NHI price-cut & Biosimilars' penetration	2.8	27%
Nesp-AG	4.4	3.5	-1.0 (-22%)	·	13.8	25%
Duvroq	1.1	1.8	+0.7 (+65%)	Market penetration (Launched in Aug 2020)	7.8	23%
Orkedia	2.2	2.2	+0.0 (+1%)		11.2	20%
G-Lasta	7.1	7.0	-0.1 (-1%)		33.5	21%
Poteligeo	0.5	0.4	-0.0 (-6%)		2.0	22%
Rituximab BS	2.5	2.2	-0.3 (-14%)	NHI price-cut	8.7	25%
Romiplate	2.2	2.7	+0.5 (+23%)	Market penetration (New indication in 2019)	11.2	24%
Allelock	2.4	1.9	- 0.5(-19%)	NHI price-cut	4.7	42%
Nouriast	1.8	1.7	-0.1 (-5%)		7.5	22%
Haruropi	0.8	0.9	+0.2 (+21%)	Market penetration (Launched in Dec 2019)	4.7	20%
Crysvita	2.0	2.3	+0.3 (+18%)	Market penetration (Launched in Dec 2019)	11.1	21%

<sup>1</sup> 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)

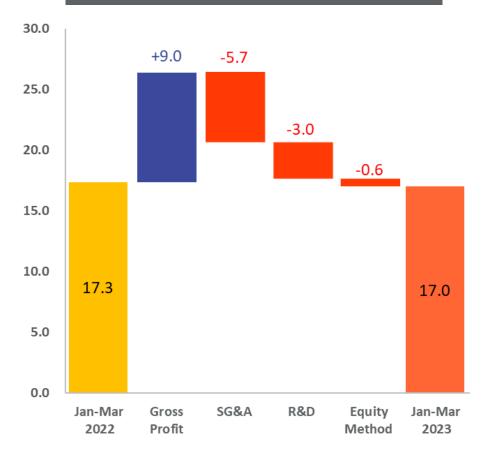
ltem	2022Q1 Results	2023Q1 Results	Changes	Reasons	2023 Plans	Progresses
Crysvita	22.2	27.1	+4.9 (+22%)		138.0	20%
North America	15.8	18.8	+3.0 (+19%)	[North America] Market penetration		
EMEA	6.3	8.0	+1.7 (+27%)	[EMEA] Geographical expansion & Additional indication (Adult/TIO)		
APAC	0.0	0.3	+0.2 (+726%)			
Poteligeo	4.2	5.8	+1.6 (+38%)		27.5	21%
North America	3.3	4.3	+1.0 (+31%)	[North America] Market penetration	19.4	22%
EMEA	0.9	1.5	+0.6 (+60%)	[EMEA] Geographical expansion  & Market penetration	8.0	19%
APAC	-	-	-		0.2	-
Nourianz	1.1	1.7	+0.5 (+46%)	Market penetration	7.5	22%
Nesp	1.9	2.2	+0.3 (+18%)		8.0	28%
Gran	2.1	1.4	-0.7 (-31%)	Listed on Chinese tender list	8.2	17%
Neulasta	1.7	1.3	-0.4(-23%)		5.7	23%
Tech-licensing	7.7	8.9	+1.2 (+16%)	Growth of Fasenra	39.0	23%
Benralizumab Royalty <sup>1</sup>	4.7	5.7	+1.0 (+22%)	Glownion asema		

<sup>1</sup> Sales royalties of Fasenra which has been marketed by AstraZeneca, including our own estimation.



# **YoY Analysis -Core OP-**

# -0.4 billion yen (incl. forex effect +1.6)



### • Gross Profit +9.0 (incl. forex effect +5.2)

Increased in conjunction with JPY5.8B rise in revenue. Margin improved by 5% (75%  $\rightarrow$  80%) due mainly to increased proportion of profitable "Global 3 brands" and techlicensing revenue.

### • SG&A -5.7 (incl. forex effect -2.6)

Increased in HR exp, etc by preparation for the transition of Crysvita commercial leadership role and investment in IT/Digital infrastructure and human resources for global business foundation, in addition to Crysvita profit sharing expenses for North America.

[HR exp -2.2 / Sales promotion -1.6 (incl. Crysvita profit sharing expenses -1.3)]

### ■ R&D -3.0 (incl. forex effect -1.1)

Increased in clinical study costs of KHK4083.

### Gain/Loss on Equity Method -0.6

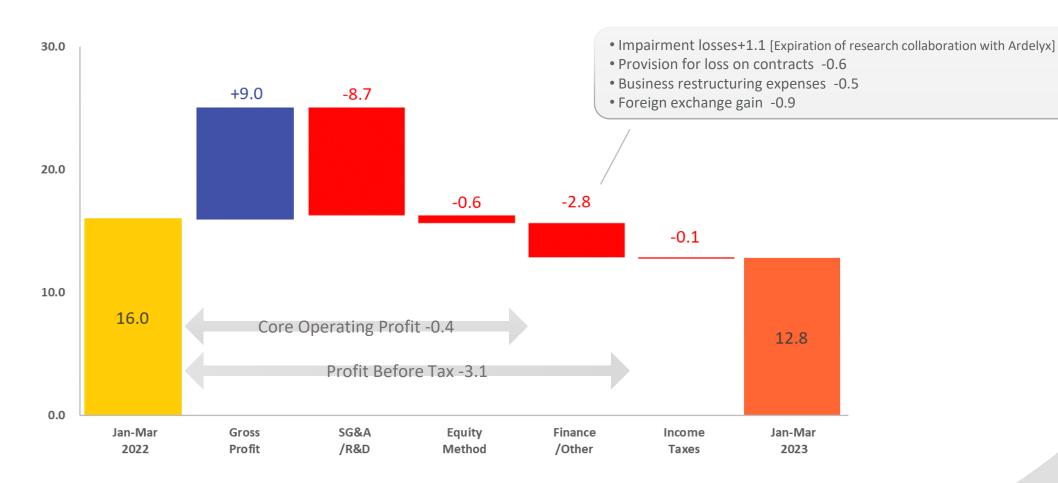
While revenue of Hulio (FKB327/Adalimumab biosimilar) increased, FKB's profit declined due to decrease in tax-accounting effect.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.



# **YoY Analysis -Profit-**

# Profit (Jan-Mar) -3.3 billion yen





# **Commercial Update**

Coordinated Actions to Maximize the Patient Access to G3B





### **2023** Key Actions & Q1 Topics

#### **2023 Key Actions**

- North America:
   Start own sales (Establish and start own operation of the direct sales force).
- EMEA:
   Continue to focus on geographical & indication expansion.
- Japan: Strengthen promotional activities centered by the dedicated personnel.

#### Q1 Topics

- North America:
  - •Establishment of own operation of the direct sales force progressed as planned.
  - •The number of patient enrollments in the treatment preparation stage increased steadily, despite a rebound sales from year-end load-up purchase by wholesales.
  - Patient penetration rate in U.S.\*: Pediatric XLH 39%, Adult XLH 11%
- EMEA:
  - ·Launched in Italy, Romania, and Scotland for adult XLH
- Japan:
  - Patient finding is progressing steadily.
  - \*Patient penetration rate in US is a rough estimate based on our calculations.

### Sales Revenue (Billion Yen)



\*Revenue from EAP ( Early Access Program ) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

# Launched Countries / Regions (XLH)



\*Excludes Latin America and Turkey, where Ultragenyx records sales.





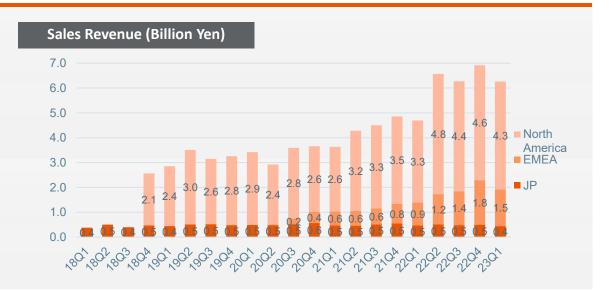


#### **2023 Key Actions**

- Strengthen promotional activities utilizing evidences including blood tumor data.
- Raise awareness of importance of blood testing among early-stage patients

#### **Q1** Topics

- Continued promotional activities utilizing evidences including blood tumor data.
- Continued raise awareness of importance of earlier consultation with specialists and blood testing though the disease awareness website (PROBE IN CTCL).





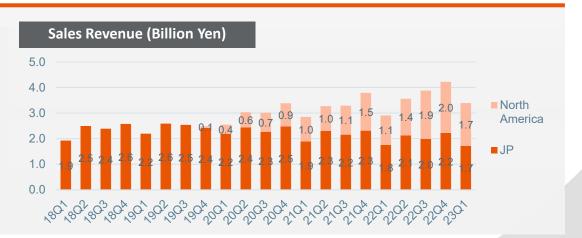
### **2023 Key Actions & Q1 Topics**

#### **2023 Key Actions**

- Further instill importance of adenosine A<sub>2A</sub> receptor antagonism in treating wearing-off.
- Strengthen field level activity through further collaboration and knowledge sharing between Japan and the US, and through maximizing available resources by utilizing effective approaches including digital.

#### Q1 Topics

- Established a social media channel in North America which stores all videos that has been created including mechanism of action of NOURIANZ, patient testimonial video and others.
- Implemented digital tool that provide standardized information (e.g., market access-related data) to field personnel.



<sup>\*</sup>Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.



# **R&D Update**



# **Upcoming Events: Main Development Pipeline Products**

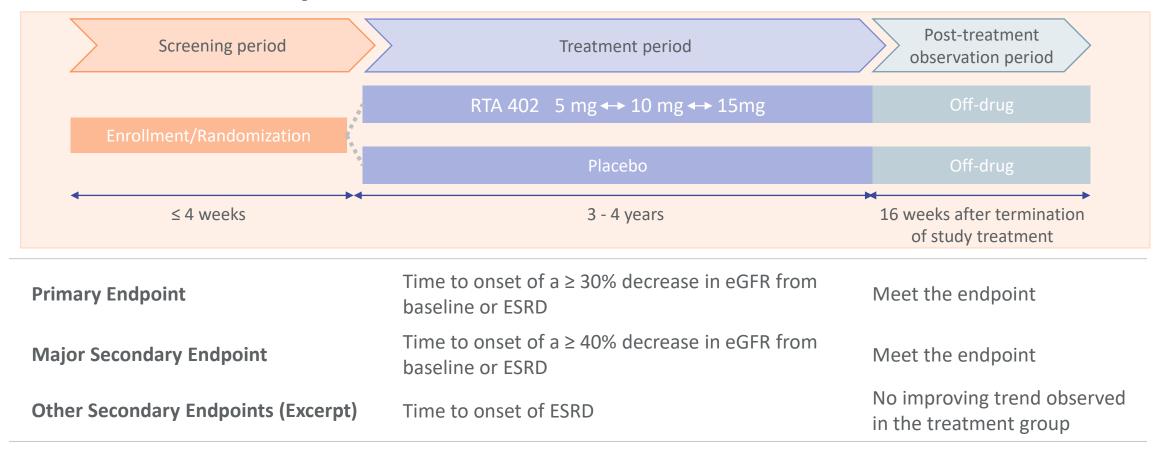
<b>Code</b> Generic Name	<b>Events</b> (Completed are in bold)	<b>Timeline</b> (Completed are in orange)
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis P3 Initiation	Dec. 2022
KHK4951 tivozanib	nAMD P1 LPO P2 Initiation	Aug. 2022 H2 2023
ME-401 zandelisib	Discontinuation of development in Japan	Disclosed May 2023
RTA 402 bardoxolone methyl	Discontinuation of development for AS, DKD, and ADPKD	Disclosed May 2023
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis: Regulatory decision to be announced (JP)	H2 2023
KW-3357  antithrombin gamma (genetical recombination)	Preeclampsia P3 LPO Topline data	H2 2023 H2 2023

LPO: Last Patient Out; DKD: Diabetic Kidney Disease; AS: Alport Syndrome; ADPKD: Autosomal Dominant Polycystic Kidney Disease; nAMD: Neovascular age-related macular degeneration

# RTA 402 Ph3 study results







- Primary and major secondary endpoints were significantly improved vs. placebo
- ◆ In the course of the regulatory review for Alport Syndrome (AS) and others, in addition to "Decrease in eGFR," which was set in the primary and major secondary endpoints, "Time to onset of ESRD" became important. However, the improving trend of ESRD was not observed in the treatment group. Through discussions with KOLs and the regulatory authority in Japan, and after a thorough review of these results, Kyowa Kirin decided to discontinue the development of RTA 402.
- Regarding Alport Syndrome, the existing regulatory application is scheduled to be withdrawn.
- Our participation as In-Country Clinical Care-taker for the ongoing AS/ADPKD studies in Japan will end. © Kyowa Kirin Co., Ltd.



# **News Flow in 2023**



# **Year-to-date Key News Flow**

Category	Date	Headline As of May 10, 2023
ESG	Mar 8	Kyowa Kirin Selected for a "Health & Productivity Stock" and awarded as a "Certified Health & Productivity Management Outstanding Organization" (White 500) (Japan)
R&D	Mar 17	Presented New data from Phase 2b clinical study of Rocatinlimab in Atopic Dermatitis at the American Academy of Dermatology Annual Meeting 2023
SCM	Mar 28	Completed construction of a new building at Ube Plant (Japan)
ESG	Apr 6	Introduced RE100 renewable electricity to all purchased electricity at its two plants and three laboratories (Japan)
SCM	Apr 7	Completed construction of a multipurpose facility relating to Quality Assurance (Q-Tower) at Takasaki Plant (Japan)
R&D	Apr 27	Started collaboration in drug discovery technology with School of Life Science and Technology, Tokyo Institute of Technology (Japan)
R&D	May 10	Announced Phase III Study Results of bardoxolone methyl (RTA 402) in Japan and Discontinuation of Development (Japan)

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management

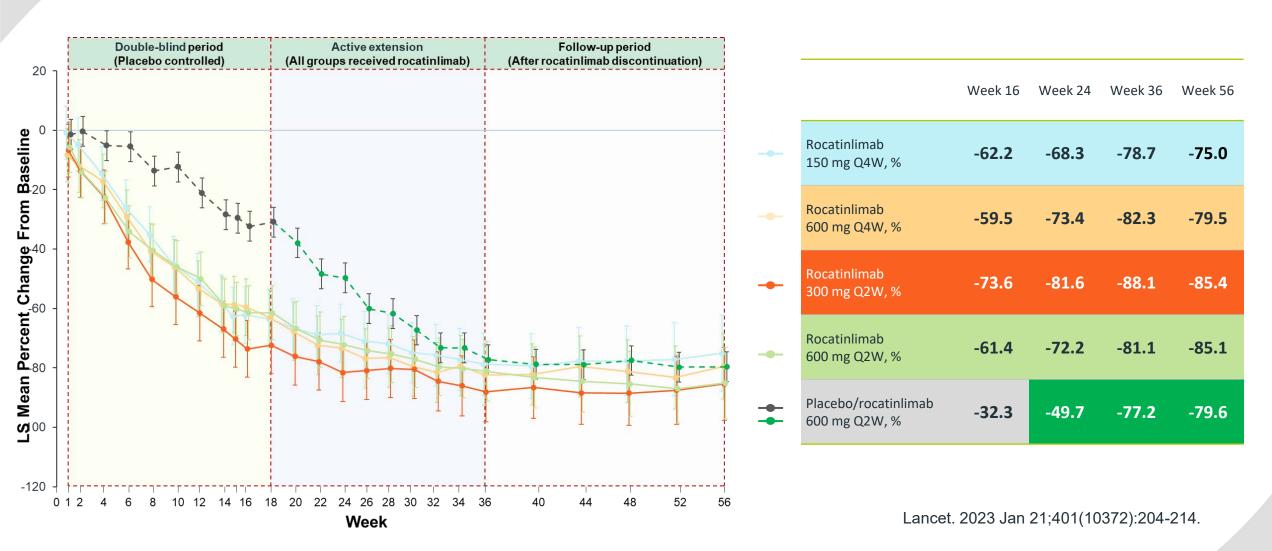
As ADVANZ PHARMA has announced on April 25, 2023, we have signed the agreement to transfer Kyowa Kirin International's rights for Tostran, established medicine brand, to ADVANZ PHARMA



# **Appendix**



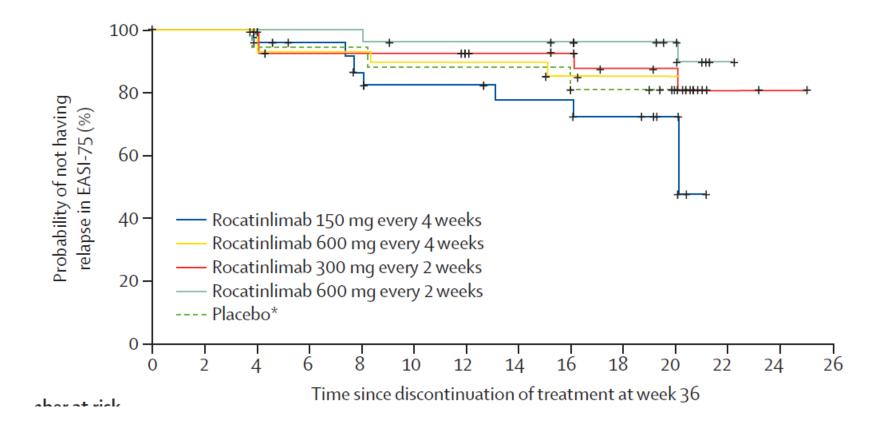
# Least-squares mean percent change in EASI score



Sustained improvement in EASI after treatment discontinuation (= after Week 36)



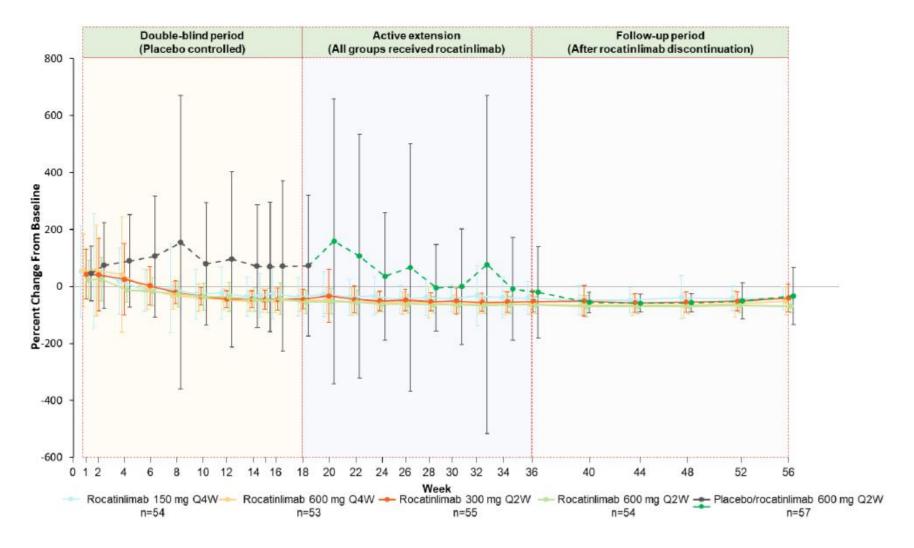
# Durability of EASI-75 response after treatment discontinuation (Full Analysis Set)



Probability of not having relapse (defined as loss of EASI-75 response) during the off-drug follow-up period is shown for patients who achieved EASI-75 response at Week 36 (last dose of rocatinlimab, Week 34). Patients receiving rescue treatment before the Week 36 assessment discontinued study drug and underwent end-of-study assessment. Patients who received rescue treatment during the follow-up period while maintaining EASI-75 response (n = 37; topical corticosteroids, n = 32; systemic therapy, n = 5) were not considered as having relapsed. However, they were censored at the visit date of that EASI evaluation as efficacy assessments were omitted after initiation of rescue therapy. For patients who completed the study or discontinued the study during the follow-up period, data were censored at the visit date of their last EASI evaluation. +, censored; EASI, Eczema Area and Severity Index; Q2W, every 2 weeks; Q4W, every 4 weeks.



# Biomarker levels over time: Serum TARC (CCL17) (Safety Analysis Set)



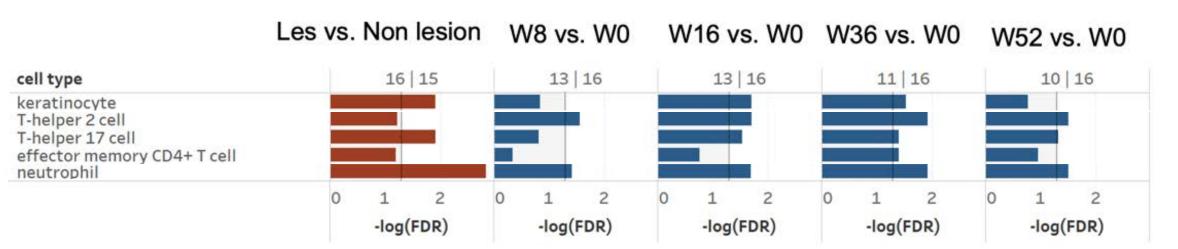
Q2W, every 2 weeks; Q4W, every 4 weeks; TARC, thymus and activation-regulated chemokine

Data presented from safety analysis set, which included patients who received at least 1 dose of investigational product; 273 of the 274 randomized patients were included in the safety analysis set.

# Transcriptome Deconvolution Analysis (Microarray Analysis): Differential Cell Contribution

 Significant decreases in keratinocytes, key immune cells (Th2/Th17 cells), and neutrophils were observed

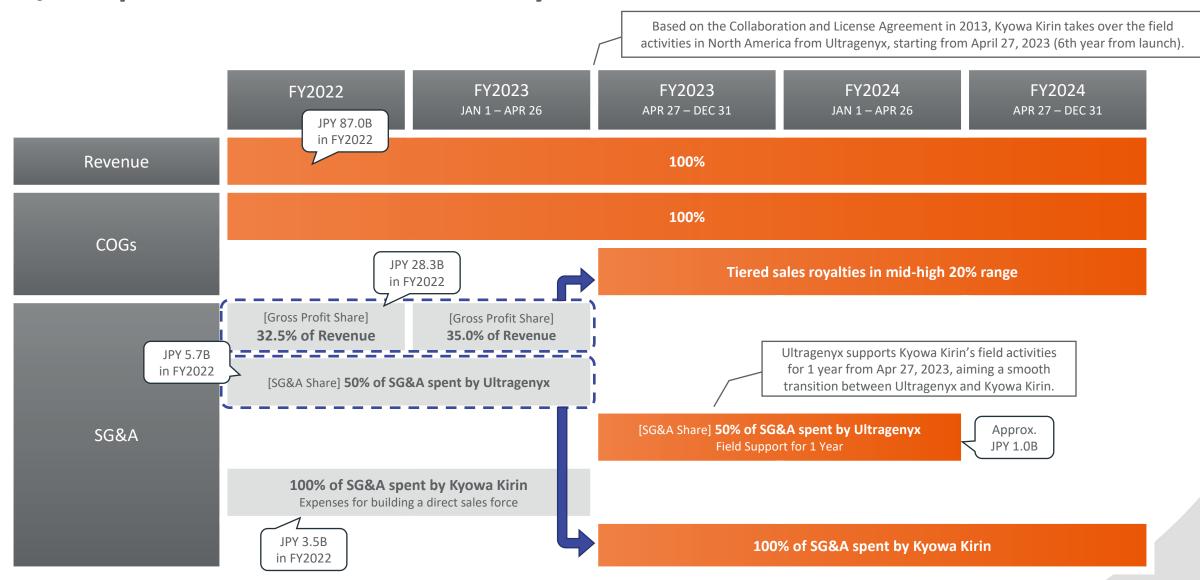




Differential cell contribution analysis between AD lesion and non-lesion samples at baseline, and between before (W0) and after (W8, W16, W36, and W52) KHK4083 treatment in lesion samples. Bar lengths indicate the significance level (-log10(FDR)) of each comparison, while the bar color represents the direction (red=increase in cell levels in disease or in post-treatment samples; blue=decrease in these samples). The vertical lines indicate an FDR cutoff of 0.05. At the top of each graph, the number of samples participating in each comparison is indicated.



# P/L Impact on North American Crysvita Business





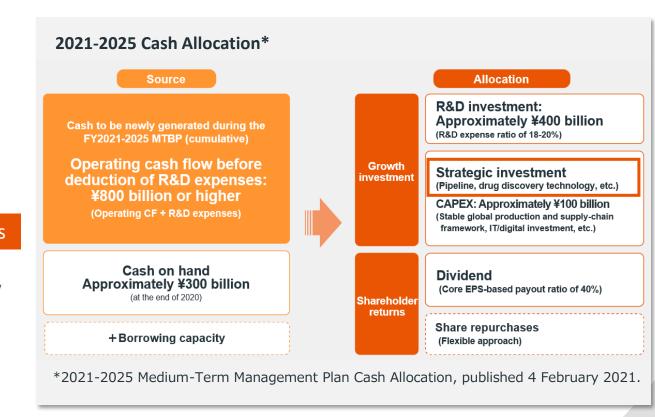
### **Strategic Investment** ~For successful creation and delivery of life-changing value

#### Licensing-in and M&A investments to strengthen the portfolio

- Development pipeline with synergies with Crysvita and Poteligeo
  - ◆ Bone, Mineral ◆ Hematologic oncology
- Implementing the strengths of each region
  - ◆ Nephrology ◆ Hematology / Oncology
  - **◆**Immunology

### Investment in science and technology to create new strengths

- Investments aimed at acquiring new drug discovery technologies and early pipelines and accelerating cooperation and collaborations
- VC investment and CVC activities for exploring and accessing information.





# Main Development Pipeline Products: Future plans

As of 2023, May 10



★: Anticipated timing of regulatory decision



# **Main Development Pipeline Products**

	Diseases under development*1	Planned Approval Year*2	Development status	Total addressable market*3	No. of Patients*4
KHK4083/ AMG 451 rocatinlimab	Moderate and severe Atopic Dermatitis	2026/2027	Ph3 (Global)	****	16M
KHK4951 tivozanib	Neovascular (wet) age- related macular degeneration	TBD	Preparing for Ph2 (US and JP)	***	2,300K~
KHK7791 tenapanor Hyperphosphatemia under maintenance dialysis		2023	Filed (JP)	*	250K
KW-3357 antithrombin gamma (genetical recombination)	Preeclampsia	2024	Ph3 (JP)	*	15K

<sup>\*1</sup> Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities

<sup>\*2</sup> Expected year of first approval

<sup>\*3</sup> Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in \*1, not projected sales or the Company's targets. Colored areas represent estimates for global, and the rest are for Japan.

<sup>★:</sup> less than ¥50Bn、★★: ¥50Bn-¥100Bn、★★★: Over ¥100Bn-¥500Bn、★★★★: Over ¥500Bn-¥1Tn、★★★★: Over ¥1Tn

<sup>\*4</sup> Total number of estimated patients by Kyowa Kirin. Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan.



### **FOREX Information**

### Average FOREX Rates (yen)

2022Q1	2023Q1	Changes	2023 Plans
114	132	+18	130
154	161	+7	160
129	141	+12	135

### Q1 YoY FOREX Impacts (billion yen)

Revenue	Core OP
+4.3	+1.1
+0.2	-0.1
+0.5	+0.3

### FY2023 FOREX Sensitivities (based on 2023 Plans, billion yen)

USD

**GBP** 

**EUR** 

USD

**GBP** 

**EUR** 

USD

GBP

**EUR** 

Changes	Revenue	Core OP
+1 yen	+1.2	+0.4
+1 yen	+0.2	-0.0
+1 yen	+0.3	+0.2



# **Crysvita - Collaboration with Ultragenyx -**

### **Economic Terms**

### **US & Canada**

- Kyowa Kirin books sales
- 50/50 profit share for 5 years from the U.S. launch
  - Supply price: 35% of net sales through 2022, 30% thereafter (No impact on the sales royalties stated below)
- After 5 years (April 27, 2023-), Kyowa Kirin pays tiered sales royalties in mid-high 20% range to Ultragenyx \*Ultragenyx has sold 30% of its royalty interest, subject to a 1.45x cap, to OMERS Capital Markets

### **Europe**

- Kyowa Kirin books sales
- Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx
   \*Ultragenyx has sold its royalty interest, subject to a 1.9x or 2.5x cap depending on when the cap is achieved, 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><li>Amgen leads development</li><li>Share development cost</li></ul>	<ul><li>Amgen leads development</li><li>Share development cost</li></ul>	Kyowa Kirin leads development
Commercialization	<ul> <li>Amgen commercializes and books sales</li> <li>Kyowa Kirin co-promotes and shares promotion cost</li> </ul>	<ul> <li>Amgen commercializes and books sales</li> <li>Kyowa Kirin has opt-in rights for co-promotion</li> </ul>	<ul> <li>Kyowa Kirin commercializes and books sales</li> </ul>
Sales Royalties	• Double-digit royalty to Kyowa Kirin	<ul> <li>Double-digit royalty to Kyowa Kirin</li> </ul>	
Commercial supply	Amgen supplies	Amgen supplies	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.



# **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)
CICL	US	1,500 / y		SEER Data (2001-2007)
	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
	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
nAMD	JP, US		2,300,000	Study by Decision Resources
PE	JP		15,000	Estimate based on the Demographic Survey by the Ministry of Health, Labour and Welfare and the estimated incidence of this disease



## **List of Acronyms**

AD Atopic Dermatitis

ADPKD Autosomal Dominant Polycystic Kidney Disease

AG Authorized Generic

AP, APAC Asia-Pacific

AS Alport Syndrome

ATL Adult T-Cell Leukemia/Lymphoma

BS Biosimilar

CKD Chronic Kidney Disease

CLL Chronic Lymphocytic Leukemia

DKD Diabetic Kidney Disease

EMEA Europe, the Middle East and Africa

FL Follicular Lymphoma

iB-NHL Indolent B-cell Non-Hodgkin Lymphoma

JP Japan

LCM Lifecycle Management

MZL Marginal Zone Lymphoma

NA North America

nAMD neovascular Age-related Macular Degeneration

PD Parkinson's Disease

PE Preeclampsia

PTCL Peripheral T-Cell Lymphoma
TIO Tumor Induced Osteomalacia
XLH X-linked Hypophosphatemia

# GYOWA KIRIN

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