Results Presentation
Fiscal 2025 First Quarter

協和キリン株式会社

Agenda

Financial Review
Managing Executive Officer, Chief Financial Officer (CFO) Motohiko Kawaguchi

Commercial Update
Managing Executive Officer, Chief Strategy Officer (CSO) Yasuo Fujii

R&D Update
Director Executive Vice President, Chief Medical Officer (CMO) Takeyoshi Yamashita, Ph.D.

News Flow in 2025
Managing Executive Officer, Chief Strategy Officer (CSO) Yasuo Fujii

Q&A
Director Executive Vice President, Chief Medical Officer (CMO) Takeyoshi Yamashita, Ph.D.
Managing Executive Officer, Chief Financial Officer (CFO) Motohiko Kawaguchi
Managing Executive Officer, Chief Strategy Officer (CSO) Yasuo Fujii

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

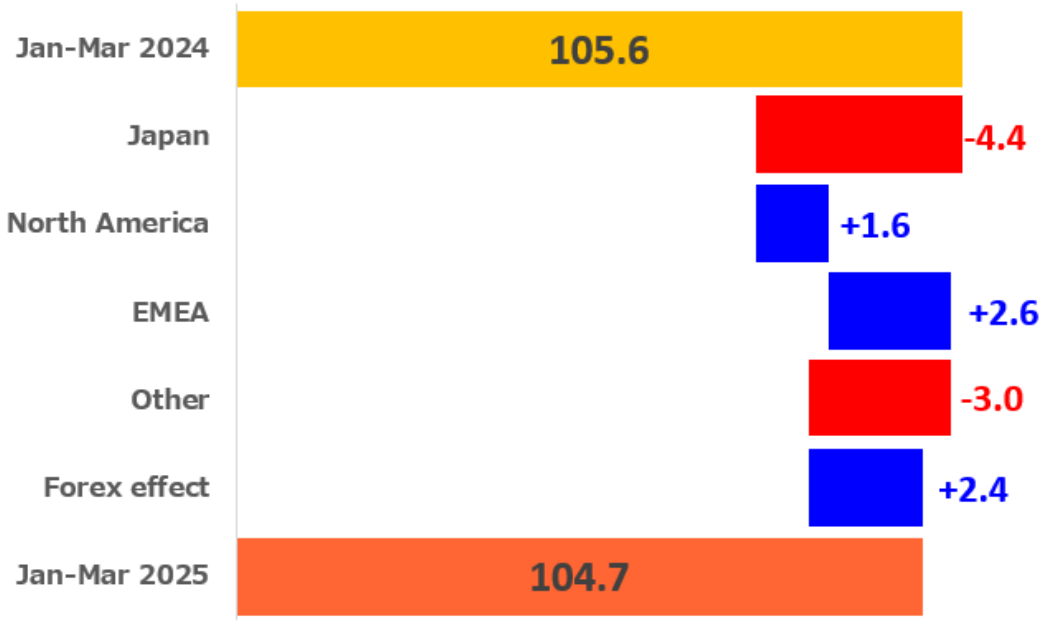
(Billion Yen / Rounded)

	2024Q1 Results	2025Q1 Results	Changes	FY2025 Plans	Progress to goal
Revenue *[Overseas Ratio]*	105.6 *[68%]*	104.7 *[73%]*	-0.8 (-1%)	478.0 *[73%] **	22%
Gross Profit *[Gross Profit Margin]*	80.0 *[76%]*	80.1 *[77%]*	+0.2 (+0%)	352.0 *[74%]*	23%
SG&A *[SG&A Ratio]*	40.2 *[38%]*	42.0 *[40%]*	+1.9 (+5%)	166.0 *[35%]*	25%
R&D *[R&D Ratio]*	23.3 *[22%]*	28.6 *[27%]*	+5.2 (+22%)	107.0 *[22%]*	27%
Gain/Loss on Equity Method	0.9	-0.9	-1.8 (-201%)	1.0	-91%
Core Operating Profit *[Core OP Margin]*	17.4 *[16%]*	8.6 *[8%]*	-8.8 (-50%)	80.0 *[17%]*	11%
Profit	14.6	6.2	-8.5 (-58%)	57.0	11%

* The FY2025 Plan for the *[overseas ratio]* has been corrected from the 70% announced on February 6, 2025.

YoY Analysis -Revenue-

-0.8 billion JPY
(-3.2 B excl. forex impact)



- **Japan -4.4**
  Although Phozevel, Duvroq and Crysvita increased, revenue in Japan region decreased by 14% due mainly to the termination of the sales partnership agreement for Dobovet (-1.8), negative impact by annual NHI price-cut and shrink in G-Lasta affected by competitive products.

- **North America +1.6 (excl. forex impact +1.7)**
  Revenue in North America region increased by 5% with the growth of Crysvita (+1%) and Poteligeo (+5%).

- **EMEA +2.6 (excl. forex impact +0.3)**
  Revenue in EMEA region increased by 16% with the growth of Crysvita (+20%) and Poteligeo (+31%).

- **Other -3.0 (excl. forex impact +0.4)**
  Decreased by 12% due to the impact on restructuring of the APAC business, although sales of Libmeldy/Lenmeldy and royalties from Fasenra (Benralizumab) increased.

- **Forex impact +2.4**
  USD +2.1, GBP +0.1, and EUR +0.2

Revenue of Major Items

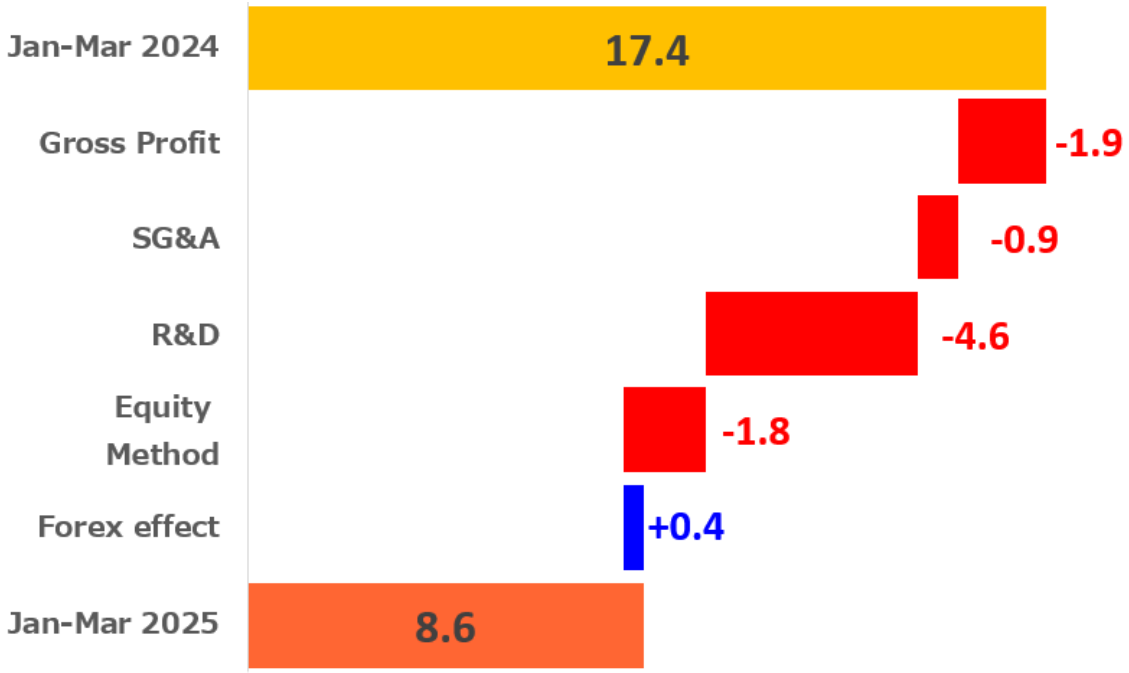
(Billion Yen / Rounded)

Item		2024Q1 Results	2025Q1 Results	Changes	Reasons	FY2025 Plans	Progress to goal
Crysvita		37.8	42.4	+4.6 (+12%)	Market penetration	210.2	20%
	JP	2.5	2.8	+0.3 (+13%)		13.1	21%
	NA	22.8	24.1	+1.3 (+6%)		197.1	20%
	EMEA	11.9	14.8	+2.9 (+24%)			
	Other	0.6	0.8	+0.1 (+21%)			
Poteligeo		8.6	9.8	+1.2 (+13%)	Market penetration	45.4	22%
	JP	0.4	0.3	-0.2 (-36%)		1.9	15%
	NA	6.3	6.9	+0.6 (+10%)		34.1	20%
	EMEA	1.9	2.6	+0.7 (+35%)		9.2	22%
	Other	0.0	0.0	+0.0 (+80%)		0.3	11%
Libmeldy / Lenmeldy		1.1	2.1	+1.0 (+92%)	Market penetration (FDA approval in Mar 2024)	6.9	31%
	US	-	1.1	+1.1 (- %)			
	EMEA	1.1	1.0	-0.1 (-5%)			
Phozevel	JP	0.6	1.5	+0.9 (+148%)	Market penetration (Launched in Feb 2024)	8.9	17%
Duvroq	JP	2.5	3.0	+0.5 (+22%)	Market penetration	15.5	19%
Nesp + Nesp-AG	JP	3.5	2.8	-0.7 (-19%)	NHI price-cut & Biosimilars' penetration	11.6	24%
G-Lasta	JP	5.8	4.3	-1.5 (-26%)	NHI price-cut & Biosimilars' penetration	17.0	25%
Romiplate	JP	3.0	3.4	+0.4 (+12%)	Market penetration	14.6	23%
Tech-licensing		12.1	13.0	+0.8 (+7%)	Growth of Fasenra	52.3	25%
Benralizumab Royalty		6.4	7.4	+1.0 (+16%)			

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 Sales royalties of Fasenra which has been marketed by AstraZeneca. Including our own estimation.
3 Overseas items are displayed at the net value including FX impact. Items for the Japan region are displayed at gross amounts before any discounts or deductions.

YoY Analysis -Core OP-

-8.8 billion JPY
(-9.2 B excl. forex impact)



- **Gross Profit -1.9 (excl. forex impact +2.1)**
  Decreased in conjunction with the 3.2B (excl. FX impact) down in revenue.

- **SG&A -0.9 (excl. forex impact -1.0)**
  While there was a decrease due to the restructuring of the APAC business, there was an increase due to the impact of the new consolidation of Orchard (Feb 2024) and the launch readiness of ziftomenib.

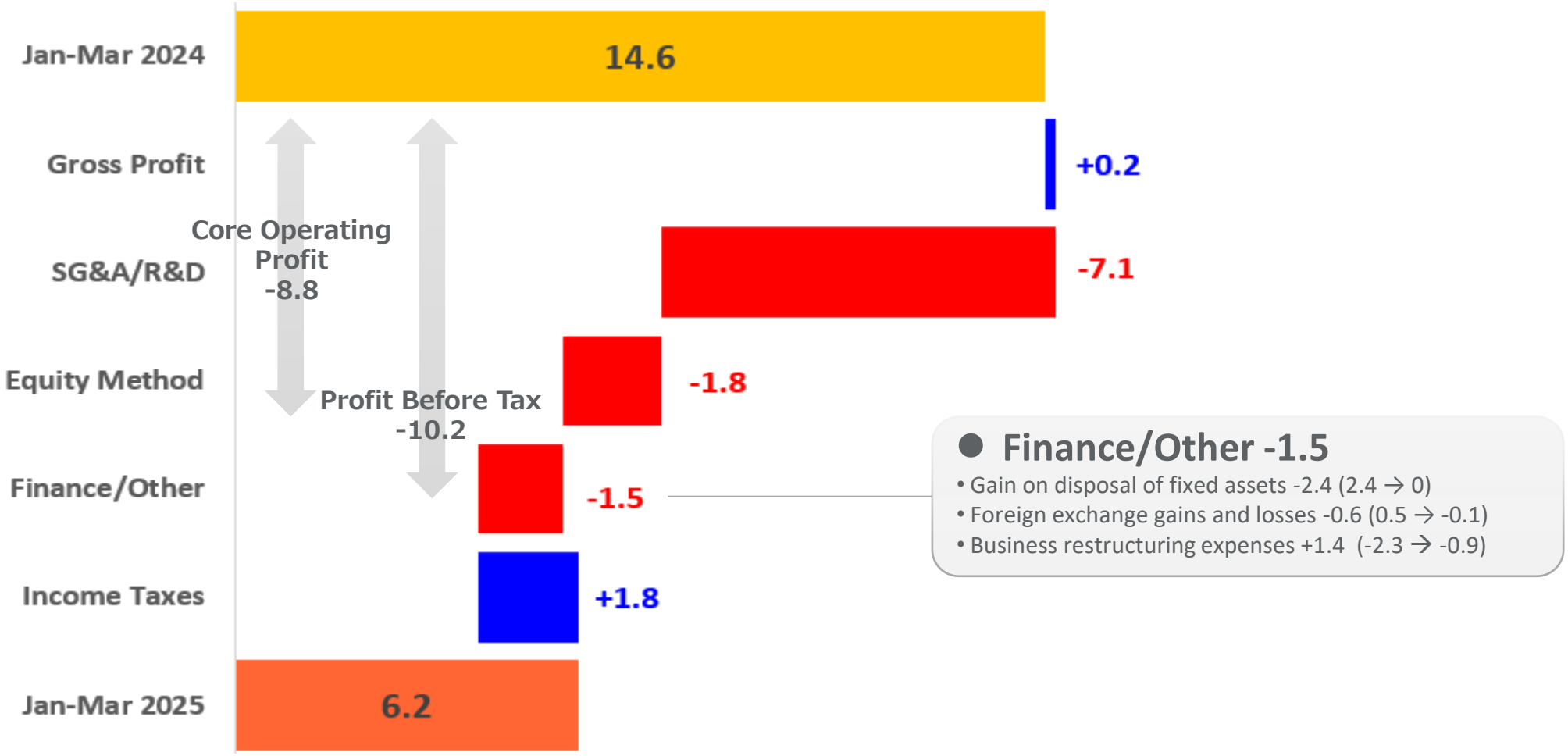
- **R&D -4.6 (excl. forex impact -0.6)**
  In addition to the impact of the new consolidation of Orchard (Feb 2024), our change to using Activity-Based Costing (ABC) for estimating R&D project expenses starting in 2025 has led to a smoothing of costs incurred each quarter, resulting in a significant increase compared to Q1 of the previous year.

- **Gain/Loss on Equity Method -1.8 (excl. forex impact +0.0)**
  Decreased sales at FKB (due to shipping timing) have led to a decline in profits.
  FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

- **Forex impact +2.4**
  USD +0.4, GBP -0.1, and EUR +0.1

YoY Analysis -Profit-

Profit (Jan-Mar) -8.5 billion yen



● **Finance/Other -1.5**

- Gain on disposal of fixed assets -2.4 (2.4 → 0)
- Foreign exchange gains and losses -0.6 (0.5 → -0.1)
- Business restructuring expenses +1.4 (-2.3 → -0.9)

Commercial Update

2025 Key Actions & Q1 Topics

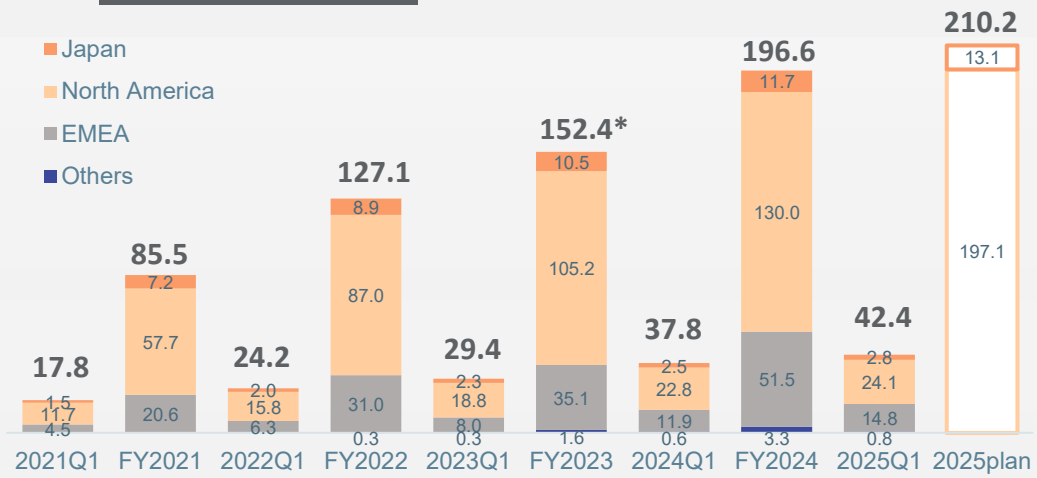
2025 Key Actions

- Strengthen evidence-based marketing activities.
- North America:
  Strengthening promotional activities. Further market penetration through disease awareness initiatives and patient support programs.
- EMEA:
  Continue to focus on geographical & indication expansion. Increase market penetration in adult XLH.
- Japan:
  Further strengthening of promotional activities by dedicated personnel, and enhancement of disease awareness activities for patients.

Q1 Topics

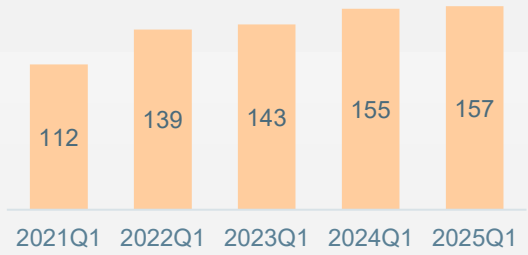
- Global; Sales rev. YoY +12%, annual plan progress rate 20% (typical for Q1 level).
- North America: Sales rev. YoY, in Yen +6%, in local currency +1%
  Negative impacts from seasonal factors are larger than last year, resulting in only 1% sales growth in local currency, but a steady growth trend persists when excluding these factors.
  Efforts are being made to advance disease awareness initiatives and patient support programs.
- EMEA: Sales rev. YoY, in Yen +24%, in local currency +20%
  Revenue growth continues, as new adult patients surpass pediatrics for the first time.
  Efforts to identify new patients via DX and promote adult XLH are ongoing.
- Japan: Sales rev. YoY +13%,
  Strengthening promotional activities led by dedicated personnel and disease awareness efforts has been effective.

Sales Revenue (Billion Yen)

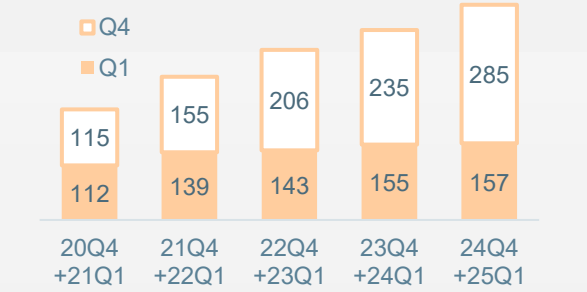


*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

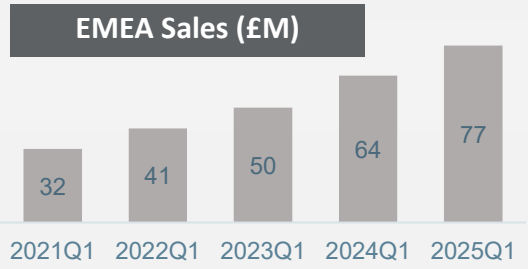
North America Sales ($MM)



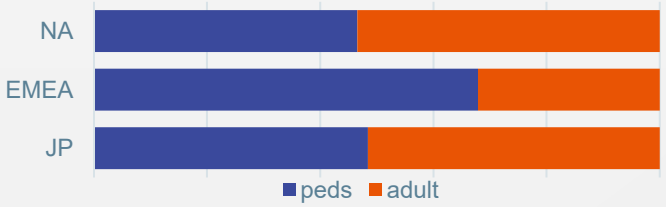
Ref: North America Q4+Q1 Sales ($MM)



EMEA Sales (£M)



XLH Patient Distribution by Crysvita Prescription



2025 Key Actions & Q1 Topics

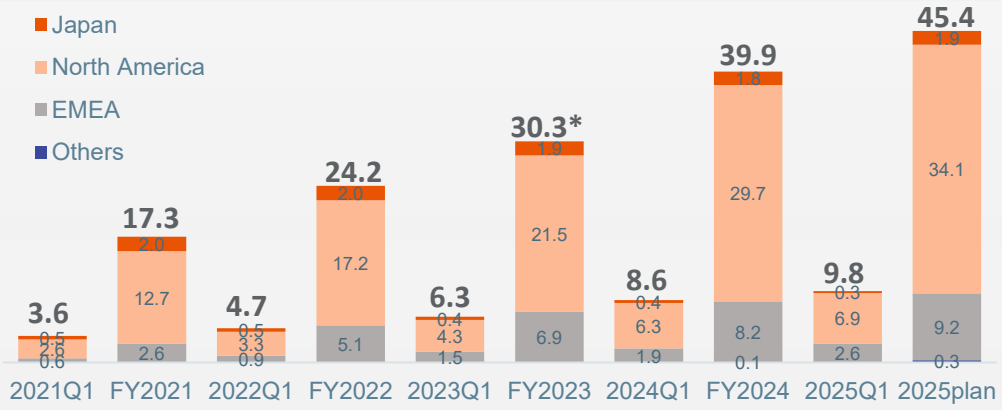
2025 Key Actions

- Global :
  - Evidence-based promotion activities will continue to expand, addressing both cases with predominantly blood involvement and early-stage cases with skin compartment involvement.
- NA (North America) & EMEA :
  - Increasing access to medical facilities through the strengthening of the sales organization.
  - Continuing evidence-based disease awareness activities.
- NA :
  - Further development in promotional activities focused on medical facilities with a high potential for use based on data analysis, leveraging ML & AI based technology.

Q1 Topics

- Global; Sales rev. YoY +13%, annual plan progress rate 22% (typical for Q1 level).
- NA : Sales rev. YoY, in Yen +10%, in local currency +5%
  - During Q1, despite negative impacts from inventory compression in specialty pharmacy, the strengthened sales organization, further development in promotional activities leveraging ML & AI based technology, and robust actual demand contributed to a YoY increase in sales in local currency.
- EMEA : Sales rev. YoY, in Yen +35%, in local currency +31%
  - Growth continues through patient penetration across EMEA market and the expansion of promotional activities into early-stage cases with skin compartment involvement.

Sales Revenue (Billion Yen)



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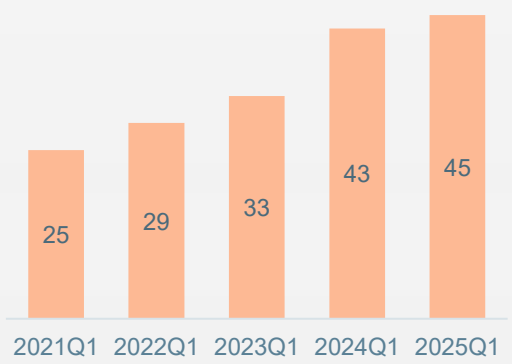
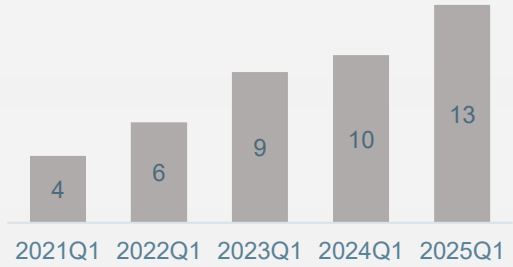
North America Sales ($MM)



EMEA Sales (£M)



R&D Update

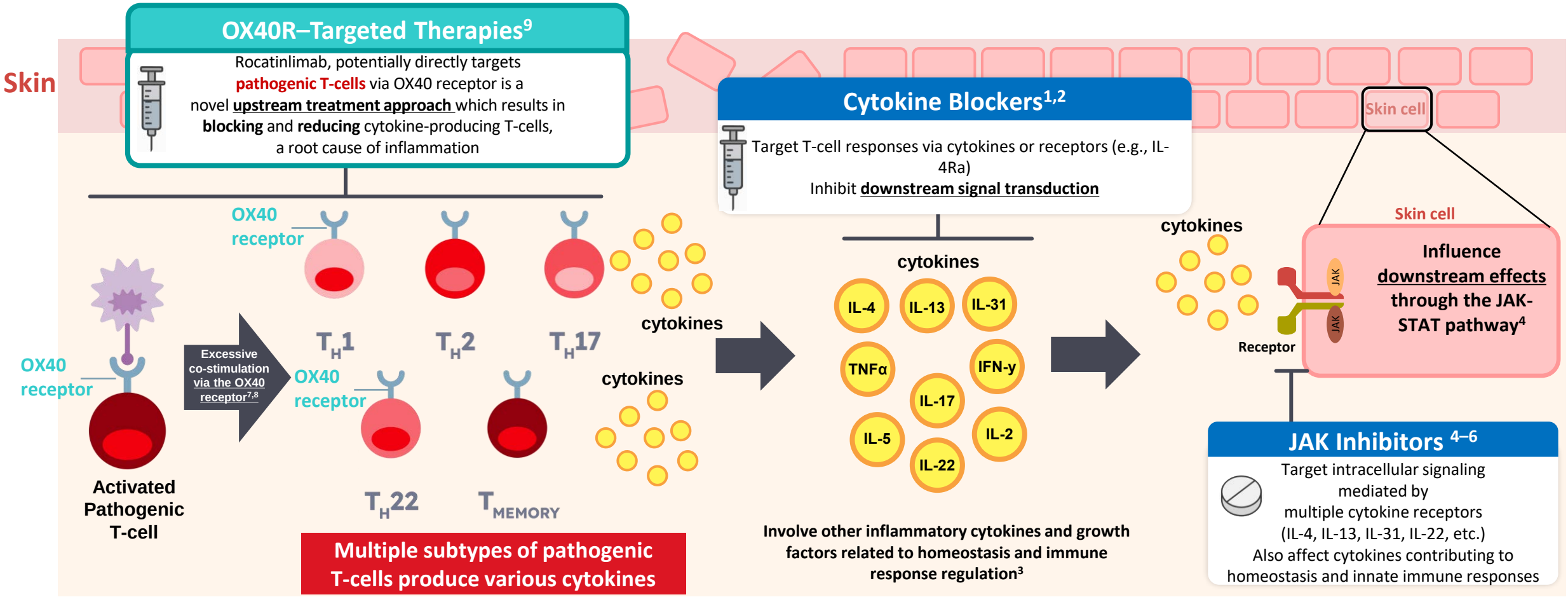
News Flow of Development Pipeline Products

New information highlighted in orange

As of May. 1st , 2025

Products	Diseases under development	Events	Status/Schedule
rocatinlimab KHK4083/AMG 451	Moderate to severe atopic dermatitis	ROCKET HORIZON (P3) Detailed data ROCKET IGNITE, SHUTTLE and VOYAGER (P3) Topline data	March 2025
		ROCKET ASCEND and ASTRO (P3) Topline data	H2 2025
	Prurigo Nodularis	P3	In progress
	Moderate to severe asthma	P2	In progress
ziftomenib	AML (2L+ mono)	KOMET-001 (P2) Detailed data Regulatory submission in US	Q2 2025
	AML (1L combo)	KOMET-017 (P3) initiation	H2 2025
OTL-203	MPS-IH (Hurler Syndrome)	Registrational study (Equivalent to P3 study)	In progress
KK8398 infigratinib	Achondroplasia	P3	Preparation underway
KHK4951 tivozanib eyedrop	DME	P2	In progress
	nAMD	P2	In progress
OTL-201	MPS-IIIA (Sanfilippo syndrome type A)	PoC study (Equivalent to P1-2 study)	In progress
KK4277	SLE, CLE	P1	In progress
KK2260	Advanced or metastatic solid tumors	P1	In progress
KK2269	Advanced or metastatic solid tumors	P1	In progress
KK2845	AML	P1	In progress
KK8123	XLH	P1	In progress
KK3910	Essential Hypertension	P1 initiation	April 2025

By directly targeting pathogenic T-cells via the OX40 receptor, rocatinlimab is a novel approach for the management of Moderate-to-Severe AD[10]

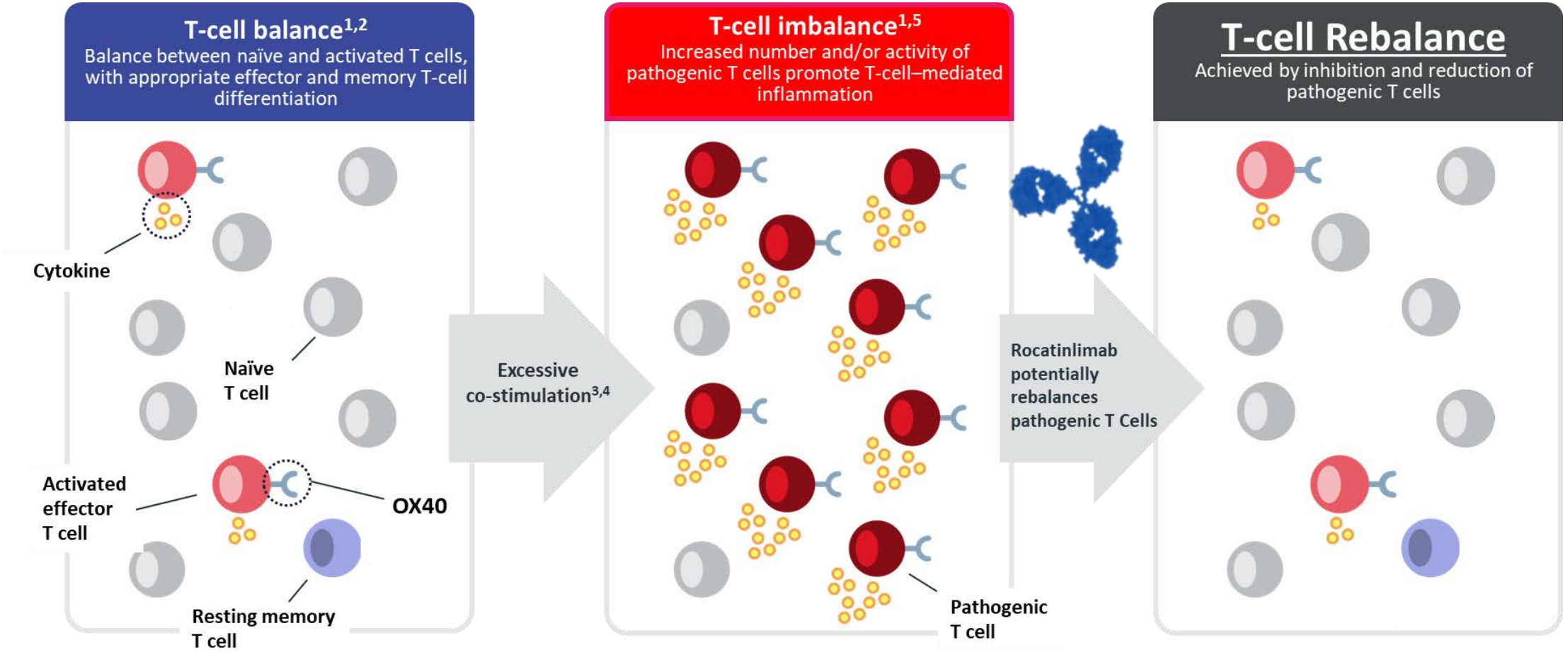


AD, atopic dermatitis; IFN-γ, interferon gamma; IL, interleukin; IL-4Rα, interleukin 4 receptor alpha; JAK, Janus kinase; JAK-STAT, Janus kinase-signal transducer and activator of transcription; TH, T helper cell; TNFα, tumor necrosis factor alpha.

1. Bieber T. *Nat Rev Drug Discov.* 2022;21:21-40. **2.** LEO Pharma. Prescribing information, 2023. [Accessed Jan 2025]. **3.** Huang IH, et al. *Front Immunol.* 2022;13:1068260. **4.** Kamata M, Tada Y. *JID Innov.* 2023;3(3):100195. **5.** Wollenberg A, et al. *J Eur Acad Dermatol Venereol*. 2020;34:2717-2744. **6.** Pavel AB, et al. *J Allergy Clin Immunol.* 2019;144:1011-1024. 7. Zheng C, et al. Front Immunol. 2023:14:1081999.
8. Zhang Q, Vignali DAA. Immunity. 2016;44(5):1034-51. 9. Bieber T. Nat Rev Drug Discov. 2022;21:21-40, 10. Croft M, et al. Am J Clin Dermatol. 2024;25(3):447-461.

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

T-cell Rebalance – Aiming for broad and sustained therapeutic effects by addressing a root cause of inflammatory diseases



Novel OX40-mediated mechanism targeting pathogenic T-cells improves T cell imbalance, root cause of inflammatory diseases, aiming for T cell rebalancing. Potential action on memory T cells for sustained symptom control and disease modification

1. Croft M, et al. *Am J Clin Dermatol.* 2024;25(3):447-461. **2.** Sun L, et al. *Signal Transduct Target Ther.* 2023;8(1):235. **3.** Zhang Q, Vignali DAA. *Immunity.* 2016;44(5):1034-1051. **4.** Zheng C, et al. *Front Immunol.* 2023:14:1081999. **5.** Sadrolashrafi K, et al. *Cells*. 2024;13(7):587.

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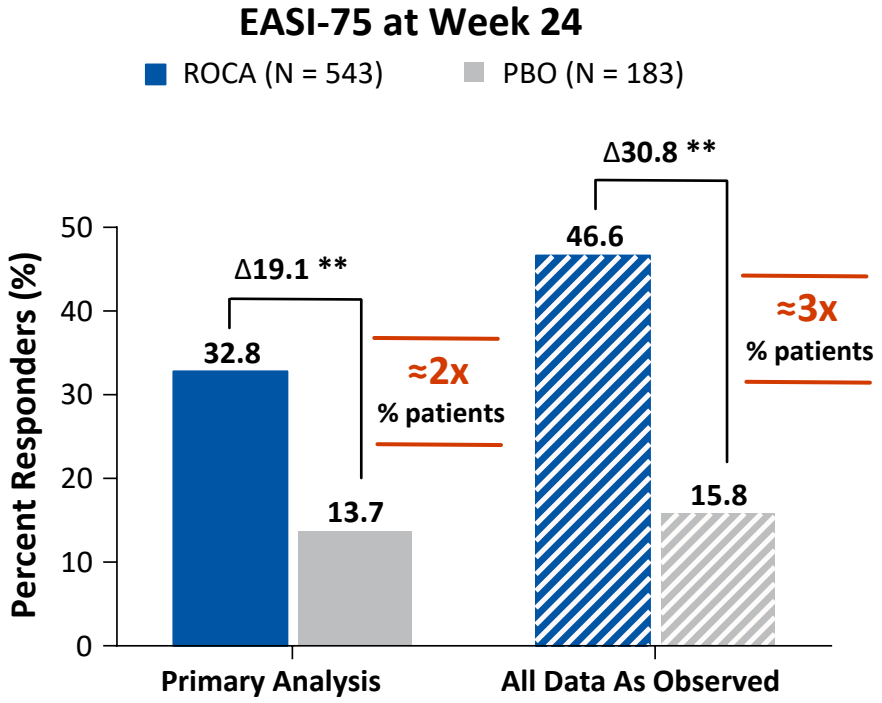
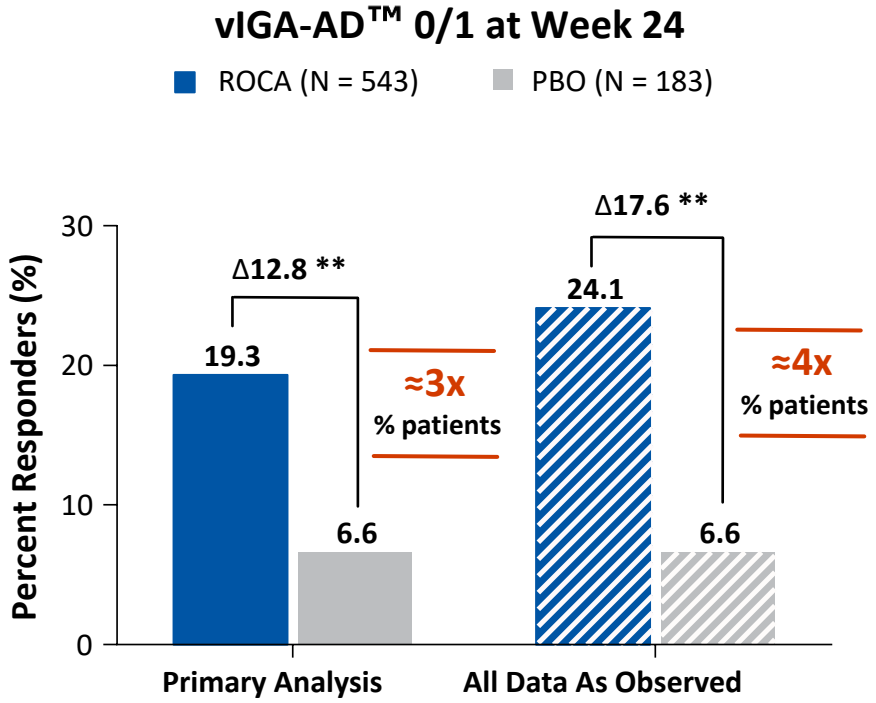
ROCKET HORIZON: EASI-75 and vIGA-AD™ 0/1 Responses at Week 24

Primary analysis set (patients with any rescue use classified as non-responders)
All Data as observed (patient population analyzed based on observed data regardless of rescue therapy use)





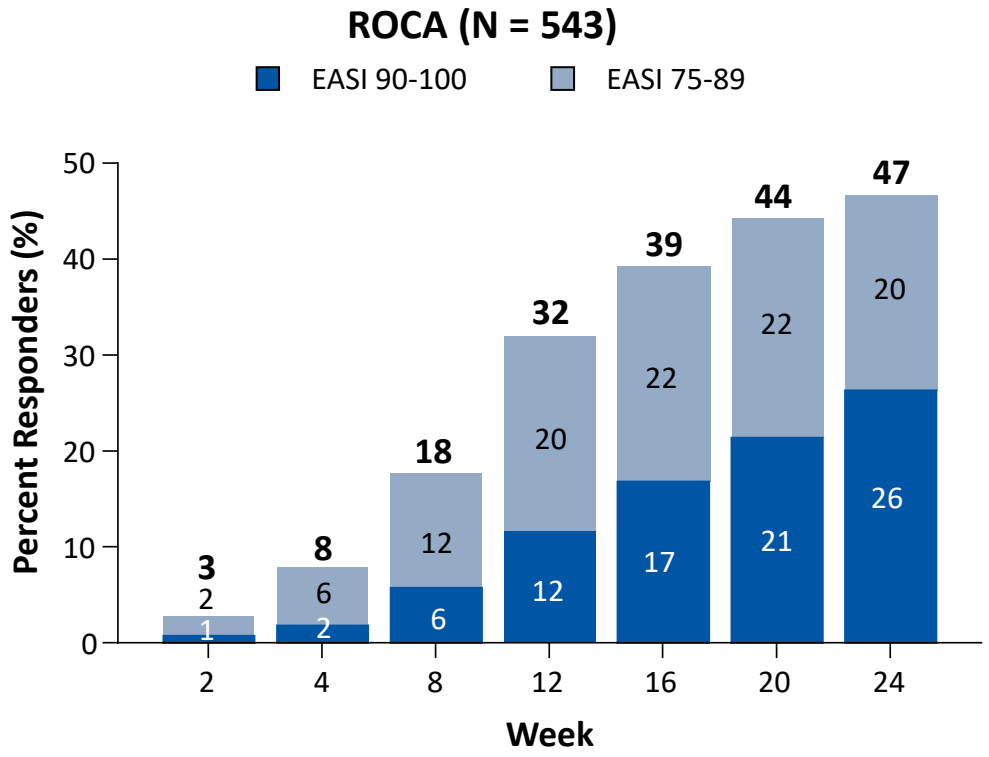
- **Rocatinlimab met its coprimary endpoints**
- **All Data as observed analysis : higher EASI-75 and vIGA-AD™ 0/1 achievement rates in rocatinlimab group**

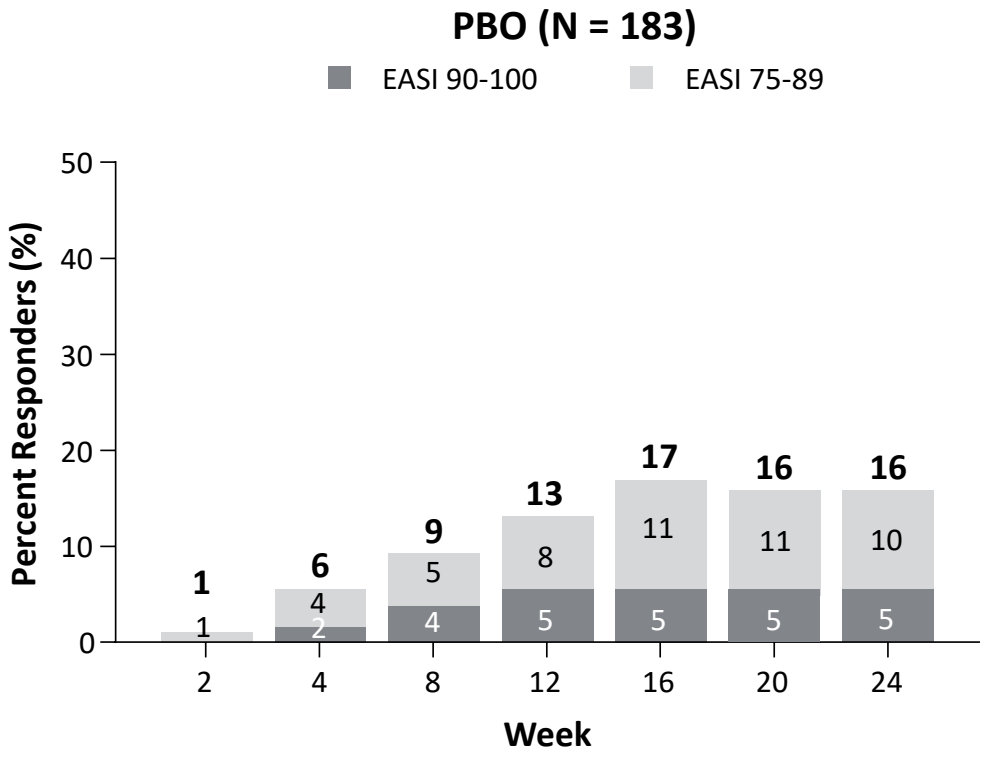
** *P*< 0.001. [a]Values represent the common risk difference. *P* values were obtained from a Cochran-Mantel-Haenszel test and adjusted for the stratification factors of baseline disease severity and geographic region.
EASI-75, ≥ 75% reduction in Eczema Area and Severity Index score from baseline; PBO, placebo; ROCA, rocatinlimab; vIGA, validated Investigator Global Assessment.

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

ROCKET HORIZON: EASI 75-89 and EASI 90-100 at Week 24

All Data as observed (patient population analyzed based on observed data regardless of rescue therapy use)



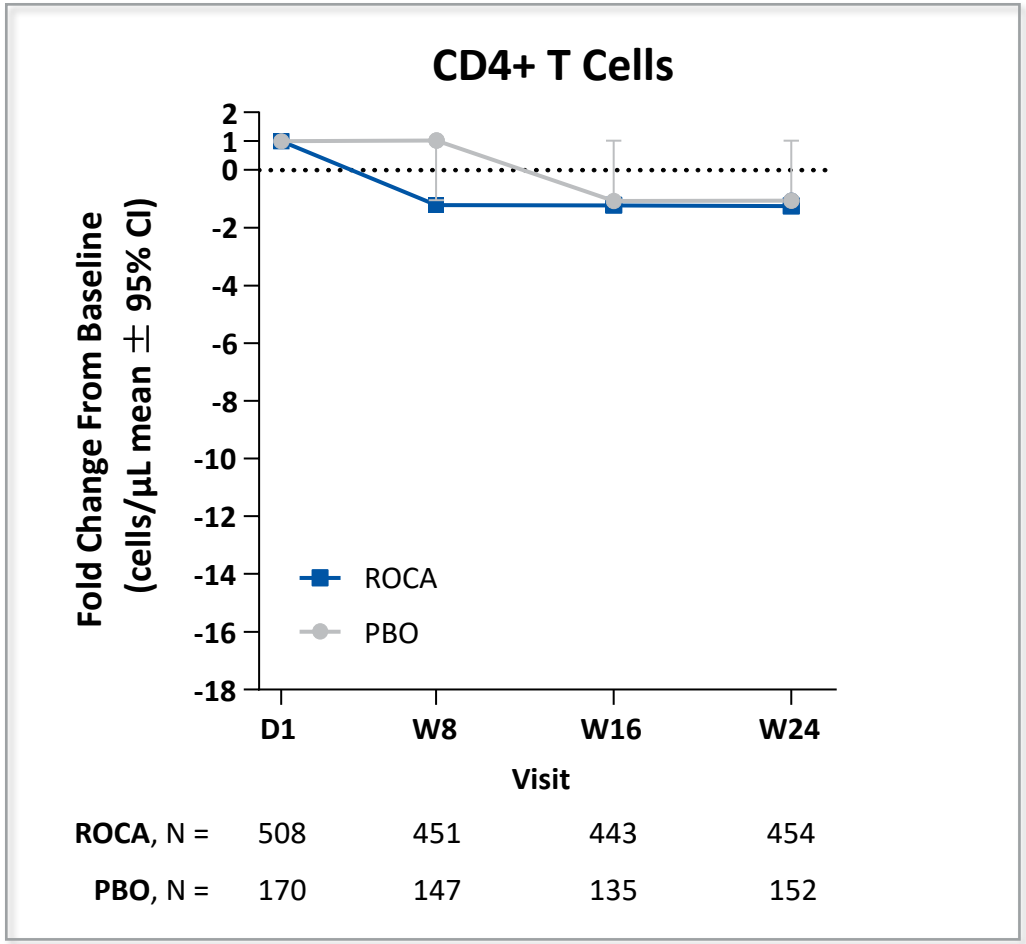


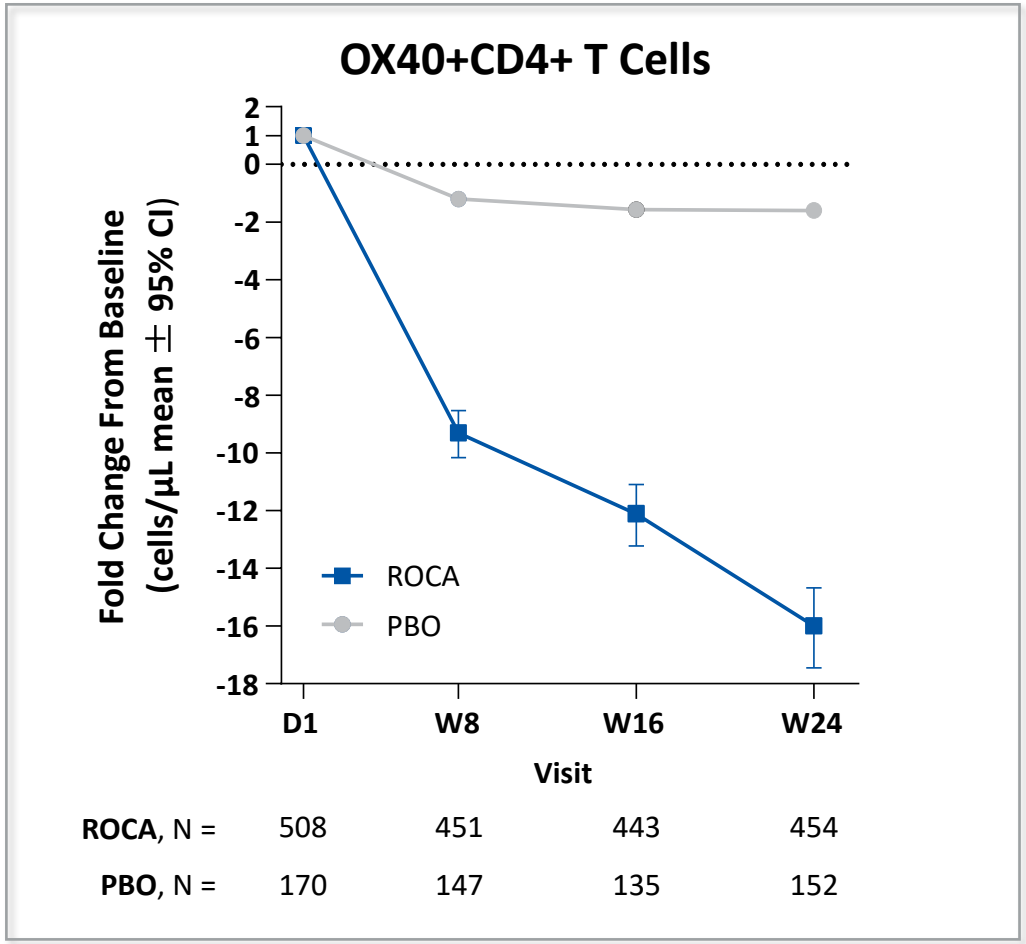
Rocatinlimab-treated patients showed a continuous increase in deep remission (EASI 90–100) rates

Values above bars indicate the percent of patients that were EASI-75 responders.
EASI, Eczema Area and Severity Index; EASI-75, ≥ 75% reduction in Eczema Area and Severity Index score from baseline; EASI 75-89, ≥ 75% to ≤ 89% reduction in EASI score from baseline; EASI 90-100, ≥ 90% to ≤ 100% reduction in EASI score from baseline; PBO, placebo; ROCA, rocatinlimab.

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

ROCKET HORIZON: Longitudinal change of T cell number after rocatinlimab treatment





Rocatinlimab effect: specific reduction of OX40+ T cells; conventional T cells* preserved

*Conventional T cells defined as CD4+ T cell that is not a T regulatory cell; conventional T cells include effector and memory cells.
CD, cluster of differentiation; D, Day; PBO, placebo; ROCA, rocatinlimab; W, Week.

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

Topline Data: ROCKET IGNITE, SHUTTLE, VOYAGER

https://ir.kyowakirin.com/en/news/news-303296477782016180 8/main/00/link/e20250308.pdf

ROCKET ignite
24-week placebo-controlled trial evaluating rocatinlimab monotherapy in adult patients

Monotherapy

Primary Endpoint*	rocatinlimab Higher Dose (Week 24)		rocatinlimab Lower Dose (Week 24)	
	%	**Difference from placebo** (p-value)	%	**Difference from placebo** (p-value)
EASI-75	**42.3**	**29.5** (p<0.001)	**36.3**	**23.4** (p<0.001)
vIGA-AD 0/1	**23.6**	**14.9** (p<0.001)	**19.1**	**10.3** (p=0.002)
rIGA-0/1	**22.7**	**14.4** (p<0.001)	**16.3**	**8.0** (p=0.01)

ROCKET shuttle
24-week placebo-controlled trial evaluating rocatinlimab combination therapy in adult patients

Combination with TCS/TCI

Primary Endpoint*	rocatinlimab Higher Dose (Week 24)		rocatinlimab Lower Dose (Week 24)	
	%	**Difference from placebo** (p-value)	%	**Difference from placebo** (p-value)
EASI-75	**52.3**	**28.7** (p<0.001)	**54.1**	**30.4** (p<0.001)
vIGA-AD 0/1	**26.1**	**13.8** (p<0.001)	**25.8**	**13.5** (p<0.001)
rIGA-0/1	**23.3**	**11.5** (p<0.001)	**22.7**	**10.9** (p=0.002)

ROCKET voyager
24-week placebo-controlled trial evaluating rocatinlimab on vaccine antibody response in adult patients[4]

Responses to vaccinations

Demonstrated that rocatinlimab does not interfere with responses to tetanus and meningococcal vaccinations.

*In the US, revised Investigator Global Assessment (rIGA) replaces vIGA as co-primary endpoint

ROCKET Program: Summary of previous Phase 3 studies

HORIZON Study Detailed Results @ 2025 AAD Late-breaking Abstract

- Achieved co-primary endpoints and key secondary endpoints with monotherapy 300 mg once every 4 weeks dosing (with a loading dose at week 2)
- The proportion of patients achieving EASI 90-100 increased over time and had not reached a plateau at week 24
- Adverse effects were similar to Phase 2 study

New Topline data

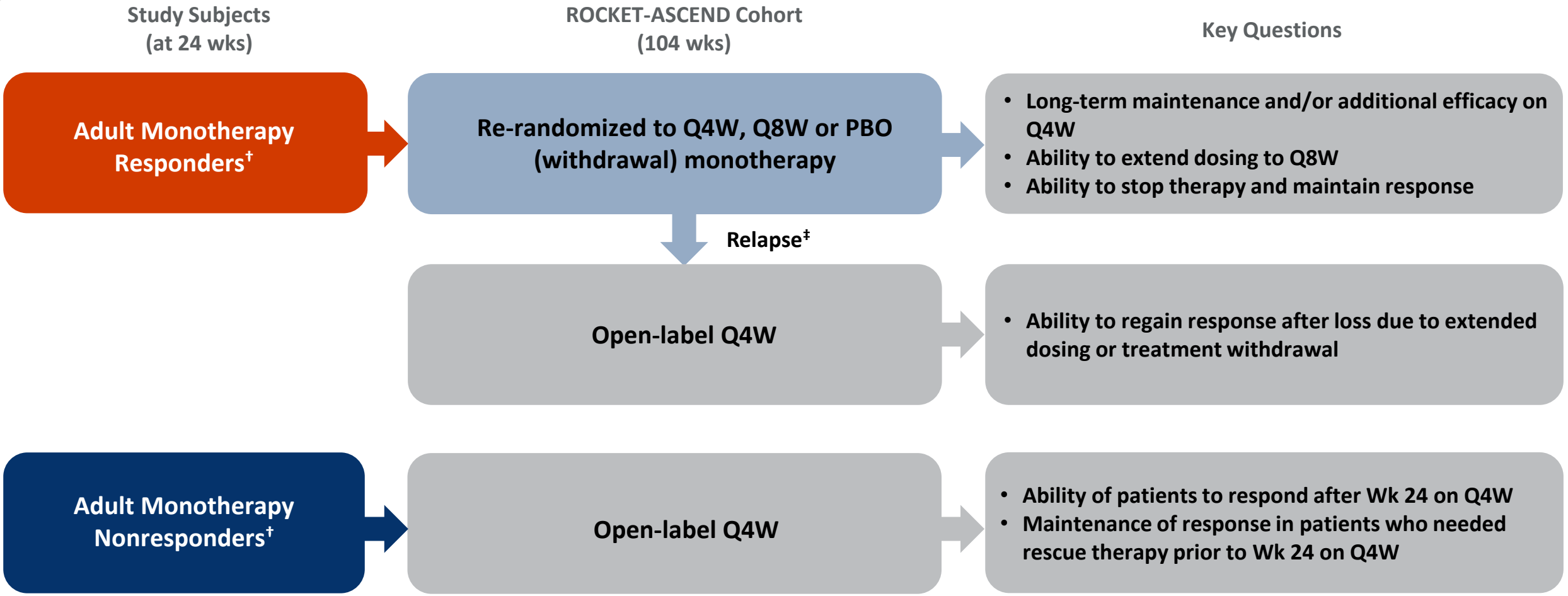
- **ROCKET IGNITE**: Both doses achieved primary and secondary endpoints, demonstrating higher efficacy scores than HORIZON. Notably, efficacy had not reached a plateau at week 24
- **ROCKET SHUTTLE**: Both doses achieved primary and secondary endpoints
- **ROCKET VOYAGER**: Did not affect immune response to vaccines

Overall

- **All 4 studies (total of over 2,400 adult Moderate-to-Severe AD patients) achieved co- primary endpoints and key secondary endpoints**
- Common AEs with rocatinlimab (≥5%): fever, chills, headache; fever/chills primarily post-first dose, resolved within 48hrs
- GI ulcers (<1% incidence): higher in rocatinlimab group vs. placebo

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

Future Looking: ROCKET ASCEND Design – Adult Cohorts[1,*]



*Additional data will be generated in adolescents including Q4W maintenance, Q8W extension and treatment withdrawal (not shown). †Responders are defined as achieving EASI-75 and/or vIGA 0/1 at Wk 24 without the use of rescue therapy. ‡Relapse defined as loss of at least 50% of improvement in EASI response at Wk 24 of parent study from parent study baseline, or initiation of rescue therapy for AD.
AD, atopic dermatitis; PBO, placebo; Q4W, every 4 weeks; Q8W, every 8 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid; Wk, Week

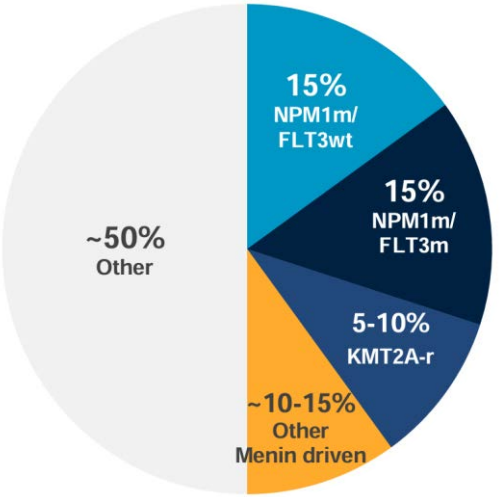
1. Guttman-Yassky E, et al. [Published online ahead of print February 26, 2025]. *Immunotherapy*.

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

Updates of ziftomenib

Summary of the product

- Oral small molecule Menin inhibitor
- Target disease：Acute Myeloid Leukemia (AML) with NPM1 mutations or KMT2A rearrangement
  - In the United States, about 20,800 new AML diagnoses occur annually[1]
  - Approximately 50% of AML cases are considered menin-dependent[2-6]
  - Up to 70% of patients who achieve remission relapse within 3 years[7]



https://ir.kuraoncology.com/static-files/dcabbd07-f160-4023-a2c7-56217801eb4d

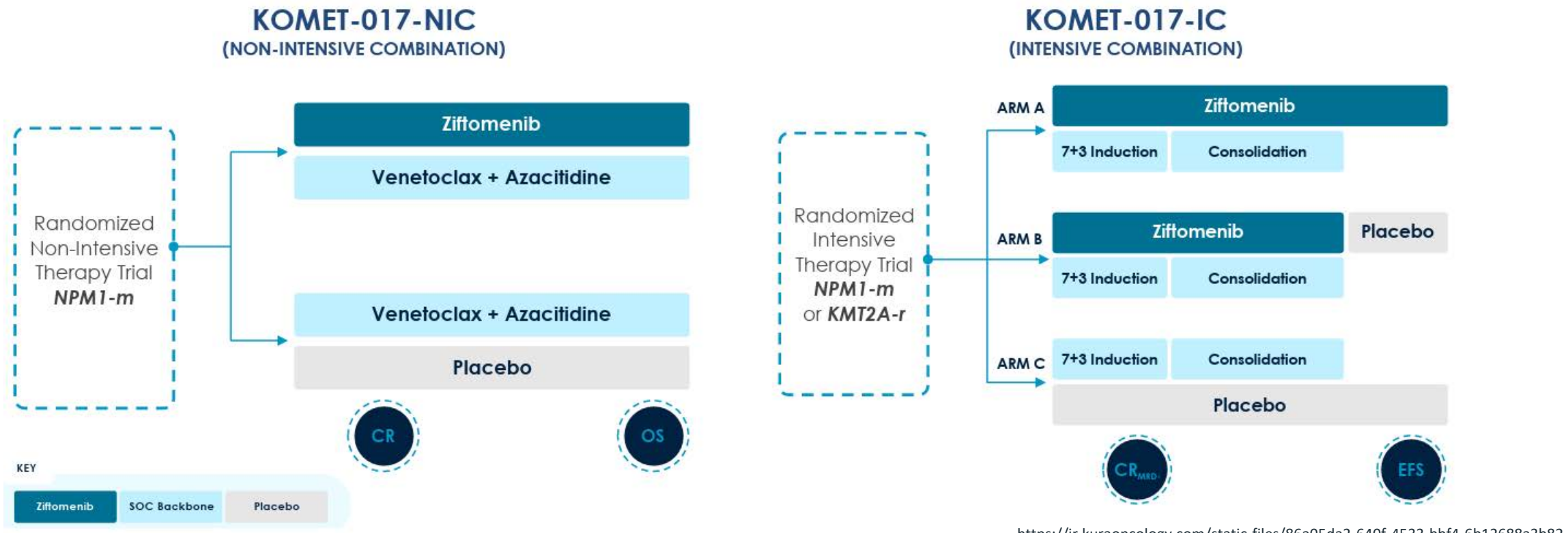
Development status

- FDA submission for approval in adults with relapsed and refractory AML with NPM1m (Press release: April 8, 2025)
- P2 study KOMET-001 (2nd Line+, mono) results to be presented at 2025 ASCO Annual Meeting
- P3 study KOMET-017 (1st Line, combo) scheduled to begin in H2 2025

1. American Cancer Society. Updated June 5, 2024. Accessed August 27, 2024. https://www.cancer.org/cancer/types/acute-myeloidleukemia/about/key-statistics.html ; 2. Issa GC et al. Leukemia. 2021;35(9):2482-2495. doi:10.1038/s41375021-01309-y; 3. Candoni A, Coppola G. Hematol Rep. 2024;16(2):244-254. doi:10.3390/hematolrep16020024; 4. Bertrums EJM et al. Haematologica. 2023;108(8):2044-2058. doi:10.3324/haematol.2022.281653; 5. National Cancer Institute. Accessed October 16, 2024. https://seer.cancer.gov/seertools/hemelymph/ 51f6cf59e3e27c3994bd547d/; 6. National Cancer Institute. Accessed October 16, 2024. https://seer.cancer.gov/seertools/hemelymph/5a7e288d1ef557f9c8636d31/ 6. 7. Kumar CC. Genes Cancer. 2011;2(2):95-107. doi:10.1177/1947601911408076

Study Design of KOMET-017

Based on the promising results in 1st line therapy from P1 combination study (KOMET-007), a P3 1st line combination study will begin in H2 2025



https://ir.kuraoncology.com/static-files/86a05da2-640f-4533-bbf4-6b12688a3b82

Aim to deliver new therapeutic option for a broad range of patients with AML

News Flow in 2025

Year-to-date Key News Flow

As of Feb. 6th, 2025

Category	Date	Headline
R&D	Jan 20	Received the 7th Prime Minister's Award for the Japan Medical Research and Development Grand Prize, recognizing the accomplishment of developing mogalizumab featuring our proprietary Potelligent technology and achieving success in the development of the first antibody drug for cancer originating in Japan.(Japan)
R&D	Feb 6	Announced positive topline data from the KOMET-001 trial, which evaluated ziftomenib as a monotherapy for R/R NPM1-m AML
R&D	Feb 27	Presented the results of the Phase 3 ROCKET-HORIZON trial of rocatinlimab in adult patients with moderate to severe atopic dermatitis as a late-breaking abstract at American Academy of Dermatology (AAD) 2025 Annual Meeting
LCM	Mar 7	Approval for Partial Change of Rituximab Biosimilar for the treatment of refractory nephrotic syndrome received by Sandoz. strategic partner of this business
R&D	Mar 8	Announced Top-line results of three trials including IGNITE trial from rocatinlimab Phase 3 ROCKET PROGRAM for Adults with Moderate to Serve Atopic Dermatitis
R&D	Apr 8	Submitted a new drug application for the oral menin inhibitor ziftomenib, targeting acute leukemia to the U.S. Food and Drug Administration (FDA) in collaboration with Kura Oncology
SCM	Apr 11	Completed Construction of a New Biopharmaceutical DS Manufacturing Facility (HB 7 building) at Takasaki Plant
		Updates after the previous earnings announcement

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP; strategic partnering MKT; marketing MGMT; management

Appendix

Story for Vision 2030

Strategies for creating and delivering life-changing value

Disease Science

Focus disease areas: bone & mineral, intractable hematological diseases/hemato oncology, and rare diseases

- Explore UMN, causes and mechanisms of disease in depth
- Pursuit of molecular and cellular regulatory mechanisms for therapeutic realization

Drug Discovery Technology

Strengthening Innovative Modalities: Advanced Antibody Technologies, Hematopoietic stem cell gene therapy

- Application of optimal modalities for therapeutic realization
- Evolution of drug discovery methods through AI and data science

External Collaboration

- Open Innovation
- Partnering

Life-changing Value Creation

Assets in focus disease areas

Strategic Partnering Assets *

Value delivery on our own

Global deployment of products developed by taking full advantage of the company's strengths

Collaborative value delivery

Aim to maximize value by combining the strengths of the company and its partners

Full-licensing

Maximize the value of developed products and deliver them to patients faster by out-licensing to the most appropriate partners

***Assets outside of the disease areas of focus are designated as strategic partnering assets, and value maximization is achieved through collaboration with partners.**

Main Development Pipeline Products (P2-P3)

As of May. 1st , 2025

	Diseases under development*1		Planned Approval Year*2	Development status	Total addressable market*3	No. of Patients*4
Rocatinlimab KHK4083/AMG 451	Moderate to severe Atopic Dermatitis		2026/2027	P3 (Global)	★★★★★	16M
	Prurigo nodularis		TBD	P3 (Global)	★★★★	1M
	Moderate to severe Asthma		TBD	P2 (Global)	★★★★★	13.5M
Infigratinib	Achondroplasia		TBD	P3 (Japan)	★	6K
Ziftomenib	AML (NPM1-m or KMT2A-r)	R/R	2025 (Mono)	P2 (US, EU)	★★★★	20K
		1L	TBD	P1 (US)		
KHK4951 tivozanib eyedrop	nAMD		TBD	P2 (JP, US)	★★★★	2,600K
	DME		TBD	P2 (JP, US)	★★★★	3,400K
OTL-203	MPS-IH (Hurler Syndrome)		2029/2030	Registrational study*5 (US, EU)	★	(1 in 100K live births)*6
OTL-201	MPS-IIIA (Sanfilippo syndrome type A)		TBD	Proof-of-concept study*7	★	(~1 in 100K live births)

*1 Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities. *2 Expected year of first approval. *3 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.** ★: less than ¥50Bn、★★: ¥50Bn-¥100Bn、★★★: Over ¥100Bn-¥500Bn、★★★★: Over ¥500Bn-¥1Tn、★★★★★: Over ¥1Tn. *4 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.** *5 Equivalent to P3 study. *6 "1 in 100k live birth" is estimated incidence for all of MPS-I, of which approximately 60 percent of patients have the Hurler subtype. *7 Equivalent to P1/2 study.

Main Development Pipeline Products (P1)

As of May. 1st , 2025

	Diseases under development*1	Development status	Modality, technology
KK4277	SLE, CLE	P1 (JP, Asia)	Antibody, POTELLIGENT®
KK2260	Advanced or metastatic solid tumors	P1 (JP: in progress, US: in preparation)	Antibody, REGULGENT™
KK2269	Advanced or metastatic solid tumors	P1 (JP, US)	Antibody, REGULGENT™
KK2845	AML	P1 (JP)	Antibody-Drug Conjugate
KK8123	XLH	P1 (US, EU)	Antibody
KK3910	Essential Hypertension	P1 (JP)	Antibody

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

Main Development Pipeline Products: Future plans

As of May. 1st , 2025

Product	Target Disease	Development Status		2025	2026	2027	+
rocatinlimab (KHK4083/AMG 451)	Moderate to severe Atopic Dermatitis ROCKET ROCatinlimab in Eczema Trials	IGNITE	P3	Q2 Topline data			
		HORIZON		Detailed data presentation in 1H			
		SHUTTLE		Q2 Topline data			
		ASTRO		H2 '25 Topline data			
		ORBIT					
		VOYAGER		Completed			
		ASCEND		H2 '25 Interim Data			
		OUTPOST					
	Prurigo Nodularis	P3					
	Moderate to severe asthma	P2					

The bars correspond to timelines on clinicaltrials.gov

Main Development Pipeline Products: Future plans

As of May. 1st , 2025

Products	Target	Development Status		2025	2026	2027	+
ziftomenib	AML	KOMET-001 2L+ Mono	P2[1] (NPM1-m)	Topline Data reported			
	ALL		P1a[2] (KMT2A-r)	Ongoing			
	AML		P1a[2] (non NPM1-m / KMT2A-r AML)	Ongoing			
		KOMET-007 1L, 2L+ Combinations with cytarabine + daunorubicin (7+3), and with venetoclax + azacitidine	P1a/P1b[3]				
		KOMET-008 2L+ Combination with gilteritinib, FLAG-IDA, or LDAC	P1a[2]				
		KOMET-017 1L Combinations with cytarabine + daunorubicin (7+3), and venetoclax + azacitidine	P3				

1. Patients Remain On Study in Follow-Up; 2. Dose-Escalation Now Dosing Patients; 3. Dose-Validation Now Enrolling

The bars correspond to timelines on clinicaltrials.gov

Main Development Pipeline Products: Future plans

As of May. 1st , 2025

Product	Target Disease	Phase	2025	2026	2027	+
KHK4951 tivozanib	nAMD	**P2**				
	DME	**P2**				
KK4277	SLE, CLE	**P1**				
KK2260	Advanced or metastatic solid tumors	**P1**				
KK2269	Advanced or metastatic solid tumors	**P1**				
KK2845	R/R AML	**P1**	In progress			
KK8123	XLH	**P1**				
KK3910	Essential Hypertension	**P1**				

The bars correspond to timelines on clinicaltrials.gov

FOREX Information

Average FOREX Rates (yen)

	2024Q1	2025Q1	Changes	2025 Plans
USD	147	154	+7	145
GBP	187	193	+6	190
EUR	160	161	+1	160

2025Q1 FOREX Impacts (billion yen)

	Revenue	Core OP
USD	+2.1	+0.4
GBP	+0.1	-0.1
EUR	+0.2	+0.1

FY2025 FOREX Sensitivities (vs FY25 Plan, billion yen)

	Changes	Revenue	Core OP
USD	+1 yen	+1.6	+0.5
GBP	+1 yen	+0.1	-0.0
EUR	+1 yen	+0.3	+0.2

Ziftomenib - Collaboration with Kura -

	US	ex- US
Development	• Kura leads development • Share global development cost • Kura funds development costs (~2028)	• Kyowa Kirin leads development
Commercialization	• Kura books sales • 50/50 profit share	• Kyowa Kirin commercializes and books sales
Sales Royalties		• Double-digit royalty to Kura
Commercial supply	• Kura supplies	• Kura supplies

Kyowa Kirin makes a $330 million up-front payment and future contingent milestone payments potentially worth up to $1,161 million in total, including $420 million in near-term milestone payments and $228 million opt-in right for solid tumors, as well as royalty payments on future global sales to Kura.

KHK4083/AMG 451 - Collaboration with Amgen -

	US	Europe & Asia (ex. JP)	JP
Development	• Amgen leads development • Share development cost	• Amgen leads development • Share development cost	• Kyowa Kirin leads development
Commercialization	• Amgen commercializes and books sales • Kyowa Kirin co-promotes and shares promotion cost	• Amgen commercializes and books sales • Kyowa Kirin has opt-in rights for co-promotion	• Kyowa Kirin commercializes and books sales
Sales Royalties	• Double-digit royalty to Kyowa Kirin	• Double-digit royalty to Kyowa Kirin	
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.

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.

Estimated Patient Numbers

Disease	Country/ Region	Incidence	Prevalence[1]	Reference
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
nAMD	JP, US		2,300,000	Study by Decision Resources
MLD	Global	~1:100,000		Mahmood et al. Metachromatic Leukodystrophy: A Case of Triplets with the Late Infantile Variant and a Systematic Review of the Literature. Journal of Child Neurology 2010,
MPS-I	Global	~1:100,000[2]		Puckett et al. 2021 Orphanet J Rare Dis 16:241: US NBS data (MPS-I incidence derived from NBS data in Table 3)
MPS-IIIA	Global	~1:100,000		Shapiro EG, et al. J Pediatr. 2016 Mar;170:278-87.e1-4.

1. Prevalence represents the estimated patient number per the entire population of each country or region.; 2. “1 in 100k live births is estimated incidence for all of MPS-I, of which approximately 60 percent of patients have the Hurler subtype

List of Acronyms

AD	Atopic Dermatitis
AG	Authorized Generic
ALL	Acute lymphoblastic leukemia
AML	Acute myeloid leukemia
APAC	Asia-Pacific
BS	Biosimilar
CLE	Cutaneous lupus erythematosus
CTCL	Cutaneous T cell lymphoma
DME	Diabetic Macular Edema
EMEA	Europe, the Middle East and Africa
JP	Japan
LCM	Lifecycle Management
MLD	Metachromatic Leukodystrophy
MPS-IH	Mucopolysaccharidosis type I, Hurler syndrome
MPS-IIIA	Mucopolysaccharidosis type IIIA, Sanfilippo syndrome type A
NA	North America
nAMD	neovascular Age-related Macular Degeneration
PTCL	Peripheral T cell lymphoma
SLE	Systemic lupus erythematosus
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

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