Results Presentation
Fiscal 2025 Second Quarter

協和キリン株式会社

Agenda

Financial Review
Commercial Update
R&D Update
News Flow in 2025
Q&A

Chairman and Chief Executive Officer (CEO) Masashi Miyamoto, Ph.D.
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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 Q2 Results

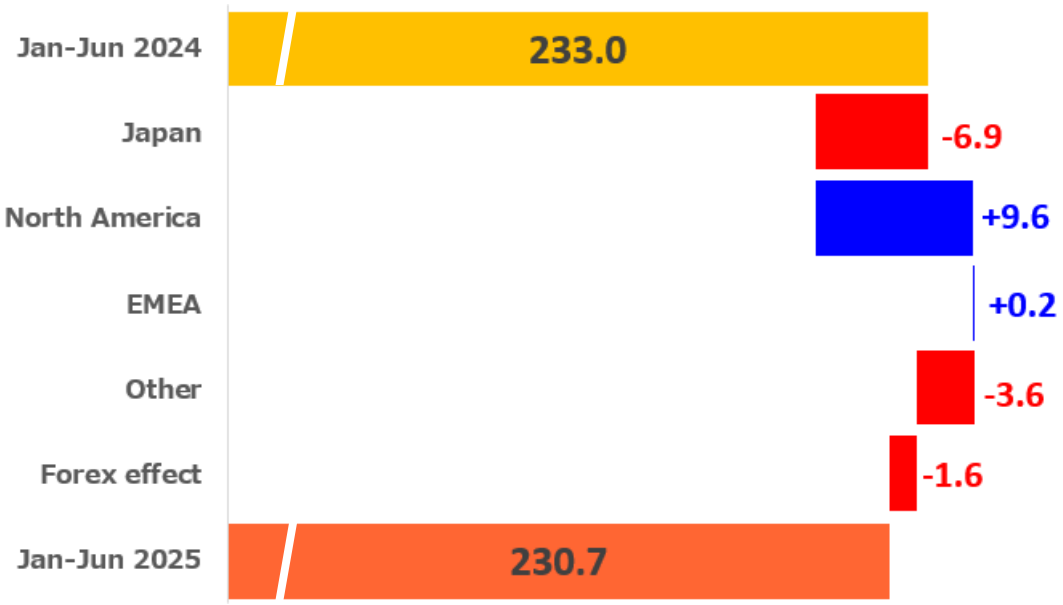
(Billion Yen / Rounded)

	2024 Jan-Jun	2025 Jan-Jun	Changes	FY2025 Plans	Progress to goal
Revenue *[Overseas Ratio]*	233.0 *[71%]*	230.7 *[73%]*	-2.3 (-1%)	478.0 *[73%] **	48%
Gross Profit *[Gross Profit Margin]*	173.5 *[74%]*	168.8 *[73%]*	-4.7 (-3%)	352.0 *[74%]*	48%
SG&A *[SG&A Ratio]*	83.2 *[36%]*	82.8 *[36%]*	-0.4 (-0%)	166.0 *[35%]*	50%
R&D *[R&D Ratio]*	49.2 *[21%]*	52.5 *[23%]*	+3.3 (+7%)	107.0 *[22%]*	49%
Gain/Loss on Equity Method	3.1	1.5	-1.6 (-50%)	1.0	155%
Core Operating Profit *[Core OP Margin]*	44.1 *[19%]*	35.0 *[15%]*	-9.1 (-21%)	80.0 *[17%]*	44%
Profit	37.8	16.3	-21.5 (-57%)	57.0	29%

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

YoY Analysis -Revenue-

-2.3 billion JPY
(-0.7 B excl. forex impact)



- **Japan -6.9**
  Although Phozevel, Duvroq and Crysvita increased, revenue in the Japan region decreased by 9% due mainly to the termination of the sales partnership agreement for Dobovet (-3.9B), and negative impact by annual NHI price-cut.

- **North America +9.6 (excl. forex impact -1.1)**
  Revenue in the North America region increased by 12% with the growth of Crysvita (+11%) and Poteligeo (+15%).

- **EMEA +0.2 (excl. forex impact -0.0)**
  Although Crysvita (+9%) and Poteligeo (+22%) increased, revenue in the EMEA region remained at the same level due to a one-off decline in Tostran revenue (1.6B), among other factors.

- **Other -3.6 (excl. forex impact -0.5)**
  Decreased by 8% due mainly to the impact on restructuring of the APAC business, although sales of Libmeldy/Lenmeldy and royalties from Fasenra (Benralizumab) increased.

- **Forex impact -1.6**
  USD -1.3B, GBP +0.1B, and EUR -0.1B

Revenue of Major Items

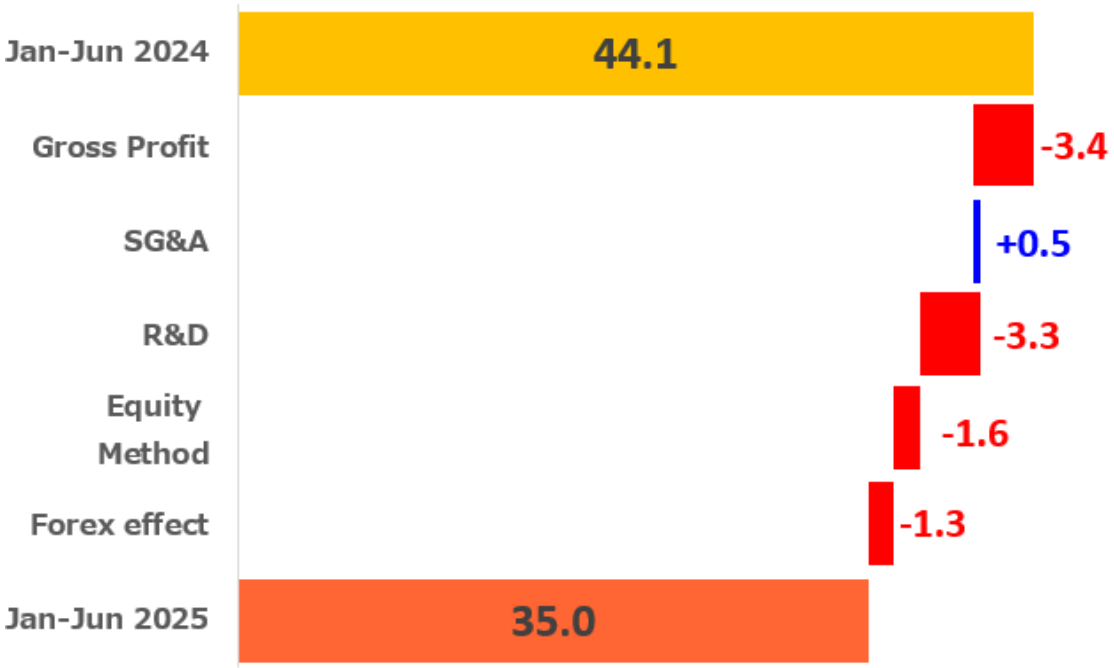
(Billion Yen / Rounded)

Item		2024 Jan-Jun	2025 Jan-Jun	Changes	Reasons	FY2025 Plans	Progress to goal
Crysvita		90.9	99.8	+8.9 (+10%)	Market penetration	210.2	47%
	JP	5.4	6.1	+0.7 (+13%)		13.1	47%
	NA	58.7	64.0	+5.3 (+9%)		197.1	48%
	EMEA	25.4	28.0	+2.5 (+10%)			
	Other	1.3	1.7	+0.4 (+28%)			
Poteligeo		19.0	21.6	+2.6 (+14%)	Market penetration	45.4	48%
	JP	1.0	0.7	-0.3 (-28%)		1.9	37%
	NA	14.1	16.0	+1.9 (+13%)		34.1	47%
	EMEA	3.9	4.9	+0.9 (+23%)		9.2	53%
	Other	0.1	0.1	-0.0 (-15%)		0.3	23%
Libmeldy / Lenmeldy		1.4	4.4	+3.0 (+206%)	Market penetration (FDA approval in Mar 2024)	6.9	64%
	US	-	1.6	+1.6 (- %)			
	EMEA	1.4	2.8	+1.4 (+97%)			
Phozevel	JP	1.7	3.7	+2.0 (+119%)	Market penetration (Launched in Feb 2024)	8.9	41%
Duvroq	JP	5.7	6.9	+1.2 (+21%)	Market penetration	15.5	44%
Nesp + Nesp-AG	JP	6.9	5.7	-1.2 (-17%)	NHI price-cut & Biosimilars' penetration	11.6	50%
G-Lasta	JP	10.5	9.1	-1.4 (-13%)	NHI price-cut & Biosimilars' penetration	17.0	53%
Romiplate	JP	6.5	7.3	+0.8 (+12%)	Market penetration	14.6	50%
Tech-licensing		24.3	25.5	+1.2 (+5%)	Growth of Fasenra	52.3	49%
Benralizumab Royalty		14.4	15.7	+1.3 (+9%)			

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-

-9.1 billion JPY
(-7.8 B excl. forex impact)



- **Gross Profit -3.4 (excl. forex impact -1.3)**
  Decreased in conjunction with the down in revenue and a one-off increase in CoGs resulting the gross profit margin fell by one percentage point YoY.

- **SG&A +0.5 (excl. forex impact -0.1)**
  SG&A decreased due to the restructuring of the APAC business, although increased HR expense rates and the launch readiness cost of ziftomenib were incurred.

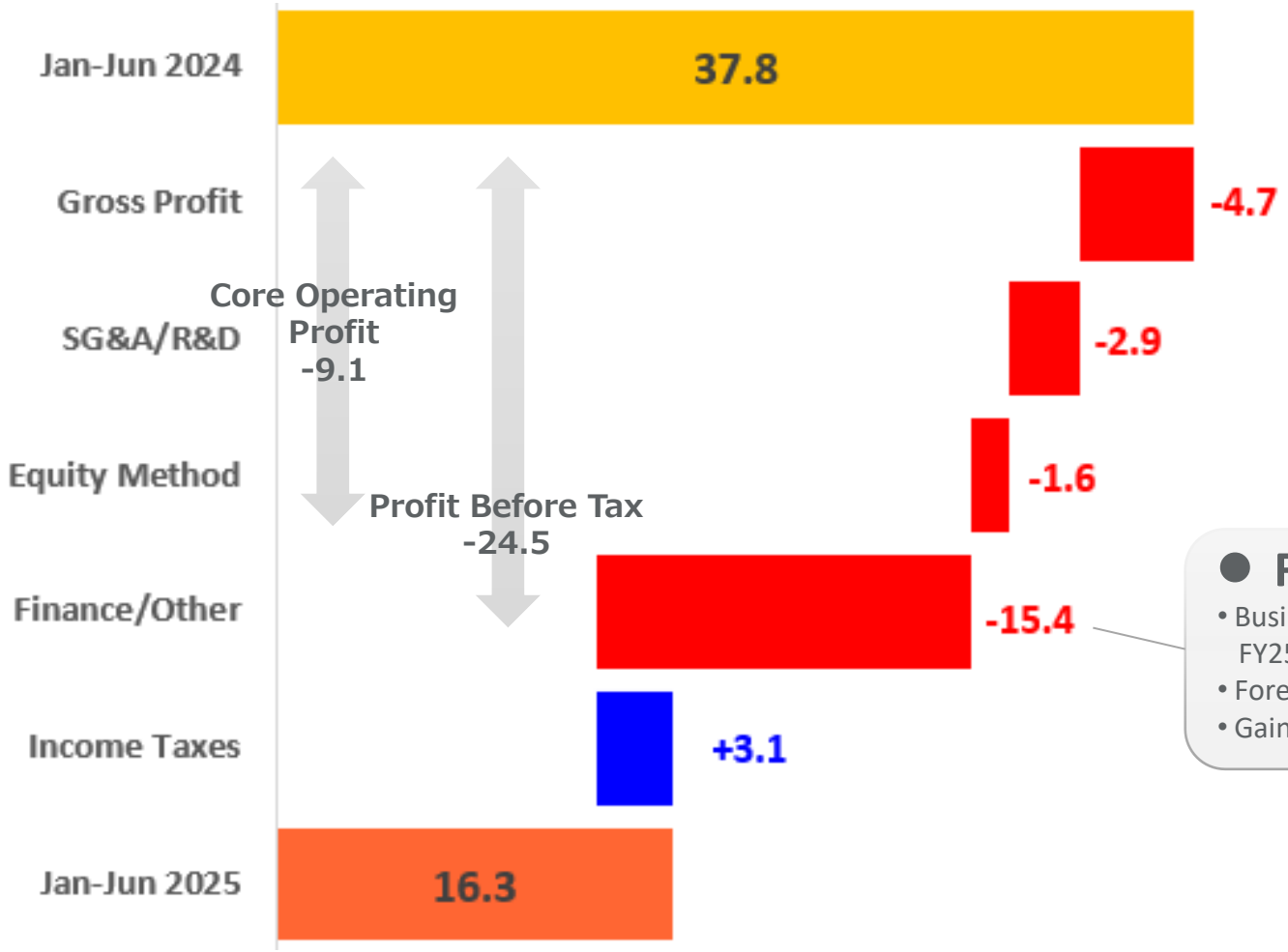
- **R&D -3.3 (excl. forex impact +0.1)**
  In addition to the impact of the new consolidation of Orchard (Feb 2024), progress in the development of each project increased R&D expenses.

- **Gain/Loss on Equity Method -1.6 (excl. forex impact -0.0)**
  Decreased sales at FKB have led to a decline in profits.
  FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

- **Forex impact -1.3**
  USD -1.0B, GBP -0.1B, and EUR -0.0B

YoY Analysis -Profit-

Profit (Jan-Jun) -21.5 billion yen



● Finance/Other -15.4

- Business restructuring expenses -7.8B (-2.7 → -10.5)
  FY25: JP Special Voluntary Early Retirement Program -9.4B
- Foreign exchange gains and losses -4.0B (2.7 → -1.3)
- Gain on disposal of fixed assets -2.4B (2.4 → 0)

Commercial Update

2025 Key Actions & Q2 Topics

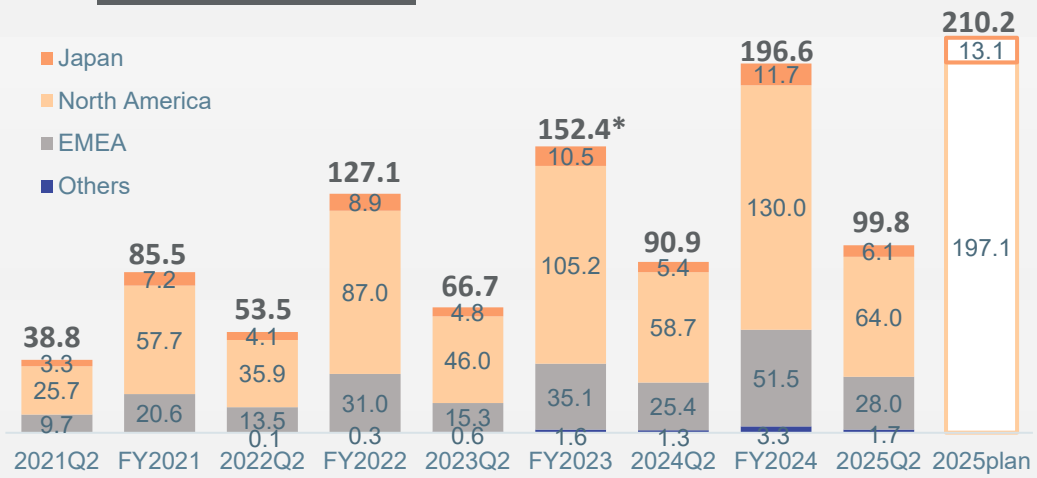
2025 Key Actions

- 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.

Topics up to Q2 (YTD)

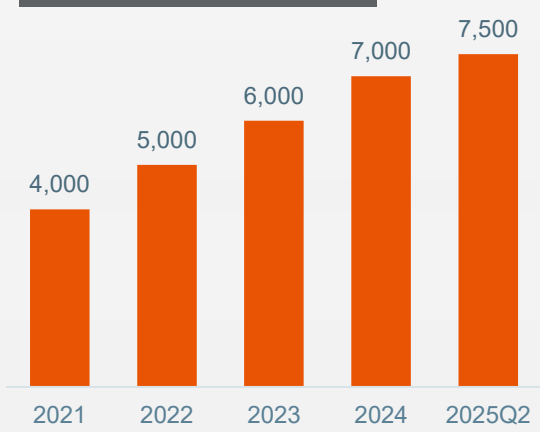
- Global; YTD Sales rev. YoY +10%, annual plan progress rate 47%
- North America: YTD Sales rev. YoY, in Yen +9%, in local currency +11%
  Sales revenue YTD grew year-over-year and actual demand is mostly on plan.
  Q2 sales growth was supported by collaboration with specialty pharmacies for patient support and their inventory buildup ahead of the price revision.
- EMEA: YTD Sales rev. YoY, in Yen +10%, in local currency +9%
  Public XLH treatment guidelines in Europe, including Crysvita prescribing, are driving commercial growth and contributing to the increase in treated patients, primarily adults.
  Efforts to identify new patients via DX and promote adult XLH are ongoing.
- Japan: YTD Sales rev. YoY +13%,
  Strengthening promotional activities led by dedicated personnel and disease awareness efforts has been effective, leading to increase in treated patients, primarily adults.

Sales Revenue (Billion Yen)

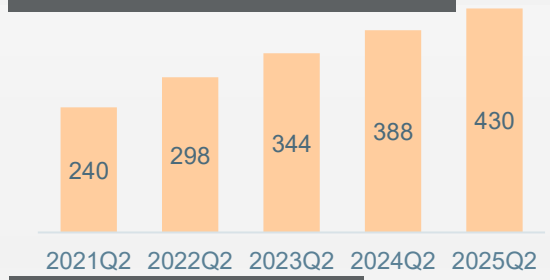


*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

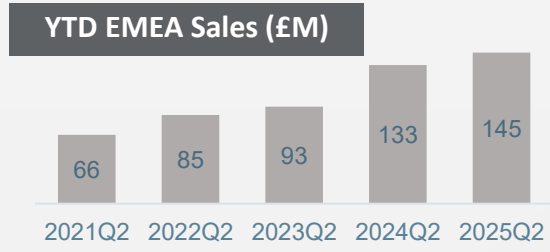
Treated Patients



YTD North America Sales ($M)



YTD EMEA Sales (£M)



2025 Key Actions & Q2 Topics

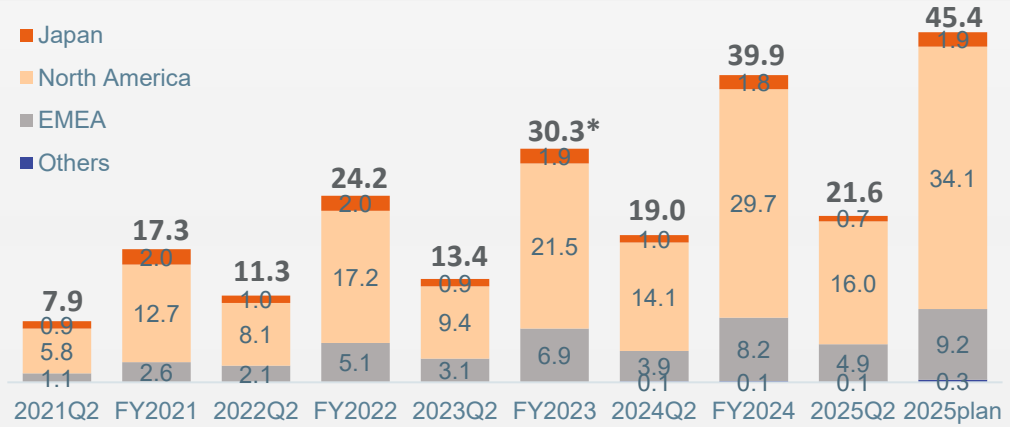
2025 Key Actions

- 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.

YTD Topics up to Q2

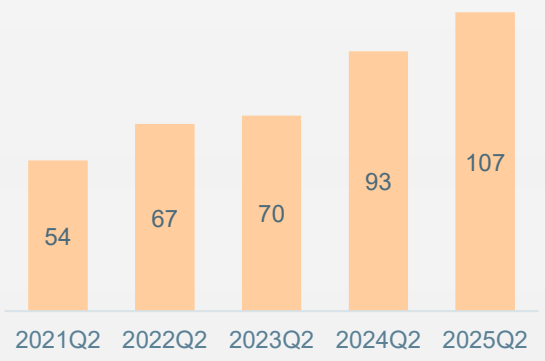
- Global; YTD Sales rev. YoY +14%, annual plan progress rate 48% (typical for Q2 level).
- NA : YTD Sales rev. YoY, in Yen +13%, in local currency +15%
  - The strengthened sales organization, further development in promotional activities leveraging ML & AI based technology, and robust actual demand contributed to a YoY increase in sales in local currency.
- EMEA : YTD Sales rev. YoY, in Yen +23%, in local currency +22%
  - Growth continues through expanding use in both early and late-stage patients and enhancing the identification of eligible patients for treatment initiation.

Sales Revenue (Billion Yen)

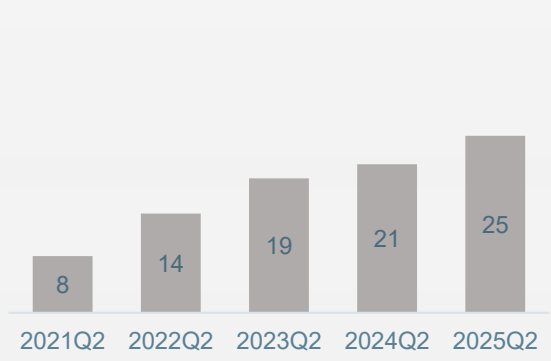


*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

YTD North America Sales ($M)



YTD EMEA Sales (£M)



R&D Update

News Flow of Development Pipeline Products

As of July 31st , 2025

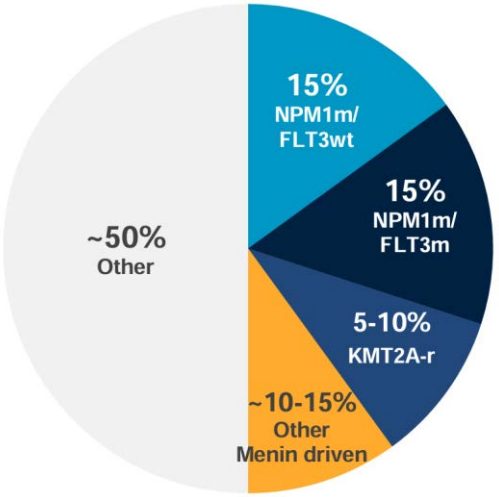
New information highlighted in orange

Products	Diseases under development	Events	Status/Schedule
rocatinlimab KHK4083/AMG 451	Moderate to severe atopic dermatitis	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 data presented at ASCO US NDA (Priority Review, PDUFA date: November 30, 2025)	June 2025
	AML (1L combo)	KOMET-007 P1b (Dose expansion) presented at EHA	June 2025
		KOMET-017 (P3) initiation anticipated	H2 2025
OTL-203	MPS-IH (Hurler Syndrome)	Registrational study (Equivalent to P3 study) – The last patient has been treated	July 2025
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	In progress

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 22,000 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]



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Development status

- FDA accepted New Drug Application for adults with relapsed/refractory NPM1-mutant AML　Press release issued on June 2, 2025
  - Granted Priority Review, PDUFA date: November 30, 2025
- Phase 2 KOMET-001 (2L+, monotherapy): Results presented at ASCO 2025　Details to be introduced shortly
- Phase 1 KOMET-007 (1L, combination): Presented at 30th EHA Congress　Details to be introduced shortly
- Phase 3 KOMET-017 (1L, combination): Planned initiation in H2 2025

1. National Cancer Institute. Accessed May 25, 2025. https://seer.cancer.gov/statfacts/html/amyl.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

KURA AND KYOWA KIRIN ARE INVESTIGATING ZIFTOMENIB ACROSS THE AML CONTINUUM IN UP TO 50% OF PATIENTS

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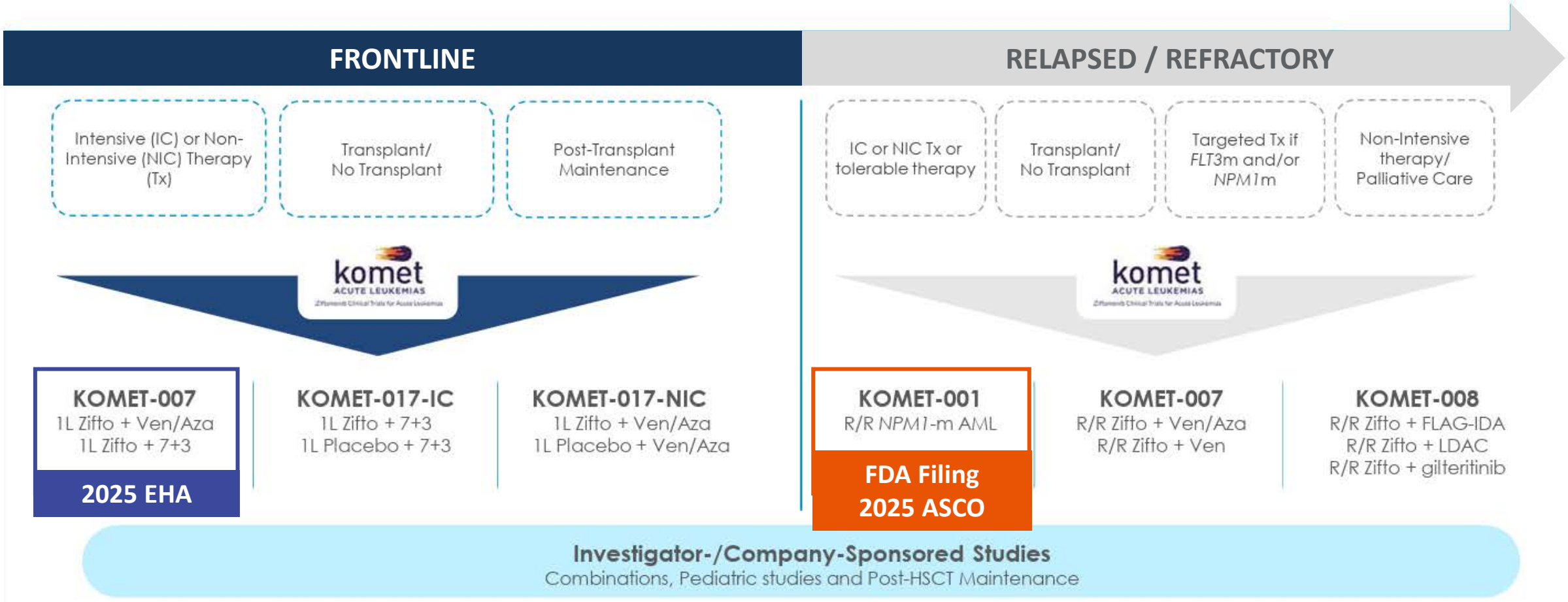

2025 ASCO

KOMET-001: RESPONSE & DURATION OF RESPONSE: R/R NPM1-m AML

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n (%)	Ziftomenib RP2D 600 mg QD Phase 2 (N=92)	Ziftomenib RP2D 600 mg QD Pooled Phase 1b/2 (N=112)
CR/CRh	**21 (23)**	**28 (25)**
Overall Response	**30 (33)**	**39 (35)**
CR	13 (14)	20 (18)
CRh	8 (9)	8 (7)
CRi/CRp	3 (3)	4 (4)
MLFS	5 (5)	6 (5)
PR	1 (1)	1 (1)
Other[a]	62 (67)	73 (65)
Median Duration of Response, months (95% CI)		
CR/CRh	3.7 (1.9–NE)	3.7 (1.9–7.7)
CRc	4.6 (2.8–11.4)	5.1 (2.8–8.1)
ORR	4.6 (2.8–11.4)	4.6 (3.6–7.7)
Restricted Mean Duration of Response[b], months (95% CI)		
CR/CRh	4.3 (3.1–5.6)	5.2 (3.6–6.7)
CRc	5.9 (4.0–7.7)	6.4 (4.6–8.1)
ORR	5.9 (4.4–7.5)	6.5 (4.9–8.1)
MRD negativity, n/N[c] (%)	**12/19 (63)**	**17/26 (65)**

Primary Phase 2 endpoint met (P value=0.0058)* vs. 12% historical control rate [1]

For Phase 2 patients, after a median follow up of 4.1 months (range, 0.1 19.7):

- Median time to CR/ CRh : 2.8 months (range, 1.0 - 15.0)
- Median time to ORR: 1.9 months (range, 0.8 - 3.7)

* Based on primary analysis data cut (Oct 28, 2024). [a] Stable disease/no response/clinical benefit/progressive disease/not evaluable. [b] Defined as the expected duration of response (area under the Kaplan Meier curve, up to the time point when 10% of patients remain at risk). [c] Among CR/ CRh responders evaluated for MRD (centrally tested).

Data cutoff: Dec 20, 2024.

1. Smith CC *et al. Blood Adv*. 2022;6(7):2144-55. CR, complete remission; CRc, composite complete remission; CRh, complete remission with partial hematologic recovery; CRi, CR with incomplete hematologic recovery; CRp, CR with incomplete platelet recovery; MLFS, morphologic leukemia free state; MRD, measurable residual disease; ORR, overall response rate; PR, partial response; QD, once daily; RP2D, recommended phase 2 dose.

2025 ASCO

KOMET-001: SAFETY & TOLERABILITY OF ZIFTOMENIB IN R/R NPM1-m AML (SAFETY POPULATION)

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Ziftomenib-related AEs in ≥5% of All Patients

	Ziftomenib RP2D 600 mg QD			
	Phase 2 (N=92)		Pooled Phase 1b/2 (N=112)	
Event, n (%)	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any ziftomenib-related AE	64 (70)	37 (40)	77 (69)	45 (40)
Hematologic AEs				
Anemia	5 (5)	5 (5)	6 (5)	6 (5)
Neutropenia	6 (7)	6 (7)	6 (5)	6 (5)
Nonhematologic AEs				
Differentiation syndrome	**22 (24)**	**14 (15)[a]**	**26 (23)**	**15 (13)[a]**
Pruritus	15 (16)	0	16 (14)	0
Nausea	8 (9)	0	13 (12)	0
Diarrhea	8 (9)	0	10 (9)	2 (2)
Alanine aminotransferase increased	6 (7)	2 (2)	7 (6)	2 (2)
Decreased appetite	5 (5)	0	6 (5)	0

Ziftomenib was well tolerated, with a safety profile consistent with previous studies, [1,2] including:

- Low rates of ziftomenib related myelosuppression
- No clinically significant QTc prolongation:
  - 3 (3%)* patients: 1 Gr2, 2 Gr3 (all investigator assessed)
- Differentiation syndrome: 15 (13%) Gr3; no Gr4-5 events
- 3% discontinuations due to ziftomenib related AEs

a No patients had Grade 4-5 differentiation syndrome.
*All 3 patients were on additional medications associated with QTc prolongation: 2 patients had electrolyte abnormalities and 1 patient had prior diagnosis of atrial fibrillation.

Data cutoff: Dec 20, 2024.

1. Wang ES *et al*. *Lancet Oncol* 2024; 25(10):1310-24. 2. Fathi AT et al. *Blood*. 2024;144(Suppl_1):2880. AE, adverse event; QD, once daily; QTc, corrected QT interval; RP2D, recommended phase 2 dose.

2025 ASCO

KOMET-001: CONCLUSIONS

https://ir.kuraoncology.com/static-files/efd05295-b2dc-4db9-94a9-6e6c778a596e

- **In the pivotal KOMET-001 phase 2 study, the primary endpoint was met**
  - Ziftomenib achieved clinically meaningful, MRD negative responses in this heavily pretreated R/R NPM1 m AML population
  - Similar response rates were seen, regardless of prior therapies, including HSCT and venetoclax
- **Ziftomenib monotherapy was well tolerated with a safety profile consistent with previous studies**
  - Low rates of ziftomenib related myelosuppression
  - 3% ziftomenib related discontinuations
  - No clinically significant QTc prolongation
  - Differentiation syndrome was managed with protocol specified mitigation strategies; no Grade 4-5 DS events
- **NDA submitted for ziftomenib monotherapy as a new potential treatment option for adult patients with R/R NPM1 m AML**
- **Ziftomenib combination studies are currently ongoing in both newly diagnosed and R/R AML** (KOMET-007 , KOMET-008)

KOMET-007: SAFETY AND TOLERABILITY OF ZIFTOMENIB IN COMBINATION WITH 7+3 in 1L AML (N=82)

https://ir.kuraoncology.com/static-files/3b737096-e139-4235-a5b8-a896d10b41be

Grade ≥3 TEAEs in ≥10% of All Patients

n (%)	*NPM1*-m 600 mg (n=49)	*KMT2A*-r 600 mg (n=33)	All Patients 600 mg (N=82)
Grade ≥3	**42 (86)**	**29 (88)**	**71 (87)**
Febrile neutropenia	25 (51)	20 (61)	45 (55)
Platelet count decreased	23 (47)	12 (36)	35 (43)
Anemia	16 (33)	8 (24)	24 (29)
Neutrophil count decreased	14 (29)	6 (18)	20 (24)
White blood cell count decreased	10 (20)	7 (21)	17 (21)
Sepsis	8 (16)	5 (15)	13 (16)
Lymphocyte count decreased	5 (10)	4 (12)	9 (11)

Grade ≥3 Ziftomenib-related Adverse Events of Interest

29 Patients (35%) had Grade ≥3 ziftomenib-related adverse events:

- Most common (≥10%) were febrile neutropenia (15%), decreased platelet count (15%), anemia (11%), and decreased neutrophil count (11%)
- 1 case of differentiation syndrome (*KMT2A*-r, Gr3), which was successfully managed
- 2 cases of investigator-assessed QTc prolongation (both *KMT2A*-r, Gr3)*

*Both patients were on other medications (posaconazole and/or piperacillin/tazobactam) at time of QT assessment. Data cutoff: Mar 21, 2025. QTc, QT corrected; TEAE, treatment-emergent adverse event.

KOMET-007: CLINICAL ACTIVITY IN ALL RESPONSE-EVALUABLE[a] 1L PATIENTS (N=71)

https://ir.kuraoncology.com/static-files/3b737096-e139-4235-a5b8-a896d10b41be

n (%)	*NPM1*-m 600 mg (n=44)	*KMT2A*-r 600 mg (n=27)	All Patients 600 mg (N=71)
CRc	**41 (93)**	**24 (89)**	**65 (92)**
ORR	**43 (98)**	**24 (89)**	**67 (94)**
CR	37 (84)	20 (74)	57 (80)
CRh	1 (2)	0	1 (1)
CRi	3 (7)	4 (15)	7 (10)
MLFS	2 (5)	0	2 (3)
PR	0	0	0
NR	1 (2)	2 (7)	3 (4)
NE	0	1 (4)	1 (1)
CR MRD-negativity, n/N (%)[b]	**24/34 (71)**	**14/16 (88)**	**38/50 (76)**
CRc MRD-negativity, n/N (%)[b]	**26/38 (68)**	**15/18 (83)**	**41/56 (73)**
Median time to CR MRD-negativity, weeks (range)	4.7 (2–17)	4.4 (3–12)	4.5 (2–17)
Median time to CRc MRD-negativity, weeks (range)	4.7 (2–17)	4.1 (3–12)	4.3 (2–17)

[a] Patients who had ≥1 response assessment or who had died.

[b] Among evaluable responders tested for MRD per local assay (NGS, RT-qPCR, FISH, flow cytometry). **Preliminary central testing also shows concordance with local MRD-negative rates.**

Data cutoff: Mar 21, 2025.

Per ELN 2022: CR / CRh/ CRi, complete remission with full / partial / incomplete hematologic recovery; CRc, composite complete remission; FISH, fluorescence in situ hybridization; MLFS, morphologic leukemia-free state; MRD, measurable residual disease; NE, not evaluable; NGS, next-generation sequencing; NR, no response; ORR, objective response rate; PR, partial remission; RT-qPCR, quantitative reverse transcription polymerase chain reaction.

KOMET-007: CONCLUSIONS

https://ir.kuraoncology.com/static-files/3b737096-e139-4235-a5b8-a896d10b41be

- **In the ongoing KOMET-007 study, ziftomenib 600 mg QD combined with 7+3 was well tolerated, with a safety profile consistent with previous reports**
  - Low rates of ziftomenib-related cytopenia and no additional myelosuppression observed with the combination
    - Ziftomenib 600 mg QD did not delay neutrophil and platelet count recovery
  - 1 case of Gr3 differentiation syndrome (*KMT2A*-r), which was successfully managed
- **Robust clinical activity with deep responses was demonstrated in newly diagnosed *NPM1*-m and *KMT2A*-r AML**
  - CRc: 93% for *NPM1*-m, 89% for *KMT2A*-r patients
    - CRc MRD negativity: 68% for *NPM1*-m at median of 4.7 weeks, 83% for *KMT2A*-r at median of 4.1 weeks
  - 96% (47/49) of *NPM1*-m and 88% (29/33) *KMT2A*-r patients remained alive and continued on-study (median follow-up of 25 and 16 weeks, respectively)
- **Taken together, we believe these data support the Phase 3 advancement of ziftomenib combination in newly diagnosed *NPM1*-m and *KMT2A*-r AML (KOMET-017)**

Study Design of P3 studies for AML: KOMET-017

https://ir.kuraoncology.com/static-files/3b737096-e139-4235-a5b8-a896d10b41be

Two independently powered, registration-enabling, randomized Phase 3 studies in fit and unfit newly diagnosed AML

KOMET-017-NIC: Non-intensive therapy – Ziftomenib + ven/aza combo

Patients
- *NPM1*-m AML
- Age ≥75 yrs, or 18 to <75 yrs with comorbidities

R 1:1

- Arm A: Ziftomenib + Venetoclax + Azacitidine
- Arm B: Placebo + Venetoclax + Azacitidine

Primary endpoints
- CR
- OS

KOMET-017-IC: Intensive therapy – Ziftomenib and 7+3 combo

Patients
- *NPM1*-m or *KMT2A*-r AML[a]
- *FLT3* wildtype or ITD ratio of <0.05[b]
- Age ≥18 yrs
- ECOG PS 0–2

R 1:1:1

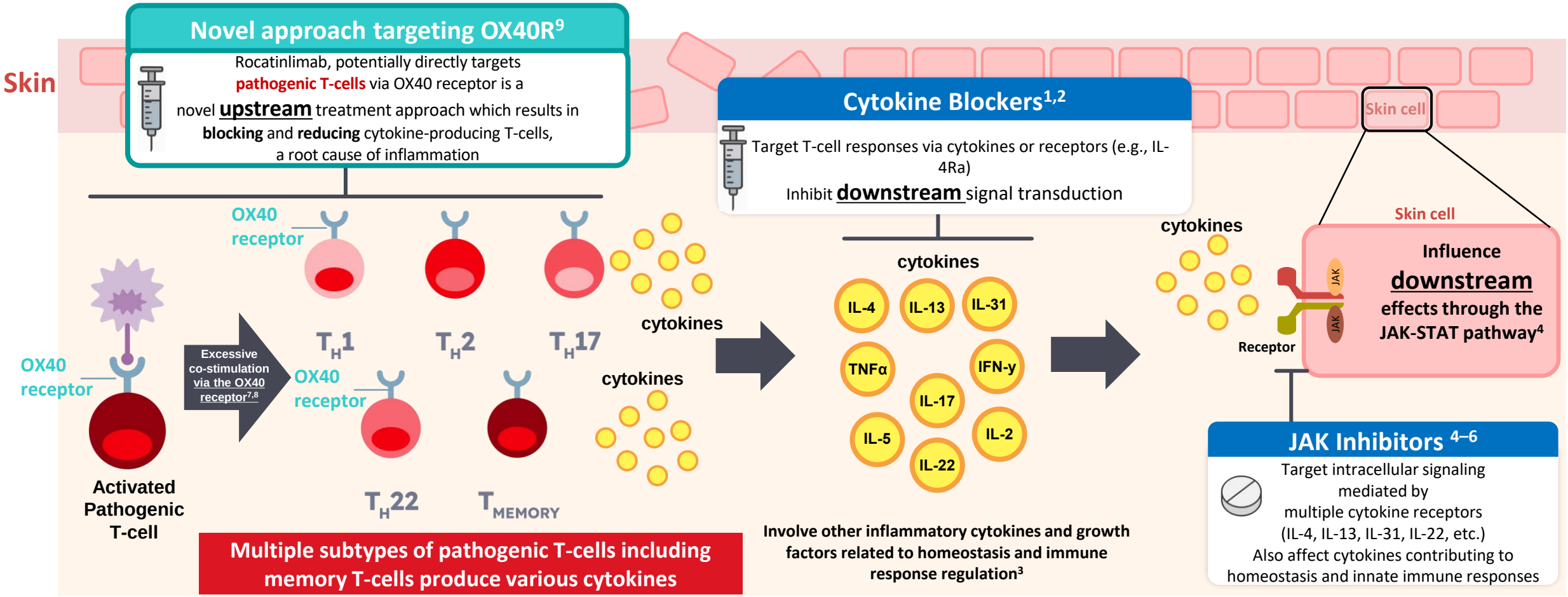
- Arm A: Ziftomenib → 7+3 Induction(s) → Consolidation
- Arm B: Ziftomenib + Placebo → 7+3 Induction(s) → Consolidation
- Arm C: Placebo → 7+3 Induction(s) → Consolidation

Primary endpoints
- CR MRD-negativity (*NPM1*-m only)
- EFS

[a]Excluding partial tandem duplication. [b]Unless ineligible for *FLT3*-targeted therapy.

Aim to deliver new therapeutic options for a wide range of AML patients

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



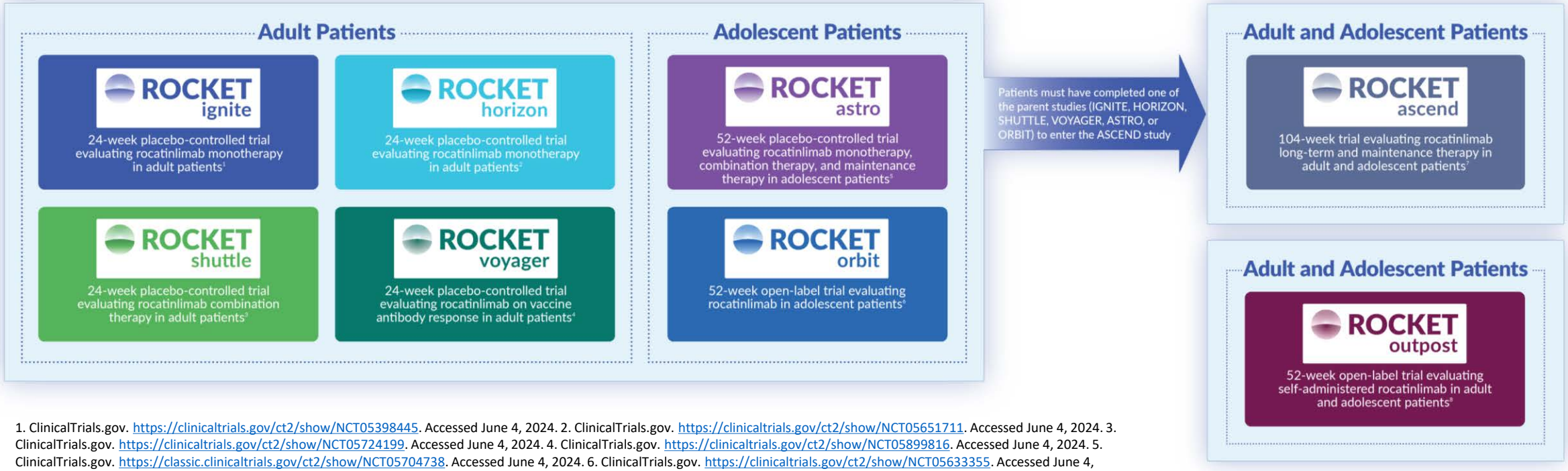
AD, atopic dermatitis; IFN-γ, interferon gamma; IL, interleukin; IL-4Ra, interleukin 4 receptor alpha; JAK, Janus kinase; JAK-STAT, Janus kinase-signal transducer and activator of transcription; TH, T helper cell; TNFα, tumor necrosis factor alpha.

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.

Rocatinlimab – Phase 3 the ROCKET Program

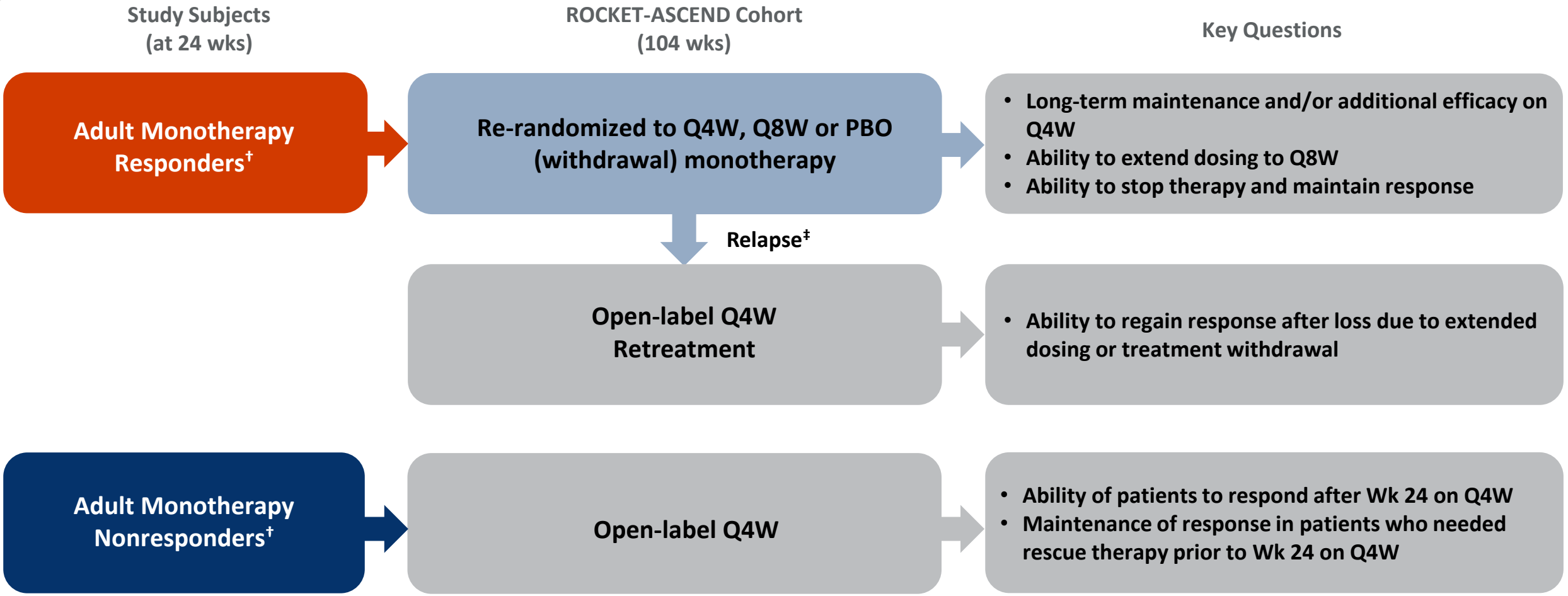
- Composed of eight global studies enrolling adult and adolescent moderate – severe AD patients
- To date, over 3,300 patients have been enrolled with seven studies having completed enrollment
- Studies were designed to examine long-term sustained efficacy and safety



1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05398445. Accessed June 4, 2024. 2. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05651711. Accessed June 4, 2024. 3. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05724199. Accessed June 4, 2024. 4. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05899816. Accessed June 4, 2024. 5. ClinicalTrials.gov. https://classic.clinicaltrials.gov/ct2/show/NCT05704738. Accessed June 4, 2024. 6. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05633355. Accessed June 4, 2024. 7. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05882877. Accessed June 4, 2024. 8. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06224192. Accessed June 4, 2024.

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 and Q8W extension (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. Immunotherapy. 2025;17(2):83-94.

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

News Flow in 2025

Year-to-date Key News Flow

As of July. 31st, 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
MGMT	May 7	Introduction of Special Voluntary Early Retirement Program (Japan)
		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

Year-to-date Key News Flow

As of July. 31st, 2025

Category	Date	Headline
R&D	May 15	New England Journal of Medicine publicities long-term clinical outcomes from its HSC Gene Therapy Orchard presents six accepted abstracts at ASGCT 2025 detail the therapeutic potential of HSC gene therapy to address severe multi-system disease
R&D	Jun 2	Acceptance and priority review of new drug application for Ziftomenib in adults with relapsed or refractory NPM1-Mutant AML by FDA
R&D	Jun 3	Reported positive pivotal Ziftomenib monotherapy data at 2025 ASCO Annual Meeting
R&D	Jun 12	Reported positive updated combination data for Ziftomenib in newly diagnosed AML at 2025 European Hematology Association（EHA) Congress
LCM	Jun 25	Approval for prefilled syringe formulation of Crysvita (Japan)
LCM	Jun 26	Approval for additional formulation of “LUMICEF® Subcutaneous Injection 210 mg Pen” (Japan)
R&D	Jul 29	Presented the results of the Phase 3 ROCKET-Ignite trial of rocatinlimab in adult patients with moderate to severe atopic dermatitis at the European Academy of Dermatology and Venereology (EADV) 2025 Annual Meeting
		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

Special Voluntary Early Retirement Program

Purpose and overview of the program

At the turning point for realization of Kyowa Kirin's vision for 2030, we aim to broaden the career development options of our employees and to provide maximum support for those who wish to move outside the company.

◎Increasing challenges facing pharmaceutical companies worldwide
◎Response to the issues related to the sustainability of the healthcare system with the ongoing decline in population and the rapid aging society in Japan.

◎Promotion of transformation aligned with the announced Story for Vision 2030 to ensure the realization of the 2030 Vision
★Boldly changing our business foundation in Japan into a more sustainable form
★ Further strengthen our organizational capabilities

【Overview】
(1) Eligibility：Employees who are at least 40 years old and have been with the company for at least three years.
*However, organizations subject to the special voluntary retirement program introduced in 2024 and certain other organizations are excluded.
(2) Number of applicants：Not specified
(3) Application period ：May 22, 2025 - June 24, 2025
(4) Date of retirement：September 30, 2025
(5) Incentives：A severance benefit premium will be paid in addition to the ordinary severance benefit. Also, outplacement assistance will be provided to those requesting it.

Result of the program

Number of Special Voluntary Retirees: 432

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 July 31st , 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 (2L+)	2025 (Mono)	P2 (US, EU)	★★★★	20K
		First Line (1L)	TBD	P1 (US)		
KHK4951 tivozanib eyedrop	nAMD		TBD	P2 (JP, US)	★★★★	3810K
	DME		TBD	P2 (JP, US)	★★★★	3470K
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 July 31st , 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 July 31st , 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	Topline data Mar. 2025			
		HORIZON		Detailed data presentation Mar. 2025			
		SHUTTLE		Topline data Mar. 2025			
		ASTRO		H2 '25 Topline data			
		ORBIT					
		VOYAGER		Topline data Mar. 2025			
		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 July 31st , 2025

Products	Target	Development Status		2025	2026	2027	+
ziftomenib	AML	KOMET-001 2L+ Mono	P2[1] (NPM1-m)	Detailed data presentation June 2025 US NDA (Priority Review, PDUFA date: November 30, 2025)			
	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
Kura Oncology is the sponsor of the trials presented here. The bars correspond to timelines on clinicaltrials.gov

Main Development Pipeline Products: Future plans

As of July 31st , 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**				
KK8123	XLH	**P1**				
KK3910	Essential Hypertension	**P1**				

The bars correspond to timelines on clinicaltrials.gov

FOREX Information

Average FOREX Rates (yen)

	2024 Jan-Jun	2025 Jan-Jun	Changes	2025 Plans
USD	151	150	-1	145
GBP	191	193	+2	190
EUR	163	162	-1	160

2025Q2 FOREX Impacts (billion yen)

	Revenue	Core OP
USD	-1.3	-1.0
GBP	+0.1	-0.1
EUR	-0.1	-0.0

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 • 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.
AML	JP US		7,000 22,000	Ministry of Health, Labour and Welfare: 2020 Patient survey (illness classification) National Cancer Institute. Cancer Stat Facts: Leukemia

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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