Kyowa Kirin Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending December 2025

August 1, 2025

Event Summary

[Event Name]	Q2 Financial Results Briefing for the Fiscal Year Ending December 2025	
[Date]	August 1, 2025	
[Number of Speakers]	4	
	Masashi Miyamoto	Representative Director, Chairman and Chief Executive Officer
	Abdul Mullick	Representative Director, President & Chief Operating Officer
	Takeyoshi Yamashita	Director, Executive Vice President & CMO
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer

Presentation

Moderator: Thank you for joining us today for the online presentation of financial results for Q2 of the fiscal year ending December 31, 2025, for Kyowa Kirin Co., Ltd.

Please note the following prior to the start of the presentation. We will keep the names and company names of all participants for a certain period of time as a participant list. Please understand this in advance.

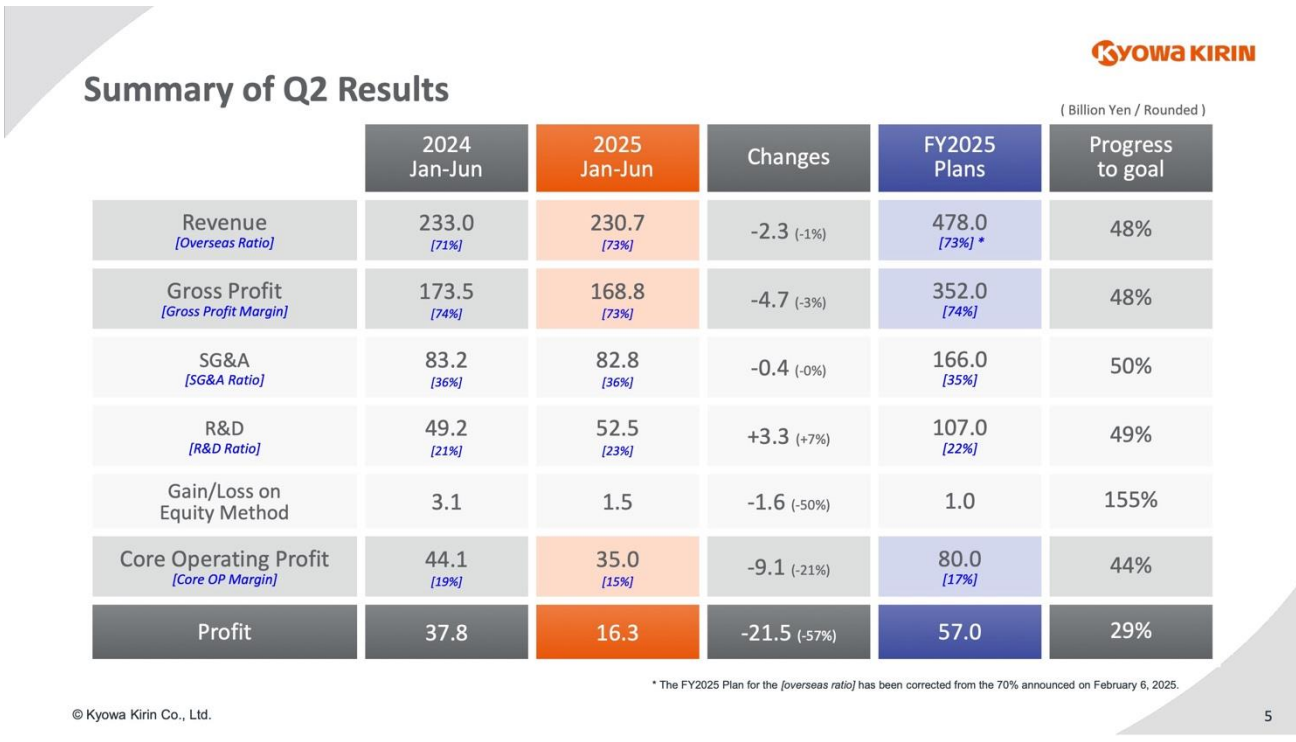
Please also note that the content of this presentation will be available on demand and as a transcript on our website, and we ask for your kind understanding of that as well.

The information presented today contains forward-looking statements. Please note that there is uncertainty due to various risks.

Today's speakers and Q&A sessions will include the following four speakers. They are Masashi Miyamoto, Representative Director, Chairman and Chief Executive Officer; Abdul Mullick, Representative Director, President & Chief Operating Officer; Takeyoshi Yamashita, Director, Executive Vice President & CMO; and Motohiko Kawaguchi, Managing Executive Officer and Chief Financial Officer.

Today's online meeting will last up to 90 minutes. First, we will explain our overall financial results and then take your questions. Please download the documents from our IR website.

Let me begin with an overview of the financial results.



Miyamoto: Good morning, everyone. Thank you for your participation. I am Miyamoto from Kyowa Kirin. Since we don’t have much time, I would like to begin the explanation immediately.

Performance summary. This is described as compared to the same period of the previous year. Revenue was JPY230.7 billion, a decrease of JPY2.3 billion, or 1%, core operating profit was JPY35 billion, a decrease of JPY9.1 billion, or 21%, and profit was JPY16.3 billion, a decrease of JPY21.5 billion, or 57%.

Revenue decreased by 1% due to the impact of last year's business restructuring in the APAC region and the NHI price-cut in Japan, despite the growth of global strategic products mainly in North America and EMEA.

Core operating profit decreased 21%, mainly due to a decrease in gross profit and a 7%, or JPY3.3 billion, increase in R&D expenses.

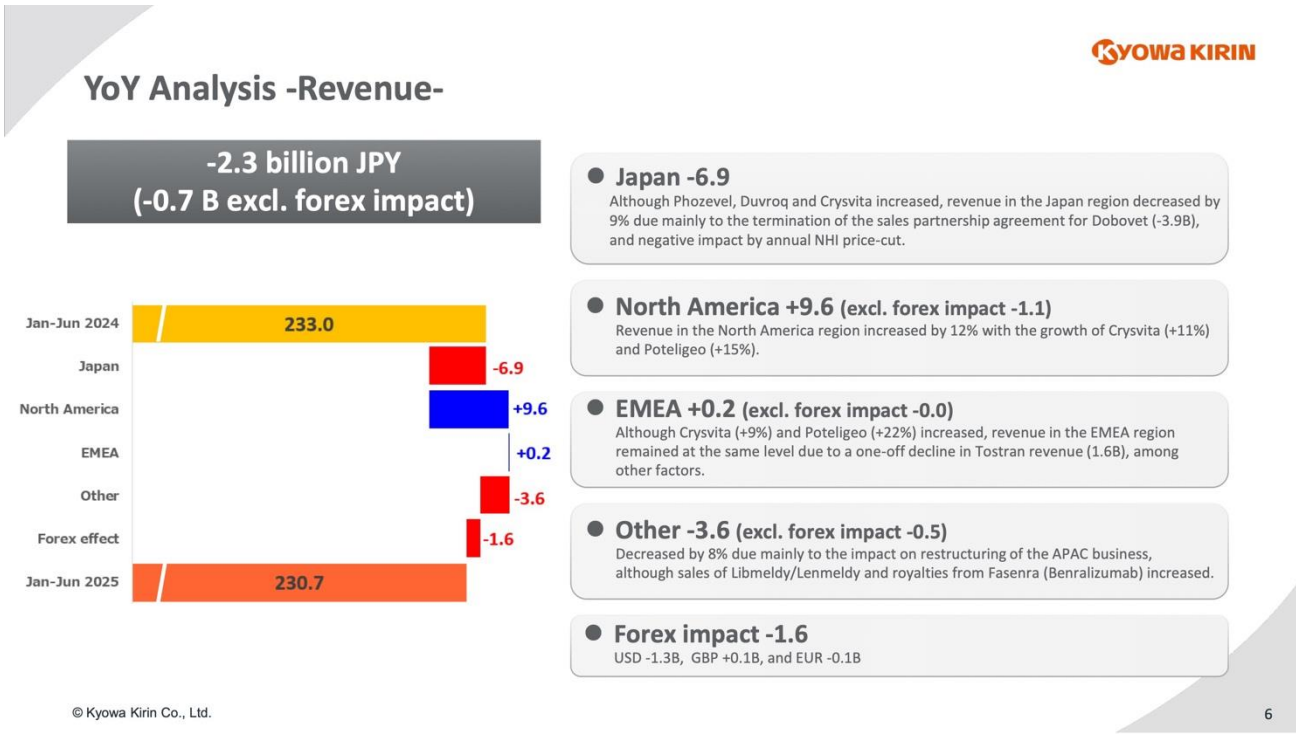
Profit decreased by 57% due to the impact of JPY9.4 billion in severance pay related to the introduction of the special voluntary early retirement program in Japan, which was announced in May.

As a percentage of the full-year forecast, revenue and gross profit are 48% and 48%, respectively, but since these tend to increase toward the latter half of the fiscal year as in past years, we consider progress to be in line with the plan.

Selling, general and administrative expenses and research and development expenses are also moving mostly in line with the plan. As a result of these factors, core operating profit has progressed 44%, which we believe is also in line with our plan.

On the other hand, the profit progress rate is 29%. As I explained earlier, we had factored in a certain amount of extra retirement payments related to the introduction of a special voluntary early retirement program in Japan in the third section, but this was a bit larger than the amount we had factored in.

As I have explained, the basic business is moving strongly almost as planned, and we will aim to achieve the full-year plan in line with the target set at the beginning of the year.



Here is a YoY analysis of revenue by region. This slide uses a format that explains the real increase or decrease excluding forex impact.

In Japan, Phozevel, Duvroq and Crysvita continue to grow. On the other hand, sales of Dobovet, for which the marketing agreement was terminated last December, declined by JPY3.9 billion, and the NHI price-cut in April last year and this April this year had a negative impact, resulting in a 9% decline in sales for the Japan Region.

In North America, sales increased JPY9.6 billion, or 12%, in real terms excluding forex impact. Crysvita and Poteligeo continue to grow strongly, 11% and 15% respectively in local currency terms.

For EMEA, sales increased JPY0.2 billion in real terms. Crysvita and Poteligeo grew 9% and 22%, respectively, but the EMEA region as a whole grew only slightly from the previous year due to one-time revenues related to the Tostran sale last year and lower royalty income from the sale of three Established Pharmaceuticals brands.

Other includes sales of established pharmaceuticals and other products in the region, which until last year had been described separately as APAC. In addition to an increase in royalties from Fasenra, sales of Libmeldy/Lenmeldy, a hematopoietic stem cell gene therapy, began to be booked in the US and increased significantly, but sales declined 8% due to a JPY6.5 billion decline in sales resulting from the restructuring of the APAC region.

The total forex impact on revenue is negative JPY1.6 billion.

Revenue of Major Items

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(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%)		210.2	47%
	JP	5.4	6.1	+0.7 (+13%)		13.1	47%
	NA	58.7	64.0	+5.3 (+9%)	Market penetration		
	EMEA	25.4	28.0	+2.5 (+10%)		197.1	48%
	Other	1.3	1.7	+0.4 (+28%)			
Poteligeo		19.0	21.6	+2.6 (+14%)		45.4	48%
	JP	1.0	0.7	-0.3 (-28%)		1.9	37%
	NA	14.1	16.0	+1.9 (+13%)	Market penetration	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%)			
	US	-	1.6	+1.6 (- %)	Market penetration (FDA approval in Mar 2024)	6.9	64%
	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.

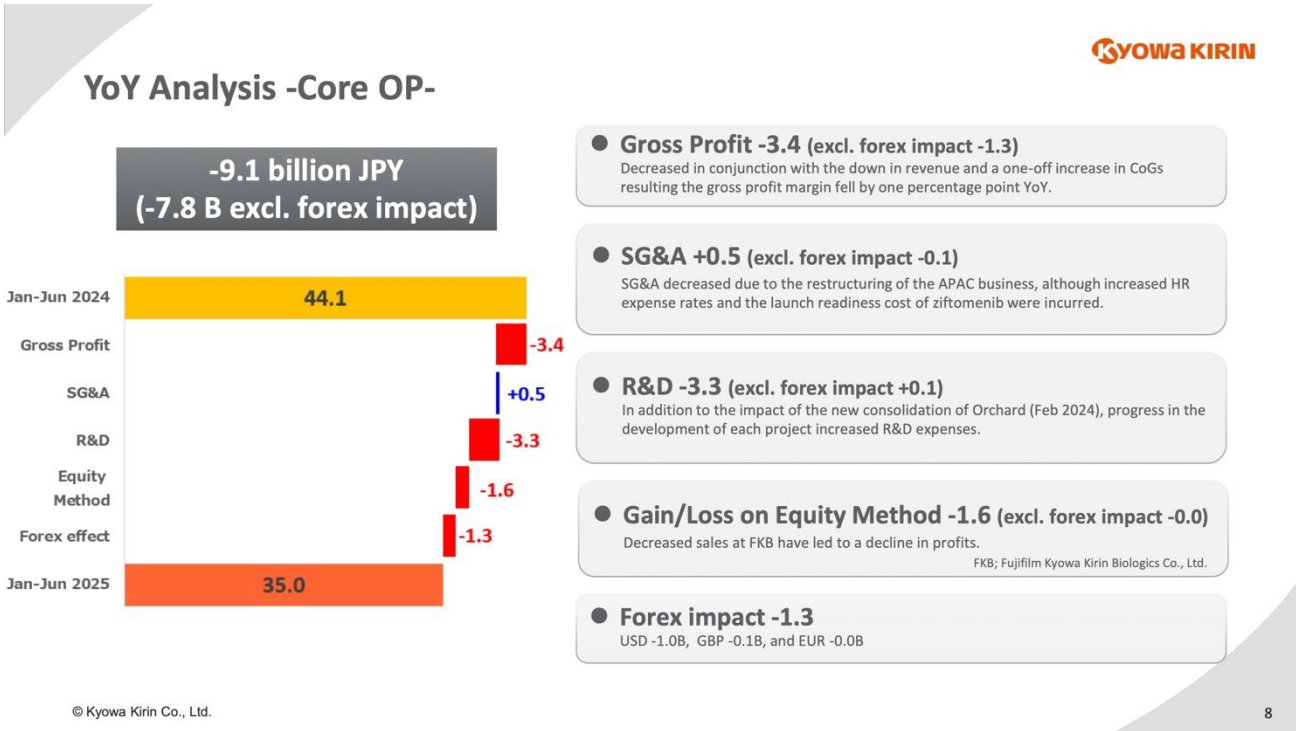
Here is the situation by major product. This page includes forex impact.

Crysvita continues to grow throughout North America, EMEA, and Japan, with revenues up 10%, or JPY8.9 billion YoY. Poteligeo also continued to grow in North America and EMEA, increasing its sales by JPY2.6 billion or 14% over the previous year.

Libmeldy/Lenmeldy is solid in Europe and has recorded sales for 3 patients in the US this year, a significant increase of JPY3 billion or 206%.

Phozevel has continued to steadily penetrate the market since its launch in February 2024, with sales up JPY2 billion, or 119%, from the previous year. G-Lasta sales decreased by JPY1.4 billion, or 13%, due to the impact of the NHI price-cut and competing products.

Technology revenues increased by JPY1.2 billion, or 5%, from the previous year due to higher royalties from Fasenra.



This is a YoY analysis of core operating profit. This form is also designed to explain the real increase/decrease excluding forex impact.

Gross profit was down JPY3.4 billion due to a 1 percentage point decline in gross margin from last year, reflecting the impact of one-time costs in cost of sales, in addition to the decline in revenue.

Selling, general and administrative expenses decreased by JPY0.5 billion in total due to a decrease resulting from the reorganization of the APAC business, despite new expenses incurred this year, such as preparation costs for the launch of Ziftomenib.

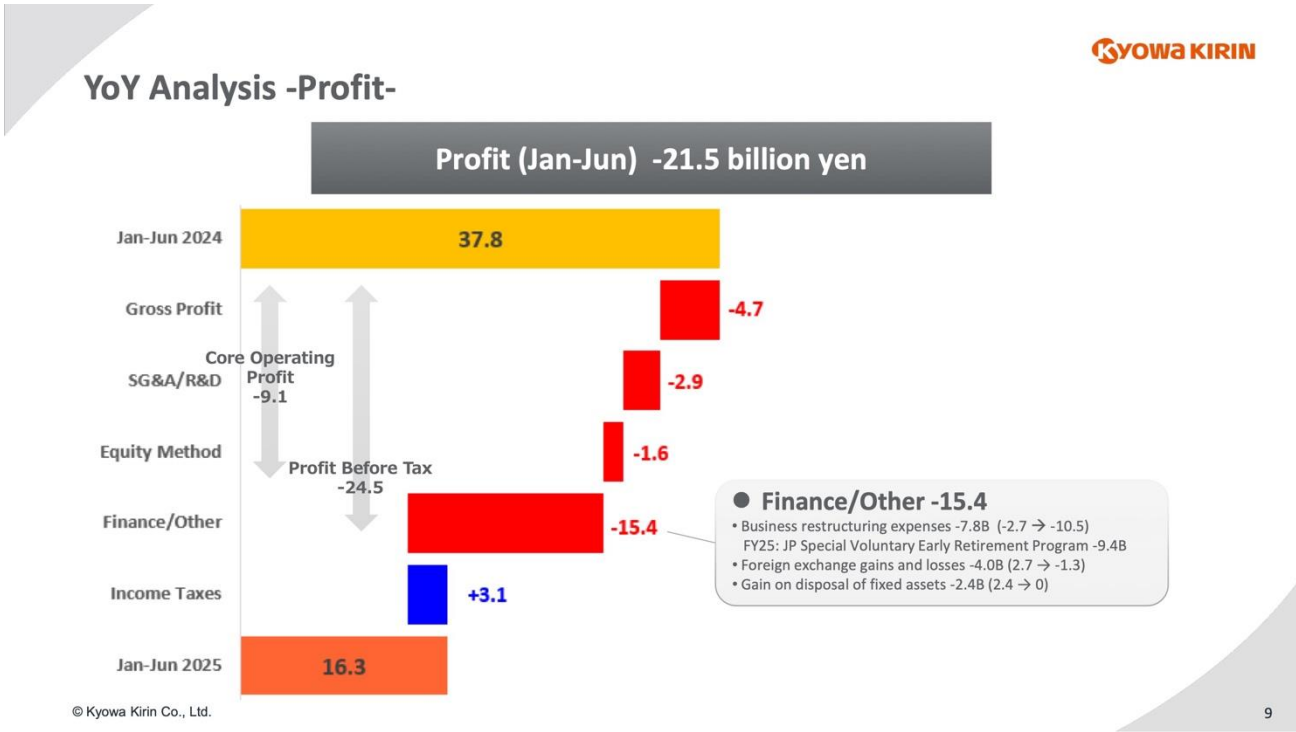
Research and development expenses increased by JPY3.3 billion. As for R&D project costs, we have changed to activity-based costing estimates starting this year, and although the rate of progress has been higher than in previous years, we believe that the overall progress is in line with our plan.

The same is true for SG&A expenses, but the one-month effect of the new consolidation of Orchard was also a factor in the YoY increase.

Gain on equity method decreased from JPY3.1 billion last year to JPY1.5 billion, mainly due to lower sales at Fujifilm Kyowa Kirin Biologics.

The forex impact on core operating profit is negative JPY1.3 billion.

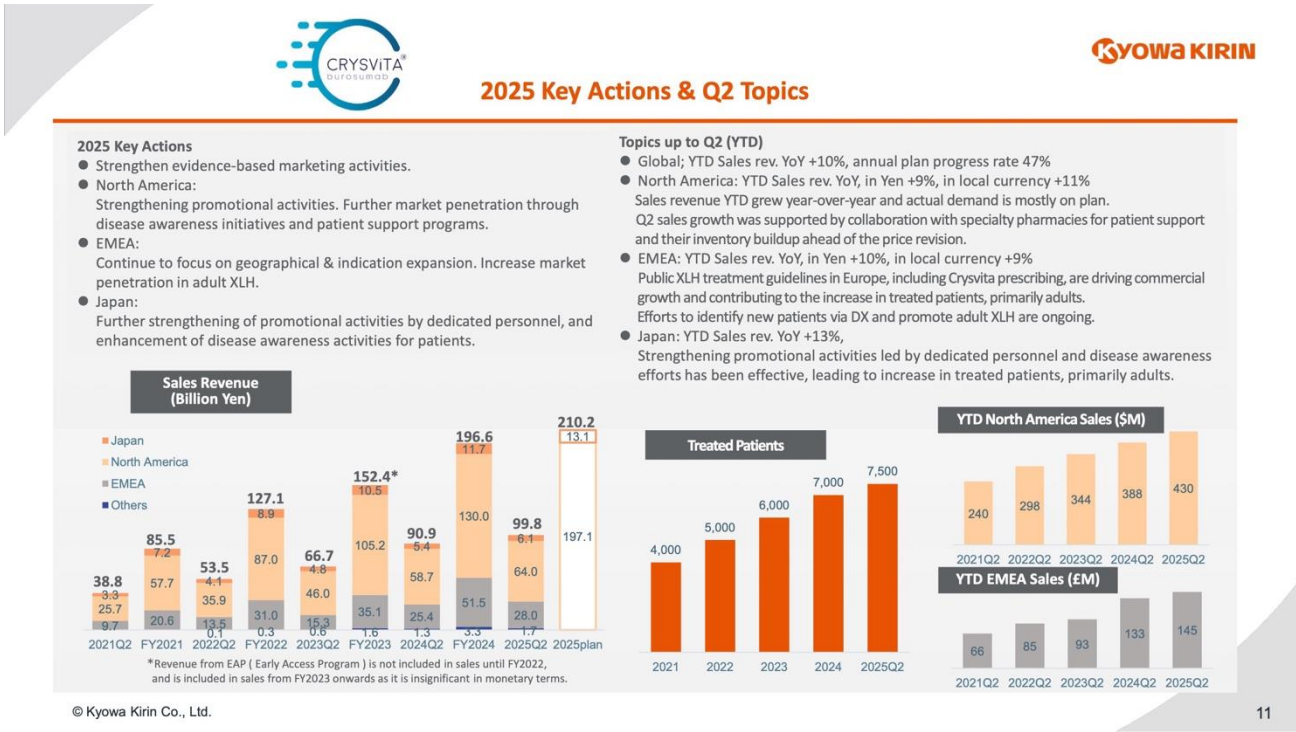
As a result of the above, core operating profit decreased by JPY9.1 billion compared with the same period of the previous year.



Core operating profit and the items below. Sorry for the lack of clarity, but this slide shows the increase/decrease including forex impact as before.

Finance/other decreased by JPY15.4 billion. The main reason for the YoY decrease was the impact of the introduction of a special voluntary early retirement program in Japan announced in May, which resulted in a total of JPY9.4 billion in severance pay and outplacement expenses, as well as a JPY4 billion negative forex impact compared to the previous year.

As a result of the above, profit decreased by JPY21.5 billion compared to the same period last year.



Next, we will discuss commercial updates.

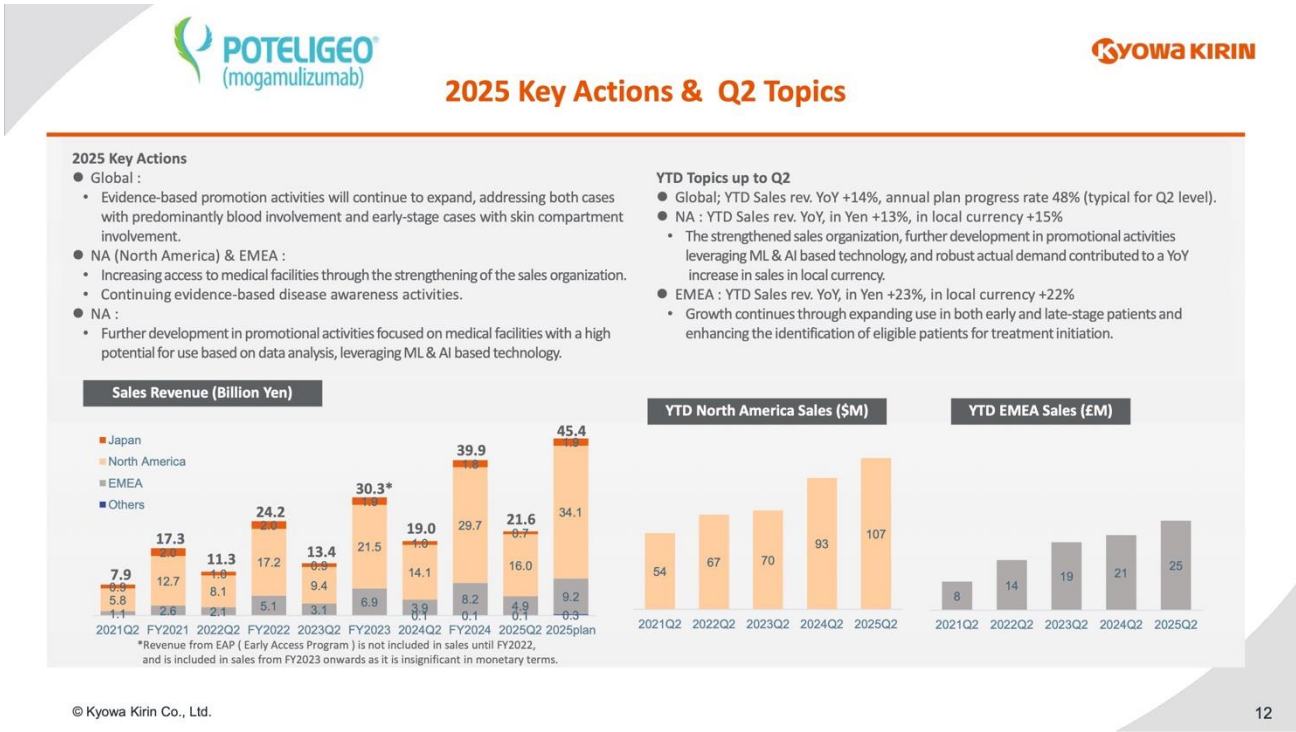
Crysvita. The Company's global sales for H1 of the fiscal year increased by 10% YoY to JPY99.8 billion, with a progress rate of 47% of the annual plan, which is a slightly higher rate of progress than in past years.

In North America, sales continued to grow steadily, generally in line with expectations. There are many barriers for patients before starting treatment and continuing treatment, and we are continuing to increase treatment penetration among patients and promote continuity of treatment through efforts aligned with the strategy, including activities to identify and support these barriers.

In addition, Specialty Pharmacy's inventory buildup in June in anticipation of the July price revision resulted in an 11% sales growth in local currency terms over the same period last year.

In EMEA, the growth is also continuing, with official guidelines for XLH treatment in Europe, including the Crysvita formulation, providing a boost to disease awareness and commercial activities, resulting in a nearly 30% increase in the number of patients treated, especially adult patients, compared to the same period last year.

In Japan, the activities and structure of our dedicated bone metabolism field staff have taken root and treatment among adult patients is increasing, resulting in steady growth.



Poteligeo. Global revenue was JPY21.6 billion, a 14% increase over the same period last year, and progress to 48% of the annual plan, generally making steady progress as planned.

Sales in North America in local currency terms increased by 15%. Through evidence-based promotion, we are working to increase penetration among patients with tumor cells in their blood and to provide information about continuing treatment for patients who develop skin symptoms after receiving Poteligeo.

In addition, promotional activities using machine learning and AI technologies have improved efficiency, allowing promotional activities to focus on medical facilities with high dosing potential. These activities are also evolving, leading to strong growth.

In Europe, in addition to strengthening the marketing system and expanding geographically, we are continuing our activities for patients presenting with skin symptoms, following North America, and are making progress in penetrating the market.

That's all for the commercial update.

News Flow of Development Pipeline Products

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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

Now I will talk about R&D. Development pipeline. Top-line data from the ROCKET-ASCEND and ASTRO trials, which are evaluating the long-term efficacy and safety of rocatinlimab in the ongoing Phase III ROCKET program, are expected to be announced in the future.

Ziftomenib presented the results of the KOMET-001 trial at ASCO in June of this year for monotherapy in relapsed and refractory acute myeloid leukemia (AML) and has also been submitted to the FDA for approval. The product has been designated for priority review, and the target date for completion of the review has been set for November 30 of this year.

For first-line combination therapy, the results of the Phase I study, KOMET-007, were presented at the EHA. We will discuss these data later.

OTL-203 is the last patient being treated in the ongoing pivotal trial. We are ahead of our original schedule and have reached it very early, and development is progressing very well.

Updates of ziftomenib

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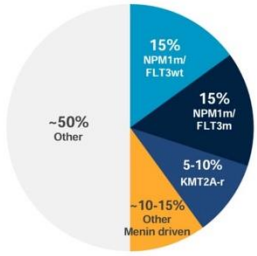
Summary of the product

- 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

Regarding Ziftomenib. Ziftomenib is an oral small molecule menin inhibitor for acute myeloid leukemia and AML with NPM1 mutations or KMT2A reconstitution.

AML is thought to be associated with about 22,000 new diagnoses per year in the United States, about half of which are related to the regulation of gene expression involving menin. The high recurrence rate is a major problem with this disease.

As for the progress, as shown on the bottom of the slide, we are planning to start Phase III of the first-line combination therapy in H2 of this year.

Today, I would like to briefly present a selection of data presented at ASCO and EHA.

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

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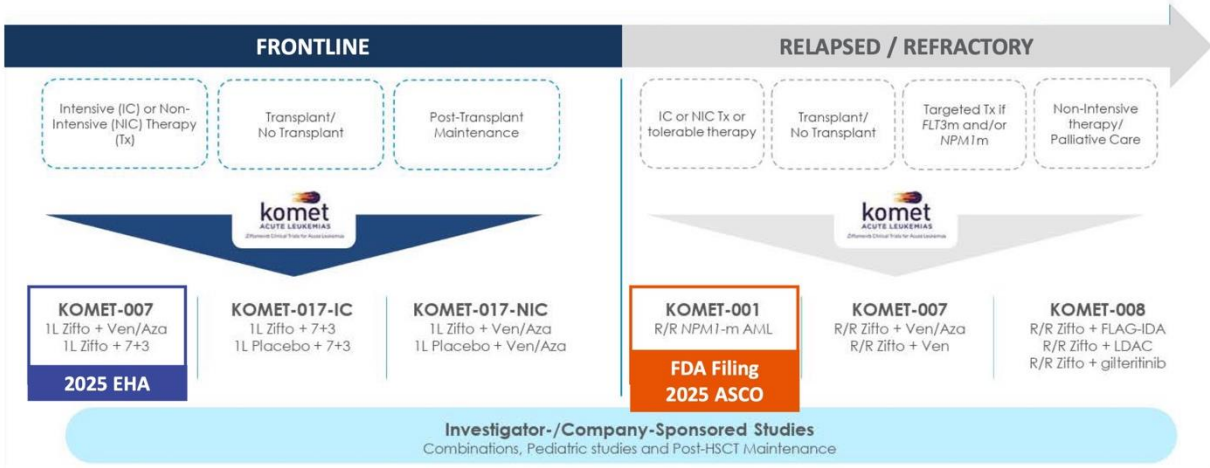

This is the overall picture of Ziftomenib development. First line and then relapse refractory, each of which is under development. In this issue, we will briefly introduce the results of the KOMET-001 and KOMET-007.

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).

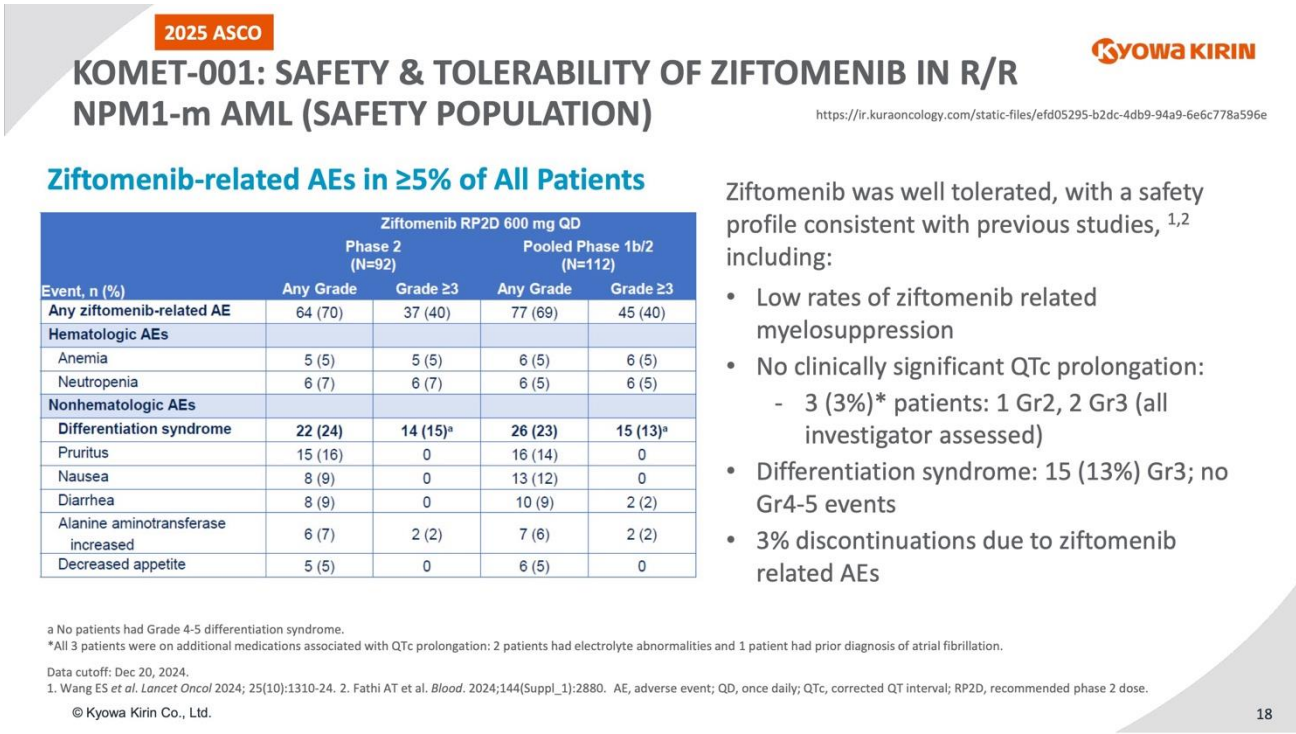
Data cutoff: Dec 20, 2024.

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.

We are showing the results of the KOMET-001 study presented at ASCO. This shows the efficacy data. The CR/CRh rate for all patients in Phase Ib and then Phase II is 25% and the overall response rate is 35%.

It is also important to note that 65% of those who achieved CR/CRh achieved MRD negativity, an indicator of achieving high remission.

Looking at Phase II alone, the CR/CRh rate was 23%, which is significantly higher than the 12% in the conventional chemotherapy data.



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.

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Safety. Myelosuppression is said to be a problem with existing AML therapies, but with Ziftomenib, the incidence of myelosuppression has been shown to be low.

Of the adverse events, 40% are grade 3 or higher, while differentiation syndromes are 13%, all of which were limited to grade 3. QTc prolongation was low, totaling 3%, and 3% of patients discontinued Ziftomenib because of adverse events.

2025 ASCO

KOMET-001: CONCLUSIONS

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- **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)

In summary, in this study of relapsed refractory AML, Ziftomenib met its primary endpoint and demonstrated a statistically significantly higher CR/CRh rate than chemotherapy alone. The safety profile was also favorable, with a low frequency of myelosuppression, differentiation syndrome, and QTc prolongation.

Based on these data, we submitted an application to the FDA for approval in June of this year.

2025 EHA

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.

Here is the presentation at EHA and the test results of KOMET-007. This shows the safety data. Grade 3 or higher adverse events related to Ziftomenib were 35%.

The major adverse events were febrile neutropenia, decreased platelet count, anemia, and decreased neutrophil count, but no additional myelosuppression was observed with the use of Ziftomenib.

Only one case of differentiation syndrome, and only two cases of QTc prolongation were reported, suggesting that this treatment has high tolerability overall and has the potential to be widely and long-term used for AML treatment.

2025 EHA

KYOWA KIRIN

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.

Efficacy. For the NPM1 mutation, the CRc was 93% and the MRD negative rate among them was 68%, and for the KMT2A reconstruction, the CRc was 89% and the MRD negative rate was 83%.

The high efficacy of both gene mutation groups and the high MRD-negative rate are expected to lead to improved prognosis.

2025 EHA

KOMET-007: CONCLUSIONS

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

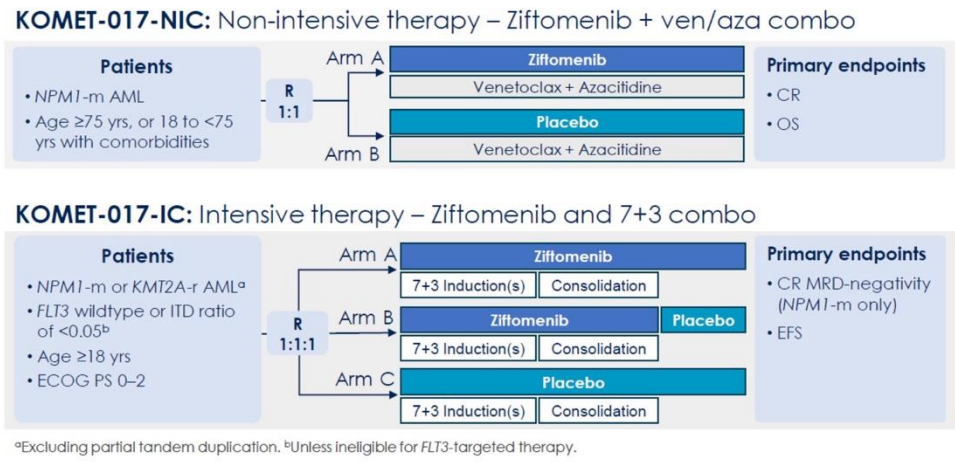
- **In the ongoing KOMET-007 study, ziftomenib 600 mg QD combined with 7+3 was well tolerated, with a safety profile consistent with previous reports**
  - Low rates of ziftomenib-related cytopenia and no additional myelosuppression observed with the combination
    - Ziftomenib 600 mg QD did not delay 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)**

In summary, we believe that Ziftomenib was still highly effective and well tolerated in this study of first-line AML. We believe that we have demonstrated good potential as a first-line combination therapy.

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

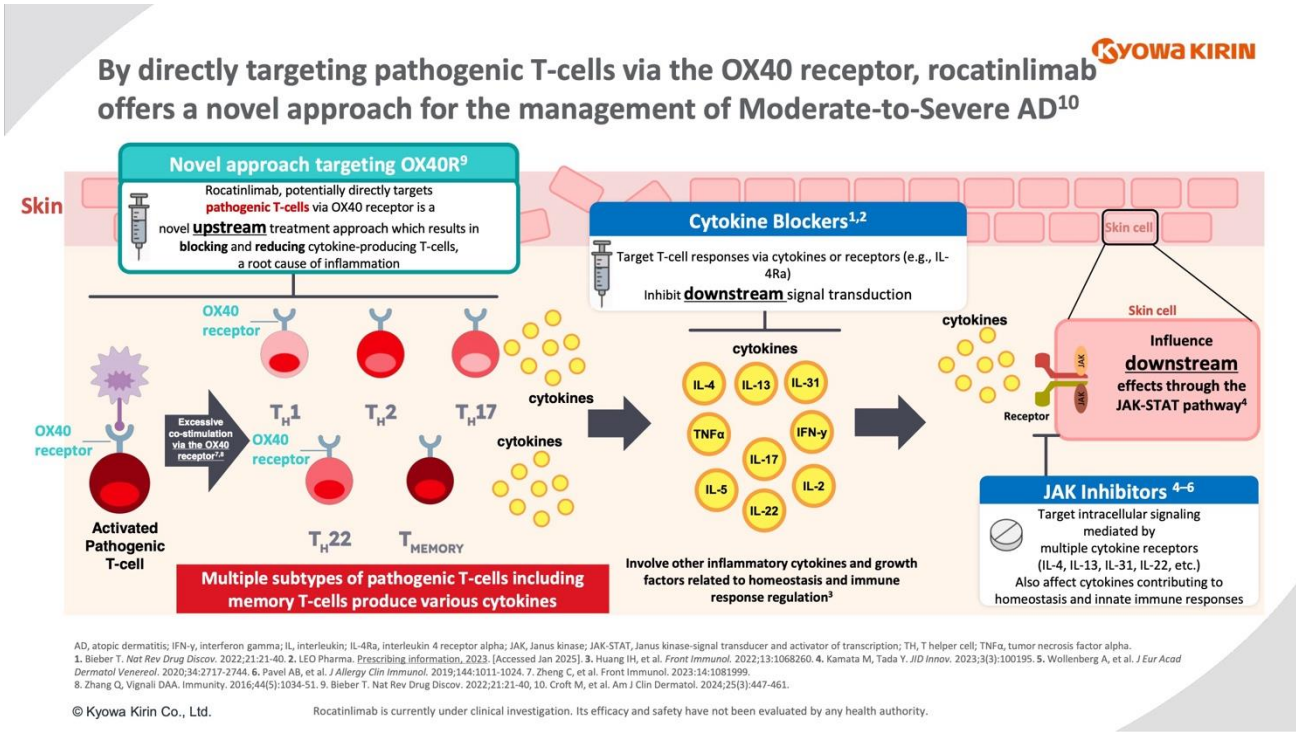


[a]Excluding partial tandem duplication. [b]Unless ineligible for *FLT3*-targeted therapy.

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

This is the study design of KOMET-017, a Phase III study in first-line combination therapy scheduled to begin in H2 of this fiscal year. It consists of two trials: NIC, or low intensity chemotherapy, and IC, intense chemotherapy.

As we have seen today, Ziftomenib has shown good results so far, and we expect good results in this Phase III study.



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. We believe that rocatinlimab can act directly on pathogenic T cells, which are thought to be one of the root causes of chronic inflammatory diseases, via OX40. We believe it can reduce their number.

Through this mechanism, which can be described as T cell rebalancing, we expect rocatinlimab to provide unique, life-changing value.

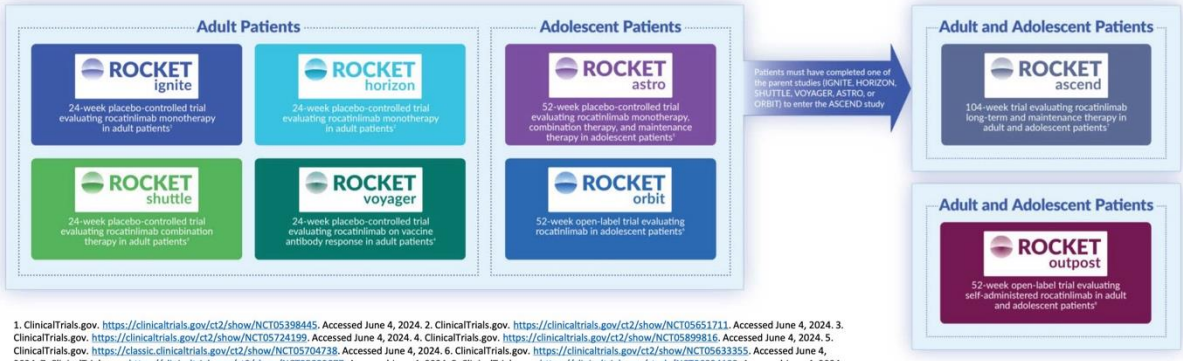
The key here is immune cells called memory T cells. These cells are thought to be responsible for causing inflammation to recur even after symptoms have temporarily subsided, as they retain the memory of having experienced atopic dermatitis in the past.

Even if superficial symptoms temporarily subside, these memory T cells remain in the body and can trigger allergic reactions, causing the immune system to overreact again and leading to atopic dermatitis flare-ups and subsequent chronicity.

It has been suggested that rocatinlimab may also act directly on these memory T cells and reduce their number. The ongoing Phase III study is also testing this effect.

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.

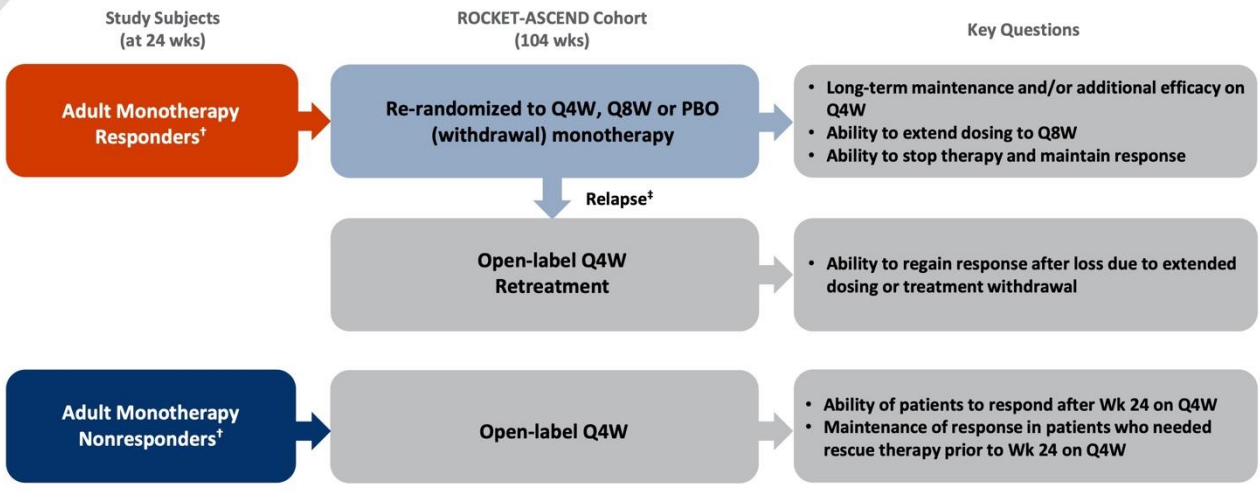
Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

Phase III, the entire ROCKET program. More than 3,300 patients have participated to date, and all four studies, HORIZON, IGNITE, SHUTTLE, and VOYAGER, have met their primary endpoints to date.

And the ROCKET-ASCEND study on the right is scheduled for readout of top-line data in H2 of this year.

Presented at the 2025 American Academy of Dermatology Association Annual Meeting March 7–11, Orlando, Florida, US

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.

This ROCKET-ASCEND trial is a study in which patients who have completed the other trials mentioned earlier will participate after they are finished and will examine the medium- and long-term efficacy and safety of the drug.

We believe that the points indicated in the key question in the upper right corner of the slide are worth noting. For example, we will evaluate from multiple perspectives, such as the effects observed when administration is continued at a frequency of once every four weeks over the long term, whether the effects persist when the interval is extended to once every eight weeks, and whether the effects persist even after treatment is discontinued.

We are now preparing to present new findings on the long-lasting efficacy and improvement of inflammatory flare-ups and chronicity, which we believe are the strengths of rocatinlimab.

KYOWA KIRIN

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

We hope you will find the news since the beginning of the year on page 28 and beyond.

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

Finally, we announced on May 7 the introduction of a special voluntary early retirement program in Japan. As a result, 432 employees including rehired employees decided to retire under this program.

As the environment surrounding pharmaceutical companies worldwide becomes increasingly severe, Japan is also facing significant challenges in terms of the sustainability of healthcare as a whole due to population decline and an aging society.

In order to respond to these changes in the external environment and ensure the realization of our vision for 2030, we are making changes in line with the Story for Vision 2030 that we announced last year.

In this period of change, we will expand career development options for our employees and provide maximum support for those who seek to transition outside the company, while boldly transforming our business foundation in Japan to a more sustainable form and further strengthening our organizational capabilities.

That is all for my explanation.

Question & Answer

Moderator [M]: I would now like to move on to the question-and-answer session.

Yamaguchi [Q]: The first question is the gross margin ratio that you just explained, and you mentioned that Q2 also seems to have a low gross margin ratio and that there were some circumstances. Q1 was also separately mentioned, but could you first explain this factor and whether it can be eliminated in the full year?

Kawaguchi [A]: As explained earlier, the cost of sales ratio increased in this Q2 due to transitory factors. This was due to the retirement and write-down of some domestic items. This is a one-time event, but it was not part of the plan, so I think it may have an impact throughout the year. The scale of the amount is approximately JPY2 billion.

The difference in cost ratio in Q1 and Q2 is due in part to seasonal factors here, and we believe this is a factor that is contained in the plan, and we hope you will understand that the transitory factor is JPY2 billion.

Yamaguchi [Q]: The second is Crysvita. I'm sure you will have some questions later on, please tell me how the balance between adults and pediatric was this time, especially in the US?

Another thing is about controlling inventory fluctuations, which are still quite significant, but please give us your thoughts on the Q2 results, including this issue.

Miyamoto [M]: I would like to ask Abdul to explain this.

Mullick [A]*: As for the adult Crysvita penetration in the US, we continue to see very strong progress. We are using the advanced technologies now to identify patients allow us to be much more efficient. Now if we look at the total growth rate in the US, the majority of the growth coming from adults.

Then the inventory level is very volatile picture. If we look at the actual patient demand, we see continue consistent growth.

Yamaguchi [Q]: Is there an adult penetration rate?

Mullick [A]*: Adult penetration is 14%.

Muraoka [Q]: I am afraid I always ask the same question. Finally, ASCEND is coming out, and I am surprised here that Chugai's recent nemolizumab sells quite well when it can be differentiated.

My question is, if the ASCEND can differentiate itself well, that would be great, but if the differentiation is too subtle, what kind of additional clinical studies will be done to increase value, or will another acquisition be accelerated, etc. What are your plans if the results are disappointing? I am afraid this is an IF question, but could you please tell me?

Miyamoto [A]: It is difficult to answer this question because, as you said, it is an IF question, but first I would like to take a hard look at the ASCEND and ASTRO lead-outs that we are working on now to see what happens. If, after seeing the result, we see that something additional is needed, we will have a thorough discussion with Amgen on that and proceed.

As you say, differentiation is also important, so we would like to explore that, but the key point, as I explained, is that rocatinlimab is a substance that can target T-cell rebalancing, so I think we should think carefully about what we can do based on that.

Muraoka [Q]: I've asked this same question before, but I've always thought it would be nice to do a switchover test from Dupixent, but has there been much discussion here yet?

Yamashita [A]: I think there are quite a few people who are using Dupixent enrolled in ASCEND this time. I am hoping that such results will come out in the future, and also that the expectations for rocatinlimab that I mentioned earlier will become clearer.

I believe that such information would be quite useful, and based on the results that emerge, I would like to consider what to do next.

Muraoka [Q]: When the ASCEND results come out, if you could show us the analysis of the subgroup that switched from Dupixent and those that did not, although I don't know the timing, we would have a better understanding.

Yamashita [A]: Yes, that's right. At this point, I am unable to say what the contents of the sub-analysis will be, but at the very least, it will be very important information to analyze the effects of pretreatment, so we will analyze the data carefully and consider how much data has been accumulated in this context.

Muraoka [Q]: One more thing, you mentioned AI promotion of Poteligeo, and I am not sure if you mentioned this before, but I think you are talking about finding hospitals and doctors who are using it and what kind of specific AI applications it has. Is there any possibility that this could be applied to other drugs as well, or is it already being done?

Miyamoto [M]: Thank you for the very interesting question, Mr. Muraoka. Abdul is quite knowledgeable about this, so I will let him explain it to you.

Mullick [A]*: This is a new approach that we've adopted now over the past year. It looks at the symptoms for various patients who have a cutaneous T-cell lymphoma and classifies them as an appropriate patient. So because of AI, we're able to use big data to identify where these patients are.

Historically we've had to go with our Reps office to office. So, AI offers us a much more efficient approach. And we're seeing that now with the increased momentum with Poteligeo. We've also now started adopting this approach with Crysvita, too. And we're beginning to see effects as well. So, this is very exciting technology which we're looking to expand.

Muraoka [M]: I understand. Thank you very much. That is all.

Wakao [Q]: First, can you give us an update on the US tariff impact? I don't think there were any comments at the last briefing, and I think a lot of things have changed so far, so please update us.

Miyamoto [A]: I am sure you are all interested in the news this morning, so I will try to summarize it for you. First of all, as to whether there are any concrete actions planned that I could talk about, I must confess that at this point we have no way of moving forward because we do not yet know the details of the various matters that need to be addressed.

What we are doing is setting up a task force team in the US. We have one in Washington, one stationed at Delegate, from Kyowa Kirin, and one at Orchard. The local team and the Japanese team are working together, exchanging information quite closely, and the entire company is now working on what is happening and what possible countermeasures can be taken.

Therefore, information is circulated within the Company very quickly, and we are able to receive this morning's news before it appears in the newspapers in Japan.

Unfortunately, although we have more information on tariffs and most favored nation prices than we did in Q1, we still don't know the details of what is actually going to be charged and where, so we are having a very difficult time.

However, the One Big Beautiful Bill Act was also passed and will be effective from 2027, and it contains various provisions regarding drugs, so we need to look at the overall impact of these provisions in order to get a clear picture of the situation. That is my honest opinion at this point.

For example, in terms of tariffs, Crysvita and Poteligeo in particular are major products, so we are currently working on various scenarios internally, including discussions on where to establish drug subsidies for these products, while considering what the impact will be.

For example, if the question is whether we are factoring in any such effects toward the most recent landing this year, the answer is that we are not factoring in any such effects at this time.

Wakao [Q]: Even if it is not incorporated on the one hand, on the other hand, I think you have been able to take measures such as building up inventory, etc. Is there going to be a certain impact this quarter? Should I view it as limited?

Miyamoto [A]: The truth is that I think it probably won't be that big this quarter, even if it is.

Wakao [Q]: I look forward to another update in the future.

Second, tell us about Ziftomenib. We are happy that the data so far has been very good and that we have a good sense of the potential of the first line. What I want to know is the target patients of this Ziftomenib, the population.

Moderator [M]: I apologize, Mr. Wakao. We are not receiving audio and will check the connection separately. In the meantime, let me move on to your next question. The next question is from Mr. Hashiguchi of Daiwa Securities. Best regards.

Hashiguchi [Q]: The first is about Crysvita's sales in North America. You mentioned that there was also an impact of inventory buildup, but if you have an estimate of how much of an impact this had quantitatively, could you please share it with us?

Miyamoto [A]: We announced a slight price increase in July, and there was a considerable amount of buying, and although we cannot disclose details, there was a certain degree of impact, and from that perspective, we are looking at a slight decline in Q3. However, we are estimating enough that the entire fiscal year will run along the planned lines.

Hashiguchi [Q]: I can’t remember right now, but did you do the same thing last year? Is the movement from Q2 to Q3 likely to be the same as last year, or will there be a greater movement from Q2 to Q3 this year than last year?

Kawaguchi [A]: Interim price revisions were made this time, but not last year. In that sense, this year's impact was significant, so compared to last year's trends, Q2 is likely to be higher and Q3 lower. However, on average, there would be no significant impact throughout the year.

Hashiguchi [Q]: Secondly, regarding OTL-203, you mentioned earlier that you were able to implement the treatment for the last patient much ahead of schedule. How is this likely to affect the timing of the application for approval? The description in the appendix of the document has not been updated, but is it safe to assume that this may be moving forward as well?

ClinicalTrials.gov says that the timeframe for the primary endpoint is two years, and many of the secondaries require up to five years of observation. At this point, do you believe that an application can be submitted once all data has been collected, or is it impossible to say without reviewing the data?

Yamashita [A]: First of all, regarding the fact that enrollment for this trial has been moved up earlier than planned, I think it is safe to say that the overall schedule is ahead of schedule.

In terms of how long it will take to follow up on the results, the standard plan is to look at the results over a five-year period, but I think there are areas where we can predict the efficacy of this drug, needs, and whether it should be approved, as well as biomarkers and other aspects of efficacy.

We will continue to pursue such a follow-up period with data and negotiation as opportunities arise.

Hashiguchi [M]: I understand. Thank you very much. That is all.

Moderator [M]: I would like to again nominate Mr. Wakao of JP Morgan Securities.

The audio cut out earlier at the point where you said in your question about Ziftomenib, so please ask again from there.

Wakao [Q]: I would like to know what to do for patients with FLT mutations regarding Ziftomenib. I believe that Phase I has started in combination with FLT3 inhibitors, and at this point we are targeting FLT3 wild type, but is it correct to understand that those with FLT3 mutations will also proceed in combination with FLT inhibitors in the future?

Yamashita [A]: The trial we are introducing today is designed for patients without FLT3 mutations or with very low levels of mutations.

Conversely, for those with FLT3 mutations, it is recommended to use inhibitors, so we will be looking at the possibility of seeing more of an add-on effect for this ziftomenib to be an add-on to that. In fact, we are considering a setup in which Phase I would be done first and then the results would be reviewed as we proceed.

Wakao [Q]: Based on the mechanism of the menin inhibitor, it is scientifically possible, on a science basis, to produce efficacy even if it contains FLT3 mutations separately, right?

Yamashita [A]: You are right. The menin pathway is very important in AML, and there are many patients who have both NPM1 and FLT3 mutations. We believe that this additive effect of this treatment will bring good news to patients in such cases.

Wakao [M]: I understand very well. Thank you very much. That is all.

Ueda [Q]: My name is Ueda from Goldman Sachs Securities.

I would first like to ask about the impact of the special voluntary early retirement program. I think that in 2024, the target was research, production, and quality-related departments, so I would like to know how other departments, such as sales, development, and headquarters, will be affected in your business structure.

In addition, in terms of the impact on business performance, I think the number of applicants was higher than expected this time and other expenses may be significant, but can you tell us if we should be particularly concerned about the impact on non-core areas in order to achieve the plan for pre-tax profit and beyond?

Miyamoto [A]: As you mentioned, what we did last year was based on causing a modality shift in small molecule domain to make them much smaller, so we are targeting a very limited sector.

Although the exact department is undisclosed at this time, we recruited a relatively broad range of applicants, cut off only by age and length of service, so of course there were sales and head office departments, and a variety of applications from each function. It is not easy to disclose details, but we received applications from all functions.

Since everyone will be retiring at the end of September, we are currently working out the details of what kind of structure we will have in place in each department for the new structure starting October 1.

Regarding financial impact, Kawaguchi will explain.

Kawaguchi [A]: This special voluntary early retirement program resulted in JPY9.4 billion in other expenses. This is a slightly larger amount than we had estimated in the plan, and this cost will remain as a negative factor for the entire year. However, we still aim to achieve our annual plan and performance forecast based on current period profits.

One of the reasons for this is that we will naturally pursue upside in our core business, and another is that there is a possibility that upside events may occur in areas below our core OP that we have not incorporated into our plan, and although this is still uncertain, it is possible that such events could occur. Our current thinking is to achieve the full-year plan, including these factors.

Ueda [Q]: Second, I would like to know about the progress of R&D expenses. While there were a very large amount of expenses in Q1 of this fiscal year, I think the level has been reduced considerably in Q2. However, as projects are being completed, the outlook for H2 is that rocatinlimab-related expenses will decrease, and is there some leeway in the current budget?

On the other hand, I am wondering if there are some areas that will become active again, including various early-stage projects, so could you please explain the progress against the current plan?

Kawaguchi [A]: As you mentioned, as for research and development expenses, we have been able to record project expenses on an activity basis starting this year, which has significantly improved seasonal smoothing, and the ratio was 49% in Q2.

We are currently planning for H2 expenses to be recorded in a similarly smoothed manner, so the answer to your question is that we are making progress as planned.

Ueda [M]: I understand. Thank you very much. That's all from me.

Sakai [Q]: The status of the development pipeline’s this time seems to show little advancement over the last six months. Certainly, Ziftomenib has moved forward, but I believe this is mainly driven by Kura, and then I don't see much change in what is happening now in terms of schedule for the ASCEND exam.

Looking at the current status of this pipeline, or rather, of course, Chairman Miyamoto sees it on a daily basis, what are your thoughts? Is there still consideration for product in-licensing as you mentioned before? I would appreciate your overall evaluation of the pipeline.

Miyamoto [A]: I personally assess that progress is going extremely well, and ROCKET is now well on its way to preparing with Amgen for the readout of ASCEND's top-line data.

As you mentioned, the FDA application for Kura's second-line indication went extremely well, and we have maintained excellent communication with the FDA since then.

For example, as I explained earlier, the Orchard OTL-203 project has advanced significantly ahead of schedule, and preparations for subsequent pipeline are also progressing smoothly. Overall, I believe things are moving well.

Furthermore, we recognize that more activity is still needed, especially in the latter stage of the pipeline, to further strengthen it. Our Business Development team is actively working in this area. While we have no publicly disclosable progress to share yet, we are continuously reviewing and advancing various projects internally.

Sakai [Q]: As a follow-up to that, the ASCEND trial, this is the interim analysis, and this is the package that will be submitted, is it correct that this submission is still planed for within 2025? Or is the target timing the end of Q1 for 2026. I would like to know the timing.

The reason I ask is that I think this will trigger a milestone payment from Amgen at some point. I think it was 850 million USD, but I was wondering if you could provide some insight into the total amount and whether the timing of that milestone is linked to the submission or the approval, since there could be various possibilities.

Also, I think it is very important to know how you are going to present the results, and in what form you are going to present them jointly with Amgen. This had a significant impact on the stock price at the time of the last ROCKET, so please let me know how you intend to coordinate this.

Miyamoto [A]: I am aware that we caused a lot of trouble at the time of HORIZON, but since then, we have been communicating closely with Amgen, reflecting on that experience, and I believe we have been able to make announcements in a manner that minimizes inconvenience. We intend to continue following this practice.

Yamashita is more familiar with the application timeline, so I will hand over to Yamashita for details.

Yamashita [A]: First, the ASCEND study is proceeding as planned. We would like to quickly move forward with the process of obtaining data, analyzing it, and submitting the application. We believe that the time required for analysis will depend on when the data becomes available, but we would like to submit the application as soon as possible.

We would like to discuss this part with Amgen, as well as what kind of message we can convey in the disclosure I mentioned earlier, and we would like to proceed with these discussions promptly after the data is opened. In that sense, we would like to proceed according to the timeline originally set forth in our goals.

Sakai [Q]: So, you don't expect any milestones at all during 2025?

Kawaguchi [A]: The purpose of your question is that we have announced a USD400 million upfront income at the time of contract signing, and thereafter up to USD 850 million in cumulative milestone payments, depending on the terms and conditions. Unfortunately, we cannot disclose the specific details of the milestones, but as the best hint we can provide, the payments will come according to the general milestone schedule.

Another point is that we have not factored milestone revenues related to rocatinlimab in this year's plan.

Sakai [M]: I understand. Thank you very much.

Wada [Q]: In the performance section, I would like to briefly ask about the difference from the initial plan shown on the bottom of page five, where it says that the ratio of overseas sales has changed. Can you tell us how the assumptions here have changed since the beginning of the period?

Kawaguchi [A]: We sincerely apologize for this. We noted that it was corrected in Q1, but when we published this last February, the figure was 70%, which was simply incorrect, and we have now corrected it to the accurate figure of 73%.

Wada [Q]: Basically, you mean a YoY increase in the overseas sales ratio to 73%, mainly due to stronger growth overseas compared to last year.

Kawaguchi [A]: That's what I mean.

Wada [Q]: One more point, I noticed that the primary completion date for rocatinlimab on ClinicalTrials.gov seems to have shifted, it was originally scheduled for around June 2025, but it has now been changed to 2027 or so, is there some factor? I understand that the interim analysis data will be available this year, but I would like to know if there is any possibility of data surplus or insufficiency.

Also, I have the impression that Sanofi's Amlitelimab will probably present its first data in H2 of this year, and that the submission process may be expedited. I would like to ask whether the application strategy, including these developments, has changed from the initial plan. What is your thoughts?

Yamashita [A]: For this rocatinlimab application, where we are analyzing the ASCEND data and preparing the submission, the plan there has not changed. The ASCEND study is still in the process of collecting data, and we continuously discuss whether additional data should be included while reviewing existing data, and minor adjustments such as how long to continue ASCEND may occur in the future.

We have not changed for this application, so please do not worry.

Wada [M]: I understand. Thank you very much.

Wakao [Q]: Crysvita is raising its prices in July. I believe that until last year, the price was only raised once at the beginning of the year, but now that you are raising it twice this year, can you tell us if there are any changes in Crysvita's pricing strategy?

Miyamoto [A]: Thank you, Mr. Wakao. Abdul will answer this.

Mullick [A]*: We consider the price every year. Usually, we revise it twice a year. In the case of last year, we decided to increase it by 5% once instead of twice. We balanced it that wat, but the approach changes depending on the situation at the time.

Wakao [M]: So basically, it hasn't changed. I understand.

Muraoka [Q]: 4951. Eye drops, I had a conversation with the IR person yesterday that the timing of the exam was delayed to September 2026. You mentioned that the enrollment method is somewhat unique, so to the extent possible, could you explain why there is a delay and what efforts are being made to increase the probability of success?

According to ClinicalTrials.gov, should we assume there will be no updates on 4951 until around next fall, or should we expect some updates? Please advise.

Yamashita [A]: I can't disclose the details of 4951, but we planned an unprecedented study, and although we had carefully studied the protocol and started the study, it did not proceed at the speed we had expected.

That is, we hoped the trial would gain momentum over time, but it remained slow and behind schedule, so we made some protocol modifications, which will extend the timeline.

Currently, patient enrollment is proceeding very smoothly, and although the overall plan was delayed, the trial is now progressing according to the current schedule without further delays.

Muraoka [Q]: So if we wait until next fall or the end of the year, can we reasonably expect to hear updates on both?

Yamashita [A]: Yes, we intend to proceed accordingly.

Muraoka [M]: I understand. Thank you very much. That is all.

Moderator [M]: Thank you very much. This concludes the online presentation of financial results for Q2 of the fiscal year ending December 31, 2025.

Thank you very much for your participation today. Thank you for your continued support of Kyowa Kirin.

[END]