Kyowa Kirin Co., Ltd.

Q1 Financial Results Briefing for the Fiscal Year Ending December 2025

May 1, 2025

Event Summary

[Event Name]	Q1 Financial Results Briefing for the Fiscal Year Ending December 2025	
[Date]	May 1, 2025	
[Number of Speakers]	3	
	Takeyoshi Yamashita	Director, Executive Vice President and Chief Medical Officer
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer
	Yasuo Fujii	Managing Executive Officer and Chief Strategy Officer

Presentation

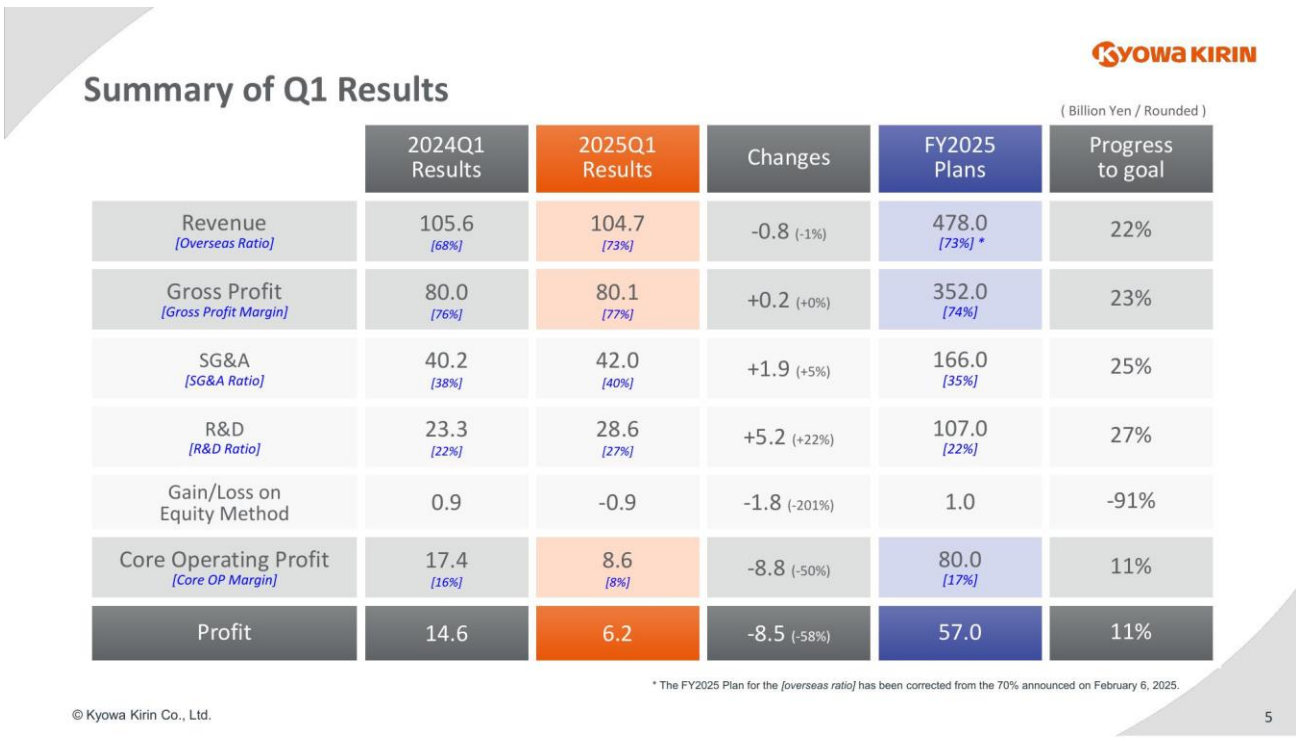
Moderator: Thank you very much for joining us today for the online information session on Kyowa Kirin Co., Ltd.'s financial results for Q1 of the fiscal year ending December 31, 2025. Please note the following prior to the start of the briefing. Please be advised that we will keep the names and company names of all participants today for a certain period of time as a list of participants. Please also note that the content of this presentation will be available on our website as an on-demand stream and transcript. We would appreciate your understanding in this regard before making any comments.

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

Today's speakers including those in the Q&A session are Takeyoshi Yamashita, Director, Executive Vice President and CMO; Motohiko Kawaguchi, Managing Executive Officer, CFO; and Yasuo Fujii, Managing Executive Officer, CSO.

Today's online conference is scheduled to last up to 90 minutes. We will provide the overview of the financial results and then we will take questions from the audience. Please download the materials from our IR website.

Kawaguchi will now give an overview of the financial results.



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Summary of Q1 Results

(Billion Yen / Rounded)

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

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

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Kawaguchi: Yes. I will now start with the performance summary for Q1 of 2025. Please see page five of the slide.

Compared to the same period last year, revenues were JPY104.7 billion, down JPY800 million or 1%, core operating profit was JPY8.6 billion, down JPY8.8 billion or 50%, and profit was JPY6.2 billion, down JPY8.5 billion or 58%.

Revenue decreased by 1% due to the impact of the business restructuring in the APAC region and the NHI price standard reduction in Japan, despite the growth of global strategic products, mainly in North America and EMEA.

As for core operating profit, gross profit was on par with the previous year, but SG&A expenses increased slightly and R&D rose sharply by JPY5.2 billion or 22%, due to faster progress than in previous years, resulting in a 50% decrease in core operating profit.

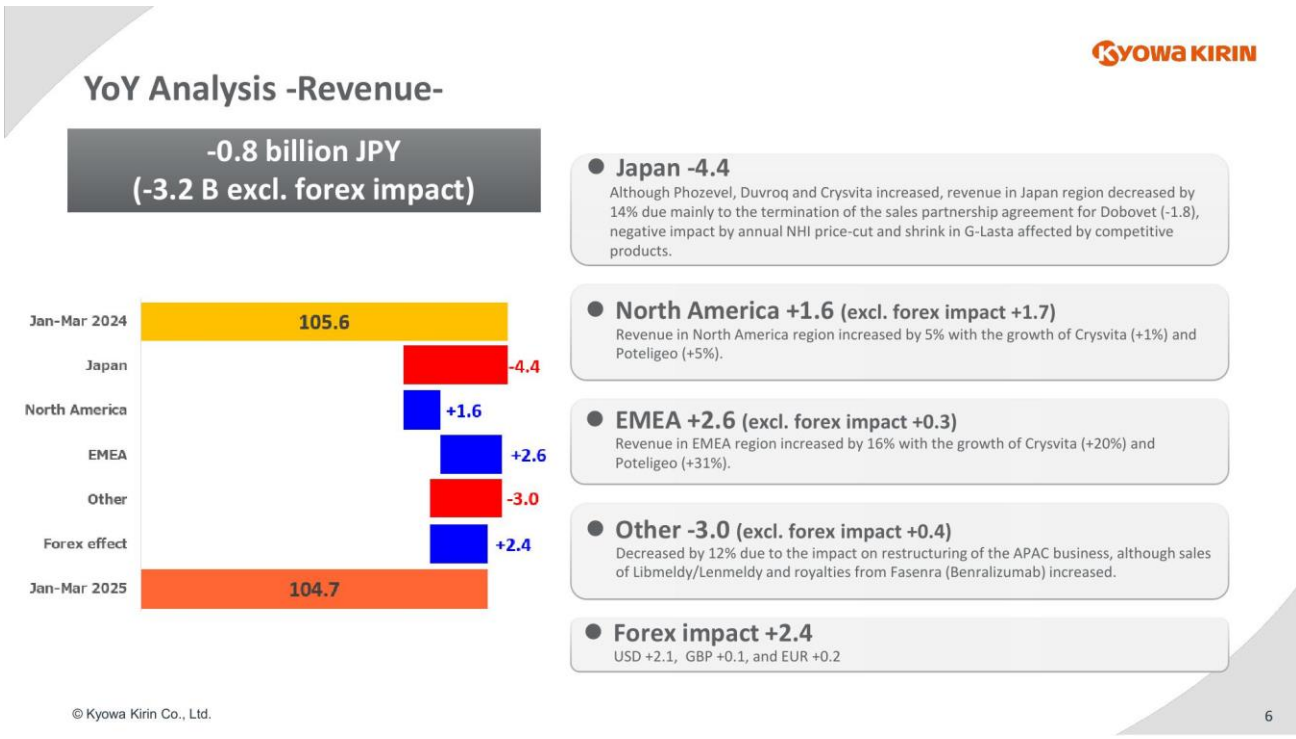
Quarterly income decreased by 58%, partly due to the impact of gains from the sale of fixed assets in the previous year.

As for the percentage of progress toward the full-year forecast, revenue and gross profit were 22% and 23%, respectively, which are below 25%, a quarter of the full-year forecast. However, as usual, revenue and profit tend to increase in the second half of the fiscal year, so Q1 results were generally in line with our plan.

SG&A also remained in line with the plan.

The progress rate for R&D has tended to be low in Q1 in past years, but as a result of the change to activity-based estimates from Q1 2025, expenses incurred in each quarter have been smoothed out, resulting in a progress rate of 27%.

As a result, core operating profit and quarterly profit appear to be progressing at a low 11%, but are generally within the plan. We will continue to strive to achieve our full-year plan by growing sales of Crysvita and other core products and controlling expenses.



Next, please see page six. This is a YoY analysis of revenue by region. Starting this year, the format has been changed to explain the real increase/decrease, excluding the effect of exchange rate fluctuations.

First let's look at Japan. As for Japan, Duvroq, Phozevel, and Crysvita continue to show solid growth, but sales of Dovobet, whose marketing agreement was terminated last December, declined by JPY1.8 billion, and the

impact of the NHI price revision last April, in addition to a decline in sales of G-Lasta, due to competition from follow-on biotech products, resulted in a 14% decline in Japan region sales.

In North America, sales increased by JPY1.6 billion or 5%, in real terms, excluding the positive impact of JPY1.7 billion from exchange rate fluctuations. Sales of Crysvita and Poteligeo grew 1% and 5%, respectively, in local currency terms.

In EMEA, sales increased by JPY2.6 billion or 16%, in real terms, excluding a foreign exchange impact of JPY0.3 billion. Sales of Crysvita and Poteligeo grew strongly by 20% and 31%, respectively.

The "Other" category includes sales of established pharmaceuticals and other products in the region which, until last year, were separately listed as under APAC. In addition to higher royalties from Fasenra, sales of Libmeldy/Lenmeldy, a hematopoietic stem cell gene therapy, increased significantly as sales began to be recorded in the US. However, sales in this segment declined 12% due to a JPY3 billion decrease in revenue resulting from the restructuring of the APAC business.

The foreign exchange impact on sales revenue was a positive JPY2.4 billion.

Revenue of Major Items

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(Billion Yen / Rounded)

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

1 AG stands for Authorized Generic. Official product name is Darbepoetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.
2 Sales royalties of Fasenra which has been marketed by AstraZeneca. Including our own estimation.
3 Overseas items are displayed at the net value including FX impact. Items for the Japan region are displayed at gross amounts before any discounts or deductions.

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Now, please refer to page seven. Here is the situation by major product. This page includes the impact of exchange rates.

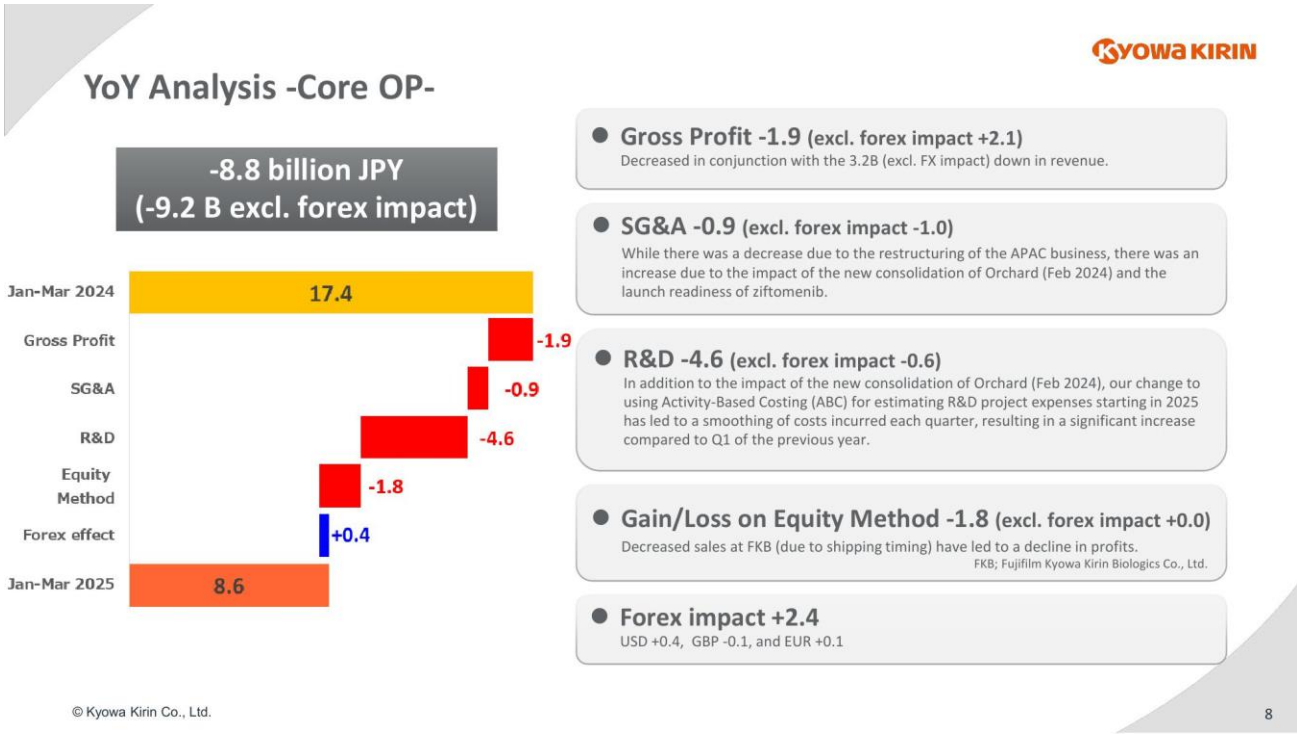
Crysvita sales grew by JPY4.6 billion, or 12%, YoY, continuing to show growth in North America, EMEA, and Japan.

Sales of Poteligeo also continued to grow in North America and EMEA, with a YoY increase of JPY1.2 billion, or 13%.

As for Libmeldy/Lenmeldy, in addition to solid sales in Europe, two sales were recorded in the US for the first time this year, resulting in a significant increase in sales of JPY1 billion, or 92%.

Sales of G-Lasta decreased by JPY1.5 billion, or 26%, due to competitive products and the NHI price revision.

Technical revenues increased by JPY0.8 billion, or 7% over the previous year due to an increase in royalties from Fasenra.



Please see page eight. This is a YoY analysis of core operating profit. This format has also been changed to explain the breakdown of the real increase/decrease, excluding the effect of foreign exchange.

Gross profit decreased by JPY1.9 billion in real terms, excluding the foreign exchange impact of JPY2.1 billion, due to the decline in sales revenue.

SG&A expenses increased by JPY0.9 billion due to the impact of the new consolidation of Orchard in February of last year and preparation costs for the launch of ziftomenib, despite a decrease due to business restructuring in APAC.

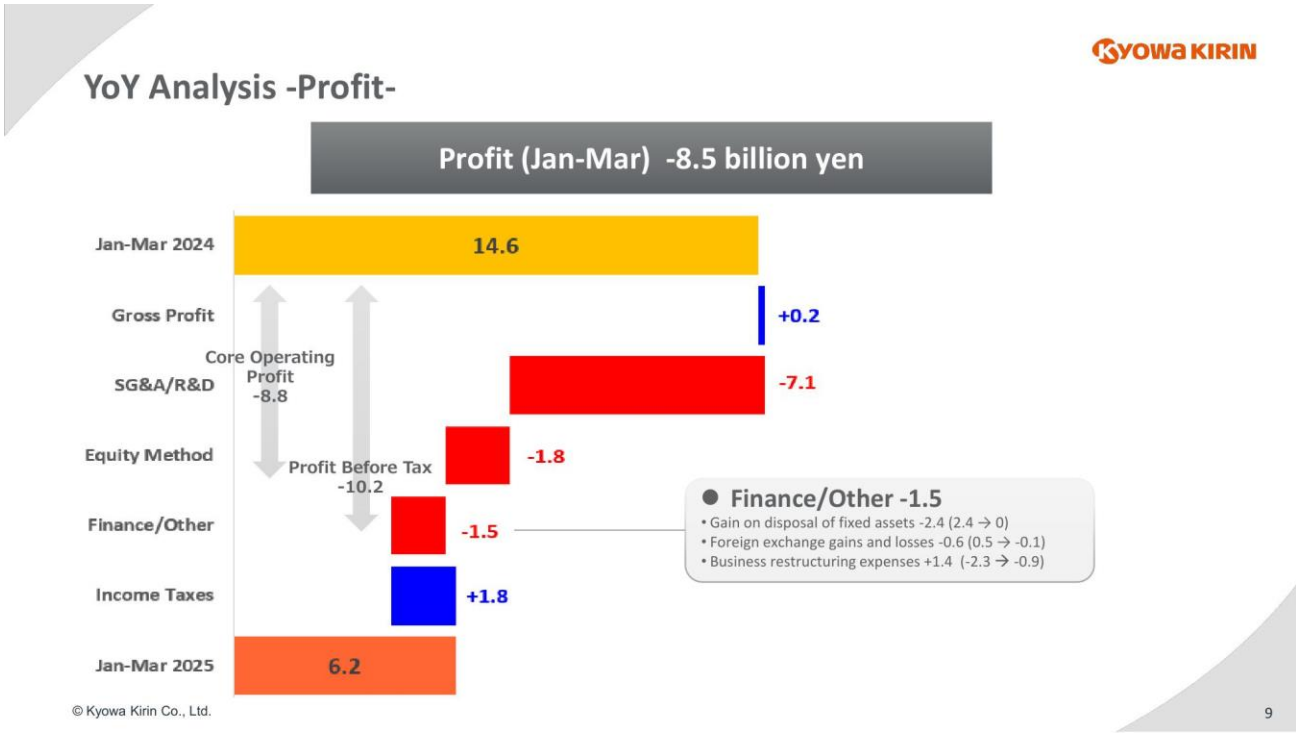
R&D expenses related to R&D projects will be estimated using activity-based costing from 2025, and we expect that expenses will be spread evenly across each quarter.

In the past, on an invoice basis, expenses tended to be incurred less in Q1 and more in Q4. Therefore, although the increase appears large compared to Q1 of the previous year, we expect progress to be in line with the plan. As with SG&A, the one-month impact of the new consolidation of Orchard was also a factor in the YoY increase.

The gain/loss on equity method decreased from JPY0.9 billion last year to a loss of JPY0.9 billion, resulting in a total decrease of JPY1.8 billion. This was mainly due to a decrease in sales caused by the timing of shipments at Fuji film Kyowa Kirin Biologics (FKB). This means that there were zero shipments in Q1 of this year.

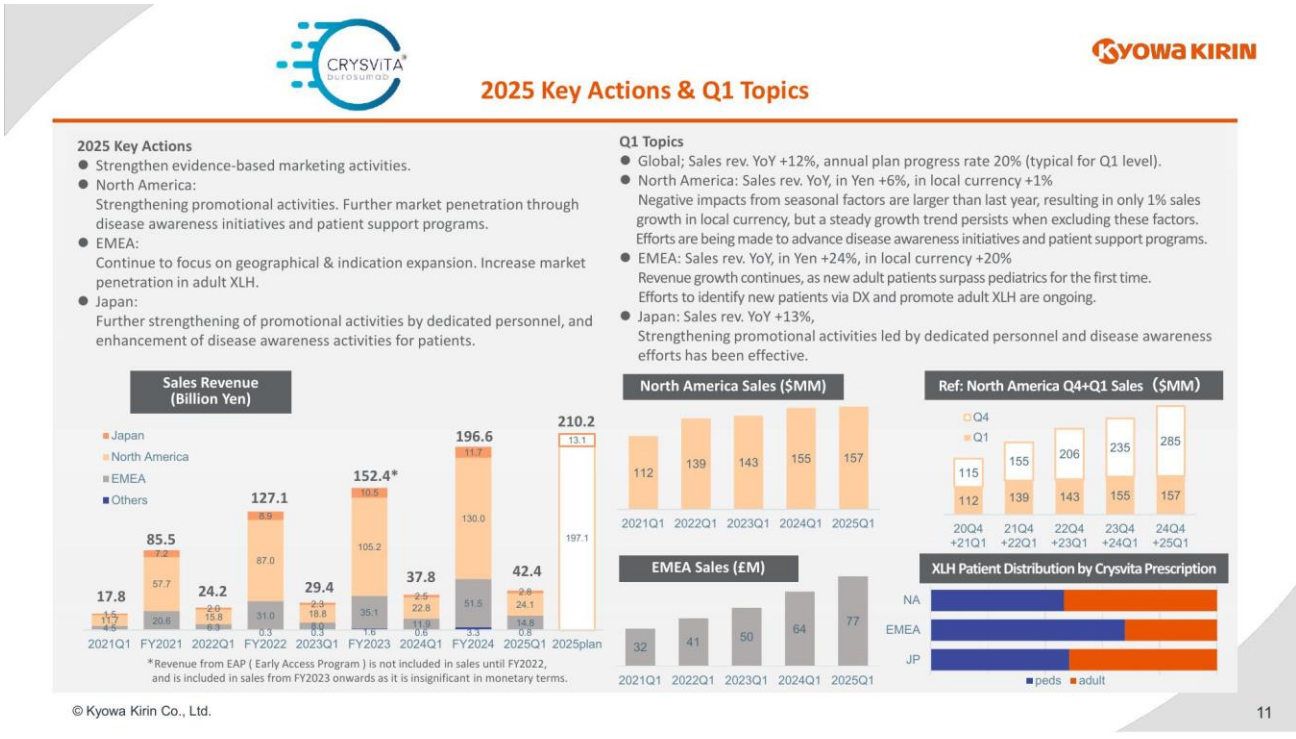
The foreign exchange impact on core operating profit was a positive JPY0.4 billion.

As a result, core operating profit decreased by JPY8.8 billion compared to the same period of the previous year.



Now, please refer to page nine. In this slide, I would like to show you the section below core operating profit. Please note that this slide shows the increase/decrease including foreign exchange effects, as in the past.

Finance/Other decreased by JPY1.5 billion. Last year, there was a gain on the sale of fixed assets, so this year's figure is negative compared to the previous year. As a result, quarterly profit decreased by JPY8.5 billion compared with the same period of the previous year.



Fujii: Next, Fujii will explain about the commercial update. Please turn to page 11.

First, we will start with Crysvita. The bottom left graph of sales revenue in yen shows a five-year trend with respect to Q1 sales and annual sales.

In Q1 of 2025, global sales revenue totaled JPY42.4 billion, up 12% from the same period last year, and continued to grow steadily.

Progress against the annual plan appears to be slightly behind schedule at 20%, but Q1 is typically affected by seasonal factors in North America, such as a reactionary decline due to inventory buildup in specialty pharmacies in Q4, and increased patient burdens associated with insurance changes at the beginning of the year, and therefore starts at around 20% of the annual target. We are not particularly concerned about this.

To give you an idea of growth excluding currency effects, the bottom right-hand corner shows sales trends in North America and EMEA on a local currency basis.

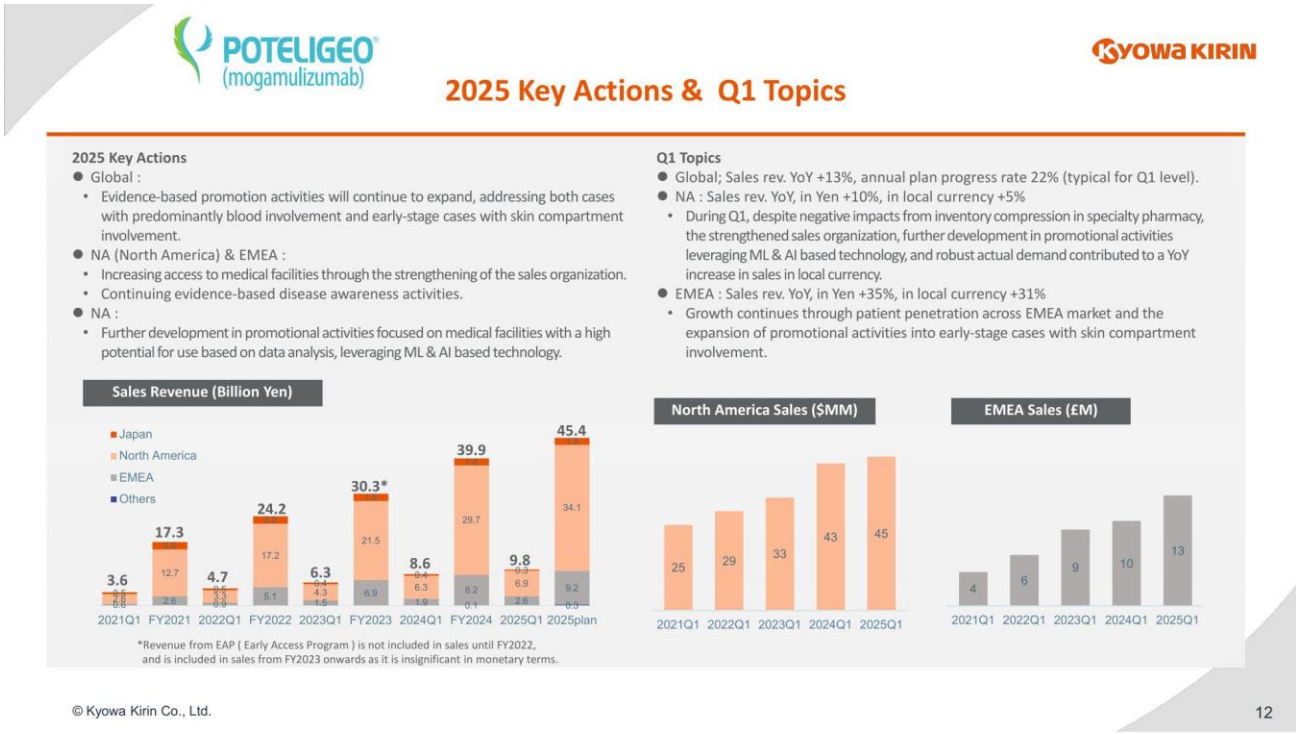
In addition, for North America, in order to simplify and eliminate the effects of inventory buildup and depletion in specialty pharmacy, sales trends in local currency terms are shown for Q4 of the previous year and Q1 of the current year combined.

Seasonal factors in North America were greater than we had seen at the time of the February presentation, with only 1% growth in local currency sales, but excluding seasonal factors, the growth was solid. In addition to continued disease awareness, we aim to achieve continued growth by evolving our patient support program to meet the diversifying needs of our patients, along with patient penetration.

In EMEA, through patient penetration, Crysvita continues to grow steadily in local currency terms. In terms of pricing, growth is driven by patient penetration, which exceeds the impact of drug price reductions in some regions, such as the UK, where reimbursement was made last year for adults.

In EMEA, the gradual expansion of the market has resulted in slower adult penetration than in other regions, but for the first time, the number of new adult patients exceeded the number of new pediatric patients this Q1.

The dedicated personnel system has taken root in Japan and continues to grow steadily.



Please see page 12.

Next is about Poteligeo. Q1 sales revenue was JPY9.8 billion globally, up 13% from the same period last year, and 22% of the annual plan, continuing steady growth generally as planned.

Sales in North America in local currency terms continued to grow, albeit slightly.

Demand remains strong, and through evidence-based promotion, we are advancing penetration among patients with tumor cells in their blood, and improving access for patients with skin symptoms.

Strong growth has also come from the use of machine learning and AI technology in promotional activities, and the evolution of promotional activities to focus on medical facilities with higher dosing potential.

On the other hand, specialty pharmacy inventories in North America were reduced throughout Q1. Although Poteligeo does not have the pronounced seasonality of Crysvita, especially as inventory levels were compressed at the end of Q1, offsetting strong actual demand, sales in Q1 were only slightly higher. We are not concerned about future growth, as actual demand is strong.

In Europe, in addition to strengthening our marketing structure and expanding geographically, we have also begun accessing patients with cutaneous symptoms, following North America, and we continue to grow through patient penetration through disease awareness activities. That's all for the commercial update.

News Flow of Development Pipeline Products

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New information highlighted in orange

As of May. 1st , 2025

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

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Yamashita: Next, Yamashita will introduce the R&D update. Please move on to page 14.

Changes in the development pipeline from the previous presenation are shown in red.

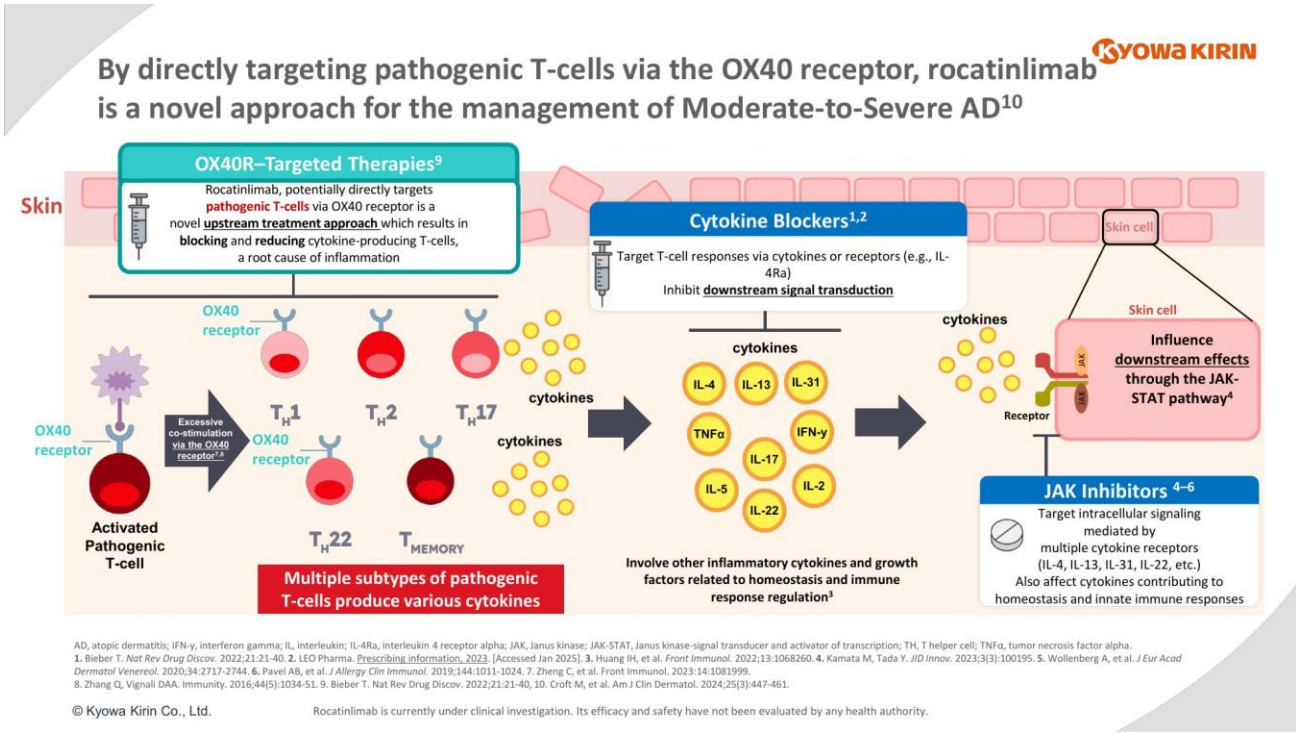
As for rocatinlimab, we announced detailed data from the ROCKET HORIZON study and top-line data from IGNITE, SHUTTLE, and VOYAGER in March of this year for the ROCKET program, a Phase 3 study for atopic dermatitis. We will discuss this content again later.

In H2 of this year, we plan to read out top-line data from the ROCKET ASCEND and ASTRO trials.

Then there is ziftomenib. In April of this year, we submitted an application to the FDA for approval of a single-agent second-line treatment for AML with NPM1 mutations.

In addition, during Q2, we plan to make a conference presentation on the Phase 2 part of the KOMET-001 study used in this application.

And as shown at the bottom, we started Phase 1 trials in April for a new development product, KK3910. This one is an attempt to develop an antibody drug against essential hypertension.

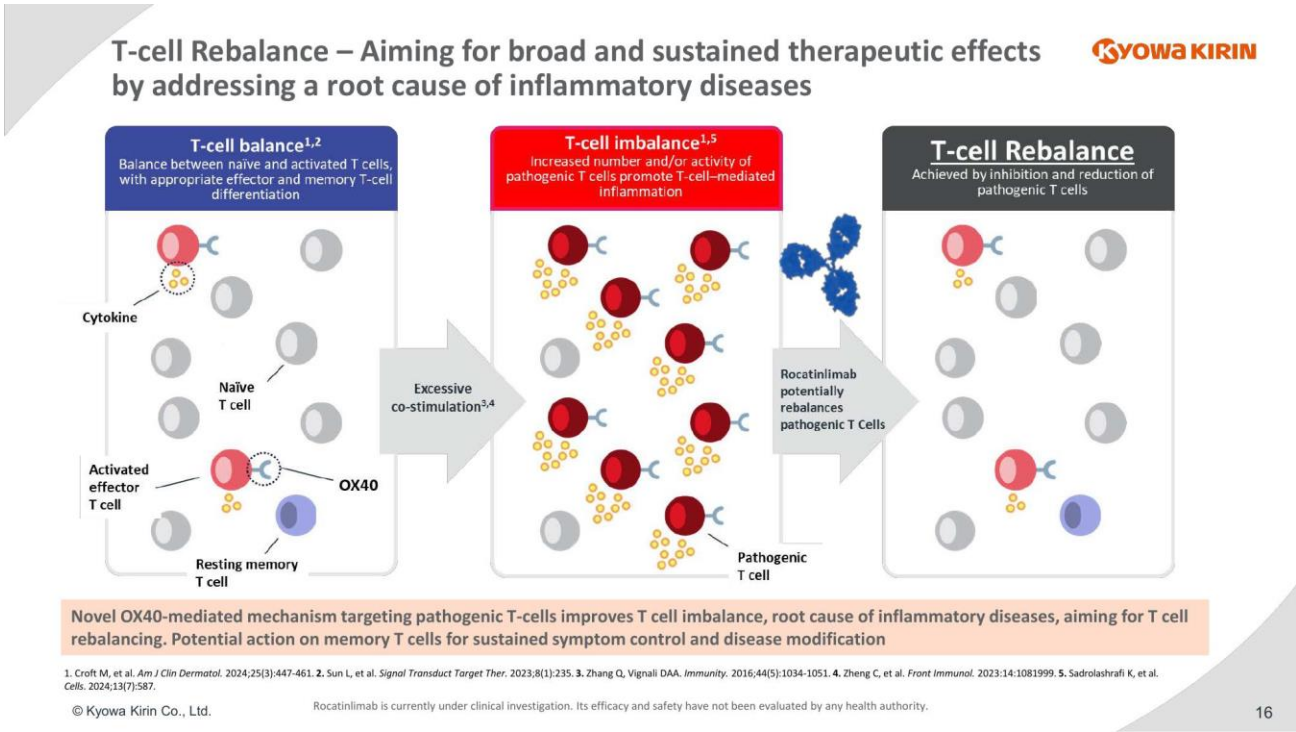


From here, we will reiterate the contents of the information meeting held in March regarding rocatinlimab and introduce the results of each study and our plans for the future.

First, we will explain the mechanism that causes atopic dermatitis and the systemic therapy for atopic dermatitis.

Existing therapies include inhibitors of cytokines resulting from T-cell activation, shown in the center of the slide, and JAK inhibitors that suppress cytokine signaling, shown to the right. These drugs attempt to control the disease similar to extinguishing the fire of inflammation that has already occurred.

Rocatinlimab is expected to act on activated pathogenic T cells, the source of inflammation that is upstream of the disease-triggering mechanism, and control them from starting a fire, so to speak.

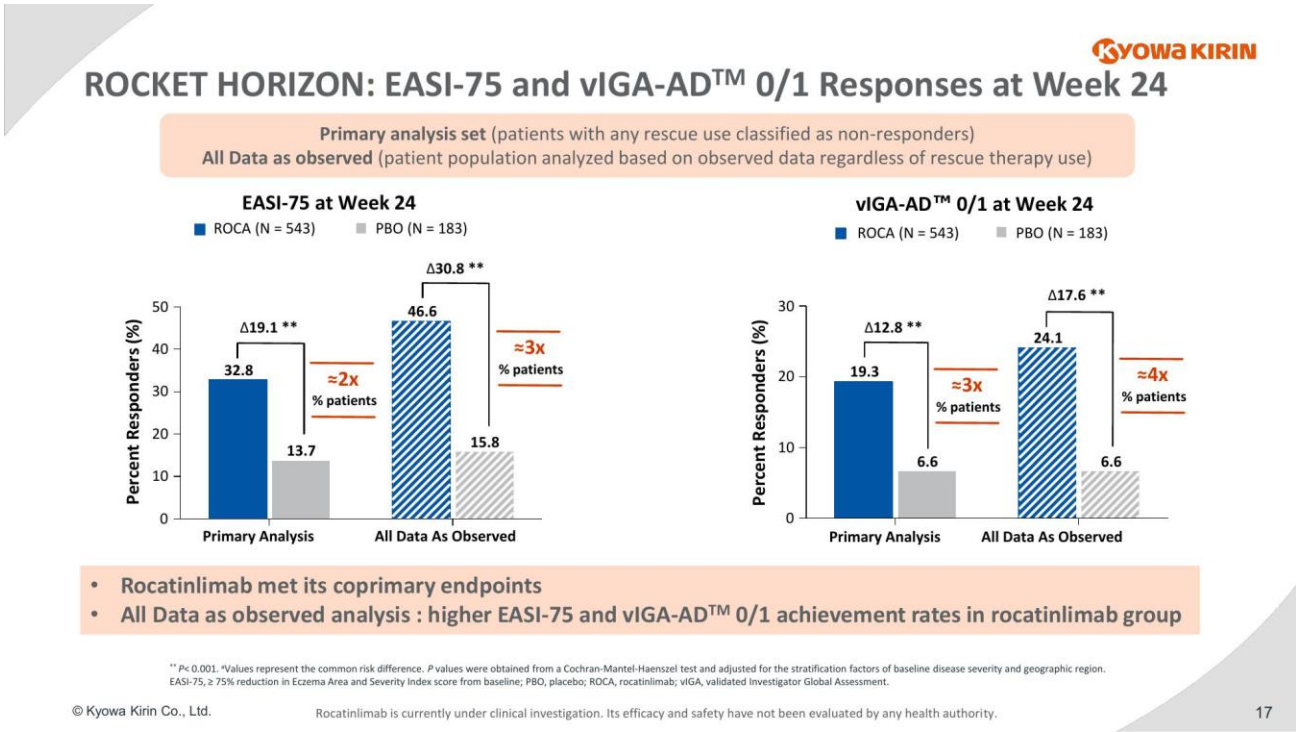


Originally, T cells are normally in a very resting state, as shown in the figure on the left, and some T cells are typically activated for the necessary immune response.

Patients with moderate to severe atopic dermatitis have an abnormal condition with an excess of activated pathogenic T cells that release large amounts of cytokines, as shown in the center figure. We call this T-cell imbalance.

As soon as T cells are activated, they express OX40 on their cell surface. Rocatinlimab is an antibody drug that binds to OX40 and reduces activated T cells. In other words, when rocatinlimab is administered at the T-cell imbalance where pathogenic T cells are abnormally increased, as shown in the middle figure, it can selectively decrease activated pathogenic T cells and normalize the T-cell status, or what we call T-cell rebalancing, as shown in the figure on the right. We believe that we can do this.

Furthermore, once activated, T cells remain as memory T cells and are known to contribute to the recurrence and chronicity of inflammation. However, rocatinlimab can reduce these memory T cells, and therefore, it is expected to have a longer-lasting therapeutic effect compared to existing systemic therapies.



I would like to introduce the progress of Phase 3, the ROCKET program from here.

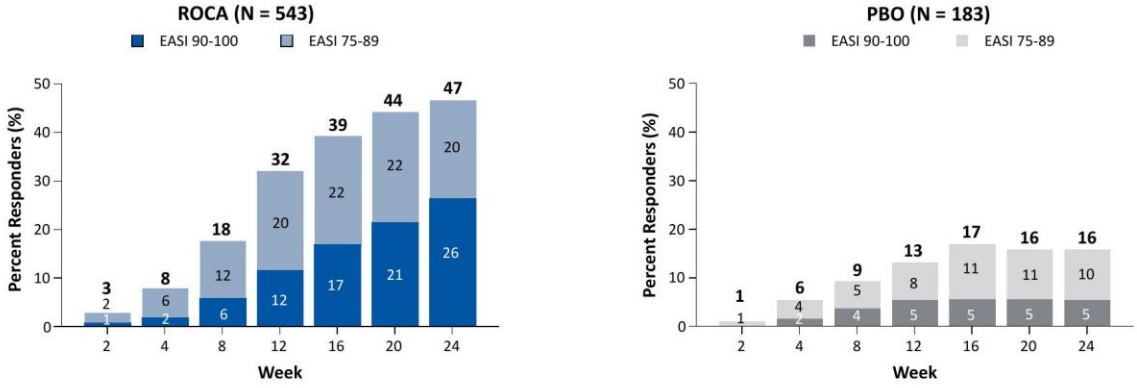
First, we present data from the ROCKET HORIZON study. When we announced last year's top-line data, we reported only the results of the primary analysis, which considered rescue therapy as non-responders, and announced that the primary endpoint had been achieved.

In addition to this, we also present All Data as observed analysis, which analyzes the results regardless of whether rescue treatment was administered.

When rescue treatment is included, rocatinlimab shows a larger difference versus placebo drugs, which may mean that the treatment is also effective for patients undergoing rescue treatment.

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

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



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

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

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

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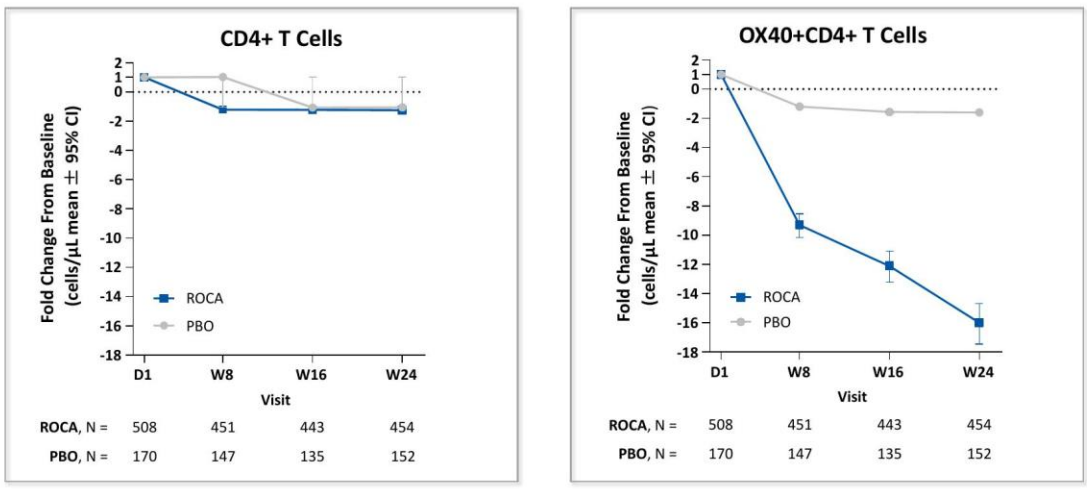
This shows the trend of EASI scores of 75 or higher, using the results of All Data as observed as shown earlier.

As can be seen in the graph on the left, the percentage of patients who achieved an EASI of 90 or higher continued to increase in the rocatinlimab group, suggesting that a plateau had not yet been reached at around 24 weeks. It is hoped that the ASCEND study, which will evaluate long-term efficacy and safety beyond 24 weeks, will further characterize this drug.

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



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

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

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

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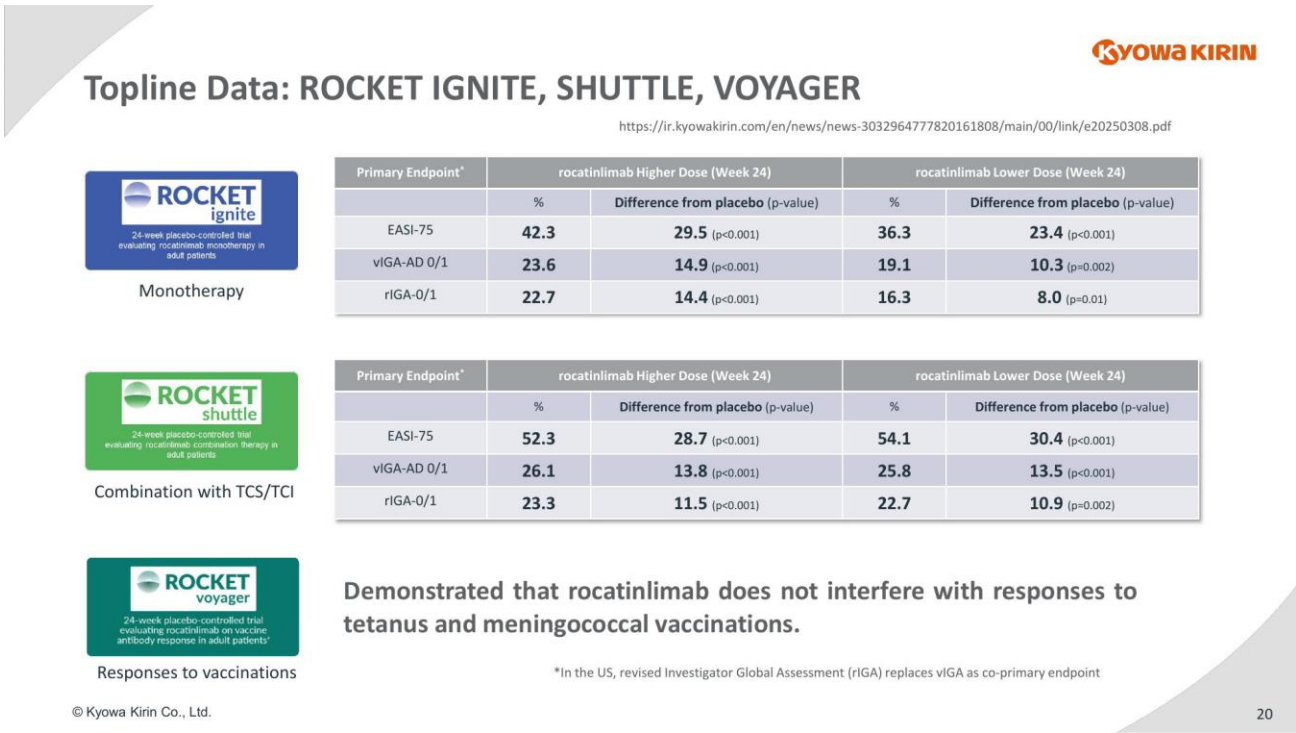
I mentioned that rocatinlimab is expected to reduce pathogenic T cells, and the data here confirm this.

There was no difference in the total number of CD4-positive T cells between the placebo and rocatinlimab groups. However, as the figure on the right shows, the number of activated T cells in this group decreased with each passing day in the rocatinlimab group.



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Topline Data: ROCKET IGNITE, SHUTTLE, VOYAGER

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

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

Monotherapy

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

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

Combination with TCS/TCI

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

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

Responses to vaccinations

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

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

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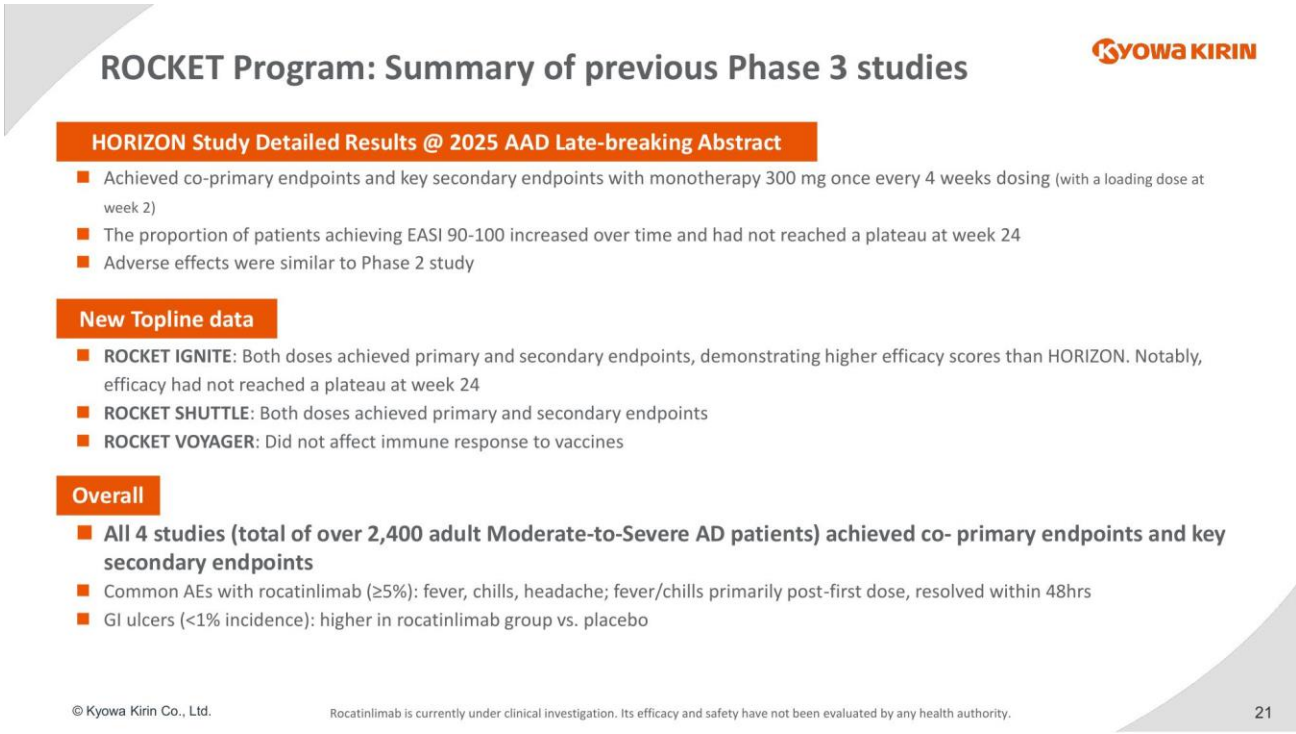
This is a summary of top-line data for the ROCKET IGNITE, SHUTTLE, and VOYAGER studies.

The IGNITE study, which included two doses of the drug as a single agent, and SHUTTLE, which included a topical formulation, both met their primary endpoints as well as key secondary endpoints.

VOYAGER confirms that rocatinlimab does not interfere with the immune acquisition response from vaccination. Rocatinlimab has met its primary endpoint in all four studies presented to date.

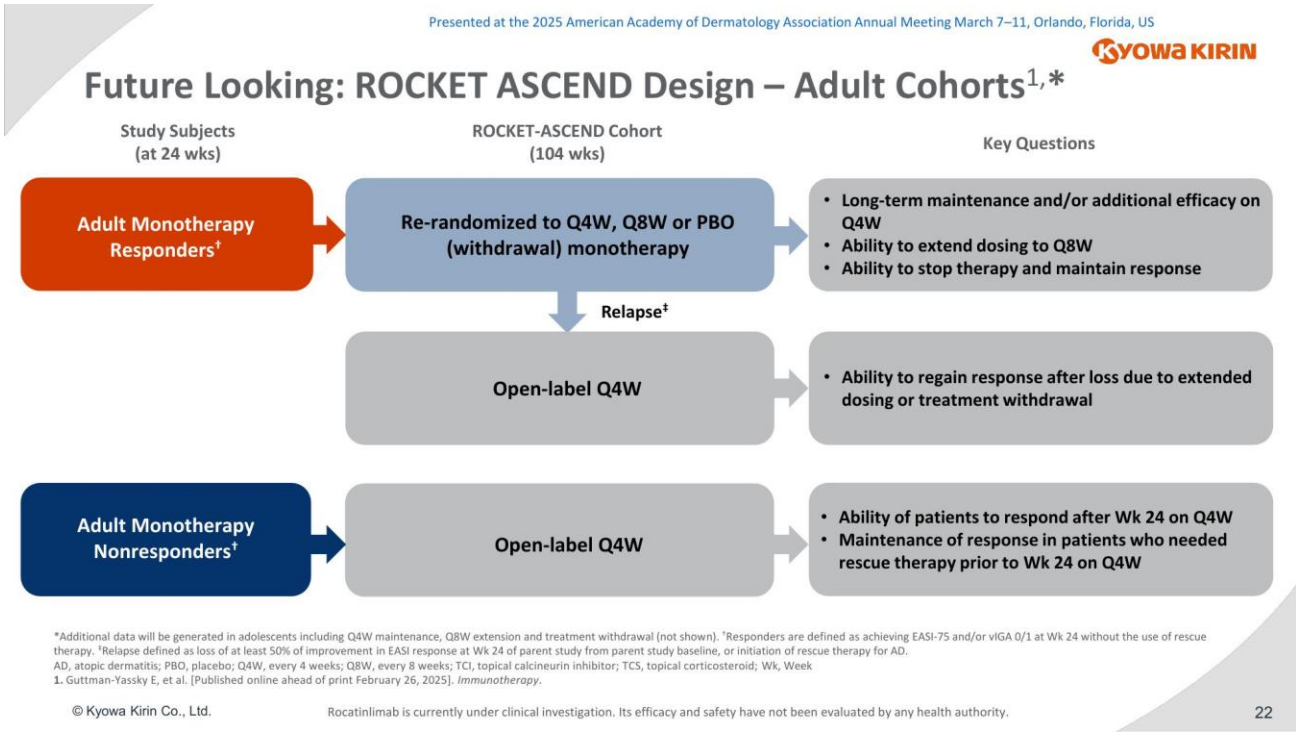


This is a summary of the results to date.

Further analysis of the ROCKET HORIZON data showed that the percentage of patients achieving an EASI score of 90 or higher, indicating extremely high cure, was still increasing at 24 weeks.

The IGNITE, SHUTTLE, and VOYAGER studies have all shown positive results, and all four studies met their primary and secondary endpoints.

Adverse events were observed at a rate of less than 1% for gastrointestinal ulcers. We confirmed that fever and chills observed in Phase 2 trials were mainly seen after the first dose and resolved within 48 hours.



I would like to introduce the ASCEND study briefly.

This study is designed to confirm the long-term efficacy and safety of the drug by continuing to enroll subjects who have already been evaluated for 24 weeks in the parent trial.

This allows us to obtain data on the use of rocatinlimab in different patterns. For example, in patients who received monotherapy with HORIZON or IGNITE, those who were determined to have a monotherapy effect were switched to one of the following groups: continued administration once every four weeks, extended administration once every eight weeks, or placebo. This will provide insights into the continuity of treatment efficacy, the effects of extending the treatment interval, and how long treatment efficacy persists after discontinuation.

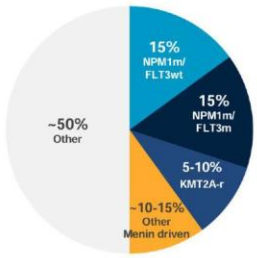
It will also be known if patients who were found to have no response to monotherapy in the previous study will continue treatment, and if a therapeutic effect will appear after 24 weeks.

Given that EASI-90, which I mentioned earlier, was still increasing at 24 weeks for rocatinlimab, I am hopeful that this long-term study will reveal more of rocatinlimab's characteristics and differentiation from other agents.

Updates of ziftomenib

Summary of the product

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



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

Development status

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

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

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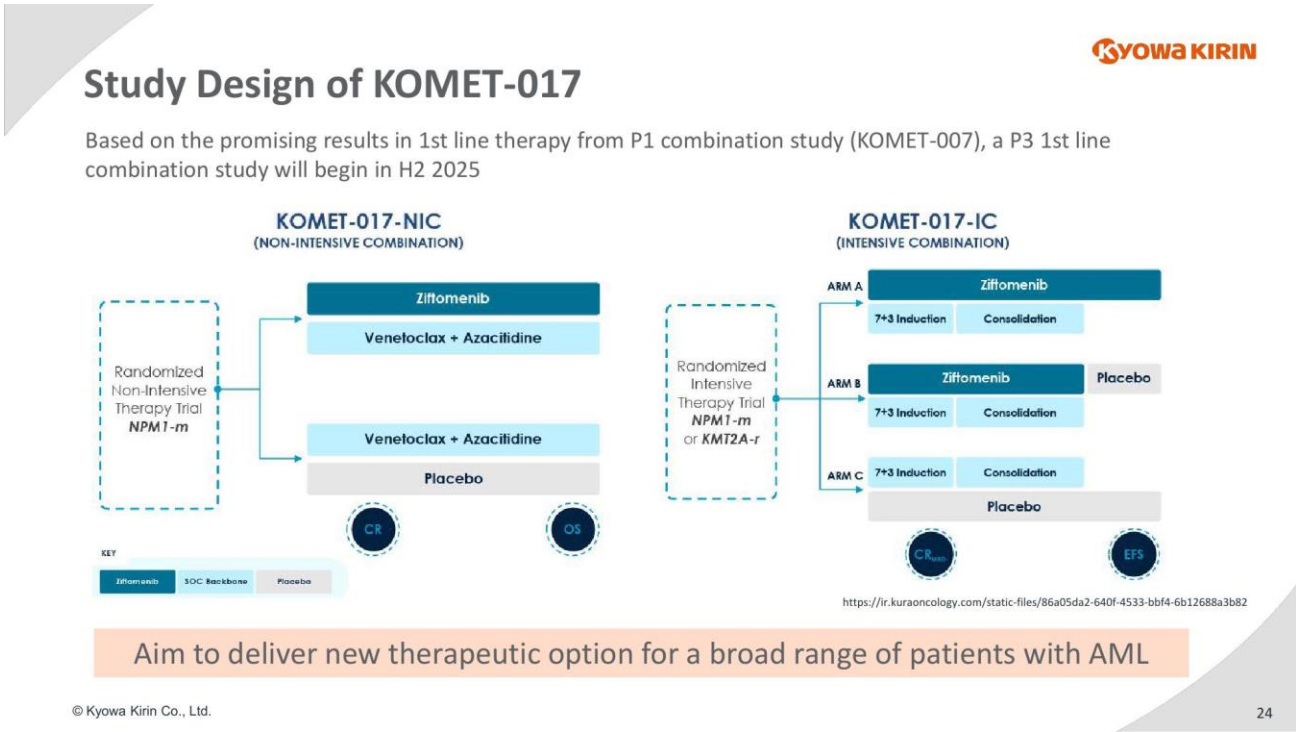
Here is an update on the progress of ziftomenib.

This product is an oral small molecule menin inhibitor, and the target disease is AML with NPM1 mutation or KMT2A reconstruction. In the United States, 20,800 new cases of AML are diagnosed annually, and about half of all AML cases are considered menin-dependent. AML has a high relapse rate, and it is hoped that new treatment methods will emerge.

As we announced in a press release last month, we have submitted a new drug application to the FDA for this product for the treatment of relapsed/refractory adult AML with NPM1 mutations.

We also plan to present the results of the P2 study KOMET-001 used in this application at this year's ASCO.

In H2 of this year, we plan to start a Phase 3 study, KOMET-017, for the first line.

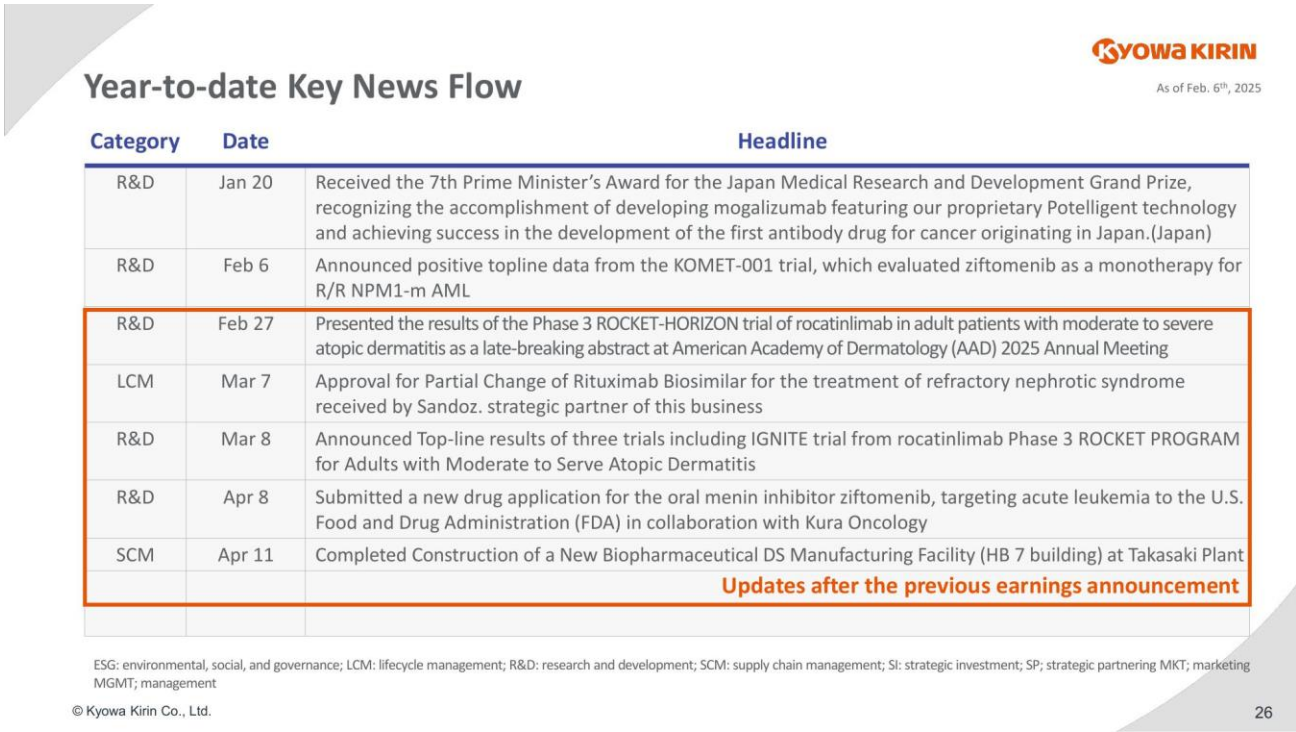


I would like to present the design of the KOMET-017 study that I just mentioned.

This study will be conducted with the aim of obtaining approval based on the positive results obtained in the earlier Phase 1 KOMET-007 study, which was conducted in combination with other drugs for first-line patients.

The study will verify the add-on effect of ziftomenib in these two groups: the NIC, low-intensity chemotherapy combination group, and then the IC, intense chemotherapy combination group.

With the emergence of a new class of therapeutic agents, menin inhibitors, which are expected to contribute significantly to the treatment of AML patients, we will strive to provide new treatment options as quickly as possible through studies such as this one. That's all for the R&D update.



Year-to-date Key News Flow

KYOWA KIRIN

As of Feb. 6th, 2025

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

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

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Fujii: Please go on to Page 26. You can see the news since the beginning of the year here.

We will omit explanations that overlap with the R&D section, but at the beginning of March, we completed construction of the HB7 building, a new biopharmaceutical DS manufacturing facility at our Takasaki Plant.

We will establish a global production system utilizing the Takasaki Plant, which includes the HB7 building, and the Sanford Plant in North Carolina, whose construction was announced last year, while aiming to achieve a global level of technology and human resource circulation. We will accelerate development by completing bio-pharmaceutical manufacturing primarily in-house, from initial development to late-stage development and initial launch. This completes today's presentation.

Question & Answer

Moderator [M]: We would like to start the question-and-answer session.

Yamaguchi [Q]: You didn't explain directly in the financial statements, but I believe your company, including Crysvita, probably manufactures the products in Japan and brings them to the US. I would appreciate it if you could provide any estimates regarding the tariffs in the US. That is my first question.

Kawaguchi [A]: As for your question about the tariffs on pharmaceuticals in the US, as you are aware, there are many uncertainties regarding these tariffs, and it is difficult at this point to estimate the specific impact.

Of course, internally, we are analyzing and estimating various scenarios and possibilities, and considering and discussing how to respond to them. However, given the current uncertain situation, I am afraid there is nothing we can disclose externally.

Yamaguchi [Q]: I assume that with regard to manufacturing, the information about what and where it is produced, as well as where shipped, is the same level of detail, so it is not subject to disclosure, after all.

Kawaguchi [A]: Yes, as you understand, the supply chain for each product, including the manufacturing location and the details of the supply chain, are considered trade secrets, so they are not disclosed.

Yamaguchi [Q]: I see. Thank you very much. The second question is about Crysvita. The actual figures show that demand is strong, but there is quite a large discrepancy between Q4 and Q1.

Regarding your comment, I think it is often the case that it is not clear until later whether the products sold by your company are in stock or not. I have the impression that the inventory increase was quite large, especially in the previous Q4.

Activities that standardize this in a sense, or activities that disclose in advance that, if it occurs, it will be reported as is, have been causing fluctuations in Crysvita's performance, which ultimately affects the appearance of performance, making it look good or bad. This pattern has been repetitive. Are there any measures or disclosures regarding the difference between the actual situation and the reported performance?

Fujii [A]: We are trying to standardize this seasonality as much as possible, but we still have to accept orders from our customers, so we inevitably end up with a large amount of inventory in Q4 to meet these order patterns.

However, as I just explained, actual demand remains strong, and inventory levels for Q4 have already declined significantly. This is supported by the steady release of starting forms, and we believe that future growth will proceed as planned.

Yamaguchi [Q]: So, Q1 will be quite low, as it was last year, but conversely, Q4 may see another increase, and if you look at the full year, all in all, the results are already favorable at the end of the year, so you think you can meet the company forecast, is that right?

Fujii [A]: Yes, as I mentioned earlier, we would like to avoid a sudden increase in sales in Q4, but I think that such seasonality will probably remain at the end of this year.

Yamaguchi [M]: Yes, I understand. That is all from me. Thank you very much.

Wakao [Q]: First, let me check whether the profit level for Q1 is even slightly above your company's plan or not.

I believe that the exchange rate has settled at a lower level for the yen. Therefore, if the top line is generally in line with the current forecast, Q1 results may appear to show a decline in profits, but I think it would not be unreasonable for them to be slightly higher than the forecast. Could you please provide your thoughts on this point?

Since the exchange rate moves relatively quickly, I would like to know if it is possible to achieve your company's full-year plan when the yen appreciates significantly from Q2 onward.

Kawaguchi [A]: I think your question is about the status of Q1 relative to the budget, or rather the plan, within the Company.

As an image, foreign exchange rates were favorable for this Q1 compared to the plan, with the weak yen providing a tailwind, so the results were higher than expected. Excluding foreign exchange, the figures are almost in line with the plan.

Wakao [Q]: I see, I understand. So, you mean there has been some savings.

Kawaguchi [A]: For the amount of the exchange rate impact. However, since we are currently planning at an exchange rate of JPY145, it is difficult to foresee what the future holds.

Wakao [Q]: I see, I understand. Thank you very much. Secondly, I would like to know about rocatinlimab. Sanofi's amlitelimab has shown efficacy in patients with asthma with high levels of eosinophils and neutrophils, and in Phase 3, I think Sanofi will proceed with development for asthma in such patients.

I believe that your company is also developing this rocatinlimab for asthma, but do you think that the subgroup of patients who are likely to benefit would be the same as those with amlitelimab?

Yamashita [A]: We are currently conducting Phase 2 study at our company for asthma, but we are not yet in a position to analyze the data. I am very interested in the results of amlitelimab and would like to see what actions will be taken in the future.

We still do not have enough comparative data on the difference between the ligand antibody and our OX40 antibody, so we will have to wait and see if there is any difference or if the results are similar.

Wakao [Q]: Based on the clinical data you have, the clinical data on amlitelimab, and the respective mechanisms, is it your current opinion that there seems to be no difference in efficacy?

Yamashita [A]: I think we need to look at the data more carefully to understand that. I'm not sure if it's a matter of dosage intervals, challenging dosage settings, or whether the settings are adequate.

At this point, our data looks like that right now, and we understand that the data there is still only up to week 24, so we do not believe that it is yet possible to make a sufficient evaluation.

Wakao [Q]: I understand very well. As a follow-up, regarding the ASCEND results related to rocatinlimab, which week's patient data has been released? I understand that ASCEND is supposed to give the results of the interim analysis with the most recent data, so I was not sure how many weeks of patient data are available, so please tell me if you could.

Yamashita [A]: I am sorry, this is also a situation where we are not yet ready to disclose. However, we believe that the test is progressing well, and that we will obtain sufficient data for the application, analyze the data,

and submit the application. We are going to finalize that and will consider it. I can't disclose that part yet at this time.

Wakao [Q]: That said, based on the initial data from ASCEND, can we expect to see data on the duration of administration that will allow us to determine whether the effects increase with longer administration, as you mentioned earlier?

Yamashita [A]: Yes, after the trial is completed and the data is ready to be read out, we will consider what kind of drug proposal we can actually make based on the data, and then we will proceed with the application.

At this point, what kind of data is available, and to what extent can we disclose it -- and we would like to prioritize submitting the application as soon as possible -- so we will do our best to ensure that everyone understands the situation correctly, but we are currently working hard to disclose as much information as possible.

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

Muraoka [Q]: I'm also just checking in with you about ASCEND.

You said that what will come out in H2 is an interim analysis and that you cannot give details now, but is there a possibility that the application in this interim analysis could be a very aggressive or optimistic scenario?

In other words, if we wait until the full analysis, the clinicaltrials.gov says May 2027, but should we consider the risky possibility that we may have to wait that long? I would appreciate your insight on that.

Yamashita [A]: As for how we will submit this application, we will look at the data from ASCEND and make a firm decision.

The trials that have already been conducted have been successful, such as at the 24-week Q4W that we have already introduced, so I think we are seeing some level of approval without having to wait for the ASCEND trial.

In the ASCEND study, I think we need to consider how to add longer-term verification, or how much to add in terms of usage, and so on. Also, although it is unclear at this point, there is a possibility that we may negotiate to submit additional data during the review process.

We would like to do our best to achieve both goals: to obtain approval as soon as possible, and to have the value of the drug evaluated as high as possible.

Muraoka [Q]: Thank you. By the way, the clinicaltrials.gov shows that the primary completion is June 25th of this year; could it be in time for the upcoming Q2, or just the headline?

Yamashita [A]: No, the lead-out is now scheduled in H2. Toward completion, it will take time from there, so I hope you would understand.

Muraoka [Q]: I see. And I have a chance to ask two questions, so what is the concept for Q2? The figures for Q1 showed that Crysvita performed poorly due to a rebound effect, Poteligeo performed poorly due to inventory adjustments, and equity in earnings of affiliates performed poorly because sales happened to be low. I think all of this is going to come back positively in Q2.

The expense digestion may indeed even out, but in its own way, can we expect a positive and very solid return in Q2 and, say, six months cumulative, can we expect momentum to return to almost half of the budgeted

JPY80 billion in core operating income? Or no, no, we should think that it won't go that far. Could you tell us a little bit about how much of a positive Q2 rebound should be produced?

Kawaguchi [A]: In terms of rebound, for example, regarding Crysvita, the rebound decline in shipments from the previous year occurred in Q1, so the rebound in Q2 is not structured in such a way.

Basically, if we proceed along the lines of what we are planning for Q2, we will reach the projections we have commited for the year. As I mentioned earlier, regarding Q1, the figures are surprisingly low compared to the previous year, as there is a noticeable decrease in profit; but compared to the plan, we are making good progress according to the Company's plan. In that sense, I think Q2 will go ahead as planned.

So, regarding H1 overall, as I mentioned earlier in terms of sales progress, we tend to see growth in the top line toward H2, so it does not mean necessarily be exactly half. Does that answer your question?

Muraoka [Q]: I see. If R&D expenses have leveled off, it means that the next three months will also see a certain amount of YoY spending, so the six-month total is still not as good as the YoY comparison, but you will still manage to reach JPY80 billion for the year, is what you mean.

Kawaguchi [A]: Yes, that's what we are aiming for, and we would like to control the situation well so that we can meet expectations.

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

Moderator [M]: Thank you very much for your questions, Mr. Muraoka. The next question is from Mr. Hashiguchi of Daiwa Securities. Mr. Hashiguchi, please ask questions.

Hashiguchi [Q]: The first is about seasonality. In comparison to the previous quarter, I understand your explanation of seasonality, but in comparison to sales in the same quarter of last year, I think the impact of seasonality is greater than last year.

Crysvita is growing by only 1% in North America in local currency terms, and Poteligeo is growing by 5%. How should we understand the reasons for this significantly increased seasonality compared to the previous year?

Fujii [A]: This is due to the stockpiling of specialty pharmacy inventory every year and the insurance changeover procedures at the beginning of the year. These two elements, I believe these two factors have a major impact on seasonality.

However, we have not yet been able to clearly identify the reason why it was slightly higher last year. At this point, we can only speculate that it may have been due to large order patterns. The point is that we have not been able to determine the cause of what clearly and significantly manifested at the end of last year.

Hashiguchi [Q]: Thank you very much. The other question is about research and development expenses. You mentioned that you changed the accounting method from invoice-based to activity-based, but could you disclose the amount of the impact?

Kawaguchi [A]: Thank you very much. As you mentioned, we used to record expenses based on invoices, but this year we introduced a project portfolio management system for research and development, and now that it has become operational, we have been able to estimate and record research and development project expenses, mainly using activity-based costing. This allows us to record expenses more appropriately in line with the progress of research activities.

In that case, rather than being based on invoices, development costs are recorded proportionally according to the progress of clinical trials, for example. Therefore, if the content of activities does not change significantly from quarter to quarter, the costs for each quarter will level off.

It is extremely difficult to calculate the impact of this, but in the past, for example, in Q1 of last year, we estimated that 25% of the progress rate was attributable to activity-based costing. Since this was 23% of progress last year, we estimate that about 2% was due to the impact of activity-based costing.

Then, with 27% progress, if the progress rate is about 2% higher, this is due to another factor, namely the Phase 3 trial for KHK4083, rocatinlimab. Out of eight trials, seven have already reached their peak, so the R&D expenses for KHK4083 are expected to gradually decrease toward the latter half. This combination results in a progress rate of 27%, and we hope this explanation helps clarify the situation.

Hashiguchi [Q]: Thank you. Just one last point, if we continue to follow that trend, which is a slight decrease each quarter, is it safe to assume that, on a fiscal year basis, research and development expenses will decrease from the current fiscal year to the next fiscal year? Or, considering that ziftomenib's activity and rocatinlimab are also associated with the development for asthma, is that not the case? Or how should we interpret this? I am concerned that this may sound like an impatient-sounding question.

Kawaguchi [A]: That is correct for R&D expenses for rocatinlimab for atopic dermatitis, and they will gradually decrease from the latter half of the fiscal year this year, so in 2026, the expenses will be less than this year.

Regarding ziftomenib, I am sure you should understand that the global R&D expenses will be borne by Kura for four years, so this one will not affect the R&D expenses.

On the other hand, I hope you can consider next year as a combination of the expansion of rocatinlimab’s indications for asthma and a slight increase in trials in areas like PN.

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

Ueda [Q]: I would like to ask, the first question from me is, if you could tell me more about the progress of SG&A expenses. I understand that 25% is on track and in line with the plan, but in the past few years, the progress in Q1 was around 22% to 24%, so I have the impression that the progress in this quarter is high, although I wonder if there are some foreign exchange effects.

I am also concerned that if preparations for the launch of ziftomenib and rocatinlimab increase in H2 of the year, this will also exceed the amount of R&D expenses. I was wondering if you could give us an idea of the general trend of the quarter, or rather, an image of the areas that you mentioned earlier in the R&D expenses section.

Kawaguchi [A]: Thank you for your question. As you mentioned, the 25% figure was probably 24% last year, so we think it is a margin of error, or about a mere 1% difference. As you mentioned, there is a tendency for ziftomenib's launch preparation costs to increase a little in H2.

However, I can't talk about it right now, but we have factored into our plan some expenses that will be slightly lower in H2 of the year, and in that sense, I hope you understand that we are making progress within our plan. In any case, I hope you understand that the SG&A expenses for Q1 are now accruing just in line with the plan.

Ueda [Q]: I understand. Thank you very much. The second point is the tariffs mentioned at the beginning of the question-and-answer session, and you mentioned that you are currently considering how to respond. The response your company is currently considering is to increase inventory, or to transfer manufacturing processes, such as production bases and export timing. If you have any specific point to make in this area, please share it with us.

Kawaguchi [A]: I think that the inventory buildup you mentioned is a short-term measure, and that the question of what to do about the manufacturing base is a long-term measure. Internally, we also, of course, consider all possibilities and scenarios, and of course discuss everything, such as long-term measures, short-term measures, and whether we should really take them.

However, there is nothing we can say at this point, including when and in what form the so-called Trump tariffs will actually take effect, and whether this is a truly permanent system, and we are still having many internal discussions. We are still in the process of discussing this internally.

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

Sakai [Q]: Regarding the current point, regarding the country of origin or production site of Crysvita, in the FDA's Full Prescribing Information, equivalent to the package insert in Japan, the last section states "Manufactured by Ultragenyx Pharmaceutical, manufactured in Novato, California, US, License Number 2040." How should we interpret this information?

Does this mean that your company is licensing out, and Ultragenyx is producing it locally? Has your company talked about this mechanism, including some form of production disclosure, when you partnered with Ultragenyx in the past? Let me check about this point.

Kawaguchi [A]: The information you have just given me is the first time I have heard of it, so I am afraid I cannot give you an accurate answer right now. The IR team will check it and reply to you; would that be all right for you?

Sakai [Q]: So, you and Ultragenyx have not disclosed any production arrangements in the past? I'm not asking about the content, but whether there was or was not, so you are correct that there was no disclosure?

Kawaguchi [A]: Yes, no disclosure, of course. I don't think we do that kind of disclosure at all.

Sakai [Q]: I understand. I'll wait for your information later, I guess.

Kawaguchi [A]: In any case, I think that the country of origin, the so-called country of origin in terms of tariffs, has almost nothing to do with what you just mentioned.

Sakai [Q]: You said it is irrelevant.

Kawaguchi [A]: I have a feeling that it is not very relevant, but I don't have the exact information right now, so in any case, I would like to refrain from giving an answer now.

Sakai [Q]: I understand. Then I will wait for your answer for a moment. Then I would like to ask Mr. Yamashita about this T-cell count on page 19. I understand that you are saying that this is indeed one of the features of this OX40 in terms of T-cell rebalancing.

The table on the right. The T cells, CD4, and OX4 of patients who received the so-called rocatinlimab, are decreasing as shown in the blue graph. I think this will be the result. What is the meaning of this, this clinical -- do you call this a clinical symptom? And will you be making any references to the data in the future? Or whether it is possible to reflect this in the label in some way. The simple question is, there was an effect, so what happens next?

Yamashita [A]: In explaining the mechanism of the action of rocatinlimab, we have decided to disclose this data to demonstrate that it can reduce pathogenic T cells.

In reality, we are investigating various biomarkers in conjunction with clinical trials, and by including these, we believe that we will be able to demonstrate how and which drugs generally affect the immune state in a so-called pathological condition.

However, in order to obtain approval for efficacy through assessment, the clinical efficacy in humans is very important, so we would like to use this information as supportive information.

I also believe that this data is very important for understanding what rocatinlimab is, including for specialists.

Sakai [Q]: I understand. So, for the time being, this is just data, but you have not yet reached the point of improvement of clinical symptoms, right?

Yamashita [A]: This is the HORIZON study, which shows clinical trial data over a period of 24 weeks, and during that time, there was a gradual decrease in cells thought to be pathogenic T cells. As with the EASI 90 data mentioned earlier, it is not yet clear from the data available whether this decline has bottomed out, or whether it will continue to fall further. I wonder if this might be related to increasing clinical effectiveness.

I think it is somewhat the opposite of the graph I just showed you, so I think it can be interpreted as a phenomenon occurring in parallel with the clinical effects.

Sakai [Q]: I understand. I'm sorry to ask a little bit more. Were these results captured by blood tests?

Yamashita [A]: I believe so. Probably from peripheral blood, I guess. Sorry.

Sakai [Q]: Peripheral blood, not biopsy.

Yamashita [A]: No.

Sakai [M]: I understand. Thank you very much. We will continue to pay attention to this issue. Thank you.

Kawaguchi [A]: Just some information we found out regarding the earlier question. The name of the company in charge of manufacturing is listed on the package insert in the US, rather than the location of the factory where the product is actually manufactured. Therefore, the name of the company or organization responsible for the manufacture of the product is shown on the label, that seems to be the local system.

Therefore, as I mentioned earlier, we have received information that this may be different from the concept of country of origin in tariffs. I hope you understand that the name of the company, when the approval is obtained, will be listed.

Wada [Q]: Thank you very much. I would like to ask something related to Mr. Sakai's question. Is there such a thing as a PD marker to distinguish responders and non-responders? Would that be this OX40 or CD40 cell?

I was wondering if it would be easier to use your rocatinlimab if you could identify patients who respond well and those who don't at a certain early stage in clinical practice, since it is quite slow to show efficacy and EASI 75. Could you tell us if you have any ideas in that area, even if they are more in the research phase?

Yamashita [A]: There may be various early markers. At the research stage, I think there are probably markers that appear at a very early stage.

However, when it comes to whether this directly leads to therapeutic effects, treatment involves factors such as how long a drug continues to exert its effects, where it is delivered, and whether the necessary concentration reaches the necessary location. I think it is difficult to predict all of these factors using a single marker.

However, we believe that the idea you mentioned is a point that we should consider carefully. We will continue to examine whether there are patients who would benefit from these markers, maybe with a combination as mentioned earlier, and those who would not, and if so, we will need to continue to identify them. Thank you for your question.

Wada [Q]: Yes, thank you very much. The other point is how to administer it in an actual clinical setting. The ASCEND study is basically a trial in which patients from HORIZON and IGNITE were recruited before the ASCEND trial, and so on.

Therefore, based on the current clinical design, would the basic regimen be to administer once every 4 weeks up to week 24, followed by either maintenance therapy once every 8 weeks or discontinuation of treatment?

Yamashita [A]: I think that is generally a good understanding. We are asking people to participate in the study in this way from the places where they are already doing it. As mentioned earlier, there was also talk about the interim analysis of the ASCEND trial, but this trial is not one where all subjects start at the same time. Instead, patients are gradually enrolled as they complete the previous trial.

Therefore, those who participated in the parent trial at an early stage will reach 24 weeks early and participate in this trial at an early stage, and ultimately, those who have been administered the drug for a long period of time, or those who were the last patients in the parent trial, will have the shortest period of participation in this trial, resulting in data from that sort of groups.

In this context, we will analyze various statistical aspects. Based on the parent study, we will examine the newly randomized data obtained, and consider where significant differences can be observed in terms of efficacy and whether this can be verified.

Wada [Q]: Another intention of the current question is whether the group of once-in-eight-weeks dosing is set from the beginning. With amlitelimab, it's set up from the beginning to be given once every 12 weeks, as a group. Is there such a group? Are there patients who go from placebo to, say, ASCEND every eight weeks?

Yamashita [A]: I would have to check a little bit, but I think there is. There is, isn’t there? You are asking if someone who was receiving placebo at HORIZON would suddenly go to a group with once every eight weeks.

Wada [A]: Yes, you are right.

Yamashita [A]: I need a little confirmation.

Wada [M]: Okay. Thank you very much. That is all. Thank you very much.

Muraoka [Q]: There are too many things in the tariff that you can't talk about from a little while ago. I would like to know from the published information that I have, including confirmation, that this is true here.

Your Takasaki plant began commercial production in 2019, and I thought it was built specifically for Crysvita, as it was formerly owned by Kirin. So, I understood that Crysvita was manufactured in Japan and shipped overseas.

In addition, on page 37 of today's materials, on the page about the economic conditions for Crysvita, there is a section that has been there for a long time. In the fourth line from the top, it says that the product supply price is 35% of sales up to the point where it was in alliance with the US, and 30% thereafter. This has been written there for a long time.

In other words, either the Crysvita API or the final product made in Japan is shipped to the US with a transfer price of 30% of sales. I understand that you are almost saying that that is how you communicate with your US subsidiary, but please tell me how accurate this understanding is or is not.

Kawaguchi [A]: As for the supply chain, as I mentioned earlier, I would like to ask that it not be disclosed. One more point: Regarding the product supply price stated in the economic terms of the collaboration with Ultragenyx, based on the assumption of profit sharing, we will consider the product supply price and cost of sales to be 35%, and divide the remaining gross profit equally between two parties.

This is not the actual cost of the product, nor is it the product supply price we use for transfer pricing with our US subsidiary. Please understand that this is a prerequisite to agreeing on economic terms with Ultragenyx.

Muraoka [Q]: I see. Thank you very much. By the way, is it higher or lower than 30%?

Kawaguchi [A]: Please let that be part of nondisclosure.

Muraoka [Q]: I see. Thank you very much. And one more thing, sorry, I'm talking about rocatinlimab. When I attended the information session in March, I thought that if you took the switch study from dupilumab, the significance of rocatinlimab would become very clear. I don't think you are doing anything like a switching study at the moment, but I wonder if you are considering this.

Yamashita [A]: There is no study in which we have set up such a protocol for switching. However, among those who have entered this study, many have a history of prior treatment and have undergone systemic treatment, yet still have insufficient systemic treatment.

Among them, this rocatinlimab has shown effectiveness, and it is a trial in which many patients are participating. If we analyze such data, we will be able to obtain data and information, such as the effect of this drug on patients with such a background of previous treatment.

First, I think that we can promote various things to a certain extent in such areas, and we will also consider whether testing is necessary, including such things.

Muraoka [Q]: Thank you. In other words, at this point, you are saying that you are not thinking about it, you have no plans, and as far as switching studies are concerned, you are not thinking about switching as the main focus of the study, is that correct?

Yamashita [A]: Yes, we do not make such disclosures.

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

Moderator [M]: Thank you very much for your questions, Mr. Muraoka.

This concludes the online presentation on the financial results for Q1 of the fiscal year ending December 31, 2025. The audio of today's online meeting will be available on demand on our IR website.

A transcript including the question-and-answer session will also be available for your review of the content. Thank you very much for your participation today. Thank you for your continued support of Kyowa Kirin.

[END]