Kyowa Kirin Co., Ltd.

Q3 Financial Results Briefing for the Fiscal Year Ending December 2025

October 30, 2025

Event Summary

[Event Name]	Q3 Financial Results Briefing for the Fiscal Year Ending December 2025	
[Date]	October 30, 2025	
[Number of Speakers]	3	
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer
	Takeyoshi Yamashita	Director, Executive Vice President and Chief Medical Officer
	Yasuo Fujii	Managing Executive Officer and Chief Strategy Officer

Presentation

Moderator: Thank you very much for joining us today for the online presentation of Kyowa Kirin Co., Ltd.'s financial results for Q3 of the fiscal year ending December 31, 2025.

Before we begin the briefing, let me remind you of a couple of things.

Please note that we will keep the names and company names of the participants in our company for a certain period of time as a list of participants.

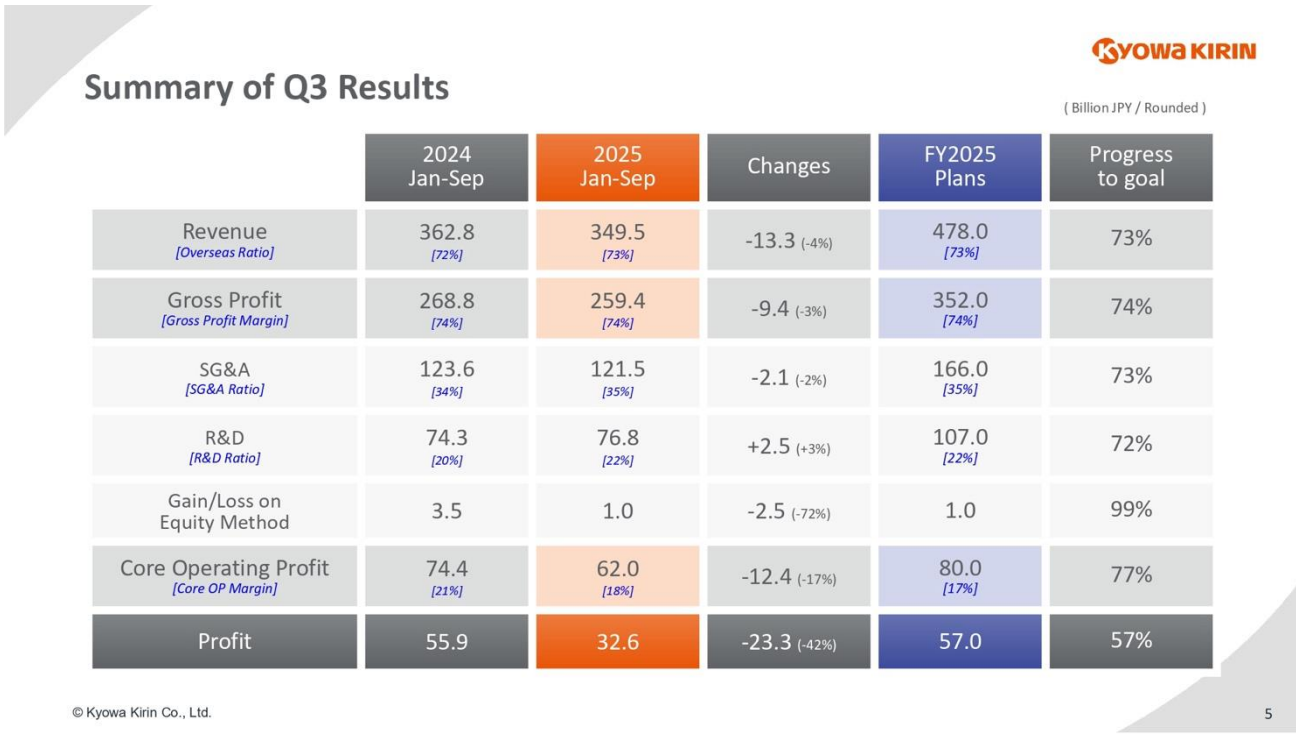
Please note that the content of this presentation will be available as a video and a transcript on our website.

Please be aware that the information presented today contains forward-looking statements that are subject to uncertainty due to various risks.

Participating in today's presentation and Q&A session are Takeyoshi Yamashita, Director, Executive Vice President and Chief Medical Officer; Motohiko Kawaguchi, Managing Executive Officer and Chief Financial Officer; and Yasuo Fujii, Managing Executive Officer and Chief Strategy Officer.

Today's online meeting will last up to 70 minutes. First, we will explain the overall financial results and then take your questions. Please download the document from our IR website.

Mr. Kawaguchi will now begin with an overview of the financial results.



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Summary of Q3 Results

(Billion JPY / Rounded)

	2024 Jan-Sep	2025 Jan-Sep	Changes	FY2025 Plans	Progress to goal
Revenue *[Overseas Ratio]*	362.8 *[72%]*	349.5 *[73%]*	-13.3 (-4%)	478.0 *[73%]*	73%
Gross Profit *[Gross Profit Margin]*	268.8 *[74%]*	259.4 *[74%]*	-9.4 (-3%)	352.0 *[74%]*	74%
SG&A *[SG&A Ratio]*	123.6 *[34%]*	121.5 *[35%]*	-2.1 (-2%)	166.0 *[35%]*	73%
R&D *[R&D Ratio]*	74.3 *[20%]*	76.8 *[22%]*	+2.5 (+3%)	107.0 *[22%]*	72%
Gain/Loss on Equity Method	3.5	1.0	-2.5 (-72%)	1.0	99%
Core Operating Profit *[Core OP Margin]*	74.4 *[21%]*	62.0 *[18%]*	-12.4 (-17%)	80.0 *[17%]*	77%
Profit	55.9	32.6	-23.3 (-42%)	57.0	57%

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Kawaguchi: I will explain the performance summary for Q3 of FY2025.

Please see page five.

Revenue was JPY349.5 billion, down JPY13.3 billion, or 4%, from the same period last year. Core operating profit was JPY62 billion, down JPY12.4 billion, or 17%, and profit for the quarter was JPY32.6 billion, down JPY23.3 billion, or 42%.

Revenue decreased 4% due to the impact of business restructuring in APAC, the impact of the transfer of three brand licenses in EMEA in the previous year, and the impact of NHI price revision in Japan, despite the growth of global strategic products mainly in North America and EMEA.

Core operating profit declined 17% due to lower gross profit, higher R&D expenses, and lower gain on equity method.

Profit for the quarter decreased by 42%, mainly due to the impact of a gain on the sale of a Chinese subsidiary and a gain on the sale of fixed assets in the same period of the previous year.

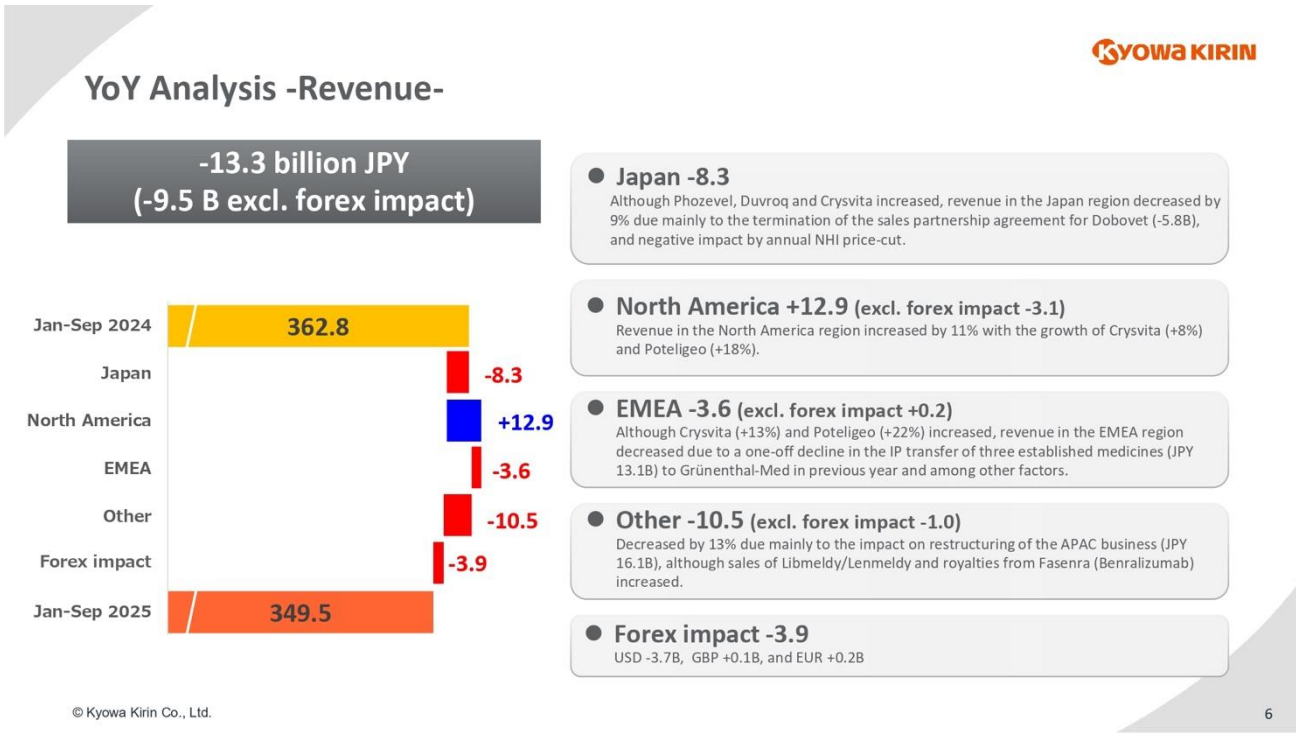
Progress against the full-year forecast is 73% for revenue and 74% for gross profit. This rate of progress is in line with plans, as revenue tends to grow toward the latter half of the fiscal year as in past years.

Selling, general and administrative expenses and R&D expenses progressed slightly below plan at 73% and 72%, respectively.

As a result of these, core operating profit is steadily progressing at 77%.

On the other hand, the progress rate of profit for the quarter is 57%. This was mainly because we recorded a special retirement payment due to the introduction of a special voluntary retirement program.

Although progress is lagging behind the full-year plan, we hope to bring the result closer to the full-year forecast through the upfront payment from Boehringer Ingelheim, as announced today, and an upturn in core operating profit due to the recent yen depreciation.



Page six provides a YoY analysis of revenue by region.

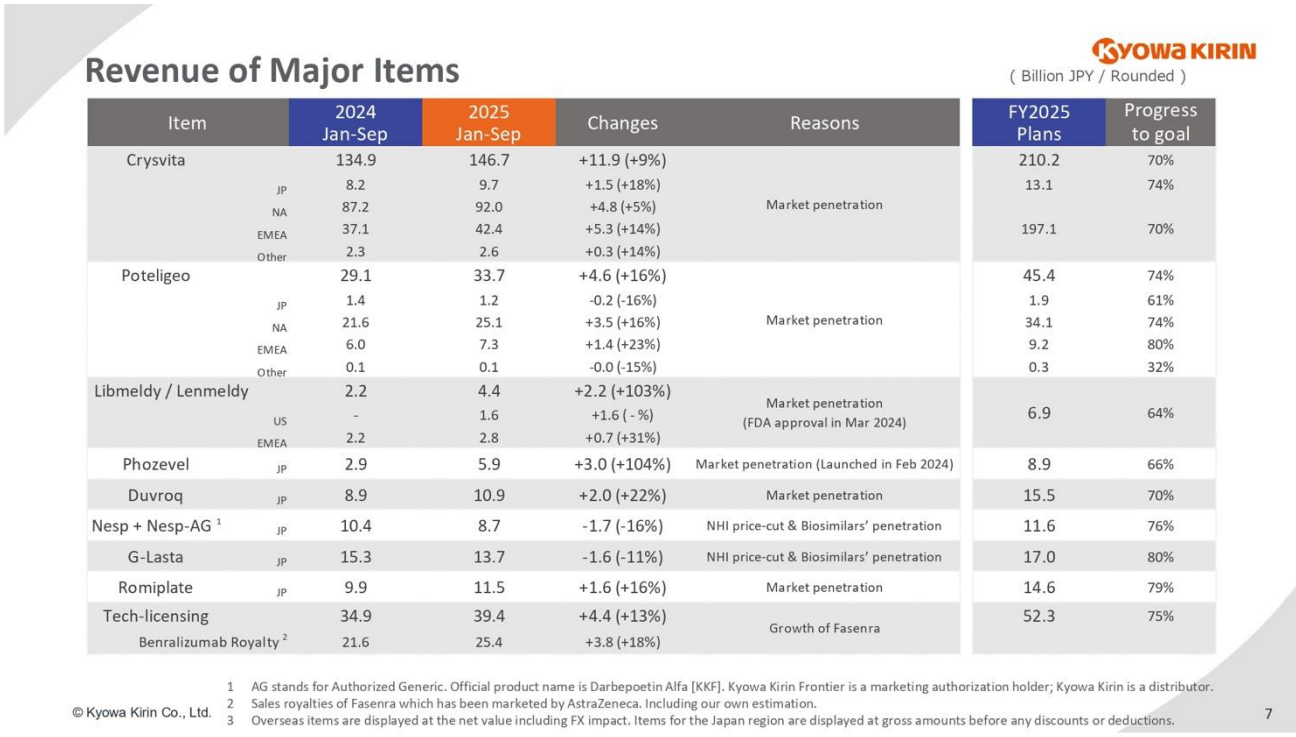
In Japan, revenue from Phozevel, Duvroq and Crysvita are growing, while revenue from Dobovet, whose sales collaboration agreement ended last December, declined by JPY5.8 billion. In addition, revenue in the Japan region declined 9%, mainly due to the impact of NHI price revisions.

In North America, revenue increased by JPY12.9 billion, or 11%, in real terms excluding the foreign exchange effect of JPY3.1 billion. Crysvita and Poteligeo grew their revenue by 8% and 18%, respectively, in local currency terms.

In EMEA, revenue declined JPY3.6 billion in real terms. Crysvita and Poteligeo continue to grow with revenue growth of 13% and 22%, respectively. In July, there was a JPY6.1 billion gain from the transfer of a license for one established medicine to a joint venture with Grünenthal. However, EMEA as a region as a whole saw a 5% decline in revenue, as the region received JPY13.1 billion from the transfer of licenses for three brands in the same period of the previous year.

Other includes sales of established medicines and other products in the region, which until the previous year had been classified as APAC. In addition to the increase in royalties from Fasenra, revenue from Libmeldy/Lenmeldy, a hematopoietic stem cell and gene therapy, began to be recorded in the US, resulting in a significant increase in revenue. However, revenue in the other region declined 13% due to a decrease in revenue resulting from the restructuring of the APAC region.

The foreign exchange impact on revenue was a negative JPY3.9 billion.



Revenue of Major Items

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(Billion JPY / Rounded)

Item		2024 Jan-Sep	2025 Jan-Sep	Changes	Reasons	FY2025 Plans	Progress to goal
Crysvita		134.9	146.7	+11.9 (+9%)		210.2	70%
	JP	8.2	9.7	+1.5 (+18%)		13.1	74%
	NA	87.2	92.0	+4.8 (+5%)	Market penetration		
	EMEA	37.1	42.4	+5.3 (+14%)		197.1	70%
	Other	2.3	2.6	+0.3 (+14%)			
Poteligeo		29.1	33.7	+4.6 (+16%)		45.4	74%
	JP	1.4	1.2	-0.2 (-16%)		1.9	61%
	NA	21.6	25.1	+3.5 (+16%)	Market penetration	34.1	74%
	EMEA	6.0	7.3	+1.4 (+23%)		9.2	80%
	Other	0.1	0.1	-0.0 (-15%)		0.3	32%
Libmeldy / Lenmeldy		2.2	4.4	+2.2 (+103%)		6.9	64%
	US	-	1.6	+1.6 (- %)	Market penetration (FDA approval in Mar 2024)		
	EMEA	2.2	2.8	+0.7 (+31%)			
Phozevel	JP	2.9	5.9	+3.0 (+104%)	Market penetration (Launched in Feb 2024)	8.9	66%
Duvroq	JP	8.9	10.9	+2.0 (+22%)	Market penetration	15.5	70%
Nesp + Nesp-AG [1]	JP	10.4	8.7	-1.7 (-16%)	NHI price-cut & Biosimilars' penetration	11.6	76%
G-Lasta	JP	15.3	13.7	-1.6 (-11%)	NHI price-cut & Biosimilars' penetration	17.0	80%
Romiplate	JP	9.9	11.5	+1.6 (+16%)	Market penetration	14.6	79%
Tech-licensing		34.9	39.4	+4.4 (+13%)	Growth of Fasenra	52.3	75%
Benralizumab Royalty [2]		21.6	25.4	+3.8 (+18%)			

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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Page seven shows revenue by major product. The figures on this page include foreign exchange effects.

Crysvita's revenue increased JPY11.9 billion, or 9%, YoY and continues to grow in North America, EMEA, and Japan.

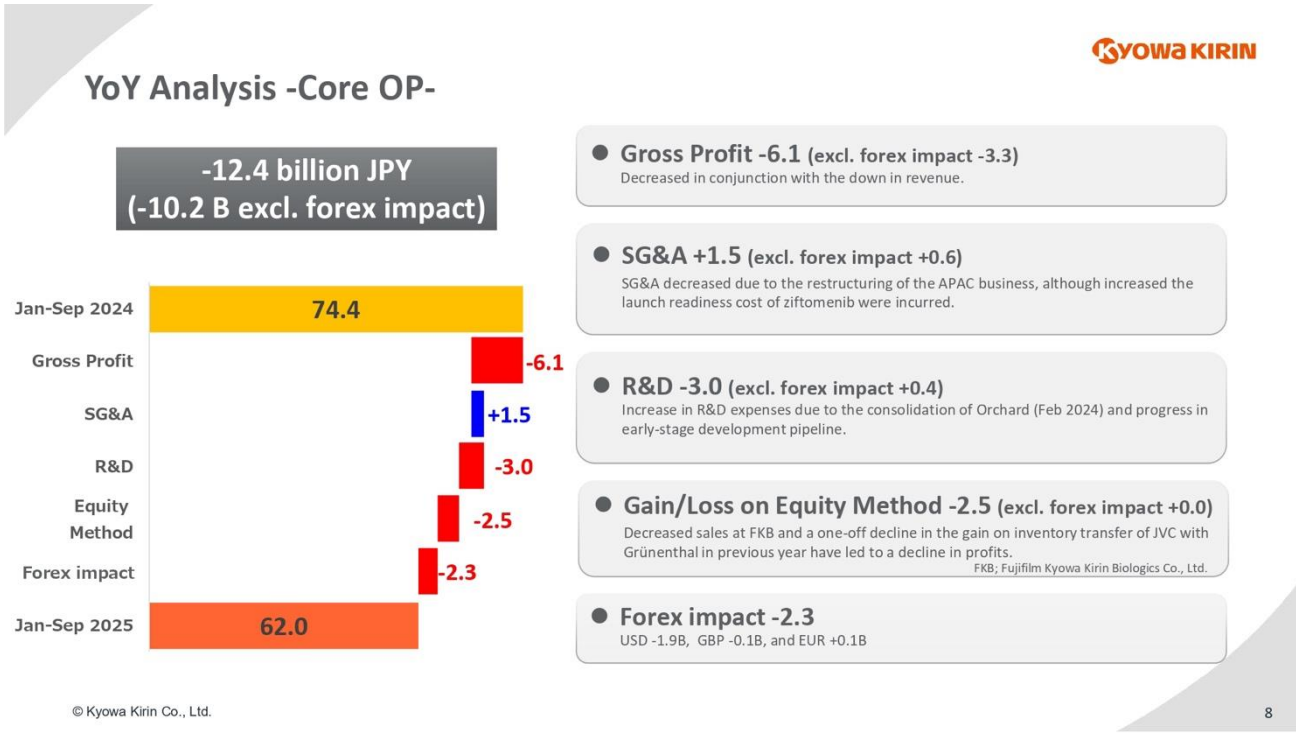
Poteligeo also continued to grow in North America and EMEA, with revenue up JPY4.6 billion, or 16%, YoY.

Libmeldy/Lenmeldy revenue increased by JPY2.2 billion, or 103%, due to strong sales in Europe and, for the first time this year, sales to three individuals in the United States.

Since its launch in February 2024, Phozevel has steadily penetrated the market, increasing revenue by JPY3 billion or 104% over the previous year.

G-Lasta revenue decreased by JPY1.6 billion, or 11%, due to competitive products and the NHI price revision.

Technology-licensing revenues increased JPY4.4 billion, or 13%, from the previous year due to higher royalties from Fasenra.



Page eight is a YoY analysis of core operating profit.

Gross profit decreased by JPY6.1 billion due to the decrease in revenue.

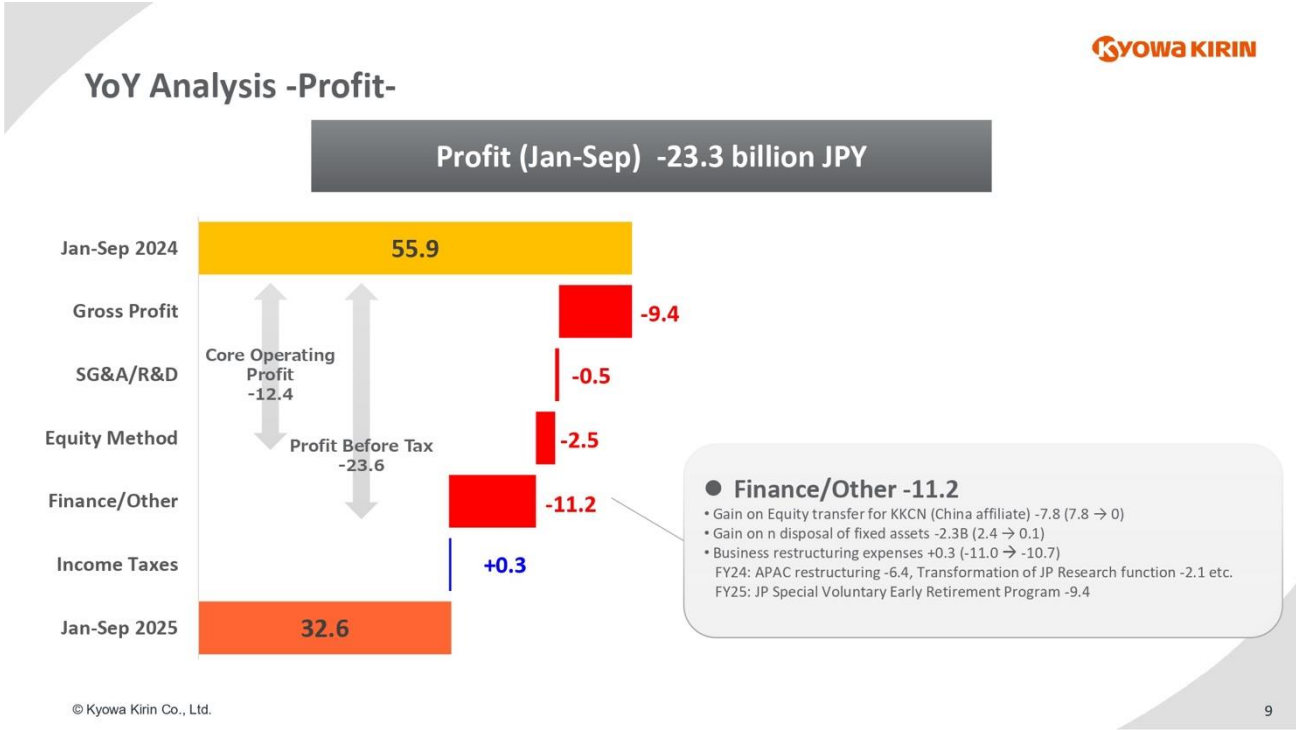
Selling, general and administrative expenses decreased by JPY1.5 billion in total due to a decrease resulting from the reorganization of the APAC business, despite new expenses incurred this year in preparation for the launch of ziftomenib.

R&D expenses increased by JPY3 billion. This was due to the one-month impact of the new consolidation of Orchard, as well as progress in testing of the initial development pipeline.

Gain on equity method decreased by JPY2.5 billion due to lower sales at FKB and the absence of gains on the transfer of inventories associated with the transfer of operations in certain countries that were recorded in the previous year at the joint venture with Grünenthal.

Foreign exchange effects on core operating profit were negative JPY2.3 billion.

As a result, core operating profit decreased by JPY12.4 billion versus the same period last year.

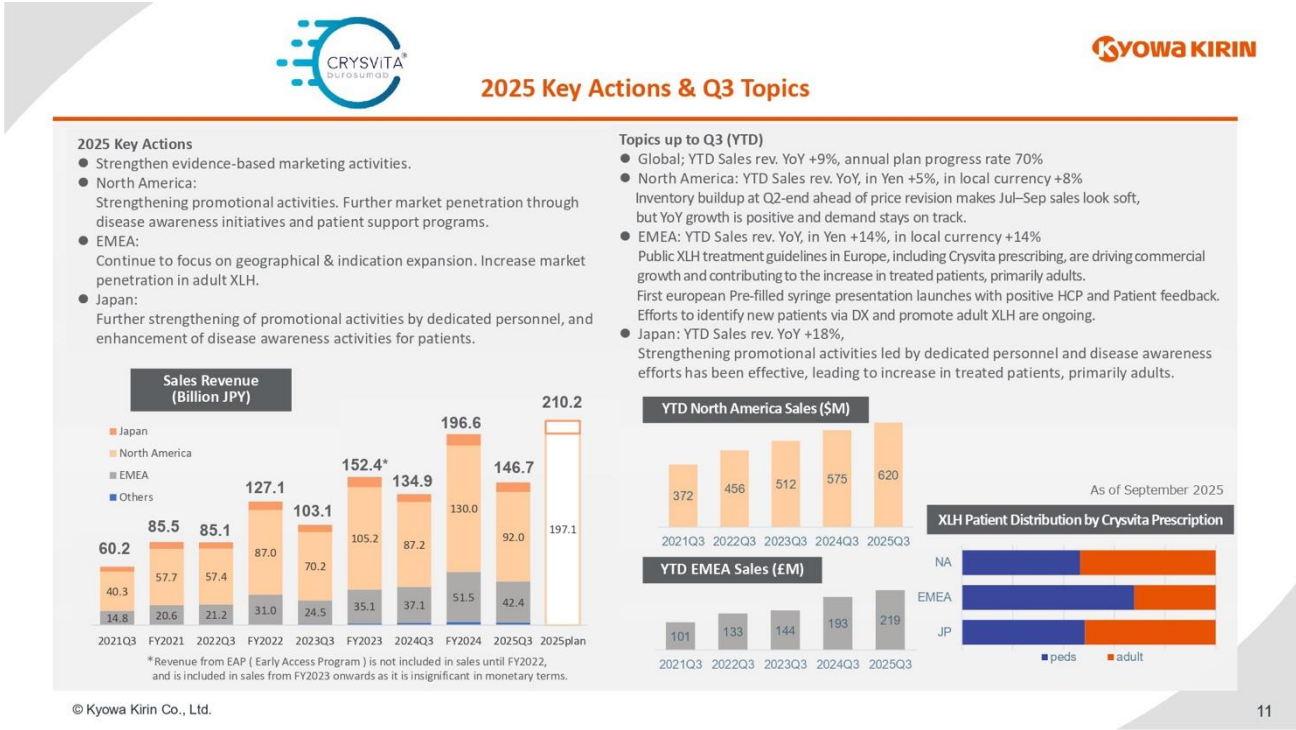


On page nine, I will explain the items below core operating profit.

In Finance/Other, profit decreased by JPY11.2 billion. The main factors were the absence of a JPY7.8 billion gain on the sale of a Chinese subsidiary and a JPY2.4 billion gain on the sale of fixed assets, which were recorded last year.

With regard to business structure improvement expenses, the Company recorded JPY9.4 billion in special retirement payment and other expenses associated with the introduction of a special voluntary retirement program in the current fiscal year. On the other hand, in the previous year, there were expenses recorded for business restructuring in the APAC region and for the reorganization of the research system in Japan. As a result, expenses were at the same level as in the same period of the previous year.

As a result, profit for the period decreased by JPY23.3 billion compared with the same period of the previous year.



Fujii: Next, I will provide the commercial update.

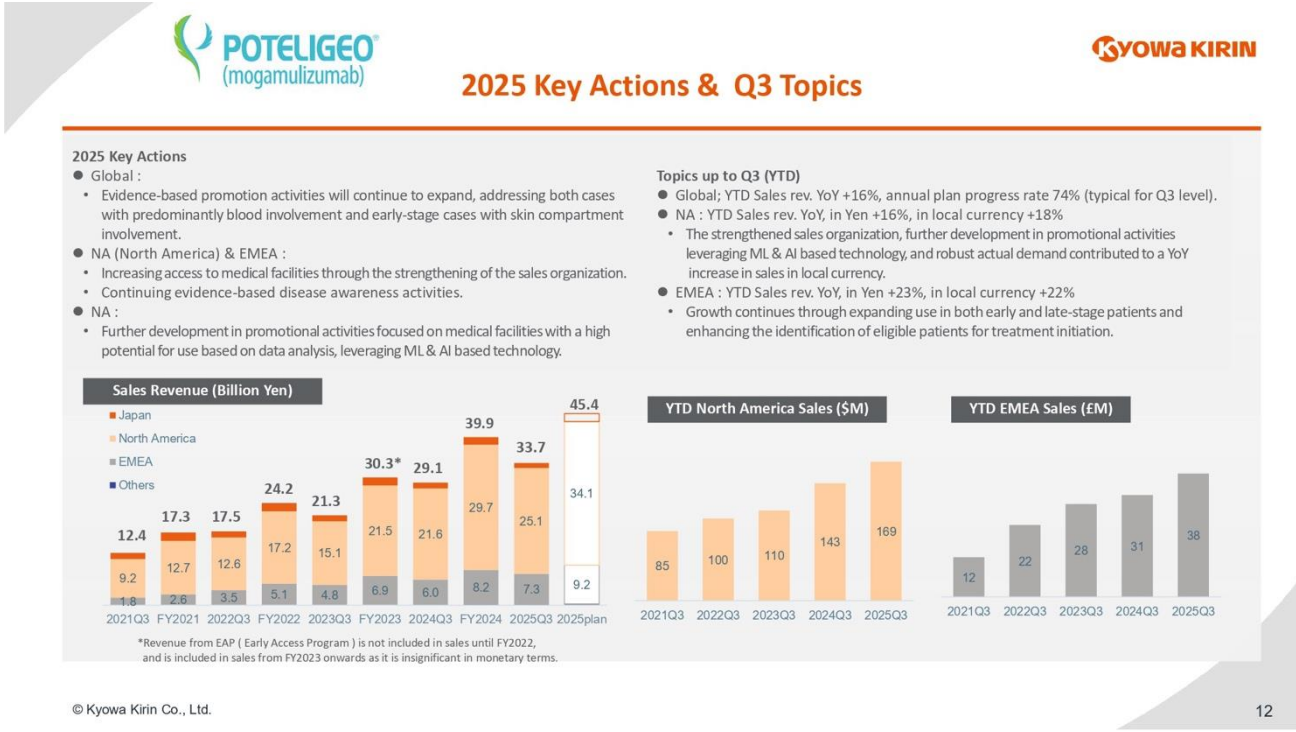
Page 11 describes Crysvita.

Overall global sales for Q3 were JPY146.7 billion, up 9% from the same period last year. The 70% progress rate against the full-year plan is slightly higher than the progress rate after Q3 in previous years.

In North America, the revenue figure for July through September was slightly weaker due in part to a rebound from the specialty pharmacy inventory buildup that occurred at the end of Q2 in anticipation of an interim price revision. However, year-to-date sales growth was 8% YoY in local currency terms. Despite fluctuations in shipment-based sales, actual demand continues to be strong.

In EMEA, the drug continues to grow. In Europe, official guidelines for XLH treatment, including Crysvita prescriptions, have been provided, a factor that has encouraged disease awareness and commercial activities. In addition, the pre-filled syringe presentation has been launched in some countries, leading to improved convenience for healthcare professionals and patients.

In Japan, this drug continues to grow steadily as a system of dedicated bone metabolism specialists has taken root and penetration into the adult patient population has increased.



Page 12 describes Poteligeo.

Overall global revenue for Q3 was JPY33.7 billion, up 16% from the same period last year, and 74% of the annual plan, showing steady growth generally in line with the plan.

Sales in North America in local currency terms increased 18%. Through evidence-based promotion, we continue to promote the penetration of the product into patients with tumor cells in the blood and provide information regarding the continuation of treatment for patients who develop skin symptoms after receiving Poteligeo.

In addition, the use of machine learning and AI technologies in promotional activities and focused visits to medical facilities with higher dosing potential have led to strong growth, including the evolution of promotional activities.

In Europe, in addition to strengthening our marketing structure and expanding geographically, we continue to access patients presenting with cutaneous symptoms, as we did in North America. The drug continues to grow as penetrated into patients through disease awareness activities.

That's all for the commercial update.

News Flow of Development Pipeline Products

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As of October 30th, 2025

New information highlighted in orange

Products	Diseases under development	Events	Status/Schedule
rocatinlimab KHK4083/AMG 451	Moderate to severe atopic dermatitis	ROCKET ASCEND (P3) Interim data	September 2025
	Prurigo Nodularis	P3 Enrollment Completed	October 2025
	Moderate to severe asthma	P2	In progress
ziftomenib	AML (2L+ mono)	US NDA (Priority Review, PDUFA date: November 30, 2025)	June 2025
	AML (1L combo)	KOMET-017 (P3) initiation	September 2025
		KOMET-007 (P1) FLT3-m/NPM1-m cohort initiation	October 2025
OTL-203	MPS-IH (Hurler Syndrome)	Registrational study (Equivalent to P3 study)	In progress
KK8398 infigratinib	Achondroplasia	P3	Preparation underway
KHK4951 tivozanib eyedrop	nAMD	P2	In progress
	DME	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
OTL-200	MLD	Orphan Regenerative Medicine Product Designation for Early-onset MLD in Japan	October 2025

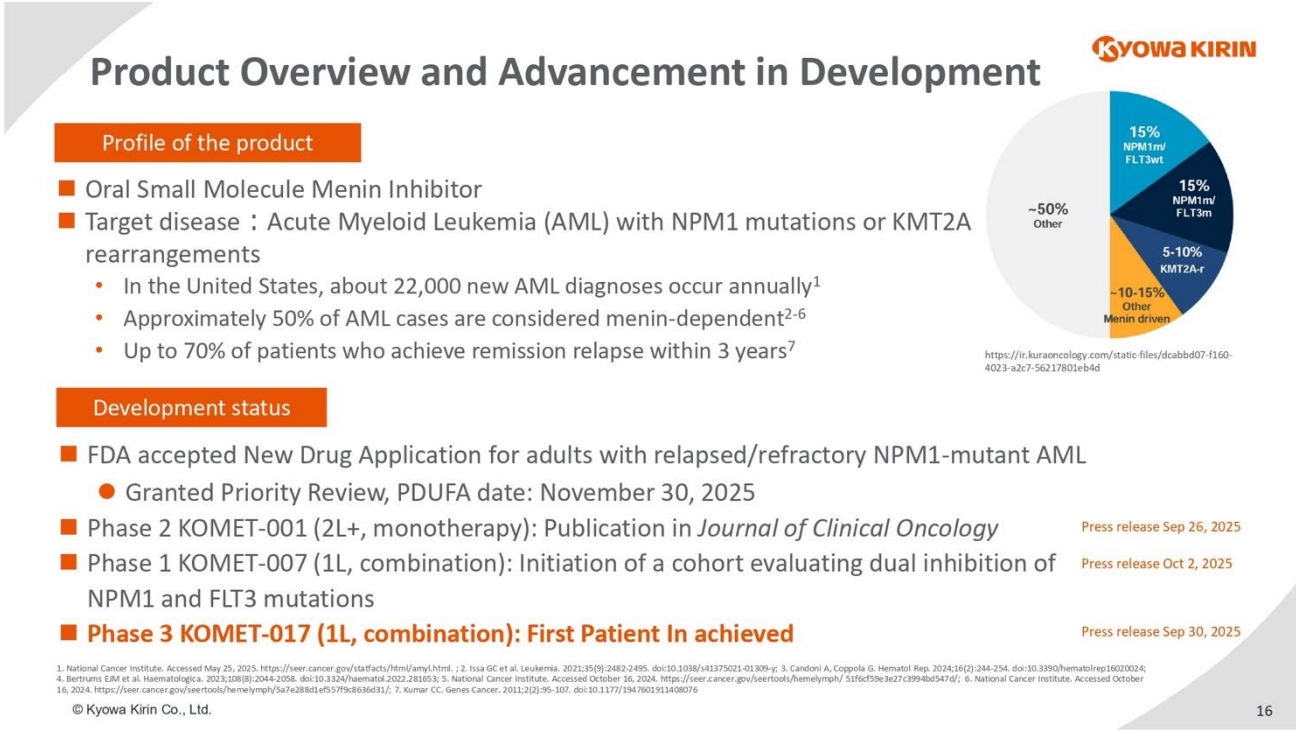
Yamashita: I will now provide the R&D update.

Page 14 is the news flow of development pipeline products. Areas that have been updated since the last financial report are shown in orange.

In September, we announced the results of the interim analysis of the ASCEND study of rocatinlimab. Also, this October, we completed a patient registry for prurigo nodularis.

Also in September, we reported the start of the KOMET-017 study, a Phase III study of ziftomenib in combination with first-line ziftomenib. In October, we reported the initiation of a Phase I study in AML patients with FLT3 and NPM1 mutations. Regarding ziftomenib, the FDA is reviewing the second-line single agent.

In addition, OTL-200, which is marketed in the US and Europe as Libmeldy/Lenmeldy, recently received Orphan Regenerative Medicine Product Designation in Japan.



First, an update on ziftomenib.

ziftomenib is an oral small molecule menin inhibitor for the treatment of patients with acute myeloid leukemia with NPM1 mutations or KMT2A rearrangements. In the United States, 22,000 new cases of AML are diagnosed annually, and half of these are considered menin-dependent. It is known that up to 70% of patients who achieve remission will relapse within three years.

As for the current development status, the FDA has just accepted the application for approval for the treatment of relapsed and refractory adult AML patients with NPM1 mutations, with a PDUFA date set for November 30.

We published a paper in the Journal of Clinical Oncology on the KOMET-001 study, which is also the study used in this application.

We have initiated a Phase I study for newly diagnosed AML patients with FLT2 mutation in addition to NPM1 mutation. A Phase III study of first-line therapy in patients with NPM1 mutations or KMT2A rearrangements is also underway.

We are working to bring this drug to more patients who may benefit from menin inhibitors.

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Atopic Dermatitis (AD) is a chronic, heterogeneous inflammatory skin disease that imposes a substantial burden on patients and caregivers

Many patients continually strive to find relief, and hope for new treatment options

Impact of Moderate-to-Severe AD:

Skin Symptoms
Excessively dry, itchy, and painful skin
Repeated scratching can lead to thickened, hardened skin and increased infection risk

Sleep Disruption
Chronic symptoms negatively impacts sleep in **up to 80% of children and 90% of adults**

Mental Health
Adults are **twice as likely** to experience depression and anxiety

Daily Life
Reduced productivity, limited social interactions and an overall decrease in Quality of Life

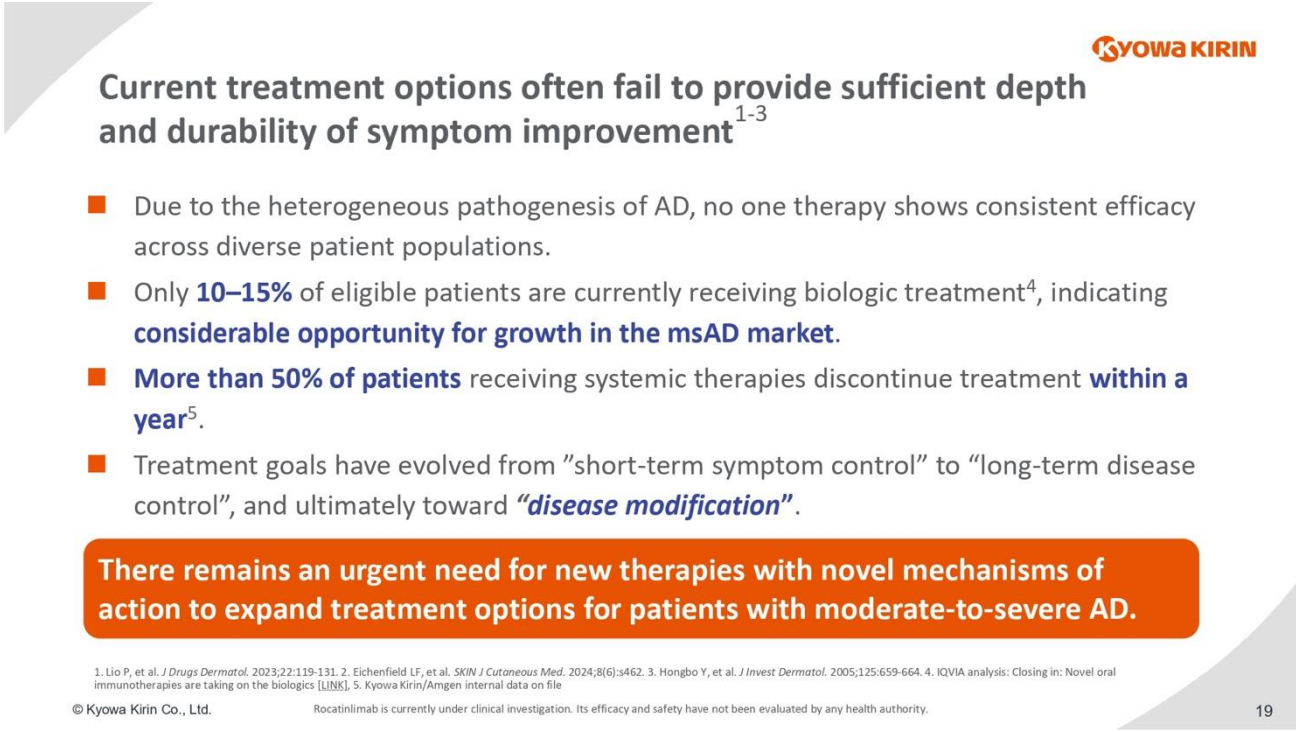
Despite existing therapies, many patients with moderate-to-severe AD continue to experience inadequate disease control. [1,2,3]

1. Lio P, et al. *J Drugs Dermatol.* 2023;22:119-131. **2.** Eichenfield LF, et al. *SKIN J Cutaneous Med.* 2024;8(6):s462. **3.** Hongbo Y, et al. *J Invest Dermatol.* 2005;125:659-664.

Next, I will provide the update of rocatinlimab.

The target disease for rocatinlimab is moderate to severe atopic dermatitis, and the very diverse symptoms shown here impose a significant burden on patients and those who care for them. These have a significant impact on patients' daily lives and significantly reduce their quality of life.

Existing treatments have not been sufficient to control the disease, and many patients are still clamoring for new treatment options to alleviate their symptoms.



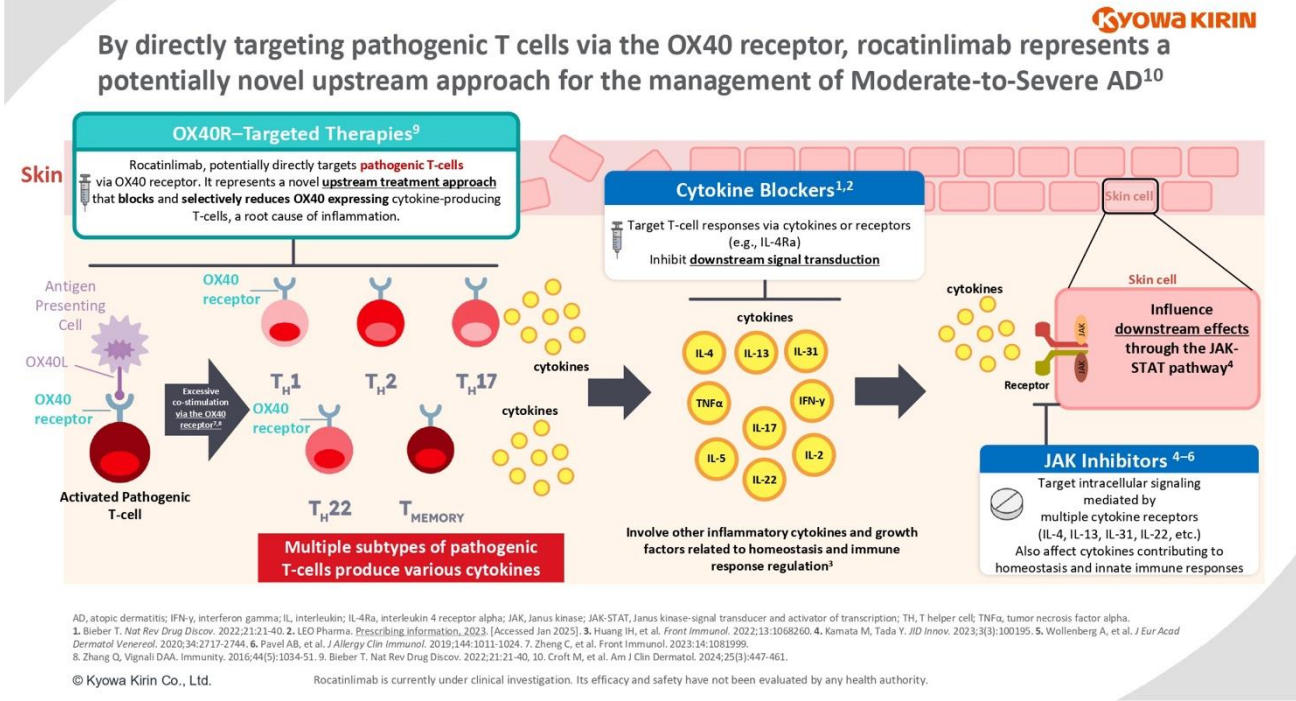
We believe that atopic dermatitis is a diverse condition that differs from one individual to another, and that no single treatment will work equally well for many patients.

The use and response to biopharmaceuticals in patients who are difficult to control with conventional therapies is becoming more widespread every day. However, we believe that there is still room for growth for biopharmaceuticals as a whole, as it is reported that only 10% to 15% of patients who are considered eligible for treatment are actually administered the drug.

We also have information that more than 50% of patients receiving systemic therapy, including biopharmaceuticals, are unable to continue that therapy and discontinue it within one year. We believe that there is a high need for new drugs that show continuous effective therapeutic effects.

In recent years, there has been a lively discussion in the clinical community that the goals of treatment for atopic dermatitis have evolved from "short-term disease control" to "long-term disease control," and further beyond that, that "disease modification," or treatment that returns the patient to a healthy state, should be set as a goal.

Thus, we are developing rocatinlimab as a drug to address the unmet medical needs that still exist.

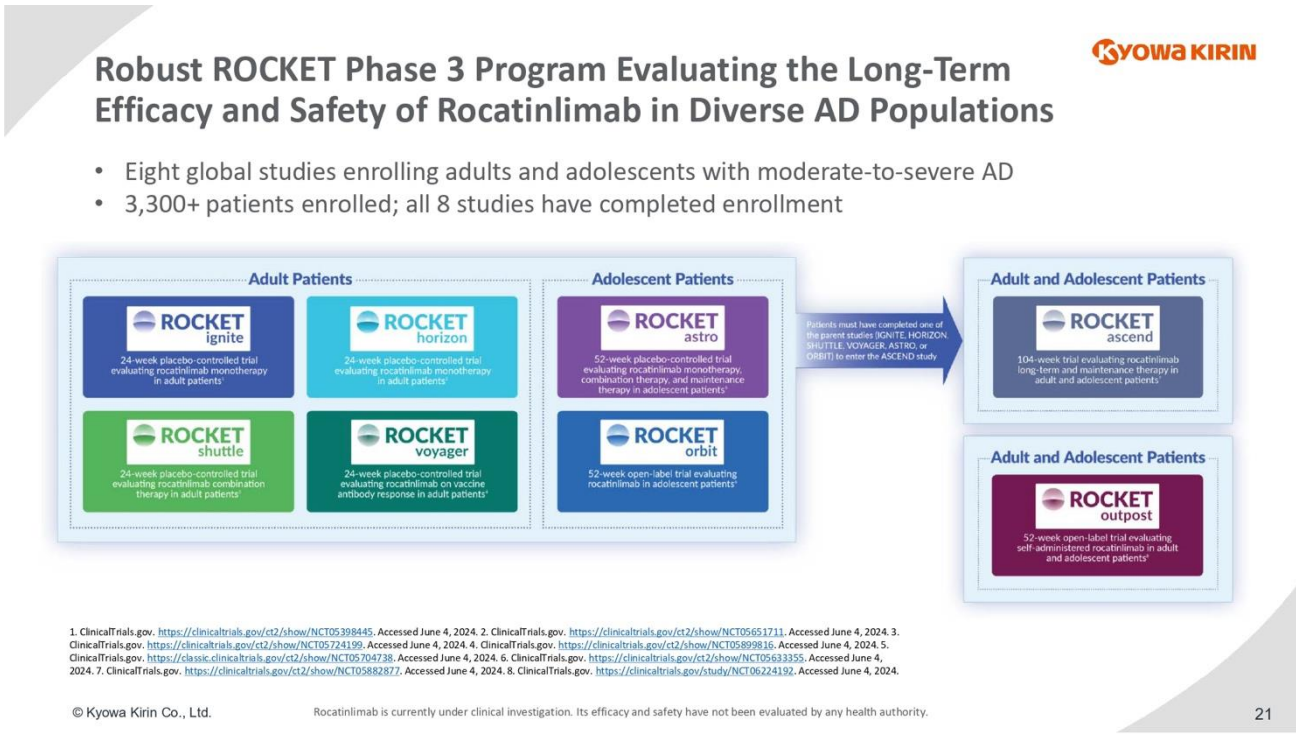


AD, atopic dermatitis; IFN-γ, interferon gamma; IL, interleukin; IL-4Ra, interleukin 4 receptor alpha; JAK, Janus kinase; JAK-STAT, Janus kinase-signal transducer and activator of transcription; TH, T helper cell; TNFα, tumor necrosis factor alpha.
1. Bieber T. *Nat Rev Drug Discov.* 2022;21:21-40. **2.** 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 is distinct from existing agents in that it is an OX40-mediated agent that acts directly on pathogenic T cells, which are upstream of the signaling pathway that causes atopic dermatitis.

As shown here, it acts upstream to reduce the number of pathogenic T cells, thereby working toward normalizing the T cell state, which we call T-cell rebalancing. By achieving this, we expect that the drug will be effective close to the cause of a variety of symptoms and will demonstrate broad and deep efficacy for patients on a sustained basis.



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.
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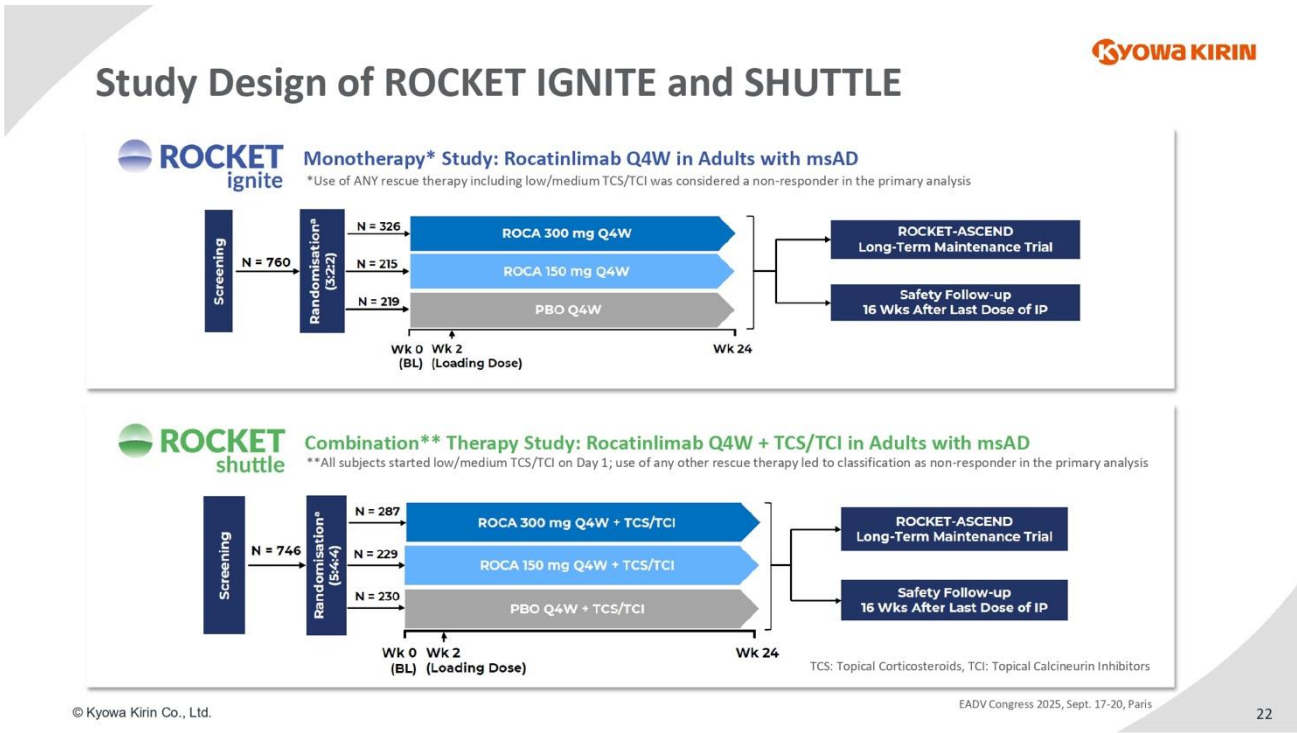
For rocatinlimab, a Phase III study, the ROCKET program, is ongoing.

The interim analysis results of the ASCEND study, shown at right, were reported last month. Today, we are pleased to present excerpts from the results of the ROCKET IGNITE and ROCKET SHUTTLE studies presented at the European Academy of Dermatology, EADV, in September of this year.



Here is the study design.

The upper row is the ROCKET IGNITE study, in which patients were treated with a single agent. The bottom row is the SHUTTLE study, which was a study of combination treatment with topical agents. In both cases, the dosing period was 24 weeks.

Rocatinlimab showed significantly greater improvement in EASI-75 and vIGA-AD 0/1 response rate at Week 24 vs. placebo

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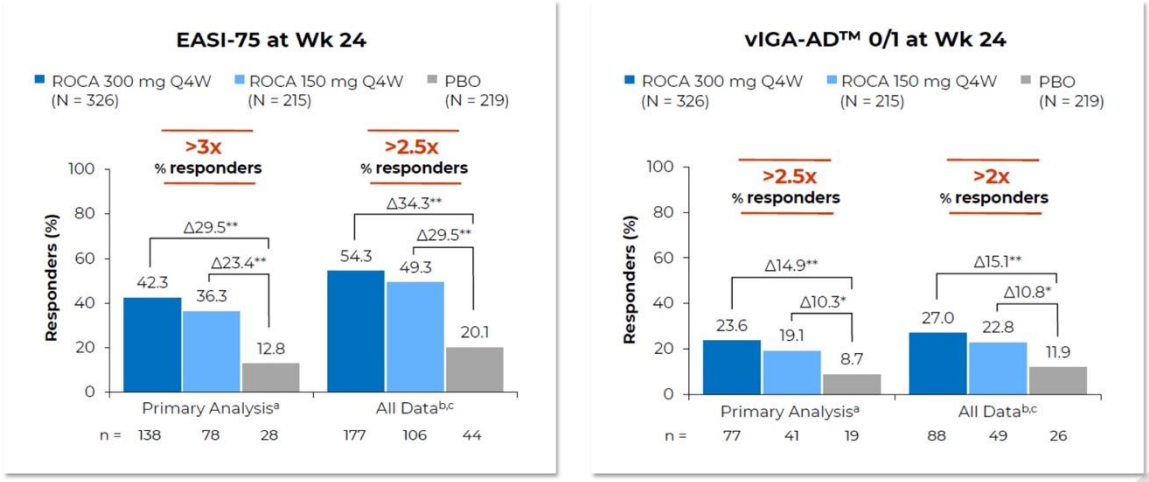
ROCKET ignite



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

EADV Congress 2025, Sept. 17-20, Paris

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Here are the results of the IGNITE study conducted with a single agent.

The left side shows the results of EASI-75 and the right side shows the results of vIGA-AD 0/1. Both showed significant improvement over placebo at 24 weeks.

Rocatinlimab Demonstrates Deepening of Response (EASI 90-100) Over Time

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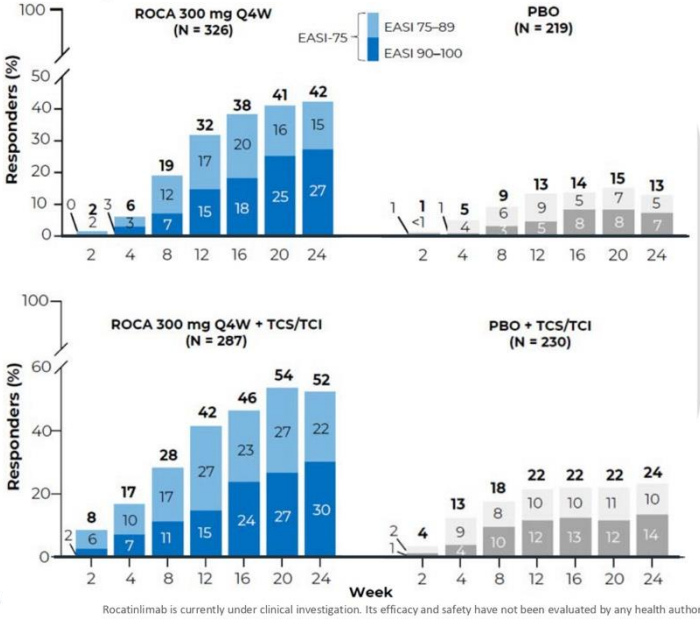
ROCKET ignite
Monotherapy Study

ROCKET shuttle
Combination Therapy Study



Rocatinlimab shows continuous improvement over time in both monotherapy and combination therapy, with **EASI-90 responders** increasing through Week 24 without plateau

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

EADV Congress 2025, Sept. 17-20, Paris

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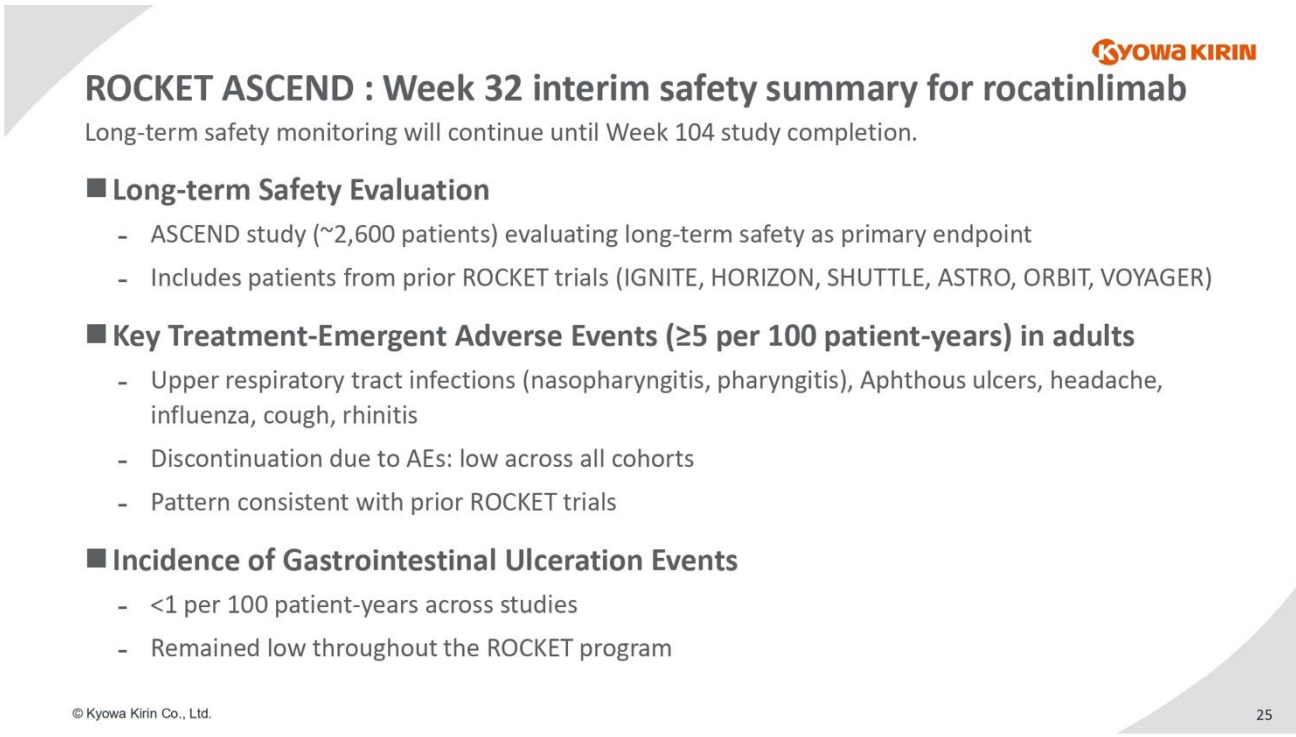
This slide shows the percentage of EASI-90 to 100 achieved over time, which is a more in-depth drug effect in addition to EASI-75.

As you can see, the percentage of patients achieving EASI-90 to 100 with rocatinlimab, shown in dark blue, increased over time in both the single agent and combination studies. The increase is still upward at 24 weeks, which gives hope that further treatment may increase this rate even more.

Similar results were seen in the ROCKET HORIZON study presented in March of this year. We expect that the potential for further deepening of efficacy beyond 24 weeks, which is suggested here, may well reflect the unique features of the drug based on the specific mechanism of action of rocatinlimab.

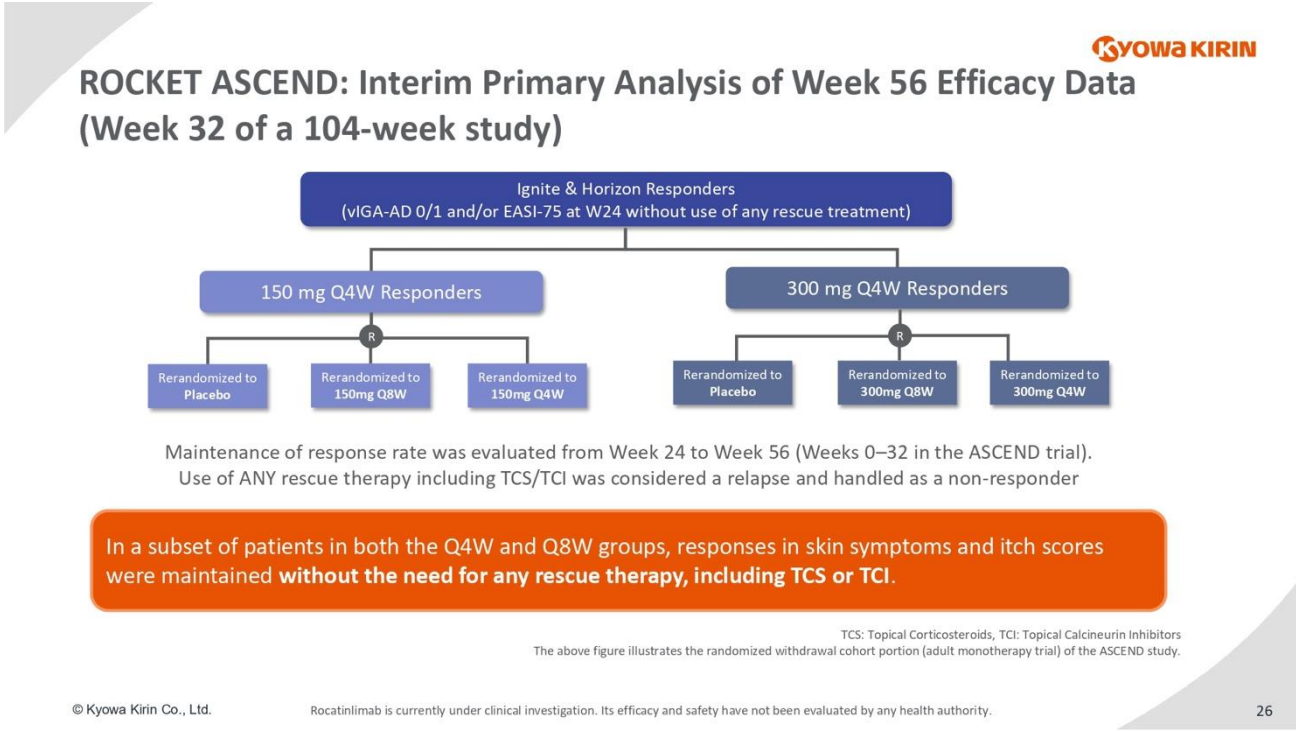


The following is a summary of the safety profile of the ASCEND study at week 32.

The primary endpoint of this study is to evaluate the long-term safety of approximately 2,600 patients who were transferred from parent studies such as IGNITE, HORIZON, SHUTTLE, ASTRO, ORBIT, and VOYAGER to this ASCEND study and monitored through week 104.

Adverse events in adults included upper respiratory tract infections, aphthous ulcers, and headaches, as shown here, in five or more cases per 100 patients during the year. The discontinuation rate of the study due to these adverse events was very low in all cohorts. The pattern of occurrence is also consistent with that seen in previous ROCKET studies.

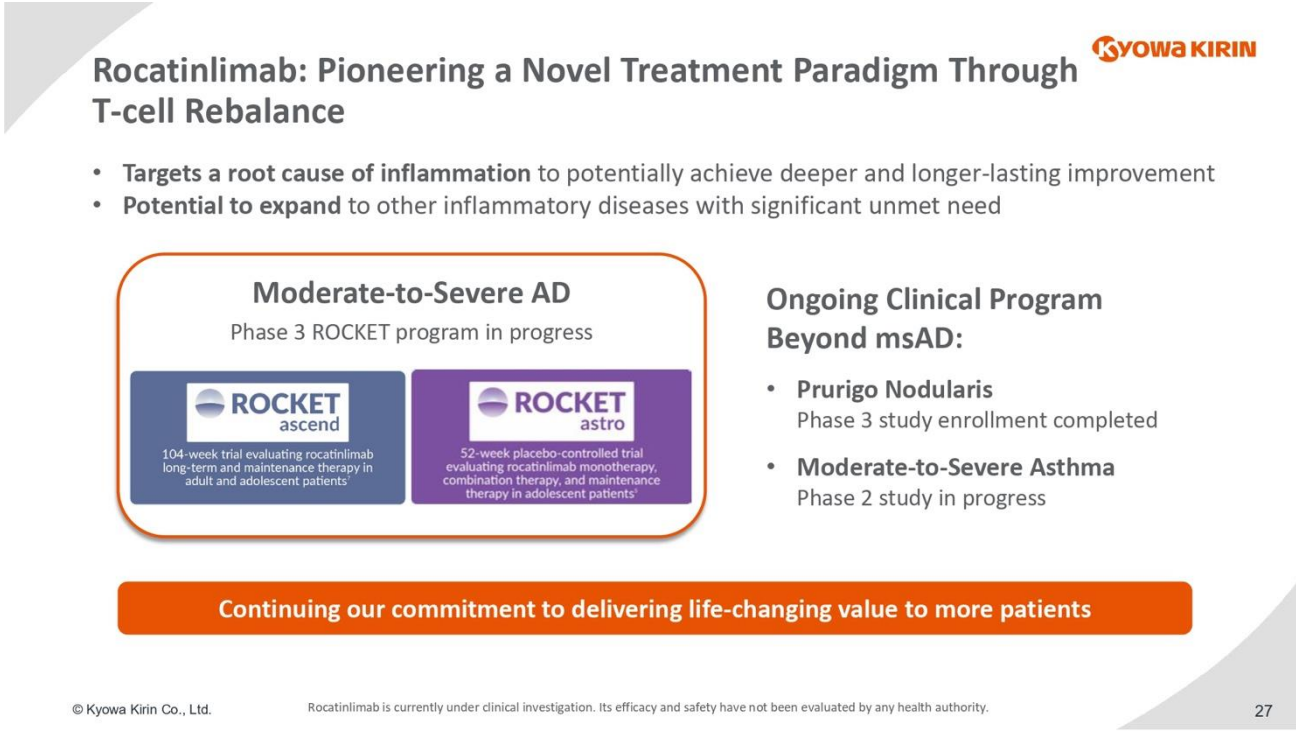
The event rate of gastrointestinal ulcers was low throughout the program, at less than one per 100 patients per year in all cohorts.



Here we reiterate the results of the 32-week interim analysis of the ROCKET ASCEND study, which we reported last month.

Here are the results of the evaluation at a total of 56 weeks, after a 24-week single-agent study of IGNITE and HORIZON, and 32 weeks of the ASCEND study. The Q4W group and the Q8W group with extended dosing intervals showed that improvement in skin symptoms and itch scores could be maintained.

This study is based on the criterion that those who have used rescue therapy at least once are considered non-responders. The Company views these results very positively. Please wait for future conference presentations for more detailed data.



In summary, we expect rocatinlimab to open up a new treatment paradigm for multiple inflammatory diseases, including atopic dermatitis, through T-cell rebalancing, which is a new standard for adoption.

Although not included in this material, we have just recently received top-line data from the ASTRO study in adolescent patients. The results shows that both co-primary and secondary endpoints were achieved, and safety events were consistent with other studies. These will be analyzed in more detail and presented at a future conference as well as the ASCEND study.

Phase III for prurigo nodularis and Phase II study for moderate to severe asthma are underway, and patient enrollment for prurigo nodularis has just been completed.

We expect that acting at the root of inflammation will lead to deeper and more sustained improvement in these inflammatory diseases as well.

That is all I have to say about R&D.

Year-to-date Key News Flow

KYOWA KIRIN

As of October 30th, 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)

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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Year-to-date Key News Flow

KYOWA KIRIN

As of October 30th, 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

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 refer to the news since the beginning of the year on page 29 and thereafter.

Year-to-date Key News Flow

As of October 30th, 2025

Category	Date	Headline
R&D	Sep 9	AMGEN AND KYOWA KIRIN ANNOUNCE TOP-LINE RESULTS FROM ROCATINLIMAB PHASE 3 ASCEND LONG-TERM EXTENSION STUDY IN ADULTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS
R&D	Sep 11	Kyowa Kirin Announces Late-Breaking Abstract Presentation at the European Academy of Dermatology and Venerology Congress
R&D	Sep 26	KURA ONCOLOGY AND KYOWA KIRIN ANNOUNCE PUBLICATION OF PIVOTAL ZIFTOMENIB DATA IN RELAPSED/REFRACTORY NPM1 MUTATED AML IN THE JOURNAL OF CLINICAL ONCOLOGY
R&D	Sep 30	KURA ONCOLOGY AND KYOWA KIRIN ANNOUNCE FIRST PATIENT DOSED IN PIVOTAL PHASE 3 KOMET-017 TRIAL OF ZIFTOMENIB FOR FRONTLINE ACUTE MYELOID LEUKEMIA (AML)
R&D	Oct 2	KURA ONCOLOGY AND KYOWA KIRIN LAUNCH CLINICAL TRIAL EVALUATING DUAL INHIBITION OF NPM1 AND FLT3 MUTATIONS IN PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML)
R&D	Oct 28	OTL-200 Granted Orphan Regenerative Medicine Product Designation for Early-onset MLD in Japan
SP	Oct 30	Boehringer Ingelheim acquires license from Kyowa Kirin aimed at developing a novel treatment for patients with autoimmune diseases
MGMT	Oct 30	Announcement regarding the Transition to Company with Audit and Supervisory Committee

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

Let me briefly introduce today's news. See page 31.

See the bottom two items. The first is the conclusion of a licensing agreement for a new compound to Boehringer Ingelheim. The other is a release regarding the transition to a company with an Audit and Supervisory Committee.

Transition to Company with Audit and Supervisory Committee

Purpose

- ✓ Ensure sufficient decision-making agility to further enhance competitive advantage for sustainable growth.
- ✓ Clearly separate execution matters from Board discussions, focus the Board on medium- to long-term strategies, and ensure swift, decisive decision-making and execution.
- ✓ Enhance supervision through diverse outside directors and strengthen collaboration between the Audit and Supervisory Committee and internal audit functions to improve audit effectiveness on directors' execution.

Timing

- ✓ At the Annual Shareholders Meeting scheduled to be held in March 2026, the necessary changes to the Articles of Incorporation will be approved and transitioned.

Finally, I would like to briefly explain the release regarding the transition to a company with an Audit and Supervisory Committee.

We have resolved to evolve our governance structure by transitioning from the current company with a board of corporate auditors to a company with an Audit and Supervisory Committee, subject to approval of the necessary changes to our articles of incorporation at the annual general meeting of shareholders to be held in March of next year.

The objectives are to increase the mobility of decision-making, to improve the quality of discussions at Board of Directors meetings by making a sharp distinction between matters that should be left to the execution of duties and those that should be discussed at Board of Directors meetings, and to enhance the effectiveness of audits of directors' business execution by strengthening cooperation between the Audit and Supervisory Committee and the Internal Audit Department.

That is all for today's explanation.

Question & Answer

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

Yamaguchi [Q]: The first question is about the relationship between the Boehringer Ingelheim deal and the Company's forecast for this fiscal year.

First, is this deal with Behringer an extension of the previous clinical study? It also states that you may receive a total of EUR640 million. Can you tell us if and how many milestones will be in the FY12/2025 or FY12/2026?

Kawaguchi [A]: First of all, the Boehringer Ingelheim compound we announced last year and this case are completely different. It is also a deal with Boehringer, but it is a new deal for a completely different compound.

In addition, the plan for this fiscal year does not, of course, include the out-licensing of this.

As for the impact on the current fiscal year, I believe that a one-time contract payment will be recorded this October. Therefore, this will have an upward impact on the sales and profit for the Q4 results.

Yamaguchi [Q]: What is the amount?

Kawaguchi [A]: I will refrain from responding to anything more than what we have disclosed, given our relationship with the partner.

Yamaguchi [Q]: I understand.

In your presentation, you said that while there is no problem with operating profit, there is a delay in progress toward the full-year plan with respect to net profit due to the severance allowance, but that this may be covered by the coming in of this. You mentioned that in this context.

Kawaguchi [A]: Yes. Since this was completely unplanned, it is safe to assume that it is an upside factor.

Yamaguchi [Q]: I understand.

Next, I would like to ask about Crysvita. The same arguments are always made, but it appears that sales, especially in the US, increased rapidly in Q2 and then decreased in Q3. You said that given the seasonality, the rate of progress is good. In that sense, is there a possibility that the full-year result will exceed the plan? Or are the results likely to be in line with your expectations for the full year? Could you comment on Crysvita's Q3 sales in the US and your Q4 sales forecast?

Fujii [A]: As you noted, sales rose sharply in Q2, but we believe that inventory returned to its standard state in Q3.

In addition, we believe that actual demand, which we can gauge in certain units, is progressing very well. So, we currently believe that we will be able to achieve our plan by the end of the year.

Yamaguchi [Q]: Isn't it likely to be above or below the plan? From what you said, I thought the result was going to exceed your plan.

Fujii [A]: It isn't. It is in line with the plan.

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

Wakao [Q]: First, I would like to know about the outlook for the next fiscal year. Profits declined this fiscal year due in part to the restructuring of overseas operations, but if that has run its course, is it possible for earnings to bottom out this fiscal year and profits to increase in the next fiscal year and beyond?

Since the Boehringer contract upfront payment, etc. will also come in, on a core OP basis, if the result is slightly exceeded the plan this fiscal year, the increase in profit may make the next fiscal year more difficult. If SG&A expenses will increase further due to marketing expenses for ziftomenib, etc., the next fiscal year looks difficult. Please let us know if there is anything you can tell us at this point.

Kawaguchi [A]: As for plans for the next fiscal year, we are now diligently preparing a budget. There are so many more internal and external variables than in previous years that it is unfortunately difficult to answer at this time what the level will be compared to this year. So, I would be happy to withhold my response until February. I am sorry.

Wakao [Q]: I understand.

Now, let me change the question. What levels of SG&A and R&D expenses do you expect to see in the next fiscal year? As for R&D expenses, there does not seem to be a factor that would increase them by much. On the other hand, if there are more marketing costs for ziftomenib and rocatinlimab, I expect SG&A to increase.

Kawaguchi [A]: I think the trend is as you say. We are in the process of working out the details of that as well.

Wakao [Q]: I understand.

By the way, is the one-time payment for Behringer expected to be as much as the restructuring costs?

Kawaguchi [A]: As I mentioned earlier, I cannot tell you the scale of the amount. Sorry.

Wakao [Q]: But it is normal to think that way. Is this thinking correct?

Kawaguchi [A]: I did not mean to imply that Boehringer's lump-sum payment would make up for all the shortfall in the plan caused by special retirement benefits. We hope to make up as much as possible for the current delay in the progress of net profit by means of Boehringer's one-time payment or the impact of the yen's depreciation.

Wakao [Q]: I understand very well.

The second is about page 24. Although you have mentioned that further dosing over the long term will increase the efficacy over time, this seems, by all means, to have reached its peak by now. Is your earlier comment due to your company seeing ASCEND results that we are not seeing?

Yamashita [A]: No, it is not based on the results. We have determined that even though there may be a slight sense of peaking out at EASI-70, we are seeing deeper medicinal effects over time after that.

Wakao [Q]: This data is only for responders, right?

Yamashita [A]: Yes.

Wakao [Q]: If you also add non-responders, the data will be rather good. So, I think it would be very good if the attached document would include ITT data instead of responder data, is that possible?

Yamashita [A]: What will happen to the attachment will be based on the analysis that will be done.

Wakao [Q]: Does that mean there is room for negotiation?

Yamashita [A]: That depends on what kind of data we get. I think it all comes down to how we look at the effectiveness of the product on patients. As we conduct various other studies, including combination studies, I believe that the usefulness of this drug can be supported by various data. We would like to organize that in the future.

Wakao [M]: I understand. That is all.

Muraoka [Q]: Thank you very much. I am Muraoka from Morgan Stanley.

I would like to ask an additional question regarding the forecast for the next fiscal year. Earlier, Mr. Kawaguchi mentioned that there will be many variable factors in the next fiscal year. Could you please tell us the factors of variation, qualitative or otherwise? It doesn't seem like there are that many variables.

Kawaguchi [A]: The situation in the US, for example, will also change down the road, perhaps next month, when more details on tariffs will be announced. So, there are many factors, including that.

Muraoka [Q]: You said internal and external. What are some possible internal factors?

Kawaguchi [A]: At this stage, I cannot speak about internal factors.

Muraoka [Q]: I understand. Thank you very much.

Now, let me change the question. In February, probably, you will issue a five-year mid-term plan for the period 2026-2030. I believe that only about NOURIAST will reach LOE by 2030, and that your business is likely to grow rather straight forward and steadily. Is this idea correct? Can you please tell me if there is some discontinuous element that I am forgetting?

Kawaguchi [A]: I am sorry, but we are still considering the possibility of announcing it in the form of a mid-term plan next February. We hope you can wait until next February. I am sorry.

Muraoka [Q]: Is there a possibility that you will not announce the mid-term plan?

Kawaguchi [A]: We are considering that as well.

Muraoka [Q]: I would love to have you present it.

Kawaguchi [A]: We appreciate your feedback.

Muraoka [M]: That's all. Thank you very much.

Ueda [Q]: I would first like to ask about the progress of the expenses. I would like to know how R&D and SG&A expenses are progressing against the plan.

As for R&D expenses, I think the current Q3 level was low, as Phase III of rocatinlimab is gradually coming to an end. Is there some leeway? Also, could there be another decrease in normal SG&A expenses in Q4 due to the special voluntary retirement program? In that case, there still appears to be a margin against the full-year budget. Could you please tell me how to look at this?

Kawaguchi [A]: As I mentioned earlier, since net profit is lagging behind the full-year plan, we are optimizing costs on a global basis for both SG&A and R&D expenses.

We identify priorities in the budget and try to contain the costs of, for example, business travel and new hires, even if they are in the plan. Through this, we are trying to achieve our annual plan. Our goal is to land at a level below the planned budget, and as I said in my explanation, the rate of progress has been slightly below the planned level.

Ueda [Q]: Thank you very much.

In other words, since the current result is somewhat below the plan, do you expect to achieve net profit sufficiently for the current term?

Kawaguchi [A]: We cannot say yet that we expect to achieve this goal, but we are now making efforts to reduce SG&A expenses in order to get as close to the plan as possible.

Ueda [Q]: Thank you very much.

Second, I would like to know your current thinking on the US business environment, including tariffs, which was commented a little earlier on the topic of uncertainty. In previous presentations, you mentioned that your company is discussing various measures, such as building up inventory, reviewing manufacturing locations, etc. As an update to that, are there any changes to your business strategy, including a review of your current situation, particularly your manufacturing locations? Also, regarding MFNs and other drug prices, can you tell us what you consider to be the risk factors in your business at present?

Fujii [A]: We are currently creating a cross-functional, plus cross-regional, task force within the Company for customs and MFN. As for MFN, it is not just a US issue, so a task force across regions and functions is considering various scenarios and is in the process of developing countermeasures for each scenario.

However, since many things are not clear yet, I will refrain from making specific comments at this time and place. Again, we have set up a task team to address both issues, and we are working diligently on various scenarios.

Ueda [M]: Understood. Thank you very much. That is all from me.

Sakai [Q]: I haven't read through the original release yet, but is the aim of the transition to a company with Audit and Supervisory Committee as described here? What do you hope to gain by this? Certainly, the description here is standard. However, in the case of your company, the relationship with the parent company is always a topic of discussion. Is the transition partly due to that? What is the aim? Please let me know if there are any changes we can perceive.

Yamashita [A]: The relationship with the parent company, as you mentioned in your question, was not taken into consideration at all in this issue. That has nothing to do with it at all.

Until now, we were a company with a board of auditors and various important decisions were made by the board of directors. With a majority of outside directors, it took repeated meetings to discuss matters thoroughly, and it also took time to get a firm understanding of the issues.

With the change to the new form, a significant portion of the authority will be delegated to the executive side to make quicker decisions. Naturally, important matters will be resolved by the Board of Directors. However, in detailed pharmaceutical matters, a system in which the Audit and Supervisory Committee firmly supervises and audits that the executive side is making decisions through appropriate processes, without the Board of Directors having to get deeply involved, would be more agile. For this reason, we have considered making this change.

Sakai [Q]: So, you are saying that for the time being there will be no change in the members, including the outside directors?

Yamashita [A]: The final form has not yet been decided. We will report back to you as soon as it is finalized.

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

Another question is about rocatinlimab. I think the weight of prurigo nodularis is quite large in new drugs that have recently been launched and in existing and competing products that already exist. Your company has just barely finished Phase III and patient registration has just been completed. How soon can you bring in an application? Also, the drug will first come out with an indication for atopic dermatitis; could you tell us about the competitiveness of this in the market?

Yamashita [A]: First of all, we have reported that patient enrollment has been completed today for prurigo nodularis. I would like to refrain from introducing it at this time when the examinations will be completed or when the applications will be submitted.

I feel that new drugs are being introduced for the indication of atopic dermatitis, and market penetration is surprisingly increasing. I was able to confirm once again that distinctive biologics drugs have an unmet medical need and are accepted by the market to some extent. I believe this will be the first drug to suppress the OX40 pathway and will penetrate the market in a good way.

Sakai [Q]: Is the fact that there will be no application for prurigo nodularis for the time being, but only for atopic dermatitis, not a cause for concern, and is there no particular problem with competitiveness in the market?

Yamashita [A]: That's right. We have been conducting trials for atopic disease first, and naturally, we have been considering how to deliver this product to patients with atopic disease. Whatever indications for prurigo nodularis may be added to that, we believe we can handle it well.

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

Hashiguchi [Q]: The first is about Libmeldy/Lenmeldy. It looks like there were no sales in Q3, and progress against the full-year forecast is also low. Also, I understand that since it is a single dose, it is somewhat volatile on a quarterly basis, but I wonder if you could tell us what level of constant sales you expect to see in the next fiscal year and the year after that.

Fujii [A]: As I mentioned in the Poteligeo section, we are using AI and machine learning to find patients for MLD.

This has led to the discovery of a considerable number of patients, more than I expected. But based on the symptoms, we use machine learning or AI to find them, so those patients already have symptoms and are not eligible for Libmeldy or Lenmeldy.

The most common case so far is that the patient found already has MLD symptoms and cannot be treated, but when their family or siblings are examined, it is discovered by chance that they have MLD due to a defective gene and treatment is initiated.

However, recently, newborn screening is becoming more and more widespread, and in addition to the pattern I have just described, there are patients being found by newborn screening.

Because of this situation, at this stage, depending on the quarter, it is possible that not a single case may occur. However, as newborn screening becomes more widespread, we assume that this will no longer be the case.

Hashiguchi [Q]: For some time after the product was launched, there were pre-diagnosed patients to some extent, but from now on, new patients will need to be found for continued sales to be recorded. In that sense, might a quarter with zero sales not necessarily be irregular?

Fujii [A]: I don't think it is surprising that there is currently such a period. However, to reiterate, we assume that newborn screening will gradually become more widespread in the future. At that stage, we now know, as a result of using machine learning, etc., that there are a surprisingly large number of patients. Therefore, I believe that fluctuations from period to period and consecutive periods of zero sales will be very rare in the future.

Hashiguchi [Q]: I understand. Thank you very much.

The second point is about licensing out to Boehringer Ingelheim. What did you lead to the full out-licensing? In the past, there were three ways to provide value for assets as you indicated in the Story for Vision: in-house, joint, and full out-licensing.

The program this time was only introduced as an autoimmune disease, and I think there are many kinds of autoimmune diseases. In the future development of rocatinlimab, I think that to some extent you can expect to create a franchise for autoimmune diseases. With that in mind, could you explain the background behind the decision to fully license out the asset, rather than doing in-house or jointly?

Yamashita [A]: We have been studying this drug in-house, and in the research phase, we have very interesting data that it is very promising.

However, last year, in our Story for Vision 2030, we defined our focus areas. Autoimmune diseases are a fairly broad area, and to maximize the value of this drug, we have to do a pretty hard job of developing it.

Therefore, we discussed the possibility that we might choose to enlist the help of another company rather than proceeding on our own. We made this decision because we found that there are opportunities even in the very early stages of development, and we believe that we can still produce more candidate products for development.

Hashiguchi [Q]: The reason why you chose joint licensing for rocatinlimab while you chose full out-licensing here is due to the internal and external environment of your company at the time you made that decision? Or does that depend on the diseases the drugs are targeting?

Yamashita [A]: Well, our environment is changing, especially the breakdown of the pipeline.

There was also a change in strategy and a change in how we view the probability of success for each asset. As for rocatinlimab, at that time we did not yet have much going toward late-stage development. Also, because this is a very unique drug, we were proceeding on our own, believing that other companies would not be easily interested until sufficient clinical data were available. After that, we received inquiries because of some very interesting data.

In the case this time, such an option arose because we found a partner who could appreciate the value of the so-called drug discovery concept and the data from our research phase. As I mentioned earlier, we have a wealth of early development products now compared to when we considered rocatinlimab, which led us to this decision.

Hashiguchi [M]: Thank you. That is all.

Mamegano [Q]: I would like to ask a question about the rocatinlimab data. EADV data was introduced today. You explained that both IGNITE and SHUTTLE have shown deep responses over time. I think this is very good data and is consistent with the HORIZON data.

However, I still believe that everyone is concerned about the data going forward. It is about how it is in the medium to long term. I think the top line of the last ASCEND only provided qualitative data on the safety and the response in the parent study. When will we see this bar chart in the medium to long term? Do you have any comments on that at this time?

Yamashita [A]: In the ASCEND study, we are continuing with the single-agent study that showed efficacy in HORIZON and IGNITE, although we are not presenting the figures this time. This time, we have only qualitatively introduced that good results have been obtained at 32 weeks after entering ASCEND. We would like to present the results of this trial in a presentation at an academic conference at some point in the future.

However, we cannot yet say when that announcement will be made now, as there are still more studies to come.

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

Wada [Q]: Thank you very much. I am Wada of SMBC Nikko Securities. I would like to ask you about your partnership with Boehringer.

First, this release states that it is a low molecular weight compound. For the 2024 deal, it stated that it was low molecular weight-like; is this an antibody? I would like to know if the modality is disclosed.

Yamashita [A]: Considering the convenience of the other party, we will refrain from disclosing the information.

Wada [Q]: Thank you very much.

Last year, I believe you mentioned the reduction of R&D for small molecule compounds. I am guessing that this story came up in connection with that. Is there any mention of whether there are still bullets in the non-clinical pipeline due to the reduction of these research functions?

Yamashita [A]: We do not disclose the status of any research that we do not disclose.

The initial process of screening low-molecular compounds, such as high-throughput screening, or the process of narrowing down candidates from a large number of compounds, has become very commoditized, and it is difficult to differentiate oneself from competitors in terms of speed and use of AI. Therefore, we are downsizing such processes for low-molecular-weight compounds, partly because we want to shift resources to antibodies and gene and cell therapy, on which we intend to focus our efforts.

This is not to say that we will not develop small molecule drugs, but we will not discard those that are already promising, and if we can introduce good ones from outside, we will proceed with those as well. This case is not directly related to the previous release on small molecules.

Wada [M]: Understood. Thank you very much.

Moderator [M]: Thank you, Mr. Wada.

This concludes the online presentation on the financial results for Q3 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]