



Kyowa Kirin Co., Ltd.

Kyowa Kirin to Regain Control of Rocatinlimab Development and Commercialization Program

February 2, 2026

Event Summary

[Event Name]	Kyowa Kirin to Regain Control of Rocatinlimab Development and Commercialization Program	
[Number of Speakers]	4	
	Motohiko Kawaguchi	Managing Executive Officer and Chief Financial Officer
	Masashi Miyamoto	Representative Director, President and Chief Executive Officer
	Yasuo Fujii	Managing Executive Officer and Chief Strategy Officer
	Abdul Mullick	Representative Director, President & Chief Operating Officer

Presentation

Moderator: Thank you very much for joining us today for this online briefing with regard to our press release about the beginning of the rocatinlimab development and commercialization program control.

Before we begin, I would like to explain that the participants list will be stored internally for a while with your kind permission.

Today, we will be using the Zoom function and providing simultaneous translation in Japanese and English. There are three languages you can choose from: Japanese, English, or original. Please select your preferred language. When you select Japanese or English, please make sure that you ask your question in the same language as the channel that you have selected.

The content of this briefing will be published as on-demand streaming as well as a transcript on our website. Please keep that in mind when you make your comments.

Today, we'll be touching upon contents that are related to the future, and due to various risks, there are uncertainties. I hope you understand.

Kyowa Kirin to Regain Control of Rocatinlimab Development and Commercialization Program

February 2nd, 2026

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

President and Chief Operating Officer (COO) Abdul Mullick, Ph.D.

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

Managing Executive Officer, Chief Strategy Officer (CSO) Yasuo Fujii, MBA

協和キリン株式会社

The logo for Kyowa Kirin, featuring the company name in white capital letters on a dark orange background that is shaped like a semi-circle.

For the presentation and Q&A today, we have Chairman and Chief Executive Officer (CEO) Masashi Miyamoto; President and COO Abdul Mullick; Managing Executive Director and CFO Motohiko Kawaguchi; and Managing Executive Officer and Chief Strategy Officer Yasuo Fujii. All of them will be participating.

This online meeting is for a maximum of 60 minutes. We would like to provide the overview and then open the floor for questions. Please download the material from our IR website.

Mr. Mullick, the floor is yours.

Mullick*: Good morning, everyone. I'm Abdul Mullick, President and Chief Operating Officer of Kyowa Kirin. Thank you so much for joining this important IR briefing this morning.

As you know, last Friday evening, January 30, we announced an update regarding rocatinlimab, which is currently under development, and regarding the termination of our existing co-development and commercialization agreement with Amgen.

As a result of this, Kyowa Kirin will now take full control of the global rocatinlimab program, including regulatory filings and future commercialization.

Today, I'd like to provide you with an overview of this matter and to explain our future management strategy for rocatinlimab.



Kyowa Kirin will continue to advance rocatinlimab development to create Life-changing value that makes people smile

- Existing license and collaboration agreement will be terminated following Amgen's strategic portfolio prioritization, and Kyowa Kirin will regain control of the global rocatinlimab program
- Kyowa Kirin affirms commitment to developing rocatinlimab as a Life-changing differentiated asset with significant market potential
- Regulatory submissions are planned for the first half of 2026
- Amgen will provide transitional long-term manufacturing and supply of rocatinlimab to Kyowa Kirin
- All eight Phase 3 studies (ROCKET Program) successfully met their primary and key secondary endpoints. Of note, rocatinlimab demonstrated a significant improvement in the co-primary endpoint required for US regulatory submission, the revised Investigator's Global Assessment (rIGA) score of 0 or 1 (defined as achieving a vIGA-AD score of 0 [clear skin] or 1 [almost clear skin] with presence of only barely perceptible erythema) at week 24

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1

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In summary, the existing license and collaboration agreement will be terminated following Amgen's strategic portfolio prioritization. As a result, Kyowa Kirin will regain full control of the global rocatinlimab program.

We'd like to affirm our commitment to developing rocatinlimab as a true life-changing, differentiated asset with significant market potential. Our regulatory submissions are planned for H1 of this year. We'll continue to receive the manufacturing and supply of rocatinlimab from Amgen.

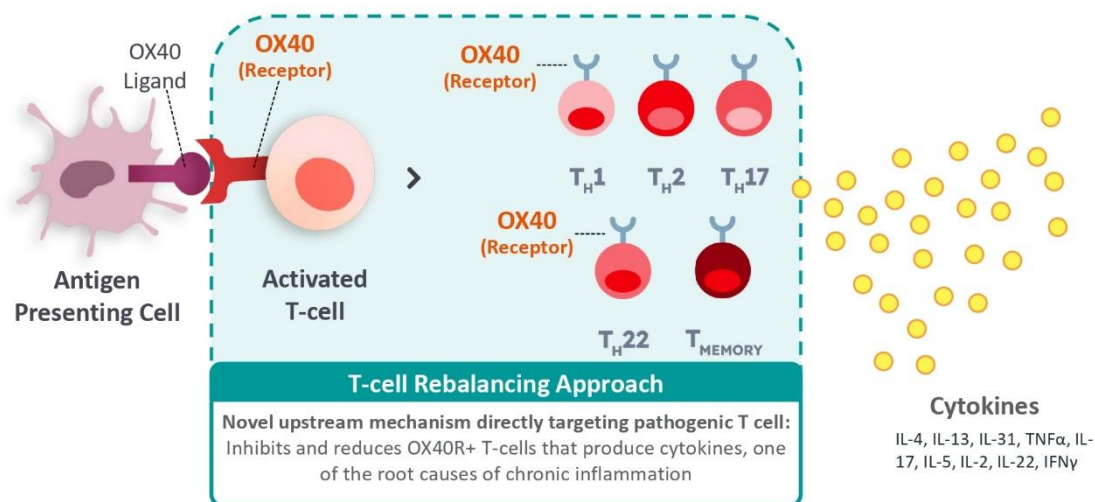
Regarding the clinical development status, all eight Phase III trials in the ROCKET program have achieved their primary endpoints and key secondary endpoints.

Most notably, rocatinlimab has demonstrated a significant improvement in the co-primary endpoint, which was required and stipulated by the US regulatory agency. This is the revised Investigator's Global Assessment, rIGA, at a score of 0 or 1 at week 24. This is an extremely high bar in terms of regulatory approval and, in simplest terms, represents almost total clearance of disease.

Given these excellent results we have achieved to date, we will continue development and have strong expectations that rocatinlimab will undoubtedly play an active role in our portfolio as a product that delivers life-changing value.



Rocatinlimab is a T-cell Rebalancing Therapy which directly targets a root cause of AD, activated pathogenic Effector and Memory T-cells



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2

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If we look at the mode of action of rocatinlimab, we believe rocatinlimab, which has achieved these results, may address one of the root causes of atopic dermatitis through its unique mechanism of T-cell rebalancing.

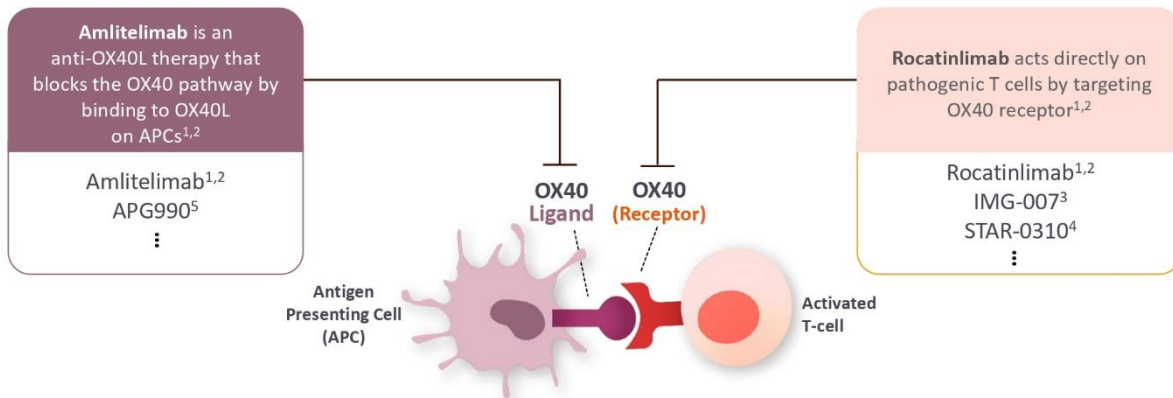
The target of rocatinlimab is a receptor molecule called OX40, which is expressed on activated T cells. OX40 interacts with OX40 ligand, which is expressed on antigen-presenting cells. These are separate from T cells.

As a result, activated T cells differentiate into the various effector T cells and also memory T cells, as we show here. We call these activated T cells pathogenic T cells. We believe they're the root cause of various inflammatory diseases, as they produce diverse cytokines that actually cause the symptoms of the inflammatory diseases themselves.

Because rocatinlimab can act directly on the OX40 expressed on these cells, we believe it can achieve medium- to long-term disease control and deep efficacy.

At present, more than 10 assets related to OX40/OX40L are in clinical stage globally

OX40 signalling leads to the activation of downstream pathways that drive effector and memory T-cell differentiation, proliferation and survival^{1,2}



Note: AD, atopic dermatitis; APC, antigen-presenting cell; OX40R, OX40 receptor; OX40L, OX40 ligand.

1. Croft, et al. Am J Clin Dermatol 2024;25:447-461; 2. Le AM, et al. Pharmaceutics 2022;14:2753; 3. Shen Y, et al. Br J Dermatol 2024;191(Suppl 2); 4. Biris N, et al. Presented at EAACI 2024. Poster D1.343; 5. Wong M et al. RAD 2025., Kyowa Kirin internal search

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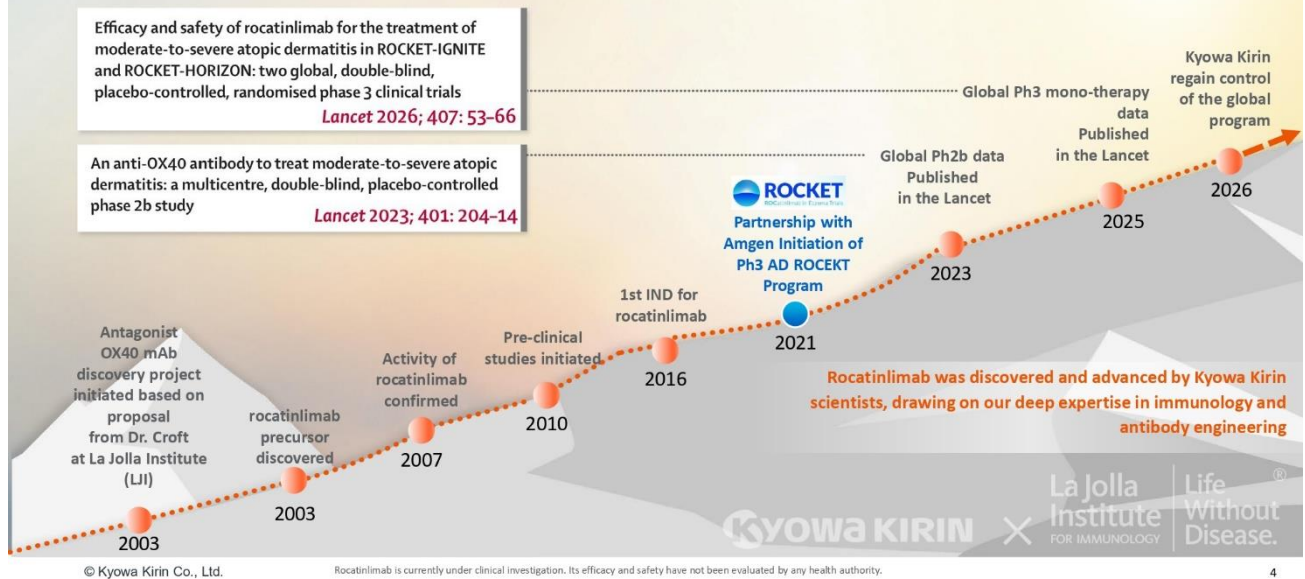
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This is a competitive space with a lot of scientific interest from other companies. We know there are currently more than 10 products related to this pathway, each undergoing clinical trials globally. As evidenced by the number of development candidates, this is a pathway that is attracting significant attention worldwide as a novel agent for inflammatory diseases.

As demonstrated here, it's important to note that anti-OX40L antibodies and anti-OX40 antibodies act at different sites, as OX40L is expressed on antigen-presenting cells, whereas OX40 is expressed on activated T cells themselves.

Kyowa Kirin has absolute conviction in rocatinlimab's science and excited to advance Rocatinlimab program to the next chapter



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Rocatinlimab is an unparalleled product created by our own scientists in Kyowa Kirin through the utilization of our proprietary drug discovery technologies. More than 20 years ago, through collaborative research between the La Jolla Institute for Immunology and Kyowa Kirin, an OX40 antagonist antibody, the precursor to rocatinlimab, was created.

Subsequently, leveraging our high-level immunology expertise and antibody technologies, we achieved our first IND in 2016 and entered into a partnership agreement with Amgen in 2021. That's when we initiated the ROCKET program, a global Phase III trial program currently ongoing. It's the biggest program ever conducted in atopic dermatitis, with over 3,300 patients across eight studies.

During this time, we have continued to achieve favorable results in both the Phase IIb and Phase III trials and have published multiple papers regarding the clinical efficacy and safety of rocatinlimab. The research and development of rocatinlimab are a very exciting endeavor for us, and we continue development with confidence in the results we've achieved so far.

Moderate-to-Severe Atopic Dermatitis (msAD) is a chronic, heterogeneous inflammatory skin disease that imposes a substantial burden on patients and caregivers



Many patients 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.

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It’s important to remember just how severe this disease is and what a big impact it has on patients and their families.

We’re targeting, in the first instance, moderate to severe atopic dermatitis, which is a chronic condition that presents with highly diverse symptoms and characteristics, imposing a significant burden on patients and their carers. It manifests with severe skin symptoms, which in turn lead to sleep disturbances in many patients.

This has a significant adverse impact on mental health and daily life, making it a disease that greatly reduces quality of life.

Furthermore, many patients we speak to continue to yearn for new treatment options in search of symptom relief, and it's believed that existing therapies provide inadequate disease control.

Current treatment options often fail to provide sufficient depth and durability of symptom improvement¹⁻³

- Due to the heterogeneous pathogenesis of AD, no one therapy shows consistent efficacy across diverse patient populations.
- Only 10 - 15% of eligible patients are currently receiving biologic treatment⁴, indicating considerable opportunity for growth in the msAD market.
- More than 50% of patients receiving systemic therapies discontinue treatment within a year⁵.
- Treatment goals have evolved from "short-term symptom control" to "long-term disease control", and ultimately toward "disease modification".

There remains an urgent need for new therapies with novel mechanisms of action to expand treatment options for patients with moderate-to-severe AD

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. 4. IQVIA analysis: Closing in: Novel oral immunotherapies are taking on the biologics [LINK]. 5. Kyowa Kirin/Amgen internal data on file

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6

Let's go to the next slide, please.

Let's look at the current treatment setting. Because atopic dermatitis has diverse pathologies, it's a difficult disease for a single treatment to provide sufficient efficacy to many patients.

Moreover, if we think about biologics that are considered effective for patients who are not well controlled with conventional therapies, there's information suggesting that only 10 to 15% of eligible patients actually receive these treatments, indicating there's significant room for growth in biologics as a whole.

Moreover, it's become clear that even among those patients on the advanced treatments, more than 50% of these patients don't receive adequate efficacy and discontinue their treatment within one year.

While such unmet medical needs are recognized, recent clinical conferences have begun discussing whether treatment goals for atopic dermatitis should actually move from short-term disease control to long-term disease control and beyond, to disease modification. Thus, the importance of new treatment options with novel mechanisms of action remains high for moderate to severe atopic dermatitis.

For patients with Atopic Dermatitis, Unmet Medical Needs (UMN) still exist



- *There remain significant unmet medical needs in AD. Few patients are able to continue existing advanced treatments over the long term. Patients are eagerly waiting for innovative new options.*
- *I welcome new drug candidates with novel mechanism of actions that have the potential to deliver unique value that other therapies are not able to provide.*



Professor Kenji Kabashima
Department of Dermatology,
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COI Disclosure
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Professor

The following conflicts of interest (COI) should be disclosed in relation to this material.
• Receives consulting fees from Kyowa Kirin Co., Ltd.

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7

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If we talk to key opinion leaders and patients outside our company, here's an example from Professor Kabashima of Kyoto University Graduate School of Medicine. He's a leading expert on atopic dermatitis. He reinforces the significant unmet medical needs that still exist in atopic dermatitis, that few patients can continue long-term treatment with existing medicines, and that there is a need for innovative drugs.

Given this situation, he welcomes a product with a novel mechanism of action that has the potential to deliver unique value that other therapies are not able to provide. Let's look at the marketplace.

Strong Growth Expected in the msAD Markets Driven by increasing penetration of biologics and the introduction of novel therapies

Atopic Dermatitis Market Overview

Estimated U.S. AD patient 12y+ population

>23 million

Biologic penetration in the U.S.



15- 20%

Projected sales growth

Over 15%

Atopic Dermatitis Market Outlook

AT*-treated # of Patients in U.S.**

400-450K

2026

- 6 therapies launched to date
- Dupixent
 - Adbry
 - Rinvoq
 - Cibinqo
 - Nemluvio
 - Ebglyss

800-850K

2030 and beyond

- Rocatinlimab
- Amitelimab
- Zumilokibart
- Temtokibart
- Rezpegaldesit eukin

~75% anticipated increase in AT treated population from 6 to 10+ products launched based on similarities with psoriasis market

SOURCE: National Eczema Association; Asthma and Allergy Foundation of America; US Census Data; WHO, CDC, analyst research, FDA labels; corporate presentations; Clinicaltrials.gov; Allergy & Asthma Network; Datamonitor; Chan et al., J Am Acad Dermatol (2025); Hanlin et al., Dermatitis (2007); Silverberg et al., J Allergy Clin Immunol (2013); Datamonitor; Therapeutic Categories Outlook, TD Cowen (2024); Gorriz et al., J Derm Treat (2022); Heratizadeh et al., J Eur Acad Dermatol Venereol (2024); Lio et al., J Drugs Dermatol (2023); Fuxenich et al., J Inv Dermatol (2019); Boystov et al., J Derm Treat (2022); * Advanced Therapy, ** Based on L.E.K. epidemiology assessment

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8

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If we look at the market environment, we see that there are more than 80 million patients globally. As we said before, penetration rates for biologics remain low at about 15% to 20% in the US, indicating substantial room for growth and improvement of patient outcomes.

The overall market is growing at a rate exceeding 15%, and it's estimated that the current number of patients receiving advanced therapies in the US is between 400,000 and 450,000.

In recent years, we've seen diverse new drugs being introduced, such as those shown here. These have entered the market and expanded it. Also, we know there are new drugs under development, including rocatinlimab. These are amplifying this trend.

Estimates suggest patient numbers could more than double by 2030. This suggests that this is a marketplace that continues to grow at high speed, driven by the significant unmet need.

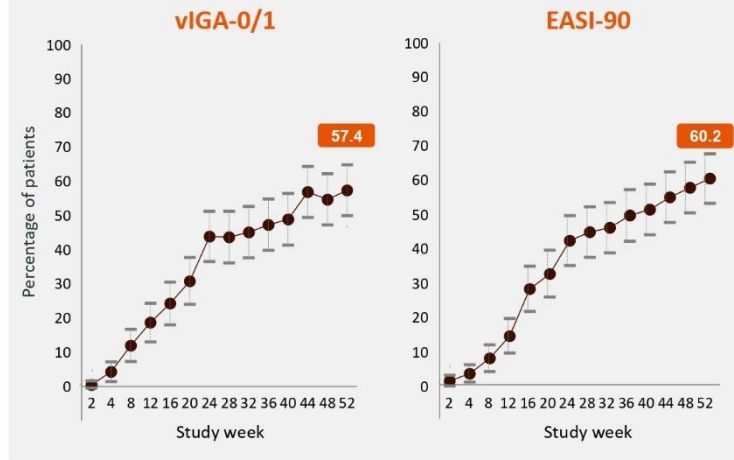
Rocatinlimab delivers progressive increases in the proportion of patients achieving deep responses through Week 52



ROCKET-ORBIT Topline: 52-week Open Label Adolescent Trial*



- Safety results are consistent with those observed in the ROCKET 24-week and 56-week adult trials.
- The most frequent TEAE in ROCKET-ORBIT were headache, pyrexia, aphthous ulcer, upper respiratory tract infection, and nasopharyngitis.
- Low discontinuation rate due to adverse events.



AD = atopic dermatitis; AU = aphthous ulcers; vIGA-AD = Validated Investigator's Global Assessment for Atopic Dermatitis; EASI = Eczema Area and Severity Index; TEAE = Treatment-Emergent Adverse Event

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*Data on file

9

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Let's look at rocatinlimab specifically now. We're going to share data with you here, which you won't have seen before. But as we've seen before, there are unmet needs, and we continue to see impressive results with rocatinlimab.

These are the results from the ROCKET-ORBIT trial, which is in adolescents. These are children aged between 12 and 18 years old. The primary endpoint of this trial is safety, and results consistent with those in adults have been observed.

The most frequently reported treatment-related adverse events are headache, pyrexia, aphthous ulcer, upper respiratory tract infection, and nasopharyngitis. We see treatment discontinuation due to adverse events remains at a low rate.

We also conducted an exploratory analysis on efficacy, which you see on the right-hand side, and this is a really important point. This analysis was prespecified in our statistical analysis plan before database lock. It is not a post-hoc analysis.

What we saw was that rocatinlimab demonstrated progressive increases in the proportion of patients achieving deep responses through week 52, and importantly, without any plateau.

We believe the possibility of achieving the medium- to long-term disease control and deep efficacy expected from rocatinlimab is demonstrated in these studies, and we continue to deepen our understanding and our confidence in rocatinlimab. We are seeing these progressive increases in the proportion of patients achieving deep responses in all other studies as well.

We look forward to revealing these data in near-term future congresses.

A Robust Launch Readiness Upon Regulatory Approval

Kyowa Kirin has established operations in Japan, U.S., and Europe with proven track records

- Japan: Strong track record in dermatology
- U.S. and Europe: Excellent core teams across Sales, Marketing, Market Access, Medical, Patient Support; proven success with Crysvida and Poteligeo

U.S. Dermatology Launch Preparation

- Multi-year preparation for co-promotion with Amgen
- Core functional teams already in place
- Continued investment to ensure readiness for potential approval and launch

Robust Manufacturing Capabilities Established

- Combines Amgen's world-class manufacturing capability with Kyowa Kirin's global supply infrastructure to ensure stable and reliable product supply

Next slide, please.

Regarding launch readiness, you've seen the high unmet need in atopic dermatitis as well as the encouraging clinical results seen with rocatinlimab. Through our partnership with Amgen, we've also firmly established our capabilities to deliver this value to patients.

Firstly, Kyowa Kirin has established strong operations across three regions: Japan, the United States, and Europe, all with proven track records. You'll learn more about this in our earnings call next week.

In Japan, we built a strong track record, specifically in the dermatology field, demonstrating our deep expertise and market understanding in this therapeutic area.

In the United States and Europe, we have excellent core teams across all critical functions, including sales, marketing, market access, medical affairs, and patient support, all of which are capabilities that will be essential for a successful rocatinlimab launch.

These teams have already demonstrated proven success with our products, Crysvida and Poteligeo, in the United States with Nourianz, which validates our commercial and operational capabilities in these markets.

Moving on to the US dermatology launch preparation, it's important to remember that we have been preparing for several years for a co-promotion in our partnership with Amgen. Our core functional teams are already in place and ready to execute. We continue to make strategic investments to ensure complete readiness for potential approval and launch.

Finally, regarding our manufacturing capabilities, we've established a robust infrastructure that combines the best of both companies. By leveraging Amgen's world-class manufacturing capability together with Kyowa Kirin's global supply infrastructure, we can ensure stable and reliable product supply to meet patients' needs.

This transition will allow Kyowa Kirin to bring Rocatinlimab with the highest priority and urgency to patients around the world

Item	Original Agreement	After Original Agreement Termination
Market Authorization Holder	Amgen	Kyowa Kirin
Manufacturing	Amgen	Amgen will provide transitional long-term manufacturing and supply of rocatinlimab to Kyowa Kirin
Development	Led by Amgen	Led by Kyowa Kirin with certain transition services from Amgen
Commercialization	Japan: Kyowa Kirin US: Amgen (Kyowa Kirin co-promotion) Europe/Asia: Amgen (Kyowa Kirin retains co-promotion rights)	Japan & US: Kyowa Kirin Europe/Asia: Kyowa Kirin explores all options

Next slide, please.

This shows the division of roles between our company and Amgen following contract termination.

Assuming we gain regulatory approval as planned, our company will be the market authorization holder. Regarding manufacturing, Amgen will provide transitional long-term manufacturing and supply of rocatinlimab to Kyowa Kirin. Development will be conducted by our company with support from Amgen as it's needed.

Regarding commercialization, we've decided that our company will conduct it in Japan and the US, while we'll consider all options for Europe and Asia going forward.

It's important to remember that our collaboration with Amgen has allowed us to develop rocatinlimab in a way that we could never have done alone, and the prelaunch market preparation between the two companies has been ongoing for a number of years now.

Impact on P&L: Short-term cost increase, but substantially beneficial over the mid to long term

Item	Original Agreement	After Original Agreement Termination
Revenue	Kyowa Kirin receives double-digit % royalty	Kyowa Kirin records sales revenue
COGS	—	Amgen supplies products at an agreed-upon price
SG&A Expenses	Shared equally by both companies	100% borne by Kyowa Kirin
R&D Expenses	Shared equally by both companies	100% borne by Kyowa Kirin Service fee payment to Amgen for transition support (FY2026-2027)

Future Prospects



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12

Next slide, please.

Looking at the impact on the P&L, revenue will be recorded by Kyowa Kirin. Whilst we can't disclose the detailed economic terms, this should be considered a return of rights due to the termination of the existing agreement, but not a buyback of rights previously licensed to Amgen.

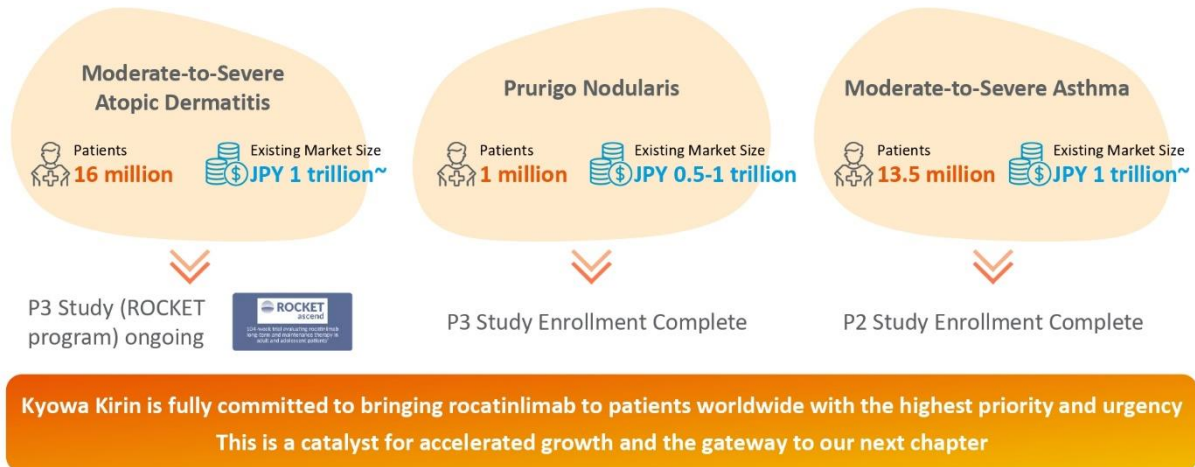
For cost of goods sold, we will receive manufacturing supply from Amgen at an agreed price, paid by Kyowa Kirin to Amgen for a certain period of time. Kyowa Kirin will bear 100% of SG&A and R&D expenses. We will pay Amgen a service fee as consideration for the transfer of responsibilities. These are the overall structures of the transactions this time.

Rocatinlimab's peak sales potential is currently assumed to be over JPY200 billion, and we anticipate profit contribution timing around 2028.

Rocatinlimab: Pioneering a Novel Treatment Paradigm Through T-cell Rebalance



- Directly targets a root cause of inflammation and chronicity to potentially achieve deeper and durable improvement
- Potential to expand to other inflammatory diseases with significant unmet need



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Next slide, please.

Rocatinlimab is currently under development in multiple diseases, as you know, to pioneer a new treatment paradigm for inflammatory diseases based on a unique mode of action called T-cell rebalancing. In addition to the moderate to severe atopic dermatitis indication, which we've been talking about today, we are also conducting clinical trials in prurigo nodularis and moderate to severe asthma.

Finally, through collaboration with Amgen, we've been able to advance the development of rocatinlimab to this point through large clinical trials that demonstrated the efficacy and safety of rocatinlimab. We've also advanced launch preparations together over the past several years.

Together, we've made tremendous progress to prepare for the approval and launch of rocatinlimab, and the partnership with Amgen has been critical to our progress.

I really would like to take this opportunity to express our sincere gratitude to Amgen, which has been a strong partner to Kyowa Kirin for many decades.

Now we're ready to make even greater efforts to deliver rocatinlimab to patients around the world as Kyowa Kirin. We're convinced of the benefits that rocatinlimab can bring to patients if approved. We are committed to delivering it to patients as our top strategic priority and as quickly as possible.

We truly believe this matter is a catalyst that accelerates our growth towards our vision, and it's an important milestone that opens the door to the next chapter in our company's history.

By regaining the global rights to rocatinlimab, we've established an important new treatment option in our portfolio, which can change the trajectory of our company. Kyowa Kirin will continue to strive towards the ongoing creation and delivery of life-changing value that makes people smart.

Thank you very much.

Question & Answer

Moderator [M]: Now, we would like to open the floor for questions.

Yamaguchi [Q]: This is Yamaguchi from Citi.

My first question is about the impact on the P&L. You can see on the slide that milestone was originally in the plan. Also, I think the profit was going to be shared, and all of this was basically removed. Kyowa Kirin will pay for everything going forward. Looking at the pros and cons, based on what's written here, I believe the assessment is that while costs will inevitably increase in the short term, there should be profitability in the medium to long term due to economies of scale. But are the milestones also removed?

Also, have you decided to do the United States on your own? Can you please clarify this point?

Kawaguchi [A]: Let me start with whatever we received in the existing contract and also the expected milestones. In 2021, USD400 million of one-time was received. From the signing of the contract up until we know that there is going to be approval from the FDA, revenue is recognized based on that contract.

Now the contract is terminated, and we no longer have the obligation to execute this. In Q1 2026, the deferred revenue total amount is about JPY9.7 billion at the end of FY2025. This total amount will be recognized as revenue in Q1. On the other hand, as you have rightly mentioned, a maximum of USD850 million of approval- and sales-related milestones will not be received because of the termination of this existing contract.

By changing this contract, how does it impact our performance? As you can see on the slide, although over the short term the cost will increase, mid- to long-term, we will see a major improvement in profitability. These are the key points.

In the existing contract, excluding Japan, development in the rest of the world. Also, sales cost for the United States was basically a 50-50 split between Amgen and Kyowa Kirin. After launch, Kyowa Kirin was going to receive the sales royalty of a double-digit percentage. But R&D, as well as SG&A, will be borne by Kyowa Kirin 100% under the new situation. But we can also recognize the revenue 100%.

Therefore, from FY2026 to FY2027, this is before the full-scale recognition will start; for the short term, R&D costs, the launch preparation, and SG&A cost will have an impact.

Based on this update, in FY2026, the performance impact, compared to the existing contract, is estimated to be minus JPY15 billion to JPY20 billion. Having said that, as you can see on the slide, from FY2028, profit contribution is expected to start. The peak sales, JPY200 billion potential, is also estimated.

Therefore, over the mid- to long-term, revenue can be fully recognized. We will have this new business model. By converting into this business model, we expect a huge improvement in profitability.

The 2026 performance outlook will be announced on February 9, and the details will be explained in the briefing on February 10, after reflecting these changes.

That's my answer.

Yamaguchi [Q]: Yes. Just one point of confirmation: JPY15 billion to JPY20 billion. You mentioned deferred revenue of JPY9.7 billion; is that already included in that number?

Kawaguchi [A]: It is separate. Originally, we had planned to record deferred revenue in 2026 in the same manner as before. This 9.7 billion yen includes the portion where deferred revenue that was scheduled up through the first quarter of 2027 will be recorded in a lump sum, but the impact is not that big.

Yamaguchi [Q]: I see. Another simple question: JPY200 billion or more peak sales, this is the first time you're disclosing this to us. Is this only for AD? What about nodularis or asthma? Is that included? JPY200 billion, AD market is pretty big. How much market share is expected for this number, JPY200 billion?

Kawaguchi [A]: This is only for atopic dermatitis. As far as the market share is concerned, we cannot really share the details right now.

Wakao [Q]: I'm Wakao from JPMorgan.

Regarding the background of the termination of the collaboration with Amgen, I'd like to know more. Amgen decided to prioritize their portfolio. I understand it may be difficult for you to comment since it's due to a portfolio review on Amgen's side, but from an outside perspective, given the data obtained so far, it seems like perhaps the potential that both companies envisioned at the time of the initial agreement couldn't be found. I appreciate your comment on this.

And if Amgen thought the outlook was worse than initially anticipated, your company's figure of 200 billion yen also appears somewhat optimistic, so I'd like to hear your view. That's my first question.

Mullick [A]*: The reason, as we've stated, for Amgen's decision is really purely related to their portfolio prioritization. We can't comment more than that. All we can tell you is that, from our perspective, as we've seen the clinical data emerge, we have become extremely confident about the value that this asset brings and our ability to bring it to market.

Wakao [Q]: My second question: You're showing us the data from the ORBIT trial, and I'm sure your company is very confident. But to fight in the competitive market alone can be challenging. Do you think you can realize your goal in Europe and in the United States? Is there any possibility of forming a tie-up with another company?

Mullick [A]*: Thank you for the very important question.

I think the most important thing to drive our decision is, number one, the degree of unmet need in the market; and number two, the ability of the product to address the unmet need. With rocatinlimab in atopic dermatitis, both those conditions are satisfied.

We see a really interesting analog in the atopic dermatitis market with the launch of nemolizumab by Galderma. Here's a product which is addressing a specific unmet need in a specific patient population, and resourcing and executing in a way that is probably a lot more modest than some of the mega pharmas are deploying.

As you look at the prescription data in the United States, we now see that the uptake of that product is extremely high, especially in second-line therapy. That gives us a degree of confidence that, if you're able to target the patient appropriately with a product that addresses the need, you can be successful.

In addition to that, I think it's important to remember that when we signed this agreement with Amgen in 2021, we still hadn't taken back Crysvita from Ultragenyx. Over the past years, we brought Poteligeo to market and demonstrated really solid growth.

Crysvita now, through our own capabilities which we built over the past years, we've delivered to more and more patients. All of those capabilities will be required for rocatinlimab.

When we think about raising awareness around disease and the OX40 pathway, we've been doing that with cutaneous T-cell lymphoma and XLH now for the past years, identifying the right patients. We've deployed AI and machine learning to find specifically the patients our therapies address best, and we're able to target those with very targeted and sensible use of resources.

Coalescing and aligning, expanding KOL networks, we've been doing that, supporting market access, which is, of course, quite complex in the United States. We've built strong capabilities around that with our patient support functions. We're very confident that now, with rocatinlimab, we'll be able to deploy those capabilities in the same way.

We've looked very carefully, and after careful assessment and the launch preparation we've already been conducting with Amgen, we feel confident that we're able to take this to patients ourselves. Of course, we feel the same way in Japan, as we said. But outside of those two markets, we really will look pragmatically at the best way to bring this life-changing therapy to as many patients as possible.

Thank you.

Wakao [Q]: Is a partnership not an option for you with another company? Are you considering the possibility of forming a tie-up with another company?

Mullick [A]*: As management, we always need to look at whatever is best for the Company and what's better to bring the medicine to patients. We'll continue to evaluate our decisions as we move forward.

Muraoka [Q]: This is Muraoka, Morgan Stanley.

First, I'd like to dig a bit deeper into the future cost burden. Earlier, Mr. Kawaguchi, you said FY2026 would be negative by 15 to 20 billion yen. So I was thinking, since your company will now be covering Amgen's portion too and costs will basically double, doesn't that really mean it's more like a negative of 30 to 40 billion yen? But I also want to hear about what happens from FY27 onward.

I'm trying to think through FY27 and FY28 as well, and if the peak is 200 billion yen, then I figure sales probably need to hit somewhere around 40 to 50 billion yen by FY28, right? And if you're breaking even at that point, that means you'd be spending around 40 billion yen a year going forward.

So when I'm revising my projections, should I be thinking that you'll spend more in FY27 than in FY26, somewhere around 40 billion yen annually? These are just my rough calculations, but it would really help if you could tell me whether I'm way off base or if I'm in the right ballpark.

Kawaguchi [A]: First, in comparison to the original contract, there will be an impact of 15 to 20 billion yen, so I believe your understanding is correct that the increased burden amounts to 15 to 20 billion yen.

Mainly for 2026, the R&D expenses that were previously borne at half will now double, and there will be certain preparation costs for the U.S. launch, so the SG&A burden will also double compared to what was previously anticipated. These amounts total 15 to 20 billion yen.

In that sense, when we get to 2027, naturally full-scale SG&A expenses will kick in. The burden for this portion will also double, but since it won't yet be the timing when sales will make a full contribution, we anticipate that the negative impact of increased cost burden on the P&L from this contract will appear during these two years through FY27.

However, since we expect profit contribution starting from 2028, conversely, sales should exceed our company's doubled burden amount. And this revenue will be greater than what was anticipated under the previous contract. We expect this portion to begin contributing to profits from FY28.

I'd like to refrain from commenting on your specific assumptions.

Muraoka [Q]: Regarding the R&D portion, if the Phase 2 for asthma goes reasonably well, will you proceed with Phase 3 independently as well?

If so, I'm thinking that R&D expenses, which should decrease from around FY27, might actually increase instead. As for asthma, considering various factors, I think it could be an option to discontinue it unless the results are exceptionally good. Amurtelimab was at least underwhelming. How should we think about this?

Miyamoto [A]: For asthma, as you said, we are in Phase II right now. We are waiting for the data readout. We need to look at the data and see how the data looks in order to make further decisions. In other words, your understanding is more or less in line with our expectations. Of course, if the result is great, we are already having internal discussions about how to develop this, but we have to look at the data first.

Muraoka [Q]: If the outcome is really great, maybe you can find another partner just for asthma? Or would you want to have a partner for both asthma and AD?

Miyamoto [A]: Well, there are different possibilities. We are discussing this internally now.

Thank you for your question.

Seki [Q]*: Seki from UBS Securities. My first question is about the safety. In the investment community, I have heard about a controversy regarding the Kaposi sarcoma observed in the competitive study. Can I ask if you have no cases of Kaposi sarcoma in your rocatinlimab programs?

Miyamoto [A]: Regarding safety, we always give it importance when we conduct clinical studies.

In a program, in the ROCKET program, there was one case of Kaposi sarcoma; in that particular patient, the patient was given rocatinlimab. As for the background, the patient did have risk factors, as we heard. Kaposi sarcoma was observed. The treatment was discontinued, but we hear that the patient is recovering.

Seki [Q]: When you say risk factors, usually in a study like this, at baseline, HIV patients are excluded. After enrollment, do risk factors develop afterward?

Miyamoto [A]: As for Kaposi sarcoma, HIV is not the only risk factor. There are several other factors as well. Of course, patients met the inclusion criteria to be enrolled. When we look at the background, there was such a factor.

Seki [Q]: Second question: The timing of the NDA submission, originally, was 2026. That timing will not change?

Miyamoto [A]: This year, in H1. In that sense, there's going to be no change.

Barker [Q]: Jefferies Securities, Stephen Barker.

Cost increase of JPY15 billion to JPY20 billion, that is my understanding. This includes a one-time payment to Amgen as well. How much is this? The amount that you have to pay Amgen with regard to the rights being transferred. Can you please explain?

Miyamoto [A]: Regarding the termination of the contract with Amgen, we cannot disclose the financial conditions, I'm afraid.

Fujii-san, do you have any additional comment?

Fujii [A]: This is Fujii speaking. Thank you for your question.

With regard to the existing contract, it is being terminated. This is not a buyback. I just wanted to clarify that point.

Thank you for your question.

Barker [Q]: JPY15 billion to JPY20 billion cost increase is over how many years?

Miyamoto [A]: JPY15 billion to JPY20 billion cost increase is expected just for this fiscal year, just one year. For next fiscal year, do we have any comments? JPY15 billion to JPY20 billion, as I have explained, is R&D and SG&A being doubled. That's the impact. As I said before, we will see the same impact in FY2027 as well. Same impact of cost increase in FY2027 as well.

Barker [Q]: In order to launch on your own, you will need a new sales force. Will you be hiring new MRs?

Kawaguchi [A]: Yes, of course.

Mullick [A]*: We've already been building our launch teams over the past years, and our intention is now to continue building those out to ensure we're ready for launch.

Ueda [Q]: Ueda from Goldman Sachs Securities, speaking.

First, I'd like to have a follow-up question about the impact on financials. Regarding the negative 15 to 20 billion yen in 2026, there was also mention that the milestone payments you were originally scheduled to receive would no longer be coming in, so I'm wondering if this is factored into that figure. Or is the impact of the service fees for supporting Amgen more significant? Could you provide a bit more color on this? In particular, I'd appreciate it if you could provide a breakdown of R&D expenses and SG&A expenses.

Kawaguchi [A]: In 2026, the amount of impact, as I said many times, R&D and SG&A expenses will increase as a burden, and that is giving us an impact. Originally, in our plan for 2026, the approval milestone will be gone, as I said, and was not included in the assumptions. That potential impact is not included in our assumptions here.

Ueda [Q]: My second question is about 2027 and your outlook for 2027. The JPY15 billion to JPY20 billion level could have a similar impact in 2027. Revenue will increase for sure, but in the meantime, mainly SG&A expenses and sales-related costs will increase. Will a similar level of negative impact continue?

Kawaguchi [A]: We have not stated that there will be an impact of the same amount in 2027. While it is our current assumption that there will be a negative impact in 2027 as well, regarding the specific amount of impact in 2027, I believe we'll be able to answer that when we announce the 2027 plan after reviewing the 2026 situation. But as of now, we'd like to refrain from commenting.

Ueda [Q]: Then, as of now, towards 2027, is it going to be improving, or is there going to be a negative impact on your revenue?

Kawaguchi [A]: We cannot comment on this point. Regarding revenue and SG&A expenses, this is going to be the matter of the balance between the two. Detailed sales and marketing plan and future sales forecast will be examined carefully. The numbers can be subject to change.

Wada [Q]: This is Wada, SMBC Nikko Securities.

I have questions about sales and development structure. Amgen and Kyowa Kirin co-developed. Also, you've been preparing together for marketing. In terms of headcount, do you plan to absorb people from Amgen into Kyowa Kirin? Or will you be increasing the headcount on your own? How will the personnel be transferred?

Mullick [A]*: Yes. We've already hired some super people from outside our company who have deep expertise in this area, and we'll continue to build those out. What we can't talk about is whether we take people from Amgen or not. We will just look for the best people that we need. We're very confident about the level of investment we need and the type of people we need to make this happen.

Wada [Q]: About peak sales, what are your assumptions? Europe and Asia are included in your assumptions. Is that the correct understanding? When you were co-promoting with Amgen, you had a plan, and now things are changing. Have you changed the peak sales accordingly and the assumptions for peak sales?

Kawaguchi [A]: As for peak sales, we are including regions outside of the US as well. Earlier, we said JPY200 billion just based on AD. But prurigo nodularis is also actually included. My apologies, I have to make a correction.

Wada [Q]: Peak sales estimation has not been changed due to the change in the contract. Is that the correct understanding?

Miyamoto [A]: Working with Amgen versus Kyowa Kirin doing this alone. In terms of the top line, of course, it will make a difference. That's what we assume. But as we have already explained, the original contract was half of the cost, but also half of the profit. Now we have to pay 100% of the cost, but we can also enjoy 100% of the profitability.

Overall, even if the peak sales estimate changes, this is going to be a positive impact for us. This is how we see this.

Matsubara [Q]: Matsubara from Nomura Securities.

First, I have a question for you about manufacturing. Looking at page 12, it shows that Amgen will supply to your company, and looking at page 11, it's written as 'transitional and continuing in the medium to long term.'

Could you tell me whether there's a possibility, looking at a long-term timeframe, that rocatinlimab will be manufactured at your North Carolina facility going forward?

Fujii [A]: This is a transition period until we can manufacture on our own. We are assuming supply from Amgen. At which facility are we going to manufacture? We still cannot disclose. But in the future, we'd like to receive the handover so that we can manufacture at a facility and supply to the market.

Matsubara [Q]: How long is it going to take until you can manufacture?

Fujii [A]: It's specified, but we'd like to refrain from disclosing that information right now.

Matsubara [Q]: My second question may be a repeated question, but from Amgen, you regain control of this program. ROCKET ORBIT study data is seen. Patient symptoms improved in the mid- to long-term. But regarding the other clinical study results, in other aspects, it's not the reason worse results are seen. Is that why you're regaining control?

Mullick [A]*: I think one of the things that we're aware of is that, as we released results study by study, we've kind of missed the bigger clinical picture of this asset.

First of all, we need to look at the development program in totality. It's 3,300 patients, eight separate studies, looking at various patient populations. We have separate studies for adolescents and separate studies for adults. We've looked in our studies at naïve patients. Also, which is important, patients who failed existing therapies.

Now, this is very unusual for any development program. Although we can't compare our results to other products directly, we know that this kind of stringent inclusion criteria has not been used by other companies. The reason I'm telling you this is that it impacts the results you see.

But when you look at the results in totality, what we do see now emerging is a very strong efficacy picture: one that is deeper, as we see by the FDA-required primary endpoint of IgA1, and one that improves over time, as you see here in the ORBIT study. That's really, I think, on us.

As more scientific congresses and more publications come, we'll be able to see in totality the full picture, which I think will transform the way people look at this asset and have looked at it up until this point.

Thank you.

Kawamura [Q]: Thank you for the presentation. SBI Securities, Kawamura speaking.

I'd like to ask a question to get a better understanding of the image for future sales and how revenues will materialize. You've explained that this drug addresses an unmet need and that data has been generated that can fulfill that need.

Additionally, you referenced Galderma's nemolizumab, but nemolizumab is quite a fast-acting drug, whereas your drug is one where patients gradually experience the effects from weeks 26 to 52.

As you move away from Amgen and handle marketing independently, I'm wondering how quickly you can penetrate the market with a drug that doesn't have immediate effects, or whether the current situation is such that there are plenty of patients who have no other options and are willing to wait about 26 weeks.

Regarding this point—the actual market conditions and what you need to do and to what extent now that Amgen is no longer involved and you're operating independently—if you have a concrete picture, could you provide some explanation, even though this is a qualitative question?

Mullick [A]*: Firstly, as you rightly said, nemolizumab is actually gaining the majority of its use as a second-line treatment. In other words, patients who have been unsuccessful on their first-line treatment.

Yes, it's true that the predominant use of nemolizumab is for itch, and this is what you see. But there is a greater need for total and deep efficacy, skin clearance, and this is what we see with rocatinlimab.

When we talk to the investigators who've been involved in our clinical development program, their feedback is very consistent: this is a product that, once patients start it, they really stay on it, and they continue to want to stay on it. This gives us confidence that this will address this unmet need.

Ultimately, when you look at the burden of this disease, patients go on to a therapy. It may act fast, but within a matter of time, they have a flare as the symptoms of the disease come back. The reason is that we're not addressing the root cause of the disease.

What patients want, of course, is immediate relief, but also what they're looking for is something that prevents that constant cycle of flare, relief, flare, relief. This really disrupts their life.

With our novel mechanism of action, by addressing the pathogenic T cells, and also the memory cells, we believe that this deep, enduring, and improving efficacy over time will really bring the relief patients are looking for. As I said, this is what we see from our clinical trials so far.

Thank you.

Kawamura [Q]: My second question may be a bit premature, but let me ask from the perspective of amurtelimab versus Sanofi. They released their earnings last week, and I believe there was a comment that they would file this in the second half of 2026.

Their clinical trials also show regional differences, so it's hard to say at this point, but regarding how you'll differentiate this drug against a mega-pharma company that has Dupixent, if you have any thoughts on that, please share them at the end.

Miyamoto [A]: We are watching what the other companies are doing, but we would like to refrain from commenting. The big difference between this and Amltelimab was explained on the slide. Rocatinlimab targets OX40 itself. Pathogenic T cells, activated T cells, are the direct target of Rocatinlimab, whereas Amltelimab targets OX40L. This is a big difference.

According to the data from the study so far, what we call "T cell rebalance," the T cell status or the status of the T cell population, is being normalized. We believe that this is the root cause. As Abdul mentioned earlier, the root cause of AD. This is what we are targeting with Rocatinlimab, and this is the most important aspect of this treatment. Based on evidence, we will continue to take a close look at this point.

Wakao [Q]: Just one additional question. Regarding this drug, you are confident in the data you have obtained. On page nine, EASI-90, I have a question on this. Compared to others, this seems to be a high level. This is the data not in adults. Do we have this level of data in adults as well? This is the primary analysis for [ITT]. Also, do other longer-term data show a similar level?

Miyamoto [A]: The ORBIT study is an open-label study. The primary endpoint is safety in the study. Secondary endpoints include efficacy before database lock. After database lock, we look at the results in terms of efficacy trends compared to similar results in other studies. We cannot mention specific numbers, but the answer to your question is yes.

With longer-term use of the drug, efficacy, vIGA-0/1, EASI-90, or EASI-100, without reaching a plateau, shows a tendency toward a higher proportion of patients achieving this over time. That's seen in other studies as well.

Wakao [Q]: So with the data showing that the long-term efficacy levels of amurtelimab are improving, I can somewhat understand that targeting this pathway leads to enhanced efficacy over the long term.

Therefore, in terms of the level of efficacy, should we view other trials with a bit more of a discount? Should we not expect too much that these kinds of numbers will emerge? I'm asking about the absolute values.

Miyamoto [A]: Regarding the efficacy, we can't disclose that right now, so we'd appreciate it if you could wait for our presentations at academic conferences.

Wakao [Q]: AAD? Should we wait until AAD?

Miyamoto [A]: Including when we can disclose and at which congress, we shouldn't tell you when we can disclose. Please understand.

Muraoka [Q]: This is Muraoka from Morgan Stanley.

Next week, at the earnings announcement, we don't know whether the midterm plan is going to be presented or not. But based on what has happened, are you going to present the midterm plan?

If that is the case, I understand breaking even in 2028. But if it's five years, then 2030. By 2030, what is the profit target? Is that going to be higher than before because of this regaining of control?

Kawaguchi [A]: Please wait until February 9 to see what we will announce on that day. I am sorry. Please have expectations. Please wait.

Muraoka [Q]: There is a possibility that you'll be announcing a midterm plan at that point. Is that correct?

Kawaguchi [A]: Well, we cannot really answer your question. We have to refrain from answering. It's just another week. Please wait.

Muraoka [Q]: Understood. Over the next two to three years, expenses are going to be bigger. I understand that Kyowa Kirin was planning to license in other assets from external pipelines. Has that thinking changed because of this?

Miyamoto [A]: This is Miyamoto speaking. Thank you very much for your question.

It hasn't changed. We have to look at the overall balance, of course. It's something that we have always been doing. Continuously, we are looking for other pipeline assets as well, and that hasn't changed.

Muraoka [Q]: I see. So, you invest in rocatinlimab and, in parallel, you'll be looking at other assets as well.

Miyamoto [A]: We have to think about the overall balance again. If we acquire another license from outside, we can, for example, discontinue other pipeline assets internally. We are always looking for opportunities externally as well.

Moderator [M]: Thank you for joining us. Thank you very much for your support of Kyowa Kirin going forward as well. Thank you very much.

[END]