



Kyowa Kirin Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending December 2023

August 4, 2023

Event Summary

[Event Name]	Q2 Financial Results Briefing for the Fiscal Year Ending December 2023	
[Date]	August 4, 2023	
[Number of Speakers]	4	
	Masashi Miyamoto	Representative Director, President and Chief Executive Officer
	Motohiko Kawaguchi	Managing Executive Officer, Director, Finance Department
	Yoshifumi Torii	Executive Officer, Head of R&D
	Tomohiro Sudo	Executive Officer, Head of Global Product Strategy

Presentation

Moderator: We will now begin the online financial results briefing of Kyowa Kirin Co., Ltd., for Q2 of the fiscal year ending December 31, 2023, as announced yesterday at 3:30 PM.

Please note the following prior to the start of the briefing. Please note that we will keep the names and company names of all participants for a certain period of time as a list of participants.

Please note that the content of this presentation will be available as an on-demand audio stream and a transcript on our website. We appreciate your understanding in this regard when you speak. The information presented today contains forward-looking statements. Please note that there is uncertainty due to various risks.

Today's speakers are Masashi Miyamoto, Representative Director; Motohiko Kawaguchi, Managing Executive Officer, Director, Finance Department; Yoshifumi Torii, Executive Officer, Vice President, Head of R&D Division; and Tomohiro Sudo, Executive Officer, Director, Global Product Strategy Department, Strategy Division. Those four are giving a presentation and answer to questions you may have.

Today's briefing is scheduled for maximum of 90 minutes. After explaining the overall financial results, we will take your questions. Please download the documents from our IR website.

Miyamoto: Good morning, everyone. Thank you for your participation. I would like to provide an overall explanation using the financial results presentation materials that have been uploaded on our website.

Summary of Q2 Results

Kyowa KIRIN

(Billion Yen / Rounded)

	2022Q2 Results	2023Q2 Results	Changes	2023 Revised Plans	Progresses
Revenue <i>[Overseas Ratio]</i>	185.3 <i>[59%]</i>	199.2 <i>[63%]</i>	+13.9 (+8%)	426.0 <i>[64%]</i>	47%
Gross Profit <i>[Gross Profit Margin]</i>	141.9 <i>[77%]</i>	152.2 <i>[76%]</i>	+10.3 (+7%)	326.0 <i>[77%]</i>	47%
SG&A <i>[SG&A Ratio]</i>	76.4 <i>[41%]</i>	82.4 <i>[41%]</i>	+6.0 (+8%)	162.0 <i>[38%]</i>	51%
R&D <i>[R&D Ratio]</i>	27.9 <i>[15%]</i>	33.7 <i>[17%]</i>	+5.7 (+21%)	79.0 <i>[19%]</i>	43%
Gain/Loss on Equity Method	2.4	1.4	-1.0 (-41%)	3.0	46%
Core Operating Profit <i>[Core OP Margin]</i>	39.9 <i>[22%]</i>	37.5 <i>[19%]</i>	-2.4 (-6%)	88.0 <i>[21%]</i>	43%
Profit	35.0	21.6	-13.4 (-38%)	76.0→70.0	31%

I would like to start by explaining the financial figures. Please skip to slide five to see it.

First, I would like to mention about YoY comparisons. Sales revenue increased by JPY13.9 billion, or 8%. Then core operating profit declined JPY2.4 billion, or minus 6%. Quarterly profit decreased by JPY13.4 billion, or minus 38%.

The decrease in core operating profit was mainly due to an overall increase in R&D expenses in conjunction with progress in the development of KHK4083, and an increase in SG&A expenses, such as personnel expenses associated with own sales of Crysvita in North America.

The decrease in quarterly profit was mainly due to an impairment loss of JPY8.3 billion resulting from the discontinuation of RTA 402 development, and then a provision for loss on contracts related to the closing costs of the discontinued clinical trials.

I would like to explain the percentage of progress toward the full-year forecast, which was revised in Q1. Revenue progressed at 47%. As you know, it is lower than the 50% progress in H1, as is the case every year, since the growth of global strategic products, especially Crysvita, continues to be strong.

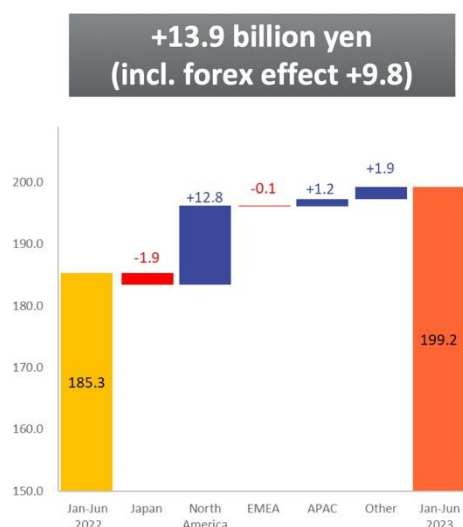
Then there are SG&A expenses. This is 51% progress. Although it appears to be high, it is in line with our plan. There is an impact of profit-sharing expenses to Ultragenyx prior to the start of North American Crysvita own sales. After the start of North American Crysvita own sales from April 27, the Company switched from SG&A expenses to cost of sales as a sales royalty from profit sharing, and this structure makes the progress rate of SG&A expenses appears higher against the full-year plan in H1 of the fiscal year.

R&D expenses increased significantly by 21% YoY, but this represents 43% of the full-year plan. We plan to continue to invest in R&D, mainly in KHK4083 and other products.

These results mean 43% of progress in terms of core operating profit. Although quarterly profit progress rate is at 31%, this is because the full-year forecast includes a gain on the sale of shares of a subsidiary and a valuation gain associated with the transfer of 51% of the shares in a joint venture with Grünenthal, 13 established pharmaceutical brands in Europe. The transfer itself was completed on August 1.

Overall, we aim to achieve our full-year plan by continuing to grow sales, especially of global strategic products, and by properly controlling expenses.

YoY Analysis -Revenue-



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● Japan -1.9

Although Duvroq, Romiplate, and Crysvita increased, revenue in Japan region decreased by 3% due mainly to negative impact by annual NHI price-cut and shrink in Nesp-AG and Allelock affected by competitive products.

● North America +12.8 (incl. forex effect +5.8)

Revenue in North America region increased by 27% with the growth of Crysvita(+28%), Poteligeo(+21%), and Nourianz(+47%).

● EMEA -0.1 (incl. forex effect +2.0)

Revenue in EMEA region decreased by JPY0.1B due to the impact of generic penetration of Abstral despite the continued growth of Crysvita(+13%), and Poteligeo(+42%).

● APAC +1.2 (incl. forex effect +0.7)

APAC revenue increased by 8% with the growth of Crysvita, and Nesp, while Gran was down due to the Chinese national tender system.

● Other +1.9 (incl. forex effect +1.3)

10% growth in the other revenue was due to the royalties of growing Fasenra (Benralizumab).

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I would now like to explain revenues and other in order compared to the previous year. Page six shows a breakdown of revenue by region.

In Japan, sales of Duvroq, Romiplate, Crysvita, and other products continued to grow. However, the NHI price-cut in April 2022 and April 2023, and the impact of these price-cut on Nesp-AG, Allelock, and other products, resulted in 3% decrease in sales for the Japan region.

Sales in North America increased by 27% due to solid growth in global strategic products, especially Crysvita, as well as the yen's depreciation.

In EMEA, sales of Crysvita and other global strategic products continued to grow, but sales of Abstral and other established drugs declined, resulting in JPY100 million decrease in sales.

In Asia, sales of Gran declined due to being listed in the national tender system in some parts of China, but sales of Crysvita, which was launched in Australia last November, grew steadily, and sales increased 8%, partly with a tailwind from FX impact.

As for Other revenue, there was a continuous increase in Fasenra royalties, which led to 10% increase in revenues.

Revenue of Major Items (Japan)

(Billion Yen / Rounded)

Item	2022Q2 Results	2023Q2 Results	Changes	Reasons	2023 Plans	Progresses
Nesp + Nesp-AG ¹	10.5	8.4	-2.1 (-20%)		16.6	50%
Nesp	1.6	1.5	-1.5 (-8%)	NHI price-cut & Biosimilars' penetration	2.8	54%
Nesp-AG	8.8	6.9	-2.2 (-22%)		13.8	50%
Duvroq	2.7	4.2	+1.5 (+57%)	Market penetration (Launched in Aug 2020)	7.8	54%
Orkedia	4.9	5.0	+0.1 (+1%)		11.2	44%
G-Lasta	14.8	15.0	+0.2 (+1%)		33.5	45%
Poteligeo	1.0	0.9	-0.0 (-5%)		2.0	47%
Rituximab BS	5.0	4.4	-0.6 (-12%)	NHI price-cut	8.7	51%
Romiplate	4.8	5.7	+1.0 (+20%)	Market penetration (New indication in 2019)	11.2	51%
Allelock	3.8	3.1	- 0.7 (-19%)	NHI price-cut	4.7	66%
Nourias	3.9	3.7	-0.2 (-5%)		7.5	49%
Haruropi	1.8	2.1	+0.3 (+17%)	Market penetration (Launched in Dec 2019)	4.7	44%
Crysvita	4.1	4.8	+0.7 (+17%)	Market penetration (Launched in Dec 2019)	11.1	44%

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.

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Next on page seven shows an analysis of sales revenue of major items in Japan.

As I explained earlier, sales of Nesp-AG are declining due to the NHI price revision and an impact from the competitor, Biosimilars, but we recognize that it is on track against the plan.

I believe Duvroq will continue to grow steadily and will be number one in the market share. Sales revenue of Romiplate increased steadily, with 20% increase over the previous year. Crysvita is also growing steadily with 17% increase over the previous year.

Revenue of Major Items (ex-Japan)

(Billion Yen / Rounded)

Item	2022Q2 Results	2023Q2 Results	Changes	Reasons	2023 Plans	Progresses
Crysvita	49.4	61.9	+12.5 (+25%)		138.0	45%
North America	35.9	46.0	+10.2 (+28%)	[North America] Market penetration [EMEA] Geographical expansion & Additional indication (Adult/TIO) [APAC] Geographical expansion		
EMEA	13.5	15.3	+1.8 (+13%)			
APAC	0.1	0.6	+0.5 (+600%)			
Poteligeo	10.3	12.5	+2.2 (+21%)		27.5	45%
North America	8.1	9.4	+1.3 (+15%)	[North America] Market penetration [EMEA] Geographical expansion & Market penetration	19.4	49%
EMEA	2.1	3.1	+0.9 (+42%)		8.0	38%
APAC	-	-	-		0.2	-
Nourianz	2.6	3.5	+0.9 (+37%)	Market penetration	7.5	47%
Nesp	3.9	4.2	+0.3 (+9%)		8.0	53%
Gran	3.8	2.8	-0.6 (-17%)	Listed on Chinese tender list	8.2	39%
Neulasta	3.0	2.8	-0.2 (-7%)		5.7	49%
Tech-licensing	15.3	17.8	+2.5 (+16%)	Growth of Fasenra	39.0	46%
Benralizumab Royalty ¹	9.3	11.6	+2.3 (+25%)			

¹ Sales royalties of Fasenra which has been marketed by AstraZeneca, including our own estimation.

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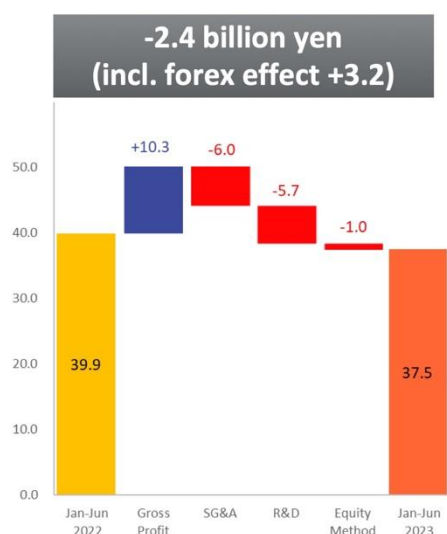
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Next on page eight shows the major items overseas.

Crysvita. Sales continued to grow steadily with 25% increase over the same period last year. Poteligeo is also growing at 21% YoY. North America is doing well. In EMEA, we are expanding the number of countries marketed, and market penetration is also progressing. This means that Nourianz are growing steadily.

As explained earlier, on technical-licensing revenues, Fasenra royalty increased by JPY2.3 billion.

YoY Analysis -Core OP-



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● Gross Profit +10.3 (incl. forex effect +9.0)

Increased in conjunction with JPY13.9B rise in revenue. Margin % remains at the same level (76.6% → 76.4%) thanks to increased proportion of profitable "Global 3 brands" and tech-licensing revenue, despite the COGs have increased due to the North America Crysvita-related scheme change from 'Profit-sharing (SG&A)' to 'Sales royalty (COGs)' after Apr 27, 2023.

● SG&A -6.0 (incl. forex effect -4.1)

Although decreased in Crysvita profit sharing expenses due to the North America Crysvita-related scheme change after Apr 27, 2023, increased in HR exp, etc by the Crysvita commercial operation and investment in IT/Digital infrastructure and human resources for global business foundation.

[HR exp -5.1 / Sales promotion +2.1 (incl. Crysvita profit sharing expenses +3.2)]

● R&D -5.7 (incl. forex effect -1.6)

Increased in clinical study costs of KHK4083.

● Gain/Loss on Equity Method -1.0

While revenue of Hulio (FKB327/Adalimumab biosimilar) increased, FKB's profit declined due to decrease in tax-accounting effect.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

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Page nine, YoY analysis of core operating profit.

Gross profit was increase by JPY10.3 billion, in line with JPY13.9 billion increase in sales revenue.

Although there was an increase in cost of sales due to the recognition of sales royalties after the company started own sales of Crysvita in North America on April 27, gross profit margin was 76.4%, the same level as the same period last year, due to an improved product mix resulting from growth in global products and an increase in technology revenues.

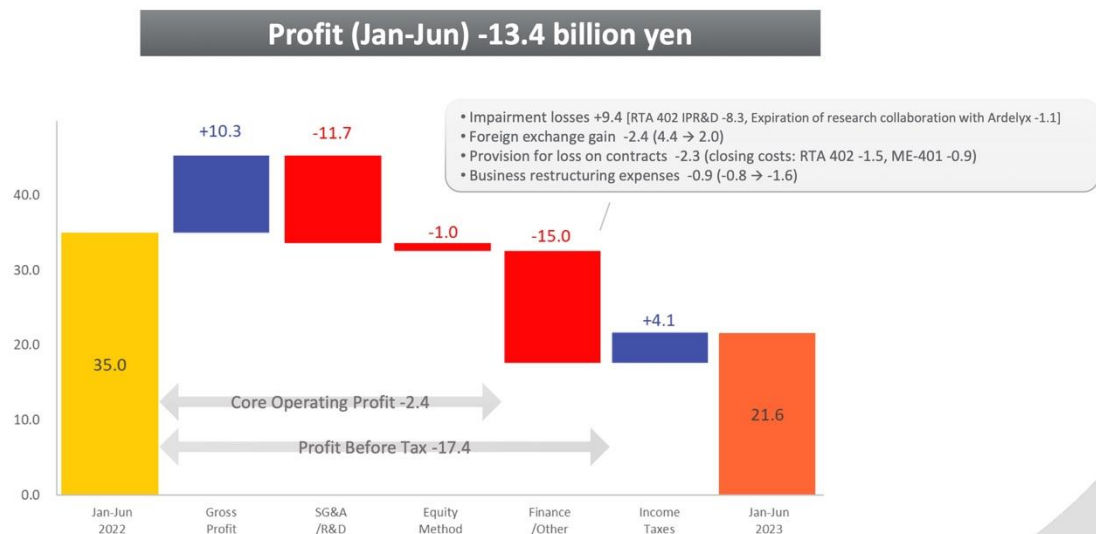
SG&A expenses increased by JPY6 billion. Although there was JPY3.2 billion decrease in profit-sharing expenses since the start own sales of Crysvita, there was an increase in SG&A expenses due to the increase in personnel and other costs associated with Crysvita's own sales in North America, as I explained earlier, and there was an increased investments in IT digital infrastructure and human resources to establish a global business foundation. There is also an impact from foreign exchange rate by JPY4.1 billion.

R&D expenses increased by JPY5.7 billion, mainly due to progress in the development of KHK4083. The foreign exchange impact is JPY1.6 billion.

Next one is an investment gain/loss by equity method. This was a negative JPY1 billion. This was because there was an additional deferred tax assets were recorded at Fujifilm Kyowa Kirin Biologics in the same period of the previous year, but this was not the case this year.

As a result, core operating profit decreased by JPY2.4 billion.

YoY Analysis -Profit-



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Page 10, quarterly profit. This slide shows profits under core operating profits.

Please take a look at the balloon, it says minus JPY15 billion in finance and others. This includes a new impairment loss of JPY8.3 billion recorded in Q2 due to the decision to discontinue the development of RTA 402. In addition, the provision on contract losses as the cost of closing clinical trials that have been discontinued, an increase in business restructuring expenses in EMEA, and a decrease in foreign exchange gains, contributed to a total decrease in profits of JPY15 billion. As a result, bottom profit decreased by JPY13.4 billion from the same period last year to JPY21.6 billion.

2023 Key Actions

- North America:
Start own sales (Establish and start own operation of the direct sales force).
- EMEA:
Continue to focus on geographical & indication expansion.
- Japan:
Strengthen promotional activities centered by the dedicated personnel.

Q2 Topics

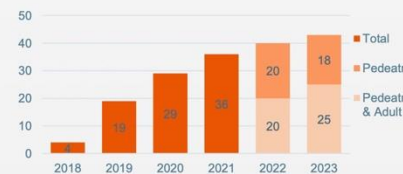
- North America:
• Own sales operation has made smooth start with the establishment of solid base for it.
• The seasonal factor has been resolved, and sales grew as expected.
• The number of patient enrollments in the treatment preparation stage and treatment patients continued to increase steadily.
- EMEA:
• Patient penetration in each country has been steadily increased.
• Revenues increased only slightly YoY due to price settlement payments including those for previous years for renegotiation of insurance reimbursement prices in connection with the expansion of sales scale in Germany.
- Japan:
• Continued to strengthen promotional activities, such as holding webinars for medical professionals.

Sales Revenue (Billion Yen)



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

Launched Countries / Regions (XLH)



* Excludes Latin America and Turkey, where Ultragenyx records sales.

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Next, I would like to give commercials update. Could you please jump to page 12?

First of all, Crysvita. As we always show, the graph on the left shows sales trends by quarter since 2018, when the product was launched.

First is North America. The seasonal factors have been resolved, and we believe that the growth in Q2 has been as strong as expected. The number of patient enrollments in the treatment preparation stage continued to increase steadily. We started our own sales in North America on April 27 and are off to a good start, and we will continue to work closely with Ultragenyx to promote market penetration.

Market penetration is steadily increasing in Europe as well, but we are currently renegotiating of insurance reimbursement prices in connection by the expansion of sales scale in Germany. Based on this negotiation, price adjustments in Germany were recorded in the current quarter including those for prior years, resulting in only a slight increase in sales revenue over the previous year. We hope you will consider this a transitory factor.

In Japan, we are also making progress as planned at the beginning of the year, and we are working to strengthen our activities with the aim of further expanding the market.

2023 Key Actions

- Strengthen promotional activities utilizing evidences including blood tumor data.
- Raise awareness of importance of blood testing among early-stage patients

Q2 Topics

- North America: Steady growth by virtue of promotional activities utilizing evidences including blood tumor data or raising awareness of importance of earlier consultation with specialists and blood testing.
- EMEA: Sales grew steadily y-o-y, despite an increase in Mandatory Discount to public health insurance organizations in Germany and the U.K.

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

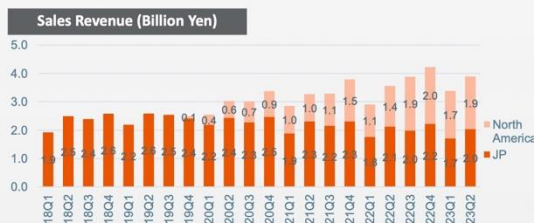


2023 Key Actions

- Further instill importance of adenosine A_{2A} receptor antagonism in treating wearing-off.
- Strengthen field level activity through further collaboration and knowledge sharing between Japan and the US, and through maximizing available resources by utilizing effective approaches including digital.

Q2 Topics

- US: Sales increased YoY. Introduced a new interactive case-based speaker program and continued strong field activity to enhance the messaging of importance of A2A pathway in treating OFF episodes. Lower coverage gap utilization had a positive cause for this quarter sales.



Next, page 13, please. Poteligeo. In North America, we continue to conduct activities to penetrate the market, such as marketing utilizing evidence or raising awareness of importance of earlier consultation with specialists and blood tests. I believe that sales revenue is also steadily increasing.

In EMEA, although there were some negative factors such as the increase in Mandatory Discounts for public health insurance organizations in Germany and the United Kingdom, it is growing steadily resulting in an increase in sales revenue.

Lastly, Nourianz. It is growing steadily in the US as planned. We continue to strengthen our promotional activities by, for example, holding new interactive programs in the form of workshops.

That's all for the commercial update.

Upcoming Events: Main Development Pipeline Products

Code Generic Name	Events (Completed are in bold)	Timeline (Completed are in orange)
KHK4083/AMG 451 rocatinlimab	Atopic Dermatitis P3 (ROCKET PROGRAM) Asthma P2	In progress TBD
KHK4951 tivozanib	nAMD P1 data presentation P2 initiation	Q4 2023 Q4 2023
KHK7791 tenapanor	Hyperphosphatemia under maintenance dialysis: Regulatory decision to be announced (JP)	Sep. 2023
KW-3357 antithrombin gamma (genetical recombination)	Preeclampsia P3 LPO Topline data	Jun. 2023 Q3 2023

LPO: Last Patient Out; nAMD: Neovascular age-related macular degeneration

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R&D-related updates. Page 15, news flow of the main development pipeline products.

The first one is KHK4083, rocatinlimab. The whole study information is now available for the ROCKET Program, Phase III program being conducted in collaboration with Amgen. I would like to briefly explain the program later.







In addition, as for rocatinlimab, it has been decided to expand the indication to asthma. Amgen and our company are currently working together for various things, and we hope to discuss the details at a later date at an appropriate time.


KHK4951. We are now preparing to present the results of the Phase I study at a conference in Q4 of this year. We are currently preparing for Phase II trial to start this year and hope to have an opportunity to explain the details at a later date.

KHK7791 is currently under review in Japan, and the results are expected in September, which we are eagerly awaiting.

Finally, we have KW-3357. The last patient out of the Phase III trial for preeclampsia, which is currently being conducted in Japan, was achieved in June. We are in the process of compiling the data and hope to be able to disclose the top line data soon.

ROCKET is a comprehensive phase 3 development program designed to evaluate the efficacy, safety, and tolerability of rocatinlimab (monotherapy or combination therapy) in adult and adolescent patients with moderate-to-severe AD

						
Trial Duration	24 weeks	24 weeks	24 weeks	24 weeks	52 weeks	52 weeks
Trial Design	Placebo-controlled	Placebo-controlled	Placebo-controlled	Placebo-controlled	Placebo-controlled with re-randomized maintenance	Open-label
Rocatinlimab Dose	Dose 1 or Dose 2 Q4W*	Dose 1 Q4W*	Dose 1 or Dose 2 Q4W* + TCS/TCI	Dose 1 Q4W*	Initial Period: Dose 1 or Dose 2 Q4W* ±TCS/TCI Maintenance Period: Dose 1 or Dose 2 Q4W or Q8W ±TCS/TCI	Dose 1 Q4W*
Population	Adults with msAD†	Adults with msAD†	Adults with msAD†	Adults with msAD†	Adolescents with msAD†	Adolescents with msAD†



Adults and adolescents who complete a rocatinlimab parent study are eligible to enter ROCKET-Ascend, where they will be randomized to receive rocatinlimab dose 1 or dose 2 Q4W or Q8W or placebo Q4W†

- *Loading dose at week 2. †All trials will enroll patients with moderate-to-severe AD with inadequate response, contraindication, or intolerance to topical medications (biologic-naïve and biologic-experienced patients). ‡Available doses for subjects entering ROCKET-Ascend will vary based on the parent study they participated in.
- AD, atopic dermatitis; msAD, moderate-to-severe atopic dermatitis; Q4W, every 4 weeks; Q8W, every 8 weeks; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid.

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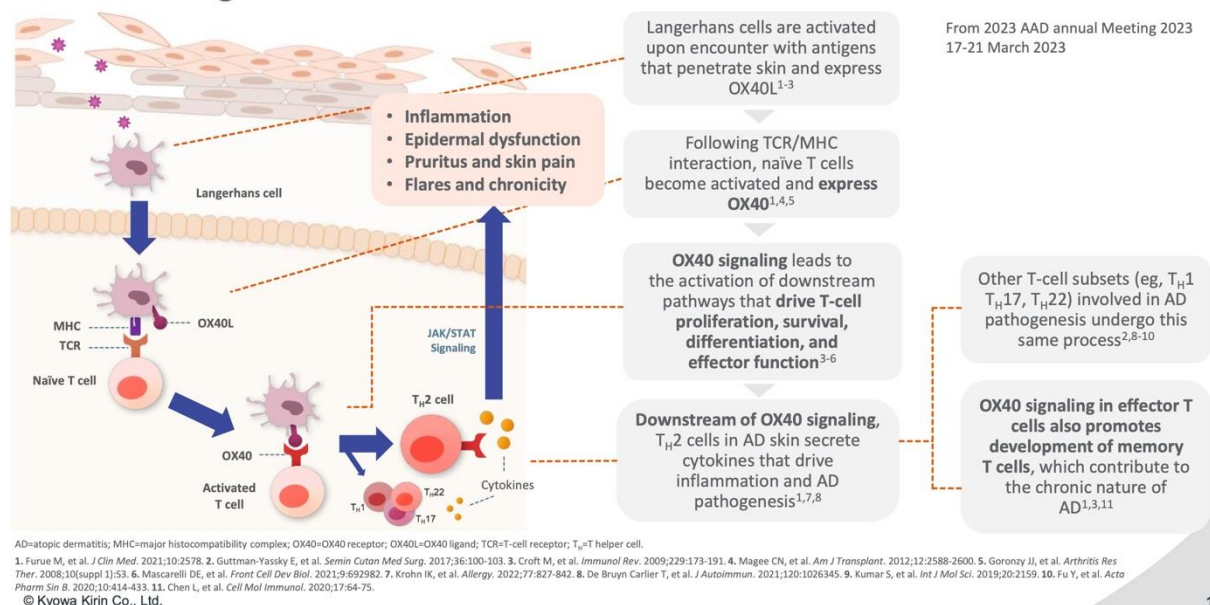
Page 16 shows Phase III for rocatinlimab, ROCKET program overview.

In last year's full-year financial results, we introduced five studies other than ROCKET voyager and ROCKET ascend. We are now in a position to introduce all the studies. The overall structure is that patients will participate in one of the six studies, from ignite to orbit. After the completion of these studies, patients will be transferred to the ROCKET ascend study.

Patients will be randomized again from dose 1 to dose 2, or a placebo group when they enter the ascend trial.

In this study, we will evaluate the strength of this product, its expected sustained effect on atopic dermatitis, as well as its safety and tolerability after long-term administration.

Critical Role of OX40 Signaling in Orchestrating T-Cell Driven Inflammation and AD Pathogenesis KYOWA KIRIN



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See next, page 17. I would like to recap the characteristics of rocatinlimab from a science perspective.

OX40, the target of rocatinlimab, is a molecule that is expressed on activated T cells upon stimulation of antigen-presenting cells, and the OX(40) signaling which occurs by an interaction between OX40 and OX40 ligand, induces proliferation, survival, and differentiation of various helper T cells associated with atopic dermatitis.

As a result, multiple subclasses of helper T cells, mainly Th2 cells, release various cytokines that promote the pathogenesis of atopic dermatitis in the patient's skin. This is said to cause symptoms such as inflammation, itching, and pain.

OX40 signaling also contributes to the chronicity of symptoms by inducing the formation of memory T cells, and thus OX40 signaling is thought to be deeply involved in the inflammation and pathogenesis of atopic dermatitis.

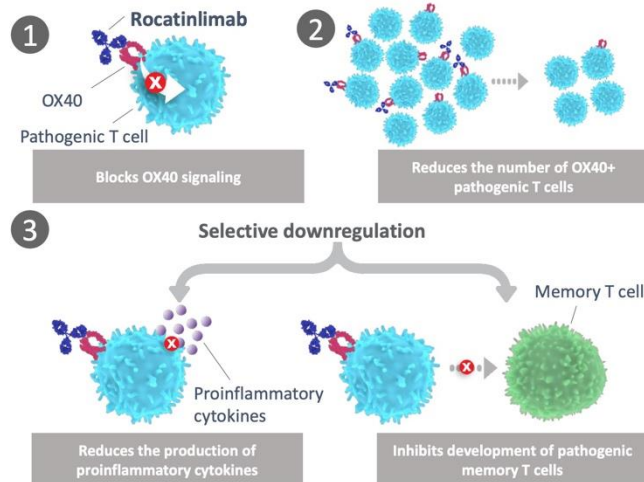
Rocatinlimab is an investigational anti-OX40 monoclonal antibody that targets the underlying AD pathogenesis¹⁻³

KYOWA KIRIN

From 25th WCD Congress 3-8 July 2023

OX40 is a co-stimulatory molecule expressed on **Th2 cells**, as well as other T-cell subsets (**Th1, Th17, Th22**) that are **upregulated** in patients with AD⁴

Rocatinlimab inhibits and reduces the number of **OX40-expressing pathogenic T cells**, responsible for driving systemic and local inflammatory responses¹⁻³



AD, atopic dermatitis; Th, T helper

¹ Nakagawa et al. *J Dermatol Sci.* 2020;99(2):82-89; ² Papp KA, et al. *J Eur Acad Dermatol Venereol.* 2017;31(8):1324-1332; ³ Guttman-Yassky et al. *Lancet* 2023;401(10372):204-214; ⁴ Furue & Furue. *J Clin Med* 2021;10(12):2578.

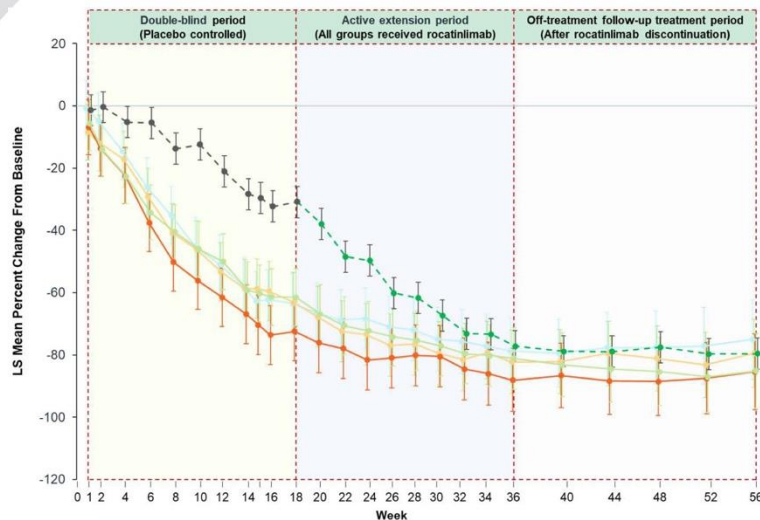
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See next, page 18. Rocatinlimab, which is currently in Phase III, is a monoclonal antibody against OX40 and inhibits OX40 signaling by binding to this molecule. In addition, owing to our own POTELLIGENT technology, it is expected to reduce the number of activated T cells expressing OX40 with its ADCC activity.

As a result, it is expected that rocatinlimab will continuously reduce proinflammatory cytokines produced by activated T cells. It will also inhibit the differentiation of activated T cells into memory T cells, which may lead to the suppression of chronic atopic dermatitis.

Rocatinlimab: Phase 2b data¹



The Least-squares (LS) mean percent change in Eczema Area and Severity Index (EASI) score

	Week 16	Week 24	Week 36	Week 56
Rocatinlimab 150 mg Q4W, %	-62.2	-68.3	-78.7	-75.0
Rocatinlimab 600 mg Q4W, %	-59.5	-73.4	-82.3	-79.5
Rocatinlimab 300 mg Q2W, %	-73.6	-81.6	-88.1	-85.4
Rocatinlimab 600 mg Q2W, %	-61.4	-72.2	-81.1	-85.1
Placebo/rocatinlimab 600 mg Q2W, %	-32.3	-49.7	-77.2	-79.6

Sustained improvement in EASI after treatment discontinuation (Week 36)

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1. Guttman-Yassky et al. *Lancet* 2023;401(10372):204–214

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See page 19. We would like to show you the test data obtained from the Phase II study that support some of our expectations we have presented.

This is data that also appeared in the *Lancet*. Rocatinlimab was administered at the doses described in the colored rows in the table on the right side and compared to the placebo group up to week 18. As a result, as you can see in the active treatment group, significant improvement in EASI score was observed. In addition, patients in the placebo group also started receiving the actual drug after the 18th week, and the improvement effect was also confirmed in this group.

In addition, rocatinlimab treatment was terminated at 36 weeks in this study, and you can see that EASI scores continued to improve from 36th weeks to 56th weeks, or 20 weeks after the end of treatment.

These results indicate that certain results supporting the high durability of the drug have been obtained in this study, and are expected in the ongoing Ph3 studies.

In Phase III, we will continue to work closely with Amgen to further explore the value of this product and to propose this drug as a new treatment option for patients with moderate to severe atopic dermatitis.

Year-to-date Key News Flow

Category	Date	Headline	As of August 3, 2023
ESG	Mar 8	Kyowa Kirin Selected for a "Health & Productivity Stock" and awarded as a "Certified Health & Productivity Management Outstanding Organization"(White 500) (Japan)	
R&D	Mar 17	Presented New data from Phase 2b clinical study of Rocatinlimab in Atopic Dermatitis at the American Academy of Dermatology Annual Meeting 2023	
SCM	Mar 28	Completed construction of a new building at Ube Plant (Japan)	
ESG	Apr 6	Introduced RE100 renewable electricity to all purchased electricity at its two plants and three laboratories (Japan)	
SCM	Apr 7	Completed construction of a multipurpose facility relating to Quality Assurance (Q-Tower) at Takasaki Plant (Japan)	
R&D	Apr 27	Started collaboration in drug discovery technology with School of Life Science and Technology, Tokyo Institute of Technology (Japan)	
R&D	May 10	Announced Phase III Study Results of bardoxolone methyl (RTA 402) in Japan and Discontinuation of Development (Japan)	
LCM	Jun 23	Approval for partial change of Antineoplastic Mitomycin C Agent. (Japan)	
LCM	Jul 18	Launch of Topical Ophthalmic Mitomycin C Agent and resume the supply of Antineoplastic Mitomycin C Agent. (Japan)	
LCM	Jul 24	Application for partial change of approved indication of G-Lasta® for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation. (Japan)	

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management
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Last but not least, please take a look on page 21 for the list of news released since the beginning of the year.

This is the end of my brief explanation.

Question & Answer

Moderator [M]: I would now like to move on to the Question & Answer session.

Yamaguchi [Q]: I am Yamaguchi from Citigroup. Thank you very much. The first question is about the SG&A in the financial result. I understand that Mr. Miyamoto has explained well in this regard, but I still think that SG&A expenses for the full year is sticking out and the core operating profit are not progressing well. Can you confirm once again in terms of SG&A expenses whether the forecast for the full year can be achieved as a result of the transfer of the Crysvita-related items and the growth of Crysvita from Q3 or Q4 as in the Company forecast? That is my first question.

Miyamoto [A]: Thank you, Mr. Yamaguchi. I am Miyamoto. As you mentioned, it appears a slight increase in SG&A expenses in H1 of the fiscal year, but as I explained briefly, we believe that the expenses are basically within the planned range.

As for more details, Kawaguchi is here now, so I will pass on to him.

Kawaguchi [A]: I am Kawaguchi. Thank you for your question. As you understand, in regard to the rate of progress, Crysvita's profit share is factored in until April and this portion disappeared from May onward. This will have the greatest impact on the annual rate of progress.

In fact, our own selling system has been in place almost since the beginning of this year, as well as personnel, so in that sense, full selling costs are incurred throughout the year, but profit-sharing also takes until April. And when we factor that into the annual plan, the result becomes 51%. Actually, we are slightly short of the Company's plan, so I hope you will understand that we are totally in line with the plan.

Yamaguchi [Q]: Thank you. Second, you explained own sales system of Crysvita in the US. I believe that now that you have own selling system, your company will control everything, and you will be able to see all the numbers of patients to be administered and so on.

Q2 was pretty good in US dollar terms, and I think you are starting to see and find patients to come in, but how does this compare to your full-year forecast? Is there a slight upward trend? Or is it on-track? Please tell us about how you see your own sale system in the US market.

Miyamoto [A]: Thank you, Mr. Yamaguchi. Sudo will explain a few details later. Since April 27, we have been very careful, and we had a certain degree of confidence. The results for May, June, and July is still in the middle of the month, but the numbers are smoother than expected, and I think we are getting to a place where we can work with a high degree of confidence.

I think it is safe to say that we have a considerable amount of confidence, since the overall project is well within the planning line. Now, Sudo-san please.

Sudo [A]: Thank you. I am Sudo from Global Product Strategy Department. At the outset, I would like to say that I am glad that the transfer went smoothly without causing any inconvenience to patients or doctors.

As was mentioned earlier, I think we were able to smoothly transfer the activities of searching for patients and transferring them to treatment after the search was completed through our work with Ultragenyx.

It has been and will continue to be analyzed, but I think that field activities are a quite thicker than before, perhaps partially related to the SG&A expenses, which was mentioned earlier. In this sense, as Miyamoto

mentioned earlier, the identification of patients and initiation of treatment in Q2 seems to have been moving slightly higher than the data of the past two to three years, although it's slight.

It is still too early to conclude how it will evolve, but we are relieved to see that a good sign is coming out.

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

Muraoka [Q]: My name is Muraoka. Thank you very much. My question is about rocatinlimab. The start of the asthma trial was mentioned in Amgen's material this morning. Now, what is the cost sharing here? I am thinking that you will spend more money more than you did for atopic dermatitis because it is asthma. It would be helpful if you could comment quantitatively and some direction. This is the first point.

Miyamoto [A]: Thank you, Mr. Muraoka. This does not mean that we are dividing the contract in any way by indications, but rather, as a total cost-share and profit-share. We are going to work with Amgen in a firm relationship.

We also talked with Amgen about the cost and said let's do it within this range. For example, when we are going to go with asthma, the decision is made after careful consideration of the size of trials to see if we can go ahead or no.

Muraoka [Q]: I understand. How should we look at the next fiscal year and beyond, even though the recognition that you are probably going to start incurring another larger cost burden than atopic dermatitis may not be the same in Phase III because it is in Phase II?

Miyamoto [A]: As you know, we have a rough idea of the scale of asthma from the experience we worked with AstraZeneca for Fasenra, so we are working with Amgen with that in mind.

We are not sure how much it will be in concrete terms, as we will not know until further down the road. Therefore, I cannot say how it compares to atopic dermatitis at this point.

As you said, we are just starting out, so we do not expect to see something big suddenly come on top of us. Of course, we will consult with Amgen about the size of the project as the phases progress.

Muraoka [Q]: Okay, thank you. Second point. Regarding the European established medicine business, I understand that the share transfer to Grünenthal was completed in August. I understand this story in bits and pieces, and I don't understand properly. So I'm wondering how much performance impact will be. It would be helpful if you could tell me once again what the PL impact will be.

Miyamoto [M]: Thank you, Mr. Muraoka. It may indeed be difficult to understand. Kawaguchi will explain in a simpler way for you to understand easily.

Kawaguchi [A]: The pressure is on me. First, we completed the closing on August 1, and at this point the consideration of 51% of the joint venture shares would come in, which was GBP70 million. However, this does not mean that we will record a gain on the sale of 51% of the shares, there is corresponding cost portion in accounting that should be subtracted. We will record the gain of 51% minus the cost of shares of subsidiary transfer and a valuation gain on the equivalent value of the 49% that we still hold. This means that we will receive a gain on the sale, or valuation sales which is similar to the sale of 100% of the joint venture. This amount is now factored into the plan at JPY12 billion.

The actual amount is subject to the foreign exchange rates and such, so this is not a definite figure, but the JPY12 billion is factored in the plan. This is included in other income, which is below the core operating profit. Therefore, the progress of quarterly profit appears to be very low at 31%, but this is because JPY12 billion is

included in Q3 or the full year, so the figure appears to be low for Q2. I hope you understand that we are making good progress except for this part.

Muraoka [Q]: Thank you very much. Sales after August for the established medicines, I can see things in the budget, but sales are automatically almost, or rather, zero.

Kawaguchi [A]: Instead of zero sales, we will receive a certain amount of royalty income for the established medicines. So our revenue from the established medicine business will not be zero after August.

Muraoka [Q]: Okay, thank you. So the JPY12 billion comes under core operating profit, but there is not much difference between core operating profit of JPY88 billion and income before taxes of JPY86 billion in the budget for this fiscal year, after the JPY12 billion is included.

Kawaguchi [A]: If we talk after the revision of the 2023 plan, the impairment loss of RTA 402 is JPY8.3 billion, and this amount has been factored in. This will offset the other.

Muraoka [M]: I understand. Understood, thank you. That is all.

Haruta [Q]: My name is Haruta from Credit Suisse Securities. Thank you very much. I am wondering if the market is a bit concerned about the performance or the achievement of the mid-term management plan. Although the development of next-generation item has been halted, I am wondering the reason your company is not worried about achieving the mid-term plan is because you expect to acquire late stage development pipeline from outside sources?

Regarding this place, I think asset prices are calmer than before, but when is such an execution likely to take place? With the stock market a bit soft, I would like to know how you see your company's commitment to the medium-term management plan and your enthusiasm for the plan.

Miyamoto [A]: Thank you, Ms. Haruta. First of all, it is true that we have stopped some projects that were in the late stages of development since the last year, and we have received some concern in this regard. In the mid-term management plan period, one of the major points is we originally did not anticipate significant earnings from these items that were cancelled last year.

Of course, there may be things to worry about after the mid-term plan period. We are not considering lowering the targets of the mid-term plan at this time because we do not think that the impact will be so great by cancelling the program. This is the first answer to your question.

On the other hand, we have been told that there are not enough pipelines, specially late-stage development pipelines, and that we should do something about that. We have been talking about this since the beginning of the year, and we have been very active in looking at external assets, introducing them, and M&A possibility if they are good-sized.

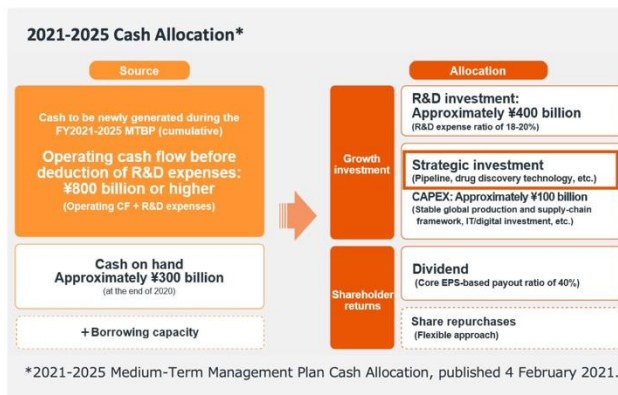
Strategic Investment ~For successful creation and delivery of life-changing value

Licensing-in and M&A investments to strengthen the portfolio

- Development pipeline with synergies with Crystiva and Poteligeo
 - ◆ Bone, Mineral ◆ Hematologic oncology
- Implementing the strengths of each region
 - ◆ Nephrology ◆ Hematology / Oncology
 - ◆ Immunology

Investment in science and technology to create new strengths

- Investments aimed at acquiring new drug discovery technologies and early pipelines and accelerating cooperation and collaborations
- VC investment and CVC activities for exploring and accessing information.



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As shown on the slide, we have a considerable amount of cash on hand, and we are currently working a quite proactively to acquire external assets by investing them in growth.

This is something that cannot be done if the other party does not want to do it, no matter how much we want it. It is not easy to say when we will do it, but I would like to mention that we are working at a very high level of enthusiasm. I hope it answers to your question.

Haruta [Q]: Okay. Then I am looking forward to it. Second point. Tell us a little about tivozanib. I thought tivozanib was intended to be a non-invasive treatment by eye drops, while vitreous injection is a highly invasive treatment for the indications here. Dr. Torii mentioned in a media that he is considering reducing the number of injections by using tivozanib eye drops in combination with intravitreal injections.

In the section on age-related macular degeneration, do you plan to treat with tivozanib alone through eye drops, or will you use intravitreal injections in combination with tivozanib? I would like to ask you a few questions about the direction of development and updates at this point.

Miyamoto [A]: Thank you. I think it is a very good point. As you know, the only treatment available now is injections into vitreous, and I think it is very significant thing that eye drops are coming out where the only treatment available is injections even in the maintenance phase. Torii is here today to explain our future policy.

Torii [A]: Thank you for your question. In terms of the combination, IVT is given at the initial induction and then eye drops when it turns into the maintenance phase. What are hoping the best is after moving on to eye drops, no IVT is needed. This will depend on the results of Phase II, which will be conducted in the future.

We are now moving forward with Phase II with the hope that we will be able to bring down the frequency of IVT at least but aiming it for close to zero as much as possible. That is all.

Haruta [M]: Okay Thank you very much.

Wakao [Q]: I am Wakao from JP Morgan. Thank you very much. I have two questions. The first is an outlook for the next fiscal year. I would like to know your current feeling whether you can achieve an increase in core

operating profit. I don't think it has occurred yet, but I think a gain on the sale of Tostran will be recorded at some point in this fiscal year. With that disappearing next fiscal, I think it will be all about how much you can grow with Crysvita and G-Lasta's BodyPods and how much they grow beyond G-Lasta's generic.

By looking at the trend at this point, I have a little feeling that the next fiscal period would be a difficult year. Could you tell me about this point? I know it's a bit early to say but I would appreciate if you could give us a sense of what you are feeling about it.

Miyamoto [A]: Thank you, Mr. Wakao. You are right, it is still too early to say. However, we are now in the process of creating a budget for the next fiscal year within the Company. Of course, for my part, I will be aiming to increase profits, and I don't think this is an unreasonable order. We are now pushing hard to create a budget that aims to increase profits, including cost control. Mr. Kawaguchi, do you have any comments?

Kawaguchi [A]: We are working hard to create a profit increase. That is all.

Wakao [Q]: I was wondering if it would be difficult to increase profits from Crysvita alone, based on this fiscal year's Crysvita plan. However, since there is considerable growth in North America right now, so I was wondering if Crysvita might grow more than I thought.

In order to increase profits in the next fiscal year, cost control is one thing, but Crysvita will also play an important role in increasing profits and gross profit, won't it? That may be true, though.

Miyamoto [A]: As you say, we are becoming a bit too much dependent on one thing, but we should make sure to grow where we can, so I have been encouraging each region and Sudo to continue to work on what we can.

Wakao [Q]: I understand. The second is KHK4083. I am sorry it is two different things. You have put the data on the Lancet again that it will last for 20 weeks. That said, I would like to know again why the part of the ROCKET program that has a maximum of once every eight weeks, and also why asthma is going to be considered this time.

Also, this asthma is still in Phase II, but if it works, how will it affect the peak sales of KHK4083? I would like to know more about the concept of potential.

Miyamoto [A]: Thank you. Torii will explain the details later. As for the asthma area, I probably can't give you an idea of the scale yet. In view of the target of KHK4083, OX40, in its own way, we decided after considerable discussion with Amgen that we could make scientific rationale quite well. We hope you will forgive us that we cannot say much but we are aiming for a reasonable scale.

Torii-san, if you have any more detailed information on how to look at the ROCKET program or why we are aiming for asthma, can you?

Torii [A]: First of all, let's start from atopic dermatitis. At ascend, the reason we set once every eight weeks for the long-term because we want to ensure effectiveness. But, on the other hand, some patients who will have benefited from the actual drug in H1 of the program will be switched to placebo. There will also be a test to see how long the effect lasts, so we will be looking at the actual level of lasting effect in Phase III.

The reason for targeting asthma is that OX40 is expected to be effective in this area, including the involvement of Th2 in the mechanism. As you know, Dupixent and our competitor OX(40) ligand are also doing this. In that context, we have chosen asthma where it is expected to be effective, though repetitive.

However, asthma is a fairly heterogeneous group, so we would like to determine in what kind of populace it can be more effective in Phase II, as well as other aspects. That is all.

Wakao [Q]: Thank you very much. Then, as you have just explained, I am wondering if it is correct to understand that if the patient is switched to placebo and a certain degree of persistence is confirmed in the ROCKET program, then Phase III will be conducted with a longer and less frequent dosing regimen.

Also, since asthma is the second indication for Dupixent, should we assume that your company's KHK4083 will be developed for the same indication as Dupixent, considering next one after asthma?

Torii [M]: Is the first question about the disease area related to asthma? Or is it atopic dermatitis?

Wakao [Q]: Is it safe to assume that when you switch to placebo in atopic dermatitis and confirm persistence, you will further test a regimen with less frequency than once every eight weeks in Phase III?

Torii [A]: We do not have a plan to that extent at this time, and we will consider labeling in the initial application during Phase III, which is currently underway.

Wakao [Q]: When you say next after asthma, should we assume a similar development to Dupixent?

Torii [A]: This is a matter of consultation with Amgen, not just our company, and we will share at the timing when we can disclose.

Wakao [M]: Okay, thank you very much. That is all.

Ueda [Q]: My name is Ueda from Goldman Sachs. I would first like to ask about Poteligeo. You mentioned that sales in the US are doing well, but looking at YoY comparison, sales appear to have leveled off to some extent in US dollar base, as if they have reached their peak or have run their course.

In addition, can you tell us whether the Mandatory Discount in Europe will continue to expand, whether it will have an impact, and do you see it will go on a growth trend, in other words, you would expect purely a volume increase in the future?

Miyamoto [A]: Thank you, Mr. Ueda. In the US, when we look at the momentum of growth, it is certainly slowing down a bit, but I believe there is still room for growth. Sudo will comment, including the part about Europe.

Sudo [A]: Thank you for your question, Mr. Ueda. Certainly, the numbers look a little better in the US, but in terms of comparing patient growth in the US market, it is actually more in Europe.

As you mentioned earlier, we have some points that we cannot see a growth trend in terms of prices, but overall growth is not bad in Europe. This is one point.

Regarding the US as mentioned at the beginning, we are considering internally that there are still more things can be done in terms of penetration rate. Especially patients are happy with taking the drug. Since the beginning of this year, we have been reviewing how we can reach to more patients by taking advantage of our past experience and re-thinking what kind of message we should convey to the segment where we are firmly focusing with our activities.

As Miyamoto mentioned, it is a solid drug and there is still a market for it, so we do not consider the peak has come yet, and we are working hard to expand the market even further.

Miyamoto [A]: I believe that the possibility expanding of the European Mandatory Discount is not zero. As you know, governments in various countries are dealing with quite severe financial constraints, and they are in the process of holding discussions with governments and insurance organizations. We will keep a close eye on the situation and will respond accordingly.

Ueda [Q]: Thank you very much. Second, I would like to know in the progress of the development pipeline products. As for KHK4951, you have indicated that the results of Phase I will be presented at an academic conference this year, but I am wondering if there were anything in the results that would suggest efficacy or change the expectations for this drug.

In terms of this year's events, you mentioned before that two bispecific antibodies will enter clinical trials this year in the field of oncology, as the second item. I wonder if there any changes in this area.

Miyamoto [A]: Thank you. I wish I could explain some details about the Phase I results of KHK4951, but I am not able to do so before the academic conference.

Based on such data, we are about to start Phase II, and we think we will be able to show the data that is reasonable enough for us to decide going into Phase II.

We are now working hard to get two bispecific antibodies into clinical trials by the end of this year, and we are getting a good feeling that we can do it, so please look forward to it.

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

Akahane [Q]: Thank you very much for taking my questions. Please let me ask one point about general business performance and the detail point within it. The first point is the overall current financial results. I am looking at page six of the material you showed. Sales revenue increased by JPY13.9 billion, of which JPY12.8 billion came from North America, so although Japan was in the negative, a simple calculation shows that 92% of the increase came from North America.

Page seven is domestic, so I see a bit of a struggle here. On page eight, you disclose overseas sales by products, including Crysvita. Since 82% of the increase in Crysvita sales is in North America, I think it can make sense that Crysvita in the North America is contributing for it.

If I look at page nine, I see that gross profit increased by JPY10.3 billion, but this is due to foreign exchange of JPY9 billion, so there is JPY1.3 billion remaining. SG&A expenses increased JPY6 billion, but since the currency exchange is JPY4.1 billion, there is only JPY1.9 billion remaining.

In the 2Q, there were changes in the environment, including the start of sales by your company of Crysvita in North America, as well as fluctuations in the exchange rate. I would like to ask you how about revenue impact of Crysvita excluding foreign exchange is. This is the first point.

Miyamoto [A]: When you say revenue, are you referring to the top line?

Akahane [Q]: Sorry, it's profit. Gross profit and operating profits are difficult to understand here, qualitative answer will suffice, even if it is not quantitative.

Miyamoto [M]: I know it's hard to understand. So, Kawaguchi-san, can you explain?

Kawaguchi [A]: Sales of Crysvita in North America increased JPY10.2 billion from the previous year, including the impact of exchange rates. If you look at it in terms of profit, royalties, which were the equivalent of profit-sharing payment through the end of April, are in the upper 20% range. So the amount subtract from it will be

profit on a gross margin basis. Since about 70% of the total is profit, I hope you will consider the same for the base excluding foreign exchange from sales.

Akahane [Q]: Would it be correct to say that the increase in profit, excluding foreign exchange, is mostly related to Crysvita in the US?

Kawaguchi [A]: I would say, almost all is an exaggeration, but there is no doubt that it is the most significant factor.

Akahane [Q]: The second question is related to it. I am sure that when the full effect of your own sale measure is realized, the volume will naturally increase in the future. As you explained when you talked about the rate of progress. What will be the impact on gross profit and operating profit when it really moves into the full of your own sales system?

Kawaguchi [A]: Regarding SG&A expenses, moving to our own sales system will not result in a significant change. Previously, Ultragenyx used SG&A expenses and we take the half of them. If we move completely to our own sales system, the cost will increase from 50% to 100%. So that part of the cost will increase, but by moving to the royalty method that I mentioned earlier, the gross profit share that we have been paying will move to the latter half of the 20% range, compared to 32.5% or 35%. Therefore profitability will increase and will be offsetting each other. We hope you understand that the total profit margin will almost remain unchanged.

Incidentally, since the trend of SG&A expenses will increase throughout the rest of the year will not continue, so please understand that profitability will increase as sales expand in the future. As for this year, we have an image that profitability is almost the same.

Akahane [M]: So you are saying that we only need to look at the top line. I understood very well. Thank you very much.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities. Thank you very much. I have a question about asthma for rocatinlimab I believe that in the early development stages of rocatinlimab, you were exploring several autoimmune diseases. I remember that IBD and other diseases were being explored at that time, but my memory of asthma is hazy, so I wonder if you could tell us what the development was like at that time.

Miyamoto [A]: Thank you, Mr. Hashiguchi. Initially, we actually did not consider asthma. Therefore, we have decided to do this after consulting with Amgen based on the results of previous trials and a science rationale base.

Hashiguchi [Q]: So, in your explanation today, I think you were talking about considering it from the mechanism. I think that even in the initial development stage, the research was focused to some extent on autoimmune diseases, narrowing down the candidates based on the mechanism. Was asthma not covered then but it is this time because of some new information, or because it reflects Amgen idea, or because the life cycle of your product has changed? How should I understand it?

Miyamoto [A]: In the early days, we didn't start with thinking various indications and seek each possibility randomly. We decided to start with IBD first. So it's not about from a science rational.

Next, we decided to try atopic dermatitis, and we found it work well for atopic dermatitis. That was a long time ago, and I think that now we would do a more extensive study of various areas and then move on, but that is the way when we see its history.

Meanwhile, various base science rationales have been accumulating during that time, and asthma has also become a target. As Torii mentioned earlier, a competitor is doing for asthma as well. From a strategic point of view including it, we and Amgen has made the decision that it would be better to do asthma after all.

Hashiguchi [Q]: Thank you. So, as for the future timeline, Phase III of the asthma trial will start up around the time the Phase III atopic dermatitis trial is almost complete. Therefore, is it correct to assume that the R&D expenses incurs by your company will not increase significantly, but will be maintained at a high level?

Miyamoto [A]: I haven't drawn a detailed timeline for this yet, but I personally have a rough image of what you just said. We are also discussing with Amgen, and as Torii mentioned earlier, we are still considering various other indications. With the addition of such things, I think there is a good possibility that R&D investment in rocatinlimab will continue to increase.

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

Wakao [Q]: I'm sorry, this is the second time, but thank you. I would like to ask about the adjustment made to response with the German price reductions for Crysvita in Europe this time. How much was the impact as sales, or how much was the reduction in Germany? Also, how should we look at Europe after Q3?

You mentioned that you need to keep a close watch on the financial situation in other countries as well, so I was somewhat concerned about the future growth in Europe, so please tell us about it.

Miyamoto [A]: Thank you, Mr. Wakao. I am sorry, I am afraid that I cannot give you any details. As I mentioned earlier, we are still negotiating with the German authorities. In those negotiations, what I can say is if this is quite such a tough attitude, we have to take them into account, including past years as per German system. We made an adjustment for this area. and as I explained earlier, this applies for this fiscal year only.

As for the future, not only our company, but also presidents of other companies are also having headaches. Since each country is in a difficult situation, the first thing to do is negotiating prices properly and having the right data to do so. However, the situation is still tough, so we have to keep a close eye on the future business in Europe, and I think it is an important point in terms of strategically.

Sorry, this is a bit vague, but I would appreciate it if you could forgive me.

Wakao [Q]: Thank you very much. I understand that it's tougher situation than expected, but I wonder if there is a possibility that sales would fall flat immediately in the short term. Since the volume should be growing, it is safe to assume that sales will keep growing in EMEA, right?

Miyamoto [A]: Yes, you are right. As Sudo mentioned earlier, we have a solid patient base for both Crysvita and Poteligeo, and the shipping volume is increasing steadily, so I am not worried about that.

Wakao [Q]: I understand. I would like to ask for a second one. Someone asked earlier about M&A. I believe, you said the last time in Q1 that you wanted to make a deal this year. I was wondering the possibility of M&A within this fiscal year, in terms of timing. Also, if you purchase, will it be in North America? Not in Japan?

Miyamoto [A]: As you can see on the slide 24, we are looking for something that can become an interesting platform for our portfolio, preferably around Crysvita and Poteligeo, as well as in each region, and also in the science technology below that, where we are still weak in. We are working on quite a bit now, including these things.

Of course, my own goal of at least one by the end of this year, has not been withdrawn. So members are working very hard, and they are doing quite a bit right now.

Wakao [Q]: When you say a region, you are trying to get with a license in North America.

Miyamoto [A]: It is basically global. As you mentioned, North America is the largest market in the global market, so we would like to include North America if possible, but this is also a matter of a partner. If they insist North America, I think we have no choice but to do so, but our goal is global.

Wakao [M]: I understand. Thank you, that's all.

Moderator [M]: Thank you very much. There being no further questions, this concludes the online presentation of financial results for Q2 of the fiscal year ending December 31, 2023.