



Kyowa Kirin Co., Ltd.

Q1 Financial Results Briefing for the Fiscal Year Ending 2020 Conference Call

May 1, 2020

Event Summary

[Event Name] Q1 Financial Results Briefing for the Fiscal Year Ending 2020 Conference Call

[Date] May 1, 2020

[Number of Speakers] 3


Motohiko Kawaguchi	Director, Finance Department
Yoshifumi Torii, Ph.D.	Vice President, Head of the Research & Development Division
Takeyoshi Yamashita, Ph.D.	Director, Corporate Strategy & Planning

Presentation

Moderator: We will hold a teleconference to discuss the results for the first quarter of the fiscal year ending December 2020, which were released at 3:30 PM today, for Kyowa Kirin Co., Ltd.

Today's speakers include three executive officers: Director of the Finance Department, Motohiko Kawaguchi; Vice President and Director of the Research & Development Division, Dr. Yoshifumi Torii; and Director of the Corporate Strategy & Planning Department, Dr. Takeyoshi Yamashita.

First, Mr. Kawaguchi will present the financial results, and then Dr. Torii will talk about the development pipeline. Dr. Yamashita will then discuss current business topics, and finally, I will take your questions. Please download the materials from our IR website.



Summary of FY2020 Results

(Billion Yen / Rounded)

	2019Q1 Results	2020Q1 Results	Changes	2020 Plan	Progress
Revenue <small>[Overseas Ratio]</small>	75.8 <small>[36%]</small>	77.3 <small>[44%]</small>	+1.5 (+2%)	327.0 <small>[47%]</small>	24%
Gross Profit <small>[Gross Profit margin]</small>	56.1 <small>[74%]</small>	57.9 <small>[75%]</small>	+1.8 (+3%)	250.0 <small>[76%]</small>	23%
Core OP <small>[Core OP margin]</small>	17.3 <small>[23%]</small>	16.8 <small>[22%]</small>	-0.6 (-3%)	65.0 <small>[20%]</small>	26%
Profit <small>from continued operation</small>	9.3	13.8	+4.5 (+49%)	49.0	28%
Profit <small>from discontinued operation</small>	-1.2	—	+1.2 (-100%)	—	—
Profit	8.1	13.8	+5.7 (+71%)	49.0	28%

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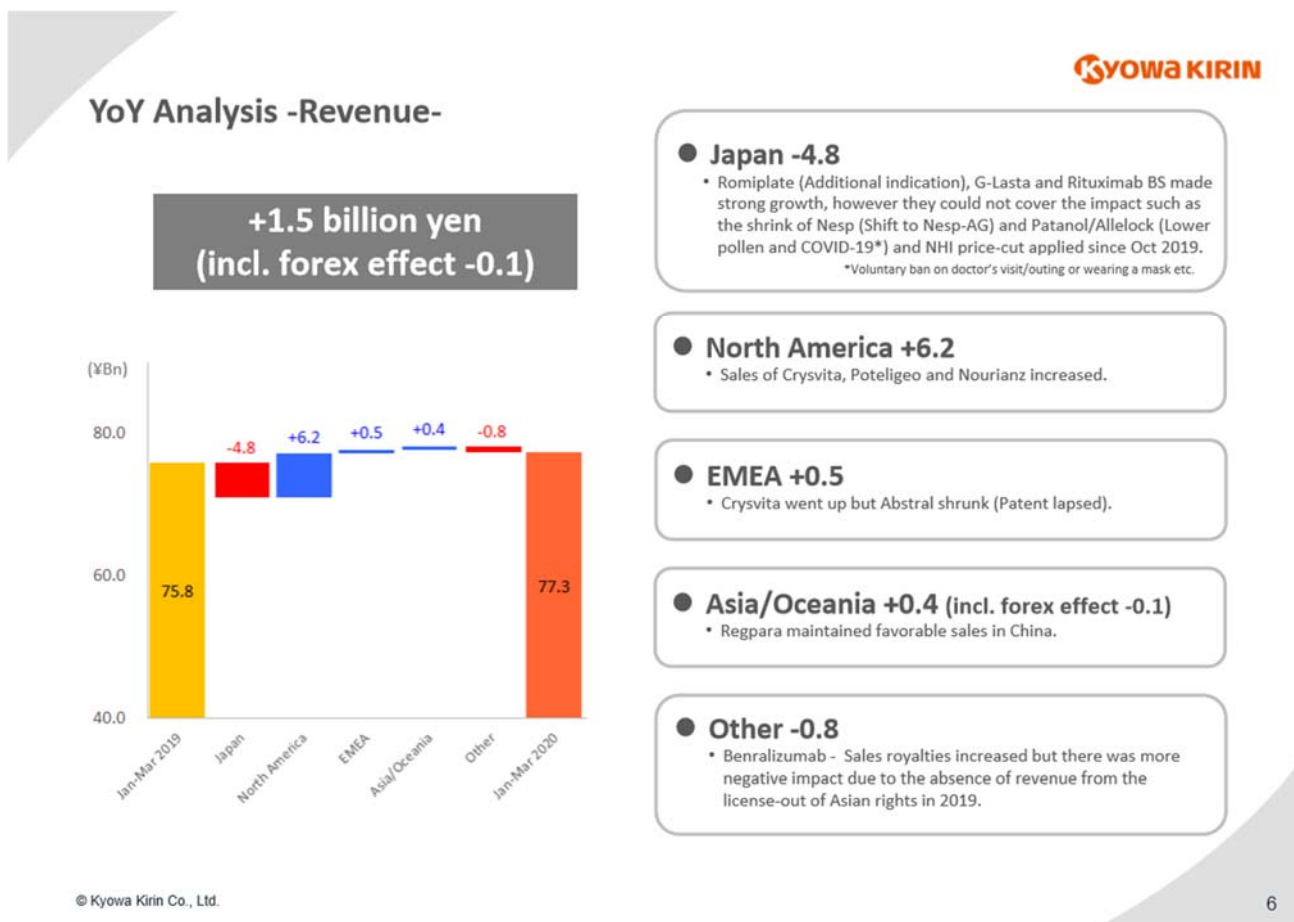
Kawaguchi: Thank you.

First, page five of the presentation. This is a summary of the financial results for the first quarter.

Sales were JPY77.3 billion, an increase of JPY1.5 billion compared to Q1 of the previous year. Core operating profit declined JPY600 million to JPY16.8 billion. The bottom figure, quarterly profit, was JPY13.8 billion, an increase of JPY5.7 billion.

As shown in the right-most column, progress toward the full-year forecasts is as follows: revenue, 24%; core operating profit, 26%; and quarterly profit, 28%. Regarding the rate of progress toward achieving this plan,

we plan to increase the number of global strategic products currently in the growth stage toward the end of the year. On the other hand, in Japan, the seasonality of allergy drugs means that sales will be weighted toward the first quarter; therefore, it is impossible to set 25% as a criterion for judgment. However, we believe that, as planned, good progress has been made in the period to the end of March.



This is a comparison of revenue from the corresponding period of the previous fiscal year.

Starting from this fiscal year, we have changed our reporting to a classification by region. This conforms with our internal global management classification based on our new "One Kyowa Kirin" system, which started from April last year. The system corresponds to the Company's regional headquarters, located in Japan, the US, the UK, and Singapore. The main categories in the "other" section at the bottom are revenue from technology licensing and contract manufacturing.

In Japan, revenue decreased by JPY4.8 billion. Sales have increased for Romiplate, which was approved in June of last year for the additional indication of aplastic anemia, as well as for G-Lasta, whose demand is growing with increase of new cancer treatments. Sales have continued to increase for Rituximab BS, which was launched in January 2018. On the other hand, sales of Nesp, which we launched its AG to market last August, and Allelock/Patanol have decreased significantly. Last year's NHI drug price revision has also had an impact on sales.

Regarding the reduced sales for Nesp, the switchover to Nesp-AG is thought to have had an effect. For Allelock/Patanol, pollen counts have been lower this year, and issues related to coronavirus, such as the use of masks, reduced medical consultations, and lockdown, have affected sales.

In North America, sales of all three global strategic products grew steadily, resulting in a significant increase of JPY6.2 billion.

With regard to EMEA, although sales of Crysvita continued to grow, sales of Abstral declined, due to patent expiry. Overall, sales increased by JPY500 million.

In the Asian region, sales increased by JPY400 million as Regpara, which was placed on the Chinese National Essential Drugs List in October 2018, continued to grow strongly.

In “other,” although sales royalties from AstraZeneca related to Fasenna increased, there was a decline in revenue. This was largely due to the absence of lump-sum payments from Asian rights licensing last year.



Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2019Q1 Results	2020Q1 Results	Changes	Reason	2020 Plan	Progress
Nesp + Nesp-AG*	11.8	7.4	-4.4 (-37%)		34.7	21%
Nesp	11.8	1.2	-10.6 (-90%)	Nesp-AG launched in Aug 2019	4.0	29%
Nesp-AG	—	6.3	+6.3		30.7	20%
Regpara	1.8	1.0	-0.9 (-48%)	Switch to Orkedia	3.2	30%
Orkedia	1.2	2.0	+0.7 (+61%)	Steady market penetration	10.1	19%
G-Lasta	5.3	6.1	+0.9 (+17%)	Market expansion	28.1	22%
Poteligeo	0.4	0.5	+0.0 (+10%)		2.0	24%
Rituximab BS	1.8	2.6	+0.7 (+40%)	Steady market penetration	10.1	25%
Romiplate	0.8	2.0	+1.2 (+158%)	Indication added in Jun 2019	7.2	28%
Allelock	4.0	3.0	-1.0 (-24%)	Lower pollen in the air and COVID-19 (Voluntary ban on doctor's visit/outing or wearing a mask etc.)	8.3	37%
Patanol	8.5	5.9	-2.6 (-31%)		9.5	62%
Nourias	2.2	2.2	-0.0 (-0%)		10.5	21%
Haruropi	—	0.1	+0.1	Launched in Dec 2019	1.9	5%
Crysvita	—	0.5	+0.5	Launched in Dec 2019	3.5	15%
Technology licensing	0.9	0.3	-0.6 (-66%)		3.7	9%

* AG stands for Authorized Generic. Official product name is Darbepoetin Alfa Injection Syringe [KKF].
Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

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7

This slide shows revenue for major items.

With regard to the YoY comparison of these products, the main points were explained in the previous slide, so we will comment on progress toward forecast for each item individually.

First of all, regarding Nesp-AG, progress to forecast is 20%. Nesp-AG is facing competition from other companies' biosimilars, and we are facing a tough market. We intend to utilize our knowledge in the field of nephrology, which is one of our strengths, to minimize the impact.

As you can see, progress toward the shifting plan is a little behind for Regpara and Orkedia.

Sales of G-Lasta are expected to continue growing this fiscal year, so although the progress figure is 22%, it is in line with the plan.

Use of Romipate for aplastic anemia is increasing, so progress is strong at 28%.

The progress of Allelock/Patanol is extremely high, but the two drugs are sold mainly in January to March, which is the hay fever season. Compared to the previous year, coronavirus and pollen counts both had a significant negative impact. However, given that this is a highly seasonal product, we are not predicting further effects on the full-year sales figures.

Furthermore, with regard to new products, such as Haruopi and Crysvida, restrictions on sales activities as a result of coronavirus have led to a slight delay in recruitment of medical institutions.

The rate of progress in technology revenues appears to be somewhat low, but we expect a one-time profit within the year, so at this point, we have not made any changes to the plan.



Revenue of Major Items (Overseas)

(Billion yen / Rounded)

Item	2019Q1 Results	2020Q1 Results	Changes	Reason	2020 Plan	Progress
Crysvida*1	5.7	12.0	+6.3 (+110%)	Steady market penetration	56.6	21%
North America		9.2				
EMEA		2.8				
Poteligeo	2.4	2.9	+0.5 (+22%)	Launched in Oct 2018	14.3	20%
Nourianz	—	0.4	+0.4	Launched in Oct 2019	2.8	13%
Abstral	3.1	2.8	-0.3 (-11%)	Patent lapsed	9.0	31%
Regpara	1.1	1.7	+0.6 (+49%)	Listed on Chinese NEDL*2 in Oct 2018	7.3	23%
Technology licensing	3.2	3.1	-0.1 (-4%)		18.8	17%
Benralizumab Royalty*3	2.0	2.7	+0.7 (+34%)	Launched in 2018		

*1 Launched countries as of March 31, 2020 (excluding South America):

USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain

*2 National Essential Drug List

*3 Sales royalties of Fasenna, marketed by AstraZeneca. Includes our own estimation.

Next is overseas sales.

Crysvida sales for the fiscal year under review amounted to JPY12 billion, an increase of JPY6.3 billion. Progress is 21%, but as we anticipate further increases in the rest of the year, this progress is in line with the plan. The breakdown by region is as follows: JPY9.2 billion in North America and JPY2.8 billion in Europe. Progress in both regions is on track with the plan made at the beginning of the year.

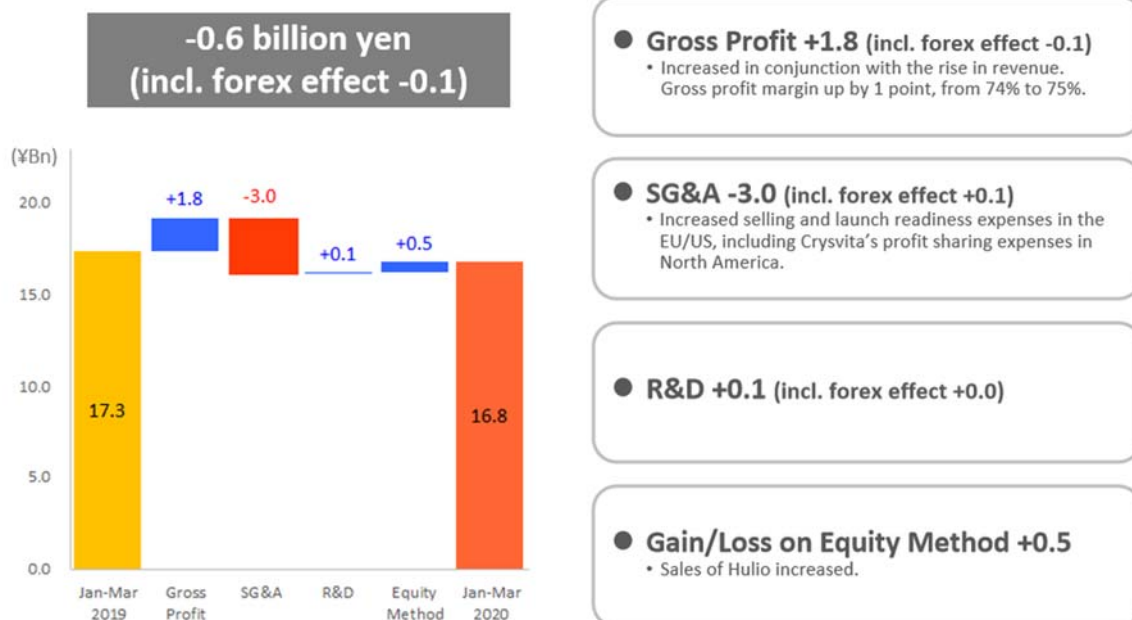
Poteligeo is continuing to see steady progress. We plan to start sales in Europe in the second half of the fiscal year. Current progress is in line with the plan.

Nourianz launched in October 2019. As it has only recently launched, the progress seems a little low, but sales have increased at a level above the target in March. From April onward, we will be paying close attention for any potential delays in market penetration due to the impact of coronavirus.

Finally, regarding overseas technology revenue, as same as the domestic tech revenue, we anticipate a one-off profit, so we have no plans to change the forecast at this point.



YoY Analysis -Core OP-



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9

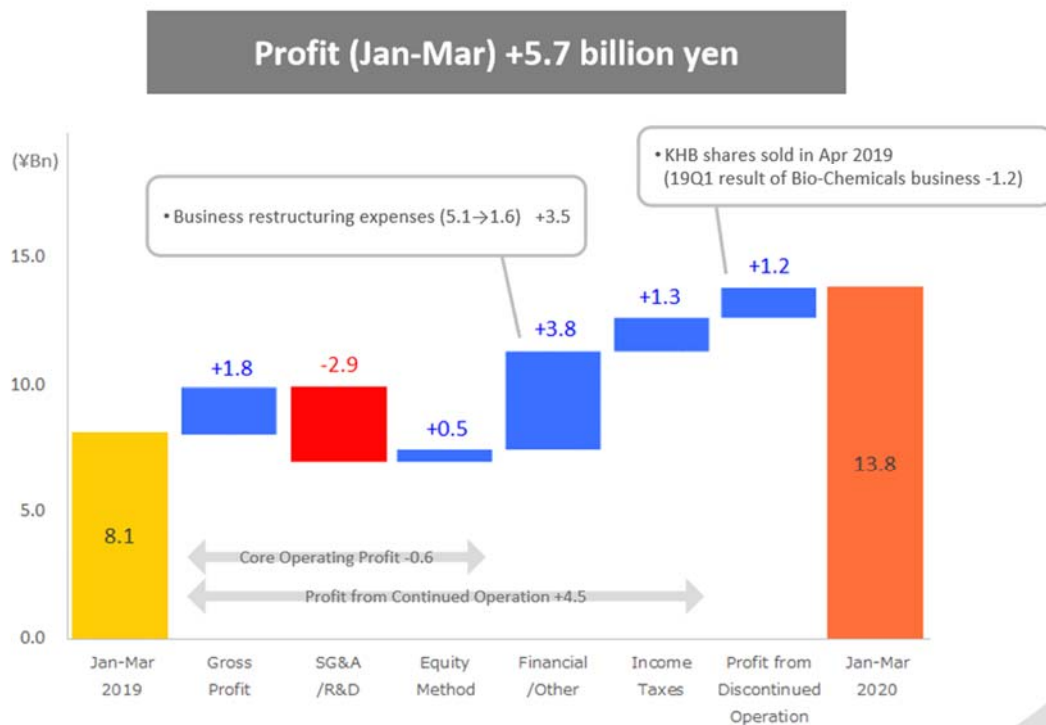
Core operating income declined slightly, by JPY600 million, and this slide shows an analysis of the factors behind this decline.

First, gross profit increased by JPY1.8 billion. The gross profit margin has been gradually improving, but in the fiscal year under review, it increased by 1%, from 74% to 75%. This is mainly due to the increasing weight of the highly profitable globally strategic products, such as Crysvida.

Selling expenses increased by JPY3 billion, due to the continued increase in selling expenses and preparations for market launches in Europe and the United States. As I have mentioned in previous presentations, as sales of Crysvida in the US increase, SG&A expenses increase due to higher profit-share payments to Ultragenyx Pharmaceutical. A portion of the SG&A expenses increase is a result of higher sales of Crysvida. The selling expenses figure also includes sales promotion expenses for Nourianz, which was launched in October 2019.

The figure at the bottom is earnings (losses) of affiliates accounted for using equity method. This is up JPY500 million, to a gain of JPY400 million in the current fiscal year, compared with a loss of JPY200 million in the previous fiscal year. Increased sales of Hulio in Europe have contributed to our business.

YoY Analysis -Profit-



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10

Finally, a YoY analysis of quarterly profit.

Quarterly profit increased greatly, by JPY5.7 billion, over the previous year. Core operating profit is down JPY600 million YoY, as I explained earlier. Therefore, there was a JPY6.3 billion profit increase during this period. I will now discuss the details.

Firstly, financial and other gains and losses resulted in a JPY3.8 billion increase in profits. Last year, as part of business restructuring expenses, we recorded JPY5.1 billion for supplementary retirement payments accompanying voluntary retirement in Japan. However, for the current fiscal year, we recorded JPY1.6 billion for business restructuring expenses in EMEA, with the aim of accelerating our transformation into a global specialty pharmaceutical company. As a result, we have reduced costs by JPY3.5 billion. This is the main reason for the positive JPY3.8 billion.

With regard to tax expenses, income before income taxes has increased, so the tax burden may be expected to increase. However, tax expenses also decreased by JPY1.3 billion, which is a factor behind the increase in income. Regarding this matter, there have been changes in the tax system in the UK, where the corporate tax rate supposed to be reduced to 17%. However, this reduction was cancelled, and the tax rate have kept at 19%. This resulted in the accumulation of deferred tax assets of the UK subsidiary.

As a result, the tax burden rate for the first quarter was 11%, which is extremely low. This is a temporary special factor, which should be taken into account when looking at the full-year profit figure.

Finally, regarding discontinued operations, the bio-chemicals business, which was consolidated until the first quarter of last fiscal year, saw a net loss of JPY1.2 billion last year. This loss was absent this year.

This concludes the financial review.

Key Development Updates in 20Q1

- **Acceptance of marketing authorization application for approval of KW-6002 for Parkinson's disease¹ in Europe (January)**
- **Application for marketing authorization of KHK4827 for axial spondyloarthritis and psoriatic arthritis in Taiwan (February)**
- **Initiation of the phase 1 study of automated injection device of KRN125 in Japan (February)**
- **Acceptance and priority review designation of supplemental biologics license application of KRN23 for tumor-induced osteomalacia in the U.S. (February)**

¹ Filed indication is an adjunctive treatment to levodopa-based regimens in adult patients with Parkinson's disease experiencing "wearing-off" time

Torii: I will briefly update the R&D progresses during the first quarter.

Highlights of the period from January to March of this year are listed on slide 12.

First, applications for marketing authorization were accepted by the European authority in January for KW-6002, or Istradefylline (Japanese trade name: Nourias; US trade name: Nourianz). This topic has already been presented at the previous financial results briefing as a topic from January onward.

In February, we filed an application in Taiwan for marketing approval for KHK4827, Brodalumab (trade name Lumicef), for the indications of axial spondyloarthritis and psoriatic arthritis. We will continue with the process of applying for marketing authorizations in Asian countries and steadily promote life cycle management by expanding indications.

Regarding KRN125, or Pegfilgrastim (brand name G-Lasta), in February, we began the Phase 1 trial for automated administration devices in Japan. At present, in order to administer G-Lasta the day after a cancer chemotherapy is completed, a patient needs to visit the hospital at least twice. However, this device is equipped with a system in which G-Lasta is automatically administered the day after it is used, and we are developing this device with the expectation that it will be possible to use it at the same time as cancer therapy. This is expected to reduce the burden on both patients and healthcare professionals.

Regarding KRN23, or Burosumab (trade name Crysvita), an application for the additional indication of tumor-induced osteomalacia (TIO) was filed in December last year. It was accepted by the FDA in February. The application was designated as a priority review, and the target date for completion of the review is scheduled for June 18.

Business Topics after April

- **A Global partnership with MEI Pharma on Global license, Development, and Commercialization for ME-401 (April)**
- **Impacts of COVID-19**
 - No impact has been reported regarding procurement and the product supply.
 - In order to take required actions in a timely manner, we will keep monitoring the changes that would affect our clinical trials, regulatory reviews, and sales: that includes the situations of our supply chains, updated access restrictions of the medical institutions, the change in patient behaviors, and operational changes of the healthcare authorities.

Yamashita: I will touch on the business topics after April on page 14.

First, I would like to explain about the agreement of a global licensing contract for ME-401 with MEI Pharma Inc. We agreed to a contract with MEI Pharma to expand our ME-401 alliance globally. The domestic licensing agreement for ME-401, which was agreed in 2018, will be maintained and consolidated.

Through this contract, we have a lump-sum payment of USD100 million to MEI Pharma. In addition, the milestone associated with the development progress will be, at most, USD582.5 million.

If ME-401 is approved in the United States, we will work with MEI Pharma to provide information on ME-401 in the United States. Revenue from sales of finished goods in the United States is to be recorded by MEI Pharma. We and MEI Pharma will divide our sales-related income and R&D-related expenses in the US evenly between us.

On the other hand, as we have exclusive sales rights in countries and regions other than the United States, we will record all revenue from ME-401 in countries and regions other than the United States. We have set up a tiered royalty system for that sales revenue starting in the 10% level, and we will pay MEI Pharma.

We also bear the clinical development costs, regulatory application costs, CMC costs, and sales costs incurred outside the US.

Next, I will explain the impact of the coronavirus outbreak on our business.

Currently, there are no obstacles to the procurement of raw materials and the supply of products, either in Japan or overseas. Changes in the supply chain, restrictions on access to medical institutions, changes in

patient behavior, and activities of regulatory authorities that may affect clinical trials, reviews, and sales will be monitored individually, and appropriate responses will be considered.

For your reference, I would like to talk about the current state of our sales activities. In Japan, employees at sales offices nationwide are, in principle, working remotely until May 13. We are working to undertake necessary activities, such as product recalls, PV activities, and provision of product quality information, in accordance with the wishes of medical institutions.

In Europe, the headquarters in the United Kingdom, as well as offices in each country, were closed on March 13, and employees are telecommuting.

In North America, all offices are currently closed, and we are conducting activities remotely.

In Asian countries, activities are being resumed in China. In other countries, we have taken measures such as prohibiting visits to medical institutions.

Regarding drug sales, we have not seen a significant impact in Japan at present, but as we reported earlier, we believe that sales of the hay fever agent Allelock/Patanol may have been affected by the use of masks and by self-isolation.

In addition, if this coronavirus continues to have an impact, we believe that the market penetration of products in Europe, North America, Asia, and other overseas markets may be delayed. We also believe that the review schedule of the authorities will be affected.

Regarding the impact on development, in order to ensure the safety of patients and to reduce the burden on medical institutions, some clinical trial facilities are subject to restrictions on visits. If the impact is prolonged, it is possible that the entry of subjects into clinical trials will slow. There could also be an effect on the schedule of visits to medical institutions by the subjects, or other such effects on schedules.

As described above, there is a possibility that coronavirus will have an impact on our business in various ways. However, looking ahead, we intend to anticipate the situation and take appropriate measures to minimize the impact on our business.

That concludes my presentation.

Question & Answer

Moderator: I would like to move on to the question-and-answer session. Please limit your questions to two questions at a time.

Yamaguchi: I'm Yamaguchi from Citi Group Global Markets Japan. I would like to ask a few questions about the performance of Crysvida. First, although the breakdown by region of the JPY5.7 billion in Q1 2019 has not been disclosed, I would like to ask about the growth rate for this item. How does the breakdown from this quarter, JPY9.2 billion and JPY2.8 billion, correspond to the breakdown from the Q1 2019 figure of JPY5.7 billion?

Kawaguchi: Thank you for your question. We are not able to disclose this information at this moment. We started disclosing it from Q2 2019, and we intend to continue disclosing the figures by region in the future. Thank you for your understanding.

Yamaguchi: I see. While the growth rate is somewhat difficult to understand, I think the understanding is that the growth rate in the United States is considerably higher and that the growth rate in Europe is somewhat modest. For the US, it may be a matter of "ask Ultragenyx," but could you say a little about factors affecting the growth in Europe?

Kawaguchi: In Europe, for example, there has been considerable growth in Q1 compared with the preceding Q4. However, this is an expensive drug that is used in a very small number of patients, so it is difficult to get an accurate picture when looking at it on a shipping basis. There are some countries where orders come in every few months, so it's hard to tell if you look at figures in the short term. What we can say is that performance is in line with our Company's plan.

However, in this first quarter, the product was not launched in any new countries. Another question is whether there will be any delays to new launches due to coronavirus. We are currently paying close attention to the situation.

Yamaguchi: Understood. With regard to coronavirus, I am concerned that it will have some impact on the acquisition of new patients. I have been told that nurses will continue to administer to existing patients, especially in the US, at home. Could you tell us about the impact on existing and new patients?

Yamashita: Similar to the situation in the US, administration of the drug at home by nurses seems to be common in Europe, and we expect that the administration can be kept continued.

Yamaguchi: As you mentioned earlier, it is understandable that there may be some impact on new patients.

Yamashita: That's right. Looking at the Q1 figures, it's difficult to discern any effect.

Yamaguchi: Finally, regarding ME-401. Kyowa Kirin acquired the rights in the US, and is it correct that the US Phase 2 was designated as Priority Review?

My understanding is that you can apply in the US after Phase 2, and if it's a priority review, the product will be available in the US quite soon. Is this related to your company's approach with Poteligeo? Regarding the development schedule in the US, I appreciate this may be a question for MEI Pharma, but can you tell us anything about the development schedule in the US?

Torii: Thank you for your question. Regarding the Phase 2 study you mentioned, this is a monotherapy study. Based on the results and on discussions with regulatory authorities, we plan to conduct Phase 3 trials for combination therapy.

For more information, after concluding the contract, the two companies are scheduled to discuss Role and Responsibility and other matters in the future.

Yamaguchi: Is there a possibility of submitting an application for the monotherapy after Phase 2?

Torii: Yes, that is my understanding.

Yamaguchi: Okay. Thank you very much.

Hashiguchi: Hashiguchi from Daiwa Securities. The first question is about sales. I understand that other companies have seen temporary increases in prescription volume as a result of COVID-19 for patients who have to stay at home. This has resulted in impacts on sales for other companies in the January to March period. Has your Company seen any similar effects on sales?

Kawaguchi: Thank you for your question. Honestly speaking, we have not been able to conduct a detailed analysis related to that, but we are not aware of any such effect for our products.

Hashiguchi: Thank you very much. The second point is about the impact on clinical trials. Could you tell us a little more about the effects on trials for items such as Bardoxolone (RTA 402) and KHK4083? I understand that your Company has high expectations for these compounds.

Torii: Thank you for your question. This depends on a number of factors, such as the stage each protocol is in and the situation on the ground in individual medical institutions.

Regarding the example you gave of RTA 402, with Reata Pharmaceuticals, Inc., patient enrollment is nearly complete, so the remaining question is whether it is possible to continue supplying the study drug. In this regard, there are some patients hesitant to go to the hospital, so whether the hospital can deliver the drug to patients is the issue. We are currently examining such matters, while also considering the views of the authorities.

With regard to KHK4083, we recognize that COVID-19 has no significant impact at this point.

Hashiguchi: Thank you very much.

Wakao: Wakao from Mitsubishi UFJ Morgan Stanley Securities. The first question concerns the sales of Crysvida. Regarding the use of Crysvida in Europe, I have heard that an approval decision will be announced in the second half. Could you please tell us a little more about whether or not the regulatory review is likely to be delayed at this point?

In addition, as your Company's staff are working from home, could you tell us whether there is any impact on promotional or other activities for the launch after the approval of the adult indication?

Yamashita: An application for adult indications in Crysvida in Europe was accepted by EMEA on November 5 of last year. The timing of the approval has not been finalized, but we are currently considering approximately one year from that time.

As for whether there is a delay in review due to the influence of COVID-19, there is no sign of that, at the moment.

In addition, we are preparing for the launch of the new drug, and I believe that we will be able to carry out various procedures with staff working remotely, such as negotiations on the price of the drug when it is launched in various countries.

In addition, we have already launched Crysvida, albeit it is an indication for children, and we believe that we can respond to the situation to a certain extent by extending such a scheme.

Wakao: That being the case, I understand that nothing particularly worrying has occurred, at this point in time.

My second question is related to individual drug figures, for which data has not been disclosed. When the sales of major products and the technology revenues are subtracted from the total sales in Japan, the projected figure for the full fiscal year is JPY4.8 billion, and if we calculate that from the result figure for Q1, it would be JPY2.5 billion. It seems like the progress so far in the year is very favorable, compared with that projected figure. Could you tell us specifically about any temporary factors affecting the result for Q1? Also, how should we consider these influences going to be changed from the second quarter?

Kawaguchi: We are not able to explain the details of what is being analyzed, but there are areas where price improvements are contributing a little. It seems to be on track for our full-year forecast, and there are some factors bias the figures toward the first quarter.

Wakao: Okay. Thank you very much.

Ueda: I'm Ueda from Goldman Sachs Japan. I would like to start by asking about the impact of coronavirus. Looking at Q1 sales of Crysvida in the US and other countries, have you seen any movements to secure more inventory, for example, because patients are at home? From the previous question, I understand that the answer to this question is that there was no such effect in Q1?

Are there any of your products that are particularly susceptible or immune to such impacts? Or any conditions that increase the likelihood of this type of impact?

Also, I would like to ask about the impact on costs, if I may. It was mentioned in the presentation that you did not include the influence of coronavirus in the forecast. Could you first tell us what impact you are seeing when it comes to profit?

Yamashita: This question is about whether there has been a temporary increase in sales due to buying in for home administration, I believe. For the US, you would need to ask Ultragenyx. From what we have heard from Ultragenyx, the number of patients is confirmed, and then the number receiving the medication is followed, giving some information about usage.

I think that, for the Q1 figures, there has not been a significant change in the ratio between increase in number of patients identified and increase in use of the drug. I do not believe there has been a significant impact that you are describing.

Kawaguchi: I would like to explain about the impact on business results. We have little concern about a decline in sales for existing patients. Our plan is based on the growth of the three global products that are the driving force of our growth with steady acquisition of new patients. If the impact of coronavirus continues for a long period, however, we think it will have a certain negative impact. The level and breadth of the effect are difficult to read, but I am very concerned about the impact, in that case.

For example, when starting a new medication administration of Crysvida, it is necessary to confirm the safety and effectiveness of the administration, determine the dosage at the hospital, and then treat using on-site nurses. Therefore, depending on the circumstances of the medical institution, there is a possibility that a slight delay will occur in this area.

On the other hand, costs such as travel expenses and lecture expenses will, of course, decrease. However, we do not assume that those costs will decrease by the same degree as the sales. Therefore, we are making efforts to minimize this impact by paying close attention to the speed of acquiring new patients.

Ueda: Thank you very much. Second, I would like to know about the situation with Nesp. It was mentioned in the presentation that the market is tough. The figure for Nesp and Nesp biosimilars combined is down 35% to 36% YoY. It seems a shift from the branded Nesp to AG has been almost completed, when we look just at the figures. Could you tell us more about market conditions, such as whether you have taken some market shares from competitors, and/or whether competition with biosimilars is becoming more intense?

In considering the second quarter and beyond, it seems the growth rate will have to be higher to achieve the forecast. Could you tell us whether you can expect that to happen and whether there is room for that to happen?

Yamashita: Nesp-AG launched last year. Nesp biosimilars emerged after that, and we understand that biosimilars are currently showing a certain level of growth.

We think that this trend is a little difficult to read. We believe that, in the actual market, there is probably a price difference between our Nesp-AG and Nesp biosimilars. Under these circumstances, we understand that some biosimilars are gaining market share in price-sensitive areas.

I believe that those price-sensitive areas will move at an early stage, so the question is how long this will last and to what extent it will go.

Ueda: Do you think that there is some room for growth in line with the forecast from Q2 onward?

Yamashita: On the whole, we intend to secure the presence of Nesp-AG. In this context, I think one point is how the balance between the branded products and biosimilars will shift on the whole.

In that context, I think we will focus on how much market share we can take.

Ueda: Okay. That is all. Thank you very much.

Muraoka: Muraoka from Morgan Stanley MUFG Securities. Sales of Crysvita in the US were JPY9.2 billion in Q1, and JPY8.8 billion in the preceding Q4, so QoQ growth was only JPY400 million. Assuming that there are no temporary coronavirus-related impacts, as explained in previous questions, I think questions still remain about the QoQ growth.

While six months ago, in the third quarter, changes in sales were considered due to changes in inventory level, then there was a big increase in sales in Q4. Could you tell us about the background behind this QoQ growth to JPY9.2 billion?

Yamashita: There was a lot of movement in the figures in Q2, Q3, and Q4 of the previous fiscal year. As mentioned, the performance in Q3 was slightly weak, and the performance in Q4 was relatively strong, and I think it is somewhat volatile. Increase in Q1 seems to be a little slower than the preceding Q4, which I think can be ascribed to this volatility.

Muraoka: I think a graph of the number of patients will appear in the Q1 data from Ultragenyx that will come out in the next week. Would it be correct to assume from what you are saying that we won't see a flattening of the graph for the January to March period?

Yamashita: We are not able to comment on that data, at this time.

Muraoka: I understand. Thank you very much. Regarding royalty income, the achievement rate for both Japan and overseas is currently low, so it seems there is an expectation for earnings to increase in the latter half of the year.

Incidentally, if partners' approvals are available for Potelligent-related program, will this be in Japan or overseas? Since your Company's region classification has changed recently, can you give us some more clarification on this point?

Kawaguchi: Thank you for your question. I am afraid the change of region classification makes it a little difficult to follow. The technical revenue of Kyowa Kirin in Japan is classified into other categories, but BioWa in the US will receive royalties and milestones related to Potelligent technology will be included in sales in North America. However, with regards to the data by product in this briefing material, if they are happened, they will be included in the category of overseas technical revenue.

However, my previous explanation about factoring the temporary nature of overseas technology revenues into the plan does not necessarily mean that such Potelligent-related revenue is a part of the plan.

Muraoka: I understand. Thank you very much.

Sakai: I'm Sakai from Credit Suisse Securities. Firstly, how is your Company currently accounting for Crysvita's exports from Japan? I assume that it is considered an export, since it is going to Ultragenyx in North America. In what way does this affect your Company's profit and loss?

Also, since Europe is a territory for your Company, I think this will be offset, when it is consolidated. I think there will be some internal offsets, even if you are doing it on an arm's length basis. Are there situations where differences in returns on that side effect—for example, the profit share in some way? I would like to clarify this point.

Crysvita - Collaboration with Ultragenyx -

	Kyowa Kirin Group	Ultragenyx
U.S.A /Canada	<ul style="list-style-type: none"> ● Books sales ● For first 5 years, splits profits in half ● After 5 years, pays mid to high 20% range sales royalty 	<ul style="list-style-type: none"> ● For first 5 years, splits profits in half ● After 5 years, receives mid to high 20% range sales royalty
Europe	<ul style="list-style-type: none"> ● Books sales ● Pay up to 10% sales royalty to Ultragenyx 	<ul style="list-style-type: none"> ● Receives up to 10% sales royalty
Latin America	<ul style="list-style-type: none"> ● Receives low single-digit sales royalty from Ultragenyx 	<ul style="list-style-type: none"> ● Books sales ● Pays low single-digit sales royalty
Turkey	<ul style="list-style-type: none"> ● Receives up to 20% sales royalty from Ultragenyx ● Retains an option to take over commercialization rights after a certain period 	<ul style="list-style-type: none"> ● Books sales ● Pays up to 20% sales royalty
Japan/Asia /ROW	<ul style="list-style-type: none"> ● Books sales 	

* Kyowa Kirin supplies commercial products in all regions.

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21

Kawaguchi: Thank you. Regarding sales of Crysvita in North America, these sales are 100% our sales. For details, please refer to the financial results briefing materials on page 21. Our subsidiary in North America accounts for 100% of the sales, and half of the profit is paid to Ultragenyx. That is the profit share expense that has been included in SG&A expenses.

Therefore, internal transactions or a transfer cost do not affect at all, but all of the internal transactions are eliminated, and the final North American sales are recorded on our profit and loss. All of the half of the gross profit is included in SG&A expenses, so if Crysvita sales in North America increase, SG&A expenses will increase in tandem. On the other hand, we do not pay the half portion on the profit in Europe.

Sakai: This is a rough calculation, but I think it would have been advantageous if there were some improvement in the cost of sales and gross profit. Is it correct to say that this gross profit is roughly within the bounds of your expectations?

Kawaguchi: Yes. In our gross profit plan, you can see the full-year forecast of 76% for the year, but we understand that 76% of the forecast is for this fiscal year and that 75% for this period will be steadily moving toward that goal.

Sakai: Understood. In addition, the table on page eight contains a note at the bottom stating that royalties of Fasenera, from AstraZeneca, includes the Company's estimates. When we look at AstraZeneca's Q1 results, there was a figure of USD187 million, and extremely positive comments from them. Are there any discrepancies between your own estimates and AstraZeneca's estimates?

The reason I am asking about this is that, against the full-year forecast of JPY18.8 billion, the results in Q1 were JPY3.1 billion, of which JPY2.7 billion is Benralizumab, Fasenera. Mr. Kawaguchi commented earlier that

the Company would be able to achieve JPY18.8 billion because some lump-sum payments were to be received in the future. Does this mean that there is an expectation that the royalty rate of Benralizumab will not increase in this momentum? Could you please provide some clarification on that point?

Kawaguchi: I apologize for the slightly difficult explanation. I will explain it carefully. First, about our own estimates. Regarding the recording of our royalty income, royalty income corresponding to Fasenra sales by AstraZeneca in the first quarter will be recorded in our accounts in the first quarter.

However, as the January to March results for AstraZeneca are provided too late to be recorded by us, planned figures are used, and if there is a difference from the actual figure, it is adjusted in the next quarter. If results exceed the plan, the next quarter will be posted as a positive settlement, so rather than AstraZeneca's figures being completely linked to the quarter, the difference will be posted one quarter behind schedule.

In the annual plan, since we have forecast that the Benralizumab royalty will continue to increase, we certainly see that the rate of progress is low in that area. In addition, we have incorporated one-time income into the plan in the latter half of the fiscal year, so the progress rate appears to be low due to these two factors. However, the results in Q1 are as planned.

Sakai: Thank you very much.

Tanaka: I am Tanaka from Mizuho Securities. Regarding RTA 402 for Alport syndrome, when will the application timing in Japan be? I understand there is also development in the US for ADPKD. Could you tell us if there is any possibility of making this an international (joint) clinical trial?

Torii: Thank you for your question. First, regarding your Alport Syndrome question, Reata Pharmaceuticals is currently in discussions with the FDA, so we are observing the progress of those discussions while we consider the time of application in Japan. Regarding ADPKD, we are also in the process of considering it.

Tanaka: The second question is about the G-Lasta automated administration device. It was mentioned that it could be fitted while the patient receives cancer treatment. I believe the exclusivity period of G-Lasta ends around 2023, but do you think that this is a way of addressing that issue, to a certain extent? Are there the possibilities to be authorized (generic), as in the case of Nesp?

Torii: Thank you for your question. This automated administration device is part of LCM, and we are working to extend the exclusion period associated with patents. Regarding AG, we have not even started to consider it internally yet.

Tanaka: Okay. Thank you very much.

Moderator: Thank you very much for joining us today and thank you for your continued support of Kyowa Kirin.

[END]