



Kyowa Kirin Co., Ltd.

Q3 Financial Results Briefing for the Fiscal Year Ending December 2019

October 29, 2019

Event Summary

[Event Name] Q3 Financial Results Briefing for the Fiscal Year Ending December 2019

[Date] October 29, 2019

[Number of Speakers] 3

Mitsuo Satoh, Ph.D.	Vice President, Head of R&D Division
Takeyoshi Yamashita, Ph.D.	Director, Corporate Strategy & Planning Department
Motohiko Kawaguchi	Director, Finance Department

Presentation


Moderator: We will now hold a telephone conference on the results for the third quarter of the present fiscal year to December 2019 for Kyowa Kirin Co., Ltd., which was announced at 3:30 PM today.

Today's speakers are Mitsuo Satoh, Executive Officer and Head of the R&D Division, Motohiko Kawaguchi, Executive Officer and Director of the Finance Department, and Takeyoshi Yamashita, Executive Officer and Director of the Corporate Strategy & Planning Department.

Today's telephone conference is scheduled to take up to 60 minutes. First, Mr. Kawaguchi will present the Company's financial results, and then Dr. Satoh will discuss the Company's development pipeline. We will then take audience question

Please also refer to our Investor Relations (IR) website for downloads of our financial results, supplementary materials for the financial results, and teleconference materials for today.

I will now hand it over to Mr. Kawaguchi for a presentation on the financial results.



Summary of Q3 Results

(Billion Yen / Rounded)

	2018Q3 Results <small>[Cumulative]</small>	2019Q3 Results <small>[Cumulative]</small>	Changes	2019Q4 Plan* <small>[Cumulative]</small>	Progress
Revenue <small>[Overseas Ratio]</small>	197.7 <small>[32%]</small>	225.5 <small>[38%]</small>	+27.7 (+14%)	305.0 <small>[39%]</small>	74%
Gross Profit <small>[Gross Profit margin]</small>	143.8 <small>[73%]</small>	168.4 <small>[75%]</small>	+24.6 (+17%)	224.0 <small>[73%]</small>	75%
Core OP <small>[Core OP margin]</small>	39.5 <small>[20%]</small>	45.8 <small>[20%]</small>	+6.2 (+16%)	53.0 <small>[17%]</small>	86%
Profit <small>from continued operation</small>	42.8	26.9	-15.9 (-37%)	37.0	73%
Profit <small>from discontinued operation</small>	4.6	29.4	+24.8 (+537%)	31.0	95%
Profit	47.4	56.3	+8.9(+19%)	68.0	83%

*Announced on February 5, 2019

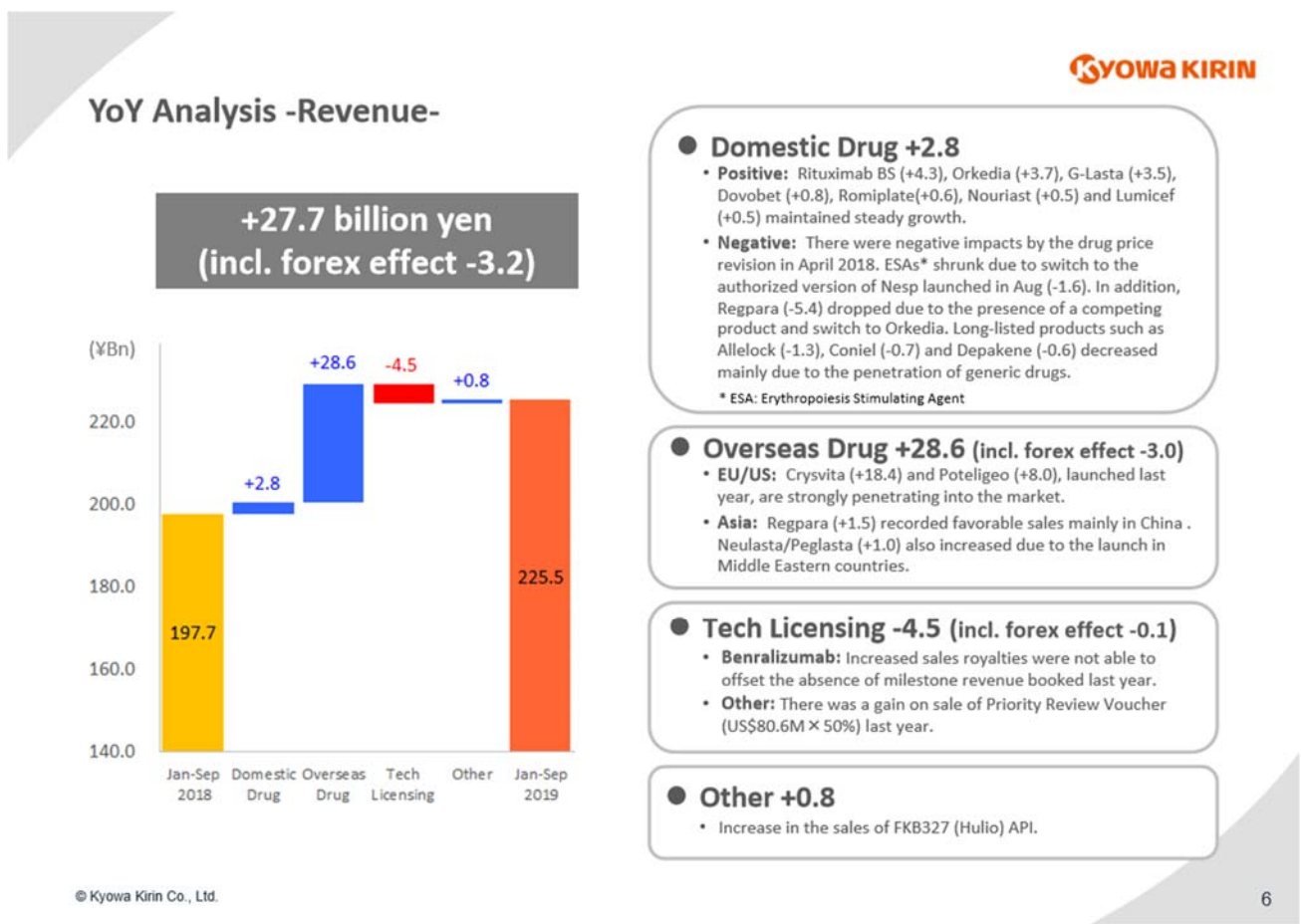
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Kawaguchi: Please refer to page five of the financial results briefing materials on hand. This is a summary of the third quarter financial results.

The four rows from the top show the results from our continuing operations, the pharmaceutical business. Revenue increased by 27.7 billion yen, or 14%, year-on-year. Gross profit rose 17%, or 24.6 billion yen. Due to an increase in the number of highly profitable global strategic products, the overseas sales ratio and the sales profit margin have progressed or increased in line with the plan.

Despite a significant increase in expenses, core operating profit rose 16%, or 6.2 billion yen. Profit of the pharmaceutical business for the period was 26.9 billion yen, a decrease of 15.9 billion yen from the previous fiscal year, due to the absence of one-off income that was recorded in the previous fiscal year. One-off expenses incurred in the current fiscal year also had an effect.

Profit for the period of discontinued operations increased by 24.8 billion yen due to a gain on the sale of shares in Kyowa Hakko Bio Co. Ltd. The quarterly profit, shown at the bottom, increased by 8.9 billion yen, or 19%, to 56.3 billion yen.



Next, I will give a breakdown of the 27.7 billion yen increase in revenue, as detailed on page six. Domestic sales of pharmaceuticals rose by 2.8 billion yen, overseas sales of pharmaceuticals increased by 28.6 billion yen, and technology revenues declined by 4.5 billion yen. In subsequent slides, I would like to talk about these elements individually.

Sales of other products rose about 800 million yen. This includes a variety of items, but the biggest positive factor is FKB327, Hulo. Increased sales of this active pharmaceutical ingredient have contributed to the overall increase.



Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2018Q3 Results [Cumulative]	2019Q3 Results [Cumulative]	Changes	Reason	2019Q4 Plan [Cumulative]	Progress
Nesp+Authorized ver.	39.2	37.6	-1.6 (-4%)	Switch to the authorized ver. launched in Aug 2019	48.4	78%
Nesp	39.2	32.0	-7.2 (-18%)			
Authorized version*	—	5.6	+5.6			
Regpara	10.7	5.2	-5.4 (-51%)	A competitor's penetration & switch to Orkedia	5.1	103%
Orkedia	1.1	4.8	+3.7 (+324%)	Launched in May 2018	9.5	51%
G-Lasta	14.8	18.3	+3.5 (+24%)	Steady market penetration	22.8	80%
Rituximab BS	2.4	6.8	+4.3 (+177%)	Launched in Jan 2018	8.4	81%
Allelock	9.7	8.5	-1.3 (-13%)	Generic drugs' market penetration	9.3	91%
Patanol	11.5	11.7	+0.2 (+2%)		11.3	103%
Nouriastr	6.8	7.3	+0.5 (+7%)	Steady market penetration	10.0	73%
Technology licensing	2.2	3.7	+1.5 (+66%)		4.4	84%

* Official product name is Darbepeotin Alfa Injection Syringe [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

Moving on to page seven, you can see the main items in Japan. First of all, a word about Nesp. As you may know, Nesp AG has been on sale since August 5th. In the roughly two months since its launch, sales of AG amounted to 5.6 billion yen. Sales of Nesp decreased by 18% from the previous year to 32 billion yen. Total revenues decreased by 1.6 billion yen, or 4%, compared with the same period of the previous fiscal year.

Regarding the overall progress, including the switch, we are basically in line with our plan, and we expect to achieve our full-year forecast of 48.4 billion yen for the current fiscal year.

With regard to Orkedia, the switch from Regpara continues to lag behind the plan. However, long-term prescriptions started in June, and the indications are expected to expand in the future, so we will continue to encourage switching and aim to capture new markets.

Regarding G-Lasta, there has been a strong positive growth, with a 24% increase. Thanks to the emergence of a variety of new cancer treatments and an increasing number of new combinations of these treatments, we believe there is a growing demand for G-Lasta, a supportive treatment to control febrile neutropenia.

Rituximab BS is also making steady progress. There is a possibility that another company's biosimilar will emerge this year, so we are seeing progress that move in line with the plan.

Regarding Allelock and Patanol, as previously explained, we expect them to exceed the full-year forecast due to greater-than-expected pollen counts.

Finally, regarding technology revenues in Japan, there was a significant increase of 2.1 billion yen over the three months of the third quarter. This is because FKB decided to discontinue the development of the third compound. In the past, we had received technical revenues related to this from FKB. The amount remaining in B/S as a contractual liability was written off in a lump sum during this fiscal year, and the revenue was recognized as a percentage of domestic technical revenues in this present fiscal year.



Revenue of Major Items (Overseas)

(Billion yen / Rounded)

Item	2018Q3 Results [Cumulative]	2019Q3 Results [Cumulative]	Changes	Reason	2019Q4 Plan [Cumulative]	Progress
Crysvita^{*1}	3.2	21.6	+18.4 (+572%)	Launched in Apr 2018	Undisclosed	—
North America		16.3				
Europe & others		5.3				
Poteligeo	—	8.0	+8.0	Launched in Oct 2018	10.0	80%
Abstral	9.5	8.3	-1.2 (-12%)	Preparation for Brexit	12.3	68%
Technology licensing	13.9	7.9	-6.0 (-43%)	Benralizumab milestone & Crysvita PRV^{*3} in 2018	12.9	62%
Benralizumab Royalty ^{*2}	1.7	6.1	+4.4 (+254%)	Launched in 2018		

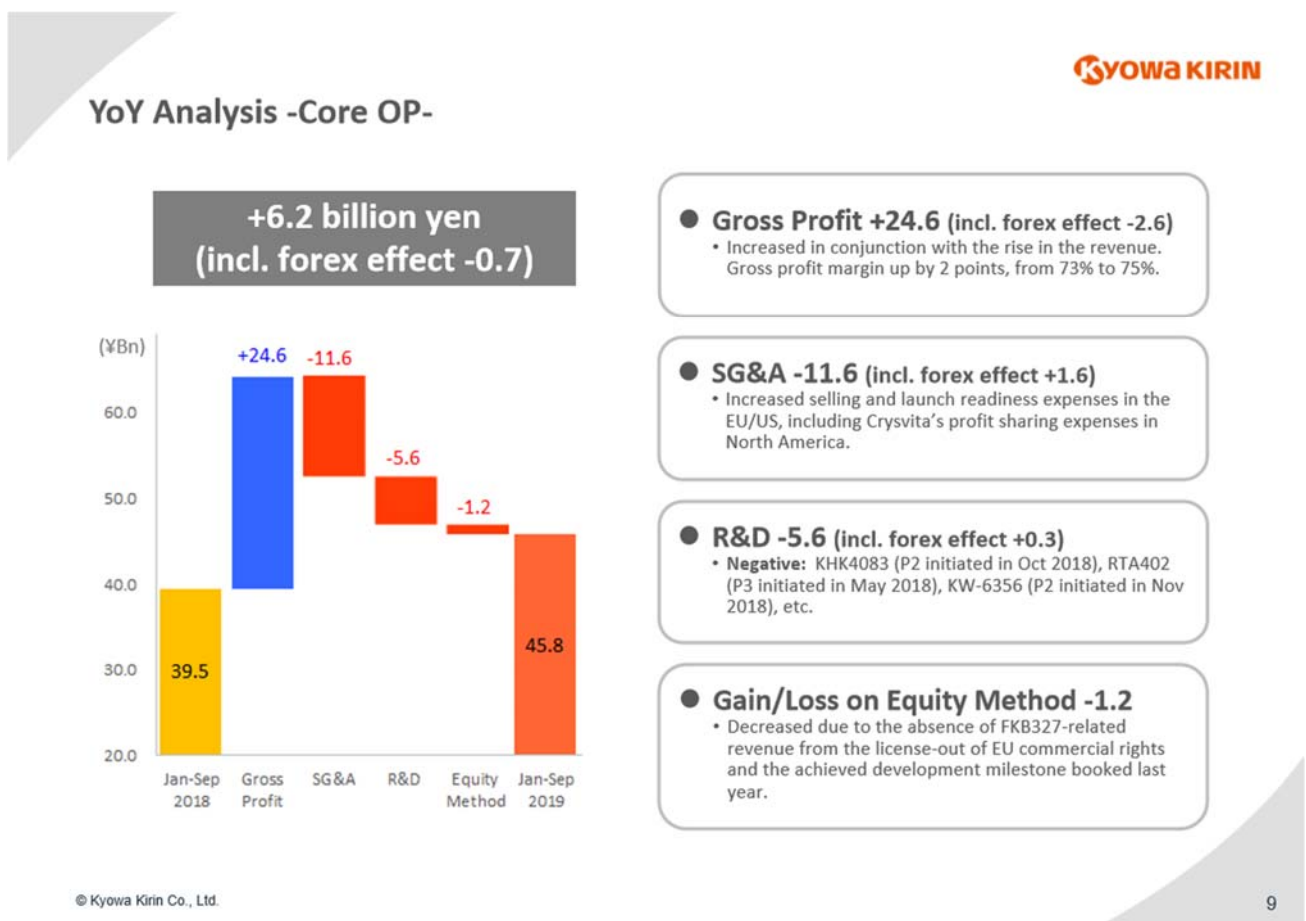
*1 -In January, sales started in England at the list price of GBP2,992 per 10mg vial.
 -Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).
 -Launched countries as of September 30, 2019:
 USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE
 *2 Sales royalties of "Fasenra" marketed by AstraZeneca. Includes our own estimation.
 *3 PRV = Priority Review Voucher

The major overseas items are outlined on page eight. Crysvita posted net sales of 21.6 billion yen, up 18.4 billion yen from the previous fiscal year. By region, sales in North America and Europe were 16.3 billion yen and 5.3 billion yen, respectively. We are making steady progress. As described in the note below, there have been no launches into new countries from July onward. We will continue to conduct drug price negotiations with the necessary authorities and make other preparations for new launches. We are aiming to increase the number of countries this product sells in as soon as possible.

Poteligeo has had sales of 8.0 billion yen, which is very much on track towards the full-year forecast of 10.0 billion yen. All of these figures show sales in the United States. The drug has already been approved in Europe, but we need to assess the balance of supply and demand in response to strong demand in the United States. Therefore, we plan to launch sales in Europe from the second half of FY2020.

Regarding Abstral, this has been slightly negative due to the impact of shipment adjustments related to Brexit, as well as the emergence of generics.

With regard to foreign technical revenues, royalties on sales of Benralizumab have continued to increase steadily. However, the overall figure is lower year-on-year due to the absence of several milestone revenues, as well as the absence of revenues from the sale of the priority review voucher obtained by the development of Crysvita.



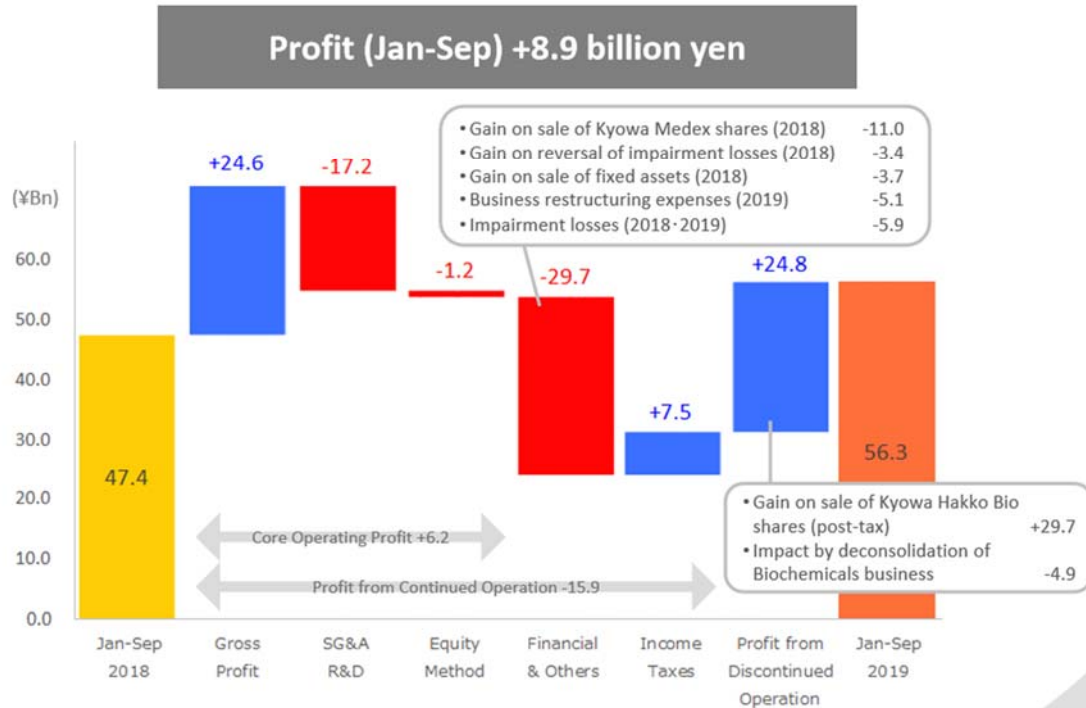
Please refer to page nine. The following is an analysis of changes in core operating income. Gross profit increased 24.6 billion yen from the previous fiscal year due to an increase in sales. The gross profit margin was 75%, showing a steady improvement.

Selling, general and administrative (SG&A) expenses increased by 11.6 billion yen year-on-year. In addition to the increase in sales expenses for Crysvita and Poteligeo, there were costs associated with the October launch of Nourianz.

R&D expenses also increased by 5.6 billion yen. The main reason for this has remained unchanged, as development progresses from last year. Major products under development are listed on the slide.

Equity in earnings of affiliates fell by 1.2 billion yen. Last year, there were some payments from Mylan N.V., but this year there was no such payment.

YoY Analysis -Profit-



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Please refer to page 10. This is a breakdown of the 8.9 billion yen increase in profit. I would like to explain the changes in items after core operating income. In finance and other activities, the Company posted a net negative of 29.7 billion yen. A breakdown is shown in the bubble. The top three are due to the absence of the one-time revenues that were posted last year.

The remaining two items were recorded this year. The business restructuring expenses included special retirement benefits related to voluntary retirement recorded in the second quarter. Impairment losses on intangibles related to Moventig recorded in the second quarter accounted for a large percentage of the impairment losses.

For discontinued operations, as mentioned the figure, is 24.8 billion yen, but the gain on the sale of shares of Kyowa Hakko Bio is 29.7 billion yen, which is the same as in the second quarter. In addition, the Biochemicals business recorded earnings from January to September last year, but for this year, only the first quarter was recorded, which was from January to March. This difference has been widening, and the effect of exclusion from consolidation is presented here.

As explained so far, core operating income was extremely strong and remained slightly stronger than planned. However, as there were impairment losses that were not in line with the full-year plan, we expect the bottom-line net income to be basically in line with the plan.

This concludes the financial review.

Moderator: Dr. Satoh will now give a presentation about our pipelines.



Key development updates in 19Q3

- **Initiation of the phase 3 clinical study of KHK4827 for the treatment of palmoplantar pustulosis in Japan (August)**
- **Approval of KW-6002 for the treatment of Parkinson's disease in the U.S. (August)**
→ The marketing strategy to be elaborated at the investor event on November 19th
- **Approval of KRN23 for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Japan (September)**

Satoh: Please refer to page 12. Major events occurring between July and September are listed below.

Regarding KHK4827, also known as Brodalumab, or Lumicef, in Japan, in August we commenced a domestic Phase-3 study for treatment of palmoplantar pustulosis. This study is part of Lumicef's LCM strategy and is aimed at expanding indications to include intractable dermatological conditions. This is an area where there is a definite unmet need.

KW-6002 was approved for sale in the United States in August. The brand name in the United States is Nourianz, and the product has been on sale since mid-October. We will hold a briefing on the US sales strategies for Nourianz and the development of next-generation Parkinson's treatment on November 19 and look forward to your participation.

In September, we received approval for manufacturing and marketing authorization of KRN23, or Burosumab, in Japan. Indications are FGF23 related hypophosphatemic rickets and osteomalacia. The approval differs from that in the United States, as it includes an indication for tumor-induced osteomalacia.

Key development updates after September

- **Results of the phase 2 study of KHK4083 for the treatment of ulcerative colitis in the US and European countries:**

There was no significant difference in efficacy endpoints

I will now report the top-line result for KHK4083 in ulcerative colitis. In evaluating effectiveness in Phase-2 trials conducted in Europe and the United States, we did not find any advantage over placebo. This clinical trial was not designed to have a high statistical power, as it was planned to enroll only 60 patients. We have almost completed the detailed analysis, and we are preparing to publish in a journal by around the end of this year.

I am not at liberty to discuss the details before publication. However, in short, the treatment concept is to get rid of invasive OX40-positive cells from the gut. We have confirmed that this can be done to a high degree.

However, there was heterogeneity in the relationship between OX40 cell counts and Mayo scores, the main indicator of disease activity in ulcerative colitis. I feel that just doing a large clinical trial does not work well for this indication, ulcerative colitis. We need to conduct a detailed analysis of the data we have before going further. This will give us information about exactly what types of patients this drug is most effective in.

The efficacy results of Phase-1 in atopic dermatitis are looking very good. At this point, we are aiming to prioritize the development of KHK4083 as a treatment for atopic dermatitis.

This concludes the R&D review.

Question & Answer

Moderator: I would now like to move on to the question-and-answer session. The first question is from Mr. Yamaguchi, from Citi Group Global Markets Japan.

Yamaguchi: Thank you.

The first question is about the results for Crysvida. I know this is a short-term view, but Europe has seen very little quarterly increase, and there has been a slight increase in the United States. To the extent that you are able, what can you tell us about the reasons for this?

Kawaguchi: The fundamentals for Crysvida have been steady, but the revenue recorded are based on shipments, so there are some factors that are slightly delayed in 3Q. I think that might make it difficult to analyze these results.

There could be things that shipments at the end of quarter are shifted to the beginning of next quarter and vice versa. This has certainly played a role.

Yamaguchi: Would this effect be manifested in a larger scale for the European or the US results?

Kawaguchi: This time around, this effect has been reflected in the results for both areas to a fair degree.

Yamaguchi: Understood. Next, I'd just like to clarify something about FKB. The development of the third drug was discontinued, and as a result, the portion that was on the balance sheet was drawn down and profits were taken.

On the other hand, you said that an unexpected impairment had occurred, but the bottom line was in line with your expectations. Is this related to what you were just saying?

Kawaguchi: That's a completely different topic.

Yamaguchi: Okay. I understand the answer to the first question. So, there will be no further FKB development, in terms of the pipeline? There won't be a fourth product?

Moderator: I'll pass this question to Dr. Yamashita.

Yamashita: Regarding FKB, we are going to develop a fourth drug.

Yamaguchi: So, the third drug is being dropped?

Yamashita: That's right.

Yamaguchi: Understood. Thanks.

Moderator: The following questions are from Mr. Hashiguchi, from Daiwa Securities.

Hashiguchi: Thank you. My first question mounts on the previous Crysvida question. Which quarter has seen increased sales from the effect described before? Where can we see an artificial decrease or increase in results caused by this delay (of shipments)? It looks as if there isn't a big increase from the second to the third quarter.

I appreciate that the effect may be different between the United States and Europe. What can you tell us about this?

Kawaguchi: In the United States, a section of the third quarter is recorded in the second quarter. In addition, shipments at the end of the third quarter are recorded in the fourth quarter. As for Europe, some shipments from the third quarter are recorded in the fourth quarter.

Hashiguchi: So, we can expect good figures in the fourth quarter?

Kawaguchi: I would like to think so.

Hashiguchi: Given this situation, what is progress like compared to the original plan?

Kawaguchi: Progress is being accomplished according to our plan.

Hashiguchi: Thanks. The second question relates to Nesp and AG. What progress is being made on the ground with respect to transition? Can you give us any figures, such as recruitment numbers, that would give numerical information about the progress being made?

The pace of the switch will vary depending on the medical institution, of course, but when is the peak of the transition likely to take place?

Kawaguchi: I'm very sorry, but I cannot comment on details. The switch has been going as we predicted after we start selling AG. The full-year forecast of 48.4 billion yen, which we have announced, seems to be in line with our expectations now.

Hashiguchi: Do you feel there has already been a big push to bring about the switch over? Or is it more a case of taking small steps now with further progress still ahead? I am afraid this is quite a qualitative question, but any information would be appreciated.

Kawaguchi: As far as the third quarter alone is concerned, almost half of the sales were from AG, so if things continue at this rate, sales of AG are likely to be more than half in the fourth quarter. I'm afraid I can't say any more than that.

Hashiguchi: Okay. Thanks, that's all.

Moderator: The following questions are from Mr. Tanaka, from Mizuho Securities.

Tanaka: Thank you. First, I would like to know about Nourianz. I understand that it was launched in mid-October. Has the price in the United States been disclosed?

Kawaguchi: The price is 1,500 dollars per month on a WAC basis, and these are the only figures that have been disclosed.

Tanaka: You mean 50 dollars a day.

Kawaguchi: Yes, that's correct.

Tanaka: Although there have not been many other Parkinson's drugs launched in recent years, I think the typical price for those that have been launched is about 27 dollars. Is there any reason why it was set at 50 dollars?

Kawaguchi: In the R&D briefing to be held on November 19, which was mentioned earlier, the person in charge in the United States will explain about this in more detail.

Tanaka: Understood. Also, I have a question about Poteligeo, which has not yet been launched in Europe. The third-quarter figure is 2.6 billion yen, which is about 400 million yen less than that for the second quarter. Is this due to a product shortage?

Kawaguchi: These figures are not a reflection of the product shortage. There is a slight upward trend, but we are currently analyzing the figures, and suspect that here too there is a one-month lag at play.

However, although this is not a constant upward trend, as is the case with Crysvita, it is not falling either.

Tanaka: Is it fair to say that until the second half of next year, it will be difficult to supply it to Europe?

Kawaguchi: Yes. Regarding the issue of supply and demand, we anticipated a strong demand in the United States, so we wanted to consider the balance there first, and then aim the launch in Europe for the second half of next year.

Tanaka: Thank you.

Moderator: The following questions are from Mr. Wakao from Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.

Wakao: Thank you.

The first is about FKB. There was an impairment loss, but on the other hand, I think you said that you will exceed the break-even point for the next period. Would you like to comment on how your business is currently progressing toward that point?

Kawaguchi: I think there is one point that is misunderstood here. There is no impairment loss on FKB at this point. The impairment loss is attributable to the impairment loss on Moventig etc. in the second quarter, and some impairment loss on property, plant and equipment in the third quarter, which is not related to FKB.

Wakao: So, the break-even point will be exceeded in the next period?

Kawaguchi: Equity-method profitability figures for FKB in the next fiscal year are expected to be positive and our perspective has been unchanged.

Wakao: Thank you. Next, could you give a brief explanation of the outlook for the next fiscal year? Nesp AG has penetrated the market faster than I had expected. I know this is in line with your original plan. But this shift from Nesp to AG is going forward, I think there will be a big negative impact on profits.

Also, as positive factors, there are the favorable conditions for Crysvita and Poteligeo, as well as the launch of Nourianz in the United States.

Given this situation, if we look at the next fiscal year from a holistic perspective, it seems there will be an increase in profits? I'm not sure how much you can say at this stage, but how much of an increase do you expect? Could you give us some comments on the direction of profits from your current standpoint? Will it be difficult to increase profits when Nesp is switching to AG? Or on the other hand, are there positive factors that will guarantee profits along with the switch to AG?

I appreciate it may be early to think about some of these issues, but could you give us some comments?

Kawaguchi: Factors like the one you have analyzed are major points for the next fiscal year. We can expect considerable growth in and after 2021 because of the absence of major negative factors. As you have analyzed, there will be a negative factor for next year due to the replacement of Nesp AG in Japan, so we are currently in the process of formulating a budget in order to overcome this negative factor and achieve growth.

Wakao: Since Nourianz has been approved, I think it has become easier to secure increased profits in 2020 than before. Is it safe to assume that compared with the second quarter, before the approval of Nourianz, the prospects for the next fiscal year are better now?

Yamashita: As you mentioned, Nourianz has been approved. We started selling this product and are expecting its sales increase. We hope overall profits will increase as well.

Wakao: Thanks.

Moderator: The following questions are from Mr. Muraoka from Morgan Stanley MUFG Securities.

Muraoka: Thanks. I'm sorry to ask another question about Crysvida, but I think you just mentioned the quarter-based lag factor. If you look at the United States, if the lag factor is smoothed out, Crysvida's revenue increased almost linearly from the second quarter to the third quarter? and how do you expect from the third quarter to the fourth quarter?

Or as has been mentioned that it is relatively easy to find child patients, but it takes longer to find adults. Has there been an initial increase in treating children, and we are now in a slowdown phase?

Kawaguchi: This is a difficult question, and it is difficult to say whether the growth was linear or not because we do not have any figures with smoothing the lag factors. All I can say for now is that we are going in line with the company's plan.

Muraoka: How about the question relating to children and adults?

Kawaguchi: We have not yet been able to fully analyze the data with respect to children and adults. We are now seeing that the number of registered patients is growing steadily. We expect linear growth for a while.

Regarding your question about whether there will be some different factors that influence sales in future, I can't say anything more about that.

Muraoka: Thank you. The second question is about Nesp AG.

Are there any signs that market share has been taken from Mircera, or from the first-generation drugs?

Kawaguchi: In terms of the penetration of Nesp AG, I believe that switching from Nesp to Nesp AG is the easiest step. We also expect to see a slight shift from other than Nesp to Nesp AG.

Muraoka: What quantitative information can be said about that?

Kawaguchi: There is no information that can be disclosed at this point.

Muraoka: I understand. Thank you very much.

Moderator: The following questions are from Mr. Kohtani from Nomura Securities.

Kohtani: The margins in the first, second, and third quarters are very similar. Of course, sales from Crysvida are increasing, and also from G-Lasta. On the other hand, of course, Allelock and Nesp are decreasing. Are there any other factors that can explain this phenomenon? Were there any factors that had a big effect on the profit margin in the third quarter?

Kawaguchi: I don't think there is a particular reason for this.

Kohtani: If so, then even if Nesp declines and Darbepoetin (Nesp) AG emerge on the market, do you mean to say that there will be little impact on the gross profit margin from the increase in the Darbepoetin (Nesp) AG?

Kawaguchi: There is a possibility that there will be a slight impact in the fourth quarter, and there will also be a drug price revision. In this sense, I think there is a possibility that such factors will come into play, as the projected profit margins for the full fiscal year are slightly lower than what they are now.

Kohtani: I don't understand this argument of the effect coming not in the third quarter but in the fourth. Does this mean that the current Darbepoetin (Nesp) AG has a high profit margin?

Kawaguchi: The effect from Nesp AG is expected to increase slightly in the fourth quarter. However, it is not the whole story, in percentage terms this will have a small effect, but I think it may have a negative impact. In addition, the impact of drug price revisions from October onward may also have an impact on the profit margin.

Kohtani: Understood. The second question is for Dr. Satoh. I wanted to ask about the KHK4083 ulcerative colitis study.

You said that there was low statistical power, and I know it doesn't matter if there was no statistically significant difference in this study. But could you tell us what the significance of this study was and what you wanted to verify?

In addition, it's usually the case that when we find new drugs with new mechanisms, the results of clinical trials are presented at conferences. What is the reason the result is just being presented in paper? Was it maybe because the result was not good enough?

Satoh: Thanks for your question. In fact, there were more than 60 ulcerative colitis patients enrolled, but we explained that this was not designed to generate a statistically significant difference in the main variables.

The most obvious point was that there are many scientific reports indicating that OX40-positive T-cells penetrate inflamed areas in ulcerative colitis patients. There was considerable literature on the relationship between this and the worsening of the condition. At this point, we were most interested in seeing whether the use of our KHK4083 treatment would reduce the penetration of OX40-positive inflammatory T-cells into areas of inflammation. First, we wanted to confirm that. We wanted to see if we could see it with dose dependency.

As a result, we found that we were able to curb OX40-positive T-cell infiltration, but there wasn't necessarily a link with the Mayo score, which is the key measure. We have learned, to some extent, that the link does not exist in some patients.

Thus, it has been found that ulcerative colitis is a rather heterogeneous disease. I think it is better to give further thought to the development strategy as “Should we go for extremely large clinical trials and aim for approval for UC? Or, should we do more targeted work to aim for a narrower demographic?”

Compared to that, we feel that the outcome of the atopic dermatitis trial is very attractive, and in the overall strategy of development we will prioritize this indication. The result made me think to adopt a development strategy that seeks to get an approval for atopic dermatitis first.

Kohtani: So, whether it is on paper or a conference presentation, it is not that important?

Satoh: We are currently preparing to present the results. For us the distinction between academic society presentations and papers is not so important when we deliver the results.

Kohtani: I've had my own thoughts on this, but there are few other anti-OX40 antibody candidates. It has a very limited but interesting Phase-1 results for ulcerative colitis, psoriasis and atopic dermatitis I thought it's very interesting to see this drug candidate has the results of effectiveness in these indications.

But according to the results of this study, it seems to be a drug for atopic dermatitis. This means that there may be some JAK inhibitors, Dupilumab or CIM331 as competitors, and do you have a profile that will allow you to compete sufficiently in that context? Certainly, a decrease in EASI scores with this drug is impressive, but I was wondering whether this would be sufficient to compete. What are your thoughts?

Satoh: I would like to wait for the results of the current Phase-2 atopic dermatitis trial. We are using the term “disease modifier”. There are JAK inhibitors or IL-4/13 inhibitors like Dupilumab. With these there is a flare-up after withdrawing therapy. This is a big problem with these medications.

Currently, we only have the results of the Phase-1 trial, but we are currently conducting Phase-2 trials. We want to assess the possibility that we may see some effects such as improvements in constitution with antibodies.

We can see the top line results around next year.

Kohtani: Thank you.

Moderator: The following questions are from Mr. Sakai from Credit Suisse Securities.

Sakai: Thank you. I have a question about Crysvida. What is the present breakdown for the child and adult in the United States? I think in Europe it is still only being administered to children, but I feel that the trend of sales pickup in children there is roughly similar to that in the United States, and I think that it will be used in adults next year. I would like to confirm whether you feel that the trend in Europe is roughly similar to that in the United States.

Kawaguchi: First of all, regarding the percentage of adults and children in the United States, this will be presented at the Ultragenyx financial results briefing after this, so please refer to that briefing.

Sakai: Europe is your territory, isn't it?

Yamashita: We are currently starting treatment in Europe as well. Presently, there are no adults, and I hear that there are some cases in which treatment is terminated in children as they get older. This is a cycle in which new patients are coming in as young people enter the market.

Indications for adult patients may enable children to receive the treatment seamlessly. That may be the case in the United States where both indications for adults and children have been approved. I believe that if the indication for adults is added in Europe, it will grow slightly.

Sakai: Just to clarify, “grow slightly”? I heard that the general market ratio in US was about 6:4.

Yamashita: When I say that, I am factoring in children who will continue their treatment as adults. Naturally, if the indication for adults is approved, the number of adults will increase further because many naïve adult patients will start the treatment with this drug.

Sakai: I understand. One more question, this time regarding Darbepoetin alpha or Nesp. I understand an application has been filed in China. I have heard that there is an enormous renal anemia and dialysis market in China. Presently, there are many kinds of oral formulations in China, and I think your company applied for this application at the beginning of the year. What is the status of the review? If you have any updates, I would like to know.

Also, I would appreciate it if you could provide us with some hints about the competition in this market now.

Satoh: As you mentioned, we have applied for the approval. The response to inquiries from the Chinese authorities has also progressed very smoothly. We believe that the approval will go as planned.

Dr. Yamashita will say something regarding sales strategy.

Yamashita: We have been selling Espo in China for a long time. There are many Espo biosimilars in China, and while there are products at a range of prices, we are still doing business with Espo. I believe that we will be able to enter the market with Nesp as a successor product.

In terms of product strengths, wherever there are chances, I am looking forward to seeing growth.

Sakai: Dr. Satoh said that there is steady progress toward approval. When are you anticipating the approval to take place?

Satoh: We applied this year and so far, the process is going smoothly, I can't say more than that at this time.

Sakai: I understand. Thank you very much.

Moderator: The following questions are from Mr. Ueda, from Goldman Sachs Japan Co., Ltd.

Ueda: Thank you. First of all, about Nesp AG, what has the impact been of the initial shipments on sales recorded in this quarter? Could you give us your comments on whether the ratio of sales between Nesp and AG actually represents the reality of usage?

Kawaguchi: Initial shipments were at the level of general distributor or wholesaler inventories. There are no special initial shipments in place.

Ueda: With that in mind, does this mean there is no feeling of strangeness with the balance between the sales recorded and shares in the market?

Kawaguchi: The balance? In terms of balance, I think that if we subtract the so-called ordinary wholesale inventory portion, we can get an idea of actual consumption.

Ueda: Okay. The second point is the gross profit margin in the full-year plan. I think the gross profit margin has exceeded the plan for so far, up to the third quarter. It was mentioned earlier that the fourth quarter forecast may deteriorate slightly due to an increase in Nesp AG or the impact of drug price revisions.

I think that, at the moment, the gross profit margin is still exceeding the target. What are your impressions of the progress of the plan in this area?

Kawaguchi: You are right, I think there is a possibility that our gross margin will fall slightly in the fourth quarter. However, there is a real possibility that we will be slightly above the annual forecast.

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

Moderator: It seems that there are no more questions, therefore we will now conclude the conference call for the financial results for the third quarter on the fiscal year ending December 2019. We would like to thank you for your participation today.

Today's teleconference call will be distributed on our IR website. In addition, we will also provide a transcript, so please use it to check the content of the call.

Thank you for your continued support for Kyowa Kirin.

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