



**Kyowa Hakko Kirin Co., Ltd.**

Q1 Financial Results Briefing for the Fiscal Year Ending December 2019

May 8, 2019

## Event Summary

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<b>[Event Name]</b>	Q1 Financial Results Briefing for the Fiscal Year Ending December 2019	
<b>[Date]</b>	May 8, 2019	
<b>[Speakers]</b>	Mitsuo Satoh	Vice President, Head of R&D Division
	Takeyoshi Yamashita	Director, Corporate Strategy & Planning Department
	Motohiko Kawaguchi	Director, Accounting Department

## Presentation

**Moderator:** Now, we will start the conference call on Kyowa Hakko Kirin's financial results for the first quarter of the fiscal year ending December 31, 2019, which we announced today at 3:30 p.m.

Today's speakers are Mitsuo Satoh, Vice President, Head of R&D Division; Takeyoshi Yamashita, Director, Corporate Strategy & Planning Department; and Mr. Motohiko Kawaguchi, Director, Accounting Department.

Today's conference call is scheduled to take up to 60 minutes. First, 10 to 15 minutes will be used for a presentation from Kawaguchi on the financial figures. Next, Satoh will explain the development pipeline. Finally, Yamashita will talk about business topics.

We will then receive your questions.

The Company's IR website allows users to download the financial summary, supplementary materials for the financial summary, and conference call materials used today. Please refer to the website as necessary.

First of all, Kawaguchi will explain the financial results.

### Summary of the Consolidated Results

**KYOWA KIRIN**

( Billion Yen / Rounded )

	2018Q1 Results	2019Q1 Results	Changes	2019Q4 Plan (5-Feb-2019)	Progress
Revenue	66.5	75.8	+9.3 (+14%)	305.0	25%
Gross Profit <i>[Gross Profit margin]</i>	46.7 <i>[70%]</i>	56.1 <i>[74%]</i>	+9.4 (+20%)	224.0 <i>[73%]</i>	25%
Core OP <i>[Core OP margin]</i>	14.4 <i>[22%]</i>	17.3 <i>[23%]</i>	+2.9 (+20%)	53.0 <i>[17%]</i>	33%
Profit from continued operation	20.9	9.3	-11.6 (-55%)	37.0	25%
Profit from discontinued operation	1.1	-1.2	-2.3	31.0	n/a
Profit	22.0	8.1	-13.9 (-63%)	68.0	12%

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**Kawaguchi:** I will walk you through the financial review. Please open to page five of the financial results briefing materials for the first quarter. This is a summary of the financial results for the first quarter.

First of all, let me explain the structure of the table for this fiscal year. The structure is a little irregular, due to the share transfer agreement of Kyowa Hakko Bio shares concluded with Kirin Holdings on February 5.

The top four lines, from revenue to profit from continuing operations, are the results of continuing operations of the Pharmaceuticals business. Below that part, profit from discontinued operations shows the performance of the Bio-Chemicals business in one line.

The bottom line is the total consolidated result, including pharmaceuticals and bio-chemicals.

The same reclassification has been made to the previous year's consolidated financial statements. Please understand that this is an IFRS rule.

I will now explain the contents.

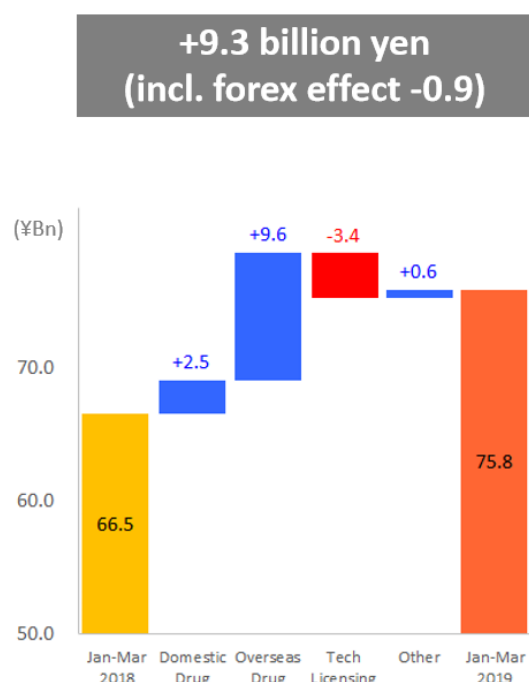
Revenue increased by 9.3 billion yen, or 14%, year on year. Gross profit grew 9.4 billion yen and core operating profit grew 2.9 billion yen, up 20% respectively, demonstrating our very good progress as a business.

Quarterly profit declined by 11.6 billion yen, about half that of the previous year, due to two reasons. In the same period of the previous fiscal year, there was a one-time extraordinary gain, and in the quarter under review, there was a one-time extraordinary loss. Therefore, the figures suggest a major decline in profits.

In the Bio-Chemicals business, there was a net loss of 1.2 billion yen, down 2.3 billion yen year-on-year. As a result, bottom line profit was 8.1 billion yen, a decrease of 13.9 billion yen year-on-year.

Looking at the progress against the full-year plan, the Pharmaceuticals Business is progressing steadily at around 25%.

The quarterly profit at the bottom does not seem favorable, at 12%. However, we completed the transfer of Kyowa Hakko Bio's shares on April 24. Given that this gain will be recorded in the second quarter, we believe that we are making steady progress in this business as well.



## ● Domestic Drug +2.5

- **Positive:** New product line including Rituximab-BS (+1.5), Orkedia (+1.2), G-Lasta (+0.9), Dovobet (+0.4), Nourias (+0.3) and Lumicef (+0.2) maintained steady growth. Patanol also increased due to the higher amount of pollen in the air (+0.8).
- **Negative:** There are negative impacts by the drug price revision in April 2018. In addition, Regpara (-1.7) dropped due to the presence of a competing product and switch to Orkedia. Long-listed products such as Allelock (-0.6), Coniel (-0.3) and Depakene (-0.2) decreased mainly due to the penetration of generic drugs.

## ● Overseas Drug +9.6 (incl. forex effect -0.9)

- **EU/US:** Crysvita (+5.7) and Poteligeo (+2.4), launched last year, strongly penetrated into the market.
- **Asia:** Regpara (+0.5) achieved favorable sales in China and Korea. Neulasta/Peglata (+0.5) increased due to the launch in Middle Eastern countries.

## ● Tech Licensing -3.4

- **Benralizumab:** Increased sales royalties were not able to offset the absence of milestone revenue booked last year.

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Let me explain in a little more detail, starting with revenue. Please see page six.

The main factor behind the 9.3-billion-yen y-o-y increase in the quarter is shown in the third bar from the left: The significant increase in overseas drug revenue.

In the domestic drug business, the impact of NHI drug price revisions was felt. The NHI drug price revision in April last year had a negative impact on revenue, but sales of new products such as Rituximab-BS continued to grow strongly.

In addition, sales of Patanol etc. due to the large amount of pollen in the air. As a result, overall revenue from domestic drugs increased by 2.5 billion yen.

The main driver of revenue growth is overseas pharmaceuticals. In particular, Crysvita and Poteligeo, which are global strategic products, recorded revenues of 8.1 billion yen in total. Due to the absence of these sales in the previous year, they contributed 8.1 billion yen to revenue growth. This is the main factor behind the increase in revenue.

Business in Asia also continued to grow. In addition to the strong performance of Regpara in China and South Korea, sales of Neulasta etc. have started in six GCC countries in the Middle East, based on a sales contract with Amgen, since January. This is a factor behind the increase in revenue.

Tech licensing revenue declined, but this was due to the absence of one-time milestone income in the previous fiscal year. Royalties on sales of Fasentra grew steadily as planned.

## Revenue of Major Items (Japan)

**KYOWA KIRIN**

( Billion yen / Rounded )

Item	2018Q1 Results	2019Q1 Results	Changes	Reason	2019Q4 Plan	Progress
Nesp+AG*	12.0	11.8	-0.2 (-2%)		48.4	24%
Regpara	3.6	1.8	-1.7 (-48%)	A competitor's market penetration & shift to Orkedia	5.1	36%
Orkedia	—	1.2	+1.2	Launched on May 2018	9.5	13%
Rituximab BS	0.3	1.8	+1.5 (+461%)	Launched on Jan 2018	8.4	22%
G-Lasta	4.3	5.3	+0.9 (+21%)	Steady market penetration	22.8	23%
Allelock	4.6	4.0	-0.6 (-13%)	Market penetration by generic drugs	9.3	43%
Patanol	7.7	8.5	+0.8 (+10%)	Higher amount of pollen in the air	11.3	75%
Nouriastr	1.9	2.2	+0.3 (+14%)	Steady market penetration	10.0	22%
Technology licensing	1.1	0.9	-0.2 (-14%)		4.4	21%

\*Nesp-AG, Darbepoetin Alfa Injection Syringe [KKF], is to be released in the 3Q of 2019 .

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Next, I will explain the revenue of the main items on pages seven and eight. I would like you to focus on the progress rate here. With regard to Nesp, it appears to be slightly negative due to the impact of the NHI drug price revision on a year-on-year basis, but it is progressing as planned.

The overall progress of other products is in line with the plan. As I mentioned earlier, due to the impact of the higher amount of pollen in the air this fiscal year, the results for Patanol and Allelock are slightly above the plan.

## Revenue of Major Items (Overseas)

**KYOWA KIRIN**

( Billion yen / Rounded )

Item	2018Q1 Results	2019Q1 Results	Changes	Reason	2019Q4 Plan	Progress
Crysvita*	—	5.7	+5.7	Launched on Apr 2018	Undisclosed	—
Poteligeo	—	2.4	+2.4	Launched on Oct 2018	10.0	24%
Abstral	3.4	3.1	-0.3 (-9%)		12.3	25%
Technology licensing	6.5	3.2	-3.3 (-50%)		12.9	25%

\*In January, sales started in UK (England etc) 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).

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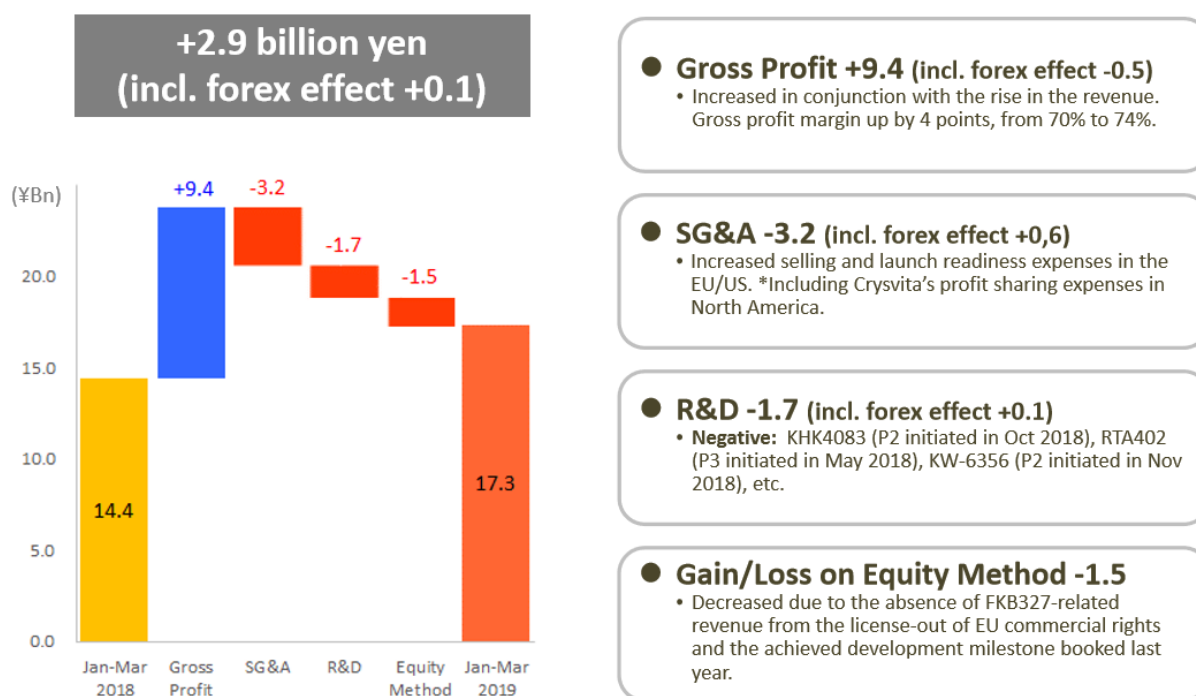
Next is the status of overseas drugs on page eight. The two items on the top, Crysvita and Poteligeo are growing steadily, as I already mentioned. While we do not disclose the annual forecast for Crysvita, it is progressing steadily in line with the Company's plan.

Poteligeo recorded 2.4 billion yen in revenue against the annual plan of 10 billion, making progress in line with the plan.

As I mentioned earlier, Fasentra, which is included in tech licensing revenue, is in line with the plan.

As described in the footnote, we launched Crysvita in the UK as planned in January, and list price is shown here.

For reference, the list price of Crysvita in Germany has been revised since May. This was a revision conducted one year after its launch, and as stated, the list price was down 25%.



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Next, on page nine, I would like to explain our core operating income. The main factor contributing to the 2.9-billion-yen increase was a 9.4-billion-yen increase in gross profit. The amount is almost the same as the increase in revenue. Thanks to the high margins of global strategic products I mentioned earlier, profitability improved, with the gross margin rising from 70% to 74%.

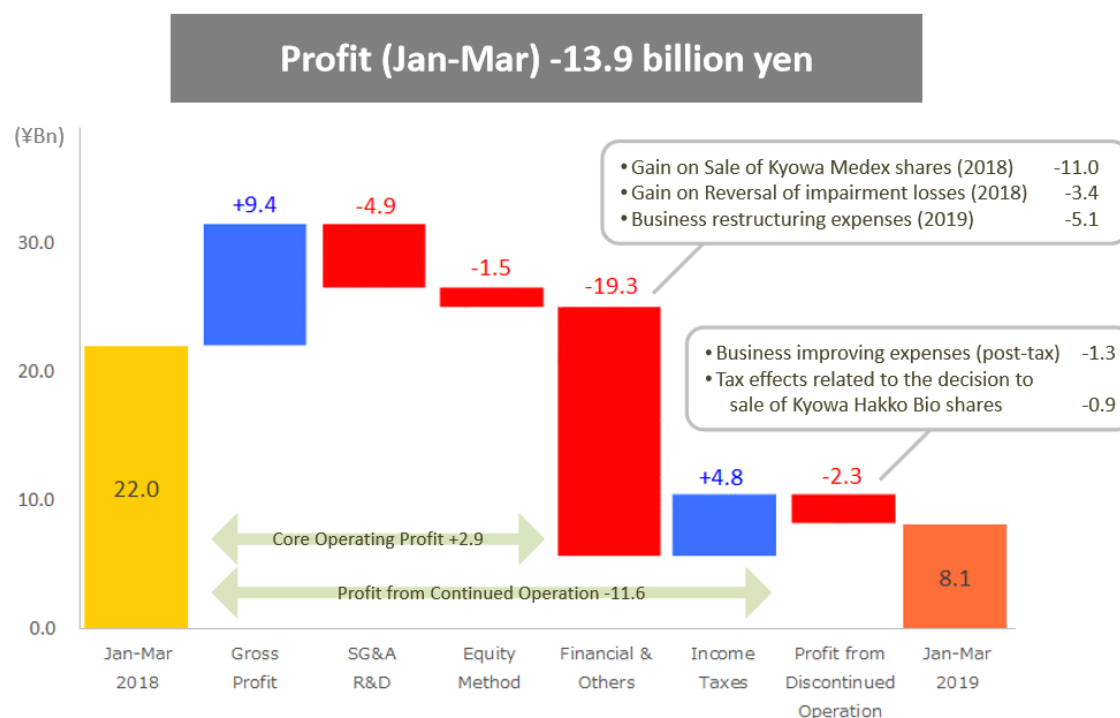
In addition, we have been making progress in cost reduction, contributing to a significant increase in gross profit.

On the other hand, selling, general and administrative (SG&A) expenses increased in Europe and the U.S. for sales expenses and preparatory costs for launch. This includes the cost of paying Ultragenyx a profit share for Crysvita's North American sales that will increase proportionately to the sales' growth.

In terms of R&D expense, while it peaked out once in the same period of the previous fiscal year, there are some late-stage developments, and expenses rose due to the Phase 2 trial for KHK4083 and Phase 3 trial for RTA402.

The last part is profit/loss on investments accounted for using the equity method. There was a decline in profit due to the absence of one-time revenue from the receipt of a lump-sum payment from Mylan for the European sales contract related to FKB327 of last year.





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Finally, on page 10, I'd like to explain the changes below Core Operating Profit.

You can see here that a major factor for the decline in earnings is Financial & Others. This is the main reason for the decline at the bottom line.

As I mentioned at the beginning, this was due to the absence of a large gain in FY2018 from the sale of Kyowa Medex shares and a reversal of impairment loss. Also, in the period under review, we recorded a 5.1-billion-yen expense related to voluntary retirement as a business restructuring expense, which was another main factor behind the decline in profits.

And as mentioned at the beginning, discontinued operations posted a decline in profit of 2.3 billion yen. There are two reasons for this: operational improvement expenses and tax accounting.

Expenses for operational improvement include consulting expenses based on improvement plans for quality assurance in the Bio-Chemicals Business. We recorded 1.2 billion yen in expenses for this purpose in the previous fiscal year, but as the plan progressed, we found out that further work and time would be required, so we have added this amount.

Tax effect accounting recognizes a 900-million-yen tax effect on investments in subsidiaries as a result of the decision to transfer Kyowa Hakko Bio shares. This is a plan that has been incorporated into the performance forecast from the beginning.

That was the y-o-y comparison of the results.

As I mentioned earlier, we will record a gain on the sale of Kyowa Hakko Bio in the second quarter, and we believe that we are making steady progress toward our initial forecasts.

I'd like to close my presentation on financial results.

## Key development updates in 19Q1

**KYOWA KIRIN**

- **Application for approval of KRN23 for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Japan**
- **Initiation of the phase 2 clinical study of KHK7791 for the treatment of hyperphosphatemia under maintenance dialysis in Japan**

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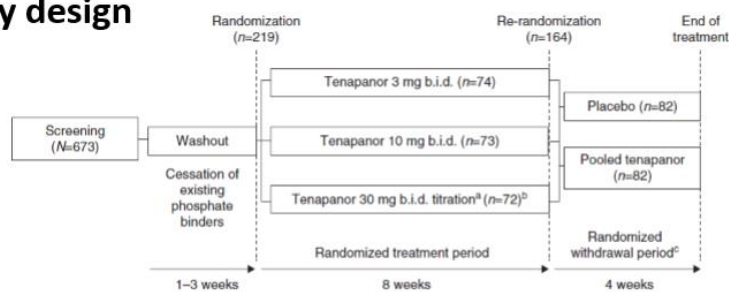
**Satoh:** I'm Satoh. I would like to walk you through the topics related to R&D in the first quarter of the fiscal year under review.

Please turn to page 12. As the first topic for the first quarter, we submitted applications in Japan for KRN23, Crysvida in January. The application is for the indication of FGF23-related hypophosphatemia.

In February, with KHK7791 in-licensed from Ardelyx, we began development in Japan by initiating the Phase 2 clinical study for phosphate control of hyperphosphatemia in hemodialysis patients.

## KHK7791: Phase 3 Study Results (conducted by Ardelyx in the US) **KYOWA KIRIN**

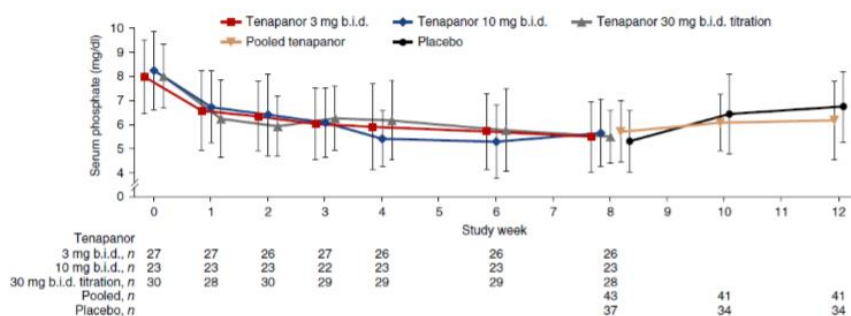
### • Study design



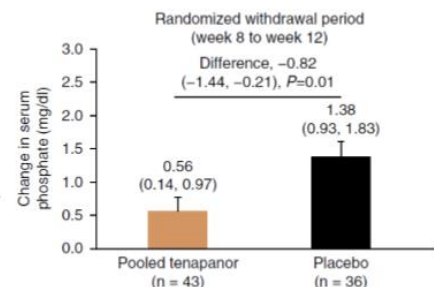
J Am Soc Nephrol. 2019 Apr;30(4):641-652.

### • Efficacy result

#### Serum phosphate levels



#### Change in serum phosphate levels during randomized withdrawal period



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Page 13 shows the content of the Phase 3 trial results of 7791 from Ardelyx conducted in the U.S.

I think the bottom right chart is easier to understand. This is a randomized withdrawal trial to see how much the phosphate level will return after withdrawal of the study drug.

Currently P-binders are the only drug in this field used for phosphate control. This new KHK7791, which is an NHE transporter inhibitor, has been confirmed to effectively control phosphate level with a new mechanism.

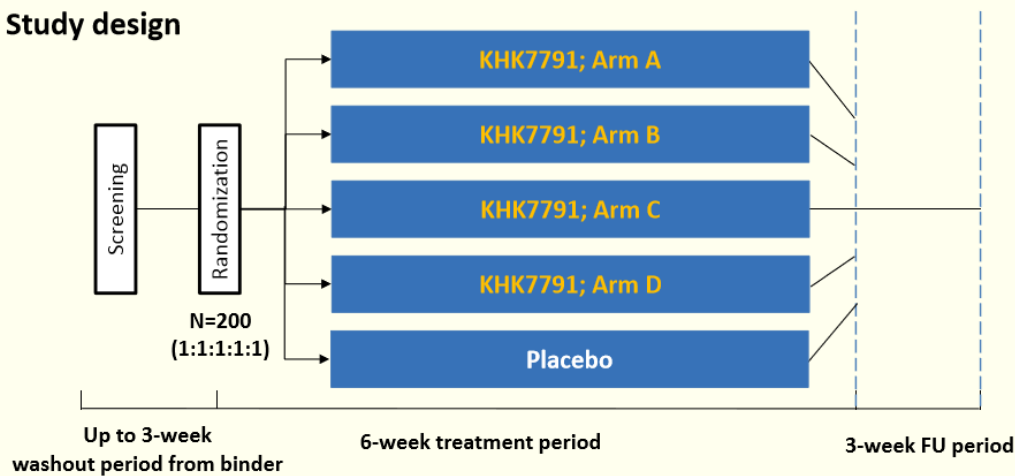
## KHK7791: Phase 2 Study Design

**KYOWA KIRIN**

### Dose-finding Study of KHK7791 in Hyperphosphatemia Patients

ClinicalTrials.gov Identifier:  
NCT03864458

#### □ Study design



#### □ Primary endpoint: To investigate the clinically recommended dose by comparing changes in serum phosphorus levels from baseline values at Week 6

**In addition to the above, two other Phase 2 studies are underway**  
(ClinicalTrials.gov Identifier: NCT03831607, NCT03864445)

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The contents of the Phase 2 study that started are shown on page 14. It will be fully developed in Japan, so in the form of a dose-response test, arms will be allocated from A to D, and the dose will be set with placebo control. We have begun a study to find a suitable dose for Japanese people.

- **Resubmission of application for approval of istradefylline for the treatment of Parkinson's disease in the U.S.**

Note: Listed event was completed between April 1, 2019 and May 7, 2019.

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As another topic, it is not about the first quarter, but allow me to report that in April, our re-application for sales of KW-6002 for the indication of Parkinson's disease was accepted in the United States.

That's all regarding R&D-related matters.

**Moderator:** Next, Yamashita will talk about business topics.

**Agreed to grant AstraZeneca exclusive development and commercialization rights for all indications, including the already agreed to rights for asthma and COPD, in Asia, including Japan**

- ◆ **With this new agreement, AstraZeneca now possesses global rights to all of the indications for benralizumab**
- ◆ **Through this agreement, it is expected that the value of benralizumab will be maximized by AstraZeneca handling the product strategy for all indications globally**

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**Yamashita:** I would like to introduce the business topics.

As already announced in a press release on March 25, Kyowa Hakko Kirin held the right for benralizumab, an IL-5 receptor antibody, for indications other than asthma and COPD in Asia. We have decided to license this right to AstraZeneca.

This gives AstraZeneca rights for all indications worldwide. Efforts to enhance the value of this drug will be unified at AstraZeneca.

That's all.

## Question & Answer

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**Moderator:** We would like to move on to the question-and-answer session. Questions and answers will be facilitated by the operator.

We appreciate your cooperation to ask up to two questions each time.

Now let me introduce the first participant.

Mr. Yamaguchi from Citi Group Global Markets Japan, please go ahead.

**Yamaguchi:** Thank you very much. As you mentioned the limit of two questions, I'd like to ask the first question.

Regarding Crysvita, Ultragenyx published some information yesterday morning. Based on the total of 5.7 billion yen, I think it's around 3 billion yen in the U.S. and 2.7 billion yen in Europe. I assume this 2.7 billion yen in Europe is growing because of the growing number of countries in which it sells, but hasn't it increased much compared to last year's Q4? I'd like to understand the situation.

And in the United States, there seems to be a view that Q-on-Q growth is slowing down a little, as the number of people using it after joining the clinical trial has run its course.

Although you have not disclosed your forecasts, and you're doing well, I believe you showed us a comparison against your assumptions in past briefings. Could you comment as much as possible on this?

**Moderator:** This is a question on Crysvita, so Kawaguchi will answer it.

**Kawaguchi:** Thank you for your question. Regarding Europe, as I mentioned earlier, the product has been on the market in the UK since January. Growth has been steady, and we are making very good progress in line with our plan.

As for the U.S., we would like you to refer to the explanation by Ultragenyx, but here we are showing almost the same growth rate as planned.

Some of the factors contributing to the growth are that most patients in clinical trials have started to use the drug, and the increase in naive patients, so there might be a slight change in the rate of growth.

In any case, it's not that growth is falling below our planned line.

**Yamaguchi:** Comparing Europe and the US, do you think that business is stronger in Europe, or is there little difference?

**Kawaguchi:** I can't comment on that. Both are well on track.

**Yamaguchi:** Both are doing well, OK. And I've heard a lot of explanation about 4083 for atopy before, and I believe that IBD and UC data are available. Are there any updates on that? If not, when will it be?

**Moderator:** Satoh will answer your question.

**Satoh:** Thank you for your question. UC data is almost complete. Due to some strategic considerations, we haven't decided yet about the timing of the announcement of this data, though.

We would like to release information once we are ready to make a proper announcement.

**Yamaguchi:** I see. So, whether it be top-line or reports at subsequent academic conferences, you are in the process of disclosing once the data is organized, rather than withholding the data.

**Satoh:** Yes, we are in the process.

**Yamaguchi:** I understand. Sorry, is this just UC, with no Crohn's?

**Satoh:** It's UC.

**Yamaguchi:** UC only, I understand. Thank you very much.

**Moderator:** The next question is from Mr. Hashiguchi at Daiwa Securities.

**Hashiguchi:** I'm Hashiguchi, nice to meet you. Thank you very much. I have two questions about the pipelines.

First, I would like to ask about Tenapanor that you mentioned earlier. Given the status of development in the United States, what are your thoughts on differentiation against existing drugs?

I think we can expect improvements in the convenience of taking drugs, but from a non-professional point of view, it seems like there is no major difference in phosphate control. What is your view on this?

Additionally, regarding adverse events, there seems to be a pretty high frequency of reports of soft stools and increased stool frequency. Is it correct to understand that this condition is milder than diarrhea? I would like to know whether safety can also be pursued as a point of differentiation.

**Moderator:** Satoh will answer your question.

**Satoh:** Thank you very much for your question. We believe that this is exactly what determines the value of this drug.

To begin with, in terms of phosphate control, we agree that the changes in blood phosphate levels are not significantly different from the existing the P-binders.

However, the mechanism is completely different, and with phosphate binders you must take a considerable amount, as you pointed out. We believe that this may lead to compliance issues with medications, and that some patients are not adequately controlled on current phosphate binders.

In this sense, I believe that the process would be to prove the benefit of this drug through clinical trials, including use in combination with phosphate binders, to seek drug approval.

In this regard, I think the key point is to decide the appropriate dose for Japanese patients in Phase 2, and carefully consider the right design for Phase 3.

Regarding side effects, you are correct in pointing out there is a tendency to cause soft stools. This drug certainly comes with that tendency.

On the other hand, phosphate binders also have some side effects, including constipation. So, we are engaging in development to offer a new drug to control phosphate in the blood of dialysis patients, in a convenient way for patients and doctors, assuming these two drugs can be used in different ways depending on the situation.



**Hashiguchi:** Thank you very much, I now understand well. It may be a little early to ask the second question, but KHK4323, an injection drug, is in Phase 1 for atopic dermatitis.

I wonder if this is positioned similarly to 4083, and if the initial development is successful, either one would go on to later stage development, with the other being something like a backup.

Or, do they have different concepts, so even if both drugs are put on the market, 4323 is used differently from 4083, and both can be expected to generate sales?

**Satoh:** In terms of mechanism of action, they are completely different. As for indication, it's true that we started with AD, a disease in which we have a good background of understanding.

However, we are not positioning it just as a backup. Basically, in this pipeline, we are observing the pharmacological action in the human body to determine what the best indication is, and how we can differentiate the drug from existing products.

**Hashiguchi:** In that sense, like 4083, you want to explore the possibilities not only for atopic dermatitis, but also for autoimmune diseases in general.

**Satoh:** Yes.

**Hashiguchi:** I see, thank you very much.

**Moderator:** The next question is from Mr. Ueda, Goldman Sachs Japan.

**Ueda:** I'm Ueda at Goldman Sachs Japan. I would also like to ask two questions.

First of all, you mentioned that progress has been made steadily in line with the plan. I believe the pollen-related products are actually doing very well. On the other hand, your plan for Nesp includes biosimilars, so it is a bit hard to evaluate whether the progress is good or bad at this point in time.

When you look at the first quarter, how was progress made toward the plan? Was there some overshooting, including the part related to pollen?

**Moderator:** Kawaguchi will answer your question.

**Kawaguchi:** Regarding the progress of products in Japan during the first quarter, there are items influenced by the amount of pollen, namely Patanol and Allelock, as you pointed out.

For this part, since our plan was based on a usual amount of pollen in the air, the portion exceeding the plan should remain as some upside for the full fiscal year.

Other products have been basically in line with the plan.

The progress rate for Nesp is 24%, but it's normal that sales are not that strong in the first quarter. Even if we look at the year-on-year comparison, it's negative 200 million yen, including the impact of NHI drug price revisions, so please understand this means we are roughly in line with the plan.

**Ueda:** Thank you very much. Second, I hope you will tell us a little more about patient trends, regarding Crysvita.

In Ultragenyx's conference call, there was a comment that about 12,000 patients exist in the United States. You previously mentioned 3,000 children plus 12,000 adults, a total of 15,000 patients, but has this view changed?

I heard that in the United States, about 1,100 patients have started using the drug. I'd like to know the usage in Europe, in terms of the number of potential patients and patients who are currently using the drug.

**Moderator:** Yamashita will answer the question.

**Yamashita:** Thank you for your question. The basis of the number of patients for Crysvita is not based on the actual patient count, but calculation from epidemiological data that suggests about one patient in 20,000 people. That's how we provided the figures.

Actually, we have started selling the drug for patients who joined and completed the clinical trial, but the area is limited, and the degree of concentration at the facilities is still unclear.

Therefore, we don't think we are at the stage to present a concrete, realistic number of patients who can actually use this drug.

Therefore, we cannot comment fully on the numbers that are provided by Ultragenyx.

**Ueda:** Excuse me, do you have any numbers for patients in Europe?

**Yamashita:** We don't have actual numbers to provide, but there are some predictions based on marketing activities on how many patients we may be able to reach.

As Kawaguchi mentioned earlier, usage is basically in line with the plan, which is all we can say for now. I apologize for that.

**Ueda:** I see, thank you very much. That's all.

**Moderator:** The next question is from Mr. Tanaka at Mizuho Securities.

**Tanaka:** Thank you very much. You mentioned the listing price of Crysvita was reduced by 25% in Germany in May. I guess 2,992 pounds for the UK was based on a conversion from the price in Europe last year.

Going forward, with the expansion of the product, I expect it will keep spreading to countries with lower prices. Do you think that prices will fall further in the future?

**Moderator:** Yamashita will respond to the question.

**Yamashita:** Thank you for your questions. Regarding the price in Germany, as you are aware of this, the list price this time was reduced based on the agreement to launch it at a higher price in the first year and revise the price in one year, based on evaluation.

As for the UK, I believe that prices have been set quite favorably, based on discussions with NICE.

Regarding your question of how prices may turn out in the future when expanding markets, it will also depend on negotiations made in each country.

In general terms, countries that are late to set prices tend to have systems that refer to the prices of other countries. So, basically, the price doesn't swing higher. Therefore, I expect that the drug's price would decline slightly as it expands to other markets.

In addition, some countries revise prices again. While we expand in Europe, Germany's prices are still quite high, and to some extent they may continue to be so in the future, but it is difficult to set expectations on whether other countries that approve the drug might set high prices like in Germany in the future.

We are aware of the details in some areas, so allow me to answer this question this way.

**Tanaka:** I think there is compassionate use in Europe, such as in Spain. Are there any plans to launch this product in a large market during the current fiscal year?

**Yamashita:** Thank you for your questions. The biggest market in the current fiscal year is our launch in England, which was mentioned earlier.

Apart from that, we have been negotiating with the respective authorities, and depending on the outcome, we would like to introduce them with the right timing. At this moment, we don't have anything impactful with a set schedule to announce.

**Tanaka:** I see. As for the products in development, the 6002 re-application was accepted in the U.S. Do you have any talks with the European authorities?

**Moderator:** Satoh will answer the question.

**Satoh:** Thank you very much for your question. In the U.S., the application was re-submitted, and we were told that the FDA accepted the application. We are currently planning to submit an application in Europe as well.

**Tanaka:** I see, Thank you very much.

**Moderator:** The next question is from Mr. Muraoka, Morgan Stanley MUFG Securities.

**Muraoka:** Thank you very much. On the income statement, the increase in revenue and gross profit was the same amount. Do you take this as an overachievement, or is this natural given the product mix? Please explain this.

**Moderator:** Kawaguchi will answer the question.

**Kawaguchi:** As I explained a little, one factor is the product mix, where the profitability of global strategic products is higher than that of conventional products. This is one point.

This quarter's cost structure was slightly improved as well. We reorganized our plants in the same period of the previous year, in which some of the costs remained slightly higher. Now that the reorganization has been completed, costs have come down to a reasonable level, which is also a factor behind the same amounts.

**Muraoka:** I see. Thank you very much. Next, about sales of Poteligeo, which was 2.4 billion yen. It looks like good progress, but is Q-on-Q growth just 300 million yen? How should we understand this part?

**Moderator:** Kawaguchi will answer the question.

**Kawaguchi:** For Poteligeo, one factor is that the shipment for the first month last year was larger than usual.

Last year's launch was very successful, but we don't anticipate a steep increase to continue like with Crysvita. We plan to increase sales gradually, following the strong initial figures.

In this sense, the figures are almost the same as those of our plan.

**Mr. Muraoka:** You mean it's not that there was more potential for usage than expected, or it might be used over a longer period, or anything like that?

**Kawaguchi:** Well, last year's performance after the launch was honestly unexpected. The speed of sales growth was quite unexpectedly good, but we reevaluated our plan for the progress made since then, and the difference from the planned figures has stayed within several hundred million yen.

**Muraoka:** Thank you very much. That's all.

**Moderator:** The next question is from Mr. Wakao, Mitsubishi UFJ Morgan Stanley Securities.

**Wakao:** My first question is about Crysvita in Europe.

What is the impact of Germany's list price revision, such as the penetration in the number of patients and progress? I'm not sure of the effect, so please give me a little more detail.

I believe that it has performed well so far in Europe. Do you think that this list price revision will cause a slight slowdown in Europe?

On the other hand, since it's also been launched in the UK, might the UK portion make up for the slowdown to maintain a strong performance in Europe?

Could you tell us a little more about the impact of the list price revision in Germany?

**Moderator:** Kawaguchi will answer the question.

**Kawaguchi:** First of all, in terms of comparison with the plan, the list price revision in Germany one year after the launch was included in the initial plan.

We can't comment on the range of the price revision, but we believe that the usefulness of the drug has been appropriately evaluated. Therefore, this revision does not mean that results will fall below the target.

That is the case with plans. And the unit price has fallen compared to the previous year, but as you mentioned, the unit price decline can be compensated for by the increase in the sales volume in Germany and the launch of the product in UK.

There is no change in our expectation that growth will be gradual and consistent.

**Wakao:** I see. And comparing Germany and the United Kingdom, do you feel any regional differences in the difficulty of identifying potential patients?

Are there any regional or national differences, such as patients being easier to identify and penetrate in Germany than in the United Kingdom?

**Moderator:** Yamashita will answer the question.

**Yamashita:** Thank you for your question. Although we don't know the details of regional differences in potential patients, a characteristic of this drug is that it targets genetic diseases, and patients are concentrated in large pediatric hospitals.

Germany and the United Kingdom have fundamentally similar characteristics in this sense.

We believe that we should start by having patients use the drug in such settings, so we don't expect a large difference in the degree of penetration at the early stage.

Later, we might start finding regional differences in awareness of the disease, or whether patients tend to be treated outside large hospitals.

We still can't comment on that stage.

**Wakao:** I see. My second question concerns the drug price of Nesp AG. I think it was set at 70% of the original. How should we think about the impact of this decision on your company's plans?

I don't think you have been announcing the drug price in the first place, but I think your strategy will change depending on whether the price is 50% or 70%.

Could you tell me if there are any changes in your company's plan, given it is 70%?

**Moderator:** Kawaguchi will answer your question.

**Kawaguchi:** As I explained at the time of last year's financial results, the full-year forecast, including Nesp and Nesp AG, is the best plan the Company could make by running a variety of scenarios, including not only NHI drug prices, but also product returns, as well as the timing of their launch.

We cannot comment on our assumptions for the NESP AG, but we do not expect to change the full-year sales outlook for Nesp, including AG, at this time. We believe this is an achievable goal.

**Wakao:** I see. That's all.

**Moderator:** The next question is from Mr. Sakai, Credit Suisse Securities.

**Sakai:** I'm Sakai. I have two questions, though I guess we've heard most of what we wanted to.

One is the full-year guidance for Crysvita. I believe last time you said you were preparing to disclose the guidance in the second quarter.

Can I understand that there are no changes to this point and coordination with Ultragenyx is proceeding?

**Moderator:** Kawaguchi will answer the question.

**Kawaguchi:** As for discussion with Ultragenyx, disclosure on Crysvita from the second quarter was about regional performance.

We have basically agreed to start disclosure of regional results of Europe and North America from the next second quarter.

We are still discussing the full-year forecasts. We are still unable to say the timing, but hoping to disclose at least by the end of this year.

**Sakai:** Disclosing by the year-end means you will disclose figures for the next fiscal year, right?

**Kawaguchi:** Yes. We would like to disclose that information.

**Sakai:** Understood. The breakdown by region means the breakdown of your net sales in Europe and the United States?

**Kawaguchi:** Yes.

**Sakai:** Understood. Regarding my second question, I assume in the second quarter you will recognize the gain, or cash-in, on the sale of Bio-Chemicals, which should amount to nearly 130 billion yen.

I think the answer will probably be to pool this money for strategic investments for the time being, but is there anything that is planned specifically after the sale has been officially decided, especially after the cash-out in the current period?

I don't think you can tell me about individual cases, as there are some loans to the parent company, and there is a problem that the balance sheet will become excessive, but could you tell us your thoughts on this issue?

**Moderator:** Kawaguchi will answer your question.

**Kawaguchi:** Thank you very much for your question. I recognize that this is an extremely important management issue, and I am aware, of course, that we will not be able to improve capital efficiency unless we effectively utilize this approximately 130 billion yen in cash.

Currently, we are considering ways to use this money effectively in prioritized growth investments.

As you are aware, I am not able to talk about individual cases, but specifically speaking about what has already emerged, we introduced daprodustat last year, and HP-3000 from Hisamitsu this year.

We will continue to bring in products in this way, and we will definitely consider all options including larger mergers and acquisitions for product introduction, as well as development expansion and growth.

If there are reasonable projects in line with our growth strategy, we will actively use cash.

In addition, we will continue to consider returns to shareholders based on the circumstances. That's all.

**Sakai:** I am aware that it is extremely technical and difficult to repurchase the Company's own shares, although you've done it in the past. Is this still an issue to be addressed? Is it possible?

**Kawaguchi:** Yes, it is an option, but we believe that the priority is to use it for growth investments.

**Sakai:** Thank you very much.

**Moderator:** Mr. Yamaguchi at Citigroup Securities will ask the next questions.

**Yamaguchi:** I have two questions. Regarding the royalty of Fasenra, the actual amount 3.3 billion yen was disclosed in the previous fiscal year. This fiscal year forecast, is it not disclosed on a full-year basis, but is the actual amount disclosed for Q1? Could you tell me if I ask?

**Moderator:** Kawaguchi will answer your questions.

**Kawaguchi:** We plan to disclose the royalty result of Fasenra in 2Q and 4Q. Please wait a little till 2Q.

**Yamaguchi:** I see. Regarding the timing of payment, AstraZeneca's January to March sales have been disclosed, so I can refer to it, but is there a difference in the timing or not?

**Kawaguchi:** Payment timing will shift by one quarter, of course, but accounting estimates are made with the same timing. It's not directly linked to AstraZeneca's revenue, but also includes our estimates. There is no delay in the accounting period.

**Yamaguchi:** So, I understand that there is no time lag.

My second question is about 6002. The PDUFA date is August 20-something, right?

**Kawaguchi:** Yes.

**Yamaguchi:** I thought so. Then, if things go well up to then, it will be approved, and you will be selling it afterwards. I think at the time of the full-year settlement, you mentioned some preparations for the launch, including costs.

I don't know about the existing partnering, but is approval based on preparation made within the existing cost base? Or if approved, will you use some additional costs to create a team?

I don't remember well, so can you explain it again?

**Moderator:** Kawaguchi will answer your question.

**Kawaguchi:** Regarding 6002, costs to sell the product includes the sales force that will be hired when approval for sales is obtained, so it will not occur if we cannot obtain the approval, but a certain amount has been incorporated into the budget for this purpose.

However, since the launch will be in the second half of the year, it is not a very large amount. It will not have a significant impact on sales or costs.

**Yamaguchi:** But you mean a small amount is actually included both in sales forecasts and costs, although it's not disclosed, right?

**Kawaguchi:** Yes, that's right.

**Yamaguchi:** And if it is actually approved, there will be various movements, so various costs will arise from the next fiscal year onwards.

**Kawaguchi:** Yes.

**Yamaguchi:** Understood, Thank you very much.

**Moderator:** We have only five minutes left, so we would now like to take the last question.

**Moderator:** The next question is from Mr. Sakai at Credit Suisse Securities.

**Sakai:** Just one question. I don't think it is directly related to your company's financial results, but just a moment ago there was a comment that the drug price of Nesp AG would be decided at 70%.

I believe that the economic division has begun to conduct a survey on AG items. In this process, it has been pointed out that the authorities hold the view that the development of biosimilars should not be hindered to a great extent, especially given the market domination of biosame products.

I don't think you can say you had or didn't have anything, and I don't know if you can say, but it would be very helpful if you can share your impression, or anything you can share about this matter.

**Moderator:** Yamashita will answer your question.

**Yamashita:** Thank you for your question. The drug price of Nesp AG was discussed by Central Social Insurance Medical Council, and was decided at 70%. As you mentioned, there were various discussions in the process of making the decision.

There was an opinion that if Nesp is treated as a generic product, it might be 50%. But there were comments that if it is too cheap, it may impede the development of biosimilars. I'm aware that such discussions took place.

We do not intend to impede the development of biosimilars, and we basically think that as patents expire for the original drugs, the drugs that are identical to the original drugs can exist as an option to be offered to the market.

In the discussion at Central Social Insurance Medical Council, there was an opinion from the insurers' side that wants to keep the cost of medical care low. There were also opinions from the medical professionals, who are the users of the drug, and after discussions centering on those points, the provisional 70% was agreed upon.

It's important to note that this was a provisional decision, and we believe there is still a lot of room for discussion on whether or not this is necessarily the appropriate drug price.

Given these circumstances, we do not plan to make any comments on this drug price.

We would like to take appropriate measures, while closely monitoring future discussions. That's all.

**Sakai:** I see. Thank you very much.

**Moderator:** Thank you very much. Now we will end our conference call on our first quarter financial results for the fiscal year ending December 31, 2019. Thank you very much for your participation today.

We plan to distribute the content of today's conference on-demand on our IR site. Please use it to confirm the contents.

We appreciate your further support for Kyowa Hakko Kirin.