



Kyowa Kirin Co., Ltd.

Q3 Financial Results Briefing for the Fiscal Year Ending December 2020

October 30, 2020

Event Summary

[Event Name]	Q3 Financial Results Briefing for the Fiscal Year Ending December 2020	
[Date]	October 30, 2020	
[Number of Speakers]	4	
	Takeyoshi Yamashita	Executive Officer, Director, Corporate Strategy & Planning Dept.
	Motohiko Kawaguchi	Executive Officer, Director, Finance Dept.
	Yoshifumi Torii	Executive Officer, Vice President, Head, R&D Division
	Tomohiro Sudo	Executive Officer, Director, Strategic Product Planning Dept.

Presentation

Moderator: Now, we will hold a teleconference on Kyowa Kirin Co., Ltd.'s Q3 Financial Results Briefing for the Fiscal Year Ending 2020, which was announced at 15:30 today.

Today, we have four speakers: Motohiko Kawaguchi, Executive Officer, Director, Finance Department; Takeyoshi Yamashita, Executive Officer, Director, Corporate Strategy & Planning Department; Yoshifumi Torii, Vice President, Head of R&D Division; and Tomohiro Sudo, Director, Strategic Product Planning Department.

Today's telephone conference is scheduled to take up to 60 minutes. First, Kawaguchi will explain consolidated results, then Torii will explain the development pipeline, and finally, Yamashita will explain the business topics. Then we will receive your questions.

First, Kawaguchi will explain the outline of consolidated results.



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Kawaguchi: This is Kawaguchi in charge of finance. First, please refer to page three. Please be aware that the future content that we will discuss today is subject to various uncertainties.

Summary of Q3 Results

(Billion Yen / Rounded)

	2019Q3 Results	2020Q3 Results	Changes	2020 New Plan	Progress
Revenue <i>[Overseas Ratio]</i>	225.5 <i>[39%]</i>	234.0 <i>[47%]</i>	+8.5 (+4%)	313.0 <i>[47%]</i>	75%
Gross Profit <i>[Gross Profit margin]</i>	168.4 <i>[75%]</i>	175.4 <i>[75%]</i>	+7.0 (+4%)	236.0 <i>[75%]</i>	74%
Core OP <i>[Core OP margin]</i>	45.8 <i>[20%]</i>	50.7 <i>[22%]</i>	+4.9 (+11%)	60.0 <i>[19%]</i>	84%
Profit from continued operation	26.9	37.5	+10.6 (+39%)	44.0	85%
Profit from discontinued operation	29.4	—	-29.4 (-100%)	—	—
Profit	56.3	37.5	-18.8 (-33%)	44.0	85%

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Next, I would like to introduce the outline of the third quarter consolidated results. Please refer to page five.

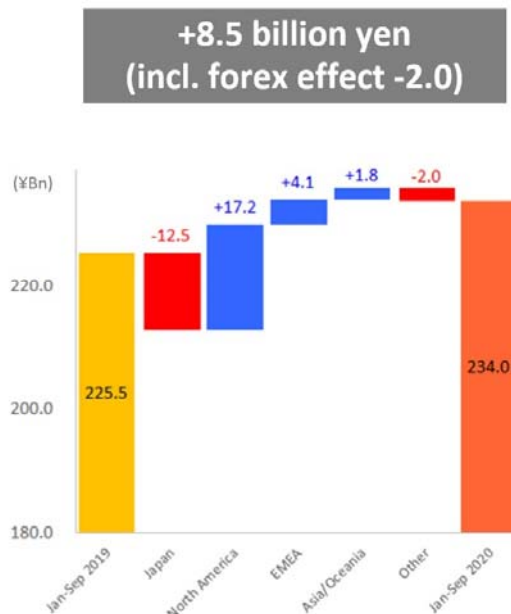
On a YoY basis, revenue increased by JPY8.5 billion to JPY234 billion, gross profit increased by JPY7 billion to JPY175.4 billion, core operating profit increased by JPY4.9 billion to JPY50.7 billion, and quarterly profit in the ongoing Pharmaceuticals Business increased by JPY10.6 billion to JPY37.5 billion.

As we will introduce in detail later, we were able to continue to achieve growth in sales and profits due to growth in overseas sales, including Crystvita, despite the impact of drug price revisions in Japan, the decline in sales of Nesp, and the impact of COVID-19.

However, the bottom-line quarterly profit declined by JPY18.8 billion due to the gain on the sale of Kyowa Hakko Bio shares last year.

On the other hand, we made downward revisions to the forecasts, JPY14 billion for revenue and JPY5 billion each for core operating profit and net profit for the year at the end of the second quarter. As you can see, we have made steady progress against the revised forecasts, which have been downwardly revised, and we intend to firmly achieve the revised forecasts for 2020.

YoY Analysis -Revenue-



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● **Japan -12.5**

- In addition to newly-launched Crysvida, Romiplate (Additional indication), Rituximab BS and G-Lasta made strong growth. However, they could not cover the impact such as the shrink of Nesp (Shift to Nesp-AG) and Patanol/Allelock (Lower pollen and COVID-19*) and NHI price-cut applied on Oct 2019 and Apr 2020.

*Voluntary ban on doctor's visit/outing or wearing a mask etc.

● **North America +17.2 (incl. forex effect -0.3)**

- Sales of Crysvida and Nourianz increased. Poteligeo was at the same level as 2019 due to the COVID-19 pandemic.

● **EMEA +4.1 (incl. forex effect -1.0)**

- Crysvida went up. Poteligeo was launched in Germany.

● **Asia/Oceania +1.8 (incl. forex effect -0.6)**

- Regpara maintained favorable sales in China.

● **Other -2.0 (incl. forex effect -0.1)**

- Benralizumab's sales royalties made steady growth, but other milestone revenue decreased.

Please refer to page six for the breakdown of revenue by region.

In terms of trends, the significant increase in sales in North America offset the decline in sales in Japan. In addition, EMEA and other Asian countries are showing steady growth, which has not changed significantly.

First of all, revenue in Japan decreased by JPY12.5 billion. In addition to Crysvida, which was launched at the end of last year, sales of Romiplate, Rituximab BS, and G-Lasta continued to grow. However, the impact of the switch from Nesp to Nesp AG, the decrease in Allelock and Patanol, and the negative impact of the two NHI drug price revisions were significant, resulting in a total decrease in revenue of JPY12.5 billion.

Revenue in North America and EMEA increased significantly by JPY17.2 billion and JPY4.1 billion, respectively. Sales of Crysvida increased significantly in both Europe and the United States. Regarding Poteligeo, although sales in North America remained at the same level as the previous year following recommendations on administration intervals under the COVID-19 pandemic, sales began in Germany in June, showing a smooth start. Regarding Nourianz, sales are still only in the US, but sales have been growing in solid performance since last October.

In Asia/Oceania, sales increased by JPY1.8 billion as Regpara continued to robust performance in China.

With regard to other revenue, technical licensing revenue and contract manufacturing sales are included here. Sales royalty for Benralizumab is increasing steadily. However, due to a decrease in one-time milestone revenue, et cetera, total other revenue decreased by JPY2 billion.

Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2019Q3 Results	2020Q3 Results	Changes	Reason	2020 New Plan	Progress
Nesp + Nesp-AG*	37.6	21.9	-15.6 (-42%)		28.9	76%
Nesp	32.0	3.3	-28.7 (-90%)	Nesp-AG launched in Aug 2019 and Biosimilars' penetration	4.6	72%
Nesp-AG	5.6	18.6	+13.0 (+232%)		24.4	76%
Duvroq	—	0.5	+0.5	Launched in Aug 2020		
Regpara	5.2	2.9	-2.4 (-45%)	Switch to Orkedia	3.3	87%
Orkedia	4.8	6.6	+1.7 (+35%)	Steady market penetration	9.5	69%
G-Lasta	18.3	19.6	+1.2 (+7%)	Market expansion	27.6	71%
Poteligeo	1.5	1.5	+0.0 (+2%)		2.0	76%
Rituximab BS	6.8	8.6	+1.8 (+27%)	Steady market penetration	11.4	75%
Romiplate	3.0	5.8	+2.8 (+94%)	Indication added in Jun 2019	7.4	79%
Allelock	8.5	6.5	-1.9 (-23%)	Lower pollen in the air and COVID-19 (Voluntary ban on doctor visit/outing or wearing a mask etc.)	8.3	79%
Patanol	11.7	8.7	-2.9 (-25%)	COVID-19 (Voluntary ban on doctor visit)	9.8	89%
Nouria	7.3	6.9	-0.4 (-6%)		9.9	70%
Haruopi	—	0.4	+0.4	Launched in Dec 2019	1.1	38%
Crysvita	—	2.4	+2.4	Launched in Dec 2019	3.5	68%
Technology licensing	3.7	1.6	-2.1 (-56%)	Absence of FKB-related one-off revenue	3.5	46%

* 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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Next, please refer to the status of major products in Japan on page seven.

First of all, Nesp and Nesp AG were negative JPY15.6 billion YoY, which was a major factor behind the decline in revenue of the domestic business.

With regard to Nesp AG, we will continue to closely monitor the state of market penetration of biosimilars and will take efforts in providing the drug information and other activities. Against the revised forecast, progress steady at 76%.

Next is Duvroq, an oral treatment for renal anemia, which was launched at the end of August. The result was JPY500 million for just over a month until the end of September. We assess this as a smooth start, and we will discuss it later in the Business Topics section.

For Regpara and Orkedia, the trend has not changed. We are working diligently to switch from Regpara to Orkedia, but due in part to restraints on MR activities with COVID-19, we are not making as much progress as we intend.

With regard to G-lasta, results exceeded the previous year due to the expansion of usage opportunities through the spread of new anti-cancer drugs and regimens. However, due to the cancellation or postponement of cancer examinations under the COVID-19 pandemic, the number of new patients is decreasing, and our progress is slightly behind the plan.

Rituximab BS and Romiplate are continuing to make solid progress.

Sales of Allelock and Patanol remained significantly lower due to less pollen dispersion compared to the previous year and the impact of COVID-19.


With regard to Nourias, sales have slightly decreased. We believe that factors include restraining visits due to COVID-19 and shifting our resources to the new product, Haruropi.

As for the new product Haruropi, although the monetary impact is small, progress has been delayed considerably. Restrictions and restraint on MR activities and the fact that long-term prescriptions are not possible until December have been identified as bottlenecks with the impact of COVID-19.

Regarding Crysvita, while growth was somewhat slow following its release at the end of the last year, it has been steadily increasing each quarter since then. Although we cannot discuss the number of patients in concrete terms, we are working hard with prospects to achieve our plan if it continues to make steady progress.

As for technology licensing revenue in Japan, it is down by JPY2.1 billion YoY.

We recorded a one-time income due to the reversal of contract liabilities following the decision last year to discontinue the development of third products by FKB. This is not the case this year, so that is the main reason for this decrease.



Revenue of Major Items (Overseas)

(Billion yen / Rounded)

Item	2019Q3 Results	2020Q3 Results	Changes	Reason	2020 New Plan	Progress
Crysvita*1	21.6	38.5	+16.9 (+79%)	Steady market penetration	51.1	75%
North America	16.3	30.3	+14.0 (+86%)			
EMEA	5.3	8.3	+3.0 (+56%)			
Poteligeo*2	8.0	8.4	+0.4 (+5%)	Launched in Jun 2020 and COVID-19 (Extended treatment interval)	10.0	85%
Nouriaz	—	1.7	+1.7	Launched in Oct 2019	2.6	65%
Abstral	8.3	7.6	-0.7 (-8%)	Generic drugs launched	9.7	79%
Regpara	3.8	6.1	+2.3 (+60%)	Listed on Chinese NEDL*3 in Oct 2018	7.4	82%
Technology licensing	7.9	10.9	+3.0 (+38%)		18.3	60%
Benralizumab Royalty*4	6.1	8.3	+2.2 (+37%)	Launched in 2018		

*1 Launched countries as of September 30, 2020 (excluding South America):
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain, Scotland, Oman, Kuwait, Qatar, Romania, Slovenia

*2 Launched countries as of September 30, 2020:
USA, Germany, Austria, Luxembourg

*3 National Essential Drug List

*4 Sales royalties of Fasenna, marketed by AstraZeneca. (Including our own estimation)

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Next, on page eight, I will walk you through our overseas products.

With regard to Crysvita, sales increased by JPY14 billion in North America and JPY3 billion in EMEA. As the progress against the revised forecast is 75%, we think it is fully possible to achieve it.

The markets where it was newly launched between July and the end of September are listed in the note below the table. The four countries are Kuwait, Qatar, Romania, and Slovenia. Also, in October, it has been reported

that we have achieved the launch in France. In Germany, sales in adult indications have also started, so we expect further growth in figures from fourth quarter onward.

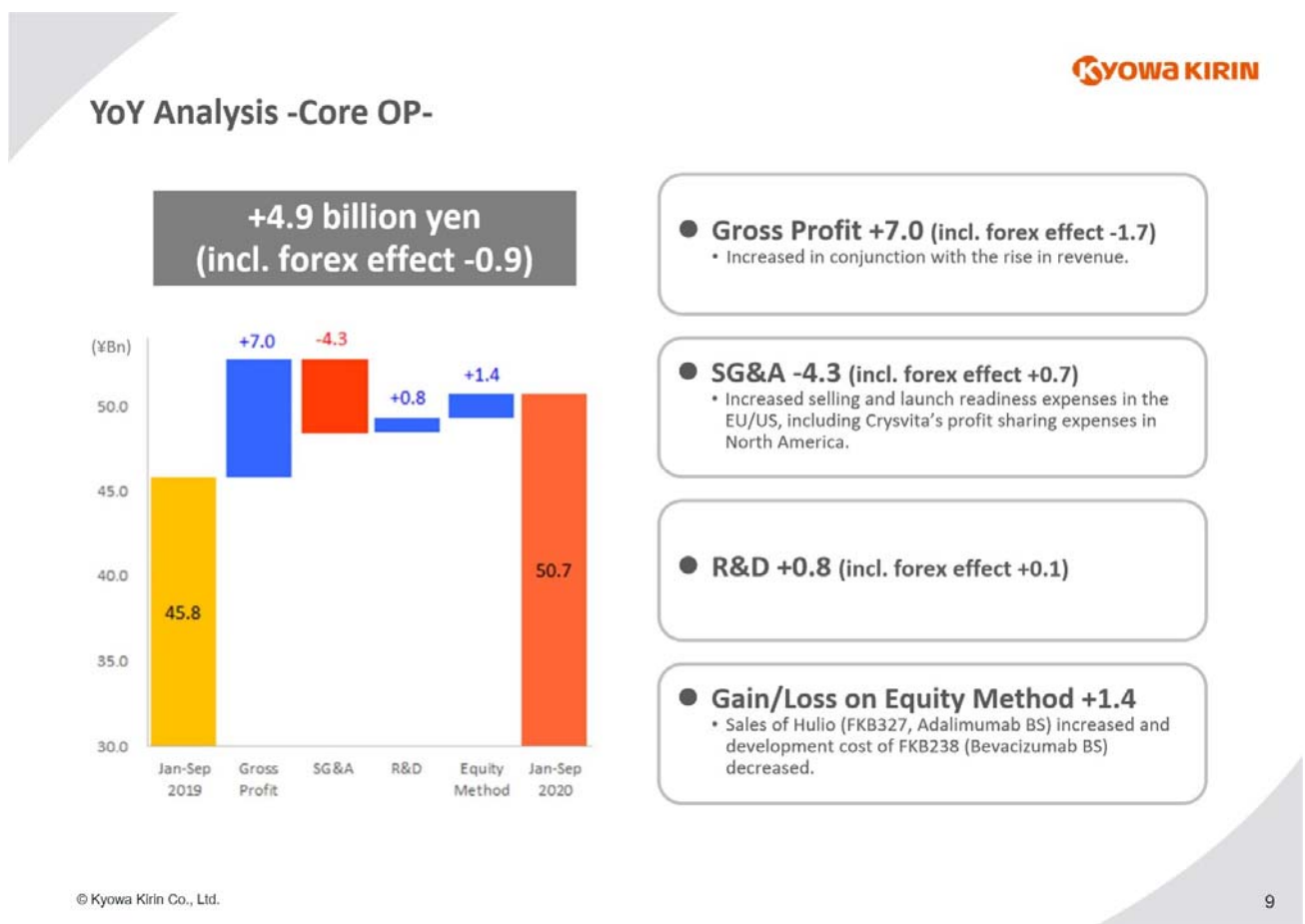
Regarding Poteligeo, in the US, where it had been launched earlier, a recommendation has been published from NCCN to consider the frequency of administration or hospital visit, as I mentioned earlier. As a result, the number remained at the same level as the previous year, but after bottoming out in May, the figures are gradually returning. In Europe, we have been able to launch this product in Germany, Austria, and Luxembourg, so it has begun contributing to the increase in sales, albeit still slightly.

Regarding Nourianz, we launched it in the US last October, so in this third quarter, it is fully contributing to the increase in sales. As I mentioned earlier, the figures have been growing each quarter since the launch, and we assume that we will be able to land not far from the revised full year forecast of JPY2.6 billion.

Regarding Abstral, a generic product was launched in Spain in July. As a result, third quarter results fell sharply, resulting in a decrease in sales of JPY700 million. We anticipate that generics will appear in other countries gradually and sales will decrease going forward.

Sales of Regpara increased by JPY2.3 billion due to robust sales in the Chinese market continuing from the first and second quarters.

Finally, regarding overseas technology licensing, revenue increased by JPY3 billion. The main reasons are Benralizumab or Fasenna, for which sales royalties increased. Other growth is the accumulation of small amounts of technology revenue. We are currently JPY7.4 billion short of the full-year forecast, which remains unchanged as expected one-time income in the fourth quarter.



Please refer to page nine. This section analyzes changes from gross profit to core operating profit.

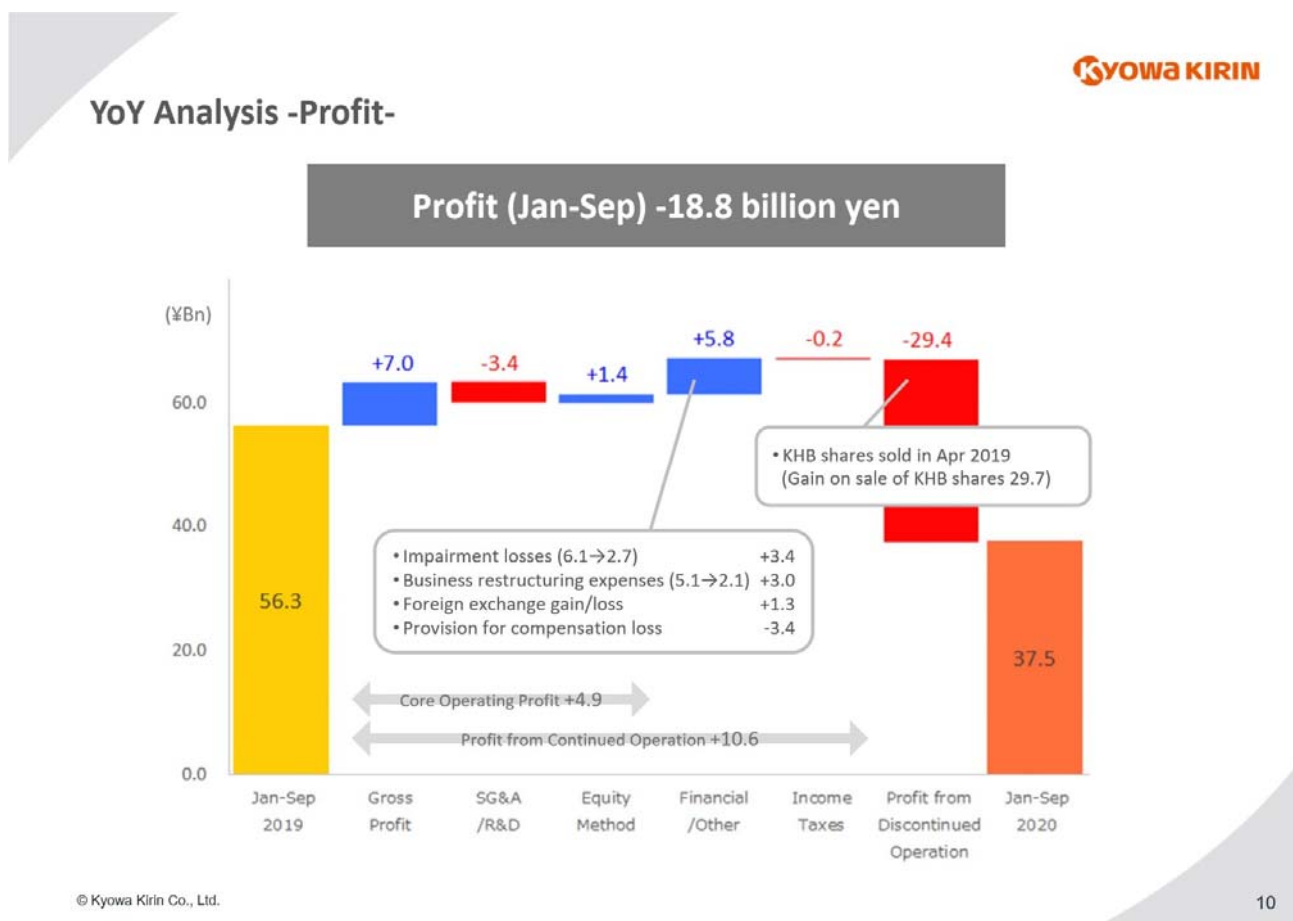
Gross profit increased by JPY7 billion due to an increase of JPY8.5 billion in revenue. The gross margin is 75%.

With regard to selling, general, and administrative (SGA) expenses, in addition to an increase in profit-share payments in North America linked to an increase in Crysvida sales, sales-related expenses in the US and Europe increased, resulting in a negative impact of JPY4.3 billion. The breakdown of SGA expenses is disclosed in the quarterly report submitted to the Financial Services Agency today. Sales promotion expenses increased by JPY5.2 billion, and personnel costs by JPY900 million. Depreciation/amortization of tangible/intangible assets decreased by JPY1 billion, and other expenses decreased by JPY900 million.

R&D expenses increased by JPY800 million at about the same level as the previous year.

Equity in earnings of unconsolidated subsidiaries and affiliates had a positive impact of JPY1.4 billion. Last year, we had a loss of JPY900 million, but this year we recorded a profit of JPY500 million, for an improvement of JPY1.4 billion. Factors are described on the slide.

As a result, the core operating profit increased by JPY4.9 billion YoY.



At the end of the Financial Section on page 10, I will explain the variance factors of finance and other cost.

Finance and other costs had a positive impact of JPY5.8 billion. It can be broken down into four main factors, as shown in the baloon.

The first was impairment loss, which decreased by JPY3.4 billion to boost operating profit. Last year's impairment was that of Moventig marketing rights introduced by AstraZeneca in 2016. On the other hand,

this year's impairment is for the in-process R&D costs of KHK2375 or Entinostat, recorded in second quarter consolidated results.

The second factor is a decrease in business structure improvement expenses, which improves profits by JPY3 billion. Last year, there were special retirement benefits related to voluntary retirement in Japan, but this year's cost is related to business reorganization aimed at focusing on global products carried out by a subsidiary in Europe.

The third is foreign exchange gains and losses, where this year's exchange gains are compared to last year's foreign exchange losses.

Finally, the provision for loss on compensation is made. This has been newly recognized in the third quarter. We have received claims for compensation from Kirin Holdings based on Kyowa Hakko Bio's share transfer agreement, and in order to prepare for the expenditure arising from this claim, we have recorded a reserve based on reasonable estimates at third quarter consolidated results. We will explain this matter later in the Business Topics section.

That's all for the Financial section. As I mentioned at the outset, the Company has achieved higher revenue and profits in the Pharmaceuticals business compared to the same period of the previous fiscal year and has made steady progress in line with the revised full-year plan. We look forward to your continued support.



Key Development Updates in 20Q3

- **Approval of KRN23 for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Korea (September)**
- **Approval of KRN23 for the treatment of adult XLH in Europe (September)**
- **Discontinuation of the development of KW-0761 for the treatment of adult T-cell leukemia/lymphoma in the U.S. and Europe**
- **Results of the phase 3 study of KW-0761 for the treatment of HTLV-1 associated myelopathy in Japan:**

There was no significant difference in the primary endpoint

Torii: Next, I would like to report on the progress made in R&D. Please turn to slide 12.

Major events that occurred between July and September of this year are listed below.

The first two are about the progress on KRN23. On September 17, we obtained marketing authorization for KRN23 in South Korea. As in Japan, we have received approval for indications including XLH and TIO for both adults and children. Subsequently, on September 30, we received marketing authorization in Europe for adult XLH in KRN23. The addition of this indication allows Crysvisa to be used to treat patients with XLH after adolescence, when the period of bone growth is past.

The following two are reports on KW-0761. First, we have discontinued the development targeting ATL in Europe and the United States. And, in the Phase 3 study in Japan targeting HAM, significant improvements versus placebo were observed in multiple items of the secondary endpoint, but no significant improvements versus placebo were observed in the primary endpoint. The policy going forward is under consideration based on a detailed analysis of clinical trial data.



Key Development Updates after September

- **Initiation of the pivotal phase 2 study of ME-401 for the treatment of indolent B-cell non-Hodgkin's lymphoma in Japan (October)**
- **Announcement of the positive phase 2b results for KW-6356 in patients with Parkinson's disease in Japan (October)**
- **Presentation of phase 2 study data on KHK7791 for the treatment of hemodialysis patients with hyperphosphatemia in Japan at ASN (October)**
- **Initiation of an innovative collaboration with Axcelead in small-molecule drug development in Japan (October)**

Please see the next slide, which shows events occurred since October.

On October 1, we launched the Phase 2 test of ME-401 for the treatment of indolent B-cell non-Hodgkin's lymphoma in Japan.

In addition, we were able to achieve the key assessment items in the Phase 2b trial of KW-6356 for Parkinson's disease. We are considering presenting detailed data at major academic meetings within the next year.

At the ASN-American Society of Nephrology, which was held virtually from October 22 to 25, we presented posters on KHK7791 Phase 2 studies. Major data will be shared during the R&D briefing held in December.

Finally, we began collaborating with Axcelead on October 2. Axcelead is the first drug discovery solution provider in Japan established by Takeda Pharmaceutical through the spinout of its drug discovery platforms

business. We aim to create innovative pharmaceuticals by integrating the technologies of Kyowa Kirin with Axcelead.

That's all about the progress of R&D.



Key Business Topics in 20Q3

- **Launch of Duvroq for Patients with Renal Anemia due to Chronic Kidney Disease (August)**
- **Centus Biotherapeutics* received European Marketing Authorization for Equidacent, biosimilar Avastin (September)**
- **Provision for the payment responding to the compensation request by Kirin Holdings Company, Limited.**

*Centus Biotherapeutics: Established in 2015 as a joint venture between Fujifilm Kyowa Kirin Biologics and AstraZeneca. Fujifilm Kyowa Kirin Biologics has granted an exclusive license to Centus for the development, manufacture, and commercialization of Equidacent on a worldwide basis.

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Yamashita: This is Yamashita from the Corporate Strategy & Planning Department. I would like to walk you through business topics. Please refer to page 15. There are three points.

First, we launched Duvroq, a drug to treat renal anemia. GlaxoSmithKline had received the approval for its domestic marketing on June 29. Since 2018, Kyowa Kirin has entered into a strategic sales alliance with GlaxoSmithKline. Kyowa Kirin take charge of the distribution and sales operations of Duvroq, as well as provision of information to medical institutions. GlaxoSmithKline and Kyowa Kirin are jointly undertaking MSL activities. I will elaborate on Duvroq later, as we have another slide.

The second point is that FKB238, which Fujifilm Kyowa Kirin Biologics is working on, has obtained approval in Europe. Fujifilm Kyowa Kirin Biologics established Centus Biotherapeutics, a joint venture with AstraZeneca in the UK. We have been developing FKB238, which is a humanized anti-VEGF monoclonal antibody and is equivalent to a biosimilar of Bevacizumab. The drug name is Equidacent. This has been approved in Europe in September.

We haven't talked much about this area so far, so I'll introduce it briefly. In 2015, Fujifilm Kyowa Kirin Biologics established a 50/50 joint venture called Centus Biotherapeutics with AstraZeneca. Centus has the exclusive right to develop, manufacture, and market this Equidacent worldwide. Centus has been advancing the clinical development of Equidacent, and this clinical development has been conducted globally in Europe, the US,

Japan, and other countries. Accordingly, the primary endpoint has been achieved, and this approval has been reached.

With this approval, we expect to be able to market in 27 EU countries and the United Kingdom and in the EEA countries Norway, Iceland, and Liechtenstein.

Next is the third point. This is about the claim for compensation from Kirin Holdings. Recently, the Company recognized a reserve for expenses incurred in relation to compensation claims from Kirin Holdings. On February 5, 2019, we decided to transfer to Kirin Holdings 95% of the shares of Kyowa Hakko Bio, which was our group company responsible for the bio-chemicals business. We signed an agreement on April 24, 2019.

Approximately a year later on April 17, 2020, in accordance with the agreement for the transfer of the shares, we received a claim for compensation from Kirin Holdings for violations of stated warranties and special indemnity events arising from violations of laws and regulations that occurred at Kyowa Hakko Bio. Currently, we are in discussions with Kirin Holdings, but this time, we recorded a reserve based on reasonable estimates in order to prepare for the expenditure incurred in relation to the compensation claim. Please be aware that the amount of compensation finalized may differ from the amount reserved this time.

Launch of Duvroq for Patients with Renal Anemia due to Chronic Kidney Disease (August)



- Launched Duvroq, an oral HIF-PH* inhibitor for the treatment of renal anemia due to chronic kidney disease (CKD), as the second group in the class for patients on dialysis, and as the first group in the class that can be used for the patients not on dialysis.
- At the end of September, the Japanese Society of Nephrology, in collaboration with the Japanese Society for Dialysis Therapy, announced the recommendation for appropriate use of HIF-PH inhibitors.
- Currently informing healthcare professionals with the drug information for appropriate use of Duvroq, especially prioritizing the safety.



*HIF-PH : Hypoxia Inducible Factor-Prolyl Hydroxylase

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Please move on to page 16.

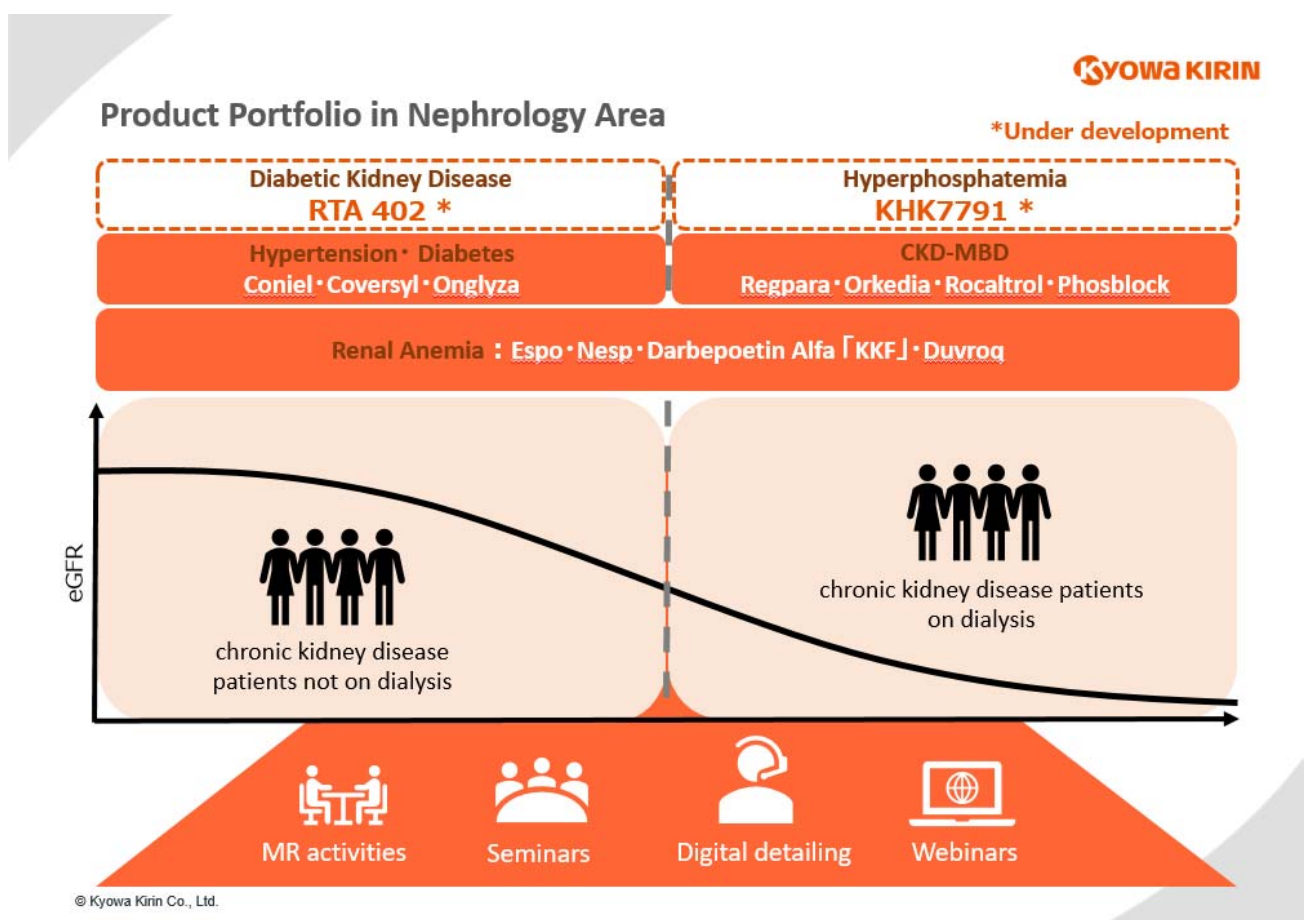
As mentioned earlier, this is Duvroq, an oral treatment of renal anemia called a HIF-PH inhibitor. This drug is the second drug in the country for the treatment of renal anemia, and the first drug is limited to the field of dialysis. Therefore, it belongs to the first group of treatments for chronic kidney disease patients before the introduction of dialysis, and it was launched in August this year.

Duvroq has been developed by GlaxoSmithKline. The mechanism of action of drug is to recognize hypoxia in the body. It is designed to stimulate the HIF pathway by facilitating the transfer of the endogenous erythropoietin gene and the production of endogenous erythropoietin. The drug improves anemia through this mechanism.

Features of Duvroq include four formulations: one-milligram, two-milligram, four-milligram, and six-milligram, as shown in this picture, for fine dosage adjustments.

Moreover, this HIF-PH inhibitor has an entirely new mechanism of action. Activation of the HIF pathway induces erythropoietin. The Japanese Society of Nephrology and the Japanese Society of Dialysis have published recommendation on the proper use of HIF-PH inhibitors because careful examination of the effects of these HIF pathways is needed.

Kyowa Kirin will utilize its wealth of experience and strengths in the field of nephrology to conduct activities to provide information on the appropriate use of such drugs with consideration for safety.



Please move on to page 17. This slide shows Kyowa Kirin's product lineup and development pipeline in the field of nephrology.

On the left side are patients with chronic kidney disease in the pre-dialysis stage, which further progress to dialysis patients. Drugs for underlying diseases such as Coniel and Coversyl for hypertension, as well as Onglyza for diabetes, are available as drugs for patients in the pre-dialysis stage.

As the patient progresses to the dialysis phase, Regpara, Orkedia, Rocaltrol, and Phosblock are drugs for the treatment of disorder of mineral metabolism or CKD-MBD associated with chronic kidney disease.

Duvroq is to treat anemia, which widely occurs in chronic kidney disease. Available drugs for this are Espo, Nesp, Darbepoetin Alfa KKF, and Duvroq has been added this time.

In addition, as shown in the top part, we are currently developing RTA 402 for diabetic kidney disease and KHK7791 for hyperphosphatemia.

Duvroq will be a very important piece in this lineup and pipeline in the field of nephrology.

As I mentioned earlier, we intend to make full use of our experience and strengths in the field of nephrology to ensure appropriate use of these drugs and to provide information and contribute to boosting sales of Duvroq.

Question & Answer

Moderator: Now, we will move on to the question and answer session. Please ask up to two questions at a time. Then, we will start.

Yamaguchi: This is Yamaguchi from Citigroup Securities. Thank you very much. The first question concerns compensation to Kirin. You are recognizing reserves to prepare for the payment, but I would like to know a little more about the treatment, including the timing of expenditures in the future and the impact on the core and non-core. This is the first question.

Yamashita: Thank you. Yamashita will answer your question. First, regarding the timing, we are currently in the process of examining the details in response to this claim for compensation. We have posted a reserve but have not yet obtained sufficient information to scrutinize the contents and not conduct a full analysis. Therefore, it's likely to take some time. In terms of whether we will reach a conclusion by the end of the year, we anticipate that the time horizon will go beyond that. We do not expect this deal to have a significant impact on our core and non-core businesses. That is all.

Yamaguchi: Thank you very much. The second question is on the progress of business performance. When we look at sales and other factors, it looks on track with the revised figures, particularly for Crysvida and Poteligeo. However, when we consider that it is recovering, it seems to have a little upside, and profits might overshoot as well. Regarding the full-year forecast, haven't you lowered it a little too much, seeing the outcome?

Kawaguchi: Thank you for your question. Looking at the situation up to the third quarter, it seems like it has improved further from the situation that was assumed at the time of the second quarter. As I mentioned earlier, Poteligeo has been recovering steadily since bottoming out in May. We think the environment may be a little better than the outlook in the second quarter, so we are hoping to exceed it as much as possible in terms of revenue.

On the other hand, the extent of undelivered expenses is gradually shrinking. And one point is that there is a tendency for expenses to concentrate significantly in the fourth quarter of each year. In the last fiscal year, SGA expenses were about JPY5 billion more than in the third quarter. At present, the undelivered portion is larger than our expectations, so the question is how much we will incur in expenses in this fourth quarter. Moreover, R&D expenses tend to be settled in considerable amounts in December, and we cannot fully predict what will happen in the fourth quarter given the COVID-19 environment. As spending has been below the budget, the situation is quite difficult to control, but regarding revenue, we are hoping to overperform.

Yamaguchi: Okay. Thank you very much. That's all.

Hashiguchi: This is Hashiguchi, Daiwa Securities. Thank you in advance.

The first is the status of Crysvida. Looking at sales every three months, I think it's growing steadily in Japan and North America. EMEA sales, on the other hand, seem almost flat every three months. Can you comment on why this is and what you anticipate from the fourth quarter onward?

Sudo: First, in Europe, the treatment of new patients has not progressed as much as we expected, compared to the US and elsewhere. In addition, we only have indications for children to date, so patients who were continuing treatment may have to stop once they reach a certain age. This also seems to have been a factor that has halted the growth of the market a little. Another point is that, as you know, we negotiate drug prices before placing the drug on the market. However, this negotiation has been delayed due to COVID-19, and the

launch has lagged considerably behind schedule. It is a challenging situation, but we were finally approved for indication for adults at the end of September, so we expect that we will be able to catch up from here on.

Hashiguchi: You mentioned several reasons. Is the first point about new treatment progressing less than expected because the treatment environment is different from Japan and the US, or do they take a different approach to the disease? Or is it related to the reason you mentioned after that, so it will be solved after a certain amount of time?

Sudo: Based on our observation so far, we feel that the drug is fairly well accepted by patients. It's not that patients who are receiving treatment are stopping, and compliance is also very good. Rather than reluctance to a new treatment, since activities to identify new patients have stopped a little, this has caused a major difference from North America. I might have explained this before, but in the US after patients are identified, they fill in a starting form where patients are already lined up waiting to be treated. Therefore, even with the impact of COVID-19, we can bring them to treatment relatively smoothly, but there is no such system in Europe, so that difference seems to be showing significantly. In the mid- to long-term, we are not very concerned.

Hashiguchi: Thank you very much. The second question is about KW-6356. I think you mentioned that it has achieved the primary endpoint for the Phase 2 trial, but what sort of responses are you feeling at this point? The innovator drug is already on the market, and this KW-6356 is not expected to have a long patent. Given this situation, have you obtained good data that suggests you should proceed to Phase 3 trials?

Torii: Thank you for your question. Regarding this point, we are currently considering Phase 3 design based on the results of Phase 2 with KOL, and we are about to start actively preparing. Unlike KW-6002, Istradefylline, which is only in the position of adjunct in combination therapy, this drug has been confirmed to be effective even in monotherapy, so we believe it is a promising drug from this perspective as well.

Hashiguchi: Thank you very much. Are you considering global development?

Torii: I will refrain from explaining in detail, but we are considering that as a possibility as well.

Hashiguchi: Thank you very much. This is all.

Kohtani: This is Kohtani from Nomura Securities.

Although I probably asked a similar question to Mr. Sato, the former head of R&D, a little before, I'd like to ask about KHK4083. I remember that you were planning to announce the results of the analysis of Phase 2 in the first quarter next year, so I'd like to confirm if this will not be delayed due to COVID-19.

In the time being, the field of atopic dermatitis has become quite busy, with entries such as Dupilumab, Nemolizumab, and the JAK inhibitor Abrocitinib. Dupilumab achieved both EASI scores and improving itchiness, and Nemolizumab mainly works on itchiness. Abrocitinib considerably improves both EASI and itchiness, but as the class effect, it affects platelet count.

In this context, does this KHK4083 still have a promising profile? I understand that the result of the last Phase 1 trial was that one administration results in a significant drop, but could you tell us whether it is still sufficiently competitive? This is the first question.

Torii: Thank you for your question. First, regarding the impact of COVID-19, as this patient enrollment has already been completed, there is no impact on the schedule. We are currently considering obtaining the final result next year and releasing it next year's first half.

Regarding the second question on competitive advantage, we have not yet fully analyzed the outcome of Phase 2b, but in the case of this drug, although it may take some time to work, it has the advantage of sustained effect compared to other drugs. As you know, Atopic dermatitis is a heterogeneous disease that can repeat worsening and remission. There are a variety of drugs, but I think that it is sufficiently possible to establish different positions within this field.

Kohtani: I understood very well. My second and last question concerns KW-6356. I understand that you will make an announcement sometime next year, but I think the AD/PD conference in March is naturally the most appropriate occasion. After that, it will be the Movement Disorder Society in September, so I wonder if my understanding is correct.

Additionally, regarding the Phase 3 trial, will it be a Phase 3 trial for combination therapy with Levodopa? But there's already Nourianz, so it might end up being just an addition to Nourianz. At the same time, honestly a monotherapy would be much more valuable, so how are you going to proceed with the test? Are you going to conduct tests both for combination and single agent? I assume that treatment algorithms will change be different with a single drug, so the hurdle might be a little higher, but what is your view?

Torii: Thank you for your question. Firstly, with regard to the academic conference presentation, we are currently considering the conference in the fall, which is the latter one you mentioned.

Regarding the second question on whether it is a mono setting or adjunct setting, I cannot answer in detail at this point, as it relates to our development strategy, but we are now considering both possibilities.

Kotani: I'd like to confirm if my understanding is correct: This will be like current Nourianz when used in conjunction with Levodopa. Using Levodopa for a long-time causes wearing-off, which always comes with side effects. If it's a monotherapy, is it right to understand that it will be a drug in a somewhat new position, perhaps in a preventive manner, where KW-6356 is used before such effects occur?

Torii: If the expected outcome of monotherapy is obtained, we intend that KW-6356 is used as first-line treatment, and then L-dopa will come in as needed. We have expectations that it may be an impactful product that changes the current standard.

Kohtani: Understood. Thank you very much.

Ueda: This is the Ueda from Goldman Sachs Japan. My first question is about how to promote Crysvita.

In the earlier explanation, you mentioned that there is a slight difference in the situation by region, but I hear that Ultragenyx in the US is quite active in web marketing or e-promotion. How is the promotion being conducted in Europe and Japan, and is it different from in the US?

And I believe that you will also launch in China in the future, so how will you promote it there, including the use of web marketing? Could you tell me about this first?

Sudo: Thank you for your question. We are shifting to digital in the US, but in fact, we are strongly shifting to digital promotion for European companies from prior to COVID. In this sense, we are promoting Crysvita and Poteligeo through digital channels.

China is also a country where digital promotion is widespread, so we will engage in digital activities in Asia with focus on China.

In Japan as well, we haven't been conducting MR activities for Crysvita so much, and most of the activities are currently taking place digitally, although we still need to look at what kind of activities will fit the best going forward.

There is progress in digital activities penetrating the market in Japan, so we will continue to monitor the situation and move forward with digital initiatives.

Ueda: Thank you very much. My second question concerns indication of Crysvida for tumor-induced osteomalacia (TIO). To my knowledge, there weren't very good drugs for this indication until now. I understand that you were approved in June in the US, so what changes have you been seeing since the approval?

As for the number of patients, I think you have explained that it is fewer than rickets, but as this drug becomes available, do you think the potential will be a little more promising as the result of identifying more patients, including through e-promotion and other measures?

Sudo: Thank you very much. In Japan, this drug was approved for a broad indication last December. I will refrain from saying specific numbers, but the situation is that TIO patients are also actively using it.

On the other hand, in the US, it was launched in June, and although we don't have as much information yet, we have already received requests from patients with TIO, and treatment has already begun.

We consider TIO to be an important indication, and we would like to be proactive in our activities to reach TIO patients while closely watching the situation and in a manner different from XLH.

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

Muraoka: Hello. This is Muraoka from Morgan Stanley MUFG Securities.

First, I would like to ask about a minor point. You mentioned that you expect one-time royalty income in the fourth quarter. Was that originally included in the initial plan? If so, what kind of income is expected? And even if it's one-time, will it be something that can lead to the next term as well? Please tell me about that.

Kawaguchi: Thank you. Regarding royalties, it was included in the plan at the beginning of the year, so it is in line with the plan. And I think you can make an assumption about a one-time royalty income that can be planned.

As for whether this will lead to the next fiscal year, this is based on a contract in which one-time payment takes place at a certain point in time, so if there will be something similar in the next fiscal year, it's also possible that this becomes a negative factor for profit in the following fiscal year.

Muraoka: I see. Thank you very much. Next, when the fourth quarter is announced, I understand that you will also announce the next mid-term business plan from 2021 to 2025.

In the next five years, if Crysvida grows, Nesp will settle down, and I think the situation allows for straightforward growth. Is my understanding correct?

Just straightforward growth would probably be boring, so what kind of issues are you thinking about now? Plus, there are five years, so there should be a strategy for Crysvida in China. I would like to see the figures you are building up. Is it possible for you to tell us about the potential of Crysvida in China?

Yamashita: Thank you for your question. Yamashita in charge of Corporate Strategy and Planning will answer your question. As you said, we are currently in the process of discussing the next mid-term business plan. If it goes smoothly, we would like to introduce it to you at the timing of the next consolidated results report.

Regarding the content, as you have already pointed out, there is still room for us to expand the three products that we have launched globally. Accordingly, our primary focus will be on steadily expanding this business.

At the same time, as we expand this business, we will push forward the globalization of the Company itself. The basic framework would be about building the foundation for this.

In terms of the issues that need to be addressed, there is the issue of COVID and how much efforts and activities will be needed to grow areas where there is still room for growth. There is the question of how much we can actually tackle in these areas.

In addition, we are aiming for smooth progress in the development products as we aim for another step of growth. This includes KHK4083 and KW-6356, as well as others, and if these drugs are successfully nurtured, it will significantly broaden the scope of our business. We intend to position these areas at the center of our plan.

Sudo, Director of the Strategic Product Planning Department, will answer your question on Crysvida in China.

Sudo: Thank you very much. I believe it is necessary to increase value of Crysvida not just in China, but globally. It has been about two years since the launch of the drug in the US. In terms of the response, we feel that the value of the drug is being accepted by patients, while there is potential for it to be used by much more people.

In that sense, one key is solid clinical data. To provide clinical data that encourages use for many people. This is important for doctors as well as patients, so we will likely concentrate our efforts here.

In addition, regarding digital promotion mentioned earlier, we think there is potential to devise a variety of ways of utilizing digital technology to provide a place closer to patients where its value can be felt.

Additionally, as you know, Kyowa Kirin has just begun globalization. In 2019, we launched a new structure as One Kyowa Kirin, and we will further evolve this system. It appears that we are entering a new era, so we are determined to stay ahead and work hard to contribute with our business, including ways to provide new pharmaceuticals.

Muraoka: Thank you very much. When we look at 2025 in the mid-term business plan, is it the assumption that Crysvida in China would be a significant pillar in business performance? Or is the thinking like, business in China entails various uncertainties, so expectations can't be fully included in the plan? Could you tell me about this point?

Sudo: I shouldn't get too forward-looking, but as you have mentioned, we currently have very strong expectations. But it's actually quite difficult to make assumptions for the plan.

On the other hand, as I mentioned earlier, given the emergence of value in various ways or changes in the environment, I believe that Asia, centering on China, still has potential, so we intend to continue to develop proactive initiatives in that sense.

Muraoka: I see. Thank you very much.

Tanaka: This is Tanaka from Mizuho Securities. Thank you very much. You mentioned earlier on that you will also talk about KHK7791 in the R&D event on December 10, but if there is anything you can say now, can you introduce something toward December 10?

Torii: I would like you to wait until December for the details, but I would like to tell you that we are energetically preparing toward Phase 3 next year because we are now seeing good results.

Tanaka: Are you going to proceed to Phase 3 next year?

Torii: We are currently preparing for that.

Tanaka: Okay. Thank you very much.

Moderator: Thank you very much for participating today. We appreciate your continued support of Kyowa Kirin.

[END]