



Kyowa Kirin Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending 2020

July 31, 2020

Event Summary

Q2 Financial Results Briefing for the Fiscal Year Ending December 2020

[Fiscal Period] FY2020 Q2

[Date] July 31, 2020

[Speakers] 4

| | |
|-------------------------|--|
| Masashi Miyamoto, Ph.D. | Executive Director of the Board, President and Chief Executive Officer |
| Motohiko Kawaguchi | Director, Finance Department |
| Yoshifumi Torii Ph.D. | Vice President, Head, R&D Division |
| Tomohiro Sudo | Director, Strategic Product Planning Department |

Presentation

Moderator: Now, we will hold a teleconference on Kyowa Kirin Co., Ltd.'s second quarter financial results briefing for the fiscal year ending 2020, which was announced at 3:30 PM yesterday. Today, we have four speakers: Masashi Miyamoto, President and CEO; Executive Officer, Motohiko Kawaguchi, Director, Finance Department; Executive Officer, Yoshifumi Torii, Vice President, Head of R&D Division; and Executive Officer, Tomohiro Sudo, Director, Strategic Product Planning Department.

Miyamoto: Good morning, ladies, and gentlemen. Thank you for your participation. I am pleased to report on our consolidated results for the second quarter of the fiscal year ending December 2020.

KYOWA KIRIN

Summary of Q2 Results

(Billion Yen / Rounded)

| | 2019Q2 Results | 2020Q2 Results | Changes | 2020 New Plan | Progress |
|--|-----------------------|-----------------------|---------------|---------------------------------|-------------|
| Revenue <i>[Overseas Ratio]</i> | 151.4 <i>[37%]</i> | 157.8 <i>[46%]</i> | +6.4 (+4%) | 327.0→ 313.0 <i>[53%]</i> | 48%→ 50% |
| Gross Profit <i>[Gross Profit margin]</i> | 112.8 <i>[74%]</i> | 116.9 <i>[74%]</i> | +4.1 (+4%) | 250.0→ 236.0 <i>[75%]</i> | 47%→ 50% |
| Core OP <i>[Core OP margin]</i> | 32.2 <i>[21%]</i> | 34.5 <i>[22%]</i> | +2.3 (+7%) | 65.0→ 60.0 <i>[19%]</i> | 53%→ 57% |
| Profit from continued operation | 18.7 | 27.8 | +9.1 (+49%) | 49.0→ 44.0 | 57%→ 63% |
| Profit from discontinued operation | 29.4 | — | -29.4 (-100%) | — | — |
| Profit | 48.1 | 27.8 | -20.3 (-42%) | 49.0→ 44.0 | 57%→ 63% |

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Now let's begin with page five for an overall summary. In the January-to-June cumulative results, revenue was JPY157.8 billion, an increase of 4%. The core operating profit was JPY34.5 billion, an increase of 7%. The Pharmaceuticals Business posted quarterly profit of JPY27.8 billion, an increase of 49%.

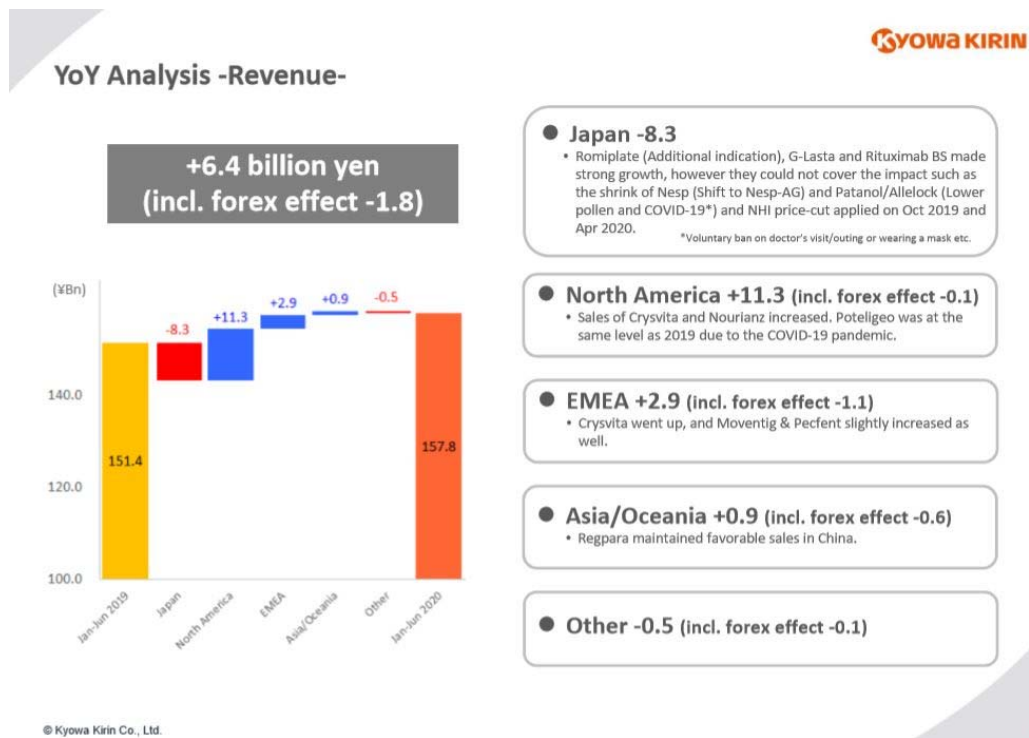
In Japan, the drug price has been revised. As you know, Nesp AG was launched in response to the expiration of the Nesp patent. In addition, Nesp's BS entered the market. In the first half of the fiscal year, the business environment was extremely challenging due to factors such as the spread of COVID-19. However, we are very satisfied with the fact that our Pharmaceuticals Business has achieved these increases in both sales and profits.

On the other hand, if we look at the progress toward the full-year plan, compared to the plan at the beginning of the year, there is a slight delay due to the impact of COVID-19. In view of this, we have decided to update our earnings forecasts at this timing.

As for the revised amount, as shown in the slide, the revenue is revised downward by 4% at JPY14 billion, core operating profit by 8% at JPY5 billion, and profit for the year by 10% at JPY5 billion.

This assumes that the current situation will continue until the end of the year. Therefore, it may change significantly, especially if the impact of COVID-19 changes significantly.

Now, I will explain the YoY comparisons and revisions to each plan on a slide that follows.



See page six. First, we analyze the revenue from the previous year. In Japan, in addition to the environment I mentioned earlier, the dispersion of pollen was extremely low this year, which resulted in an JPY8.3 billion decline in revenue.

Meanwhile, in North America and EMEA, sales of the three global products grew steadily, resulting in increases of JPY11.3 billion in North America and JPY2.9 billion in EMEA.

Asia/Oceania also performed relatively well, with Regpara in China particularly continuing to show robust performance. As a result, regional revenue increased by JPY900 million, resulting in a total increase in revenue of JPY6.4 billion.

Revenue of Major Items (Japan)

(Billion yen / Rounded)

| Item | 2019Q2 Results | 2020Q2 Results | Changes | Reason | 2020 New Plan | Progress |
|------------------------|----------------|----------------|---------------------|---|-------------------|------------|
| Nesp + Nesp-AG* | 25.6 | 14.6 | -11.0 (-43%) | | 34.7→ 28.9 | 50% |
| Nesp | 25.6 | 2.2 | -23.4 (-91%) | Nesp-AG launched in Aug 2019 and Biosimilars* penetration | 4.0→ 4.6 | 48% |
| Nesp-AG | — | 12.4 | +12.4 | | 30.7→ 24.4 | 51% |
| Regpara | 3.8 | 2.0 | -1.8 (-48%) | Switch to Orkedia | 3.2→ 3.3 | 60% |
| Orkedia | 3.0 | 4.3 | +1.2 (+41%) | Steady market penetration | 10.1→ 9.5 | 45% |
| G-Lasta | 11.5 | 12.8 | +1.3 (+11%) | Market expansion | 28.1→ 27.6 | 46% |
| Poteligeo | 1.0 | 1.0 | +0.0 (+2%) | | 2.0→ 2.0 | 49% |
| Rituximab BS | 4.2 | 5.4 | +1.2 (+30%) | Steady market penetration | 10.1→ 11.4 | 47% |
| Romiplate | 1.6 | 4.1 | +2.4 (+148%) | Indication added in Jun 2019 | 7.2→ 7.4 | 55% |
| Allelock | 6.4 | 4.9 | -1.6 (-25%) | Lower pollen in the air and COVID-19 (Voluntary ban on doctor's visit/outing or wearing a mask etc.) | 8.3→ 8.3 | 59% |
| Patanol | 9.9 | 7.1 | -2.8 (-28%) | | 9.5→ 9.8 | 73% |
| Nouriastr | 4.8 | 4.6 | -0.2 (-3%) | COVID-19 (Voluntary ban on doctor's visit) | 10.5→ 9.9 | 47% |
| Haruropi | — | 0.2 | +0.2 | Launched in Dec 2019 | 1.9→ 1.1 | 22% |
| Crysvita | — | 1.3 | +1.3 | Launched in Dec 2019 | 3.5→ 3.5 | 37% |
| Technology licensing | 1.7 | 1.0 | -0.6 (-37%) | | 3.7→ 3.5 | 30% |

* 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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Please refer to each product on page seven.

First, in Japan, the combined sales of Nesp and Nesp AG decreased by JPY11 billion or 43%. Of course, the launch of AG following the expiration of Nesp's patent is a major point. In addition, biosimilars from other companies are on the offense and we are seeing a situation where we are losing market share there. In view of these circumstances, we have revised our full-year forecast downward by around JPY6 billion.

Sales of Rituximab BS, G-Lasta and Romiplate continued to grow, but the full-year forecasts were slightly adjusted.

Allelock and Patanol were significantly negative compared with the previous year due to the situation described earlier.

With Nouriastr, there has been a slight decline in sales, possibly because of COVID-19.

In addition, regarding Crysvita in Japan, we had been a little worried about the starting-up in first quarter immediately after its launch. However, looking at the second quarter, we expect for it to continue to grow steadily and this may be within the scope of the plan.

Revenue of Major Items (Overseas)

(Billion yen / Rounded)

| Item | 2019Q2 Results | 2020Q2 Results | Changes | Reason | 2020 New Plan | Progress |
|-----------------------------|----------------|----------------|---------------------|---|-------------------|------------|
| Crysvita*1 | 13.4 | 24.7 | +11.4 (+85%) | Steady market penetration | 56.6→ 51.1 | 48% |
| North America | 9.9 | 19.1 | +9.3 (+93%) | | | |
| EMEA | 3.5 | 5.6 | +2.0 (+58%) | | | |
| Poteligeo | 5.4 | 5.4 | -0.0 (-1%) | COVID-19 (Treatment Interval Extension) | 14.3→ 10.0 | 54% |
| Nourianz | — | 1.0 | +1.0 | Launched in Oct 2019 | 2.8→ 2.6 | 37% |
| Abstral | 5.8 | 5.8 | -0.0 (-1%) | | 9.0→ 9.7 | 60% |
| Regpara | 2.4 | 3.9 | +1.5 (+60%) | Listed on Chinese NEDL*2 in Oct 2018 | 7.3→ 7.4 | 52% |
| Technology licensing | 5.2 | 7.0 | +1.8 (+34%) | | 18.8→ 18.3 | 38% |
| Benralizumab Royalty*3 | 3.8 | 5.2 | +1.4 (+38%) | Launched in 2018 | | |

*1 Launched countries as of June 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

*2 National Essential Drug List

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

Next is overseas products. See page eight.

As you can see, Crysvita is steadily penetrating the market, and this is an increase of 85% over the previous year.

However, the impact of the spread of COVID-19 is gradually emerging and the growth of new patients is slowing in both Europe and the United States. Also, particularly in Europe, the fact that there are still some delays in drug price negotiations due to authorities' circumstances in markets scheduled for launch at the beginning of the year is still having an impact. As a result, the number of the countries is still less than planned and that has impacted the revenue of Crysvita in Europe.

On the other hand, existing patients are largely unaffected by COVID-19 and the administration of drugs is continuing smoothly for the patients already started. Perhaps as Ultragenyx announced this morning, most patients are continuing their existing treatments. Considering these circumstances, while we had anticipated JPY56.6 billion in the initial plan at the beginning of the year, we have revised it downward by about 10% to a target of JPY51.1 billion.

The markets where the products are sold are listed in the footnote. In the first note, comparing the second and first quarters, Scotland and Oman have been added. In fact, we were already selling in Scotland in the first quarter, so this is our mistake, but in any case, Scotland and Oman have newly joined.

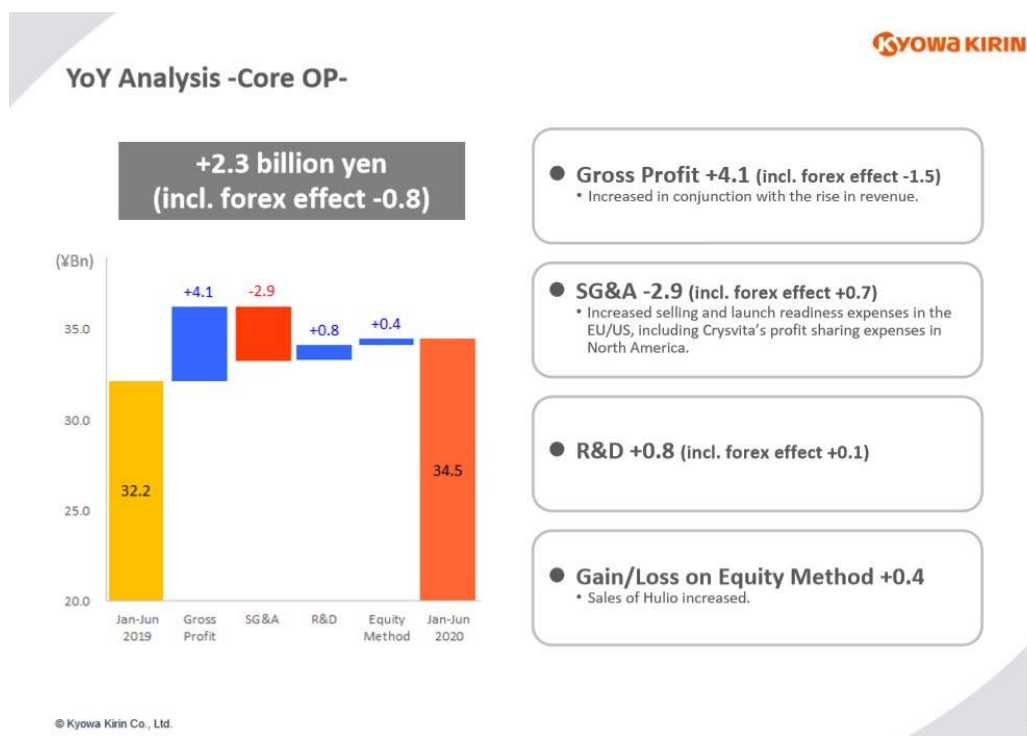
Revenue from Poteligeo was largely unchanged from the previous year, reflecting the impact of the new coronavirus. Some guidelines, such as NCCN guidelines, have provided recommendations for balancing the risks of coronavirus infection to patients with the benefits of treatment, and to allow for extending the frequency of visits and dosing intervals. These recommendations may have led to a slight increase in dosing intervals, which may also have an impact.

Also, in the same way as Crysvita, in European countries, launches are still lagging schedule, so we have revised our full-year forecast downward by JPY4.3 billion.

Regarding Nourianz, as I explained in first quarter, we have received a very high reputation among US doctors, and we are progressing almost in line with our forecasts. However, in terms of acquiring new patients, due to the impact of COVID-19, we have revised our forecasts slightly down for the full fiscal year.

Regpara continues to show robust performance in China.

In terms of technology licensing, the sales royalty for benlarizumab is increasing.

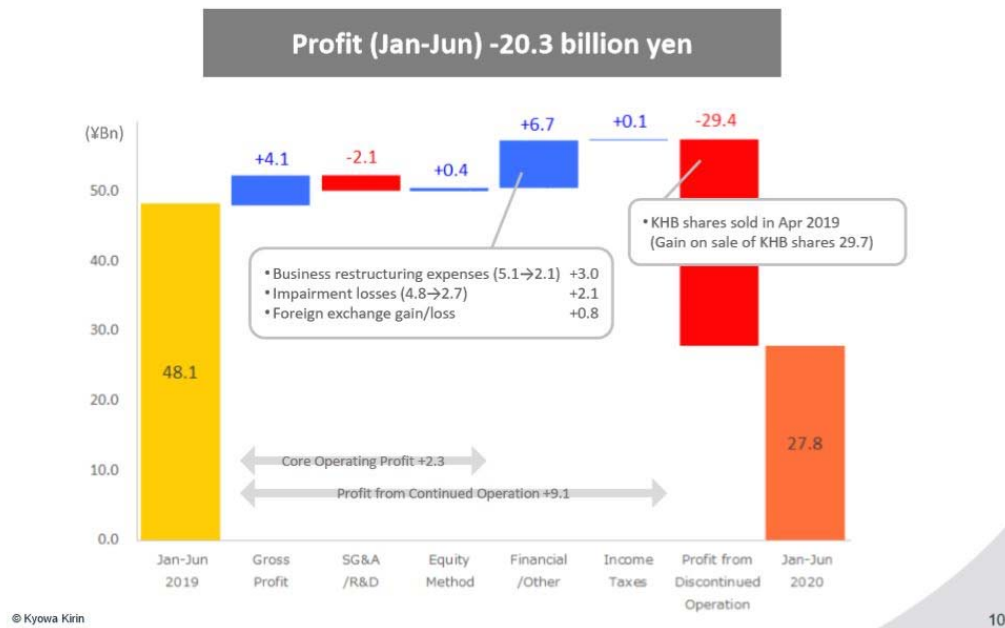


Based on the revenue performance, the YoY comparison of core Operating profit is shown on page nine.

Gross profit increased by JPY4.1 billion due to a JPY6.4 billion rise in revenue. Selling, general and administrative expenses (SGA) increased by JPY2.9 billion, which was a negative factor for profits, but this is due to the profit-sharing payments made for Crysvisa to Ultragenyx in North America. In addition, there was an increase in the cost of preparing for launch overseas.

On the other hand, R&D expenses declined slightly, which was a factor behind the increase in operating profit.

The profit/loss from investments in equity method affiliates was slightly positive, resulting in an operating profit increase of JPY2.3 billion.



The following slide explains January-June profits.

This shows financial and other gains/losses and the main points are shown in the text boxes. Business restructuring costs decreased by JPY3 billion, but as you know, JPY5.1 billion in the previous year was a special retirement allowance related to the voluntary retirement program in Japan. This year, we have begun transforming the business structure at our EMEA subsidiary to a large extent. This is the cost of making improvements to this subsidiary.

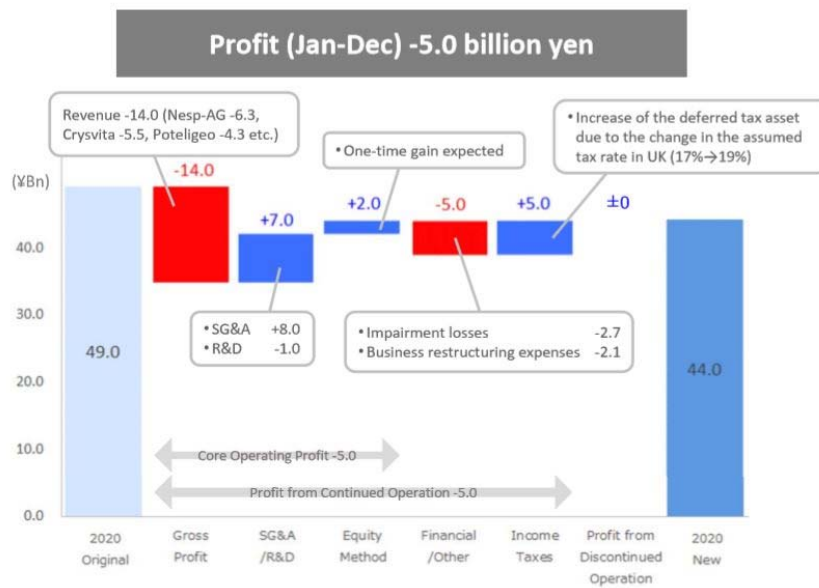
Also, impairment loss declined by JPY2.1 billion, which was another factor behind the increase in operating profit. Last year, there was the impairment of Moventig, a drug introduced in the European market. This year, Syndax, our licensor, announced the failure of Phase 3 for KHK2375, Entinostat, a drug candidate for breast cancer treatment. We have recorded an impairment due to the extremely low possibility that we will continue to develop it.

In addition, the impact of foreign exchange rates was a positive factor by approximately JPY800 million.

Tax expenses were on par with the previous year due to an increase in deferred tax assets at UK subsidiary in the first quarter.

In the final part, the gain on the transfer of Kyowa Hakko Bio's shares, which was recorded in the previous fiscal year, of approximately JPY30 billion was not recorded this year. As a result of all these factors, profit declined by JPY20.3 billion for the January to June period.

FY2020 Original Plan vs Revised Plan



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Regarding the earnings forecast, please refer to page 12. Under the circumstances described at the beginning, we incorporated a negative impact of 4% on revenue and to cover it, positive JPY7 billion on SG&A and R&D expenses.

Due to COVID-19 causing a considerable restraint in activities, we expect considerable positive impacts in this area. In addition to this, by controlling costs thoroughly, we have been able to achieve significant cost savings, which has resulted in SG&A impact of positive JPY8 billion. On the other hand, as new development that had not been planned at the beginning of the year began, we added negative JPY1 billion for R&D expenses.

In terms of equity in earnings of affiliates, the Company revised the forecast up by JPY2 billion in anticipation of a one-time revenue. Consequently, the core operating profit is revised downward by JPY5 billion, a downward revision of 8%.

Finance and Others were revised downward by JPY5 billion due to impairment loss and restructuring costs.

On the other hand, tax expenses have been revised up by JPY5 billion to reflect the increase in deferred tax assets of the UK subsidiary as I explained earlier.

Those are the details of the JPY5 billion downward revision in profit for the year. We understand that the downward revision will cause great inconvenience to investors, but we appreciate your understanding.

- Approval of KRN23 for the treatment of XLH in Hong Kong (April)
- Presentation of updated phase 1b study data on ME-401 for the treatment of follicular lymphoma and other B-cell malignancies at ASCO (May)
- Presentation of phase 2 study data on KHK7791 for the treatment of hemodialysis patients with hyperphosphatemia in Japan at ERA-EDTA (June)
- Approval of KRN321 for the treatment of renal anemia on dialysis in China (June)
- Approval of KHK4827 for the treatment of psoriasis in China (June)
- Approval of supplemental biologics license application of KRN23 for tumor-induced osteomalacia in the U.S. (June)

Please see slide 14. Of the events that occurred between April and June, we have listed the main items.

First, in Hong Kong, we have obtained marketing authorization for KRN23 for the treatment of XLH. In addition, we are still in the process of review in China and South Korea, so we hope to be able to report on it soon.

The second and third points are presentations by academic societies on ME-401 and KHK7791. I will explain briefly after this.

The fourth and fifth points are about the marketing approvals in China. First, Nesp was approved for the indication of kidney anemia, and Lumicef was approved for the indication of psoriasis.

Lastly, Crysvida received additional approval for the indication of Tumor-Induced Osteomalacia in the United States.

ME-401: Results of a Phase 1b study in B-cell malignancies

KYOWA KIRIN



ASCO 2020
ClinicalTrials.gov Identifier: NCT02914938

■ Treatment: ME-401 monotherapy or in combination with rituximab on IS



■ Overall Response Rate and Adverse Events of Special Interest

| Diagnosis | No. Evaluable Patients | ORR n (%) | Adverse Event of Special Interest (AESI) | Grade ≥ 3 |
|----------------------|------------------------|-----------------|--|-----------|
| FL | 36 | 30 (83%) | Diarrhea or colitis | |
| By treatment group | | | Diarrhea | 2 (3.5%) |
| monotherapy | 17 | 13 (76%) | Colitis | 2 (3.5%) |
| Combo with rituximab | 19 | 17 (89%) | Rash, all types | 1 (1.8%) |
| CLL/SLL | 9 | 8 (89%) | ALT/AST elevation | 1 (1.8%) |
| By treatment group | | | Stomatitis | 0 |
| ME-401 monotherapy | 3 | 3 (100%) | Pneumonia/Infectious pneumonitis | 0* |
| ME-401 + rituximab | 6 | 5 (83%) | Non-Infectious pneumonitis | 1 (1.8%) |

ME-401 on intermittent schedule showed a high response rate and was generally well tolerated in r/r FL and CLL/SLL

© Kyowa Kirin Co., Ltd. *1 patient with grade 5 COVID-19 pneumonia in Cycle 15.
IS: Intermittent schedule, 1 cycle: 28 days, ORR: Overall response rate, FL: Follicular Lymphoma,
CLL/SLL: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, r/r: Relapsed/Refractory

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This is ME-401's Phase 1b summary and outcome, which is shown on page 15. Fifty-seven patients with relapsed and refractory B-cell malignancies were treated intermittently with ME-401 alone or in combination with rituximab. It was conducted in the manner described in the treatment section.

The result is the overall response rate (ORR). This would be the primary endpoint and ORR was high at 83% for FL and 89% for CLL/SLL.

As you know, the drug's mode of action suggests that the side effects are still a concern. However, when this drug was administered on these schedules, it was discontinued due to adverse events in 7% of the patients, meaning that only 4 of 57 patients discontinued the drug. We have reported in academic conferences that the drug has a higher response rate and favorable tolerability.



ME-401: Phase 2 TIDAL study in r/r FL patients

ClinicalTrials.gov Identifier: NCT03768505



- **Subjects:** Patients with r/r FL after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody
- **Treatment:** ME-401 on intermittent schedule as monotherapy



- **Target number of cases:** 120
- **Study location:** US, Europe, Oceania, South Korea, Taiwan
- **Primary endpoint:** Overall response rate
- **Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration**

TIDAL (Trials of PI3K Delta in Non-Hodgkin's Lymphoma)

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The following slide refers to the Phase 2 TIDAL study currently being performed by MEI Pharma. In this study, MEI Pharma is examining the treatment effects of the intermittent administration of a single drug on patients as described here.

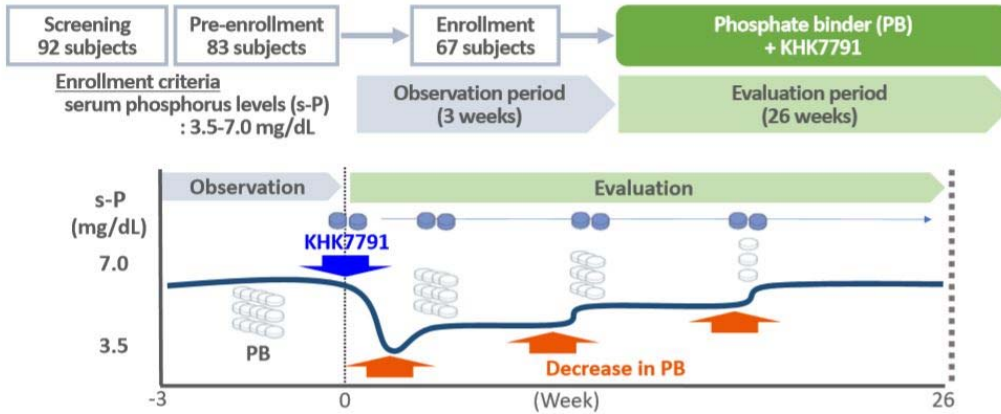
The design is almost the same as the one I just described, and the study is taking place globally with a target of 120 entries. The primary end point is overall response rate. As was press released in March this year, it was designated for fast-track approval by the FDA. Of course, it will depend on the results of the test, but if the results are satisfactory, we will aim for Accelerated Approval by submitting the results of this study to the FDA.

We are also working with MEI Pharma to develop a plan to broadly evaluate the usefulness of this drug in a variety of B-cell malignancies, including in combination with other agents. Of course, it depends on the results, but if it works out, we expect that it will grow into quite a large product.

KHK7791: Phase 2 (PB switching) study design

ClinicalTrials.gov Identifier: NCT03831607

- Open-label, single-arm, phosphate binder switch study for subjects with hyperphosphatemia undergoing hemodialysis



- Primary endpoint: Achievement of 30% decrease in the mean of the total tablets number (PB+KHK7791) compared to baseline PB

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Slide 17 provides a summary of Tenapanor's Phase 2 study. We have three Phase 2 studies for Tenapanor in Japan. Among these, this describes the switching test from a phosphorus binder.

As you know, those with higher levels of phosphorus take many phosphorus binder tablets. We tested how much they could reduce the number of tablets by taking Tenapanor. Patients took two Tenapanor tablets a day and then gradually reduced the amount of the phosphorus binder. We observed the outcome in the 26th week.

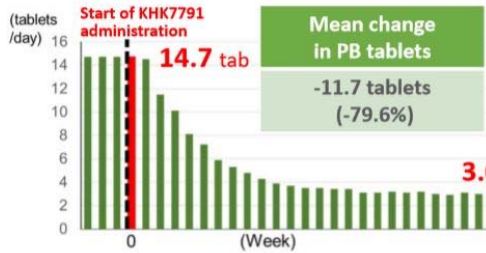
KHK7791: Phase 2 (PB switching) study results

■ Primary endpoint

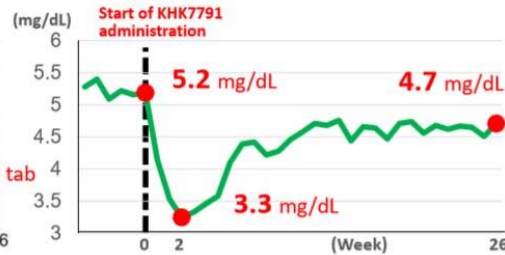
| | Achievement ratio | P value [95%CI] |
|--------------|-------------------|---------------------|
| 30% decrease | 71.6% (48/67) | <0.001 [59.3, 82.0] |

CI confidence interval.

■ Mean change in total PB tablets over time



■ Mean change in s-P over time



More than 70% patients achieved a 30% decrease of the total number of PB and KHK7791.

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As shown on page 18, according to the results of the study, the number of tablets decreased by 30% or more in 71.6% of the patients. In terms of the amount of reduction, which is shown on the right side of the bar graph below, prior to taking Tenapanor, they were taking about 15 tablets or 14.7 tablets per day. Assuming patients have three meals a day, patients who had been taking five tablets at each meal were able to reduce it to one. We think that this is an extremely impressive outcome, and phosphate was very well controlled during this period, as shown in the line graph on the right.

We are also planning to announce other Phase 2 results through press release and other channels.

Key Development Updates after June

- Receipt of a positive opinion by the Committee for Medicinal Products for Human Use on the marketing authorization application for KRN23 for adult XLH in Europe (July)

The next slide. This is an event that occurred in July. On July 27, we received positive recommendations for the indication of KRN23 for adult XLH patients from the European Commission for Pharmaceutical Evaluation (CHMP). If this goes smoothly, we expect that the results will be obtained around September.

That is all about R&D. Moving on to the next slide.

Impact of COVID-19 and Countermeasures

Supply Chains

- March to April: Disrupted logistics mainly in the EU, but no problems now
- No delays in the import and supply of raw materials
- Logistics costs are rising

Region Status

- **Japan (sales)**
 - In principle, working from home
 - Product recall, PV activities, and quality information: Responding to the requirements of medical institutions
 - Information dissemination: Telephone, e-mail, and web conferencing as needed
- **NA**
 - Major office locations closed or remote working and other flexible working practices encouraged until the end of July
- **EMEA**
 - Encourages flexible work styles, including telecommuting
 - Online training to prepare for the resumption of office and field activities
- **AP**
 - Depending on the infection situation by region or country, each business has its attendance system and other arrangements
 - China: Back to business as usual, but the transition to digital promotion is accelerated

Basic policy for working in Japan: Working from home. If the current situation continues, a 30% maximum attendance limit until the end of the year

Laboratories: Research work is conducted with adequate measures to prevent infection (Restrictions on the percentage of employees coming to work are lifted. Employees may work from home)

Production: Manufacturing operations are carried out with adequate infection prevention measures in place

Development: Cautiously following the authorities' guidance of each country

Slide 21. First, regarding the impact of COVID-19 on our business and countermeasures. Regarding supply chains, when the coronavirus was quickly spreading around March and April, there was an extremely difficult time for cross-border logistics in Europe in particular. Currently, there is no problem with logistics.

Furthermore, there were no problems with raw materials and other items related to our products. However, one thing that must be watched closely is the rise in logistics costs, so we need to keep a watch on this going forward.

Next, what is happening in various regions. In Japan, sales personnel are basically working from home. Regarding the provision of important information as described in the second bullet point, we first ask the preference of medical institutions and visit them when necessary, but basically, we provide information via telephone, e-mail, and web conferences.

We hear that movements in North America differ greatly by state, but basically, we focus on remote work, and the head office in North America is still completely run through remote work. The office is closed. We have been using digital technology to resume a considerable amount of activity.

Regarding Europe, the situation is quite different from country to country, but basically, we are managing by remote work.

In part, we are conducting online training for visiting offices in preparation for resumption of operations. The sentiment is even tougher than that in Japan and we are working on the premise that it is impossible to return to the office unless we conduct considerably strict training.

In Asia/Oceania, this also varies considerably from country to country. For example, while China and South Korea are returning to normal to quite an extent, both countries originally have strong digital capabilities, and fundamentally, the shift to digital promotion is proceeding rapidly.

Singapore, where we have a general office of the region, still has strict restrictions in place, and basically, employees of our general office are not going to the office at all.

In Japan, we also basically impose restrictions on the number of employees coming to the office. It has been eased a little from when the Emergency State Declaration was issued, but employees are requested to basically follow the same conditions as that time. The Otemachi Headquarters set the upper limit to 30%, but the actual rate is currently about 10% at most.

The laboratories and factories are carrying out their operations while paying close attention to prevent infections.

Development personnel also have the need to visit clinical trial facilities, but here too, we have been taking cautious measures while considering the situation of the facilities and we are remotely working whenever possible.

Our Supporting Activities Related to COVID-19

| | | | |
|----------------|---|--------------|---------------|
| China | Zhong Nanshan Medical Foundation | Donation | March |
| Japan | National Institution of Infectious Diseases | Provided API | March - April |
| EMEA Countries | Supported local medical systems and patients (e.g. The Red Cross in Spain) | Donation | April |
| EMEA Countries | Supported healthcare professionals who are volunteering in front line services | | |
| US | AmeriCares* | Donation | April |
| Singapore | Donated Singapore Association of Pharmaceutical Industry for providing personal PPE | Donation | April |
| Singapore | Agency for Integrated Care (Sector Emergency Fund) | Donation | |
| Japan | International Medical Volunteers Japan Heart | Donation | May |

* Supports globally including the US

Next, page 22 shows our supporting activities. In summary, in China, Europe, the United States, Singapore, and Japan, we have made the following donations. In Japan, we have provided several active pharmaceutical ingredients that are for screening for the treatment of COVID-19 at the National Institute for Infectious Diseases.

Business topics

June Commercial launch of “Poteligeo” in Europe

June Approval of “Duvroq” in Japan for Patients with Renal Anemia

**June Approval of “Adalimumab (Genetical Recombination)
[Adalimumab Biosimilar 1]” in Japan**

July U.S. FDA Approval of “Hulio” (adalimumab-fkjp)

July Positive CHMP Opinion for “Equidacent” (FKB238), Biosimilar Bevacizumab

Lastly, page 23. Other business topics not discussed in the R&D section are described here.

First, we started sales of Poteligeo in Europe. On June 15, we started sales in Germany as the first market in Europe.

Second, GlaxoSmithKline received the approval for marketing Duvroq for renal anemia. The first approval in the world has been in Japan and from here we will oversee distribution and sales operations.

We will also conduct promotional activities, but the MSL activities will be conducted jointly with GSK. I personally believe that it has an excellent profile as an inhibitor of HIF degradation and this is an area in which we are originally strong, and we would like to work closely with GSK to ensure that we can deliver this excellent drug to patients.

The pipeline in the renal field, which you may already know about, is shown on the next page.

In addition, there were three topics related to the biosimilar business of FUJIFILM KYOWA KIRIN BIOLOGICS. Humira's biosimilar was approved for manufacturing and marketing in Japan in June. This is the first biosimilar in Japan.

Then, Hulio was approved by the FDA in July. As you know, we have already launched the drug in Europe, so this is the first biosimilar formulation of Humira approved in Japan, the United States, and Europe.

In addition, regarding Avastin's biosimilar, we received an approved recommendation from CHMP in July.

In this way, we can say that our biosimilar business has made steady progress to this point.

Those were our business topics.

That is all from me. I would like to answer your questions. Thank you very much.

Question & Answer

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

Yamaguchi: Good morning. This is Yamaguchi from Citi. The first question concerns ME-401. You have a worldwide right and you introduced robust performance data. I think it is a somewhat niche space, but you seem to be competitive and the market is likely to become relatively large, but what size is your company thinking about in terms of the potential global market? I would appreciate it if you could give a rough idea on how large it may be depending on further expansion of indications.

Sudo: Thank you for your question. First, the idea is that indication will be expanded step-by-step and I understand that Miyamoto mentioned there is a high future potential. The first task is to capture an indication for third-line treatment and in this area, we do not think the market size will be so large. After that, if we can go from third line to second line and then to first-line treatment, the market will still expand significantly. And also, we would be able to expand the market size if we can expand the indication to other hematology and oncology areas, such as CTCL.

Yamaguchi: If you reach the first line, is your idea like one billion?

Sudo: Well, we can expect about three digits.

Yamaguchi: OK. For my second question for Poteligeo. The outlook has been lowered assuming that the current situation will continue, but are there any signs of recovery this year? Will it be seen depending on the situation? Alternatively, although the intervals between administration may be extended, it may return at some point because there may be needs from patients. It is very difficult to know the timing of a comeback, but what is your idea on such signs of change or lack thereof, in the United States?

Miyamoto: Thank you very much. This is Miyamoto. As Mr. Yamaguchi just mentioned, it is very difficult to answer this question. First, the reason for the downward revision is that, since the recommendations have certainly been made in the guidelines, the frequency of visits by patients is also declining. Patients who used to come every two weeks are shifting to once every three or four weeks. This is one of the major reasons. Looking at the full-year forecast, at the beginning of the year we thought that we might be able to launch in Europe a little earlier. However, there were the impact of COVID-19, and we were finally able to launch in Germany. We are hoping to keep launching in other markets, but unlike normal times, the authorities seem to be very busy, and some of these drug price negotiations do not proceed as quickly as we expect. The lack of expansion of markets has had a major impact. Regarding the current recommendations I mentioned earlier, it is to reduce the frequency of hospital visits after examining the balance between the risk of infections of COVID-19 and the benefits of treatment. It is not that the label has changed. Therefore, if there is less worry about viral infections and patients come back to the hospital as usual, we think it will return. Moreover, although it will be administered for a relatively long period of time, it is for cancer patients, so will not be used over many years, for example, as is the case with kidney anemia. New patients will keep coming in. There is an expectation that once the risk of COVID-19 is reduced it will return. But we do not know when.

Yamaguchi: Yes, I understand that we cannot tell when. OK, thank you very much.

Wakao: This is Wakao from Mitsubishi UFJ Morgan Stanley Securities. First, about Crysvita. The revenue forecast was revised downward by around JPY5 billion. Could you tell us more in detail about the declines in the United State and Europe? I imagine that figures are decreasing in both regions, but in the United States, is it a change in line with the profit share range announced by Ultragenyx? Regarding Europe, is it correct to

assume that the biggest factor is that the number of markets has not increased as you explained earlier? Furthermore regarding Europe, I think the expansion of the indication for adults was expected at the end of the year, but regarding that part, it may have not been included in the premise in the first place, so please let me know about it as well.

Miyamoto: Thank you very much. First, I would like to give an overall answer. As you said, we have lowered figures both in Europe and the United States. In terms of the percentage, the impact will probably be greater in Europe. The details will be explained from Kawaguchi.

Kawaguchi: This is Kawaguchi. Your understanding is basically correct. First, regarding Crysvida, there are decreases both in Europe and the United States, but the extent of the decline in North America is smaller and basically within the range of Ultragenyx. The biggest factor behind the large decline in Europe was the delay in the launch as you mentioned. Basically, we had the plan to launch at a relatively early timing in this fiscal year in most European countries, so the gap in the growth will become quite large in the second half of the fiscal year. Therefore, it is correct to understand that there will be a larger gap between the initial plan and revised one in Europe.

Wakao: OK. Would you give us any comments on expanding the coverage of adult patients?

Sudo: As Miyamoto explained earlier, we received a recommendation as a positive opinion from CHMP on July 24. If it goes smoothly, it will be approved at the end of September and if possible, we would like to launch it the following month for adult patients in Germany. As you know, we must negotiate the price in Europe, so the flow would be to launch products while negotiating prices.

Wakao: OK. Then, is it correct to understand that although the process itself is progressing with respect to adult indication, since the approval would be in October and subsequent price negotiations will take place, and given the COVID situation, revenue is not expected much in the current fiscal year?

Sudo: Yes. That is right. The approval will be at the end of September at the earliest and the product will be launched in October, so as you mentioned, it should make only a minor contribution to sales.

Wakao: OK. Understood. Based on Ultragenyx's consolidated results, there did not seem to be any concerns about the United States regarding Crysvida. I was not sure about that part, so it became very clear. Thank you very much. Secondly, I would like to ask about KHK4083. You said that you would conduct an interim analysis to confirm its effectiveness. Are any updates on that point? I think, in the first-quarter briefing material, regarding KHK4083, there was a chart showing that Phase 2 safety results will come out in the first half of 2021, and Phase 3 will start by the end of 2021. This time, as there is no change in the chart, if there was an interim analysis and there were data on effectiveness, I assume that positive results may have been obtained, especially if there is no change in the development schedule. Please let me know if you have anything to talk about.

Torii: Thank you for your question. As you said, we have obtained results from the interim analysis. However, since this is a double-blind study, if we disclose the results at this point, it may have an impact on the results. We are currently planning to deliver the results in the first quarter of next year and we plan to disclose the results in the first half of next year.

Wakao: OK. In that case, can I assume that nothing has happened that may lead to stopping at this point or reviewing the plan?

Miyamoto: The test itself is progressing smoothly.

Wakao: OK. Thank you very much.

Hashiguchi: This is Hashiguchi from Daiwa Securities. Thank you in advance. The first question is about the status of Crysvita in Europe. You said that drug price negotiations are delayed. Does this mean that you are not able to get to the table in the first place? Or even if you get to the table, is there a situation where the response is not positive in terms of cost-effectiveness and such, causing the need for more discussions, and more delays due to the coronavirus? In other words, I would like to confirm if you think that the issue will be resolved over time and come back on track as intended.

Miyamoto: Thank you very much. It does not mean that we are not able to get to the table, but although we have started, the authorities are very busy with various issues and sometimes it takes time. As for the point of your concern, it is certainly the situation in Europe that they have a strict view on cost effectiveness. So far, we have received very good evaluations from Germany and NICE in the United Kingdom, and we have been negotiating based on this. Sudo will provide a little more detail.

Sudo: Thank you for your question. It is true that various conditions are being set in some countries and there are some difficult situations in the negotiations. However, we are at the table and having positive discussions. There is some delay, and the number of meetings has decreased due to COVID-19, so there is an impact, but I believe that over time, we will be able to steadily expand our business.

Hashiguchi: In that sense, is it better to understand that products that seem obviously beneficial to the authorities, with few points to discuss, might proceed more quickly, but Crysvita is being impacted because it originally has some factors that call for tough negotiations?

Sudo: Well, as I mentioned earlier, there are cases in which responses differ considerably from country to country. We intend to expand the product while keeping drug prices within a certain range as much as possible, so we are currently in the process of communicating constantly and working with each agency.

Hashiguchi: Thank you very much. The second question concerns Bardoxolone methyl. I think data from the Phase 2 TSUBAKI trial was published in April. It seems that the number of adverse events is clearly higher than that of the placebo group. In addition, although it was a double-blind study, there were several patients who dropped out mid-course from the active drug group compared with placebo. Could you comment again on how we should consider the safety of this drug?

Miyamoto: Thank you very much for reading the papers. We are not very worried about adverse events. In fact, we are currently conducting a large-scale Phase 3 study, which is also a double-blind study, and it is not the case that adverse events are extremely worrisome. As you know, the TSUBAKI study was conducted when the number of cases was still very small, so we would like to take that into account as we take a close look at the large-scale Phase 3 currently underway. The Alport Syndrome study conducted by Reata has not reported adverse events as a major problem either, so it is not a serious concern at present. However, just as you said, that does not mean that we are reassured, and we will keep looking at it thoroughly. This is a substance that previously failed the BEACON study due to side effects, so we are taking a very cautious approach.

Hashiguchi: Thank you very much.

Sakai: This is Sakai from Credit Suisse. I would like to confirm about Crysvita in North America. I think Ultragenyx said in a conference call that they have not changed their guidance. Is your revision at the level of fine-tuning based on that or are there any other factors? One more related question to Crysvita. You had approval for TIO in the United States in June and I think it is the first time that you gained approval for this disease. I understand that the number of patients is not so large in the first place, but do you think there is a possibility to uncover potential patients from the second half of the year or in the future?

Miyamoto: Thank you, Mr. Sakai. As you said, Ultragenyx has not changed its guidance. It has not been changed as Ultragenyx guidance. We are also evaluating the situation based on our plan at the beginning of

the year, and we made a downward revision within the scope of Ultragenyx's assumptions, so we do not take it as a major revision. Then about TIO, as you mentioned, this is the first drug to be indicated for TIO. However, we have already an indication for TIO in Japan, and we have heard that several patients have already begun treatment. What you said is true and I think we will need further education going forward, but we feel that there might be more patients than expected. Ultragenyx has presented a somewhat rough patient number, too. In fact, it is an extremely rare form of cancer, so it takes a lot of time to reach a diagnosis. In fact, the starting point of the R&D of the drug was that we received some cancerous samples from a patient who suffered from TIO and from that we were able to clone the DNA of FGF23. That was over a decade ago, and at that time it was said that only one or two patients existed in Japan. But currently, there are experts who say that the patient count is in the double digits. Therefore, if we continue education about this disease, we might eventually find a larger number of patients. Sudo will explain in more detail about the situation in the United States.

Sudo: Thank you for your question. This is a highly uninformed disease and it is difficult to imagine. But as Miyamoto just mentioned, if we investigate Japan or China, we have an impression that there are more patients than initially expected. On the other hand, in the United States and Europe, we do not have visibility on the actual situation of patients, and I think we will start by finding out the actual situation and confirming demand. As an interesting example in Japan, four or five years ago, or a little more, there were about four or five patients being treated at the University of Tokyo. In fact, it is said that there are now nearly 50 patients. We are looking forward to finding more patients who can be treated with this drug, and TIO is quite a severe disease, so I hope that it can be used by as many TIO patients as possible.

Sakai: Thank you very much. I have one more quick question. I am sorry to ask about FKB all the time, but this time, you have revised the plan of gain/loss on equity method by JPY2 billion. Is the amount related to an event from July onward?

Miyamoto: You are correct. I am sorry, I cannot tell you the contents, but we regard it as an event from July on.

Sakai: Understood. Thank you very much.

Muraoka: Hello. This is Muraoka from Morgan Stanley. Thank you very much. Regarding Crysvita, you mentioned that approval in China is coming soon. If assuming proportionally to the population, there should be a huge number of patients. What are your thoughts on China's potential and patient development strategy?

Sudo: Thank you for your question. There is no doubt that the market has great potential, but I think that pricing and the reimbursement of insurance will be a major issue. In that sense, we are hoping to begin delivering the drug to patients using something like the patient assistant program, or PAP program. It will probably take two years for the final drug price to be confirmed following the drug price negotiation. So, until then, we will deliver the drug to patients through the PAP program that I have just mentioned. After that, we will work to set the price while making sure that the benefits are firmly established, and then we will start expanding our business. In the mid-to long-term, I think there is an extremely large market and a pool of patients. Miyamoto is saying every day that he wants to deliver the product there, and we are going to take a medium-to long-term perspective when planning business deployment.

Muraoka: Then, will the discussion of actual figures start once you have a clearer idea on the drug price?

Miyamoto: This is Miyamoto. Internally, of course, we are moving around figures, including imaginary ones. But as you mentioned, it is not without country risk, and it will take a little longer for us to find out. We have received an approval with the package of developed countries this time, but we are being asked to do something like a mandatory Phase 4 study, so we need to consider what potential we can achieve through

such studies as well. There could be certainly a lot of patients. When we ask the KOL doctors, quite a few of them say that there are many such patients in their hospitals, so we hope to expand by using such relations as well.

Muraoka: Thank you very much. My second question concerns the SG&A portion of the revised guidance for the current fiscal year. When you do a subtraction, SG&A will be JPY58 billion in the first half and JPY65 billion in the second half. If we assume that the current situation will continue, I wonder if you are able to use up this amount of SG&A, even if there might be some growth in the profit share payment to Ultragenyx. Would it be better to assume that there is a certain possibility of not fully spending the planned cost?

Kawaguchi: Thank you for your question. The cost is difficult to determine because it is the first time, we are facing such an environment with COVID-19. The figures provided this time are the best estimates. There are certain possibilities of fluctuation, but we believe these numbers are the most reasonable at this time. Regarding the fact that there is more cost in the second half of the fiscal year, this is like the tendency of SG&A in the last fiscal year, with a larger amount in the second half at JPY6.7 billion. So, in that sense, the balance for the current fiscal year is approximately the same as that in the previous fiscal year. Nevertheless, it is very difficult to see how much of expenses will remain unused under the COVID-19 environment going forward.

Muraoka: I see. Thank you very much.

Ueda: This is Ueda from Goldman Sachs Securities. First, I would like to ask about the planning assumptions. In your explanation just now, I think you mentioned the assumption that the current situation would continue. In fact, which month do you refer to as the current situation? Even monthly from March onward, I think the situation has changed from moment to moment. How have products with relatively large impacts, such as Crysvida, Poteligeo, and Nesp, been performing monthly, and how have you set your assumptions for the latest plan?

Miyamoto: Thank you very much. That is a very difficult question. We think the situation is different depending on the product. For those that are strongly affected by COVID-19, the degree of effect varies considerably from month to month. Regarding the main impact of COVID-19 on our products, we were watching the situation in May and June, and made minor adjustments in July to update the plan. Regarding Nesp, this is not the effect of COVID-19, but the erosion of the biosimilars, as we explained earlier. So, we have been watching the trends and company activities around biosimilars and made the projection based on the overall situation.

Ueda: OK. Thank you very much. My second question is about Nesp. I think there was a considerable downward revision due to the factors behind the deviation from the original plan. It is said that biosimilars are gaining market share amid the rapid decline in the share of original products. What is your current assessment of the AG strategy? In terms of actual trends, I think that the decline in sales from the first quarter to the second quarter has become much smaller. Could you also tell me if the switching is settling down?

Miyamoto: Thank you very much. It is also a difficult topic to discuss as it involves many ifs. We must consider the significant momentum of biosimilars, the situation of the new coronavirus and the recent drug price revision, in which the fee for dialysis treatment has been lowered considerably. Looking at such conditions, I think that sensitivity on prices especially for dialysis facilities is rising considerably. In this sense, we believe that it was the right decision to have started AG. If it had not been released, we might have been attacked quite a bit more by biosimilars. However, I am personally glad that we provided it. In terms of the switching, we are conducting some detailed analyses internally, but we are not sure yet. Of course, we want to do our best so that biosimilars will not damage us any further. The hope is that Duvroq will also come out, so I hope that we can firmly protect our franchise including AG by enhancing these activities. However, it is quite challenging if we are told that what ultimately matters is price. We would like to deal with this matter carefully while looking at future developments.

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

Tanaka: This is Tanaka from Mizuho Securities. First, I think the application of RTA 402 for Alport Syndrome in Japan will be made after Reata, but what is the approximate timeline? Also, I think you have expressed your intention to be involved in ADPKD, but around when will it be?

Torii: Thank you for your question. First about Alport syndrome. As you mentioned, we are currently preparing for the application abroad, and we anticipate that the application in Japan might be possible around the middle of next year. Regarding the second question on ADPKD, as you know, entries were stopped in March due to the impact of COVID-19. However, in our recent communication with Reata, we hear it is about to be resumed, so we would like to determine the timing of the resumption in Japan while looking at the situation.

Tanaka: I think you also have the right in China for this RTA. Aren't you considering development including China?

Torii: We are currently considering a development strategy in Asia, including that part.

Tanaka: OK. Second, I think that it has been remaining for a long time since last year, but when are you going to spend the JPY100 billion-plus obtained from the sale of Kyowa Hakko Bio? I think you said that you launched a project team and were considering where to invest. Of course, maybe you cannot say anything specific yet, but is there any timeline?

Miyamoto: Thank you very much. Sorry, the answer to this is remains the same. Because, as you know, if anything, I cannot say it now. Of course, members are gathered from each function under the direct control of the president and closely discussing how to spend money, so to speak, including partnerships that will contribute to our growth, licensing products, or M&A in some cases. Even now, we are holding meeting once or twice a month, in this remote environment, taking an hour or two at a time, so I hope we will be able to inform you soon. I am sorry to give a vague answer.

Tanaka: In terms of the direction, will it not simply be an in-licensed product or a product acquisition, but something like a new modality? Of course, you cannot say that though.

Miyamoto: Thank you very much. That is exactly about why members are gathered from each function. There are people from the marketing side, product side, and R&D side, wherein there not only development but those who are very close to the research side. As you said, we have new modalities in mind rather than first narrowing down our target. In addition, we are considering licensing products into fields with synergies with our products, and although our capacity may be limited, we are also considering the option of M&A if there is a good-sized company. We are looking at several options, so the number of meetings is also increasing.

Tanaka: Okay. Thank you very much.

Kohtani: This is Kohtani from Nomura Securities. Thank you for your explanation of the downward revision of the earnings forecasts for Crysvida and Poteligeo. I understood well that a considerable part is temporary. The most difficult task when we prepare earnings forecasts is how to incorporate movements of drugs such as biosimilars and Duvroq into our forecasts for Nesp. As for the biosimilars, the price structure of the competition seems to have been stricter than expected, and I heard the nuance that most dialysis facilities switched to the cheaper option. So, I think the biosimilars can be understood in this way. Regarding Duvroq you mentioned earlier, you said it has a very good profile right now. What is its benefit particularly against Evrenzo? And which part is beneficial? As far as I know, both have warnings on the risk for thrombosis: the ratio of thrombosis is 11% with Evrenzo and 4% for Nesp. Looking at Duvroq for hemodialysis, it is 7% and 9%, but what can you say about safety there? Could you tell us about the competitiveness of Duvroq on this point? This is the first question.

Miyamoto: Thank you very much. As you know, we have a long-standing relationship with kidney anemia patients through erythropoietin. For example, we have quite an amount of internal data, including insight on side effects related to the speed at which Hb is raised. From such a point of view, Duvroq has the advantage of allowing fine adjustment of dosage. In terms of Hb control, I do not have accurate information based on proper comparison with competing products, but looking at Duvroq alone, we believe it is a great advantage to be able to fine-tune the amount. In addition, it is highly effective with a very small amount in milligrams, and I feel this is also a strong point. I am sorry that I cannot share the details here, but based on our experience, we believe it has strong advantages in many aspects. I am sorry to be vague though.

Kotani: Excuse me, by Hb, do you mean HbA1c?

Miyamoto: Hemoglobin.

Kohtani: I see. Understood. Regarding my second question, I do not know what you can say about this. GSK has a medicine called Belantamab mafodotin. GSK has very high expectations for this, and a positive opinion came out at the Advisory Committees Meeting in July. Looking at the release, it says “monoclonal antibody is produced using POTELLIGENT Technology licensed from BioWa,” which means that it uses Potelligent technology. There are high expectations in the market for this drug that it might generate JPY100 billion or more. As for the question, if it reaches JPY100 billion, are you going to earn a few billion yen or so for Potelligent technology usage fees? Is that the right idea of scale?

Miyamoto: Thank you for your question. As you just mentioned, the former president Hanai launched BioWa, our subsidiary company that started in Princeton. In fact, there is a considerable number of technical licenses for Potelligent, I think there were more than a dozen. I am sorry, but I cannot say what the contents of that technology license are and how much the contract is worth. However, since it is a technical license at a very early stage, it is not like it can completely secure the future of our company.

Kohtani: That's not to say that you do not get any money at all, right?

Miyamoto: That's right.

Kohtani: OK. Thank you very much.

Arai: This is Arai from Merrill Lynch Japan Securities. Thank you for your explanation. I would like to confirm about the United States situation of Crys vita. The fact that the impact of COVID-19 was smaller than in Europe was somewhat surprising. After all, I think there is a considerable potential if we include the indication for adult XLH, but if we look at QoQ changes, we can see that the increase in adults was only about JPY 1 billion over the past year. I would like to know how you are going to accelerate this pace. Since I heard that you will be selling it in the United States from 2023 onward, how are you going to ensure expansion of the market share in this adult category? Can you share any insights from the trends over the past six months or one year?

Sudo: Thank you for your question. I think you made a very important point. Before that, in terms of the overall growth momentum, we do not recognize that growth is slowing down, but we believe that growth will continue at a sufficiently strong pace. In addition, regarding the market for adults, it certainly will be the biggest target to grow the market going forward. Talking about the trend, after the launch of this product at the end of April 2018, the percentage of adult patients is steadily increasing, albeit gradually. Nevertheless, we still have issues in sufficiently reaching patients. We have agreed with Ultragenyx that we will develop a concrete strategy and focus on the steady delivery of the value of the drug in the adult market.

Arai: Regarding that point, how do you analyze where the bottleneck lies? For example, are potential patients are not being discovered, or are approaches to doctors insufficient? At what stages there are bottlenecks in reaching adults?

Sudo: I think two things can be cited. First, the patient's locations vary greatly compared to child patients. Therefore, it is very difficult to set the focus on reaching the patients and doctors in charge of them. On the other hand, one way to search patients is first to target existing patients who are being treated. Since this is a genetic disease, and we are considering it internally about specific actions from such an approach in the future.

Arai: Hearing what you said about the current situation, when we compare the situation in the United States and Europe, it seems that the hurdle to increase the market share in Europe is higher than in the United States. When comparing the United States and Europe, how do you analyze the hurdles and how to resolve these bottlenecks by region?

Miyamoto: Thank you, Mr. Arai. As you said, the situation in Europe varies from country to country, so in terms of hurdles, it is different from the United States, which you can consider as one. Therefore, we are talking internally that we need to deal with this issue with care to details. However, coming back to where we started, I do not think there are many cases where this speed of growth is seen in products for such a rare illness, and we think it is a solid growth momentum. It is not that there is a huge number of patients and we made a major launch, so we think this speed is good enough. Of course, we are not completely satisfied and will continue to do our best, but I hope you will understand that.

Arai: Thank you very much.

Miura: This is Miura from Jefferies Securities. Regarding ME-401, Phase1b trials have shown remarkable efficacy, and we expect it to be highly safe. Why is this ME-401 so much safer than similar products of the same class? I understand that there are no side effects of Grade 3 or higher, but I would like to first confirm where the difference is from this point of view, such as whether the products themselves are structurally differentiated compared to competitors, or whether the target patients are narrowed down adequately in design of the trials.

Torii: Thank you for your question. As you said, there are three drugs of this class already on the market. However, the drugs on the market appear to be causing considerable side effects on the digestive system. In the same way as the other products, our drug was originally scheduled to be administered daily, but due to side effects on the digestive system, we switched to intermittent treatment mid-course, in which the drug is administered daily for one week and then taken off for three weeks. This regimen allows for a significant reduction of side effects on the digestive system. In this way, it is possible to reduce the "on-target" side effects as an extension of the efficacy. On the other hand, since our drug has a strong selective blocking effect on PI3K Delta, we expect that we will be able to benefit from this point compared to other companies as well.

Miura: How high is the degree of selectivity compared to competitors?

Torii: That would be detailed information, so I hope you will excuse me for not disclosing that.

Miura: Understood. My second question might be related to an earlier question from Mr. Tanaka. The cash and cash equivalents on your balance sheet are expanding rapidly this first and second quarters. Considering the reason for this, the amount of loans to the parent company has been decreasing, so I assume that this amount has been shifted to cash. As the background to this recent increase in cash, can we expect to see major strategic investments soon?

Kawaguchi: Thank you for your question. I will explain the reason why the balance sheet shows that the amount of loans extended by the parent company is decreasing. Basically, we are hoping to use the JPY300 billion that we have for growth investment, and stable dividends after that. However, as Miyamoto mentioned earlier, it is currently under consideration and not yet ready for use, so the funds are lent to the parent company as a standby fund and most advantageous way of management. This situation has not changed, but

in accounting terms, if you deposit this in a loan period of more than three months, the accounting rules do not allow us to treat it as cash equivalents, even when we regard it as cash/deposits. This caused much misunderstanding that we were prioritizing lending to the parent company over investment for growth. We have tried to explain this carefully, but the lending period was shortened to one month as it had to be shown in proper form in accounting terms. We regard this area of transactions with the parent company as a very sensitive issue and also we were provided these suggestion in our dialogues with investors, so we made improvements this on the balance sheet, which is now shown strictly by cash to avoid misunderstanding among investors as much as possible. Please understand that at the end of the year all loans to the parent will be converted to cash equivalents both in the balance sheet and the cashflow statement. In terms of whether it is usable in actual operations, it has not changed, given that cancellation has been possible from before. There has been no change in the condition where we can use it immediately when there is an investment.

Miura: Understood well. Thank you very much.

Akahane: This is Akahane from Tokai Tokyo Research Institute, thank you. I would like to ask one question on actual results and another on the outlook. I am looking at pages seven and eight, and page three of the supplementary material. I now understand well about Crysvita overseas. As for the Nesp Group in Japan, looking at the materials, you can see that the progress rate was 50%, or that this was lowered in line with actual performance. Looking at this, we can see that the original Nesp was raised, being stronger than you expected, but AG was weak, at a progress rate of 40.4% at the beginning of the period. Looking at page three of the supplementary material, AG has been declining quarterly from JPY8.4 billion to JPY6.3 billion and JPY6.4 billion. Is this simply a decline due to the price offensive of biosimilars? Also, I had the impression that AG is strong in the bio-related field, but should I think it is not that strong? What is the simplest way to understand these figures?

Miyamoto: Thank you for your question. First, one reason that Nesp is relatively strong is that Nesp is still the only drug with MDS indication. Neither AG nor BS has this indication. This accounts for higher usage than you might imagine. The number of patients is not so large, but because of their large volume per usage, it forms a market of its own. Since this remains, and the number of patients using this drug is still on the rise, there has been a slight upside. In addition, regarding the relation with biosimilars, and with Nesp and AG, biosimilars were still new at the end of last year, so they have not yet penetrated the market so much, but they started gradually taking market share from the beginning of this year. Does this answer your question?

Akahane: I see. That means that for the indication of Nesp, there was a change of JPY 600 million, and that is what the amount stands for.

Miyamoto: That is correct.

Akahane: Understood. My last question concerns Humira in June and Avastin in July. The relationship is extremely difficult, and what kind of image do you have for bio, antibodies, in the future?

Miyamoto: I am sorry. I did not quite understand the intention of your question.

Akahane: Your Humira BS has approved in June and Avastin BS in July, isn't it?

Miyamoto: Yes.

Akahane: This time, you will develop biosimilars for antibodies. In terms of the market, it will be different from Nesp, hormones, but would it be better to think that the market will expand more than anticipated?

Miyamoto: I see. Are you asking about the general prospect for biosimilars?

Akahane: Yes. As a general argument.

Miyamoto: I see. I think that general concerns about the quality of biosimilars themselves have declined considerably. The reason is that biosimilars can be created only by large-scale players. Those with the capacity to create and develop biosimilars are mostly limited to major global players, and I even think we may be the smallest player. Therefore, we believe that there have been much less significant concerns in recent years about the quality of the products themselves. For example, in Japan, we have introduced Rituximab BS from Sandoz, and we are selling this product, which is gaining considerable momentum. We feel that it is much easier for biosimilars to enter areas where price matters. For example, the reasons for the momentum of Rituximab's BS include solid quality and the fact that we endorse it, but also this is DPC as it is used by hospitalized patients. Since it is covered by flat-rate payment, the mindset tends to be that you should use BS rather than use the original. As a result, even from a global perspective, concerns about quality are probably decreasing considerably. That said, it is certainly an antibody with quite complicated structure, so it is different from the original, only similar. But we believe that the acceptance of biosimilars will increase considerably, as it gradually comes out after thorough tests.

Akahane: Understood well. Thank you very much.

Yamaguchi: This is Yamaguchi, may I ask an additional question? I think that Phase2 trial of KW-6356 has been completed. Has this been completed but is that right?

Torii: This is Torii. As you mentioned, we are now analyzing the data, and the publication of the data is scheduled for next fall's academic conference, and we are currently in the process of preparing it.

Yamaguchi: Are there possibilities for top-line disclosure in the form of news release?

Torii: It is undetermined at present.

Yamaguchi: It is undecided, I see. In addition, I think you said that restructuring expenses were newly recorded in the current fiscal year. Last year, it was for early retirement. I am sorry, I could not hear the contents of this, so could you explain it briefly once more?

Miyamoto: Thank you, Mr. Yamaguchi. That is a expense occurred in the Scotland-based subsidiary Kyowa Kirin International, previously ProStrakan when we acquired it. Roughly speaking, ProStrakan was originally focused on generics, and partly new drugs, and it had a business presence in Europe. However, it is now selling Crysvida, and Poteligeo in Germany from June. And now, as you know, Nourianz is being reviewed by EMA. Up until now, these two businesses have been moving together, but we are now handling such new drug business and the way to sell is different, so we decided to divide operations into two business units and move them separately. Since the original business was centered on fentanyl drugs, we were also thinking about using digital more thoroughly, considering compliance, and the fact that we are now implementing structural reforms on this front means that we are incurring costs.

Yamaguchi: OK. Thank you very much.

Hashiguchi: This is Hashiguchi again, thank you very much. I have two questions. The first is about Poteligeo. What is your view of the response from doctors and patients about extending the administration intervals? If there is strong concern about compromising treatment results, there might be an incentive to return to normal once COVID-19 settles down. If they don't feel that efficacy has declined too much, and actually feel benefits like reduction of adverse events, conversely there is a risk that the new administration method will become established even when the epidemic is over, without returning to its original state. What do you think?

Miyamoto: Thank you for your question. We must keep a close eye on it. Due to the nature of this disease, it will take time to know about the outcome of administration with longer intervals. Therefore, we have not yet

heard from the front lines about changes in the situation. We might know towards the end of the year, but we must wait and see. I am sorry, we do not have any information yet.

Hashiguchi: Is it possible to raise the price if this happens? Will the price per vial be increased to keep the price per patient the same?

Miyamoto: Because this is in the United States, it might depend on how the payer thinks. We cannot really tell what will happen.

Hashiguchi: Understood. My second question concerns daprodustat. You mentioned earlier that it is easier to adjust the dosage. What are the factors behind this?

My understanding was that daprodustat is relatively difficult to adjust the dosage because it is sometimes subject to overshoot as it can lead to a sudden rise in hemoglobin when compared to Vadadustat or Enarodustat. Is there any difference in the substance? Or, as you mentioned, because you have rich evidence, is it easier for doctors to adjust the dosage?

Miyamoto: I think that you can see from the formulation of the approved drug. The formulation is prepared in relatively fine particles.

Hashiguchi: I see. Thank you very much.

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

[END]