Kyowa Kirin Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending December 2019

August 2, 2019

Event Summary

[Event Name]		Q2 Financial Results Briefing for the Fiscal Year Ending December 2019	
[Date]		August 2, 2019	
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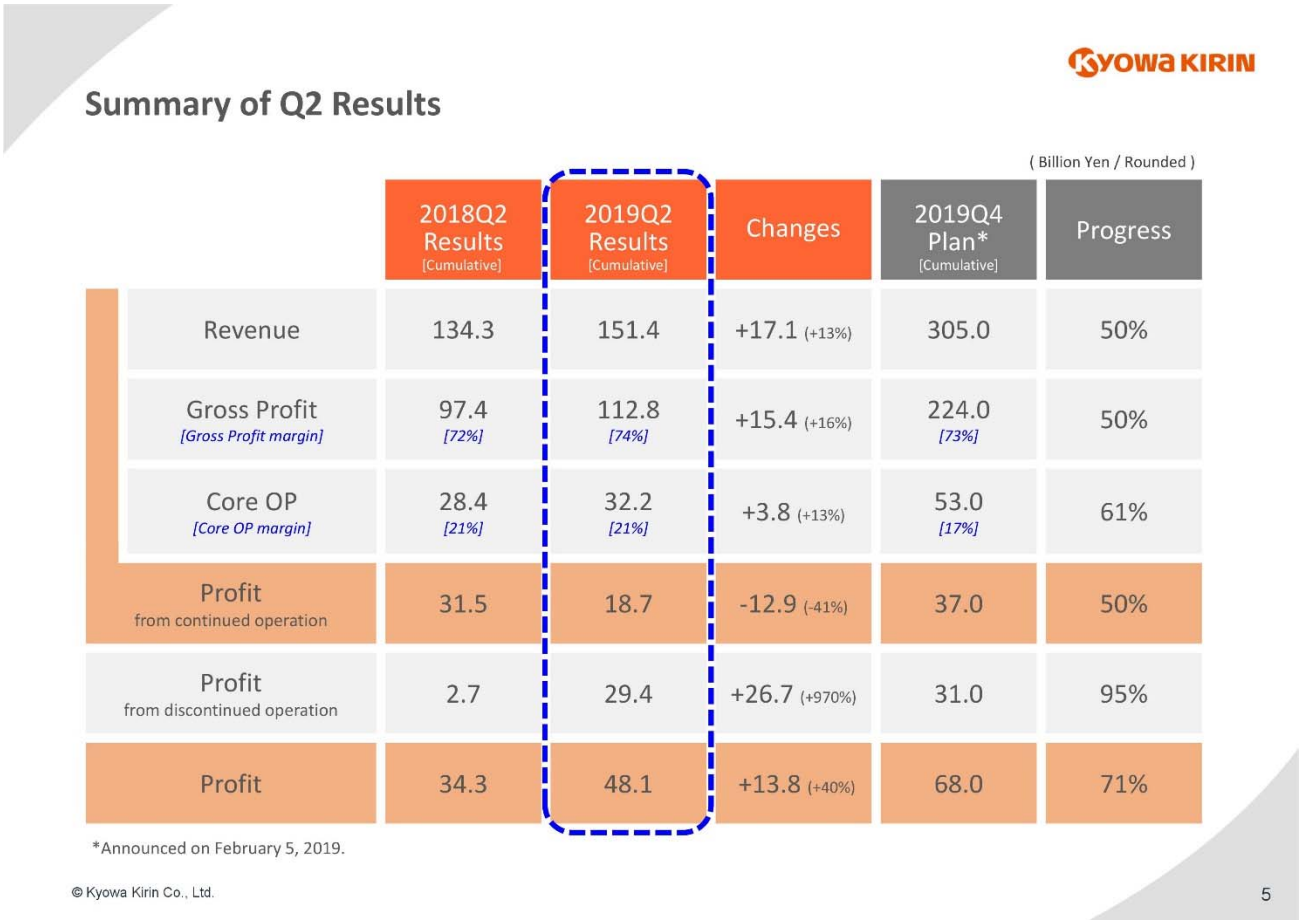
		Masashi Miyamoto, Ph.D.	Executive Director of the Board, President, and Chief Executive Officer
		Mitsuo Satoh, Ph.D.	Executive Officer, Head of R&D Division
		Motohiko Kawaguchi	Director, Finance Department

Presentation

Moderator: We will now hold a briefing on the financial results for Kyowa Kirin Co., Ltd., for the second quarter of the fiscal year ending December 31, 2019, which were announced yesterday at 3:30 p.m.

I would like to introduce today's speakers. Masashi Miyamoto, Executive Director of the Board, President, and Chief Executive Officer. Mitsuo Satoh, Executive Officer and Head of the R&D Division. Motohiko Kawaguchi, Executive Officer and Head of the Finance Department.

First of all, Dr. Miyamoto will present the financial results.



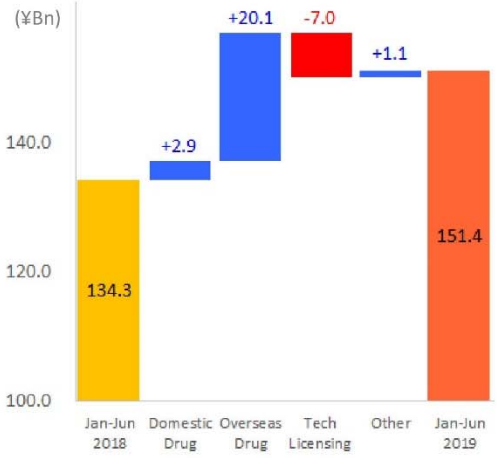
Miyamoto: Thank you for attending. I would like to briefly explain the financial results for the second quarter.

This is a brief overview of the financial statements, but we will analyze it a little later. Overall, sales and profits have increased compared with the previous year, and we believe that these second quarter results are due to continued good performance.

Revenue increased by 17.1 billion yen compared to the previous year, and gross profit increased accordingly. Core operating profit rose by 3.8 billion yen. As I will explain later on, the quarterly profit is notable given the fact that Kyowa Hakko Bio Co., Ltd., became a discontinued operation. However, the gain on the sale has resulted in a large profit, and the total quarterly profit has increased by 13.8 billion yen. The full-year forecasts show very favorable progress, and I believe that we have achieved satisfactory results.

YoY Analysis -Revenue-

+17.1 billion yen (incl. forex effect -1.4)



- **Domestic Drug +2.9**
  - **Positive:** New product line including Rituximab BS (+3.0), Orkedia (+2.7), G-Lasta (+2.0), Dovobet (+0.6), Nouriast (+0.4) and Lumicef (+0.3) maintained steady growth.
  - **Negative:** There are negative impacts by the drug price revision in April 2018. In addition, Regpara (-4.0) dropped due to the presence of a competing product and switch to Orkedia. Long-listed products such as Allelock (-1.0), Coniel (-0.5) and Depakene (-0.4) decreased mainly due to the penetration of generic drugs.
- **Overseas Drug +20.1 (incl. forex effect -1.2)**
  - **EU/US:** Crysvita (+12.5) and Poteligeo (+5.4), launched last year, strongly penetrated into the market.
  - **Asia:** Regpara (+0.9) recorded favorable sales mainly in China . Neulasta/Peglasta (+0.9) also increased due to the launch in Middle Eastern countries.
- **Tech Licensing -7.0 (incl. forex effect -0.1)**
  - **Benralizumab:** Increased sales royalties were not able to offset the absence of milestone revenue booked last year.
  - **Other:** There was gain on sale of Priority Review Voucher (US$80.6M × 50%) last year.
- **Other -1.1**
  - Increase in the sales of FKB327 (Hulio)'s API.

We will analyze the sales revenue a little. First of all, in Japan, there has been a negative impact from the NHI drug price revision last year affecting the first quarter of this year.

Because we launched a new product called Orkedia as a successor to Regpara, the switch to this new product, Orkedia, from Regpara has had a significant negative effect on the sales of Regpara. In addition, there is a competitor to Regpara and it also has a negative impact on Regpara.

Moreover, while there was a continuing decline in other long-listed products such as Allelock, Coniel, and Depakene, sales of the Rituximab biosimilar more than compensated for this. Sales of Orkedia, which I just mentioned, are also growing.

In addition, our G-Lasta sales have continued to improve, leading to very strong results. Sales of products such as Dovobet, Nouriast, and Lumicef also grew. As a result, domestic sales were up by 2.9 billion yen, overcoming the negative factors described earlier.

Overseas, I think we are doing very well, in line with the plan. Sales in Europe and North America are growing steadily as shown in the figures for Crysvita and Poteligeo, which were launched last year.

Sales of Regpara are growing dramatically, particularly in the Chinese market. The Company also took over sales in the Middle East from Amgen, Inc., and this has been positive in the current fiscal year. Overall, sales overseas have made strong progress, increasing by 20.1 billion yen.

Last year, we received upfront and milestone payments related to Benralizumab, and we also made a gain on the sale of a voucher regarding Crysvita. Compared with last year, the change in technical licensing revenue has been negative.

In terms of other revenue, there have been increased sales of FKB327, resulting in sales in the biosimilars business increasing by 1.1 billion to 17.1 billion in total.

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Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2018Q2 Results [Cumulative]	2019Q2 Results [Cumulative]	Changes	Reason	2019Q4 Plan*2 [Cumulative]	Progress
Nesp+Authorized ver.*1	25.6	25.6	+0.1 (+0%)		48.4	53%
Regpara	7.8	3.8	-4.0 (-51%)	A competitor's penetration & switch to Orkedia	5.1	74%
Orkedia	0.4	3.0	+2.7 (+717%)	Launched on May 2018	9.5	32%
G-Lasta	9.5	11.5	+2.0 (+21%)	Steady market penetration	22.8	50%
Rituximab BS	1.1	4.2	+3.0 (+262%)	Launched on Jan 2018	8.4	50%
Allelock	7.5	6.4	-1.0 (-14%)	Generic drugs' market penetration	9.3	69%
Patanol	9.7	9.9	+0.2 (+2%)		11.3	88%
Nouriast	4.4	4.8	+0.4 (+8%)	Steady market penetration	10.0	48%
Technology licensing	1.5	1.7	+0.2 (+12%)		4.4	37%

*1 Authorized version of Nesp "Darbepoetin Alfa Injection Syringe [KKF]" is to be released since August 5, 2019.
*2 Announced on February 5, 2019.

Now a breakdown by major item. Nesp's authorized version is scheduled to go on sale next week on August 5. So far, we only have the results with Nesp, and there is a slight positive change year-on-year. Performance is basically in line with the plan.

Regpara, Orkedia, G-Lasta, and the other items are as explained earlier.

Revenue of Major Items (Overseas)

(Billion yen / Rounded)

Item	2018Q2 Results [Cumulative]	2019Q2 Results [Cumulative]	Changes	Reason	2019Q4 Plan*4 [Cumulative]	Progress
Crysvita*1	0.8	13.4	+12.5 (+1474%)	Launched in Apr 2018	Undisclosed	–
North America		9.9				
Europe & other		3.5				
Poteligeo	–	5.4	+5.4	Launched in Oct 2018	10.0	54%
Abstral	6.5	5.8	-0.6 (-10%)		12.3	47%
Technology licensing	12.4	5.2	-7.2 (-58%)	Benralizumab milestone & Crysvita PRV*3 in 2018	12.9	40%
Benralizumab Royalty*2	0.5	3.8	+3.3 (+639%)	Launched in 2018	Undisclosed	–

*1 In January, sales started in UK (England etc) at the list price of GBP2,992 per 10mg vial.
Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).
Launched countries excluding South America as of June 30, 2019:
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE
*2 Sales royalties from Fasenra marketed by AstraZeneca. Includes our own estimation.
*3 PRV = Priority Review Voucher
*4 Announced on February 5, 2019.

Moving to overseas items. Revenue for Crysvita is 13.4 billion yen. We believe that sales are growing at an extremely solid pace. Sales in North America totaled approximately 10 billion, and sales in Europe and elsewhere amounted to 3.5 billion. There was a 12.5 billion yen increase year-on-year.

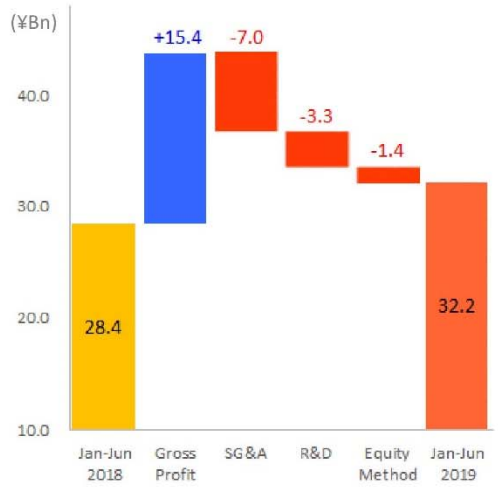
Poteligeo was launched in North America last October, and revenue from January to June of this year was 5.4 billion. This is also growing steadily.

Abstral is a fentanyl product sold in Europe. It was slightly negatively affected by adjustments to Brexit measures.

As I explained earlier, technical licensing revenues are also negative, but there is steady growth in royalties for Benralizumab, marketed as Fasenra.

YoY Analysis -Core OP-

+3.8 billion yen (incl. forex effect -0.2)



- **Gross Profit +15.4 (incl. forex effect -1.0)**
  - Increased in conjunction with the rise in the revenue. Gross profit margin up by 2 points, from 72% to 74%.
- **SG&A -7.0 (incl. forex effect +0.7)**
  - Increased selling and launch readiness expenses in the EU/US. *Including Crysvita's profit sharing expenses in North America.
- **R&D -3.3 (incl. forex effect +0.1)**
  - **Negative:** KHK4083 (P2 initiated in Oct 2018), RTA402 (P3 initiated in May 2018), KW-6356 (P2 initiated in Nov 2018), etc.
- **Gain/Loss on Equity Method -1.4**
  - Decreased due to the absence of FKB327-related revenue from the license-out of EU commercial rights and the achieved development milestone booked last year.

Looking at core operating income, gross profit increased by 15.4 billion yen.

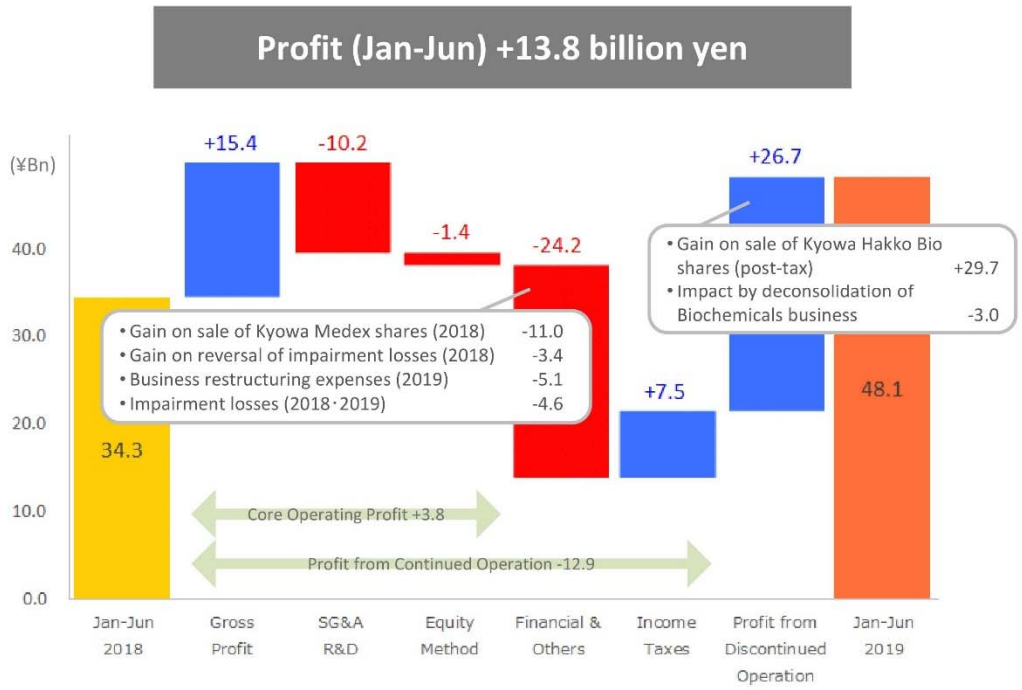
As we are preparing for the launch of new products in Europe and North America, we have increased our SG&A expenses accordingly, and as we have already explained, we have a profit share for Crysvita in North America. As sales in Crysvita grow in North America, we incur a corresponding portion of SG&A expenses. This has contributed to an increase of 7 billion yen in SG&A expenses.

Furthermore, although R&D expenditure bottomed out slightly last year, we have started major studies, such as RTA402 or KHK4083. As a result, R&D expenditures have increased by 3.3 billion yen.

In equity method gain/loss, FKB received the lump-sum contract payment for sales in Europe related to FKB327 last year. As a result, the figure this quarter was negative 1.4 billion by comparison.

However, this negative factor was covered by gross profit, resulting in an increase in core operating income of 3.8 billion yen.

YoY Analysis -Profit-



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Analyzing quarterly profit, core operating profit was increased by 3.8 billion yen, as I explained earlier. In the Financial and Other Businesses segment, there was no gain on the sale of Kyowa Medex and no gain on reversal of impairment losses last year. In addition, there was a charge of 5.1 billion yen for the special voluntary retirement plan. We have also written down 4.6 billion yen of the impairment loss, but this was due to the fact that the sales rights for products in Europe, particularly those focused on Moventig, failed to meet our expectations. We recognized an impairment loss of 4.6 billion yen in the current fiscal year.

On the other hand, as I explained earlier, the gain on the sale of Kyowa Hakko Bio is large, and as a result, these negative factors have been offset. The total amount is positive at 13.8 billion yen.

This concludes the simple summary of the financial results.

Key development updates in 19Q2

- **Application for approval of KHK4827 for the treatment of psoriasis in China (April)**
- **Application for approval of KRN23 for the treatment of XLH in Korea[1] (May) and China (June)**
- **Completion of the patient enrollment in the phase 3 AYAME study of RTA 402 for the treatment of DKD in Japan (June)**
- **Approval of AMG531 for the treatment of aplastic anemia in Japan (June)**

[1]Filed indications are FGF23-related hypophosphatemic rickets and osteomalacia

We have two more slides. In April, we submitted an application in China for KHK4827, or Lumicef, for psoriasis.

In addition, we submitted an application for KRN23 in South Korea and China. In particular as you know, the Chinese authorities have changed their regulations recently, lowering the hurdle for submitting applications for drugs approved in developed countries. Using these new regulations, we were able to submit the two applications much faster than originally planned.

AYAME is the Phase 3 trial of RTA402 in diabetic kidney disease. This is an extremely large domestic Phase 3 study. We are recruiting about 1,000 patients. Because there is a lot of interest from medical professionals, recruitment of patients has progressed very smoothly. We successfully finished recruiting in June.

Finally, in June, we received manufacturing and marketing approval of Romiplate, or AMG531, for treatment of aplastic anemia.

Business Topics

- **Kyowa Kirin Frontier to sell Darbepoetin Alfa Injection Syringe [KKF] (August)**

- **Kyowa Kirin buys back Tivozanib non-oncology rights from Aveo Oncology (August)**

The last slide concerns two business topics. First, as I explained earlier, we will launch Darbepoetin alfa injection [KKF] on August 5.

Secondly, an announcement regarding Tivozanib. Tivozanib is a low-molecule kinase inhibitor and was originally discovered by Kyowa Kirin. It was licensed to AVEO, Inc., of the United States. AVEO markets it for renal cell carcinoma in Europe also under a sublicense, but yesterday, we announced a buy-back of rights for areas other than that particular cancer.

This is the end of my presentation.

Question & Answer

Yamaguchi: Yamaguchi of Citigroup Global Markets Japan. The first question is about Crysvita. While sales in the US are once again accelerating in Q1 and Q2, it seems like Europe is flat now, but I think you have been talking about a price reduction in Europe. However, as there has been a US-Europe breakdown from the current Q2, please comment more about the trend and future outlook.

Miyamoto: Thank you. Ultragenyx Pharmaceutical had a conference call I think this morning, and I think they might talk about it. There is a continuing strong trend in the US

Europe looks flat. As Mr. Yamaguchi says, Germany is the largest country and there was a drug price revision in Germany this May. In this revision, after one year of launch, the initial selling price was restated and reduced by 25%. From our perspective, we thought that 25% could be seen as a reasonable reduction. I think this is a good demonstration of the effectiveness of the drug.

As a result, it has become slightly flat, but the number of countries where it is marketed is gradually increasing, so we plan to expand this area in the future.

Yamaguchi: One more question. I understand that Europe's royalty rate is up to 10%, so I'm wondering if there are other factors at play here.

Breaking it down, the current royalty rate seems to be around 12%, and I'm wondering if that may be a little high. I'm wondering if there may be other factors outside the Europe. Some arithmetic shows that the royalty rate is slightly higher. In short, we can calculate the royalty rate for Ultragenyx to be 10% or more. Is this accurate?

Kawaguchi: As stated in the slide, the royalty rate is up to 10%, but we do not include the early-access program sales in the sales of Crysvita in Europe. For the purpose of calculating royalties, it will, of course, be included in the calculations, so that is probably the biggest factor contributing to the difference.

Yamaguchi: Lastly, China was repeatedly emphasized in your presentation, and other companies have indeed been talking in a similar way. I was wondering if you could give us some idea of what proportion of your company's Asia sales are in China.

Miyamoto: I don't have the exact number on hand. The figure has been growing recently, and China is becoming the largest country in Asia in terms of sales. Mr. Kawaguchi?

Kawaguchi: We disclose sales in Asia as a whole. South Korea and China account for about 30% of that figure, respectively. As Dr. Miyamoto explained, South Korea was top, but this year, it is probable that China will be the top Asian country. I hope you will appreciate this given the good performance of Regpara.

Yamaguchi: Thank you very much.

Hashiguchi: Hashiguchi of Daiwa Securities. I have two questions about pipelines. In addition, I would like to confirm about signs of action with respect to a point that was not mentioned.

The approval process for Nouriast in the US seems like it is about to be completed, so assuming there are no problems, when do you plan to launch the product? Can you give any hints as to the predicted sales?

If there is a difference in the treatment system for Parkinson's disease between Japan and the United States that is likely to affect sales, can you explain if your positioning is likely to be similar or slightly different between the two markets?

Miyamoto: I think the process is going very smoothly. The due date is the end of this month, so from that viewpoint, I would like to start selling by the end of this year if possible.

We are aiming for sales in Japan of 10 billion yen this year. Given the size of the US market, we feel we will be able to exceed this level.

Although there could be some minor differences between the markets, we are basically aiming to adopt the same position. We have received a variety of input from medical professionals so far in Japan. We are currently transferring this information to the United States.

Satoh: I would like to add a little more. The approval process is proceeding very smoothly, and there are no major problems. We anticipate that approval will be obtained in the near future. Once approved, we expect to launch by the end of the year.

However, I'm aware that in an environment where the only really effective medication for Parkinson's is dopamine-based medications there is certainly a need for an adenosine A2A antagonist, which has a different mode of action.

On that basis, we plan to use a similar positioning as in Japan. Also, we are developing 6356 at present that might be able to treat Parkinson's in earlier stages and be entering a similar market.

Hashiguchi: Thank you. The second question is about Daprodustat. There are more and more competing products in the approval process. What is the situation now? I read in the release at the time of the licensing that the results of the Phase 3 would come out in first half of the year, but I don't recall seeing them. What is the situation now?

Miyamoto: This is a collaboration on the sales side, so basically, we would like you to hear from GSK. This is not something that we are concerned about. We would ask you to confirm with GSK. We are not worried.

Hashiguchi: Thank you.

Wakao: Wakao of Mitsubishi UFJ Morgan Stanley Securities Co., Ltd. Thank you for your presentation. Please tell us a little more about the Crysvita section. Regarding the outlook for Europe, I think that the number of countries it is marketed in has increased somewhat, but on the other hand, I think many of these are smaller countries.

This is why it might be better to think that moving forward Germany will continue to be the driving force for growth and then England, or on the other hand, would it be better to think that these smaller countries will all contribute in some way?

If the number of countries is to increase further in the near future, can you give us any specific names?

Miyamoto: Unfortunately, I cannot comment on future countries at this time. At present, we are selling in Europe to countries such as Germany, the Netherlands, Luxembourg, England, Northern Ireland, Israel, Wales, Slovakia, the UAE (which we treat as Europe and Others), and to Sweden. We will aim for other countries in the future. The patient populations are there, so I am sure there will be contribution.

Wakao: If that happens, will sales continue to grow in places like Germany and England, and can we expect the market to grow in other countries in line with their population sizes?

Miyamoto: Of course, there are circumstances depending on the country, such as differing drug prices. However, from a patient population perspective, that is the viewpoint.

Wakao: Thank you very much. The second question regards investment. Is there a specific plan for the profit from the sale of the biochemicals business to be invested in growth? I think you previously spoke about areas or technologies where you would like to see investment. Could you update us on your thoughts?

Miyamoto: Looking at investment for growth as a whole, there're Crysvita, Poteligeo, and Istradefylline that should be approved in the future. Based on these three so-called global products, I believe that we will be able to achieve growth over the medium term. Therefore, from the viewpoint of growth, we are looking for a pipeline that will help us to grow further in the medium term.

In addition, we have established a pipeline that looks ahead to the expiration of Crysvita's patents, as well as a technological platform with a three-part scope. We are currently working on building a special team within the company to move forward. Although we have yet to reach the point where we can communicate any details to you, I hope you will understand that we are moving fairly actively. I'm not sure if Dr. Satoh has anything to add here.

Satoh: Kyowa Kirin is moving forward with this as an R&D-oriented company, but I very much feel that it is necessary to incorporate new technologies and open innovation. I want to achieve this by all means. Now, I am working to create a special project team to introduce it.

Wakao: Thank you. Loans to the parent company on the balance sheet increased by 100 billion yen, so there was some concern about a slight delay in investment for growth on the horizon. I suppose that is not a concern.

Miyamoto: It is a loan to the parent company and can be withdrawn at any time, so there is no problem.

Wakao: Thank you very much.

Moderator: Next question.

Ueda: Ueda of Goldman Sachs Japan Co., Ltd. First of all, I would like to ask about Nesp. The AG will be launched soon, but what sales strategies do you have for after the AG is actually launched, and what segregation do you plan on?

With the emergence of oral EPO formulations, would you tell us about the outlook for the competition, and how you will differentiate yourself from existing products?

Miyamoto: Thank you. As for the second question, we believe there are a number of HIF-PH inhibitors and biosimilars of Nesp to launch in November, and we have been able to simulate such a situation in-house and have set our goal for this time. There are no changes on sales forecasts at present.

Regarding our sales strategy, this has been mentioned before, but when we decided to go ahead with the Nesp AG, it had been 30 years since we introduced our first erythropoietin formulation. Nesp, for example, is recognized as an extremely safe and effective drug, but there are actually nine formulations, starting with 5 micrograms. As you can see from this, we believe that this is a product that is difficult to use, and we feel that it is being used by medical professionals in a manner that is tailored to the circumstances of patients.

It is rare, but there are some side effects. We believe that the know-how we have accumulated over the past 30 years is an asset that has been created by us, by medical professionals, and by patients. We feel there is value here. When biosimilars were introduced, we felt a duty to stay in the market, and that led us to develop the Nesp AG.

In terms of sales strategies, of course, we will continue to provide information on AG as well, and we believe that we will be able to assist with a swift switch to AG. On the other hand, as AG biosimilars are not indicated for conditions such as MDS, we believe that the original model will still have a place in this area.

Ueda: Thank you. The second point is the R&D strategy. Since the introduction of the "Four Category Strategy" in 2014, has there been a lineup of items that will enter clinical trials?

Given that your company has an extremely strong kidney franchise, have you considered anything outside pharmaceuticals, such as devices, apps, or collaborations with other businesses?

Satoh: Thank you for your question. Although we are reorganizing our research laboratories on a per-modality basis and have been looking into this since 2014, there are some interesting technological bases from which we would like to launch products into clinical trials. This is still in the early stages, so I am not able to say anything more at this time. However, please understand that a number of such announcements will be made in the future.

In the renal field, I recognize that there are business opportunities in, for example, the use of devices or in businesses outside of pharmaceuticals. At the corporate level, in the Kirin Group, we are currently engaged in activities to explore business opportunities with Kirin Holdings to see what we can do in new areas.

Ueda: Thanks. That's all.

Arai: Thank you for your presentation. My name is Arai for Merrill Lynch Securities Japan. The first question is about Crysvita in China. Regarding the faster-than-expected application, if are you aiming for a larger scale, do you think it is important to list on the so-called national insurance reimbursement list? Is the same also true for this drug? Would you tell us about the prospects for large scale even if there is no listing on the drug list or the insurance reimbursement list?

Miyamoto: Large scale may be a keyword, but the question of whether you are thinking about it reaching, for example, the same level as in Europe and North America is still a matter of insurance, as you have just mentioned. We are thinking carefully about how products are brought in China.

You certainly have to list low-molecule products that you would like to be used by many patients if you want them to do well. Regpara is a good example of this. It was listed on the reimbursement list and is now doing very well.

Conversely, there is a risk. The Chinese government pays for medications, and there is the issue of price negotiation. I have heard that this area is managed with a great deal of care, and I think finding the right balance is an important point.

Then there is Lumicef and KRN23. We are applying for these products, but we are carefully considering how to deliver them to patients and how they will be paid for.

Arai: Thank you. The second question is about allergy drugs. Is there going to be a move to OTC for allergy drugs in the future? I think there is a debate about this issue. If this debate proceeds in the future, what would your stance be for Allelock and Patanol? Would you prefer for their status to remain the same, or if there is a move to OTC, how would this be dealt with?

Miyamoto: Thank you. If a debate emerges on this topic, we will have no choice but to deal with OTC, and in that case, we will talk to companies who are engaged in OTC. I'm sorry, I had no answer prepared for this question, as we are not looking deeply at this issue internally.

Arai: I understand that discussions may not well be progressing with the government.

Miyamoto: That can happen on an industry level, but I don't think that there will be any agreements between individual companies and the government.

Arai: Thank you.

Tanaka: Tanaka of Mizuho Securities. It was mentioned that the royalty payment of Crysvita is calculated based on the sales in Europe and early access program. Assuming a maximum royalty rate of 10%, I would like to ask about how many early access areas there are now, what prices are these based on, and how they are calculated.

Miyamoto: There are some surprisingly large countries with early access, such as Spain, France, Italy, Scotland and Portugal. I believe that Austria is also doing this, but I am not able to disclose any information about prices.

Tanaka: I appreciate those issues, but at least, are there enthusiasm with respect to launching within a set number of years?

Miyamoto: We are planning this step by step, so we would like to be able to launch in any country without taking a very long time. There are patients waiting for these medications. Needless to say, there is a basis for drug price negotiations, but I don't think the process will take many years to do.

Tanaka: Thank you very much. The second point is about the modalities mentioned earlier. Looking at your Company's patents, there are, of course, many antibody patents, but I think there are many nucleic acid patents as well. You said that it is lagging behind. I understand there is a research laboratory for regenerative therapeutics, and I would be pleased if you could tell us if you expect any developments in this area.

Satoh: Thank you for your question. Although we are doing a variety of activities, such as regenerative therapeutics, we don’t see any pipeline candidates in the near future. In the case of nucleic acid drugs, active targeting is a major keyword, and I feel that it will take some time to build a pipeline that makes good use of this technique.

Otherwise, in antibody therapy, development of new technologies is progressing well, and this area is likely to provide candidates for clinical trials earlier than those I’ve just mentioned.

Tanaka: Thank you very much.

Nakazawa: Nakazawa of SMBC Nikko Securities. Thank you very much. Please tell us about the rationale behind slide number eight. First of all, I would like to ask a few questions about Crysvita. Regarding the 13.4 billion yen, yearly sale forecast has not been disclosed, but is the expansion progressing as planned in the full-year plan? Is the pace faster or slower? Could you tell us a little more?

Miyamoto: We believe that the sales are growing steadily.

Nakazawa: Better than expected?

Miyamoto: We can just say that sales are growing steadily.

Nakazawa: Steadily. My apologies. Next, regarding Poteligeo, this is clearly over 50% progress, so I think it is expanding at a pace above your expectation. Are there any special factors behind this?

Miyamoto: We believe that this product has penetrated the market very well since its launch in October last year. The goal is 10 billion yen for the fiscal year. I believe that we are making good progress toward this goal. I do not believe that there are particular special factors.

Nakazawa: Thank you. It was mentioned that Abstral was a little weaker, and that this was a response to Brexit. If this factor were excluded, would you tell us whether this figure would be growing steadily or be on track?

Miyamoto: The first point is simply to respond to Brexit. There have been a lot of issues with respect to shipping. Second, there is the issue of patent expiry. If patents expire, some countries may push to lower drug prices.

We actually have another medication in the same fentanyl formulation, called PecFent. It is still under patent. We are moving to switch to that one. This shows the balance between the power of sales in that side, and the full-year forecasts are the figures shown here. I think we will make every effort to achieve this goal, but I think it may be a little weaker.

Nakazawa: If the switch to PecFent goes ahead, what would the prediction be?

Miyamoto: As a whole, I would like to see the situation go the same way. Abstral is still growing, so I'm telling the people there that it's a good thing to do.

Nakazawa: Thank you. Regarding technology revenue, progress seems to be slightly slow, but is this on track? Similarly, is the abandonment of the Tivozanib milestone in this plan?

Kawaguchi: Regarding technology revenue, we basically planned and factored in the growth in royalties of Benralizumab into the company, and the results up to the second quarter were in line with the plan. Therefore, we would like to achieve the plan for the year. And there is no impact from Tivozanib, as it was not originally included in the plan.

Nakazawa: Thank you.

Sakai: Sakai of Credit Suisse Securities. Regarding the buy-back of Tivozanib, as a VEGF inhibitor, it may have applications outside cancer therapy. In this morning's industry paper, I think the president commented that it was very interesting.

With 6002 and RTA402, I have the impression that the company is very good at finding new areas where medications that were not considered useful can be used in a new way.

Regarding Tivozanib, will this be used in an area that’s new for the Company or in line with existing development areas? What potential do you feel VEGF inhibitors have outside cancer?

Miyamoto: Thank you. Unfortunately, we are unable to provide any details. An interesting discovery was made at our laboratories. As a result, we decided on the buy-back. Dr. Satoh is currently under pressure to disclose what we are thinking about as early as possible.

Sakai: Is it in the ophthalmology field?

Miyamoto: No comment.

Sakai: Understood. Second, I understand this has been the case since the previous president, Dr. Hanai, but that the company has for the most part avoided cancer therapies. Is that still possible in today’s market?

Miyamoto: I don't think there has been any such clear statement. We would like to work on hematological cancers, and if we were to make a discovery, there is potential for development. If something with potential in this respect comes from Dr. Satoh, we can think about it.

It may be better to have Dr. Satoh talk about this, but because it is this area, if we do what other people are doing, we may not be able to get out of it. If something interesting and unique were to be discovered, that is another question. Dr. Satoh can explain the internal progress.

Satoh: The oncology field is extremely important in terms of medical needs, and we would like to be able to respond to these needs with our technologies and pipelines. I don't have any desire to avoid this area.

However, I don't want to follow others with similar drugs. We should go forward if our drug candidate can be the best in class or it is clear to be competitive in the therapeutic areas. The second is that we are making some progress in new drug concepts. We focus considerably on this area, with the aim of developing a drug, which is true whether it is a treatment for blood cancers or solid cancers.

Sakai: Thank you.

Moderator: Any further questions?

Yamaguchi: Yamaguchi from Citi Group Global Markets Japan.

First of all, I'd like to talk about the AYAME study. Will it be a two- or three-year observation period? On clinicaltrials.gov, it is listed to end in March 2022. Is it on track or slightly behind schedule to end by March 2022?

Satoh: Thank you for your question. The primary endpoint in this study is a 30% decline in their eGFR, a measure of kidney function, in the placebo group compared with the treatment group. We need to closely monitor what happens to understand the incidence of this event.

The authorities have asked to gather as much data as possible, ideally on the three-year administration of this drug. There are now almost 1,000 subjects. I hope that you will understand the stage at which we are looking at whether the incidence rate of this event is in line with our expectations. We will be in a much better position to comment on this after the start of the study. Although the accuracy is still somewhat low, we are moving forward in this way.

Yamaguchi: Conversely, if a significant difference in event rate between the placebo and treatment opens up, might the study be terminated early?

Satoh: It's a blind test, so we don't know which group each event is coming from. In total, we look at the power of the drug and the historical incidence of this event in the placebo group to see whether the event rates are in line with our plans.

Yamaguchi: Thank you. Regarding Tivozanib, I understand that, as it affects Treg cells, it's a bit like the old Poteligeo. In the past, I think there was a lot of work with Poteligeo in cancer and asthma. I think your company is working very hard in the area of immunotherapies. Do you have a plan to develop this drug, Tivozanib, in immunology or atopy?

Satoh: Excuse me, I am unable to answer this question for strategic reasons, but I hope to show details about it in the near future.

Yamaguchi: Thank you.

Hashiguchi: Hashiguchi of Daiwa Securities. It may be a slightly simple question, but what is difference between Nesp and its AG? I understand that the prices are different. Is the device different?

Miyamoto: The device is the same. Different companies have the marketing authorization of these drugs, Nesp and its AG. Also, the indications are a bit different.

Hashiguchi: The product name includes “plastic syringe,” in the case of Nesp. The AG one doesn’t have “plastic” in its name.

Miyamoto: The syringes are the same.

Hashiguchi: Exactly the same. I understand. Thank you very much.

Moderator: We now complete the briefing on the financial results for the second quarter of the fiscal year ending December 31, 2019, for Kyowa Kirin Co., Ltd. Thank you for participating today.

[END]