Mitsubishi Tanabe Pharma Corporation

Q1 FY2019 Business Results

July 29, 2019

Event Summary

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[Venue Size]		
[Participants]		
[Number of Speakers]	4	
	Eizo Tabaru	Member of the Board, Managing Executive Officer, CFO
	Yoshihiro Kobayashi	Member of the Board, Managing Executive Officer, Head of Ikuyaku Integrated Value Development Division
	Yasutoshi Kawakami	Executive Officer, Head of Sales & Marketing Division
	Yoshiaki Takai	Vice President, Head of Corporate Communications Department
[Analyst Names]*	Kazuaki Hashiguchi	Daiwa Securities
	Hidemaru Yamaguchi	Citigroup Global Markets Japan
	Seiji Wakao	Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.
	Fumiyoshi Sakai	Credit Suisse Securities
	Shinichiro Muraoka	Morgan Stanly MUFG Securities

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

Presentation

Operator: Good evening everyone. This is the conference call by Mitsubishi Tanabe Pharma Corporation to announce its business results for the first quarter of fiscal year 2019. First of all, we will have a presentation on the overview of the first-quarter results for about 15 minutes and then we will have a Q&A session. We are planning to hold this meeting for about 45 minutes in total. Before we start the conference, we have a cautionary statement. The statements contained in the presentation are based on a number of assumptions and beliefs, in light of information currently available to management of the Company and are subject to significant risks and uncertainties. Now, I'd like to hand over to Mr. Takai, Vice President, Head of Corporate Communications Department.

Takai: We now would like to start our meeting on the business results for the first quarter of fiscal year 2019. Today, we have the attendance of Eizo Tabaru, Member of the Board, Managing Executive Officer, responsible for Finance and Accounting Department; Yoshihiro Kobayashi, Member of the Board, Managing Executive Officer, Head of Ikuyaku Integrated Value Development Division; and Yasutoshi Kawakami, Executive Officer, Head of Sales and Marketing Division. I am Takai, Vice President, Head of Corporate Communications Department. Thank you for your time today.

First, Mr. Tabaru is going to give you an overview of the business results for the first quarter of fiscal year 2019 and then we will entertain your questions. Mr. Tabaru, please.

Tabaru: Thank you very much for participating in this meeting on our business results for the first quarter of fiscal year 2019, despite your very busy schedule today. I am Eizo Tabaru, Member of the Board, Managing Executive Officer of Mitsubishi Tanabe Pharma Corporation. Today, I'm going to explain our first quarter results, and the progress of our development pipeline. First, an overview of our first quarter business results.

Q1 FY2019 Business Results

Q1 FY2019 Financial Results

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Mitsubishi Tanabe Pharma

	FY2019 Q1	FY2018 Q1	Increase / Decrease		1H Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	98.1	105.3	(7.2)	(6.9)	187.0	52.5
(Domestic)	80.7	74.1	6.5	8.9	153.6	52.5
(Overseas)	17.3	31.1	(13.8)	(44.4)	33.3	52.1
Overseas sales ratio	17.7%	29.6%			17.8%	
Cost of sales	44.7	42.3	2.4	5.7	87.5	51.2
Sales cost ratio	45.6%	40.2%			46.8%	
Gross profit	53.3	63.0	(9.6)	(15.3)	99.5	53.6
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7
Operating profit	9.6	19.3	(9.6)	(50.2)	5.0	192.4
Net profit attributable to owners of the Company	6.8	13.9	(7.0)	(50.7)	4.0	172.0
Average exchange rate US$	¥109.67	¥109.53			¥110.00	

※ Announced on May 10, 2019 in the financial results of FY2018

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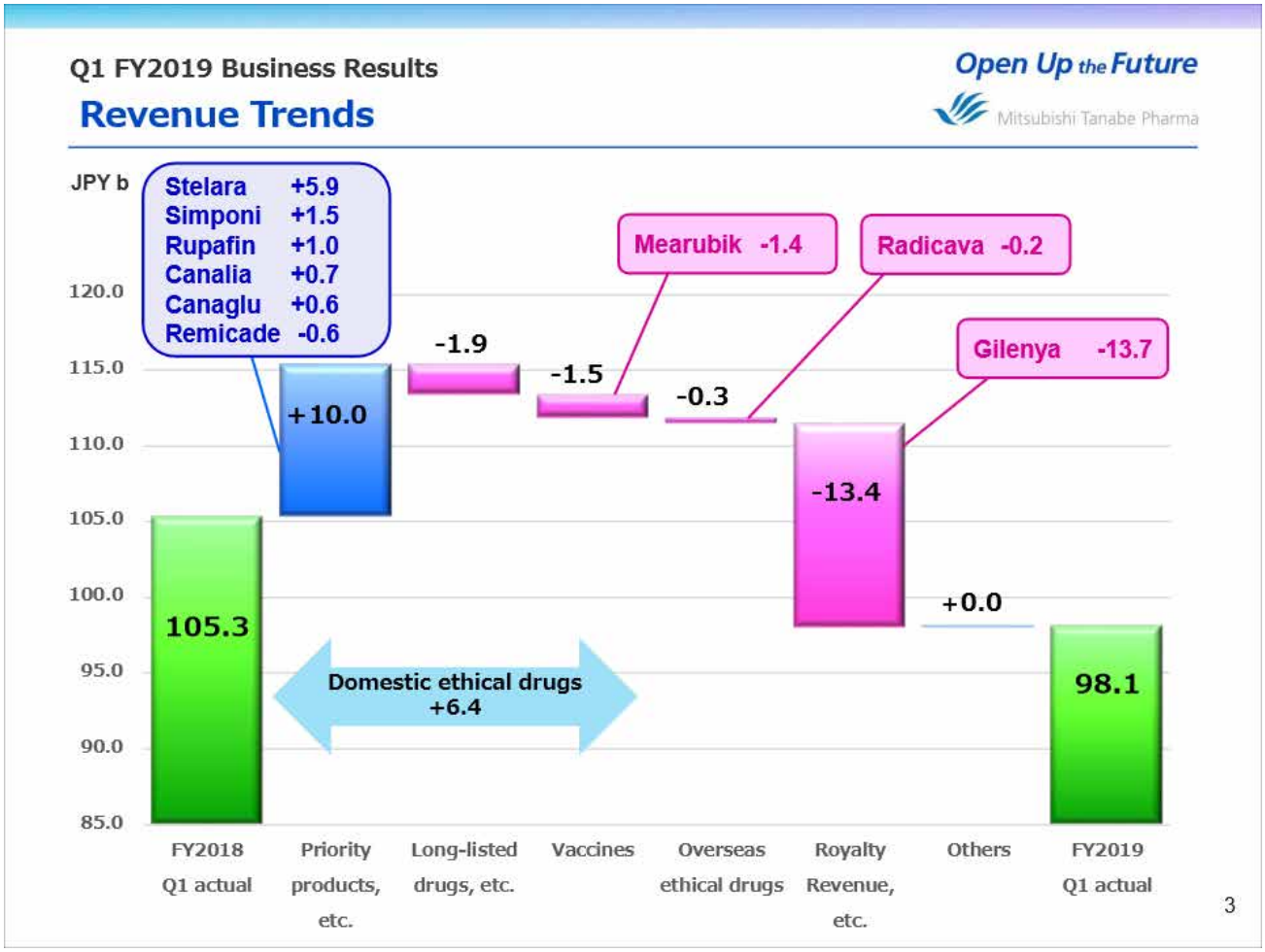
Please turn to page two. Revenues from high priority products in Japan increased in the first quarter. On the other hand, revenue declined, as MTPC decided not to recognize our sales revenue, some of the Gilenya royalty amount, in line with IFRS 15, as we are in arbitration proceedings with Novartis. As a result, our revenue declined by 6.9%, or 7.2 billion yen year-on-year, to 298.1 billion yen. Gross profit was down 9.6 billion yen to 53.3 billion yen. Core operating profit decreased by 9.5 billion yen to 9.7 billion yen. Net profit attributable to owners of the Company was down 7 billion yen to 6.8 billion yen.



Let me now explain about revenue trends, using a graph. Domestic ethical drugs recorded a year-on-year growth of 6.4 billion yen, driven by STELARA, for which we changed the sales framework with Janssen Pharma in July 2018 and by growth of Simponi, Rupafin, Canalia, Canaglu, and other priority products. Among overseas ethical drugs, Radicava fell by 200 million yen from the year before. Overseas ethical drugs, as a whole, went down by 300 million yen. The total number of patients who are administered with Radicava reached about 4,000 as of the end of June. Royalty revenue, et cetera, dropped by 13.4 billion yen year-on-year, mainly due to the decline in Gilenya as was explained before. As a result, revenues for this quarter totaled 98.1 billion yen, down 7.2 billion yen year-on-year.

Q1 FY2019 Business Results

Cost of Sales, SG&A Expense, Core Operating Profit

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	FY2019 Q1	FY2018 Q1	Increase / Decrease		1H Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	98.1	105.3	(7.2)	(6.9)	187.0	52.5
Cost of Sales	44.7	42.3	2.4	5.7	87.5	51.2
Sales cost ratio	45.6%	40.2%			46.8%	
Gross profit	53.3	63.0	(9.6)	(15.3)	99.5	53.6
SG&A expense	22.9	23.1	(0.2)	(1.0)	49.0	46.8
R&D expense	19.9	19.6	0.2	1.4	44.5	44.8
Amortization of intangible assets associated with products	0.6	0.7	(0.0)	(11.9)	1.3	49.8
Other income and expense*	(0.0)	(0.1)	0.0	-	(0.2)	-
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7

＊ Brackets indicate expense and loss.

※ Announced on May 10, 2019 in the financial results of FY2018

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I'd like, now, to move to cost of sales, SG&A expenses and core operating profit. Cost of sales increased by 2.4 billion yen and sales cost ratio went up by 5.4 percentage points from the year before to 45 6%, due to a decline in royalty revenue and changes in the product mix. SG&A and R&D expenses were almost unchanged year-on-year. Consequently, the core operating profit was 9.7 billion yen, down 9.5 billion yen.

Q1 FY2019 Business Results

Non-recurring items and Net Profit

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	FY2019 Q1	FY2018 Q1	Increase / Decrease		1H Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7
Non-recurring items*	(0.1)	-	(0.1)	-	0.5	-
Operating profit	9.6	19.3	(9.6)	(50.2)	5.0	192.4
Financial income	0.4	0.4	(0.0)	(12.6)		
Financial expense	0.8	0.0	0.7	-		
Net profit attributable to owners of the Company	6.8	13.9	(7.0)	(50.7)	4.0	172.0

* Brackets indicate expense and loss.

※ Announced on May 10, 2019 in the financial results of FY2018

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As for the items after the core operating profit, the operating profit declined by 9.6 billion yen to 9.6 billion yen. Financial income and expenses are as shown in the slide. Thus, the net profit attributable to owners of the Company was 6.8 billion yen, down 7 billion yen.

Development Pipeline

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Progress of Major Development Pipeline

Progress Update

Progress since the announcement of fiscal 2018 results in May 10, 2019

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
Central nervous system	MCI-186	Global	ALS*1				China Singapore	
	MT-1186	Global	ALS*1/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-3921	Global	Spinal cord injury					
	MT-5199	Japan	Tardive dyskinesia					
	MT-8554	Global	Vasomotor symptoms associated with menopause					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-6548	Japan	Renal anemia					
	MT-3995	Japan	Non-alcoholic steatohepatitis(NASH)					
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2271	Global	Seasonal influenza/VLP vaccine					
	MT-2355	Japan	5 combined vaccine*2					

*1: Amyotrophic lateral sclerosis
*2: Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

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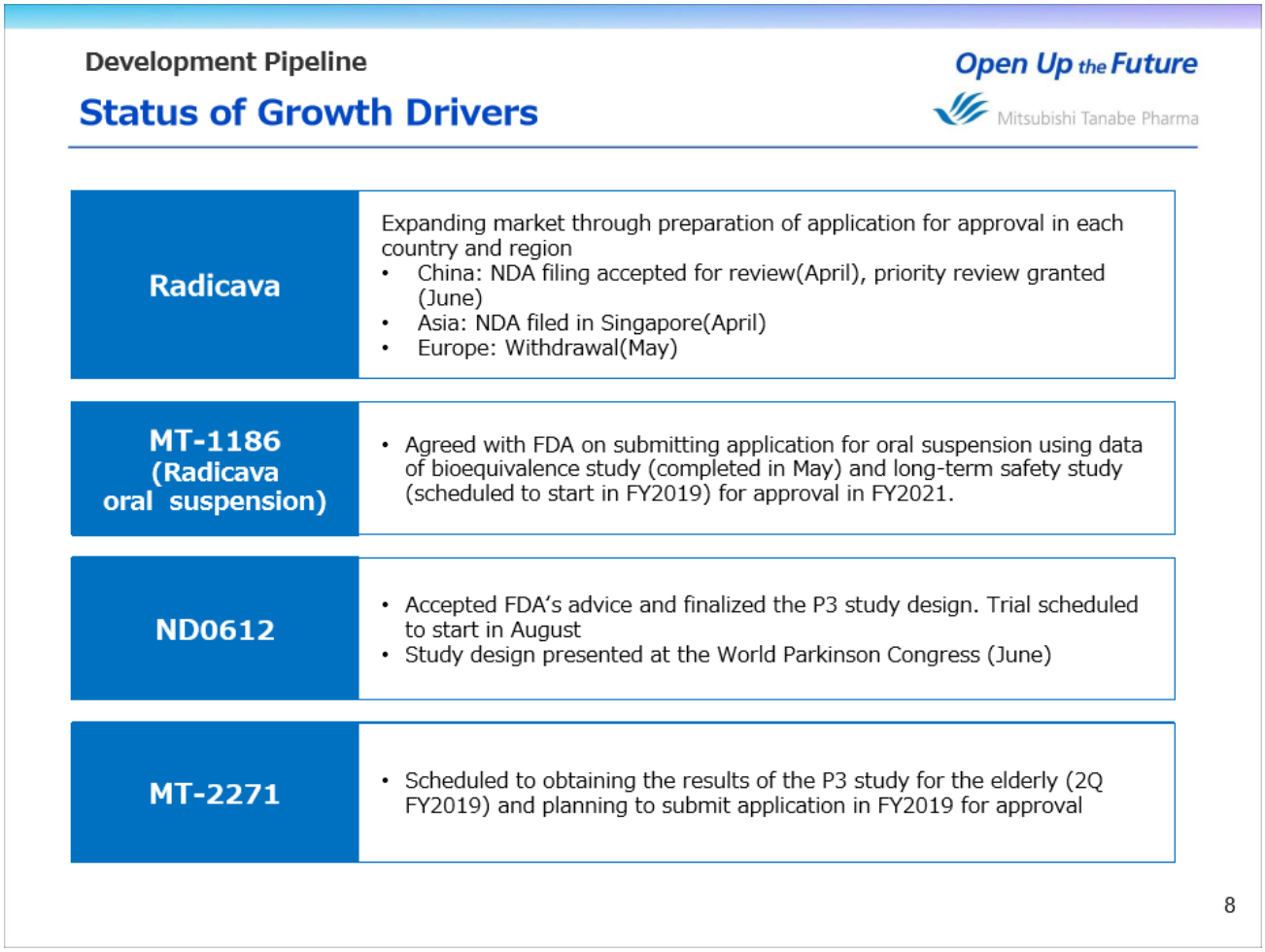
Next, let me explain the status of our development pipeline. Please turn to page seven. This shows the progress of our major development pipeline. The progress since the announcement of our fiscal 2018 results is highlighted in blue. As you can see here, we started Phase I clinical trials of MT-3921 in healthy adults in the field of CNS. Spinal cord injury is expected as a target indication in our development. In the diabetes and kidney area, which is a priority area in Japan, we filed a submission of MT-6548 for renal anemia in Japan, as we announced in our press release on July 23. I will explain the details of these two compounds later on.



Next, I'd like to explain the status of our growth drivers, and the progress of each project. Regarding Radicava for ALS, we are expanding market through preparation of application for approval in each country and region in parallel. In Europe, we withdrew our submission as was announced in a press release. We are carefully discussing our future action right now.

As for MT-1186, as the oral suspension of Radicava for ALS, we are implementing clinical trials, aiming for approval by the end of fiscal year 2021. After consultation with FDA, we are planning to start a long-term safety study by the end of the current fiscal year.

Regarding ND0612, we accepted the FDA's advice and finalized the Phase 3 study design. We plan to start the clinical trial in August.

For MT-2271, a VLP vaccine for seasonal flu, we will obtain the results of Phase 3 study for the elderly by the end of the second quarter in the current fiscal year. We will aim for filing by the end of fiscal 2019.

Development Pipeline

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Vadadustat (MT-6548) / Profile

Filed in Japan in July 2019

Mechanism of Action	Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor
Indication	Renal Anemia
Origin	Akebia Therapeutics, Inc. Signed a collaboration agreement to development and commercialize Vadadustat in Japan and Asia in December 2015
Development Stage	Japan: filed (Reference) US, EU: P3
Expected Profile	・Once-daily oral treatment ・Treatment effect for anemia by stimulate endogenous erythropoietin production within physiological range ・Easily to control hemoglobin level within target range ・Maintain treatment effect by switching from the current standard treatment for renal anemia, injectable erythropoiesis stimulating agents (ESAs)

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Next, let me share some topics related to our pipeline. Regarding Vadadustat, MT-6548, we filed a submission this month for renal anemia. This is an overview. Its mechanism of action is hypoxia-inducible factor prolyl hydroxylase inhibitor. We licensed in this compound from Akebia Therapeutics in the United States, in 2015, for development in Japan. Phase 3 studies are ongoing in the United States and Europe. We filed our submission first in Japan, ahead of the rest of the world.

Development Pipeline

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Vadadustat (MT-6548) / Results of Japan P3

Positive results of efficacy and safety for anemia

The mean hemoglobin (Hb) level at week 20th and week 24th (g/dL)*

	MT-6548 group	Darbepoetin Alfa group (DA group)	Difference (MT-6548 group – DA group)
J01 Trial [NDD-CKD**]	11.66 (11.49, 11.84)	11.93 (11.76, 12.10)	-0.26 (-0.50, -0.02)
J03 Trial [HD-CKD***]	10.61 (10.45, 10.76)	10.65 (10.50, 10.80)	-0.05 (-0.26, 0.17)

*: LSMean (95%CI)

The differences in mean Hb was achieving the non-inferiority criteria (-0.75g/dL) in each clinical trial. Both pivotal studies met the primary endpoints.

**: non-dialysis dependent chronic kidney disease
***: hemodialysis dependent chronic kidney disease

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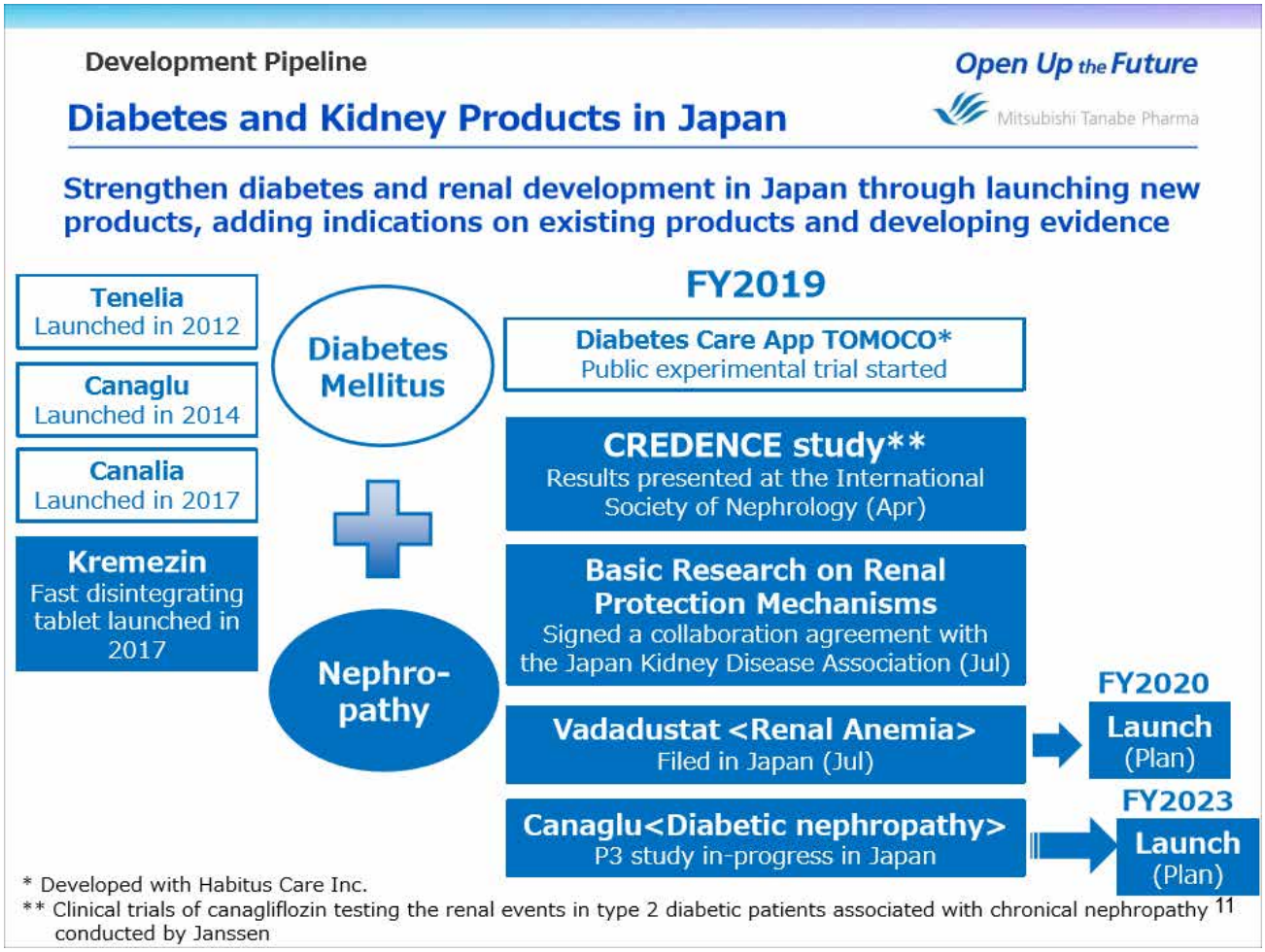
reference: Mitsubishi Tanabe Pharma News Release on March 12, 2019

Next, let me show you the results of the Phase 3 studies in Japan for Vadadustat. Positive results were confirmed in its efficacy in improving anemia and safety, in both non-dialysis and dialysis periods. In two active controlled studies, the differences in mean hemoglobin at week 20 and 24 achieved the noninferiority criteria, thus meeting the primary endpoints.



Next, I would like to discuss our initiatives in diabetes and kidney products in Japan. We have launched three anti-diabetic drugs Tenelia, Canaglu, and Canalia, so far. And in this fiscal year, we started a public experimental trial of TOMOCO, a diabetes care app as the first step in our digital medicine initiatives. In the renal area, we signed a collaborative agreement with Japan Kidney Disease Association, in an effort to overcome renal diseases. Furthermore, as a drug to follow Kremezin, we filed for approval for Vadadustat in Japan. In order to obtain additional indication of diabetic nephropathy for Canaglu, a Phase 3 clinical study is underway in Japan. We will reinforce both areas by launching new products, adding to indications for the existing products, and creating more evidence.

Development Pipeline

Open Up the Future

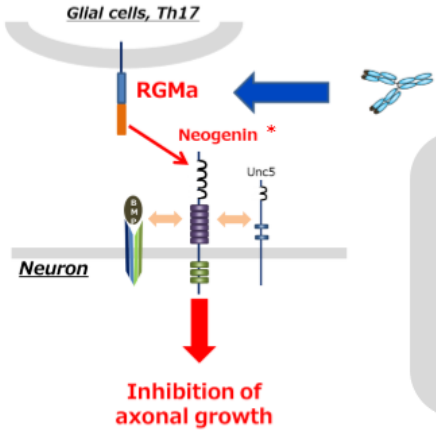
Mitsubishi Tanabe Pharma

MT-3921: Next Growth Driver in CNS Area

Initiation of clinical trial

MT-3921

- Co-discovered **humanized anti-RGMa Ab** with Osaka University
- Novel neurological drug with **neuroregeneration** and **anti-inflammatory effect**
- **Phase I clinical trial for healthy adults is on-going**
- **Traumatic spinal cord injury** is expected as target indication



Stimulate neuroregeneration by inhibiting RGMa-Neogenin* binding

MT-3921
(humanized anti-RGMa antibody)

RGMa (**R**epulsive **G**uidance **M**olecule **a**)

RGMa is expressed in glial cells, immune cells and neuron

- RGMa expression is induced after injury
- Binding with Neogenin inhibits neurite growth and affect regulates inflammation

＊ : RGMa receptor. Expresses in neurons or T lymphocytes.

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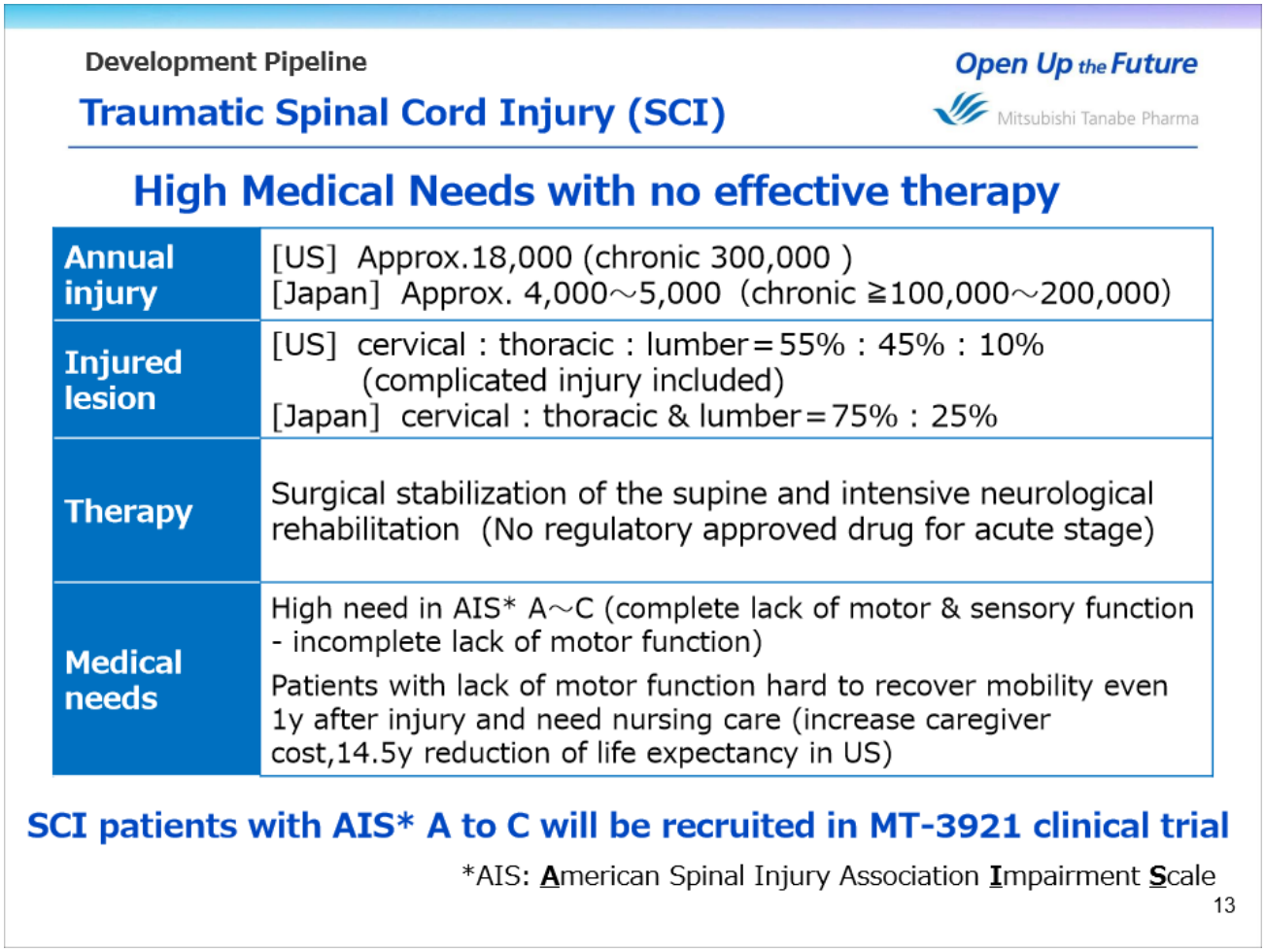
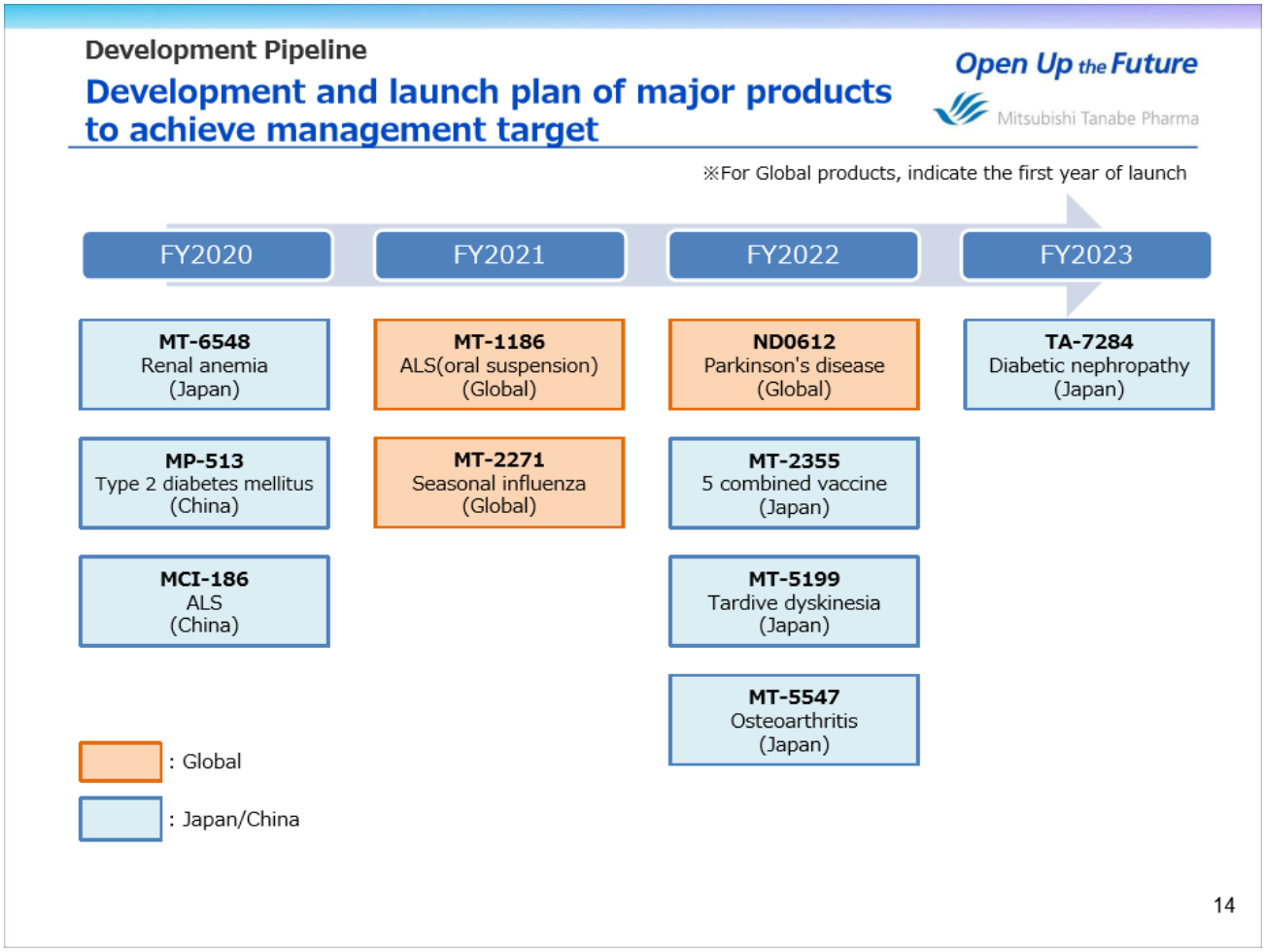
Next, I would like to explain about MT-3921, for which we started a clinical trial as a next driver to enhance the CNS area. MT-3921 is a humanized anti-RGMa antibody co-discovered with Osaka University. A Phase 1 clinical trial for healthy adults was initiated in the first quarter of 2019. RGMa is expressed in glial and immune cells and inhibits the growth of neural axons. This drug can promote the growth of axons, by blocking the actions of RGMa. RGMa is also involved in inflammation. And therefore, this drug inhibits inflammation as well. Through these mechanisms, it is expected to promote neural regeneration after a spinal cord injury.



Please move to page 13. This drug is planned to be targeted at traumatic spinal cord injury. The number of people who get injured in their spinal cord is about 18,000 per annum in the US and 4,000 to 5,000 in Japan. Therapies available are mostly surgical stabilization of the spine and intensive neurological rehabilitation. And there is no regulatorily approved effective drug. The extent of symptoms varies, depending on the severity of the injury. But patients with complete lack of motor and sensory function will not recover mobility after the injury. With increased burden on the patient, as well as on their caregivers, this is a disease with extremely high unmet medical needs. The patient population for the clinical trial for MT-3921 will range from most severe cases, with complete lack of motor and sensory function, to those with incomplete lack of motor function. In order to deliver an innovative drug to patients with the disease, with high unmet medical needs, where there is still no effective therapy, we'll move this development project forward as quickly as possible.



Last but not least, this is the development and launch plan of major products to achieve the management targets. Indicated in orange are global products and their first planned year of launch. That is it from me. Thank you for your attention.

Question & Answer

Takai: We now would like to move on to a Q&A session.

Operator: First, Mr. Hashiguchi, from Daiwa Securities, please.

Hashiguchi: Hashiguchi speaking. Thank you very much. I have a few questions. First, on Gilenya royalty, you said Gilenya royalty income was 1.6 billion yen. Are you receiving the payment you think you're entitled to receive?

Tabaru: Yes. For now. For the January-March period, we received the payment.

Hashiguchi: I think that amount paid to you is booked as liabilities on the balance sheet. Current liabilities are not increasing much, but noncurrent liabilities are going up. You may have a view that it may take around a year until you can recognize this as sales revenue, when this arbitration is over, according to my estimation. Is that too much to assume?

Tabaru: We are making appropriate accounting. You can imagine, based on that.

Hashiguchi: Thank you. Secondly on Vadadustat, this time, have you filed your submission to obtain simultaneous approval for both dialysis and non-dialysis dependent CKD as a package?

Kobayashi: Kobayashi speaking. Yes. You're right. As was shown on page 10, we filed JNDA for both dialysis and non-dialysis patients as a set.

Hashiguchi: Thank you. Next, on MT-8554, for hot flash, is Phase 2 data already published somewhere? And also, when do you start Phase 3 study? And how long do you think it's going to take? Do you have any prospect? This compound was not included in your launch plan today.

Kobayashi: As for MT-8554, we will announce our Phase 2 POC study results at an appropriate timing, according to our plan. In addition, we are also preparing for a study in the next phase. As we said before, we are also considering the possibility of partnering in parallel. We will develop this compound based on that, accordingly.

Hashiguchi: Okay. Understood. Lastly, with regards to MT-3921, you mentioned today, another company entered the clinical stage for an anti-RGMa antibody before. I think it was AbbVie. I don't know whether it worked or not. But it entered the clinical stage a long time ago. Do you know what happened to that compound in the end? How have you been able to differentiate from this competitive product, in your view?

Kobayashi: We heard that AbbVie is developing an antibody with a similar mechanism. But we are not aware of the full details of their development status, as it's about a different company. As for the differentiation, if we can get good clinical data for POC, we can differentiate, in our view. It's too early to talk about what kind of differentiation we can realize.

Hashiguchi: Okay. Understood. That's all from me. Thank you very much.

Tabaru: Thank you very much.

Operator: Thank you very much. Next, Mr. Yamaguchi, from Citigroup, please.

Yamaguchi: I'm Yamaguchi, from Citigroup. Can you hear me?

Tabaru: Yes. Thank you very much.

Yamaguchi: It's not really about the first quarter forecast numbers. But your business results are almost as much as full year forecast already. Of course, there are various factors behind. Originally, your number started from a low level, so there can be a big fluctuation. The achievement rate is extremely high. How should I interpret this? Expenses not incurred in the first quarter may be spent in the second quarter or later. I haven't been able to check in detail. How do you view this situation?

Tabaru: Tabaru speaking. SG&A cost and R&D expenditure didn't progress as much as we planned. That's why core operating profit had high numbers. There is some difference among sales items, but SG&A cost and R&D expenditures are mostly behind. On a full-year basis, there was a slow start at the beginning, but we are going to spend the money later on. That's our forecast.

Yamaguchi: Your numbers look high, but will not deviate so much overall. Just a slow start at the beginning?

Tabaru: Yes. Your understanding is correct.

Yamaguchi: All right. Next, I have two questions about MT-3921. First, there is a mention of chronic patients. But in terms of the mechanism, this drug is given to patients with acute inflammation, before worsening, to prevent it. That's how the drug is going to be used. Correct?

Kobayashi: Kobayashi speaking. Yes. You're right. This drug is administered when acute inflammation or injuries are still continuing, aiming for a recovery.

Yamaguchi: Understood. Under those circumstances, I don't know whether a placebo-controlled study is ethically possible or not. It could be difficult to demonstrate difference. Based on the assumption that the disease is going to worsen in general, is it possible to design a study to judge good or bad, based on a curve?

Kobayashi: We will consult with FDA, or the regulatory authorities in each country, to discuss study designs for Phase 2 and beyond. We will report to you when it's clear.

Yamaguchi: Understood. As for Vadadustat, global CV outcome studies are hot topics for competitive products. Sorry for my naïve question. Do you already have such data for Vadadustat? Or, it's not necessary yet in Japan? Could you share your view?

Kobayashi: As you know, globally, Akebia is conducting global studies, including a CV outcome study. Such results will be available in late 2020, according to the announcement on their website. Like diabetes, CV outcome data is not a mandatory condition for approval in Japan.

Yamaguchi: Understood. Thank you very much.

Kobayashi: Thank you.

Operator: Thank you very much. Next, Mr. Wakao from Mitsubishi UFJ Morgan Stanley Securities, please.

Wakao: Wakao speaking. Thank you for your explanation. First, I have a question on Radicava. I'd like to know the number of patients between April and June. And you withdrew your submission in Europe. How much impact should we assume? It's going to be mainly the oral suspension in the midterm business plan. But I'm sure you developed your targets by including the injectable and European region. How much impact from the withdrawal of your submission in Europe in the mid to long term?

Tabaru: First, on the number of patients on Radicava, a total of 1,840 patients will continue their treatment, as of the end of June.

Wakao: What about the monthly number of new patients?

Tabaru: From April, 100,80 and 70.

Wakao: Okay. Could you comment on the potential impact from the submission withdrawal in Europe?

Tabaru: We incorporated our European sales forecast in the midterm business plan to a certain extent, but please allow us to refrain from answering with specific numbers. We think we need to revisit the plan to a certain degree.

Wakao: Understood. As for the oral suspension, I believe you reached your agreement with FDA based on your own original plan. Bioequivalence study is to be completed at the end of May. Are you planning to present this data soon? Any particular timing?

Kobayashi: Also, for this, we are considering an appropriate timing.

Wakao: At academic society meetings?

Kobayashi: We're not able to disclose clearly, yet.

Wakao: Another question is about ND0612, Phase 3 study design. Are you sure this is a noninferiority study compared to levodopa, among others? I thought you were trying to demonstrate efficacy. Could you give us more details about this study?

Kobayashi: Thank you for the question. We have published a design of this study at the World Parkinson Congress, held in June, in Kyoto. It is a double-blind, double-dummy parallel group study to compare the carbidopa and levodopa arm, and the ND0612 arm.

Wakao: I thought you had originally planned to conduct a noninferiority study. But now you ended up with a simple comparison study. Does that mean that the bar has been raised slightly for this study?

Kobayashi: No. I don't think so.

Wakao: I see. My last question is about Vadadustat. I think uncertain results were observed in studies of other drugs with regard to MACE. As far as Japan is concerned, MACE may be irrelevant. But more recently, should we assume that lack of MACE data may affect your marketing activities after the approval was granted? And that in its effort to penetrate into the market, if the drug has not demonstrated noninferiority or superiority over ESA drugs, it may face difficulty in making inroads into the market. So, my question is, what are your thoughts on the relationship between the marketing in Japan and the MACE data?

Kobayashi: In terms of regulatory approval, as I said, it is not mandatory, but global MACE or CV data will become one of the differentiating factors in marketing the drug

Wakao: I see. Thank you.

Operator: Thank you very much. Next, Sakai-san, from Credit Suisse Securities.

Sakai: Sakai, from Credit Suisse Securities. I have two questions. First, on royalty on Gilenya. I was not able to clearly hear you at the outset. I think I heard you say payment was received for January-March period. Since there is a three-month time lag, the payment was for January March period. Its substance patent was valid until February 2019. And therefore, I thought the payment you received for January-March period has nothing to do with the arbitration proceedings. If you look at the cash balance, it has not increased that much from the end of March. I was wondering whether the amount that you decided not recognize earlier was received

in cash? I understand you will not disclose the amount, but what kind of accounting processing have you gone through? Are you expecting more payment receipt going forward? Could you enlighten me again?

Tabaru: On the question of whether payment was received in accordance with the contract, the answer is yes. The payment for January-March was actually received in April-June period. On the question of whether we have received only for the period, while the patent was valid, our understanding is that payment was done for the amount including the portion Novartis has protested the validity for. For the future, we believe the payment will be done in accordance with the contract.

Sakai: So, you're saying that the full amount, including the portion Novartis has protested the validity for, has been paid and that your understanding is that this practice will continue for the payments for April onward. Am I correct?

Tabaru: Yes. You're correct.

Sakai: And the amount will be posted in the balance sheet, will it not?

Tabaru: Yes. Since we do receive cash, we follow the due accounting process.

Sakai: Thank you. Another question is MT-3921. Life Science Institute, a Mitsubishi Chemical Group company issued a press release in July that it will start developing Muse cell therapy, which is talked about from time to time, to treat spinal cord injury, the same target as your product, though yours is an antibody. Originally, you seemed to have had no rights or interest in Muse cell therapy. But now, your product is in direct competition. Am I correct to understand that both parties are in agreement to stay at arms-length, so to speak, and engage in competition?

Kobayashi: Kobayashi speaking. On our part, based on the results of animal model experiments, we decided to target, as its first indication, acute spinal cord injury, for which the compound was found likely to be most effective. On the other hand, with regard to Muse cell, although we are not in a position to refer to it, according to the press releases and other information, it is targeting at subacute spinal cord injury. Therefore, our target segments are different, or there may be some synergy between us.

Sakai: I see. Thank you.

Operator: Thank you very much. Moving to the next question, Mr. Muraoka, from Morgan Stanley.

Muraoka: Hello. Muraoka, from Morgan Stanley. I need to get back to Gilenya royalty again. From the viewpoint of us, the analysts, can we assume ultimately, that 1.6 billion yen, or something around that figure, times four, will be recognized as sales for the full year? And that the total amount of about 6.4 billion yen in royalty revenue will be in line with your full-year forecast announced at the beginning of the fiscal year?

Tabaru: Yes. The amount we posted in the first quarter is expected to be more or less maintained.

Muraoka: Is there anything more that you can share with us about the breakdown of 1.6 billion yen?

Tabaru: We cannot disclose the break down, and so, cannot comment on that. I'm sorry.

Muraoka: I see. Another question is about the oral formulation of Radicava. The other day, Biohaven Pharmaceutical received a complete response letter for its sublingual form of Rilutek, after it has changed the formulation. It was reported that their problem had to do with API. But what I'm concerned about is such unexpected risks may arise by changing the formulation. Looking at such recent news on similar drugs, if you have found something to worry about, or something that needs more consideration, could you share that with us? If you have not, we can just forget about this question.

Kobayashi: With regard to the oral suspension of Radicava, as indicated in the slide, we reached agreement with FDA and there's nothing to be mindful of at this moment.

Muraoka: Okay. Thank you.

Kobayashi: Thank you.

Operator: Thank you very much. We are running out of time and so, would like to end the Q&A session. Lastly, I would like to ask Mr. Takai to give us closing remarks.

Takai: Thank you very much for joining us for our conference call today, despite your busy schedule. That concludes the conference call. Thank you all for staying with us 'til the end.

[END]