Mitsubishi Tanabe Pharma Corporation

2nd Quarter of FY2019 Business Results Conference Call

October 30, 2019

Event Summary

[Company Name]	Mitsubishi Tanabe Pharma Corporation	
[Event Type]	Earnings Announcement	
[Event Name]	2nd Quarter of FY2019 Business Results Conference Call	
[Fiscal Period]	FY2019 Q2	
[Date]	October 30, 2019	
[Number of Pages]	25	
[Time]	17:45 – 18:26 (Total: 41 minutes, Presentation: 17 minutes, Q&A: 24 minutes)	
[Venue]	3-2-10 Doshu-machi Chuo-ku Osaka-shi, Osaka 541-8505	
[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	Citi Group Global Markets Japan
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Fumiyoshi Sakai	Credit Suisse Securities
	Seiji Wakao	Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.

Presentation

Operator: Welcome to our conference call. Today, we are going to have a briefing on the business results of the second quarter of fiscal 2019 for Mitsubishi Tanabe Pharma Corporation. There will be a presentation on the overview of the business results for about 20 minutes, followed by a question-and-answer session. The total time for the conference call is expected to be about 45 minutes.

Before we get started, please be reminded that the presentation that follows may contain future predictions based on currently available information, all of which includes risks and uncertainties, and that actual results may vary materially from these predictions.

Now, I'd like to invite Mr. Takai from the Corporate Communications Department to moderate the session.

Takai: Let us now start the briefing on our business results of the second quarter of fiscal 2019. Attending this conference call from our Company are Eizo Tabaru, Member of the Board, Managing Executive Officer, and CFO; 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. And I am Takai, Vice President, Head of Corporate Communications Department.

First, Mr. Tabaru will give a presentation on the business results, after which we will entertain questions. Now, Mr. Tabaru, over to you.

Tabaru: Thank you very much for joining us for the conference call to report on the business results of the second quarter of fiscal 2019 of Mitsubishi Tanabe Pharma Corporation. I am Eizo Tabaru, Member of the Board, Managing Executive Officer, and CFO. I'll be discussing business results focused for fiscal 2019 development pipeline and shareholders return.

Q2 FY2019 Business Results

Q2 FY2019 Financial Results

Open Up the Future

Mitsubishi Tanabe Pharma

	FY2019 Q2	FY2018 Q2	Increase / Decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	188.1	209.7	(21.6)	(10.3)	187.0	100.6
[Domestic]	154.6	146.4	8.1	5.6	153.6	100.6
[Overseas]	33.4	63.2	(29.7)	(47.0)	33.3	100.5
Overseas sales ratio	17.8%	30.1%			17.8%	
Cost of sales	88.5	86.1	2.3	2.8	87.5	101.2
Sales cost ratio	47.1%	41.1%			46.8%	
Gross profit	99.6	123.5	(23.9)	(19.4)	99.5	100.1
Core operating profit	11.6	34.5	(22.8)	(66.1)	4.5	259.9
Operating profit	12.5	34.5	(21.9)	(63.6)	5.0	251.2
Net profit attributable to owners of the Company	8.3	24.9	(16.6)	(66.7)	4.0	207.9
Average exchange rate US$	¥108.67	¥110.71			¥110.00	

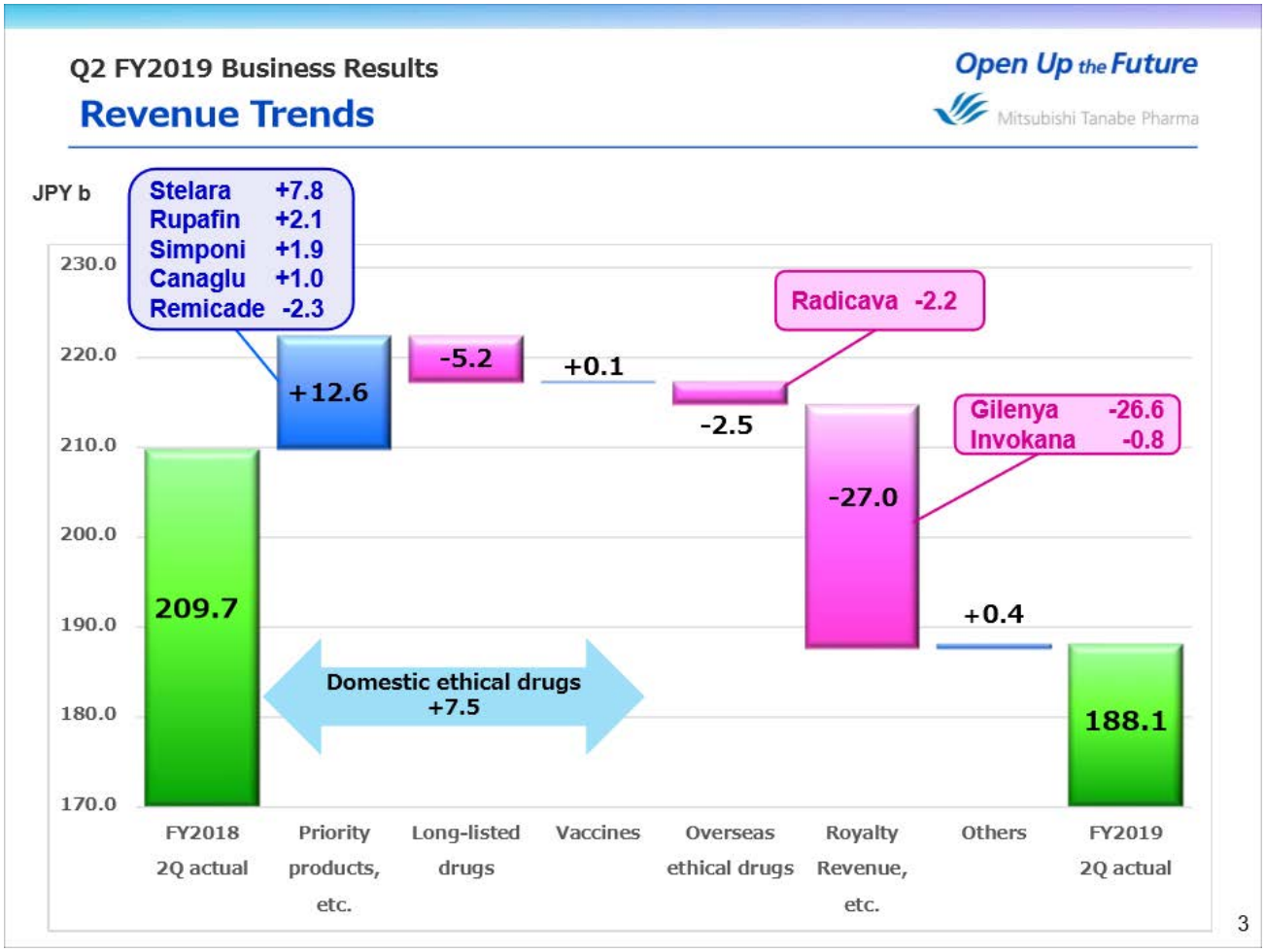
*: Announced on May 10, 2019 in the financial results of FY2018

2

Let me first explain about the business results of the second quarter of fiscal 2019. Please take a look at slide two.

Revenues continued to be driven by domestic mainstay products in the second quarter. On the other hand, as arbitration proceedings with Novartis are underway, in accordance with IFRS 15, part of the royalty income of Gilenya has not been recognized as revenue. We ended up with revenues of 118.1 billion yen, down 21.6 billion yen, or 10.3%, from the year before.

The profits at all line items of the P&L. So, a decline year-on-year, mainly due to this impact from royalty income of Gilenya. Gross profit declines to 99.6 billion yen, core operating profit 11.6 billion yen, and net profit attributable to the owners of the parent 8.3 billion yen. As we made announcement on our revisions to the forecast on October 25th, because accrual of some SG&A and R&D expenses have been postponed to the second half, core operating profit and all the other profits below in P&L significantly overachieved the forecast announced on May 10.



Let me now explain about factors behind the increase and decrease of revenues using the graph.

Among domestic ethical drugs, contribution by Stelara, for which we changed a sales arrangement with Janssen Pharma, as well as growth of mainstay products, such as Rupafin, Simponi, and Canaglu, pushed up sales by 7.5 billion yen year-on-year. Overseas ethical drugs fell by 2.5 billion yen year-on-year. Radicava declined by 2.2 billion yen, as it was prescribed to most of the patients who have been waiting for the drug to be launched, but the revenue of Radicava is still at the level of our forecast for this fiscal year. The number of patients who Radicava was prescribed to reached a total of about 4,200, as of the end of September.

Royalty revenue, etc., dropped by 27 billion yen from the year before, due to decreased income from Gilenya, as I said earlier. As a result, revenues fell by 21.6 billion yen, to 188.1 billion yen.

Q2 FY2019 Business Results

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

Open Up the Future

Mitsubishi Tanabe Pharma

	FY2019 Q2	FY2018 Q2	Increase / Decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	188.1	209.7	(21.6)	(10.3)	187.0	100.6
Cost of Sales	88.5	86.1	2.3	2.8	87.5	101.2
Sales cost ratio	47.1%	41.1%			46.8%	
Gross profit	99.6	123.5	(23.9)	(19.4)	99.5	100.1
SG&A expense	46.8	47.7	(0.9)	(1.9)	49.0	95.6
R&D expense	39.7	39.5	0.2	0.6	44.5	89.4
Amortization of intangible assets associated with products	1.2	1.4	(0.2)	(14.5)	1.3	96.5
Other income and expense*2	(0.0)	(0.3)	0.2	-	(0.2)	-
Core operating profit	11.6	34.5	(22.8)	(66.1)	4.5	259.9

*1: Announced on May 10, 2019 in the financial results of FY2018 *2: Brackets indicate expense and loss

4

Next, let me discuss cost of sales, SG&A expenses, and core operating profit.

Cost of sales increased by 2.3 billion yen. Cost of sales ratio went up by 6 percentage points, to 47.1%, due to changes in the product mix and a significant drop in the royalty revenue. SG&A expenses decreased slightly year-on-year, while R&D expenses was almost flat, but was behind the original forecast.

Consequently, the core operating profit dropped by 22.8 billion yen, to 11.6 billion yen. How it compares to the original forecast is as shown on this slide.

Q2 FY2019 Business Results

Non-recurring items and Net Profit

Open Up the Future

Mitsubishi Tanabe Pharma

	FY2019 Q2	FY2018 Q2	Increase / Decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	11.6	34.5	(22.8)	(66.1)	4.5	259.9
Non-recurring items*2	0.8	-	0.8	-	0.5	173.0
Operating profit	12.5	34.5	(21.9)	(63.6)	5.0	251.2
Financial income	0.5	0.5	(0.0)	(4.6)		
Financial expense	0.9	0.2	0.7	262.3		
Net profit attributable to owners of the Company	8.3	24.9	(16.6)	(66.7)	4.0	207.9

*1: Announced on May 10, 2019 in the financial results of FY2018 *2: Brackets indicate expense and loss

5

As for the items below core operating profit, the operating profit was 12.5 billion yen, down 21.9 billion yen. Financial income and expense are as shown in this slide. Financial expenses were incurred mostly due to foreign exchange. These have resulted in a decline of 16.6 billion yen in the net profit attributable to owners of the parent company, to 8.3 billion yen.

Forecasts of FY2019

Forecasts of FY2019

Open Up the Future

Mitsubishi Tanabe Pharma

The full-year consolidated financial forecasts for FY2019 remain unchanged from the previous announcement (Announced on May 10, 2019)

	FY2019 Forecasts	FY2018 Actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	376.0	424.7	(48.7)	(11.5)
[Domestic]	308.3	307.7	0.6	0.2
[Overseas]	67.6	117.0	(49.3)	(42.2)
Overseas sales ratio	18.0%	27.6%		
Cost of sales	178.5	180.6	(2.1)	(1.2)
Sales cost ratio	47.5%	42.5%		
Gross profit	197.5	244.1	(46.6)	(19.1)
Core operating profit	10.0	55.8	(45.8)	(82.1)
Operating profit	11.5	50.3	(38.8)	(77.1)
Net profit attributable to owners of the Company	5.0	37.3	(32.3)	(86.6)
Average exchange rate [USD]	¥110.00	¥111.07		

7

Let me now move onto the forecast for fiscal 2019. Please take a look at page seven.

Royalty revenue is expected to remain affected by the arbitration proceedings with Novartis in the second half, while the expenses postponed from the first half are expected to be incurred for the full year. Therefore, the full-year forecast has been left unchanged from the forecast as shown on this slide.

Development Pipeline

Open Up the Future

Mitsubishi Tanabe Pharma

Progress of Major Development Pipeline

Progress Update

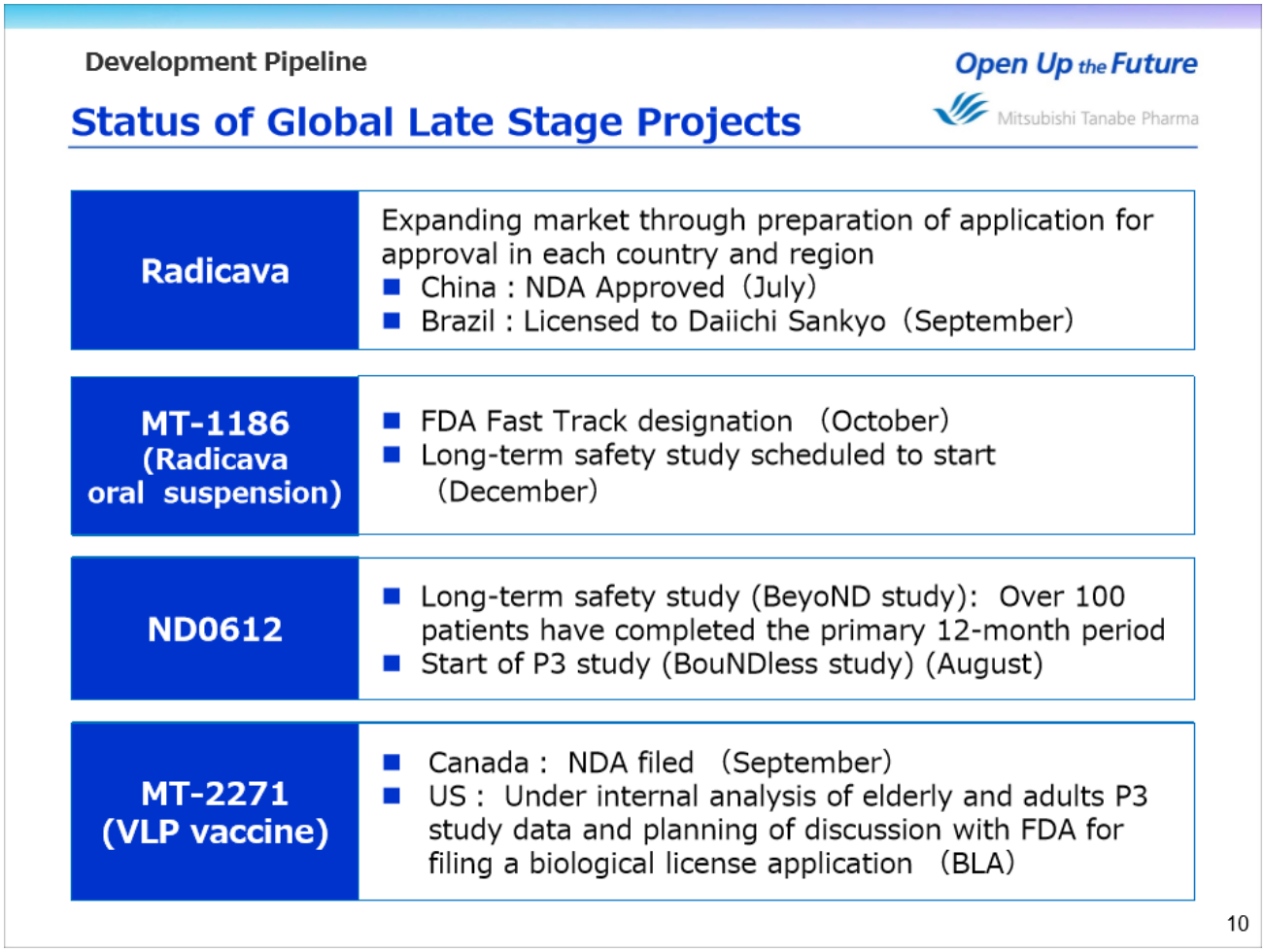
Progress since the announcement of first quarter results in July 29, 2019

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
Central nervous system	MCI-186	Global	ALS*1					China
	MT-1186	Global	ALS*1/oral suspension			Preparing		
	ND0612	Global	Parkinson's disease					
	MT-8554	Global	Vasomotor symptoms associated with menopause			Preparing		
	MT-3921	Global	Spinal cord injury					
	MT-0551/Inebilizumab	Japan	Neuromyelitis Optica Spectrum Disorder				Preparing	
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
	MT-6548	Japan	Renal anemia					
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2271	Global	Seasonal influenza/VLP vaccine*2				Canada	
	MT-2355	Japan	5 combined vaccine*3					

*1: Amyotrophic lateral sclerosis
*2: US; Under internal analysis of elderly and adults P3 study data
*3: Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

9

Now, I would like to discuss the development pipeline. Please take a look at page nine, which shows the status of major development pipeline. Items that have made progress since the earnings report for the first quarter of fiscal 2019 are highlighted in blue. They will be explained later with separate slides.

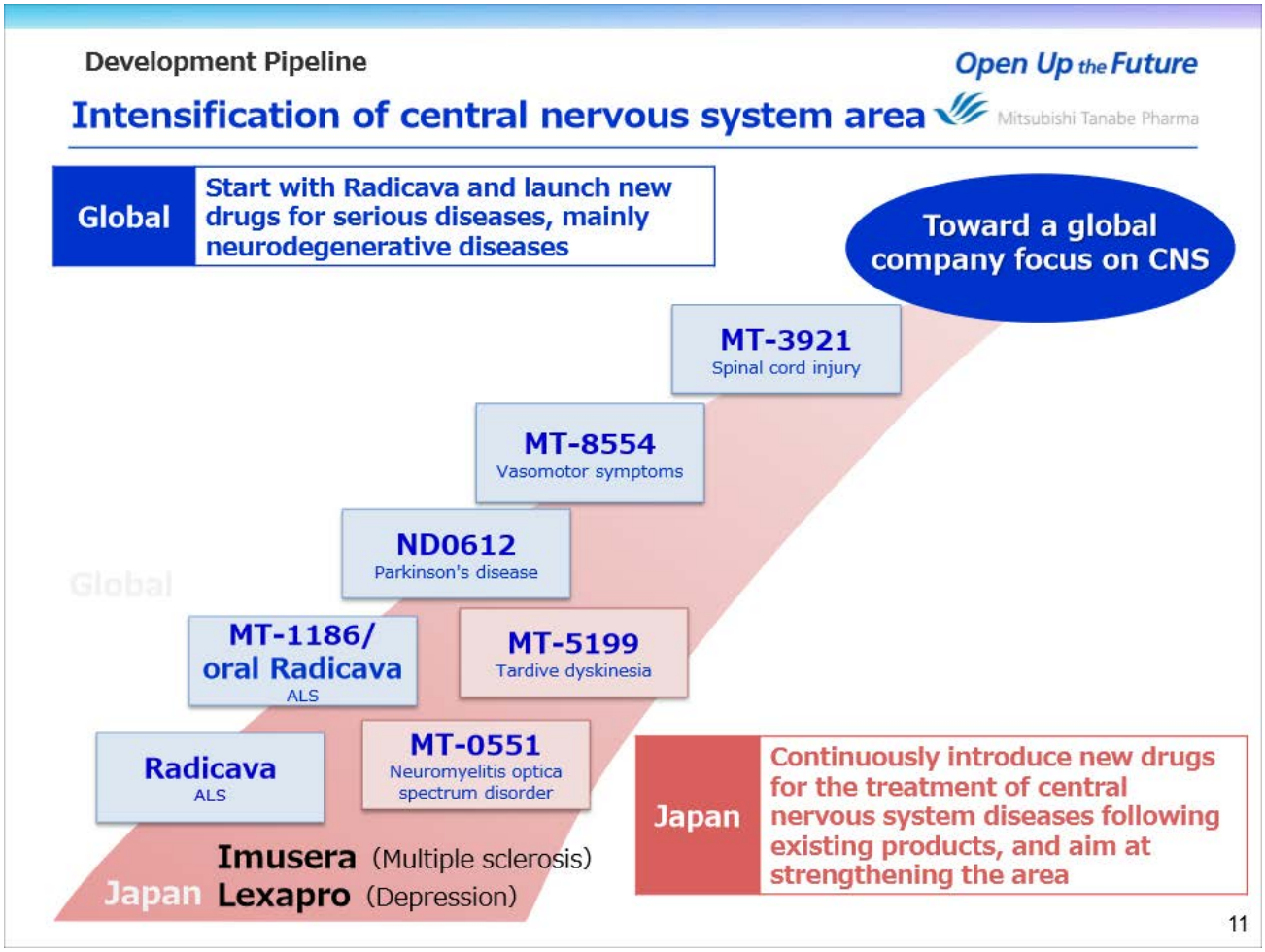


Let me discuss the progress made for global late-stage projects on page 10.

ALS treatment drug, Radicava, has been filed for approval in different countries and regions in parallel. Following Japan, Korea, US, Canada, and Switzerland, China, in July, became the latest country where approval was granted. The oral formulation of Radicava, MT-1186, was given a fast-track designation by FDA in October. A long-term safety study is planned to start in December.

ND0612, a drug for Parkinson's disease, in its long-term safety study, has reached a target sample size of 100, in terms of the number of patients on this drug for 12 months. Moreover, a phase 3 study, called BouNDless, was started in August, in which the drug is being compared to its oral formulation.

MT-2271, a seasonal influenza VLP vaccine, was filed for approval in September in Canada. In the US, data on the elderly and adults are under internal analysis, and consultations with the FDA are being scheduled prior to the application for approval.



Now, I would like to introduce measures for intensification of central nervous system area.

We are aiming to become a global company with CNS at its core. Globally, we will start with Radicava and launch new drugs for serious diseases, namely neuro-regenerative diseases including ND0612, targeting Parkinson's disease, and MT-3921, targeting traumatic spinal cord injuries. And in Japan, multiple sclerosis drug, Imusera, and depression drug, Lexapro, and we will be followed by domestic introduction of global products, in addition to MT-0551 and MT-5199, continuously introducing new drugs for the treatment of central nervous system diseases, following the existing products and aimed at strengthening the area.

Development Pipeline (Global)

Open Up the Future

Mitsubishi Tanabe Pharma

Radicava

Biomarker study for ALS patients in the United States has started

Study purpose	Identify specific biomarkers as the indicators of disease progression
Study design	A prospective, observational, multicenter study
Study subjects	Approximately 300 patients with ALS who have not been prescribed Radicava prior to this study (about 40 sites in the United States)
Treatment period	24 weeks
Study period	October 2019 to 2Q 2021
Endpoints	Biomarker testing and Clinical assessments are performed at baseline (before Radicava treatment), during the treatment periods, and at the end of treatment ■ Biomarker : Oxidative stress, Inflammation, Neuronal injury and death, Muscle injury ■ Clinical assessment : ALSFRS-R*1 (function), ALSAQ-40*2 (QOL) etc.
Schedule in future	Interim analysis is planned in 2020

*1: ALS Functional Rating Scale Revised (measuring activities of daily living, consisting of bulbar, fine motor, gross motor, and respiratory domains)
*2: ALS assessment questionnaire (measuring Quality of life specific to ALS, consisting of physical mobility, ADL/independence, Eating & Drinking, Communication, and Emotional functioning domains)

12

Next, I would like to explain the progress of each product. Please turn to page 12.

First, Radicava. Biomarker study for ALS patients in the United States has started. Approximately 300 patients with ALS in about 40 sites in the United States will have biomarker testing and clinical assessments performed at baseline before Radicava treatment and at the end of the treatment. With this study, we will identify specific biomarkers as the indicators of disease progression, to offer more appropriate treatment options for ALS patients.

Development Pipeline (Global)

Open Up the Future

Mitsubishi Tanabe Pharma

MT-1186 (oral Radicava)

Agreed development plan for oral Radicava with FDA and PMDA
Long-term safety study scheduled to start (December)

- **PK study comparing oral formulation vs IV in healthy subjects were completed**
- **Fast track designation**

Study purpose	In patients with ALS, confirm long-term safety and tolerability of oral Radicava, using equivalent dose and dosing regimen with IV
Study design	Open-label, multicenter study
Study subjects	Approximately 150 patients with ALS
Treatment period	48 weeks
Study period	December 2019 to 2Q 2021
Endpoints	■ Safety and Tolerability ■ ALSFRS-R* (function)
Schedule in future	■ Prompt NDA submission to FDA using 24-week data ■ Target launch in FY2021 (US)

*: ALS Functional Rating Scale Revised

13

Next, MT-1186, oral Radicava.

We have reached agreement for development plan towards filing for oral Radicava with FDA in July and with PMDA in August. Long-term safety study is scheduled to start before the end of the year, and bio-equivalent studies, comparing oral formulation against IV, in healthy subjects have been completed, and PK profile equivalent to IV has been confirmed. Fast-track designation was received from FDA in October with prompt NDA submission to FDA using 24-week data will be made, with a target launch in fiscal year 2021 in the US

Development Pipeline (Global)

Open Up the Future

Mitsubishi Tanabe Pharma

ND0612

Started the P3 study （BouNDless study）

Study purpose	The BouNDless is aimed to establish efficacy, safety, and tolerability data evidence of continuous subcutaneous ND0612 infusion in comparison with oral levodopa/carbidopa in patients with PD experiencing motor fluctuations.
Study design	A multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial
Study subjects	300 patients, Male and female patients, aged 30 Years to 80 Years
Evaluation period	Evaluation of the change from baseline to double-blind double-dummy maintenance period (12 weeks)
Study period	August 2019 to May 2021
Primary endpoint	ON time without troublesome dyskinesia
Patient Population*	[US] Approx. 1 million, [EU] Approx. 1.2 million, [JP] Approx. 100 thousand
Schedule in future	Submission for FY2021, launch for FY2022

*Source : US, Parkinson's foundation website (2018)
EU, European Parkinson's Disease Association web site (2011)
JP, Japan Intractable Diseases Information Center (2012)

14

Next, an update on ND0612.

As announced through press release in August, phase 3 study has started in the US and Europe. The study purpose of the BouNDless is aimed to establish efficacy, safety, and tolerability data, evidence of continuous subcutaneous ND0612 infusion, in comparison with oral levodopa and carbidopa, in patients with PD experiencing motor fluctuations. It is an active control double-blind study, with evaluation at week 12 of its superiority. We are planning for submission for fiscal year 2021 and launch for fiscal year 2022.

Development Pipeline (Global)

Open Up the Future

Mitsubishi Tanabe Pharma

MT-8554

POC study in patients with vasomotor symptoms has been completed in US

Mode of Action	TRPM8 (transient receptor potential melastatin 8) antagonist
Development stage	In preparation for P3 study (Confirmed the efficacy was based on the mechanism, and in consultation with FDA)
Target indication	Vasomotor symptoms associated with menopause
Patient Population*	Incidence with moderate to severe vasomotor symptoms [US] Approx. 10 million [Japan] Approx. 3 million
Feature	High safety profile owing to a novel non-hormonal mechanism of action
Schedule in future	Preparation for P3 program in parallel with partnering activity

*: in-house survey

15

Next is MT-8554.

The target indication is vasomotor symptoms, with phase 2 study completed in the US, confirming efficacy based on its mechanism, and we are in preparation for phase 3 study. In parallel with phase 3 study alliance activity is ongoing as high safety profile owing to another non-hormonal mechanism of action is expected for vasomotor symptoms associated with menopause.

Development Pipeline (Global)

Open Up the Future

Mitsubishi Tanabe Pharma

MT-3921

P1 study protocol in patients with Spinal Cord Injury submitted to the US IND

Mode of Action	Humanized anti-RGMa*1 antibody
Development Stage	P1 study in healthy adults ongoing in Japan
Target indication	Traumatic spinal cord injury (SCI)
Patient Population*2	Estimated annual incidence of SCI with AIS*3 A~C (complete lack of motor and sensory function ~ incomplete lack of motor function) [US] Approx. 7,000 [Japan] Approx.1,500~2,000
Schedule in future	P1 study in SCI patients is expected to start in 2019 in US

*1 : Repulsive Guidance Molecule a
*2 : in-house survey
*3 : American Spinal Injury Association Impairment Scale

16

Next is MT-3921.

It is a humanized anti-RGMa antibody from collaborative research with Osaka University. It promotes neurite elongation by blocking actions of RGMa. RGMa is also involved in inflammatory reaction, and MT-3921 has anti-inflammatory effects. With these actions, it is expected to promote nerve regeneration after spinal cord injury. Phase 1 study in healthy adults is ongoing in Japan, and phase 1 study in SCI patients is expected to start by the end of the year in the US, with phase 1 study plan submitted to the FDA.

Development Pipeline (Japan)

Open Up the Future

Mitsubishi Tanabe Pharma

MT-0551 (Inebilizumab)

MTPC has acquired exclusive development and commercialization rights

Mode of Action	Humanized anti-CD19 monoclonal antibody
Origin	Viela Bio, Inc. (Maryland, United States)
Development Stage	Under preparation of Biologics License Application (FDA has accepted Biologics License Application by Viela Bio for review)
Target indication	Neuromyelitis Optica Spectrum Disorder (NMOSD) ※ Development and commercialization in other indications are under consideration NMOSD is an autoimmune disease that causes optic neuritis and myelitis, leading to symptoms such as loss of visual acuity, limbs paralysis, neuropathic pain, and sensory loss
Territory	Japan, Taiwan, Korea, Singapore, Indonesia, Thailand, Malaysia, the Philippines, and Vietnam
Features	■ Efficacy : 73% reduction in the risk of NMOSD attacks*1, and clinically significant reduction also in EDSS*2, hospitalizations, and MRI*3 lesions ■ Administration : Every 6 months infusion*4 as a maintenance monotherapy
Patient Population	[Japan] Approx. 5,000 patients
Schedule in future	Biologics License Application expected in FY2020 / Potential launch in FY2021 (in Japan)

*1: N=230, intention-to-treat analysis
*2: expanded disability status scale
*3: magnetic resonance imaging
*4: 300 mg intravenous (Day 1, 15, and every 6 months thereafter)

17

Next is MT-0551, Inebilizumab.

We concluded license agreement with Viela Bio, Incorporated, on October 8, and we acquired exclusive development and commercialization rights in Japan and Asia for NMOSD, with global phase 3 study already completed. This is a humanized anti-CD19 monoclonal antibody. It has an action to deplete plasma blasts that produce auto-antibody and CD19 expressing B cells. It is a monotherapy product to be administered at day 1, day 15, and subsequently every six months. Clinically significant inhibitory effect is shown for EDSS, Expanded Disability Status Scale. There are no approved drugs for NMOSD here in Japan, with high unmet needs, with approximately 5,000 patients domestically. We are preparing for filing in Japan in fiscal year 2020, followed by launch in fiscal year 2021.

Development Pipeline (Japan)

Open Up the Future

Mitsubishi Tanabe Pharma

MT-5199 (Valbenazine)

P2/3 study in Japan ongoing (Subject enrollment completed)

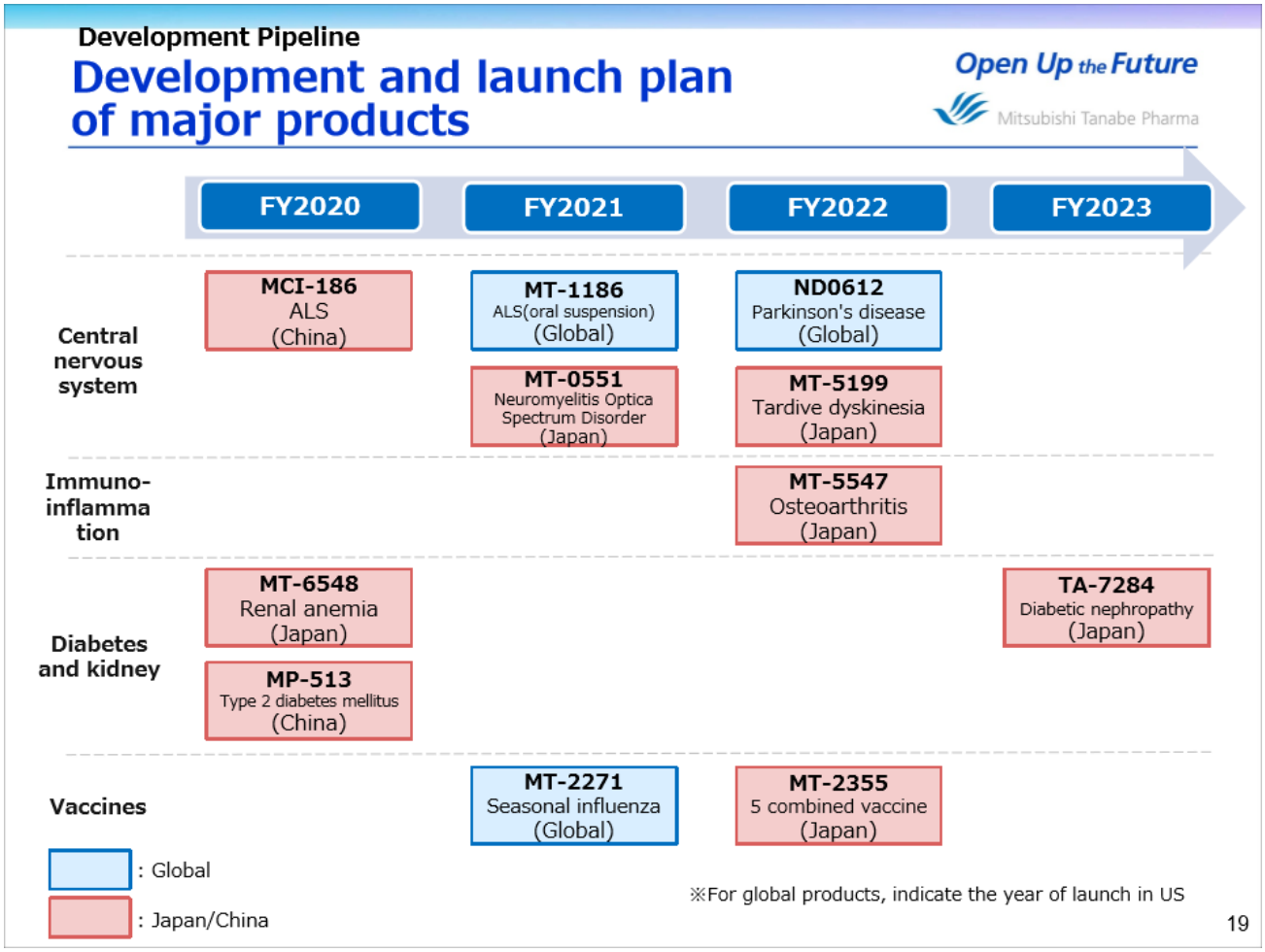
Mode of Action	Inhibition of vesicular monoamine transporter 2 (VMAT2)
Origin	Neurocrine Biosciences (US) ■ Marketing approval for Tardive dyskinesia (April 2017) and launch as "INGREZZA " in the US ■ Prix Galien USA Award* nominated
Development Stage	P2/3 study in Japan
Target indication	Tardive dyskinesia ■ A neurological condition characterized by involuntary movements. Most often it develops after long-term antipsychotic drug use. ■ There is no approved drug for Tardive dyskinesia treatment in Japan.
Territory	Japan and Asian countries
Schedule in future	NDA in FY2021, Launch in FY2022 (in Japan)

*: An authoritative award for the development of an innovative medicine where the entry criteria is approved by the FDA within 5 years and has the potential to make a significant contribution to human health

18

Next is MT-5199, Valbenazine.

We are conducting phase 2 and 3 study in Japan, with subject enrollment completed. So, this is the overview. The mode of action is the inhibition of vesicular monoamine transporter 2, VMAT2, inducted from Neurocrine Biosciences in 2015. Marketing approval for tardive dyskinesia and launch of INGREZZA in the US has been achieved. It was nominated for the Prix Galien USA award. This is a prestigious award given to innovative pharmaceutical development. There are no drugs in Japan indicated for tardive dyskinesia, and we will pursue development to offer novel treatment to patients in the fiscal year 2021 and launching fiscal year 2022 in Japan is planned.



Slide 19 shows development and launch plan of our major products.

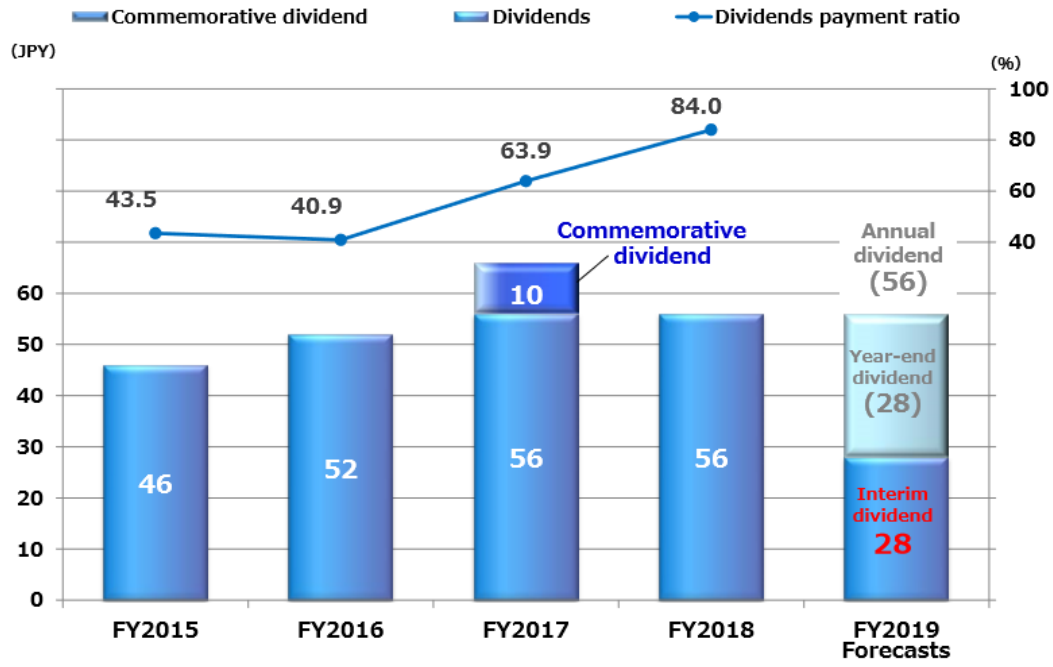
Shareholders Return

Dividends Trends

Open Up the Future

Mitsubishi Tanabe Pharma

- The company will pay the interim dividend for 2019, ¥28 as expected
- Maintain current level of dividends (annual dividend of ¥56) during period of Medium-Term management Plan 16-20



21

Lastly, allow me to explain shareholders' return. As for dividends, the Company will pay the interim dividend for 2019, 28 yen, as planned. We plan to maintain current level of dividends, annual dividends of 56 yen, during the period of the medium-term management plan, reflecting the revision announced in November of last year.

That concludes my presentation. Thank you.

Question & Answer

Operator: The first question is from Mr. Hashiguchi of Daiwa Securities.

Hashiguchi: Hashiguchi from Daiwa Securities. I have several questions on the pipeline. The first question is about Radicava in China. Could you tell us your marketing strategies? Are you going to seek to obtain insurance reimbursement, or do you plan to market the product at a free market price? Could you also comment on your view on the sales potential there?

Kobayashi: Kobayashi will answer that question. Since this is an orphan drug and we were given approval from the Chinese authority in an expedited manner, in order to ensure the drug will be delivered to patients as soon as possible, we would like to start selling the product initially at a free market price. As we consult with authority, if it is determined that reimbursement will be possible, we hope to get it reimbursed.

Hashiguchi: What levels of prices do you have in mind at the time of launch, and when do you expect to launch the product?

Kobayashi: That depends on our negotiations with the Chinese authority, and therefore, we cannot say exactly when at this time. Hopefully, as soon as possible.

Tabaru: We are hoping to launch it during the next fiscal year, but there is also an inspection on the product quality, and we are now working to determine the timing of launch.

Hashiguchi: Thank you. I also want to ask about MT-2271, an influenza vaccine. Could you comment on whether the situation in the US has not changed from what you have been describing conventionally? Previously, you have been saying that, based on the result of the phase 3 study on elderly patients, you were expecting to file for approval in the first quarter. Has the result of the study on the elderly patients been just as you had expected, and am I correct to assume that your schedule after submission has not changed?

Kobayashi: Kobayashi will answer that question. As we described on slide 10, things have not changed. We expect that, after interpreting the results of the study on elderly patients of the phase 3 study, we will consult with the FDA.

Hashiguchi: And can we assume that the result of the analysis so far was satisfactory to you?

Kobayashi: We believe that the result was positive enough for us to take to the FDA for consultation.

Hashiguchi: Thank you. My last question is about MT-3995. I recall you explained previously that you were expecting to obtain the result of the POC study for the indication of NASH in the second quarter. Can you update me on the current status of this?

Kobayashi: I think we were asked about this last time as well. We did obtain the result of the study for NASH, which was performed here in Japan. In accordance with the mode of action, we believed that we were able to determine efficacy to some extent, but as you probably know, if are we to seek approval on the indication of NASH, we would have to conduct an extremely large-scale study, and therefore, while looking for a partner to work with us, we are trying to come up with an exit strategy going forward.

Hashiguchi: Thank you.

Operator: Thank you very much, Mr. Hashiguchi. The next question is from Mr. Yamaguchi from Citi.

Yamaguchi: I am Yamaguchi from Citi. Thank you. My first question is on MT-8554. Can we see the results of the POC study disclosed somewhere?

Kobayashi: We are now preparing for publishing the result at an academic congress, and so, we expect to report it to you very soon.

Yamaguchi: I see. This product, if you plan to market overseas, will probably require a certain level of distribution network. You indicated in the slide that you are engaged in partnering activities. Does that mean your basic policy is to license it out? This is somewhat different from drugs in CNS area, or are you pursuing both opportunities in parallel? I'm asking about overseas market.

Kobayashi: Basically, we would like to look for a partner.

Yamaguchi: I see. My second question is about the arbitration proceedings for Gilenya. I understand that proceedings are ongoing, but in your eyes, has there been some new developments or any progress for the last three months?

Tabaru: They are now underway. It is not the case that there has been any major trouble or hindrance. They are underway. Since there are no other precedents from other companies, I'll assume it would a bit difficult to estimate the time to be taken.

Yamaguchi: When you say "underway," it usually implies that both parties are making preparations and having meetings in order to reach an agreement in arbitration. So, are you saying those activities are taking place steadily?

Tabaru: Well, yes, steadily. Yes. For arbitration cases, each of the parties involved is obligated to keep confidentiality, and therefore, the status of the other companies is not visible to us at all, and we are not in a position to disclose anything about us.

Yamaguchi: I see. Then, there's no telling when it will come to an end?

Tabaru: That is correct. We can't comment on the schedule, either.

Yamaguchi: As Mr. Tabaru said earlier, despite everything you have gone through, you have over-achieved the full-year forecast in the second quarter. There are also some budgeted expenses that have yet to be used. But, do you assume operating losses in the third and fourth quarters, or the probability is so low that are you going to review it as needed?

Tabaru: Some of the expenses have been moved down to the second half, and they are supposed to be incurred as budgeted on the full-year basis. With regard to how we are going to spend actually, we expect to have more visibility toward the end of the year when we report earnings for the third quarter, and so, we are going to revise our focus if necessary.

Yamaguchi: Thank you.

Operator: Thank you, Mr. Yamaguchi. The next question is from Mr. Muraoka of Morgan Stanley.

Muraoka: Muraoka from Morgan Stanley. With regard to the dividend, you said the current level will be maintained through the end of the current medium-term management plan in 2020. I would love to take your words at face value, but that would mean you will need 30 billion yen annually. I am fully aware that you have cash on hand of 15 billion yen sitting on the balance sheet. Is there any discussion inside your Company as to whether maintaining this policy is appropriate?

Tabaru: Yes, we asked the Board of Directors to deliberate on this before we announced the policy externally. We said our dividend per share will remain 56 yen. Though we are going through arbitration procedures, we kept insisting that we are entitled to the royalty income. Given that, we are at the level assumed in the medium-term management plan, and therefore, we will maintain 56 yen per share. Our understanding is that there have been no changes since we decided on this policy, and therefore, we will carry on with this plan.

Muraoka: Does that mean it is unlikely that your philosophy will be changed in the next fiscal year?

Tabaru: It would be difficult for us to make commitments for the future, but in November of last year, we announced that we will stick with this policy through the end of the current medium-term management plan, which remains unchanged on our part.

Muraoka: I see. My next question is about MT-7117, a drug for EPP. I would assume the result of this phase 2 study is out by now. Any updates you can share with us?

Kobayashi: We are on track, and so, we will be able to update you soon.

Muraoka: But you have no received the results yet, have you?

Kobayashi: No, but we are expecting to receive it soon.

Muraoka: My last question is what sort of information we can expect to get at the upcoming IR meeting on November 25th.

Takai: Takai speaking. Based on our understanding of where we are vis-à-vis the medium-term management plan, one year prior to the end of the period, we intend to make preparations to update you on our revenue forecast as well as the future strategies of NeuroDerm, if possible.

Muraoka: I see. Thank you.

Operator: Thank you very much, Mr. Muraoka. Next is Mr. Sakai from Credit Suisse.

Sakai: Yes, I have one question. I was not able to listen in to the first half of the presentation, so I'm sorry if my question is redundant. My question is on the tax rate of your Company. You may not like me asking about the period already ended, but for the fiscal year ended March 2019, I believe saw impacts of deductible expenses and the structure reform expenses, but for this fiscal year, the second quarter just ended, and the tax rate has not been done. Received royalties from Gilenya, I believe is taxable. Is this making the tax rate seem high on the surface? How are you treating this accounting-wise? In other words, how is it processed post-arbitration? If it is settled in the way you have explained, what will happen?

Tabaru: As for the tax rate, the total profit is small, at around a level of 10 billion yen, and with R&D expenses for NeuroDerm and Medicago being quite high, it results in no tax effects. This being the reason the effective tax rate seems very high on the surface, but this is not in relevance to the situation concerning Gilenya.

Sakai: I understand. However, the royalty received from the Novartis is taxable? Is that the correct understanding?

Tabaru: Yes, when the arbitration is settled, tax accounting will occur. That is when it is processed as a batch.

Sakai: Is that correct?

Tabaru: Well, taxation wise, there are complexities. So, we will refrain from disclosing the details.

Sakai: Thank you very much.

Operator: Thank you very much, Mr. Sakai. Next is Mr. Wakao from MUMSS.

Wakao: My name is Wakao from Mitsubishi UFJ Morgan Stanley Securities. I have two questions. I would like to confirm the positioning of the biomarker study targeting ALS patients. Would you be utilizing the results of the biomarker study for R&D of future products? Is there a potential for you to show analytical results, meaning upside impact, on sales of the current Radicava or the oral Radicava? Please explain how you position this study.

Kobayashi: This is Kobayashi. As you know in the US, we obtained approval just with Japanese data for ALS. So, we are short on data, and drugs available for ALS is limited at the moment. So, the various pathology is not fully known. In that sense, we will be utilizing the outcome of this study to find out the possible biomarkers, what kind of actions they may have, which will allow early diagnosis of ALS patients or confirm efficacy, etc. So, this study will deepen the understanding of this disease, as well as of Radicava.

Wakao: And interim analysis will be conducted during 2020? Will the results be disclosed?

Kobayashi: It will be disclosed at the appropriate timing. The overview of the biomarker study has already been announced at the medical congress in Orlando in April 2019. If we obtain data with the reporting, it will be done in a timely manner.

Wakao: Thank you very much. The other question is about in-licensed product MT-0551. Compared to competitor's product for this disease, like Chugai's Satralizumab or Soliris (Eculizumab), what is the potential that MT-0551 has? What are its characteristics? There seems to have high recurrence suppression rate and convenience, as it is only required to dose every six months, making it superior. Do these two characteristics show that it is superior against competitor's products?

Kobayashi: Yes, as indicated, three compounds are now being developed for NMO. I don't have good enough understanding of the data of other drugs, so how we can differentiate our product against the competitors will be made clear as we accumulate more data after launch. But, having said that, all three compounds target CD19, complements and IL-6 receptors. So, efficacy will be confirmed to advance differentiation. But as for patients, they will be offered not only one but three drugs, making it possible to choose an optimal therapy, which is a very good thing, but as you mentioned, the dosing interval is longest for Inebilizumab, which is very convenient. Short-term results show good efficacy, and it was confirmed that we can submit with short-term data, so we will continue to confirm long-term efficacy and safety, and differentiate our products from others at the same time.

Wakao: Thank you very much. I understand. Continuing with Inebilizumab, you mentioned that there are 5,000 patients in Japan. Are they all target of this drug? And as it targets B cells, urinary tract infection and other infections are listed as possible adverse events. Will this be a burden on the drug? Are there any adverse effects that cause special concerns?

Kobayashi: Well, people do mention the adverse effects, but the number of UTIs is limited, and the result is not so different from the placebo. But this is just short-term results, so we would like to follow up on a long-term basis. There are no high-risk points currently. As for the targeted population, patients have, for example, different complications and different paths of physiologies, so in the early stages, based on the data, we will choose patients in a robust manner. So, the number of patients may be small to begin with, but we believe it will continue to increase as efficacy and safety of this drug are established.

Wakao: Thank you. Now, I understand well. Thank you.

Operator: Thank you very much, Mr. Wakao. Next is Mr. Muraoka from Morgan Stanley.

Muraoka: Yes, thank you. I'd like to ask one additional question on Inebilizumab. I believe it is for aquaporin-4 positive only, where Satralizumab is for both negatives and positives. Is this a correct understanding?

Kobayashi: Well, the trial itself is run for both positives and negatives without separation.

Muraoka: In other words, the results are available for both positives and negatives as well?

Kobayashi: Well, the ratio of seronegative patients was very low, so if we extract only seronegatives and compare them against placebo and active drug, pre-efficacy was not achieved, and this was indicated in the paper and the Lancet as well.

Muraoka: But the target is both positives and negatives. So, the final label may be cited by the authority. Is that correct?

Kobayashi: Yes, I think that is a correct understanding.

Muraoka: Thank you very much. That is all.

Operator: Thank you very much, Mr. Muraoka, for your question. With that, we'd like to close this A&A session. Mr. Takai, would you like to conclude this briefing?

Takai: Yes. I'd like to thank you for your participation in this conference call.

Operator: With that, we'd like to conclude this conference call. Thank you very much for your participation.

[END]