Mitsubishi Tanabe Pharma Corporation

Q2 FY2019 Business Results
(April - September, 2019)

October 30, 2019

Eizo Tabaru
Member of the Board, Managing Executive Officer

Open Up the Future

Q2 FY2019 Business Results

Q2 FY2019 Financial Results

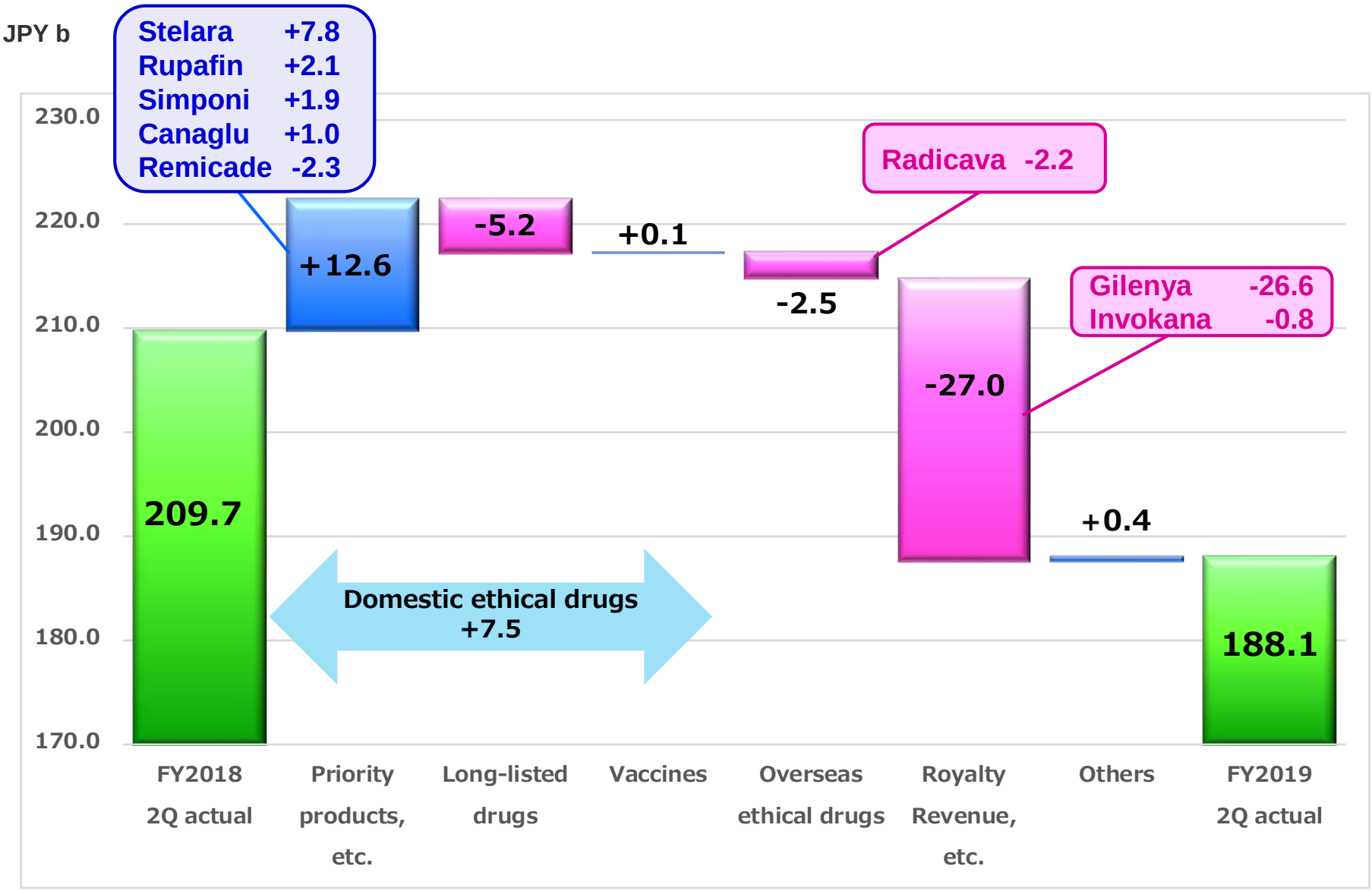
Open Up the Future
Mitsubishi Tanabe Pharma

	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

Revenue Trends

Open Up the Future
Mitsubishi Tanabe Pharma



Open Up the Future

Mitsubishi Tanabe Pharma

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

	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

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

Forecasts of FY2019

Forecasts of FY2019

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		

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

Open Up the Future
Mitsubishi Tanabe Pharma

Status of Global Late Stage Projects

Radicava	Expanding market through preparation of application for approval in each country and region ■ China : NDA Approved (July) ■ Brazil : Licensed to Daiichi Sankyo (September)
MT-1186 (Radicava oral suspension)	■ FDA Fast Track designation (October) ■ Long-term safety study scheduled to start (December)
ND0612	■ Long-term safety study (BeyoND study): Over 100 patients have completed the primary 12-month period ■ Start of P3 study (BouNDless study) (August)
MT-2271 (VLP vaccine)	■ Canada : NDA filed (September) ■ US : Under internal analysis of elderly and adults P3 study data and planning of discussion with FDA for filing a biological license application (BLA)

Open Up the Future

Mitsubishi Tanabe Pharma

Intensification of central nervous system area

Global Start with Radicava and launch new drugs for serious diseases, mainly neurodegenerative diseases

Toward a global company focus on CNS

MT-3921
Spinal cord injury

MT-8554
Vasomotor symptoms

ND0612
Parkinson's disease

MT-1186/ oral Radicava
ALS

MT-5199
Tardive dyskinesia

Radicava
ALS

MT-0551
Neuromyelitis optica spectrum disorder

Global

Japan **Imusera** (Multiple sclerosis)
Lexapro (Depression)

Japan Continuously introduce new drugs for the treatment of central nervous system diseases following existing products, and aim at strengthening the area

Radicava

Open Up the Future
Mitsubishi Tanabe Pharma

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)

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

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）

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

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

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)

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

Development and launch plan of major products

Open Up the Future
Mitsubishi Tanabe Pharma

	FY2020	FY2021	FY2022	FY2023
Central nervous system	**MCI-186** ALS (China)	**MT-1186** ALS(oral suspension) (Global)	**ND0612** Parkinson's disease (Global)	
		MT-0551 Neuromyelitis Optica Spectrum Disorder (Japan)	**MT-5199** Tardive dyskinesia (Japan)	
Immuno-inflammation			**MT-5547** Osteoarthritis (Japan)	
Diabetes and kidney	**MT-6548** Renal anemia (Japan)			**TA-7284** Diabetic nephropathy (Japan)
	MP-513 Type 2 diabetes mellitus (China)			
Vaccines		**MT-2271** Seasonal influenza (Global)	**MT-2355** 5 combined vaccine (Japan)	

: Global

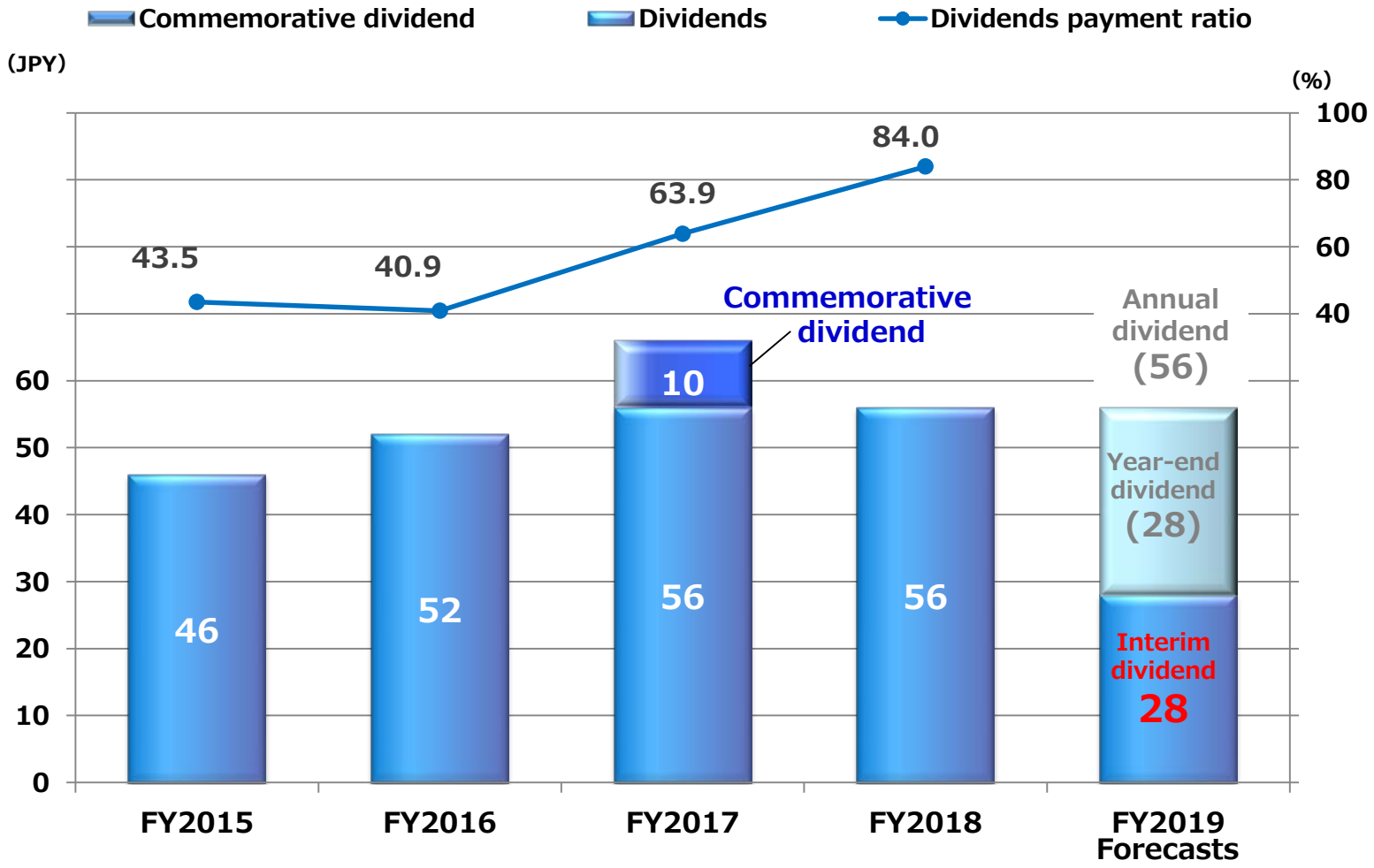
: Japan/China

※For global products, indicate the year of launch in US

Shareholders Return

Dividends Trends

- 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



Open Up the Future

Becoming a company that works with a sense
of speed and is the first to deliver differentiated value

Mitsubishi Tanabe Pharma

Appendix

Open Up the Future

Mitsubishi Tanabe Pharma

Details of Revenue (Q2 FY2019, Cumulative Total)

	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
[Overseas]	33.4	63.2	(29.7)	(47.0)	33.3	100.5
Domestic ethical drugs	149.1	141.5	7.5	5.4	147.5	101.1
Overseas ethical drugs	24.8	27.4	(2.5)	(9.4)	24.1	103.0
[Radicava]	11.6	13.9	(2.2)	(16.2)	11.0	105.3
Royalty revenue, etc.	9.2	36.3	(27.0)	(74.6)	9.8	93.9
OTC products	2.3	2.2	0.1	7.0	2.5	94.0
Others	2.4	2.1	0.3	15.3	2.9	84.7

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

Appendix

Domestic Ethical Drugs
Revenue of Priority Products and Vaccines

Open Up the Future
Mitsubishi Tanabe Pharma

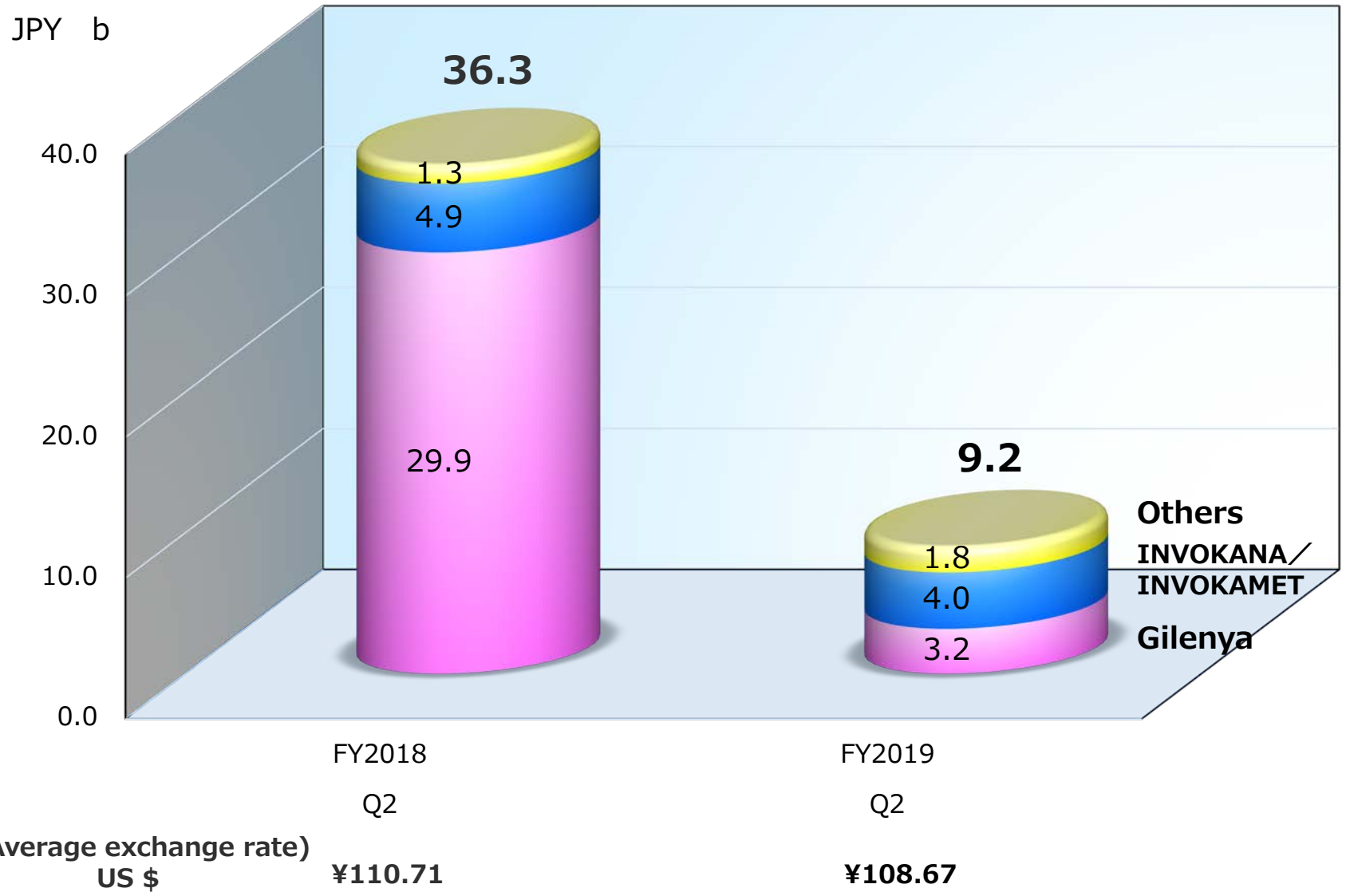
	FY2019 Q2	FY2018 Q2	Increase / Decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	27.6	29.9	(2.3)	(7.8)	26.9	102.4
Simponi	20.4	18.5	1.9	10.4	21.2	96.3
Stelara	12.5	4.7	7.8	164.1	11.0	113.5
Tenelia*2	8.0	7.2	0.8	12.0	8.0	100.0
Canaglu	4.1	3.0	1.0	34.9	4.6	87.8
Canalia*2	3.7	3.0	0.6	22.2	4.1	90.7
Lexapro	7.4	6.8	0.6	9.0	7.4	100.6
Rupafin	2.4	0.3	2.1	551.4	2.3	105.0
Imusera	2.1	2.2	(0.0)	(2.4)	2.2	98.4
Total of priority products	88.7	76.0	12.6	16.7	88.2	100.6
Tetrabik	4.5	4.1	0.4	9.7	4.9	91.8
Mearubik	3.5	4.1	(0.5)	(14.5)	2.7	125.8
Varicella vaccine	2.5	2.6	(0.1)	(4.6)	2.6	94.2
JEBIK V	2.8	3.0	(0.1)	(6.2)	2.4	116.7
Influenza vaccine	1.7	0.9	0.8	82.1	1.0	171.0
Total of vaccines	15.7	15.5	0.1	1.0	14.4	109.2
Total of priority products and vaccines	104.4	91.6	12.8	14.0	102.6	101.8

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

*2: Tenelia and Canalia are co-promoted with our partner Daiichi Sankyo and sold by Daiichi Sankyo. The Company discloses revenue from the sale of both drugs by combining product supply to Daiichi Sankyo and the promotion fees.

Royalty income, etc.

Open Up the Future
Mitsubishi Tanabe Pharma



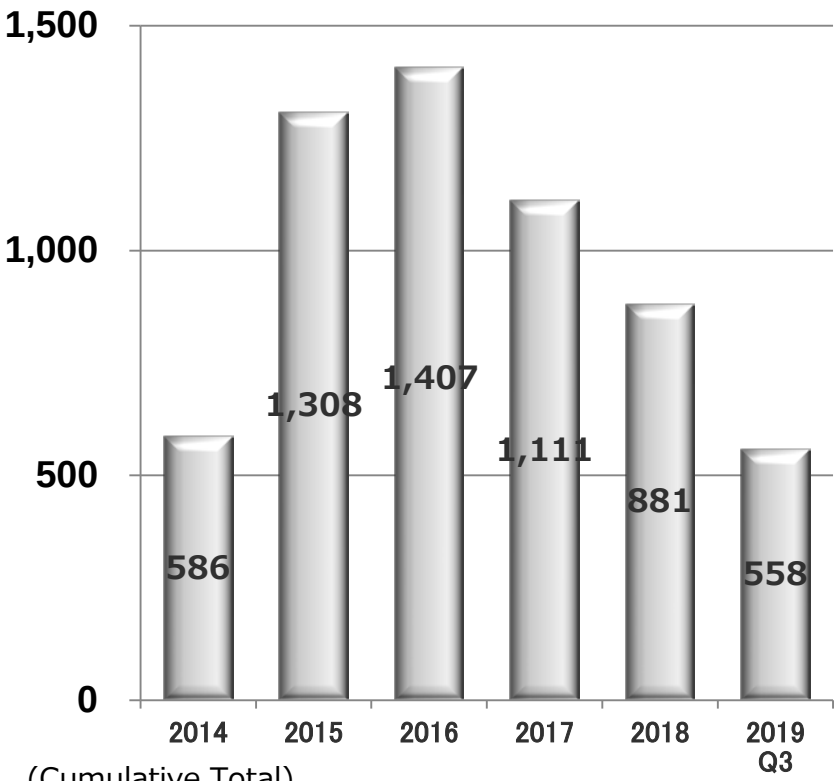
(Average exchange rate) US $	¥110.71	¥108.67

INVOKANA/INVOKAMET

Open Up the Future
Mitsubishi Tanabe Pharma

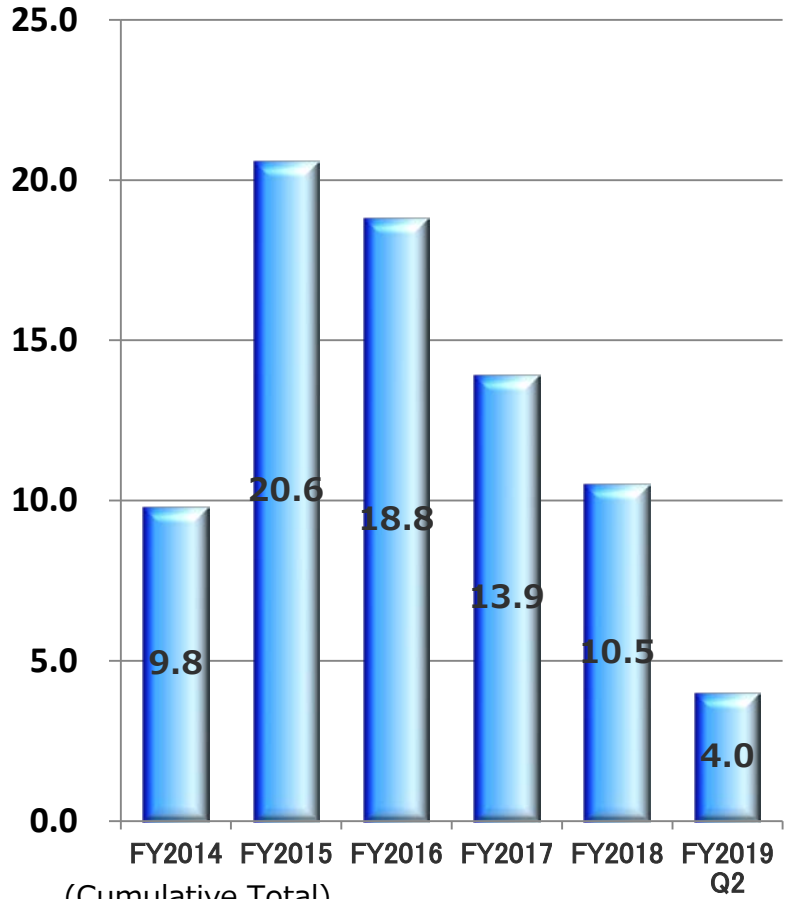
- **INVOKANA/INVOKAMET sales by Johnson & Johnson in July to September, 2019: $179m ($190m, the same period of previous year)**
- **MTPC royalty revenue in Q2 FY2019 (April to September, 2019) : ¥4.0b**

INVOKANA/INVOKAMET Worldwide sales by J&J



(Cumulative Total)

MTPC royalty revenue



(Cumulative Total)

Cautionary Statement

The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the company and is subject to significant risks and uncertainties.

It contains information about pharmaceuticals (Include products under development), but is not intended for advertising or medical advice.