Mitsubishi Tanabe Pharma Corporation

FY2019 Business Results (April 2019 - March 2020)

May 13, 2020

FY2019 Financial Results

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	FY2019	FY2018	Comparison to previous fiscal year		Comparison to forecasts	
			Increase (decrease)	Change	Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	379.8	424.7	(44.9)	(10.6)	376.0	101.0
(Domestic)	313.9	307.7	6.2	2.0	308.3	101.8
(Overseas)	65.8	117.0	(51.2)	(43.7)	67.6	97.3
Overseas sales ratio	17.3%	27.6%			18.0%	
Cost of sales	181.0	180.6	0.3	0.2	178.5	101.4
Sales cost ratio	47.7%	42.5%			47.5%	
Gross profit	198.8	244.1	(45.3)	(18.6)	197.5	100.7
SG&A expense	97.5	98.2	(0.6)	(0.7)	99.0	98.6
R&D expense	79.4	86.5	(7.0)	(8.2)	85.5	92.9
Amortization of intangible assets associated with products	2.4	2.9	(0.4)	(15.1)	2.5	99.6
Other income and expense*	(0.2)	(0.5)	0.3	-	(0.5)	-
Core operating profit	19.0	55.8	(36.7)	(65.9)	10.0	190.6
Non-recurring items*	(25.1)	(5.5)	(19.6)	-	1.5	-
Operating profit*	(6.0)	50.3	(56.3)	(112.1)	11.5	(52.8)
Financial income and loss*	(0.4)	0.1	(0.5)	-		
Net profit attributable to owners of the Company	0.1	37.3	(37.2)	(99.6)	5.0	2.9
Average exchange rate US$	¥108.95	¥111.07			¥110.00	

*Brackets indicate expense and loss

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

Details of Revenue

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	FY2019	FY2018	Comparison to previous fiscal year		Comparison to forecasts	
			Increase (decrease)	Change	Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	379.8	424.7	(44.9)	(10.6)	376.0	101.0
Domestic ethical drugs	304.3	298.7	5.5	1.9	298.1	102.1
Overseas ethical drugs	49.7	55.1	(5.3)	(9.8)	49.6	100.1
[Radicava]	23.1	27.0	(3.9)	(14.5)	22.0	105.0
Royalty revenue, etc.	17.4	63.1	(45.6)	(72.4)	19.2	90.5
OTC products	3.8	3.7	0.1	2.9	4.3	89.8
Others	4.4	3.9	0.4	11.1	4.6	95.6

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

FY2019 Business Results

Domestic Ethical Drugs
Revenue of Priority Products and Vaccines

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	FY2019	FY2018	Comparison to previous fiscal year		Comparison to forecasts	
			Increase (decrease)	Change	Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	53.3	58.8	(5.4)	(9.3)	51.5	103.5
Simponi	40.9	37.4	3.4	9.2	42.2	97.0
Stelara	26.0	15.2	10.8	71.0	21.6	120.1
Tenelia	15.2	15.2	0.0	0.1	15.0	101.0
Canaglu	8.8	6.7	2.1	31.1	10.4	84.9
Canalia	6.7	7.4	(0.6)	(9.2)	7.2	93.4
Lexapro	14.9	14.0	0.9	6.7	14.7	101.1
Rupafin	6.7	3.4	3.3	96.9	7.5	90.1
Imusera	4.2	4.3	(0.0)	(2.3)	4.2	99.4
Total of priority products	177.1	162.6	14.4	8.9	174.7	101.4
Influenza vaccine	12.6	10.2	2.3	23.1	10.7	117.2
Tetrabik	9.4	8.5	0.9	10.8	10.0	94.4
Mearubik	5.9	6.8	(0.9)	(13.6)	4.8	123.2
JEBIK V	5.1	5.5	(0.3)	(6.4)	4.5	112.4
Varicella vaccine	4.9	5.1	(0.1)	(3.5)	5.1	94.9
Total of vaccines	38.9	37.3	1.6	4.5	36.2	107.6
Total of priority products and vaccines	216.0	200.0	16.0	8.0	210.9	102.4

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

Revenue Trends

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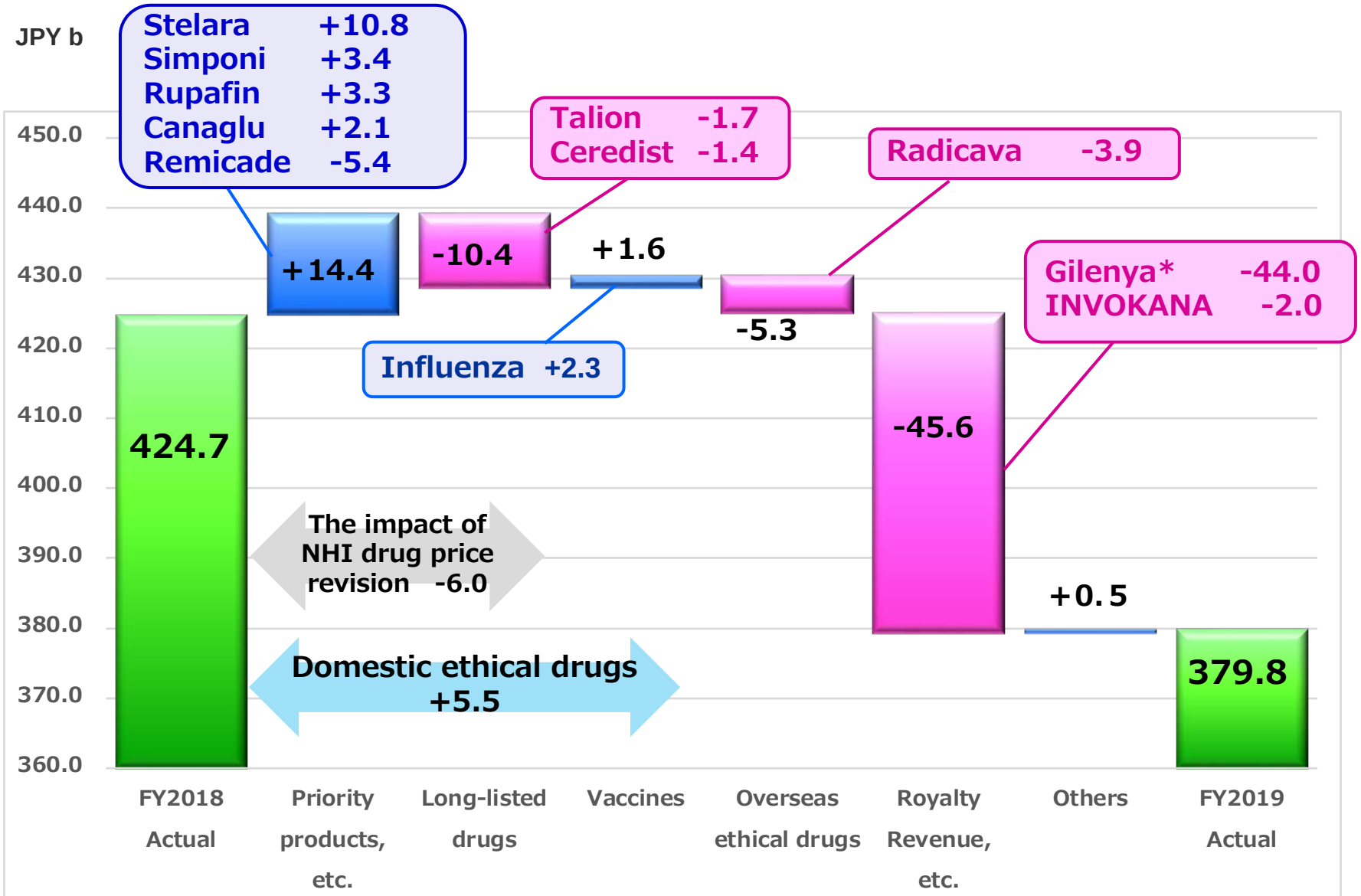

* Including a decline in sales as for the amounts among the “GILENYA® Royalty” amounts which will not be recognized as sales revenue during arbitration proceedings

Forecasts of FY2020

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	FY2020 forecasts※	FY2019 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	383.5	379.8	3.6	1.0
(Domestic)	314.1	313.9	0.1	0.0
(Overseas)	69.4	65.8	3.5	5.4
Overseas sales ratio	18.1%	17.3%		
Cost of sales	187.5	181.0	6.4	3.6
Sales cost ratio	48.9%	47.7%		
Gross profit	196.0	198.8	(2.8)	(1.4)
SG&A expense	99.5	97.5	1.9	2.0
R&D expense	83.5	79.4	4.0	5.1
Amortization of intangible assets associated with products	3.0	2.4	0.5	20.4
Other income and expense*	-	(0.2)	0.2	-
Core operating profit	10.0	19.0	(9.0)	(47.5)
Non-recurring items*	7.0	(25.1)	32.1	-
Operating profit*	17.0	(6.0)	23.0	-
Financial income and loss*	0.5	(0.4)	0.9	-
Net profit attributable to owners of the Company	8.5	0.1	8.3	-
Average exchange rate US$	¥108.00	¥108.95		

*Brackets indicate expense and loss

※ Excluding the impact of novel coronavirus (COVID-19) infection

Details of Revenue

	FY2020 forecasts	FY2019 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Domestic ethical drugs	303.5	304.3	(0.8)	(0.3)
Priority products	182.3	177.1	5.2	2.9
Vaccines	40.9	38.9	1.9	5.1
Long-listed drugs, etc.	80.2	88.2	(8.0)	(9.1)
Overseas ethical drugs	50.9	49.7	1.1	2.4
Radicava	22.3	23.1	(0.7)	(3.3)
Royalty revenue, etc.	19.8	17.4	2.4	14.1

Domestic Ethical Drugs
Forecasts of Revenue of Priority Products and Vaccines

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	FY2020 Forecasts	FY2019 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Remicade	44.7	53.3	(8.5)	(16.1)
Simponi	42.2	40.9	1.3	3.2
Stelara	32.8	26.0	6.8	26.2
Tenelia	14.9	15.2	(0.2)	(1.9)
Canaglu	9.1	8.8	0.3	3.4
Canalia	9.3	6.7	2.5	38.4
Lexapro	14.6	14.9	(0.3)	(2.1)
Rupafin	10.2	6.7	3.4	51.3
Imusera	4.1	4.2	(0.0)	(2.3)
Total of priority products	182.3	177.1	5.2	2.9
Influenza vaccine	12.2	12.6	(0.3)	(3.1)
Tetrabik	11.2	9.4	1.7	18.7
Mearubik	6.4	5.9	0.4	8.3
JEBIK V	5.3	5.1	0.1	3.4
Varicella vaccine	4.8	4.9	(0.0)	(1.7)
Total of vaccines	40.9	38.9	1.9	5.1
Total of priority products and vaccines	223.2	216.0	7.2	3.3

Notification of Changes in the U.S. Development Plan of VLP Vaccine (MT-2271) and an Impairment Loss (Non-recurring Items)

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- As Mitsubishi Tanabe Pharma Corporation (hereinafter, "MTPC") announced on April 28, 2020, the change in development plan of Virus Like Particle (VLP) vaccine for the prevention of seasonal influenza (MT-2271) in the United States which has been developed by its affiliated company, Medicago Inc.

- MT-2271 did not meet the pre-specified success criteria of the primary endpoint in the adult population, however results demonstrated significant vaccine efficacy compared to placebo in prevention of influenza infection. Furthermore, in the clinical study in elderly population, the results met the success criteria of the primary endpoint, non-inferiority to comparative licensed egg-derived vaccine in efficacy. Medicago has decided to re-evaluate its licensing strategy in the United States following the FDA's decision to request an additional clinical trial and does not plan to file an application for approval of MT-2271 in the United States.

- Following this change, MTPC has decided to write off intangible assets (in-process research and development expenses), in the amount of approximately 24 billion Japanese Yen, as an impairment loss (non-recurring items) in the fiscal year ending in March 2020.

- Since a level of efficacy has indeed been confirmed in the clinical studies compared with a placebo or a comparator (an egg-derived vaccine), Medicago will leverage the unique advantages of its plant-based VLP platform technology and continue to develop a Quadrivalent VLP vaccine to prevent seasonal influenza. To further improve the efficacy demonstrated in these studies, Medicago started to investigate the development of the product with an adjuvant* among new development initiatives.

*An adjuvant is a substance that is used concomitantly to enhance or support the effects of drugs and is expected to enhance immunogenicity when administered with vaccines.

Major Development Pipeline
Progress in FY 2019 and targets for FY 2020

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Global Projects

Study code	Indication	Phase	Progress in FY 2019 / Targets for FY 2020
MT-1186	Amyotrophic lateral sclerosis : ALS	P3	• Global P3 study (long-term safety study) was started in November 2019.
ND0612	Parkinson's disease	P3	• Global P3 study (BouNDless study) was started in August 2019. • 1-year treatment evaluation of long-term safety study (BeyoND study) was completed in October 2019.
MT-7117	Erythropoietic protoporphyria	P2	• Achieved POC in FY 2019. P3 study to be started in FY 2020.
MT-2990	Endometriosis	P2	• Plan to complete P2 study in FY 2020.
MT-8554	Vasomotor symptoms associated with menopause	P2	• Under preparation for P3 study. Continuing partnering activity.
MT-3921	Spinal cord injury	P1	• Obtained the results of P1 study in FY 2019. P1b study (in patients) was started in April 2020.

Late Stage Projects in Japan

MT-6548	Renal anemia	Filed	• J-NDA submission in July 2019. Scheduled launch in FY 2020.
MT-0551	Neuromyelitis optica spectrum disorder : NMOSD	P3	• Licensed-in from Viela Bio, Inc. (US) in October 2019. Scheduled J-NDA in FY 2020.

Change in Development Plan

MT-2271	Prophylaxis of seasonal influenza	P3	• Decided to discontinue development in US in April 2020* *Started to investigate the development of the product with an adjuvant.

Major Development Pipeline List

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As of April 30, 2020

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global	ALS /oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-8554	Global	Vasomotor symptoms associated with menopause			preparing		
	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan	Neuromyelitis Optica Spectrum Disorder				preparing	
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria			preparing		
	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-2355	Japan	5 combined vaccine*					

*Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

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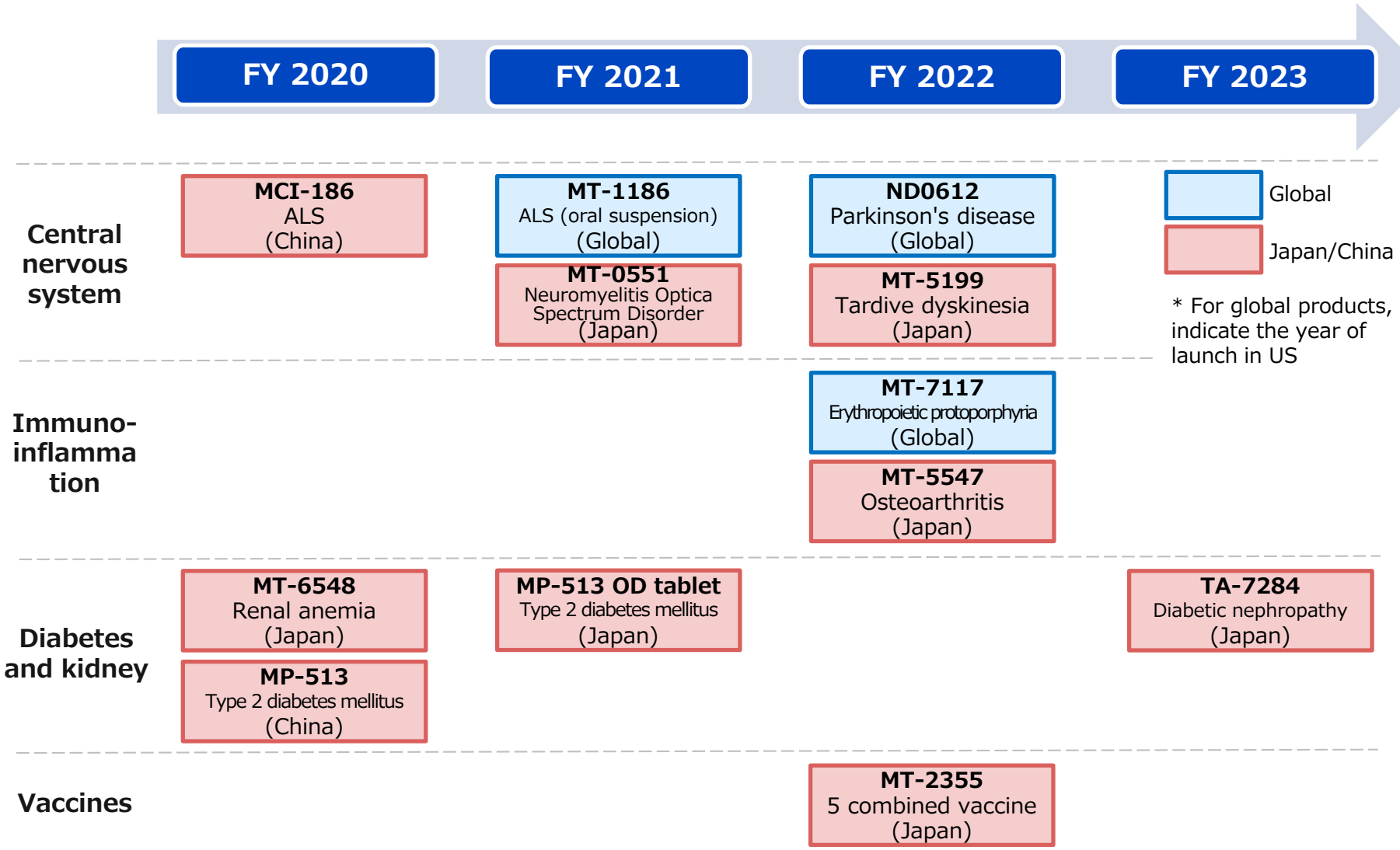
Launch Plan for Major Development Pipeline



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.