Mitsubishi Tanabe Pharma Corporation



Q1 FY2020 Business Results (April – June, 2020)

August 4, 2020

Q1 FY2020 Business Results

Q1 FY2020 Financial Results





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	Q1	Compa	arison to previou	ıs year	Comparison to forecasts*1		
	FY2020	Q1 FY2019	Increase (decrease)	Change	Full-year	Achieved	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%	
Revenue	91.8	98.1	(6.3)	(6.5)	383.5	23.9	
(Domestic)	75.7	80.8	(5.0)	(6.2)	314.1	24.1	
(Overseas)	16.1	17.4	(1.3)	(7.5)	69.4	23.1	
Overseas sales ratio	17.5%	17.7%			18.1%		
Cost of sales	45.6	44.8	0.8	1.8	187.5	24.3	
Sales cost ratio	49.7%	45.6%			48.9%		
Gross profit	46.2	53.3	(7.2)	(13.4)	196.0	23.6	
SG&A expense, etc.	36.6	43.6	(7.0)	(16.0)	186.0	19.7	
(R&D expense)	15.3	19.9	(4.6)	(23.3)	83.5	18.3	
Core operating profit	9.6	9.8	(0.2)	(1.8)	10.0	95.8	
Non-recurring items* ₂	8.1	(0.1)	8.2	-	7.0	115.6	
Operating profit	17.7	9.6	8.0	83.6	17.0	103.9	
Financial income and $loss^*$	0.2	(0.4)	0.6	-			
Net profit attributable to owners of the Company	11.5	6.9	4.6	67.1	8.5	135.3	
Average exchange rate US\$	¥107.38	¥109.67			¥108.00		

*1 Announced on May 13, 2020 *2 Brackets indicate expense and loss

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		Q1	Compari	Comparison to forecasts*			
			Q1 FY2019	Increase (decrease)	Change	Full-year	Achieved
		Billion yen	Billion yen	Billion yen	%	Billion yen	%
Do	omestic ethical drugs	73.3	78.2	(4.9)	(6.2)	303.6	24.1
	Priority products	45.3	46.5	(1.2)	(2.5)	182.3	24.9
	Vaccines	7.5	7.3	0.2	3.0	41.0	18.3
	Long-listed drugs, etc.	20.4	24.3	(3.9)	(16.1)	80.3	25.4
Ô٧	verseas ethical drugs	12.6	12.6	0.0	0.4	50.9	24.8
	Radicava	5.6	6.1	(0.5)	(8.9)	22.4	24.9
Royalty revenue, etc.		3.8	5.1	(1.3)	(25.7)	19.9	18.9

*Announced on May 13, 2020

Q1 FY2020 Business Results **Domestic Ethical Drugs Revenue of Priority Products and Vaccines**

Q1

	FY2020	Q1 FY2019	Increase (decrease)	Change	Full-year	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	11.9	14.4	(2.6)	(17.7)	44.8	26.6
Simponi	10.7	10.5	0.2	1.4	42.3	25.2
Stelara	7.0	6.2	0.8	12.5	32.8	21.2
Tenelia	4.1	4.7	(0.6)	(12.7)	14.9	27.5
Canaglu	2.5	2.2	0.4	17.3	9.2	27.7
Canalia	2.5	2.2	0.3	15.3	9.3	27.2
Lexapro	3.9	3.9	(0.0)	(0.6)	14.6	26.5
Rupafin	1.7	1.3	0.4	33.1	10.2	16.2
Imusera	1.1	1.1	(0.0)	(4.2)	4.1	26.5
Total of priority products	45.3	46.5	(1.2)	(2.5)	182.3	24.9
Influenza vaccine	(0.0)	(0.0)	(0.0)	-	12.2	(0.3)
Tetrabik	2.7	2.4	0.3	12.9	11.3	23.8
Mearubik	1.9	1.9	(0.0)	(0.4)	6.4	29.4
JEBIK V	1.4	1.5	(0.1)	(4.1)	5.3	27.1
Varicella vaccine	1.3	1.3	(0.0)	(2.1)	4.8	26.1
Total of vaccines	7.5	7.3	0.2	3.0	41.0	18.3
Total of priority products and vaccines	52.8	53.8	(1.0)	(1.8)	223.3	23.7

Comparison to previous year

*Announced on May 13, 2020

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Comparison to forecasts*

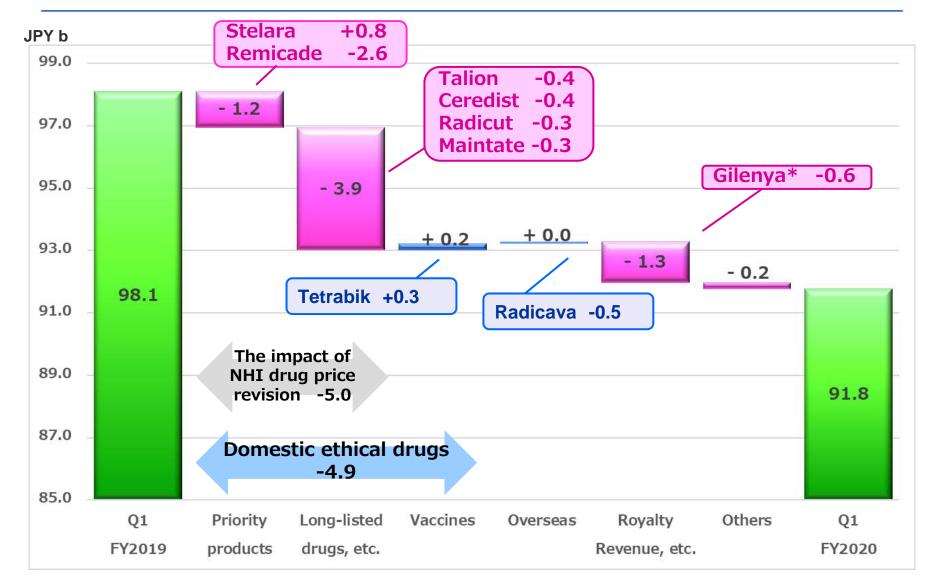
Q1 FY2020 Business Results

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Revenue Trends



Major Development Pipeline Topics in 1st Quarter of FY2020

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Global Projects

Code	Indications	Stage	Topics
MT-1186	Amyotrophic lateral sclerosis : ALS	Р3	 Global P3 study (long-term safety study) is ongoing. Due to the impact of novel coronavirus infection, etc., it is expected to be launched in FY2022.
ND0612	Parkinson's disease	Р3	 Global P3 study (BouNDless study) is ongoing. The impact of novel coronavirus infection, etc. on the development plan is being scrutinized.
MT-7117	Erythropoietic protoporphyria, X-linked protoporphyria	Р3	 Global P3 study was started in June. Orphan Drug Designation was obtained from FDA in June.
MT-2766	Prophylaxis of COVID-19 (Plant-based VLP* vaccine)	P1	 Obtained the good results in nonclinical studies. Announced a collaboration agreements with GSK and Dynavax respectively regarding the use of their adjuvants in July. P1 study was started in July.

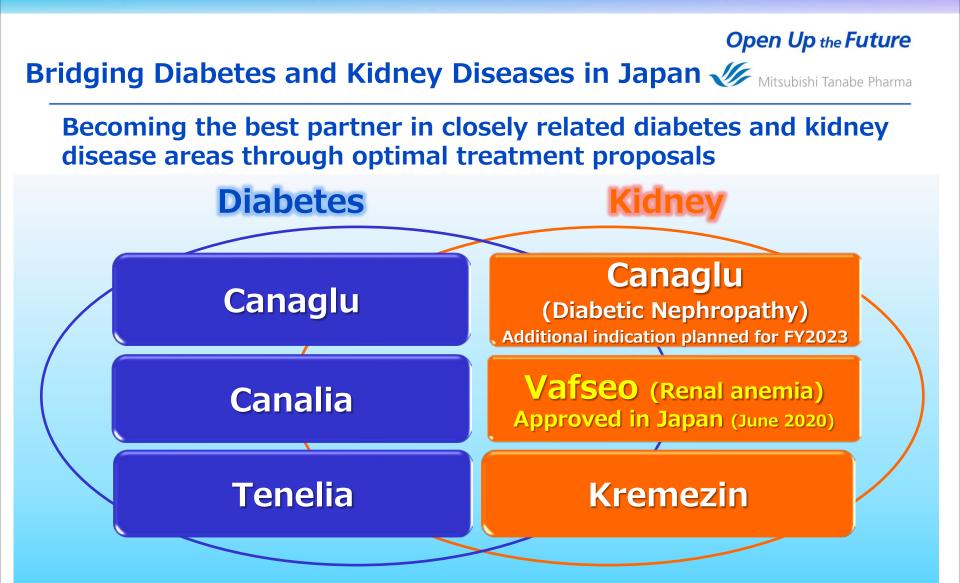
Late Stage Projects in Japan

*VLP : Virus-like particle

MT-6548	Renal anemia	Approved	• Approved in Japan in June. Product name: Vafseo
MT-0551	Neuromyelitis optica spectrum disorder : NMOSD	Filed	• J-NDA submission in June.

Obtained marketing approval in Japan in June 2020

Mechanism of action	Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor
Origin	Akebia Therapeutics, Inc. (United States)
Development stage	Approved
Indication	Renal anemia
Features	 Once-daily oral treatment Treatment effect for anemia by stimulate endogenous erythropoietin production within physiological range Can be used for renal anemia in both dialysis-dependent and non-dialysis dependent patients



October 2019: Diabetes and kidney area managers were assigned nationwide. April 2020: Diabetes and renal product marketing department was established. May 2020: Co-marketing agreement concluded with Fuso Pharmaceutical for Vafseo in the area of dialysis.

Late Stage Projects in Japan MT-0551 (Inebilizumab)





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Japan NDA filed in June 2020

Mechanism of action	Humanized anti-CD19 monoclonal antibody
Origin	Viela Bio, Inc. (United States)
Development stage	Filed in Japan (June 2020) (US: Viela Bio received approval in June 2020)
Indication	 Neuromyelitis Optica Spectrum Disorder (NMOSD): Rare, severe, relapsing, autoimmune disease of central nervous system that can be fatal. It may cause pain in the eye and vision loss, severe muscle weakness, paralysis, numbness, loss of bladder and bowel control and respiratory failure.
Number of patients	[Japan] Approximately 4,000
Features	 Every 6 months infusion as a maintenance monotherapy^{*1} 73% reduction in the risk of NMOSD attacks^{*2}, and reduction also in worsening of EDSS^{*3}, hospitalizations, and MRI^{*4} lesions Orphan Drug Designation in Japan in February 2020
Future plans	Launch in FY2021

*1: 300 mg intravenous (Day 1, 15, and every 6 months thereafter) *2: N-MOmentum Study, N=230, intention-to-treat analysis *3: Expanded Disability Status Scale *4: Magnetic Resonance Imaging

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Global P3 study was started in June 2020

Mechanism of action	Selective melanocortin 1 receptor (MC1R) agonist					
Origin	in-house created product					
Development stage	Phase 3					
Indication	Erythropoietic protoporphyria (EPP): The main symptom is photosensitivity. An inherited disease with painful redness, swelling, blisters and erosions following sun exposure					
	X-linked protoporphyria (XLP): An inherited disease with symptoms similar to EPP					
Number of	[Japan, the US., and EU Total] EPP : Approximately 10,000					
patients	XLP : Said to be lower than that with EPP					
	 An oral agent to prevent photosensitivity 					
Features	 Activation of MC1R promotes melanogenesis in melanocytes and prevents cutaneous symptoms caused by ultraviolet light 					
	 FDA Fast Track designation for EPP granted in June 2018 and Orphan Drug designation in June 2020 					
Future plans	NDA submission in FY2021					

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Medicago VLP Vaccine aims to prevent COVID-19

Category	Plant-based VLP (virus-like particle) vaccine					
Origin	Medicago Inc. (Canada)					
Stage	Phase 1					
Indications	Prophylaxis of COVID-19					
Design of P1 Study	To assess the safety and immunogenicity of MT-2766 at three dose levels unadjuvanted or adjuvanted with either GSK's or Dynavax's adjuvant*, administered on a one- and two-dose vaccination schedule, given 21 days apart					
Feature	 VLPs have the same external structure as viruses, so VLP vaccines are expected to provide high levels of immune-acquisition effect Shorter time for manufacture by Medicago's plant-based technology In July 2020, Medicago announced a collaboration agreement with GSK and Dynavax respectively regarding the use of their adjuvants 					
Schedule in future	Targeting the completion of clinical studies in 2021					

*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 List





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Progress Update

As of July 25, 2020

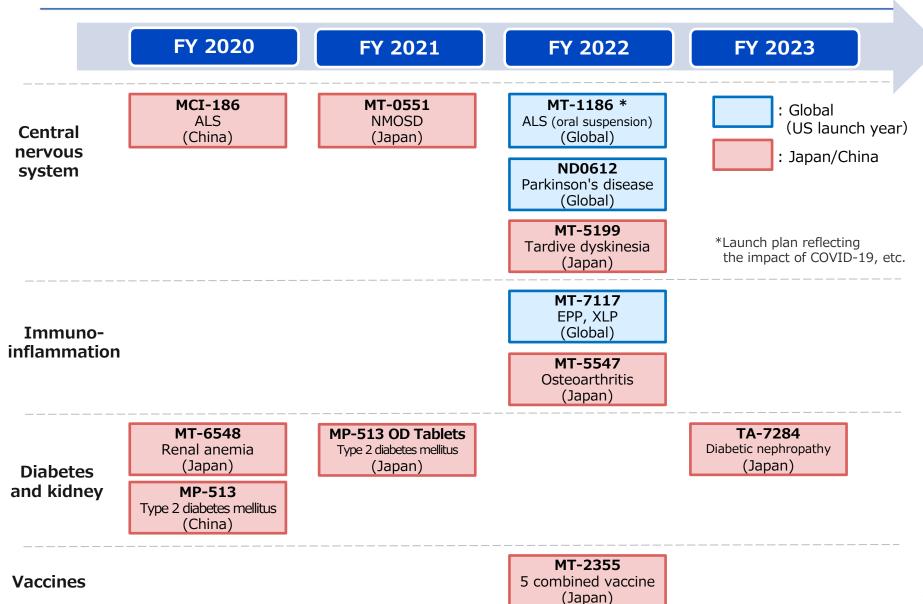
Priority areas	Code	Region	Indications	P1	P2	Р3	Filed	Approved
	MT-1186	Global	ALS/oral suspension					
	ND0612	Global	Parkinson's disease					
Central nervous	MT-8554	Global	Vasomotor symptoms associated with menopause			preparing		
system	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan	Neuromyelitis Optica Spectrum Disorder					
	MT-5199	Japan	Tardive dyskinesia					
	MT-7117	Global	Erythropoietic protoporphyria, X-linked protoporphyria					
Immuno- inflammation	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
Diabetes and	MT-6548	Japan	Renal anemia					
kidney	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
	MT-2766	Global	Prophylaxis of COVID-19					
Vaccines	MT-2355	Japan	5 combined vaccine*					

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

Launch Plan for Major Development Pipeline

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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 included products under development, but is not intended for advertising or medical advice.