Mitsubishi Tanabe Pharma Corporation

FY2020 Business Results
(April 2020-March 2021)

May 12, 2021

KAITEKI Value for Tomorrow
Mitsubishi Chemical Holdings Group

FY2020 Financial Results

	FY2020	Comparison to previous year			Comparison to forecasts	
		FY2019	Increase (decrease)	Change	Announced on Feb.3	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	377.8	379.8	(2.1)	(0.5)	373.0	101.3
(Domestic)	313.0	314.0	(1.0)	(0.3)	312.2	100.3
(Overseas)	64.8	65.8	(1.1)	(1.6)	60.8	106.5
Overseas sales ratio	17.1%	17.3%			16.3%	
Cost of sales	190.4	181.0	9.3	5.2	187.5	101.5
Sales cost ratio	50.4%	47.7%			50.3%	
Gross profit	187.4	198.8	(11.4)	(5.7)	185.5	101.0
SG&A expense, etc.	166.4	179.7	(13.4)	(7.4)	168.5	98.7
(R&D expense)	72.6	79.4	(6.9)	(8.7)	72.5	100.1
Core operating profit	21.0	19.1	2.0	10.4	17.0	123.7
Non-recurring items*	(79.6)	(25.1)	(54.4)	-	(79.5)	-
Operating profit*	(58.5)	(6.1)	(52.4)	-	(62.5)	-
Financial income and loss*	0.8	(0.4)	1.2	-	-	-
Net profit attributable to owners of the Company*	(46.9)	0.1	(47.0)	-	(52.5)	-
Average exchange rate US$	¥105.94	¥108.95			¥108.00	

*:Brackets indicate expense and loss

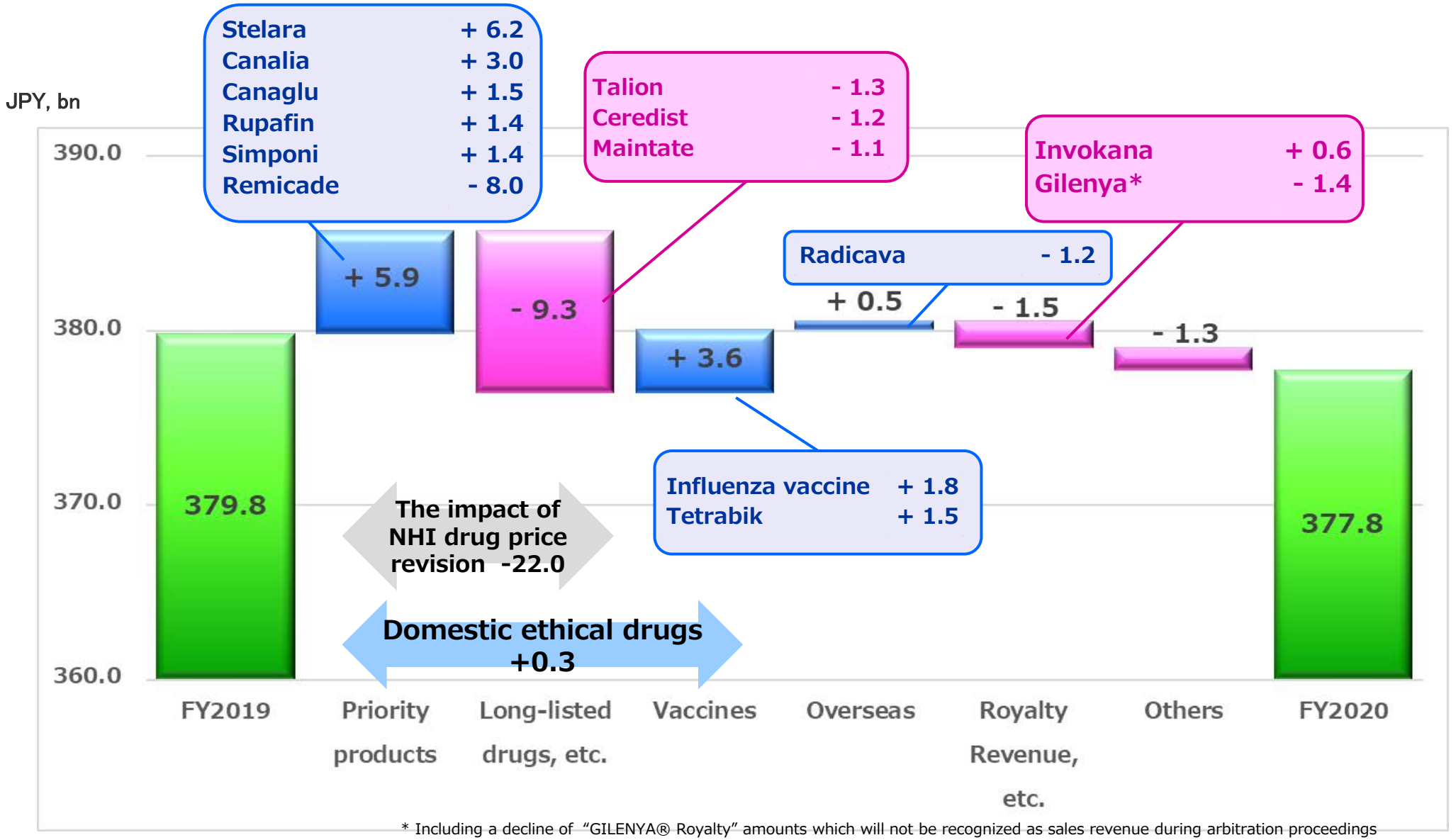
FY2020 Details of Revenue

	FY2020	Comparison to previous year			Comparison to forecasts	
		FY2019	Increase (decrease)	Change	Announced on Feb.3	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Domestic ethical drugs	304.7	304.4	0.3	0.1	302.3	100.8
Priority products	183.0	177.1	5.9	3.3	183.0	100.0
Vaccines	42.6	39.0	3.6	9.3	41.6	102.5
Long-listed drugs, etc.	79.0	88.3	(9.3)	(10.5)	77.7	101.7
Overseas ethical drugs	50.2	49.7	0.5	1.0	47.0	106.8
Radicava	22.0	23.1	(1.2)	(5.1)	20.1	109.2
Royalty revenue, etc.	15.9	17.4	(1.5)	(8.9)	15.2	104.5

Revenue of Priority Products and Vaccines

	FY2020	Comparison to previous year			Comparison to forecasts	
		FY2019	Increase (decrease)	Change	Announced on Feb.3	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	45.4	53.4	(8.0)	(15.0)	45.0	100.8
Simponi	42.3	41.0	1.4	3.4	42.7	99.2
Stelara	32.2	26.0	6.2	23.8	31.9	101.0
Tenelia	15.1	15.2	(0.1)	(0.8)	14.9	101.3
Canaglu	10.3	8.8	1.5	16.6	9.8	105.3
Canalia	9.7	6.7	3.0	44.6	9.3	104.7
Vafseo (launched in Aug.)	0.3	-	0.3	-	0.5	68.8
Lexapro	15.3	15.0	0.4	2.5	14.8	103.6
Rupafin	8.2	6.8	1.4	20.7	10.0	81.7
Imusera	4.1	4.2	(0.1)	(3.3)	4.1	100.1
Total of priority products	183.0	177.1	5.9	3.3	183.0	100.0
Influenza vaccine	14.4	12.6	1.8	14.0	13.2	109.1
Tetrabik	10.9	9.5	1.5	15.4	11.1	98.6
Mearubik	6.1	6.0	0.2	2.9	6.4	95.8
JEBIK V	5.2	5.2	0.0	0.4	5.3	97.7
Varicella vaccine	5.0	4.9	0.0	0.5	4.8	103.2
Total of vaccines	42.6	39.0	3.6	9.3	41.6	102.5
Total of priority products and vaccines	225.6	216.1	9.6	4.4	224.6	100.5

Revenue Trends



* Including a decline of "GILENYA® Royalty" amounts which will not be recognized as sales revenue during arbitration proceedings

FY2021 Forecasts

	FY2021 forecasts	FY2020 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	407.5	377.8	29.7	7.9
SG&A expense, etc.	189.0	166.4	22.6	13.6
R&D expense	85.0	72.6	12.4	17.2
Core operating profit	26.0	21.0	5.0	23.6
Non-recurring items*	4.0	(79.6)	83.6	-
Operating profit*	30.0	(58.5)	88.5	-
Net profit attributable to owners of the Company*	17.5	(46.9)	64.4	-

*:Brackets indicate expense and loss

Details of Revenue Forecasts

	FY2021 forecasts	FY2020 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Domestic ethical drugs	286.3	304.7	(18.3)	(6.0)
Priority products	145.3	137.7	7.6	5.5
Vaccines	37.0	42.6	(5.6)	(13.1)
Long-listed drugs, etc.	104.0	124.4	(20.4)	(16.4)
Remicade*1	36.5	45.4	(8.8)	(19.4)
Overseas ethical drugs*2	100.6	50.2	50.4	100.3
Radicava	19.2	22.0	(2.7)	(12.4)
Royalty revenue, etc.	12.3	15.9	(3.6)	(22.6)

*1: Classified from priority product to long-listed drugs, etc. in FY2021. Figures in FY2020 was adjusted along with this for comparison.
*2: Expected an increase by commercialization of COVID-19 vaccine(MT-2766)

Revenue Forecasts of Priority Products and Vaccines

	FY2021 forecasts	FY2020 actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Simponi	41.2	42.3	(1.1)	(2.7)
Stelara	42.7	32.2	10.5	32.4
Tenelia	14.4	15.1	(0.7)	(4.6)
Canaglu	10.1	10.3	(0.2)	(2.1)
Canalia	9.3	9.7	(0.4)	(4.2)
Vafseo	1.3	0.3	1.0	278.5
Lexapro	14.1	15.3	(1.3)	(8.2)
Rupafin	8.9	8.2	0.7	9.0
Imusera	3.3	4.1	(0.8)	(19.7)
Total of priority products	145.3	137.7	7.6	5.5
Influenza vaccine	14.3	14.4	(0.1)	(0.8)
Tetrabik	10.8	10.9	(0.2)	(1.5)
Mearubik	5.7	6.1	(0.5)	(7.5)
JEBIK V	1.3	5.2	(3.9)	(75.8)
Varicella vaccine	4.1	5.0	(0.8)	(16.8)
Total of vaccines	37.0	42.6	(5.6)	(13.1)
Total of priority products and vaccines	182.3	180.3	2.0	1.1

Mitsubishi Tanabe Pharma

Status of research and development etc.

Major Global Development Pipeline
Progress and Targets for FY2021

Code	Indications	Stage	Progress/Targets for FY2021
MT-1186	ALS/oral suspension	P3	• Global P3 study (long-term safety study) is ongoing. • After obtaining the results of P3 study, NDA is to be filed in the U.S. in 3Q of FY2021.
ND0612	Parkinson's disease	P3	• Global P3 study is ongoing.
MT-2766	Prophylaxis of COVID-19 (Plant-based VLP* vaccine)	P3	• P3 study started in March is ongoing. • Completion of NDA Submission in Canada in 2Q of FY2021, aiming at commercialization in 2021.
MT-7117	Erythropoietic protoporphyria (EPP) X-linked protoporphyria (XLP)	P3	• Global P3 study is ongoing. • The results of P3 study will be available in 4Q of FY2021.
	Systemic sclerosis	P2	• The start of global P2 study was announced in March.
MT-3921	Spinal cord injury	P1	• Global P2 study is planned to be started in 1Q of FY2021.

*VLP : Virus-Like Particle

■ Other Topics

- Mineralys Therapeutics, a licensee of **MT-4129**, announced in April that it will start P2 study for the treatment of hypertension.
- In May, the Company decided to discontinue development of **MT-5745 (STNM01)** acquired through the acquisition of Stelic Institute. we recorded an impairment loss of 3.9 billion yen for intangible assets.

Major Development Pipeline in Japan
Progress and Targets for FY2021

Code	Indications	Stage	Progress/Targets for FY2021
MT-0551	Neuromyelitis Optica Spectrum Disorder (NMOSD) *1	Approved	• It was approved in May in Japan. Preparing for the launch after NHI price listing.
MT-5199	Tardive dyskinesia *2	Filed	• In April, the application for approval was submitted in Japan.
TA-7284	Diabetic nephropathy *3	P3	• The application for approval in Japan is scheduled to be submitted in 3Q of FY2021.

*1: Submitted in Korea and Taiwan
*2: Submitted in 5 Asian countries (Singapore, Thailand, Indonesia, Malaysia and Korea)
*3: Approved in Taiwan

Other Topics

- **MP-513 (domestic product name: TENELIA) OD Tablets** was approved in Japan in February. Preparing for the launch after NHI price listing.
- In March, the Company entered into an out-licensing agreement with DT-Axis for the clinical development and marketing of **a cognitive-behavioral therapy application, MTD-810**.

MT-2766
Medicago VLP Vaccine aims to prevent COVID-19

Phase 3 study started in March. Aim to commercialize in Canada in 2021

Category	Plant-based VLP (virus-like particle) vaccine
Origin	Medicago Inc.（Canada）
Development stage	Phase 3 (started rolling submission /Canada) ※MT-2766 was granted Fast Track designation by the U.S. FDA in February 2021
Indication	Prophylaxis of COVID-19
Phase 3 Summary	• Subjects: The trial started in Canada and the U.S. and will soon start in other countries and enroll up to 30,000 subjects composed of healthy adults, elderly and adults with comorbidity. • Dosage and administration: Two doses of 3.75μg VLP vaccine candidate combined with GSK's adjuvant given 21 days apart. • Endpoints: Efficacy and safety. (comparison with placebo)
Future plans	Completion of NDA Submission in Canada in 2Q of FY 2021, aiming at commercialization in 2021

News release on March 17 and April 26, 2021

MT-7117
(generic name : dersimelagon)

Initiated Global Phase2 Clinical Trial in subject with Systemic Sclerosis

Mechanism of action	Selective melanocortin 1 receptor (MC1R) agonist
Development Stage	Phase 2
Indication	• Systemic sclerosis (SSc, scleroderma) is a rare, chronic, and systemic disease characterized by autoimmunity, vasculopathy, and fibrosis of the skin and internal organs. • SSc includes limited cutaneous SSc which is less severe, and diffuse cutaneous SSc, which is characterized by skin thickening (fibrosis) and is associated with severe organ damage. 【Number of patients】prevalence in the US: approximately 300 patients per million
Phase 2 study outline	• Evaluate efficacy, safety and tolerability of MT-7117 in subjects with diffuse cutaneous systemic sclerosis (male or female aged 18 to 75 years) • Primary outcome measurement: The ACR CRISS composite score at Week 52. Estimated enrollment: 72 patients
Future plans	Top line data of Phase 2 study will be available in Q4 of FY2022

- A global Phase 3 trial of MT-7117 in patients with **erythropoietic protoporphyria (EPP)** or **X-Linked Protoporphyria (XLP)** is underway.

News release on March 31, 2021

MT-0551
(generic name : inebilizumab, Japan brand name : UPLIZNA)

Obtained a Japan regulatory approval for Neuromyelitis Optica Spectrum Disorder (NMOSD) in March

Mechanism of action	Humanized anti-CD19 monoclonal antibody
Origin	Horizon Therapeutics plc* (Ireland)
Indication	Prevention of relapses of NMOSD (including neuromyelitis optica) • An autoimmune disease of the central nervous system characterized by severe optic neuritis and transverse myelitis and designated intractable disease. • Relapse may occur repeatedly, and a single relapse may lead to vision loss or wheelchair activity. 【Number of patients】Approximately 4,000 patients in Japan
Features	• A new mechanism of a broad depletion of B cells including antibody-producing plasmablasts and plasma cells • Convenience of a dosing interval of once every six months • Designated as an orphan drug in Japan in February 2020
Future plans	Preparing for the launch after NHI price listing

*Acquired Viela Bio, Inc. on March 2021.

- For **myasthenia gravis** and **IgG4-related disease**, global phase 3 clinical trials are being conducted in collaboration with Horizon Therapeutics.

MT-5199
(generic name : valbenazine)

Filed a marketing authorization application for the treatment of Tardive Dyskinesia in Japan in April 2021

Mechanism of action	Vesicular monoamine transporter 2 (VMAT2) inhibitor
Origin	Neurocrine Biosciences, Inc. (USA)
Indication	Tardive dyskinesia • Involuntary movement arising from the long-term administration of antipsychotic drugs or other drugs. • Symptoms, which differ by patient, are principally facial, but also in the extremities and torso. Severe cases can lead to dysphagia or respiratory distress.
Features	• The first product for the treatment of tardive dyskinesia in Japan* • Orally administered once daily
Future plans	Launch in FY 2022 (planned)

*In the U.S., valbenazine was approved in 2017.
INGREZZA (valbenazine) is commercialized in the U.S. by Neurocrine Biosciences, Inc.

News release on April 22, 2021

“TENELIA OD Tablets” Approved

“New options” in the treatment of type 2 diabetes mellitus

「TENELIA OD Tablets」

- **The first OD (Orally Disintegrating*) tablets in DPP-4 inhibitors**
- Approved on Feb.5, 2021, will be launched soon after NHI price listing. Co-promotion with Daiichi Sankyo
- Domestic oral diabetes drug market : about ¥476.4bn (Source : IQVIA 2021 Feb MAT, NHI pricing base)
- Number with strongly suspected diabetes : about 10 mil

  (Source : MHLW, The National Health and Nutrition Survey in Japan, 2016: https://www.mhlw.go.jp/content/000681180.pdf)
- Approximately 78% of diabetic patients are aged 65 years or older.

  (Source : MHLW, The National Health and Nutrition Survey in Japan, 2019: https://www.mhlw.go.jp/content/000710991.pdf)
- Providing “New options” in the treatment of type 2 diabetes mellitus that are expected to further improve convenience and medication compliance for elderly patients and patients with impaired swallowing function

*When placed on the tongue, orally disintegrating tablets disintegrate in several 10 seconds due to saliva or a small amount of water. This is useful not only for the general public but also for the elderly, who cannot swallow tablets well, and for those who are restricted in fluid intake (Source: PMDA: https://www.pmda.go.jp/safety/consultation-for-patients/on-drugs/qa/0002.html).

Major Development Pipeline List

As of April 25, 2021

Progress Update

Creating hope for all facing illness.

Mitsubishi Tanabe Pharma

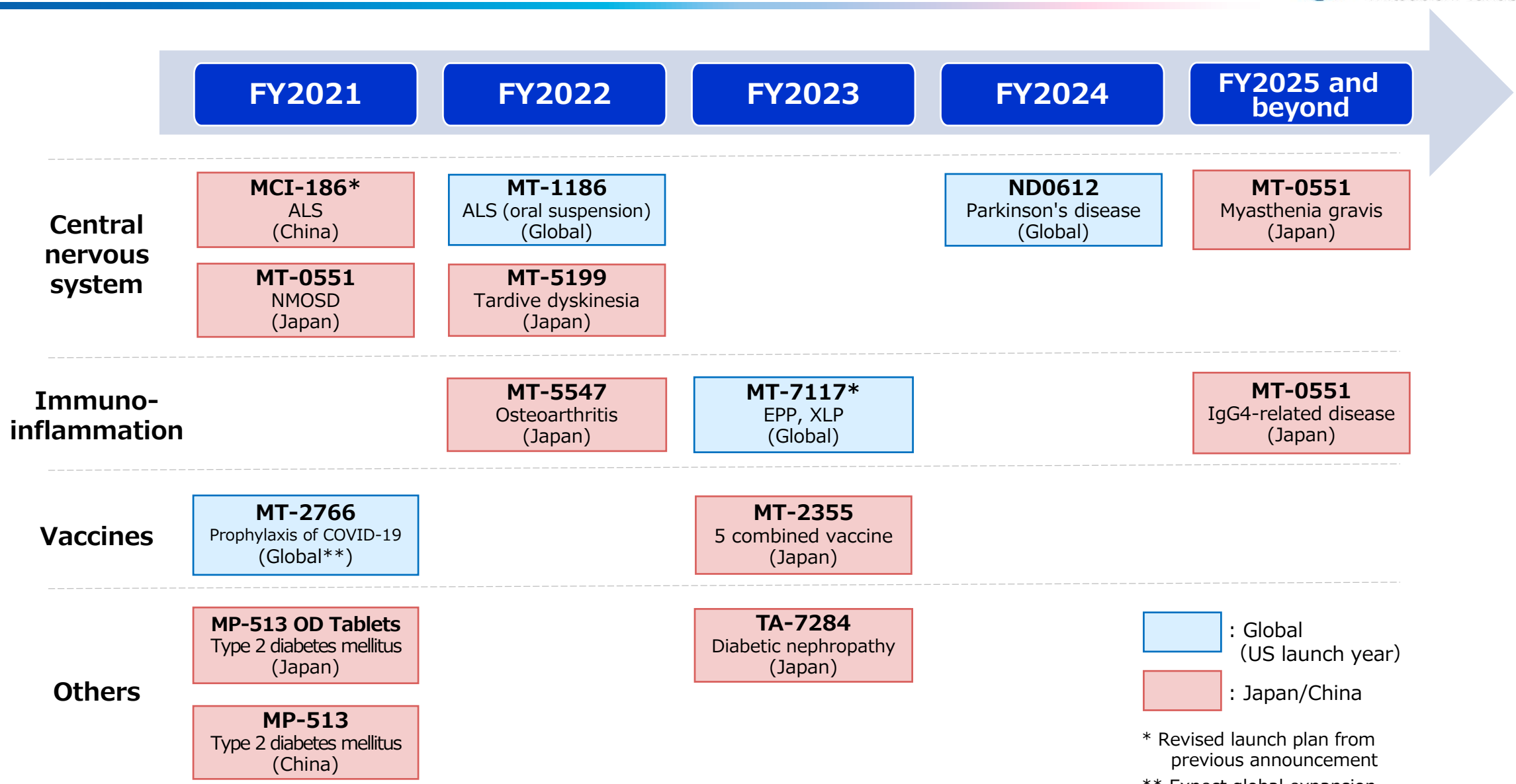
Research areas	Code	Region	Indications	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global	ALS/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan	Neuromyelitis Optica Spectrum Disorder (NMOSD)					
		Japan*	Myasthenia gravis					
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria(EPP) X-linked protoporphyria(XLP)					
		Global	Systemic sclerosis					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
	MT-0551	Japan*	IgG4-related disease					
Vaccines	MT-2766	Global	Prophylaxis of COVID-19					
	MT-2654	Global	Prophylaxis of seasonal influenza/elderly					
	MT-2355	Japan	5 combined vaccine**					
Others	TA-7284	Japan	Diabetic nephropathy					

* Co-development with Horizon Therapeutics (Global study ongoing)
** Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

Projects under Alliance Activities

Research areas	Code	Stage	Indications
Central nervous system	MT-8554	P2	Vasomotor symptoms associated with menopause
Others	MT-3995	P2	Non-alcoholic steatohepatitis (NASH)

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

Mitsubishi Tanabe Pharma

Creating hope for all facing illness.