



# Q1 FY2021 Business Results

## (April –June 2021)

August 4, 2021

# Q1 FY2021 Financial Results



	Q1 FY2021	Comparison to previous year			Comparison to forecasts* <sup>1</sup>	
		Q1 FY2020	Increase (decrease)	Change	Full-year	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	95.4	91.8	3.6	3.9	407.5	23.4
Gross profit	47.7	46.2	1.5	3.3	215.0	22.2
SG&A expense, etc.	41.9	36.6	5.3	14.5	189.0	22.2
R&D expense	18.8	15.3	3.5	22.9	85.0	22.1
Core operating profit	5.8	9.6	(3.8)	(39.2)	26.0	22.4
Non-recurring items* <sup>2</sup>	(0.0)	8.1	(8.1)	-	4.0	-
Operating profit	5.8	17.7	(11.9)	(67.1)	30.0	19.3
Net profit attributable to owners of the Company	3.1	11.5	(8.4)	(73.4)	17.5	17.5
Average exchange rate US\$	¥109.76	¥107.38			¥110.00	

\*1: Announced on May 12, 2021

\*2: Brackets indicate expense and loss

# Details of Revenue



	Q1 FY2021	Comparison to previous year			Comparison to forecasts* <sup>1</sup>	
		Q1 FY2020	Increase (decrease)	Change	Full-year	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Domestic ethical drugs	74.5	73.3	1.3	1.7	286.3	26.0
Priority products	38.9	33.4	5.5	16.4	146.6	26.5
Vaccines	6.2	7.5	(1.3)	(17.1)	37.0	16.8
Long-listed drugs, etc.	29.4	32.3	(2.9)	(9.0)	102.7	28.6
Remicade	10.4	11.9	(1.4)	(12.2)	36.5	28.6
Overseas ethical drugs	14.4	12.6	1.7	13.8	100.6	14.3
Radicava* <sup>2</sup>	6.3	5.6	0.8	13.7	19.8	32.0
Royalty revenue, etc.	4.3	3.8	0.6	15.7	12.3	35.3

\*1 Announced on May 12, 2021

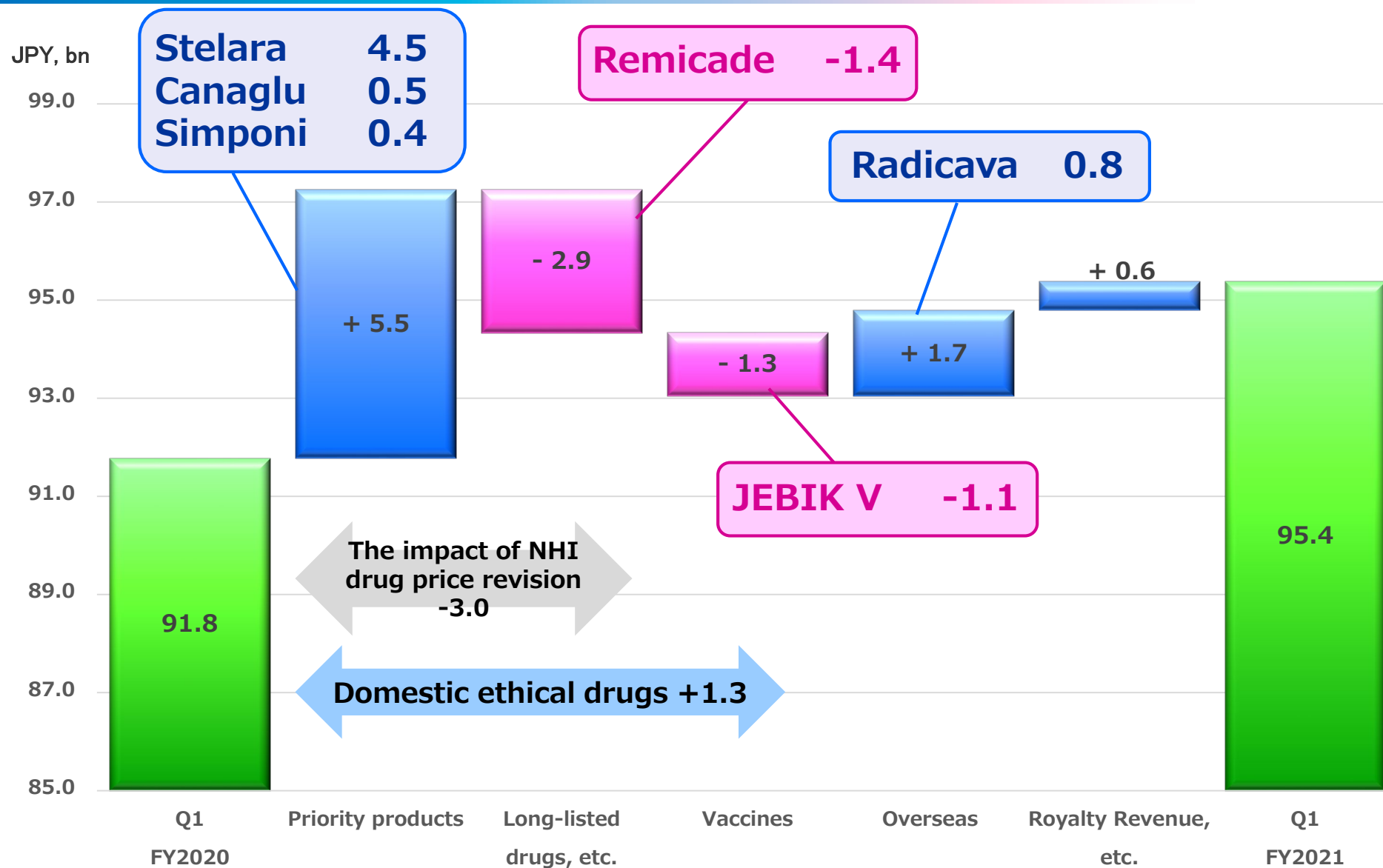
\*2 Forecast of 19.8 was corrected from 19.2 announced on May 12, 2021.

# Revenue of Priority Products and Vaccines

	Q1 FY2021	Comparison to previous year			Comparison to forecasts*	
		Q1 FY2020	Increase (decrease)	Change	Full-year	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Stelara	11.4	7.0	4.5	64.0	42.7	26.7
Simponi	11.1	10.7	0.4	4.0	41.2	26.9
Tenelia	3.8	4.1	(0.3)	(6.4)	14.4	26.7
Canaglu	3.0	2.5	0.5	18.3	10.1	29.7
Canalia	2.5	2.5	(0.1)	(2.5)	9.3	26.5
Vafseo	0.1	-	0.1	-	1.3	6.1
Lexapro	3.9	3.9	0.1	1.9	14.1	28.1
Uplizna	0.1	-	0.1	-	1.4	9.3
Rupafin	1.9	1.7	0.2	12.3	8.9	21.0
Imusera	1.1	1.1	(0.0)	(1.7)	3.3	32.8
Total of priority products	38.9	33.4	5.5	16.4	146.6	26.5
Influenza vaccine	(0.0)	(0.0)	0.0	-	14.3	(0.0)
Tetrabik	2.6	2.7	(0.1)	(3.8)	10.8	23.9
Mearubik	1.9	1.9	(0.0)	(1.0)	5.7	33.1
Varicella vaccine	1.1	1.3	(0.1)	(11.6)	4.1	27.1
JEBIK V	0.3	1.4	(1.1)	(76.0)	1.3	27.7
Total of vaccines	6.2	7.5	(1.3)	(17.1)	37.0	16.8
Total of priority products and vaccines	45.1	41.0	4.2	10.2	183.7	24.6

\* Announced on May 12, 2021

# Revenue Trends





Mitsubishi Tanabe Pharma

# Status of research and development etc.

# Development Pipeline : Central nervous system

Creating hope for all facing illness.



## 1. Central nervous system

Code	Indications	Region	Stage	Progress (blue indicates progression)
<b>MT-1186</b>	ALS/oral suspension	Global	P3	<ul style="list-style-type: none"><li>Global P3 study (long-term safety study) is ongoing.</li><li>NDA is to be filed in the U.S. (3Q).</li></ul>
<b>ND0612</b>	Parkinson's disease	Global	P3	<ul style="list-style-type: none"><li>Global P3 study is ongoing.</li></ul>
<b>MT-0551</b>	Myasthenia gravis	Japan*	P3	<ul style="list-style-type: none"><li>Global P3 study is ongoing.</li></ul>
<b>MT-5199</b>	Tardive dyskinesia	Japan	Filed	<ul style="list-style-type: none"><li>NDA submission completed (April).</li></ul>

\* Co-development with Horizon Therapeutics

# Development Pipeline : Immuno-inflammation and Vaccines

Creating hope for all facing illness.



## 2. Immuno-inflammation

Code	Indications	Region	Stage	Progress
<b>MT-7117</b>	Erythropoietic protoporphyria (EPP) X-linked protoporphyria (XLP)	Global	P3	<ul style="list-style-type: none"> <li>Global P3 study is ongoing.</li> </ul>
<b>MT-5547</b>	Osteoarthritis	Japan	P2/3	<ul style="list-style-type: none"> <li>P2/3 study completed.</li> </ul>
<b>MT-0551</b>	IgG4-related disease	Japan*	P3	<ul style="list-style-type: none"> <li>Global P3 study is ongoing.</li> </ul>

## 3. Vaccines

Code	Indications	Region	Stage	Progress(blue indicates progression)
<b>MT-2766</b>	Prophylaxis of COVID-19 (Plant-based VLP** vaccine)	Global	P3	<ul style="list-style-type: none"> <li>Global P3 study is ongoing.</li> <li>Planned to be approved in Canada in 3Q, aim to commercialization in 2021.</li> </ul>
<b>MT-2355</b>	Combined vaccine***	Japan	P3	<ul style="list-style-type: none"> <li>P3 study completed.</li> </ul>

\* Co-development with Horizon Therapeutics

\*\* VLP (Virus-Like Particle)

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



## ■ Launch for Neuromyelitis Optica Spectrum Disorder (NMOSD)

<b>Mechanism of action</b>	Humanized anti-CD19 monoclonal antibody.
<b>Features</b>	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.
<b>Number of patients</b>	Approximately 4,000 patients in Japan.*
<b>Month of launch</b>	June, 2021
<b>Peak sales forecast</b>	5.9 billion yen (at the peak of 8th year after launch)



## ■ Global P3 studies are ongoing for 2 indications following NMOSD\*\*

### [1] Myasthenia gravis

- A disease that shows muscle weakness and fatigue in the eyes, hands, and feet. It could be classified into two types; the ocular type (mainly showing eye symptoms) and the generalized type.
- Number of patients in Japan: approximately 23,000\*

### [2] IgG4-Related disease

- A disease that shows swelling and hardening of various organs; the cause of the disease is unknown. IgG4, one of the immunoglobulins, is typically elevated in blood.
- Number of patients in Japan: Approximately 8,000\*

\* Japan Intractable Diseases Information Center  
<https://www.nanbyou.or.jp/>

\*\* Co-development with Horizon Therapeutics

# EXSERVAN (RILUZOLE oral film) Launched in U.S. (in June)



## About EXSERVAN

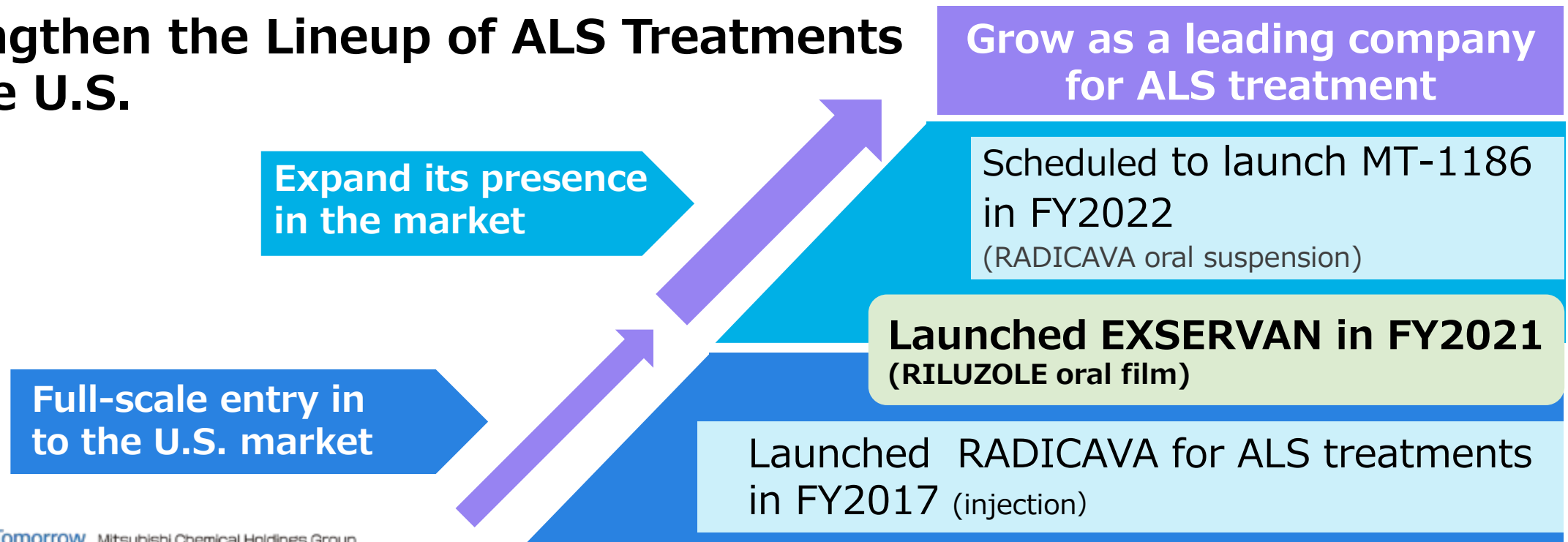


<Oral Film>



- Improves convenience for ALS patients, including those who have difficulty swallowing some medications
- Can be used in combination with RADICAVA

## Strengthen the Lineup of ALS Treatments in the U.S.



# Launched "TENELIA OD Tablets" (in June)

## ■ The first OD tablets in DPP-4 inhibitors in Japan

- Further convenience and improvement of medication compliance for elderly patients and patients with impaired swallowing function in type 2 diabetes mellitus



## ■ New options for all people facing type 2 diabetes mellitus



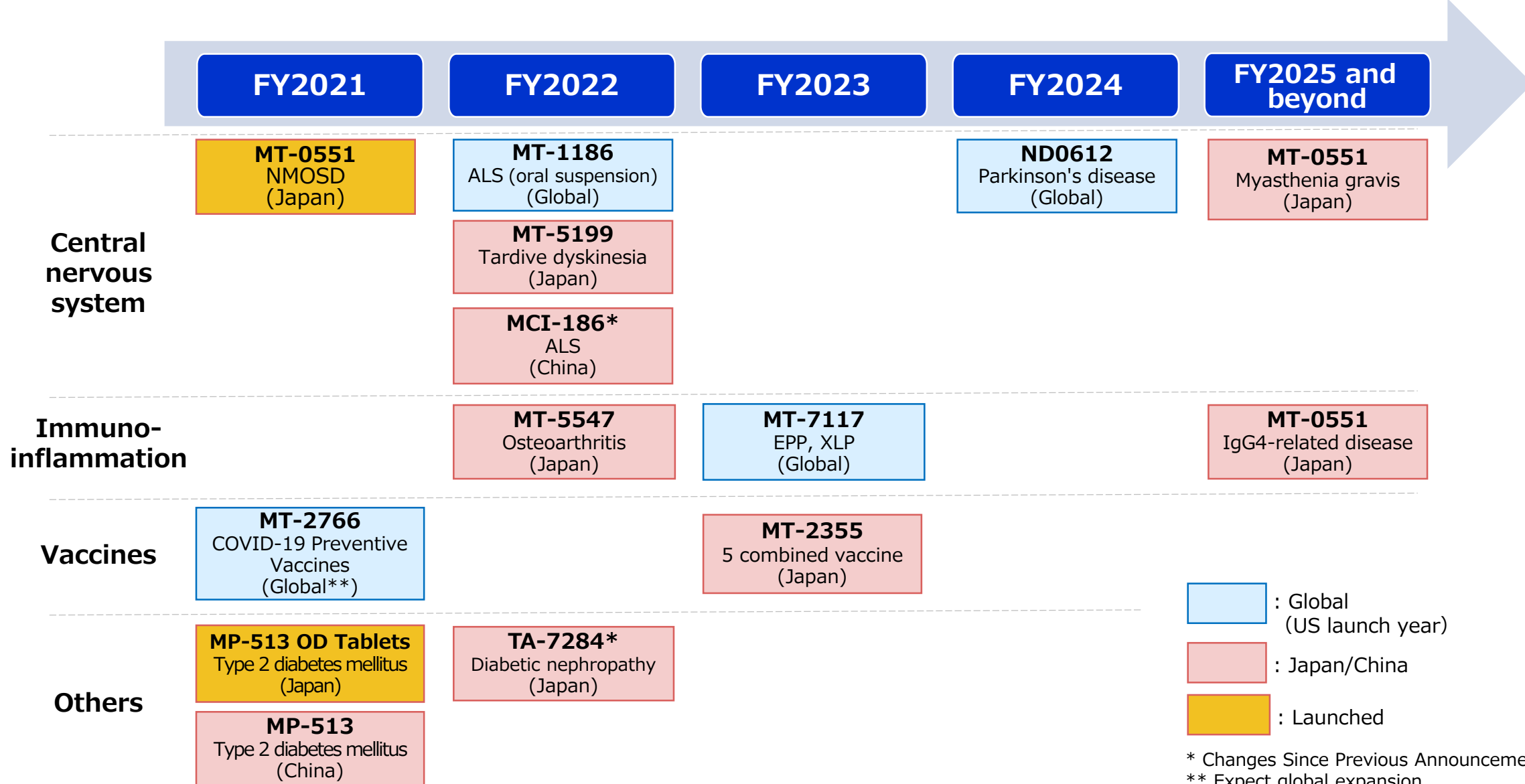
# Major Development Pipeline List

Progress Update

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)					Mar.
		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)

# Launch Plan for Major Development Pipeline



- : Global (US launch year)
- : Japan/China
- : Launched

\* Changes Since Previous Announcement  
 \*\* Expect global expansion after commercialization in Canada

## 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.**