

# Q3 FY2021 Business Results

## (April –December 2021)

February 3, 2022

# Q3 FY2021 Financial Results



	Q3 FY2021	Comparison to previous year		
		Q3 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Revenue	299.8	290.2	9.7	3.3
Gross profit	148.2	143.0	5.2	3.7
SG&A expense, etc.	141.1	118.2	22.9	19.3
R&D expense	70.2	50.3	19.9	39.6
Core operating profit	7.1	24.7	(17.6)	(71.2)
Non-recurring items*	3.4	(79.5)	82.8	-
Operating profit*	10.5	(54.7)	65.2	-
Net profit attributable to owners of the Company*	6.1	(45.3)	51.4	-
Average exchange rate US\$	¥111.45	¥105.54		

\*Brackets indicate expense and loss

# Details of Revenue

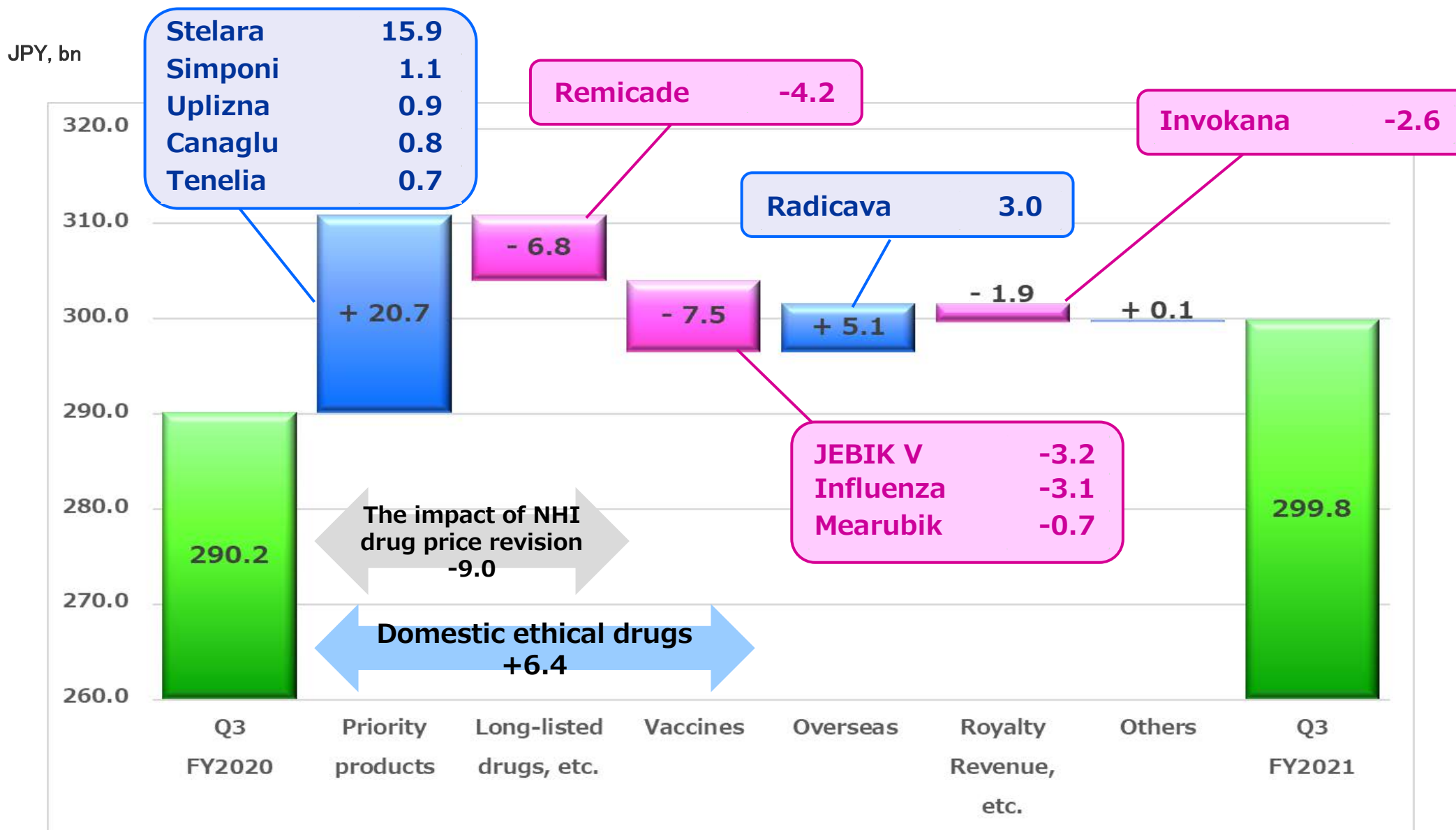


	Q3 FY2021	Comparison to previous year		
		Q3 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Domestic ethical drugs	241.3	235.0	6.4	2.7
Priority products	124.4	103.7	20.7	20.0
Vaccines	28.5	36.0	(7.5)	(20.9)
Long-listed drugs, etc.	88.5	95.3	(6.8)	(7.2)
Remicade	31.3	35.5	(4.2)	(11.9)
Overseas ethical drugs	42.1	37.0	5.1	13.7
Radicava	18.9	15.9	3.0	18.7
Royalty revenue, etc.	10.5	12.4	(1.9)	(15.3)

# Revenue of Priority Products and Vaccines

	Q3	Comparison to previous year		
	FY2021	Q3 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Stelara	38.9	23.0	15.9	69.3
Simponi	33.8	32.7	1.1	3.2
Tenelia	12.5	11.8	0.7	5.9
Canaglu	8.8	8.0	0.8	10.6
Canalia	7.8	7.5	0.3	4.1
Vafseo	0.7	0.3	0.4	113.4
Lexapro	11.9	11.9	0.0	0.3
Uplizna	0.9	-	0.9	-
Rupafin	5.9	5.2	0.7	13.7
Imusera	3.1	3.2	(0.2)	(5.4)
Total of priority products	124.4	103.7	20.7	20.0
Influenza vaccine	10.7	13.8	(3.1)	(22.6)
Tetrabik	7.8	8.2	(0.3)	(4.2)
Mearubik	4.3	5.1	(0.7)	(14.5)
Varicella vaccine	3.6	3.8	(0.2)	(6.0)
JEBIK V	1.2	4.3	(3.2)	(73.2)
Total of vaccines	28.5	36.0	(7.5)	(20.9)
Total of priority products and vaccines	152.9	139.7	13.2	9.5

# Revenue Trends





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# Status of research and development etc.

# Development Pipeline : Central nervous system

Creating hope for all facing illness.



## 1. Central nervous system

Code	Indications/Description	Region	Stage	Progress (blue indicates progression)
<b>MT-1186</b>	ALS/Oral suspension	Global* <sup>1</sup>	Filed	<ul style="list-style-type: none"><li>Acceptance of NDA in the U.S. for priority review (January 2022).</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-3921</b>	Spinal cord injury	Global	P2	<ul style="list-style-type: none"><li>Global P2 study is ongoing.</li></ul>
<b>MT-0551</b>	Myasthenia gravis	Japan* <sup>2</sup>	P3	<ul style="list-style-type: none"><li>Global P3 study is ongoing.</li></ul>

\*1 Development stage for other countries excluding US is Phase 3

\*2 Co-development with Horizon Therapeutics

# Development Pipeline : Immuno-inflammation and Vaccines

## 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-7117</b>	Systemic sclerosis	Global	P2	<ul style="list-style-type: none"> <li>Global P2 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* <sup>1</sup>	P3	<ul style="list-style-type: none"> <li>Global P3 study is ongoing.</li> </ul>

## 3. Vaccines

Code	Indications / Description	Region	Stage	Progress (blue indicates progression)
<b>MT-2766</b>	Prophylaxis of COVID-19/Plant-derived VLP* <sup>2</sup> vaccine	Global* <sup>3</sup>	P3	<ul style="list-style-type: none"> <li>NDA submission completed in <b>Canada (December)</b>, aim to commercialization in FY2021.</li> <li>P1/2 study is ongoing in Japan.</li> </ul>
<b>MT-2355</b>	Combined vaccine* <sup>4</sup>	Japan	P3	<ul style="list-style-type: none"> <li>P3 study completed.</li> </ul>

\*<sup>1</sup> Co-development with Horizon Therapeutics

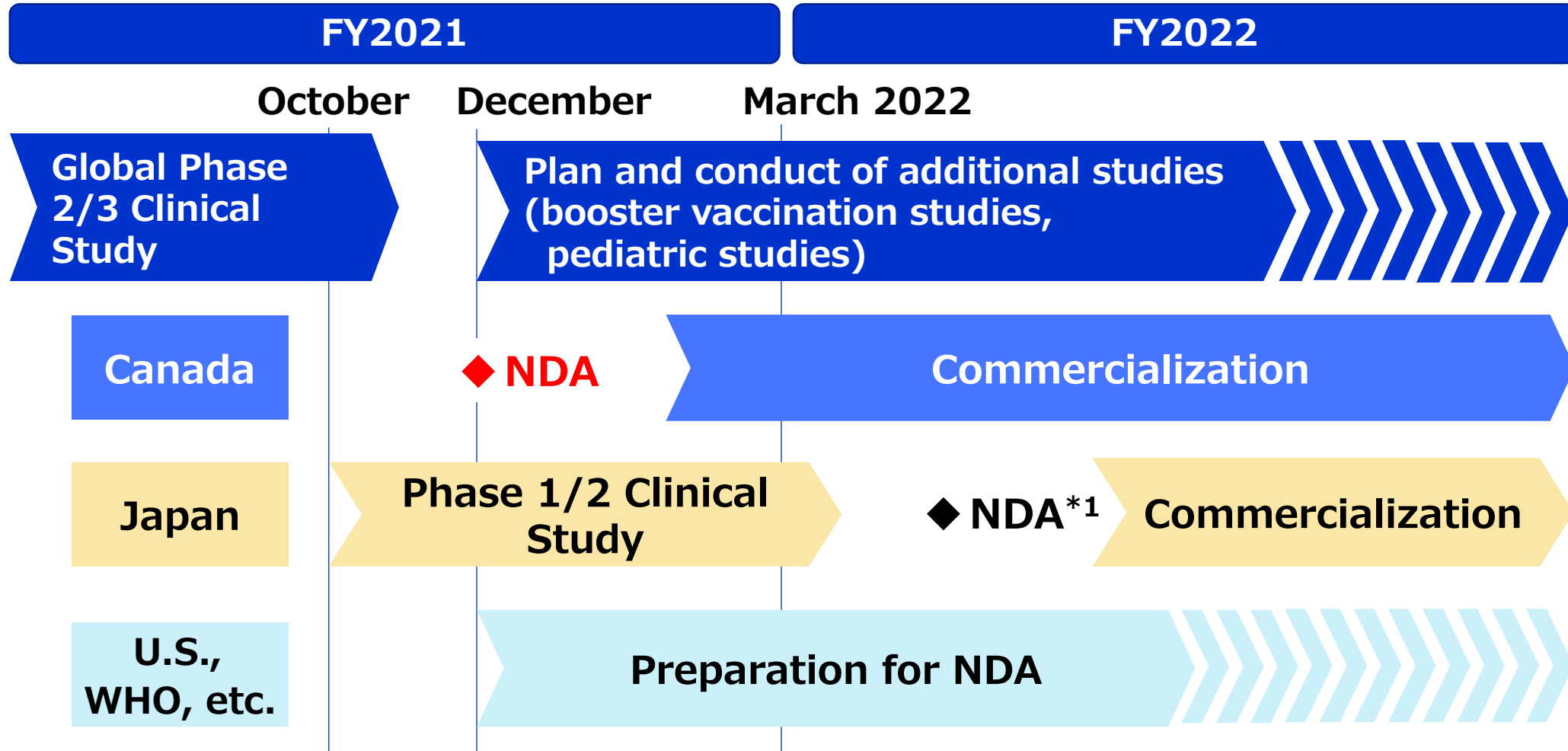
\*<sup>2</sup> VLP (Virus-Like Particle)

\*<sup>3</sup> Development stage for other countries excluding Canada is P3.

\*<sup>4</sup> Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants



### ■ Status of development in each country



\*1 Global clinical study data and Japanese clinical study data

### ■ Acceptance of MT-1186 filing in the U.S. in January

- The U.S. Food and Drug Administration (FDA) has accepted the application for priority review.
- This oral suspension contains the same ingredient as Radicava (injectable dosage form) and reduces the burden on ALS patients such as injection pain and outpatient visits, and significant improvement in convenience.

**Grow as a leader in ALS treatment**

### ■ Expanding the lineup of ALS treatment drugs in the U.S. and create new hope

Scheduled to launch MT-1186 in FY2022

**FDA acceptance of NDA for MT-1186 (RADICAVA Oral Suspension)**

Launched EXSERVAN in FY2021 (RILUZOLE oral film)

Launched RADICAVA for ALS treatments in FY2017 (injection)

# Major Development Pipeline List

As of Jan. 25, 2022

Progress Update



Research areas	Code	Region	Indications/Description	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global* <sup>1</sup>	ALS/Oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-3921	Global	Spinal cord injury					
	MT-5199	Japan	Tardive dyskinesia					
	MT-0551	Japan* <sup>2</sup>	Myasthenia gravis					
	MT-8554	Japan	Peripheral neuropathic pain					
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* <sup>2</sup>	IgG4-related disease					
Vaccines	MT-2766	Global* <sup>3</sup>	Prophylaxis of COVID-19/Plant-derived VLP* <sup>4</sup> vaccine					
	MT-2654	Global	Prophylaxis of seasonal influenza: elderly/Plant-derived VLP* <sup>4</sup> vaccine					
	MT-2355	Japan	Combined vaccine* <sup>5</sup>					
Others	TA-7284	Japan	Diabetic nephropathy					

\*1 NDA submission completed in the U.S. And P3 development stage in other countries

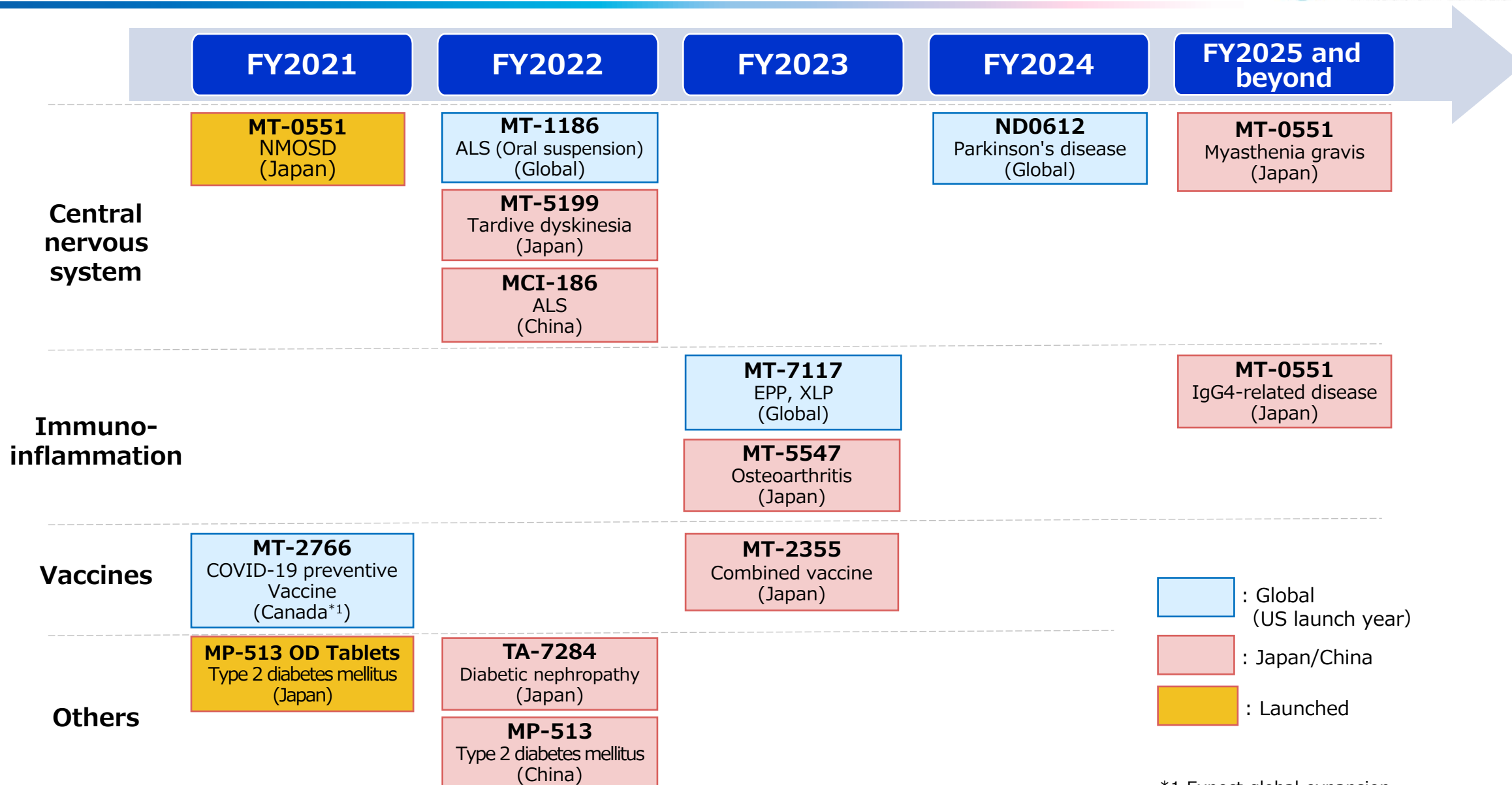
\*2 Co-development with Horizon Therapeutics

\*3 NDA submission completed in the Canada. And P3 development stage in other countries

\*4 VLP (Virus-Like Particle)

\*5 Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants

# Launch Plan for Major Development Pipeline



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

\*1 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.



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**Creating hope for all facing illness.**