

# Q2 FY2021 Business Results

## (April –September 2021)

November 2, 2021

# Q2 FY2021 Financial Results



	Q2 FY2021	Comparison to previous year		
		Q2 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Revenue	190.9	187.3	3.6	1.9
Gross profit	94.1	92.5	1.7	1.8
SG&A expense, etc.	91.5	77.9	13.6	17.4
R&D expense	45.2	33.9	11.3	33.3
Core operating profit	2.6	14.6	(11.9)	(81.9)
Non-recurring items*	(1.6)	(76.5)	74.9	-
Operating profit	1.0	(61.9)	62.9	-
Net profit attributable to owners of the Company*	(1.5)	(51.0)	49.5	-
Average exchange rate US\$	¥110.10	¥106.32		

\*Brackets indicate expense and loss

# Details of Revenue

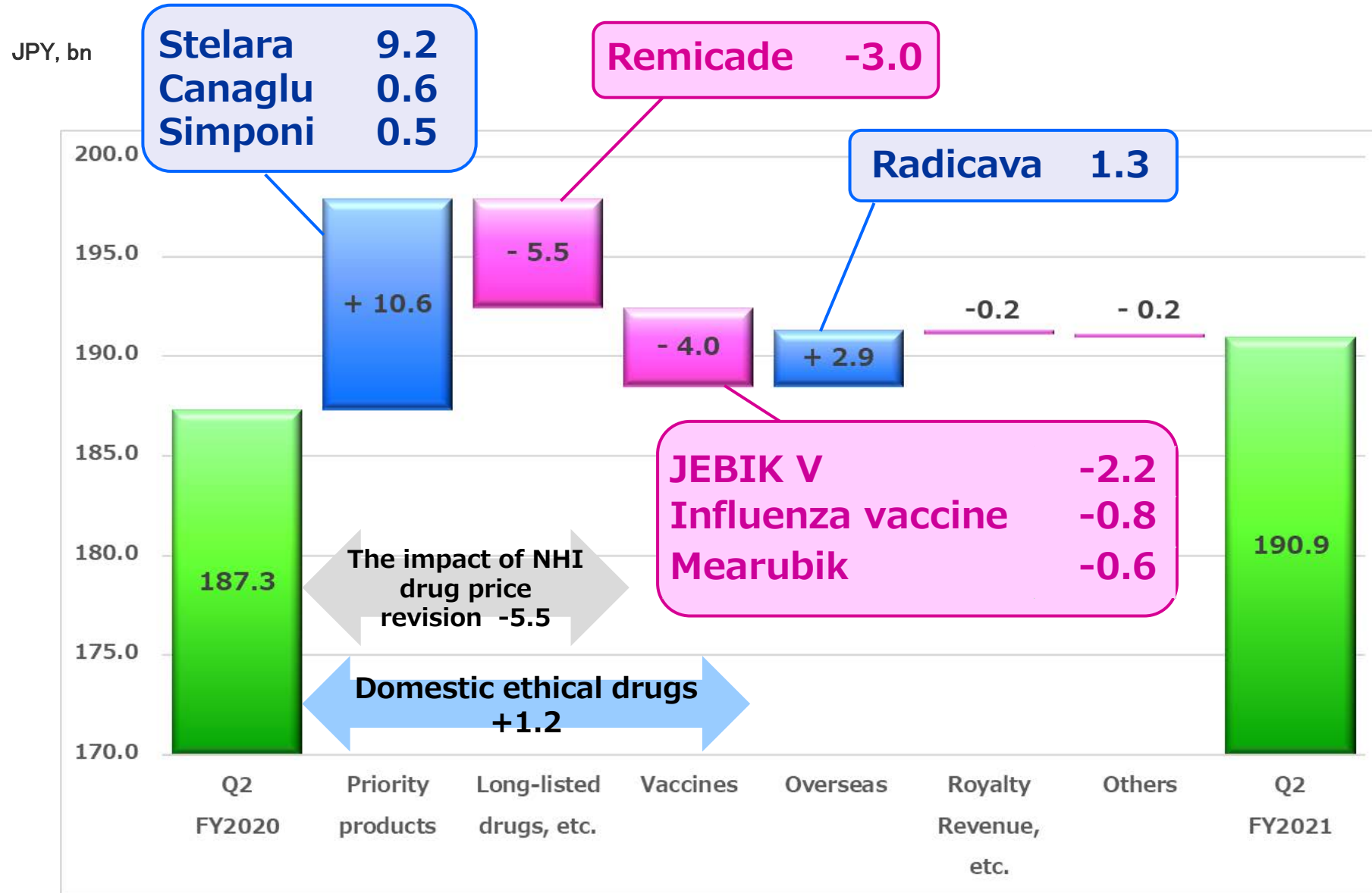


	Q2 FY2021	Comparison to previous year		
		Q2 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Domestic ethical drugs	151.5	150.3	1.2	0.8
Priority products	77.0	66.4	10.6	16.0
Vaccines	17.2	21.1	(4.0)	(18.7)
Long-listed drugs, etc.	57.3	62.7	(5.5)	(8.7)
Remicade	20.4	23.4	(3.0)	(12.8)
Overseas ethical drugs	28.0	25.1	2.9	11.4
Radicava	12.4	11.1	1.3	12.1
Royalty revenue, etc.	7.6	7.8	(0.2)	(2.6)

# Revenue of Priority Products and Vaccines

	Q2	Comparison to previous year		
	FY2021	Q2 FY2020	Increase (decrease)	Change
	Billion yen	Billion yen	Billion yen	%
Stelara	23.1	14.0	9.2	65.8
Simponi	21.7	21.2	0.5	2.2
Tenelia	7.8	8.0	(0.2)	(2.0)
Canaglu	5.7	5.0	0.6	12.5
Canalia	4.9	5.0	(0.1)	(2.2)
Vafseo	0.3	0.3	0.0	11.9
Lexapro	7.6	7.6	0.0	0.1
Uplizna	0.3	-	0.3	-
Rupafin	3.6	3.2	0.4	11.5
Imusera	2.0	2.1	(0.1)	(5.2)
Total of priority products	77.0	66.4	10.6	16.0
Influenza vaccine	5.5	6.3	(0.8)	(12.4)
Tetrabik	5.0	5.1	(0.2)	(3.8)
Mearubik	3.1	3.7	(0.6)	(16.3)
Varicella vaccine	2.2	2.5	(0.3)	(11.6)
JEBIK V	0.7	2.9	(2.2)	(75.7)
Total of vaccines	17.2	21.1	(4.0)	(18.7)
Total of priority products and vaccines	94.2	87.6	6.7	7.6

# Revenue Trends



# Revised Forecasts of FY2021

	Revised forecasts	Original forecasts <sup>*1</sup>	Increase / Decrease		FY2020 actual
	Billion yen	Billion yen	Billion yen	%	Billion yen
Revenue	398.0	407.5	(9.5)	(2.3)	377.8
SG&A expense, etc.	186.5	189.0	(2.5)	(1.3)	166.4
R&D expense	90.5	85.0	5.5	6.5	72.6
Core operating profit	16.5	26.0	(9.5)	(36.5)	21.0
Operating profit <sup>*2</sup>	19.5	30.0	(10.5)	(35.0)	(58.5)
Net profit attributable to owners of the Company <sup>*2</sup>	10.5	17.5	(7.0)	(40.0)	(46.9)
Average exchange rate US\$	¥110.00	¥110.00			¥105.94

<Reasons of revision>

Revenue : Expecting delay in the supply to the Canadian authority of COVID-19 vaccine being developed by Medicago

Core operating profit : Review contents and timing of expenses including R&D for reducing the impact of sales decline

\*1: Original was announced on May 12,2021

\*2: Brackets indicate expense and loss

# Details of Revenue

	Revised forecasts	Original forecasts <sup>*</sup>	Increase / Decrease		FY2020 actual
	Billion yen	Billion yen	Billion yen	%	Billion yen
Domestic ethical drugs	297.6	286.3	11.3	3.9	304.7
Priority products	153.8	146.6	7.2	4.9	137.7
Vaccines	36.3	37.0	(0.7)	(2.0)	42.6
Long-listed drugs, etc.	107.5	102.7	4.8	4.7	124.4
Remicade	38.2	36.5	1.7	4.6	45.4
Overseas ethical drugs	79.2	100.6	(21.3)	(21.2)	50.2
Radicava	22.4	19.8	2.6	13.3	22.0
Royalty revenue, etc.	13.2	12.3	0.9	7.2	15.9

\* Original was announced on May 12, 2021

# Revenue of Priority Products and Vaccines

	Revised forecasts	Original forecasts*	Increase / Decrease		FY2020 actual
	Billion yen	Billion yen	Billion yen	%	Billion yen
Stelara	46.4	42.7	3.7	8.7	32.2
Simponi	42.5	41.2	1.3	3.2	42.3
Tenelia	14.8	14.4	0.5	3.1	15.1
Canaglu	10.8	10.1	0.7	7.1	10.3
Canalia	9.5	9.3	0.2	2.2	9.7
Vafseo	1.1	1.3	(0.2)	(18.0)	0.3
Lexapro	14.7	14.1	0.6	4.5	15.3
Uplizna	1.2	1.4	(0.1)	(8.8)	-
Rupafin	9.1	8.9	0.2	2.3	8.2
Imusera	3.6	3.3	0.4	10.6	4.1
<b>Total of priority products</b>	<b>153.8</b>	<b>146.6</b>	<b>7.2</b>	<b>4.9</b>	<b>137.7</b>
Influenza vaccine	13.5	14.3	(0.8)	(5.7)	14.4
Tetrabik	10.5	10.8	(0.3)	(2.6)	10.9
Mearubik	5.3	5.7	(0.3)	(6.2)	6.1
Varicella vaccine	4.3	4.1	0.1	3.3	5.0
JEBIK V	1.6	1.3	0.4	31.2	5.2
<b>Total of vaccines</b>	<b>36.3</b>	<b>37.0</b>	<b>(0.7)</b>	<b>(2.0)</b>	<b>42.6</b>
<b>Total of priority products and vaccines</b>	<b>190.1</b>	<b>183.7</b>	<b>6.5</b>	<b>3.5</b>	<b>180.3</b>

\* Original was announced on May 12, 2021





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# Status of research and development etc.

# Development Pipeline : Central nervous system and Immuno-inflammation

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	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-3921</b>	Spinal cord injury	Global	P2	<ul style="list-style-type: none"> <li>Global P2 study started (August).</li> </ul>
<b>MT-0551</b>	Myasthenia gravis	Japan*	P3	<ul style="list-style-type: none"> <li>Global P3 study is ongoing.</li> </ul>

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

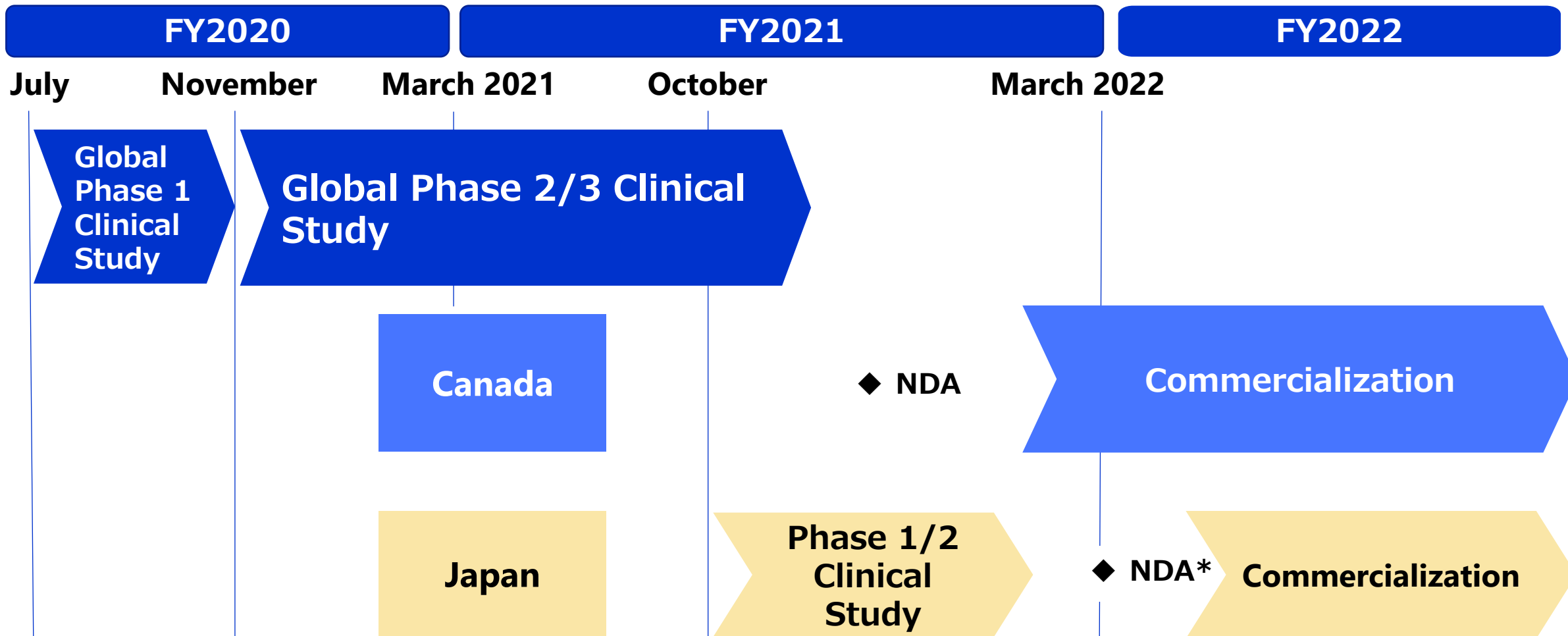
## 4. Others (Diabetes and kidney)

Code	Indications	Region	Stage	Progress(blue indicates progression)
<b>TA-7284</b>	Chronic kidney disease with type 2 diabetes mellitus	Japan	Filed	<ul style="list-style-type: none"> <li>NDA submission completed (August).</li> </ul>

\* VLP (Virus-Like Particle)

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

### Commercialization in Canada and Japan



\* Global clinical study data bridging

# Major Development Pipeline List

As of Oct. 22, 2021

Progress Update



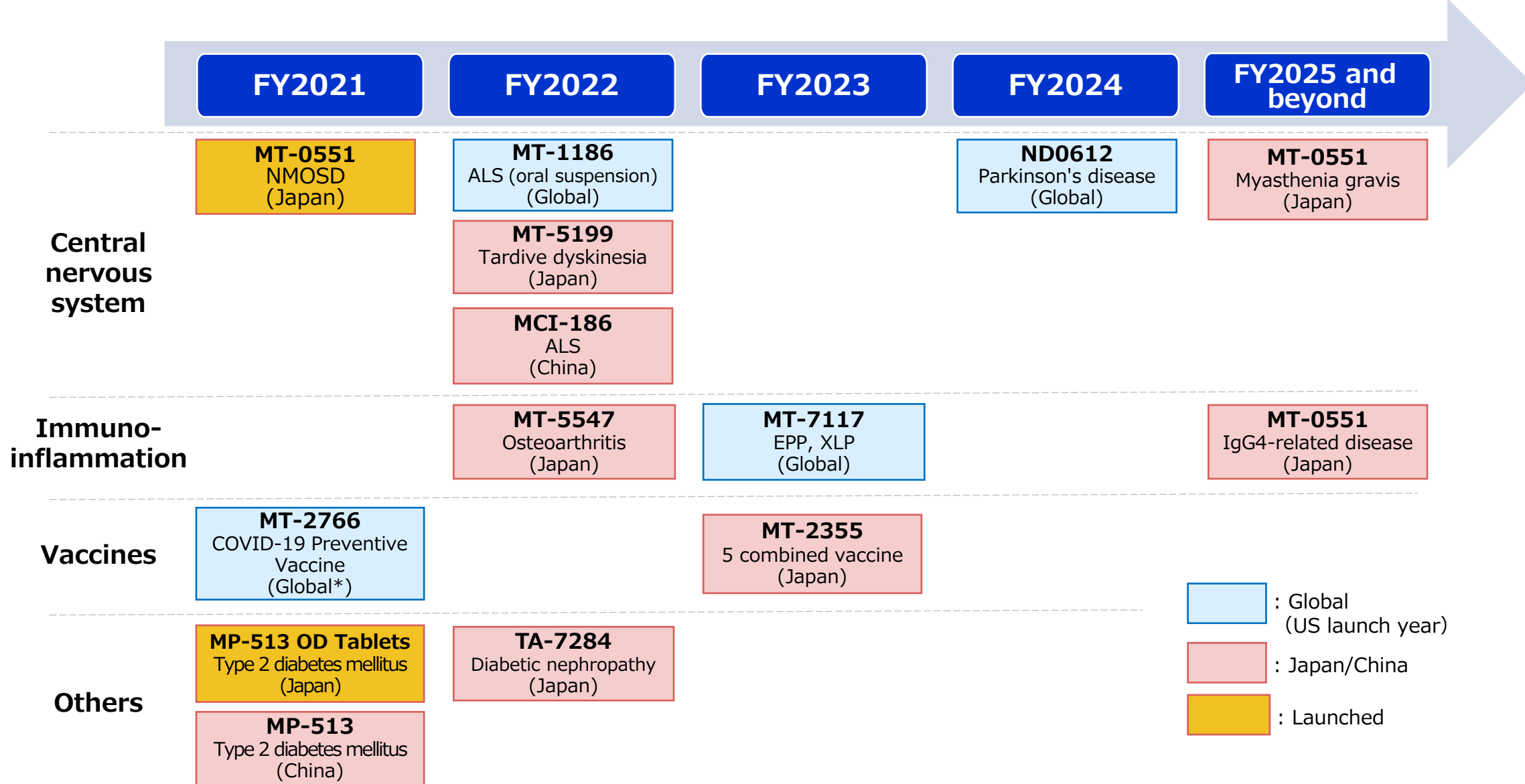
Research areas	Code	Region	Indications/Description	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global	ALS/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-3921	Global	Spinal cord injury					
	MT-0551	Japan*	Myasthenia gravis					
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	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/Plant-derived VLP** vaccine					
	MT-2654	Global	Prophylaxis of seasonal influenza: elderly/Plant-derived VLP** vaccine					
	MT-2355	Japan	5 combined vaccine***					
Others	TA-7284	Japan	Diabetic nephropathy					

\* Co-development with Horizon Therapeutics

\*\* VLP (Virus-Like Particle)

\*\*\* 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

\* 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.**