



# **Q3 FY2020 Business Results (April – December 2020)**

**February 3, 2021**

## Q3 FY2020 Business Results

# Q3 FY2020 Financial Results

	Q3 FY2020	Comparison to previous year			Comparison to forecasts	
		Q3 FY2019	Increase (decrease)	Change	Announced on Nov.4th	Progress
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	290.2	297.4	(7.2)	(2.4)	373.0	77.8
(Domestic)	241.8	247.3	(5.5)	(2.2)	312.2	77.4
(Overseas)	48.4	50.2	(1.7)	(3.5)	60.8	79.6
Overseas sales ratio	16.7%	16.9%			16.3%	-
Cost of sales	147.2	143.1	4.2	2.9	187.5	78.5
Sales cost ratio	50.7%	48.1%			50.3%	-
Gross profit	143.0	154.3	(11.4)	(7.4)	185.5	77.1
SG&A expense, etc.	118.2	130.2	(12.0)	(9.2)	168.5	70.2
(R&D expense)	50.3	57.6	(7.3)	(12.7)	72.5	69.3
Core operating profit*1	24.7	24.2	0.6	2.3	17.0	145.5
Non-recurring items*2	(79.5)	0.8	(80.3)	-	(79.5)	-
Gain from sales of Toda office	7.5	-	7.5	-	-	-
Loss from impairment*3	(84.5)	-	(84.5)	-	-	-
Operating profit*2	(54.7)	25.0	(79.7)	-	(62.5)	-
Financial income and loss*2	0.3	(0.4)	0.6	-	-	-
Net profit attributable to owners of the Company*2	(45.3)	18.2	(63.5)	-	(52.5)	-
Average exchange rate US\$	¥105.54	¥108.89			¥108.00	

\*1:¥6.8B of impact from COVID-19 included

Decreased expenses by shrinkage in sales promotion and delay in R&D expenses incurrence overtake sales decrease

\*2:Brackets indicate expense and loss

\*3:Booked impairment loss from ND0612 in Q2

# Q3 FY2020 Business Results

## Details of Revenue

	Q3 FY2020	Comparison to previous year			Comparison to forecasts	
		Q3 FY2019	Increase (decrease)	Change	Announced on Nov.4th	Progress
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Domestic ethical drugs	235.0	239.6	(4.7)	(2.0)	302.3	77.7
Priority products	139.2	137.9	1.3	1.0	183.0	76.1
Vaccines*	36.0	32.9	3.0	9.3	41.6	86.4
Long-listed drugs, etc.*	59.8	68.9	(9.1)	(13.2)	77.7	77.0
Overseas ethical drugs	37.0	37.5	(0.5)	(1.3)	47.0	78.8
Radicava	15.9	17.4	(1.4)	(8.3)	20.1	79.3
Royalty revenue, etc.	12.4	13.6	(1.2)	(8.7)	15.2	81.8

\*Corrected vaccines forecasts from 40.8 to 41.6 and Long-listed drugs, etc forecasts from 78.5 to 77.7 due to mistaken announcement on Nov.4

# Q3 FY2020 Business Results

## Domestic Ethical Drugs

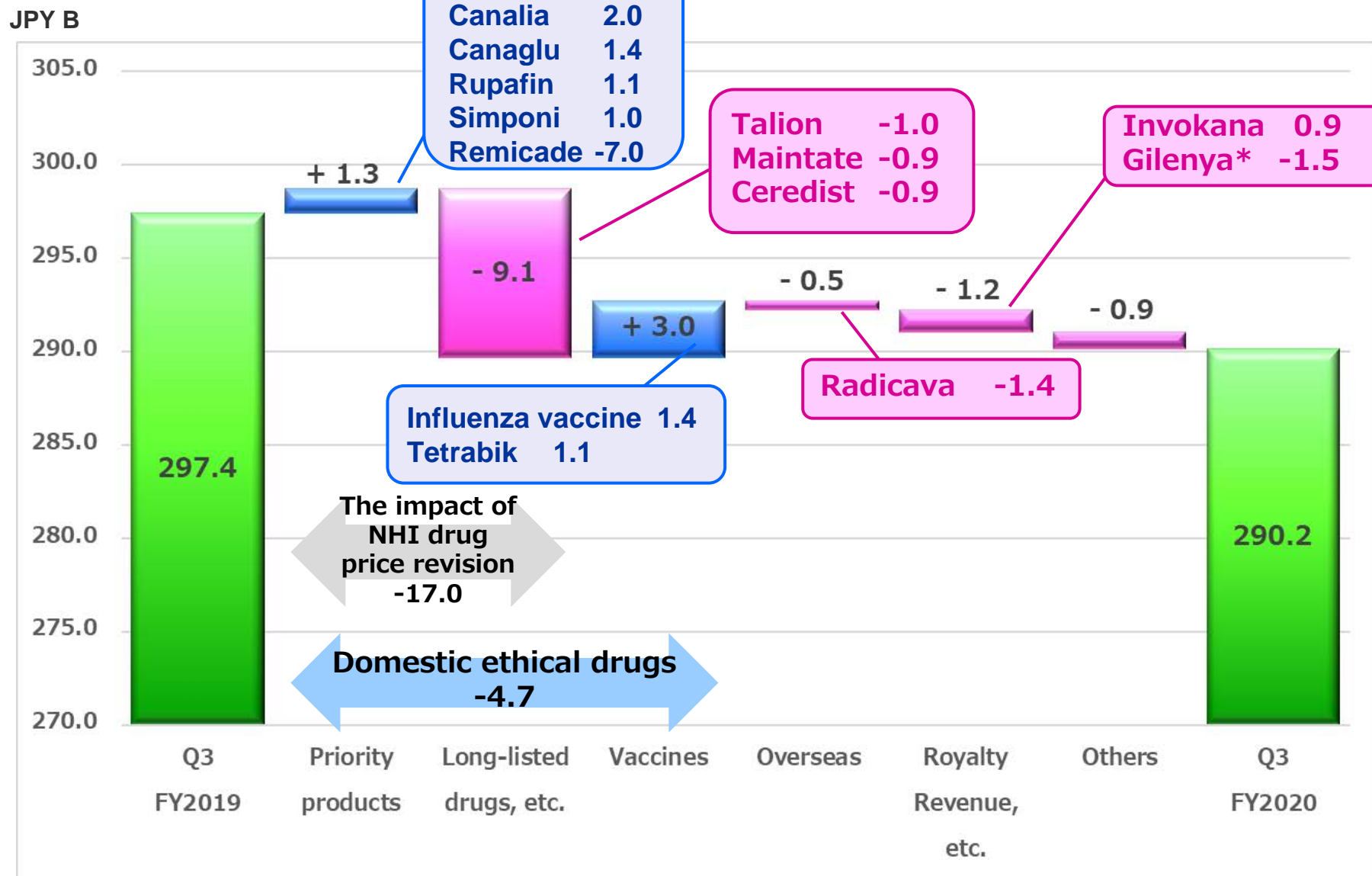
### Revenue of Priority Products and Vaccines

	Q3 FY2020	Comparison to previous year			Comparison to forecasts	
		Q3 FY2019	Increase (decrease)	Change	Announced on Nov.4th	Progress
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	35.5	42.5	(7.0)	(16.5)	45.0	78.9
Simponi	32.7	31.7	1.0	3.3	42.7	76.7
Stelara	23.0	20.4	2.6	13.0	31.9	72.1
Tenelia	11.8	12.1	(0.3)	(2.1)	14.9	79.4
Canaglu	8.0	6.6	1.4	21.3	9.8	81.5
Canalia	7.5	5.5	2.0	36.0	9.3	80.6
Vafseo (launched in Aug.)	0.3	-	0.3	-	0.5	65.6
Lexapro	11.9	11.6	0.2	2.1	14.8	80.1
Rupafin	5.2	4.2	1.1	25.3	10.0	52.1
Imusera	3.2	3.4	(0.1)	(3.2)	4.1	79.2
Total of priority products	139.2	137.9	1.3	1.0	183.0	76.1
Influenza vaccine	13.8	12.4	1.4	11.1	13.2	104.7
Tetrabik	8.2	7.1	1.1	15.3	11.1	73.7
Mearubik	5.1	4.8	0.3	6.1	6.4	79.1
JEBIK V	4.3	4.2	0.2	4.0	5.3	81.9
Varicella vaccine	3.8	3.8	(0.0)	(0.1)	4.8	78.9
Total of vaccines*	36.0	32.9	3.0	9.3	41.6	86.4
Total of priority products and vaccines*	175.2	170.8	4.4	2.6	224.6	78.0

\*Corrected total of vaccines forecasts from 40.8 to 41.6 and total of priority products and vaccines forecasts from 223.8 to 224.6 due to mistaken announcement on Nov.4



## Revenue Trends



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

# Status of research and development etc.



# FY 2020 Q3 Overview

## Major Development Pipeline

Code	Indications	Stage	Topics
MT-1186	ALS / Oral suspension	P3	• Global P3 study (long-term safety study) is ongoing. Enrollment completed in October.
ND0612	Parkinson's disease	P3	• Global P3 study is ongoing.
MT-7117	Erythropoietic protoporphyria (EPP) X-linked protoporphyria (XLP)	P3	• Global P3 study is ongoing.
MT-0551	Myasthenia gravis	P3*	• Started co-development with Viela Bio in global P3 study
	IgG4-related disease	P3*	
MT-2766	Prophylaxis of COVID-19 (Plant-based VLP** vaccine)	P2	• P2 study started in November. P3 study planned to be conducted in 30,000 subjects early in 2021

\*Co-development with Viela Bio (Global study ongoing)

\*\*VLP : Virus-like particle

## Topics

Dec. : Launched "Talion AR", new OTC drug for the exclusive use of allergic rhinitis.

Jan. : Received the arbitration award on the license agreement with Kolon Life Science

: licensing agreement for Riluzole oral film in the U.S. to strengthen our ALS product lineup

: Entered into an exclusive licensing agreement with Pharma Foods International for a new therapeutic antibody to treat autoimmune diseases

# MT-0551

## (Generic name: Inebilizumab)

As indications following NMOSD, global P3 studies are being conducted for 2 diseases

Mechanism of Action	Humanized anti-CD 19 monoclonal antibody
Origin	Viela Bio, Inc. (United States)
Our company Rights	Japan and Asia (excluding some regions such as China)
Indications	<p>① <b>Myasthenia gravis</b>: 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. [Japan] Approximately 23,000 patients*</p> <p>② <b>IgG4-related disease</b>: 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. [Japan] Approximately 8,000 patients*</p> <p style="text-align: right;">*Japan Intractable Diseases Information Center</p>
Development stage	① ②: Phase 3 (co-development with Viela Bio)
Future plans	<p>Viela Bio is conducting global studies including Japan, and the timing of regulatory submission and its approval in Japan will be determined depending on the study progress.</p> <p>※The indication of neuromyelitis optica spectrum disorder (NMOSD) was applied for approval in Japan in June 2020.</p>



## Medicago VLP Vaccine aims to prevent COVID-19

<b>Category</b>	Plant-based VLP (virus-like particle) vaccine
<b>Origin</b>	Medicago Inc. (Canada)
<b>Development stage</b>	Phase 2
<b>Indications</b>	Prophylaxis of COVID-19
<b>Phase 1 Summary and results</b>	<ul style="list-style-type: none"> <li>Subjects: 180 healthy Canadian subjects, male and female aged 18-55.</li> <li>Dosage and administration: Evaluated dosages of 3.75, 7.5 or 15 µg of the VLP vaccine candidate alone or with each of the two adjuvants – GSK’s adjuvant and Dynavax’s adjuvant after two doses.</li> <li>Results: Induced robust neutralizing antibody and cellular immune response in the adjuvant group. No severe adverse events were observed.</li> </ul>
<b>Phase 2 Summary</b>	<ul style="list-style-type: none"> <li>Subjects: A total of 900 healthy adults, elderly adults and comorbidities in Canada and the United States.</li> <li>Dosage and administration: Two doses of 3.75 µg VLP vaccine candidate combined with GSK’s adjuvant given 21 days apart.</li> <li>Endpoints: Safety and immunogenicity. (compared to placebo)</li> </ul>
<b>Future plans</b>	P2 study started in November. P3 study planned to be conducted in 30,000 subjects early in 2021. It is scheduled to be launched in Canada in 2021

## ■ Background to date

Mitsubishi Tanabe Pharma Corporation (MTPC) on April 10, 2018 filed with the International Court of Arbitration of the International Chamber of Commerce (ICC, Venue: Seoul) against Kolon Life Science, Inc. (KLS) a request for arbitration seeking return of the upfront payment and related matters regarding the license agreement on “Invossa” between MTPC and KLS in November 2016.

## ■ Summary of the arbitral award

On January 11, 2021, MTPC received the arbitral award in which the arbitral court ordered to KLS to pay MTPC 2.5 billion yen equivalent to the upfront payment under the license agreement (as well as additional payments for interest on that amount), plus approximately 130 million yen as damages (as well as additional payments for interest on that amount), plus an amount of approximately 7.9 million US dollars as arbitration costs.

## ■ Future prospects

MTPC will review the details of the arbitral award and provide updates on the impact, if any, of the arbitral award on MTPC’s business performance.

# Strengthen our ALS product pipeline in the U.S. US Licensing and Supply Deal for EXSERVAN

**On Jan. 21, 2021, Mitsubishi Tanabe Pharma Holdings America, Inc., a subsidiary in the U.S., concluded a license and supply agreement for the U.S. right of EXSERVAN (RILUZOLE oral film), a therapeutic agent for ALS, with Aquestive Therapeutics, Inc.**

## **EXSERVAN : RILUZOLE oral film**

- EXSERVAN was approved in November 2019 in the U.S.
- Mitsubishi Tanabe Pharma America, Inc., a sales subsidiary in the U.S., plans to launch EXSERVAN in the middle of 2021.
- Utilizing innovative drug delivery technology developed by Aquestive Therapeutics, EXSERVAN can be quickly dissolved without additional water or food when placed on patient's tongue.
- EXSERVAN is very convenient for ALS patients with dysphagia and potentially can be used in combination with RADICAVA.

**Oral Film**



# Entered into an exclusive licensing agreement with Pharma Foods International for a new therapeutic antibody to treat autoimmune diseases



## ■ Background to date

In the collaborative research which was started in October 2018, Mitsubishi Tanabe Pharma Corporation (MTPC) and Pharma Foods International (PFI) successfully identified a development candidate antibody by using PFI's propriety antibody production technology and MTPC's specific technology for enhancing antibody affinity, etc. PFI has been successful in producing innovative lead antibodies for drug discovery targets to treat autoimmune diseases, for which antibody production is difficult with conventional technology.

## ■ Summary of the licensing agreement

On January 26, 2021, we entered into an exclusive licensing agreement for the development candidate antibody for which we have been conducting joint research. With the conclusion of this agreement, MTPC will have exclusive rights to manufacture, develop and sell the development candidate antibody worldwide.

MTPC will pay to PFI 320 million yen as an upfront payment. In addition, MTPC will pay development milestones depending on the stage of development, as well as royalties and sales milestones based on worldwide sales after launch.

## ■ Future prospects

This antibody project is positioned as prioritized product in the area of Immuno-inflammation, which is one of MTPC's priority disease areas, and MTPC will start the P1 study as soon as possible for the development as an antibody drug.

# OTC Drug / Allergic Rhinitis Medication

## Talion AR New release

**Talion AR has been available  
in pharmacies and drugstores nationwide  
since December 2020.**



Contains the same amount of medical ingredients “Bepotastine besilate” as prescription drugs.

### **The 5 Features of Talion AR**

1. It is quickly absorbed into the body and has an excellent effect on sneezing, runny nose and stuffy nose.
2. Taking 1 tablet in the morning and evening, 2 times a day, the effect lasts for 24 hours.
3. It works well in the nose and is hard to transfer to the brain, so it does not make you sleepy.
4. It can be taken on an empty stomach before or after meals.
5. Less likely to cause dry mouth. Bepotastine besilate has less anti-cholinergic effects that cause decreased salivation.

As of January 25, 2021

Open Up the Future



Mitsubishi Tanabe Pharma

# Major Development Pipeline List

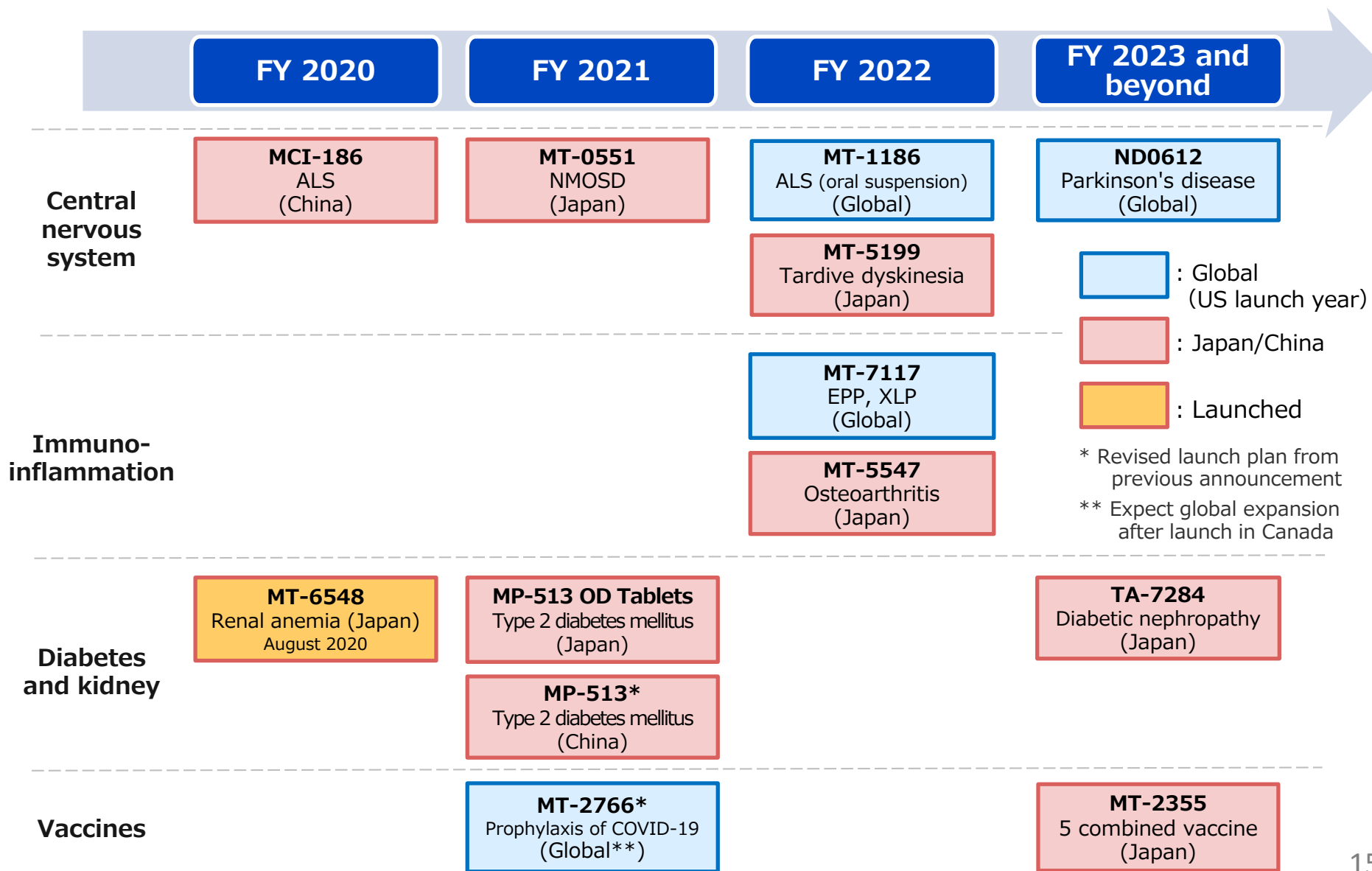
Progress Update

Priority areas	Code	Region	Indications	P1	P2	P3	Filed	Approved
Central nervous system	MT-1186	Global	ALS/oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-8554	Global	Vasomotor symptoms associated with menopause			preparing		
	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)					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
	MT-0551	Japan*	IgG4-related disease					
Diabetes and kidney	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
	MT-6548	Japan	Renal anemia					June 2020
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2766	Global	Prophylaxis of COVID-19					
	MT-2654	Global	Prophylaxis of seasonal influenza / elderly					
	MT-2355	Japan	5 combined vaccine**					

\* Co-development with Viela Bio (Global study ongoing)

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

# 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.