

# **Q3 FY2019 Business Results**

## **(April - December, 2019)**

**February 4, 2020**

**Eizo Tabaru**

Member of the Board, Managing Executive Officer

# Q3 FY2019 Business Results

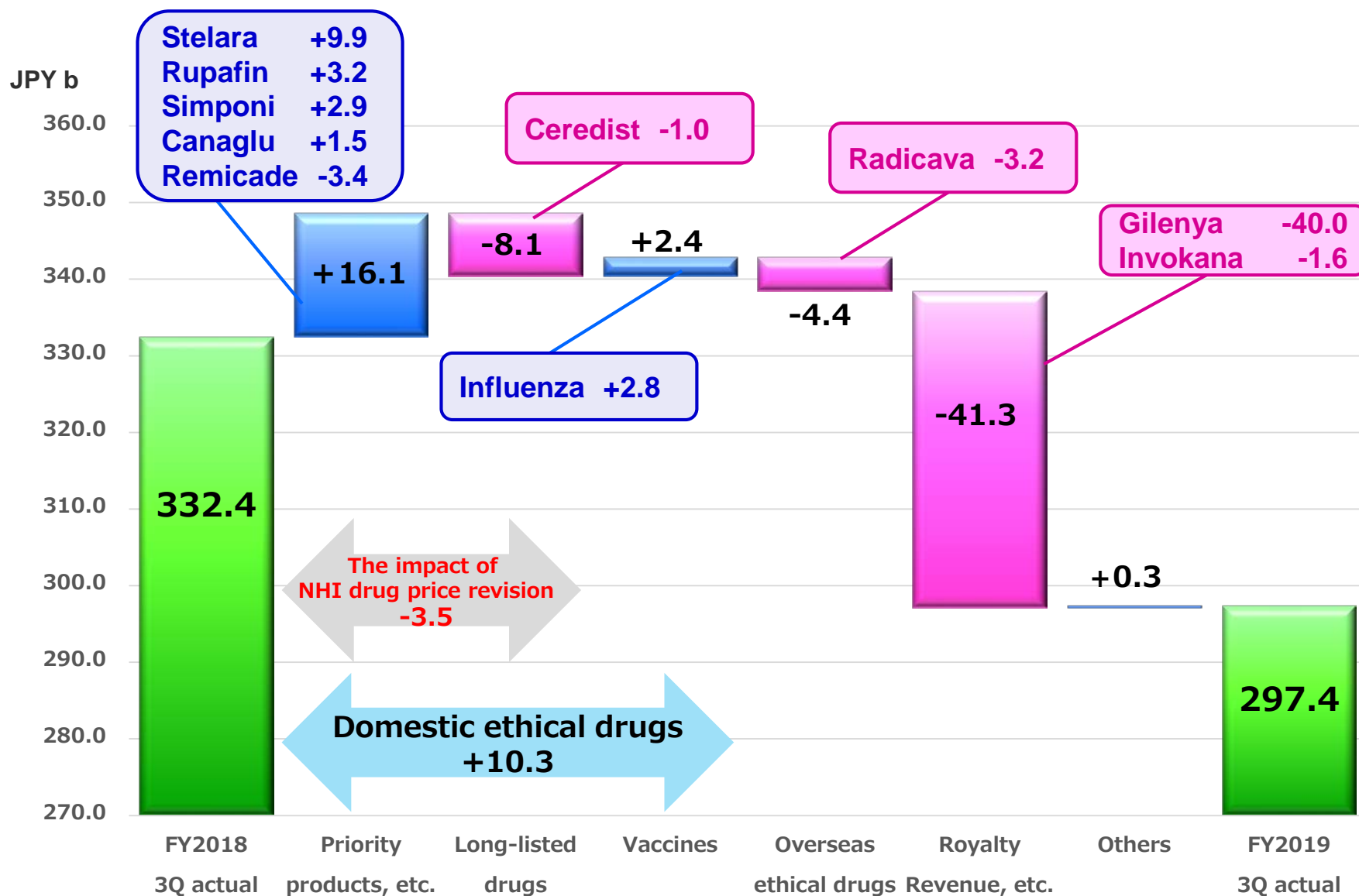


	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts <sup>※</sup>	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	297.4	332.4	(35.0)	(10.5)	376.0	79.1
(Domestic)	247.2	236.4	10.8	4.6	308.3	80.2
(Overseas)	50.1	96.0	(45.9)	(47.8)	67.6	74.1
Overseas sales ratio	16.9%	28.9%			18.0%	
Cost of sales	143.0	139.2	3.8	2.8	178.5	80.1
Sales cost ratio	48.1%	41.9%			47.5%	
Gross profit	154.3	193.2	(38.9)	(20.1)	197.5	78.2
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9
Operating profit	24.9	56.4	(31.4)	(55.7)	11.5	217.3
Net profit attributable to owners of the Company	18.2	41.4	(23.2)	(56.1)	5.0	364.5
Average exchange rate US\$	¥108.89	¥111.33			¥110.00	

※ Announced on May 10, 2019 in the financial results of FY2018

**The full-year forecasts for FY2019 remain unchanged**

# Revenue Trends



## Q3 FY2019 Business Results

Open Up the Future

### Cost of Sales, SG&A Expense, Core Operating Profit



Mitsubishi Tanabe Pharma

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	297.4	332.4	(35.0)	(10.5)	376.0	79.1
Cost of Sales	143.0	139.2	3.8	2.8	178.5	80.1
Sales cost ratio	48.1%	41.9%			47.5%	
Gross profit	154.3	193.2	(38.9)	(20.1)	197.5	78.2
SG&A expense	70.5	73.1	(2.6)	(3.6)	99.0	71.3
R&D expense	57.5	61.9	(4.3)	(7.0)	85.5	67.3
Amortization of intangible assets associated with products	1.8	2.2	(0.3)	(15.0)	2.5	74.8
Other income and expense*	(0.1)	(0.4)	0.2	-	(0.5)	-
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9

\* Brackets indicate expense and loss.

※ Announced on May 10, 2019 in the financial results of FY2018

## Non-recurring items and Net Profit

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	24.1	55.5	(31.3)	(56.5)	10.0	241.9
Non-recurring items*	0.7	0.8	(0.0)	(8.6)	1.5	53.1
Operating profit	24.9	56.4	(31.4)	(55.7)	11.5	217.3
Financial income	0.9	0.9	(0.0)	(8.2)		
Financial expense	1.2	0.8	0.4	48.2		
Net profit attributable to owners of the Company	18.2	41.4	(23.2)	(56.1)	5.0	364.5

\* Brackets indicate expense and loss.

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# Major Products



## Topics in Domestic and Overseas

### (Domestic)

#### Remicade Simponi Stelara

- **Remicade:** Q3 Total ¥42.4 billion. It is progressing as planned despite the impact of biosimilars
- **Simponi:** The number of adopting autoinjector launched in May 2019 is increasing
- **Stelara:** Q3 Total ¥20.3 billion. Moving steadily toward full-year forecast: ¥21.6 billion

#### Tenelia Canaglu Canalia

- **Tenelia:** Q3 Total ¥12.0 billion. Sales are on track  
: Application for approval of additional dosage form of OD tablet in January 2020
- **Canaglu:** The product value is enhancing through providing appropriate information on CREDENCE study\*<sup>1</sup>  
: Received the Prime Minister Award of the 3rd Japan Medical Research and Development Grand Prize in January 2020
- **Canalia:** Q3 Total ¥5.5 billion. It is growing steadily as a combination drug

\*1 CREDENCE study: Clinical trials of canagliflozin testing the renal events in diabetic patients with overt nephropathy

#### Vaccines

- The Company has the top share in the domestic vaccine market with 22.8% (April to December, 2019)
- **Influenza:** The shipment before the season worked out. Q3 Total ¥12.4 billion

### (Overseas)

#### Radicava (US)

- Q3 Total ¥17.3 billion. Sales are on track as planned.  
(Full-year forecast: ¥22.0 billion)



# Development Pipeline



## Status of Global Late Stage Projects

### MT-1186 (Radicava oral suspension)

- Start of global P3 study (long-term safety study) (November)

### Radicava

- Expanding market by serial NDA submissions in different regions/countries
- Indonesia: NDA Filed (November)
  - Thailand: NDA Filed (December)

### ND0612

- Long-term safety study (BeyoND study): Completion of 1-year treatment evaluation (October), data analysis ongoing
- Global P3 study (BouNDless): Ongoing

### MT-2271 (VLP vaccine)

- US: Under discussion with FDA for filing

**MT-7117 (MC1R\* agonist)****MT-7117, an in-house project has achieved POC and started preparations for late-stage development**

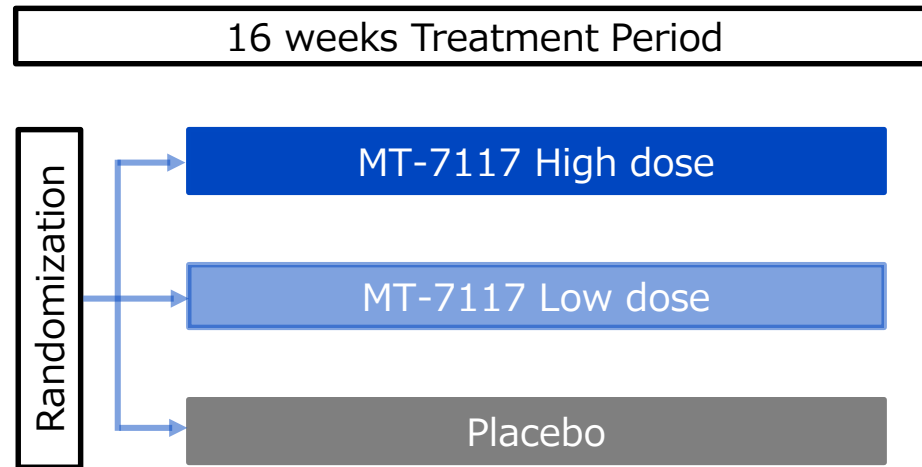
<b>MT-7117</b> <b>Features and concepts</b>		<ul style="list-style-type: none"><li>■ An oral agent to prevent photosensitivity in patients with EPP</li><li>■ Activation of MC1R promotes melanogenesis in melanocytes and prevents cutaneous symptoms caused by ultraviolet light</li><li>■ FDA Fast Track designation granted in June 2018</li></ul>
<b>Erythropoietic protoporphyria (EPP)</b>	<b>Condition</b>	<ul style="list-style-type: none"><li>■ The main symptom is photosensitivity; redness, swelling, blisters and erosions with pain following sun exposure</li></ul>
	<b>Patient Population</b>	<ul style="list-style-type: none"><li>■ [Japan, US, and EU in total] approx. 10,000</li></ul>
	<b>Current Treatment</b>	<ul style="list-style-type: none"><li>■ Protection from light, administration of <math>\beta</math>-carotene etc.</li><li>■ Afamelanotide, a subcutaneous implant, is marketed in EU and approved in US</li></ul>

\*: Melanocortin 1 Receptor

## Overview of MT-7117 POC Study

### POC Study ENDEAVOR Study

- 102 EPP patients



- Significant increase of time to the first occurrence of “prodromal symptoms” upon sun exposure observed in MT-7117 groups compared to placebo group
- Results will be presented at a scientific congress in FY 2020

### Future plans

- FY 2020: Start of P3 studies
- FY 2021: NDA submission in US

## POC study in patients with vasomotor symptoms (VMS) has been completed

<b>MT-8554 Features and concepts</b>		<ul style="list-style-type: none"> <li>■ Non-hormonal therapy with high safety profile</li> <li>■ Suppression of VMS by improving Thermoneutral Zone<sup>*2</sup></li> </ul>
<b>Vasomotor Symptoms (VMS)</b>	<b>Condition</b>	<ul style="list-style-type: none"> <li>■ Hot flashes and sweating associated with changes in hormone levels in the menopausal and perimenopausal periods</li> </ul>
	<b>Patient Population</b>	<ul style="list-style-type: none"> <li>■ Patients with moderate to severe symptoms [US] approx. 10 million, [Japan] approx. 3 million</li> </ul>
	<b>Current Treatment</b>	<ul style="list-style-type: none"> <li>■ 1st line: Hormone replacement therapy (postmenopausal women)</li> <li>■ 2nd line: Antidepressants (eg, low-dose paroxetine)</li> </ul>

\*1: Transient Receptor Potential Melastatin 8

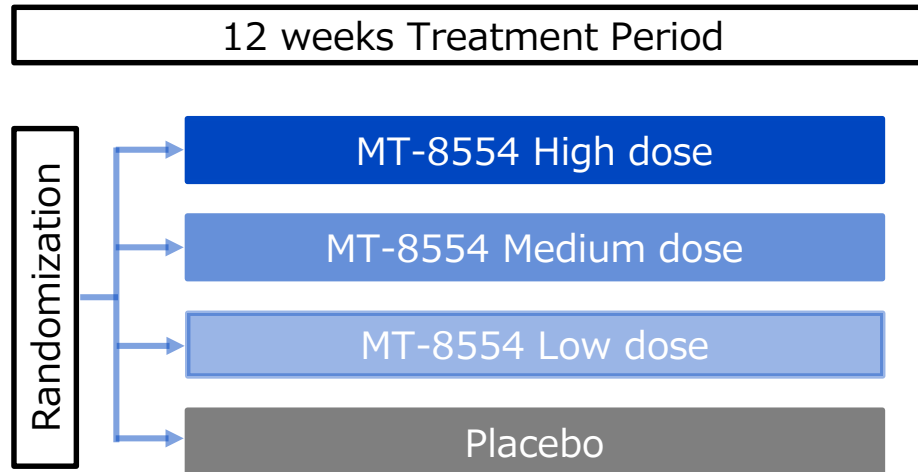
\*2: Temperature range where a constant body temperature can be maintained by adjusting heat release



## Overview of MT-8554 POC Study

### POC Study

- 375 postmenopausal VMS patients



- Efficacy of MT-8554 demonstrated in the POC study measuring changes in frequency and severity of VMS as endpoints
- Results will be presented at a scientific congress in FY 2020

### Future plans

- Preparation for P3 studies (in consultation with FDA) in parallel with partnering activity

**MT-3995 (MR\* antagonist)****POC study in patients with nonalcoholic steatohepatitis (NASH)  
has been completed**

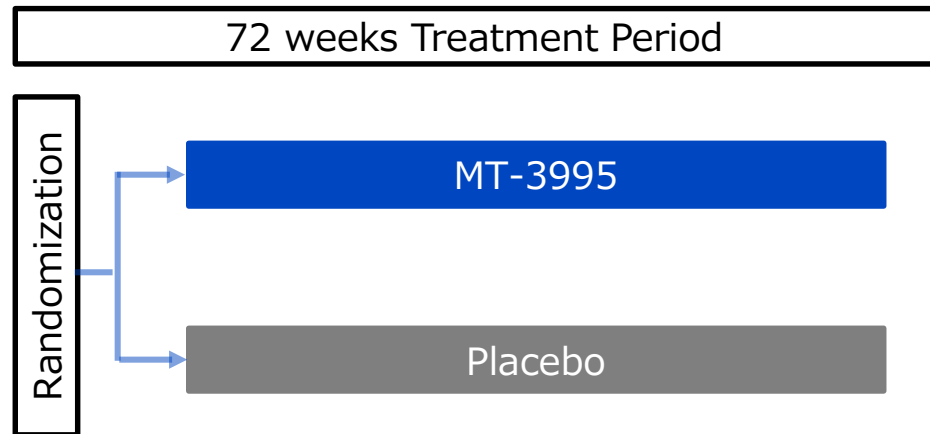
<b>MT-3995 Features and concepts</b>		<ul style="list-style-type: none"><li>■ Non-steroidal skeleton, highly specific to the target molecule, and expected to reduce adverse reactions related to sex hormones</li><li>■ Block organ damage factors by suppressing MR signaling. Expected to correct metabolic disorders by improving insulin resistance, etc., as well as exert anti-inflammatory and anti-fibrotic effects</li></ul>
<b>Non- alcoholic steatohep atitis (NASH)</b>	<b>Condition</b>	<ul style="list-style-type: none"><li>■ Characterized by steatosis, inflammation, and hepatocellular injury (ballooning degeneration)</li><li>■ The prognosis is defined by liver fibrosis. Progressive disease causing liver cirrhosis and liver cancer</li></ul>
	<b>Patient Population</b>	<ul style="list-style-type: none"><li>■ Prevalence estimated to be 3 ~ 5% of population</li></ul>
	<b>Current Treatment</b>	<ul style="list-style-type: none"><li>■ No approved therapies for NASH</li><li>■ In addition to weight loss with diet and exercise therapy, treatment for complications such as type 2 diabetes mellitus, hyperlipidemia, and hypertension is recommended</li></ul>

\*: Mineralocorticoid Receptor

## Overview of MT-3995 POC Study

### POC Study

- 48 NASH patients



- Percent change from baseline in ALT\*, the primary endpoint, and several fibrosis biomarkers showed a decreasing tendency in the MT-3995 group compared with the placebo group

### Future plans

- In partnering activity

\*Alanine aminotransferase



### Progress Update

Progress since the announcement of 2nd quarter results in October 30, 2019

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
central nervous system	MT-1186	Global	ALS <sup>*1</sup> /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				preparing	
	MT-5199	Japan	Tardive dyskinesia					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria			preparing		
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-3995	Global	Non-alcoholic steatohepatitis(NASH)					
	MT-6548	Japan	Renal anemia					
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2271	Global	Seasonal influenza/VLP vaccine <sup>*2</sup>				Canada	
	MT-2355	Japan	5 combined vaccine <sup>*3</sup>					

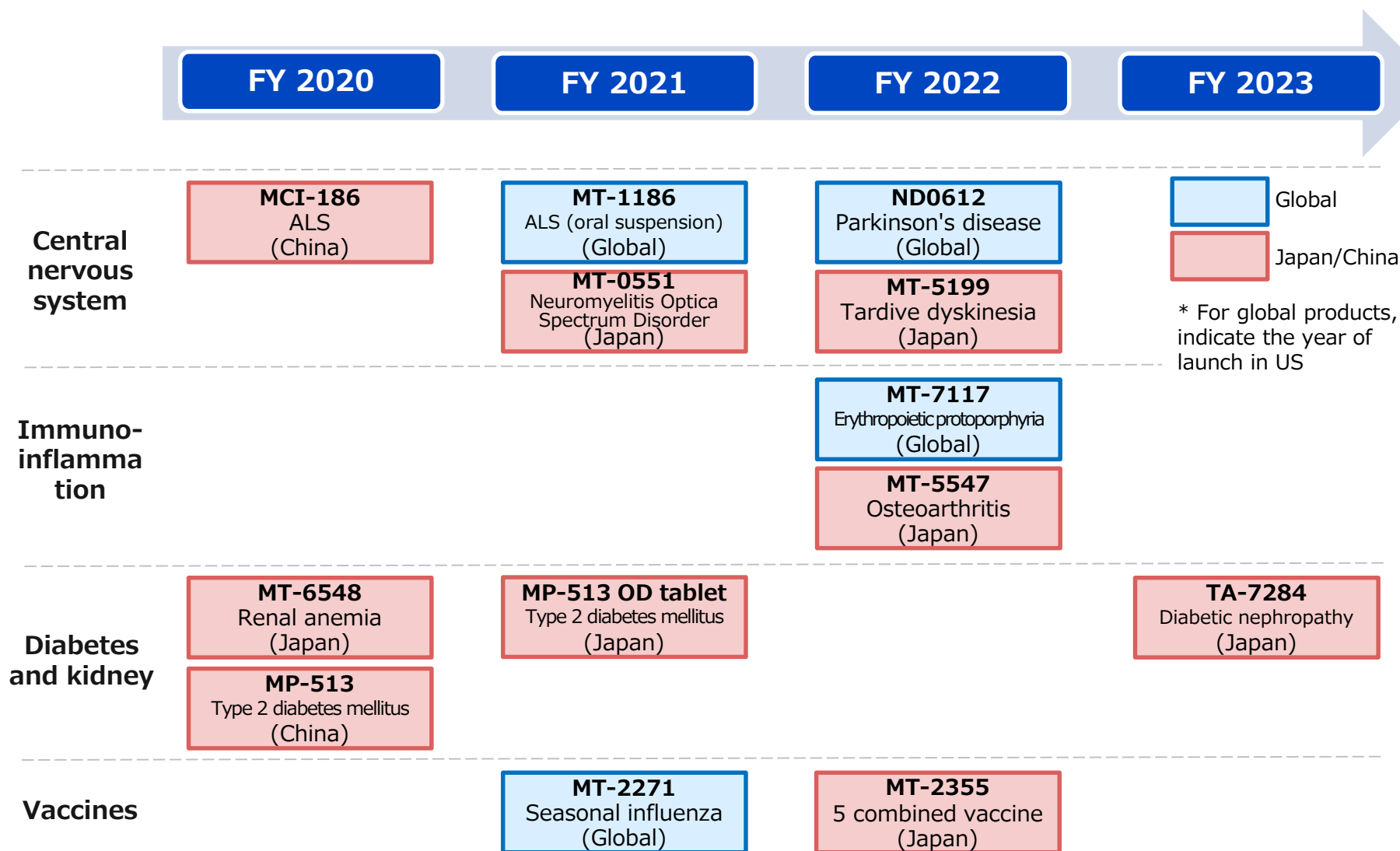
\*1: Amyotrophic lateral sclerosis

\*2: US; Under discussion with FDA for filing

\*3: Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants



## Launch Plan for Major Development Pipeline



**Mitsubishi Chemical Holdings Corporation (MCHC) to make  
Mitsubishi Tanabe Pharma Corporation (MTPC)  
its wholly owned subsidiary**

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- **Nov. 18, 2019: MCHC announced a Tender Offer for MTPC's common shares**  
**Tender Offer period: from Nov. 19, 2019 to Jan. 7, 2020**
- **Jan. 8, 2020: MCHC announced results of the Tender Offer**  
**: MCHC voting rights ownership ratio after the Tender Offer: 91.57%**
- **Jan. 17, 2020: MTPC approved the demand for sale of MTPC's common shares**

**<Schedule>**

<b>February 26, 2020</b>	<b>: Last trading day</b>
<b>February 27, 2020</b>	<b>: Delisting date</b>
<b>March 2, 2020</b>	<b>: MCHC acquires the shares to be sold and MTPC becomes MCHC's wholly owned subsidiary</b>

# *Open Up the Future*

Becoming a company that works with a sense  
of speed and is the first to deliver differentiated value



Mitsubishi Tanabe Pharma

# Appendix



## Details of Revenue (Q3 FY2019, Cumulative Total)



Mitsubishi Tanabe Pharma

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	297.4	332.4	(35.0)	(10.5)	376.0	79.1
(overseas sales revenue)	50.1	96.0	(45.9)	(47.8)	67.6	74.1
Domestic ethical drugs	239.6	229.2	10.3	4.5	298.1	80.4
Overseas ethical drugs	37.5	41.9	(4.4)	(10.6)	49.6	75.5
Royalty revenue, etc.	13.6	54.9	(41.3)	(75.2)	19.2	70.7
OTC products	3.3	3.2	0.0	3.0	4.3	76.5
Others	3.3	3.0	0.2	8.3	4.6	72.3

※ Announced on May 10, 2019 in the financial results of FY2018

## Domestic Ethical Drugs

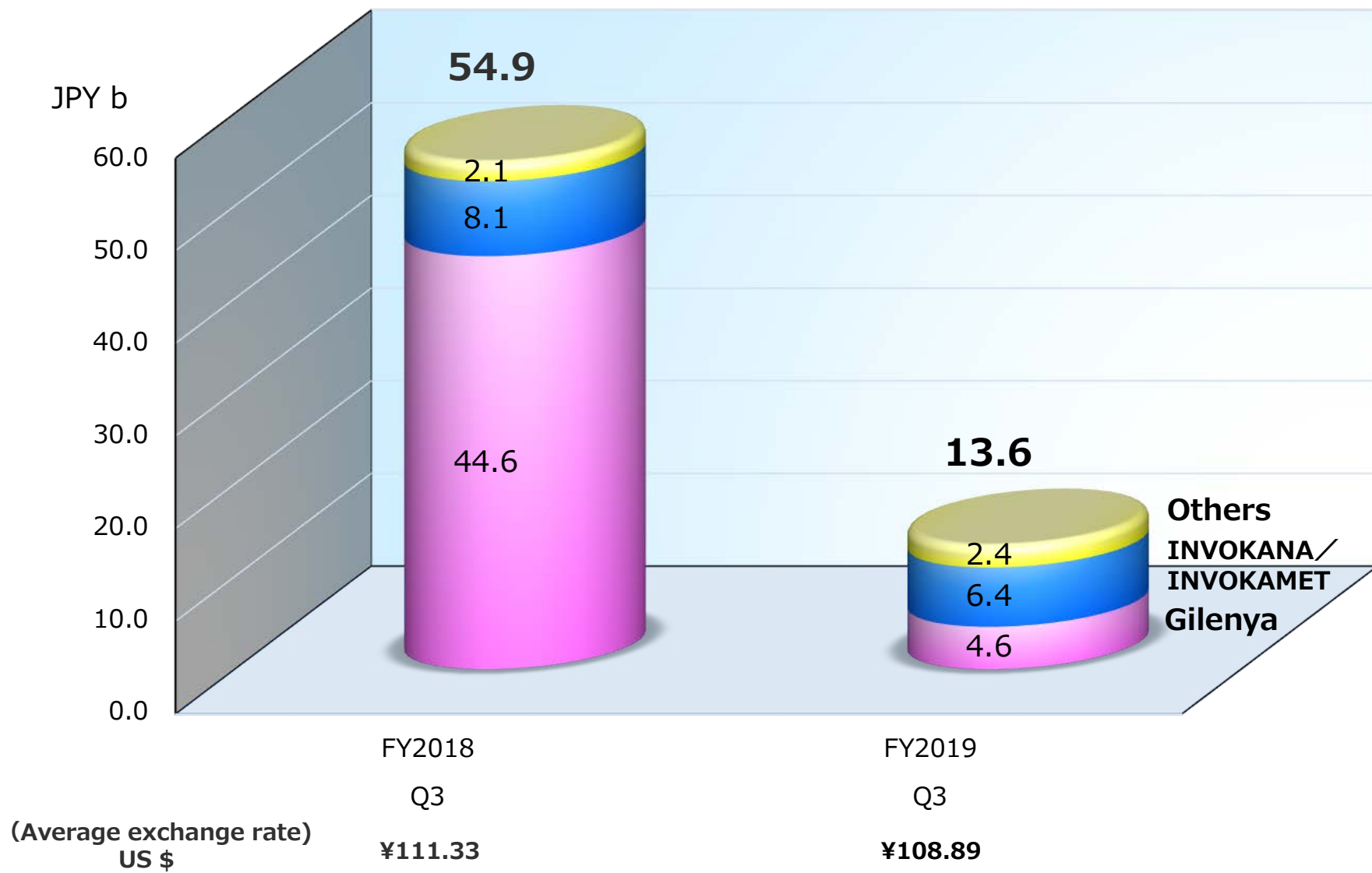
## Revenue of Priority Products and Vaccines

	FY2019 Q3	FY2018 Q3	Increase / Decrease		Full year forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	42.4	45.9	(3.4)	(7.5)	51.5	82.4
Simponi	31.6	28.7	2.9	10.2	42.2	75.1
Stelara	20.3	10.4	9.9	-	21.6	94.0
Tenelia*	12.0	11.1	0.9	8.4	15.0	80.2
Canaglu	6.5	5.0	1.5	31.2	10.4	63.3
Canalia*	5.5	5.3	0.1	2.4	7.2	76.4
Lexapro	11.6	10.7	0.8	8.3	14.7	78.6
Rupafin	4.1	0.9	3.2	334.8	7.5	55.3
Imusera	3.3	3.4	(0.0)	(2.5)	4.2	78.6
Total of priority products	134.5	118.3	16.1	13.6	170.4	78.9
Influenza vaccine	12.4	9.5	2.8	30.4	10.7	115.4
Tetrabik	7.0	6.4	0.6	9.5	10.0	70.5
Varicella vaccine	3.7	3.9	(0.1)	(3.8)	5.1	73.0
Mearubik	4.7	5.3	(0.5)	(10.1)	4.8	98.8
JEBIK V	4.1	4.4	(0.2)	(5.6)	4.5	91.0
Total of vaccines	32.9	30.4	2.4	8.0	36.2	90.8
Total of priority products and vaccines	167.4	148.8	18.5	12.5	206.7	81.0

※ Announced on May 10, 2019 in the financial results of FY2018

\* Tenelia and Canalia are co-promoted with our partner Daiichi Sankyo and sold by Daiichi Sankyo. The Company discloses revenue from the sale of both drugs by combining product supply to Daiichi Sankyo and the promotion fees.

## Royalty income, etc.

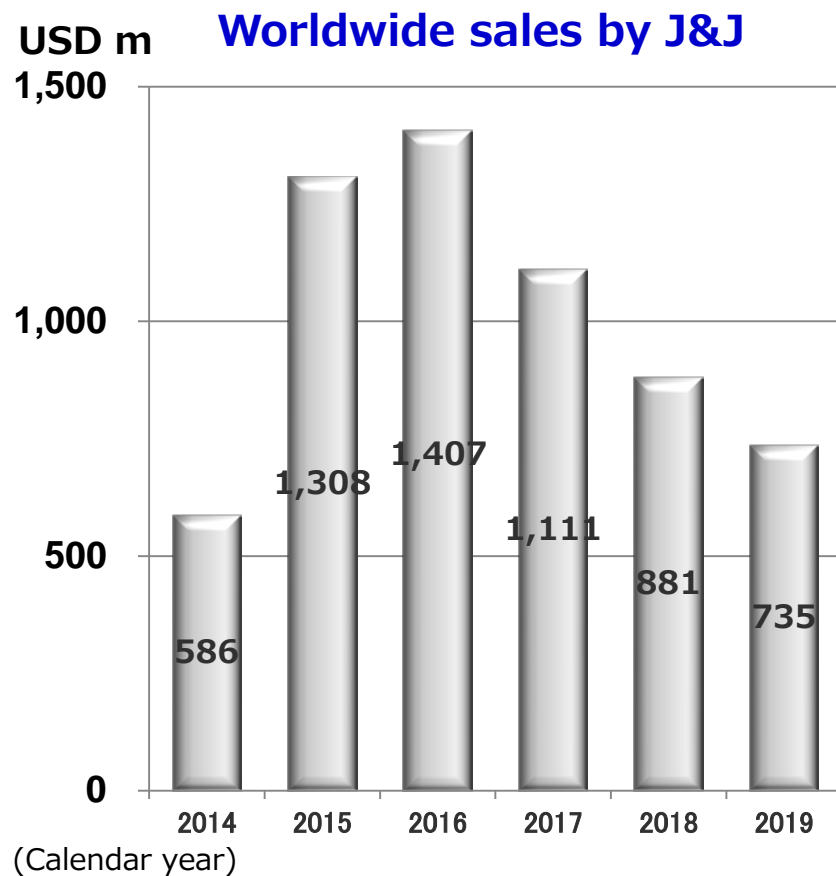




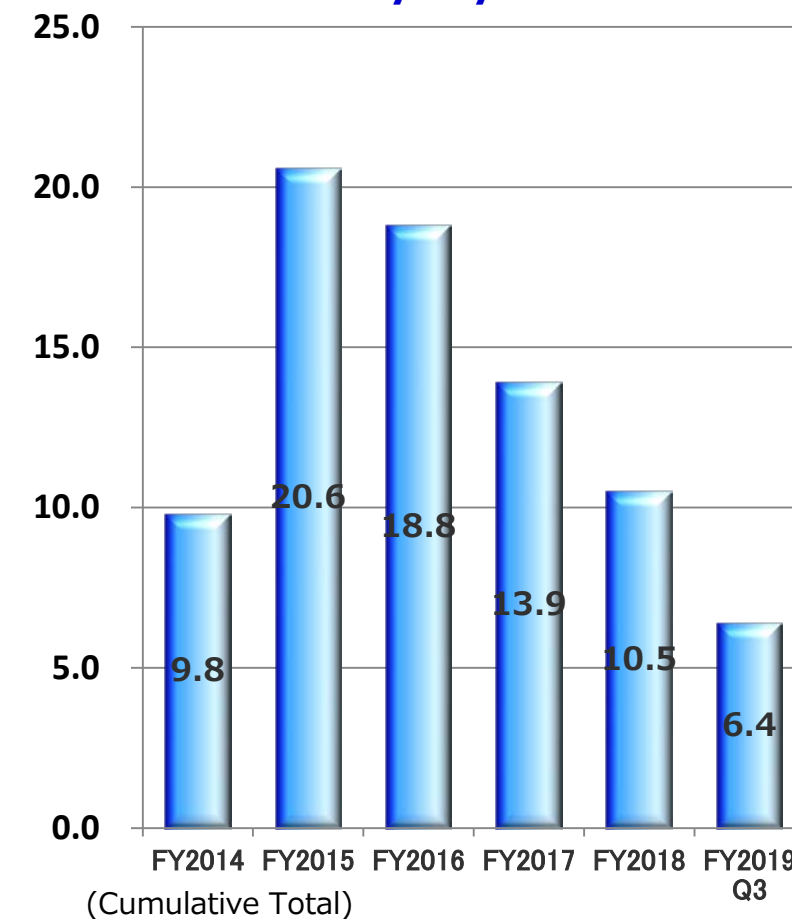
# INVOKANA/INVOKAMET

- INVOKANA/INVOKAMET sales by Johnson & Johnson  
in October to December, 2019: \$177m (\$228m, the same period of previous year)
- MTPC royalty revenue in Q3 FY2019 (April to December, 2019) : ¥6.4b

## INVOKANA/INVOKAMET



## JPY b MTPC royalty revenue



## **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 (Include products under development), but is not intended for advertising or medical advice.**