Mitsubishi Tanabe Pharma Corporation



### **Q3 FY2018 Business Results** (April-December, 2018) February 4, 2019

Eizo Tabaru Member of the Board, Managing Executive Officer

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### Q3 FY2018 Business Results (April-December, 2018)

### Q3 FY2018 Business Results

### Q3 FY2018 Financial Results





- Although Radicava contributed, sales revenue declined because of the impact of NHI drug price revision on domestic ethical drugs, etc.
- While working on reducing SG & A expenses, core operating profit declined due to an increase in R&D expenses.

	FY2018 Q3	FY2017 Q3	Increase / Decrease		Full year forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	332.4	339.3	(6.8)	(2.0)	435.0	76.4
(Domestic)	236.4	255.3	(18.9)	(7.4)	304.7	77.6
(Overseas)	96.0	83.9	12.1	14.4	130.2	73.8
Overseas sales ratio	28.9%	24.7%			29.9%	
Cost of sales	139.2	134.2	4.9	3.7	176.0	79.1
Sales cost ratio	41.9%	39.6%			40.5%	
Gross profit	193.2	205.0	(11.8)	(5.8)	259.0	74.6
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4
Operating profit	56.4	68.4	(12.0)	(17.6)	67.0	84.2
Net profit attributable to						
owners of the Company	41.4	52.1	(10.6)	(20.4)	47.0	88.2
Average exchange rate US\$	¥111.33	¥111.77			¥105.00	

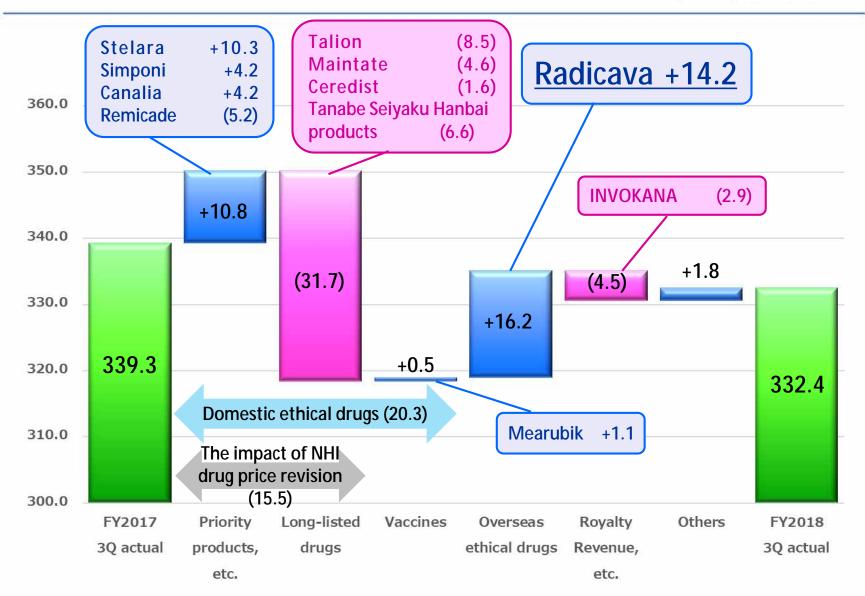
Announced on May 9, 2018 in the financial results of FY2017

### Q3 FY2018 Business Results

### **Revenue** Trends



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\* Talion has been eliminated from priority products from Q3 FY2018.

### Cost of Sales, SG&A Expenses, Core Operating Profit Mitsubishi Tanabe Pharma

- The sales of cost ratio raised due to the impact of NHI drug price revision and change of product mix, etc.
- Core operating profit declined because R&D expenses increased due to progress in the late stage of development, etc., despite efforts to reduce SG&A expenses.

	FY2018 Q3	FY2017 Q3	Increase /	Decrease	Full year forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	332.4	339.3	(6.8)	(2.0)	435.0	76.4
Cost of Sales	139.2	134.2	4.9	3.7	176.0	79.1
Sales cost ratio	41.9%	39.6%			40.5%	
Gross profit	193.2	205.0	(11.8)	(5.8)	259.0	74.6
SG&A expense	73.1	77.6	(4.4)	(5.7)	101.0	72.5
R&D expense	61.9	56.1	5.7	10.3	84.5	73.3
Amortization of intangible assets associated with products	2.2	1.7	0.4	28.0	3.0	73.4
Other income and						
expense*	(0.3)	0.0	(0.4)	-	(0.5)	-
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4

\* Brackets indicate expense and loss.

Announced on May 9, 2018 in the financial results of FY2017

### Q3 FY2018 Business Results

### Non-recurring items, Net Profit



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	FY2018 Q3	FY2017 Q3	Increase /	/ Decrease	Full year forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	55.5	69.7	(14.1)	(20.3)	70.0	79.4
Non-recurring items <sup>*</sup>	0.8	(1.2)	2.0	-	(3.0)	-
Operating profit	56.4	68.4	(12.0)	(17.6)	67.0	84.2
Financial income	0.9	2.0	(1.0)	(51.1)		
Financial expense	0.8	0.2	0.6	244.6		
Net profit attributable to owners of the Company	41.4	52.1	(10.6)	(20.4)	47.0	88.2

\* Brackets indicate expense and loss.

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### **Development Pipeline**



## Progress of Major Development Pipeline

### Progress after the financial results for Q2 FY2018

Development code Product name (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed	Approved
MCI-186 Radicava (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis : ALS)	Swiss					

### license-out products

**Development Pipeline** 

Development code Product name (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed	Approved
TA-7284* <sup>1</sup> Canaglu/INVOKANA (Canagliflozin)	SGLT2 inhibitor (Reduce the composite risk of CV death, MI or stroke in type 2 diabetes with established cardiovascular disease (CANVAS /CANVAS-R))	US					
FTY720* <sup>2</sup> Imusera/Gilenya (Fingolimod)	S1P receptor functional antagonist (Pediatric multiple sclerosis)	EU					

\* 1 Licensed to Janssen Pharmaceuticals (US)

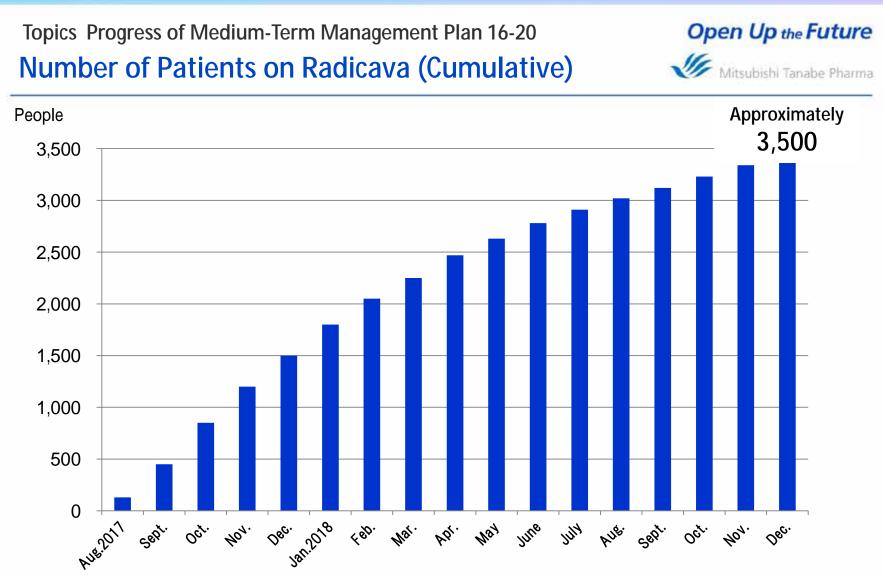
\* 2 Licensed to Novartis (Switzerland)

### As of February 4, 2019





### **Topics** Progress of Medium-Term Management Plan 16-20



Sales Revenue in April to December, 2018 : 20.6 JPY b Number of Patients (Cumulative) : approximately 3,500 Number of patients (Continuous administration) : approximately 1,900 Sales Revenue in FY2018 as expected : approximately 27.0 JPY b

### Topics Progress of Medium-Term Management Plan 16-20 Radicava Business



3P	Achievements	Plans for 2H FY2018
Physician	<ul> <li>Increased field sales activity and physician calls</li> <li>Physicians have a better understanding of the science of Radicava by education by the field Key potential physicians prioritized for greater frequency calls by field representatives.</li> </ul>	<ul> <li>Provide information to educate physicians to the Radicava value proposition.</li> <li>Introducing long-term data and scientific development history.</li> <li>Development of new scientific data Initiate biomarker studies</li> </ul>
Patient	<ul> <li>Reduced the lead-time to the start of patient treatment</li> <li>Enhanced support by nurse educators</li> <li>Support to facilitate the care environment to help patients living with ALS Improve patient convenience and access through additional contracts with infusion centers and home infusion services.</li> </ul>	<ul> <li>Improve online access to Radicava information and science</li> <li>Utilize digital marketing strategies</li> <li>Better patient access to Radicava treatment</li> <li>ALS Care Locator</li> <li>Provide listing of neighboring physicians experienced in the treatment of ALS. (From the end of Jan.)</li> <li>Offer out-of-pocket assistance through copay programs and a new copay card. (From the beginning of Jan.)</li> </ul>
Payer	<ul> <li>Provide support to initiate and approve the start of treatment</li> <li>Understand the clinical value of Radicava using science and clinical data</li> <li>Leveraging post-hoc analyses to demonstrate efficacy</li> </ul>	<ul> <li>Educate payers on Radicava's scientific clinical benefit</li> <li>Work with payers to minimize access restriction to treatment</li> <li>J-code approved to facilitate reimbursement. (From the end of Jan.)</li> </ul>

### **Progress of Major Development Pipeline**





#### **Global Late Stage Products**

Development Code	Indications (development stage)	Progress
MT-1186	Amyotrophic lateral sclerosis :ALS (P1)	• Biological equivalence test between oral agent and injection is expected to be conducted in 1Q,FY2019. Long term safety test for ALS patients is planed to be conducted in FY2019.
ND0612	Parkinson's disease (P2)	<ul> <li>Largely agreed with FDA on P3 study design. P3 study is scheduled to be conducted in 2019 summer.</li> </ul>
MT-2271	Prophylaxis of seasonal influenza (P3)	<ul> <li>Under consultation with FDA for US filing. Preparing for filing for the elderly and the adult. The initial plan for US filing in FY2018 is expected to be delayed.</li> <li>Consultation with Canadian authorities for application in Canada is completed. Preparing for application in 1Q,FY2019.</li> </ul>

### **Global Early Stage Products**

Development Code	Indications (development stage)	Progress	
MT-8554	Vasomotor symptoms (P2)	• P2 study completed. Preparing to conduct P3 study.	
MT-7117	Erythropoietic protoporphyria (P2)	• P2 study is ongoing in US. The results are scheduled to be acquired in FY2019.	
MT-3995	Non-alcoholic steatohepatitis (P2)	• The results of P2 study in Japan are scheduled to be acquired in FY2019.	11





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





### Details of Revenue (Q3 FY2018, Cumulative Total)

	FY2018	FY2017	Increase / Decrease		Full year	Achieved	
	Q3	Q3	merease /	Declease	forecasts	Admeved	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%	
Sales revenue	332.4	339.3	(6.8)	(2.0)	435.0	76.4	
(overseas sales revenue)	96.0	83.9	12.1	14.4	130.2	73.8	
Domestic ethical drugs	229.2	249.6	(20.3)	(8.2)	296.2	77.4	
Overseas ethical drugs	41.9	25.7	16.2	62.9	61.1	68.6	
Royalty revenue, etc.	54.9	59.5	(4.5)	(7.7)	69.8	78.7	
OTC products	3.2	3.1	0.0	1.7	4.3	73.7	
Others	3.0	1.2	1.8	147.3	3.3	91.8	

Announced on May 9, 2018 in the financial results of FY2017

Appendix



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### Appendix

# Sales Revenue of Domestic Ethical Drugs, Priority Products, etc. Mitsubishi Tanabe Pharma



	FY2018 Q3	FY2017 Q3	Increase / Decrease		Full year forecasts	Achieved
	Billion yen	Billion yen	-	%	Billion yen	%
Remicade	45.9	51.1	(5.2)	(10.2)	55.5	82.7
Simponi	28.7	24.5	4.2	17.3	35.0	82.0
Tenelia	11.1	15.2	(4.0)	(26.8)	17.0	65.5
Stelara	10.4	0.0	10.3	-	15.1	69.0
Lexapro	10.7	9.9	0.8	8.2	13.1	81.5
Canaglu	5.0	4.4	0.6	13.9	7.6	65.4
Rupafin	0.9	0.6	0.2	38.3	6.8	14.0
Imusera	3.4	3.7	(0.3)	(9.0)	4.9	69.0
Canalia	5.3	1.1	4.2	370.5	3.2	165.8
Total of priority products	121.8	110.9	10.8	9.8	158.7	76.7
Tetrabik	6.4	6.6	(0.2)	(3.0)	9.1	71.0
Mearubik	5.3	4.1	1.1	28.7	5.5	94.9
Varicella vaccine	3.9	4.0	(0.1)	(3.1)	5.5	71.4
JEBIK V	4.4	4.2	0.1	4.7	4.3	102.4
Influenza vaccine	9.5	10.1	(0.6)	(6.5)	11.2	85.0
Total of vaccines	30.4	29.9	0.5	1.9	36.5	83.4
Total of priority products						
and vaccines	152.2	140.8	11.4	8.1	195.2	78.0

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\* Talion has been eliminated from priority products from Q3 FY2018.

### Appendix Royalty income, etc.





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Appendi	Х
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### Gilenya

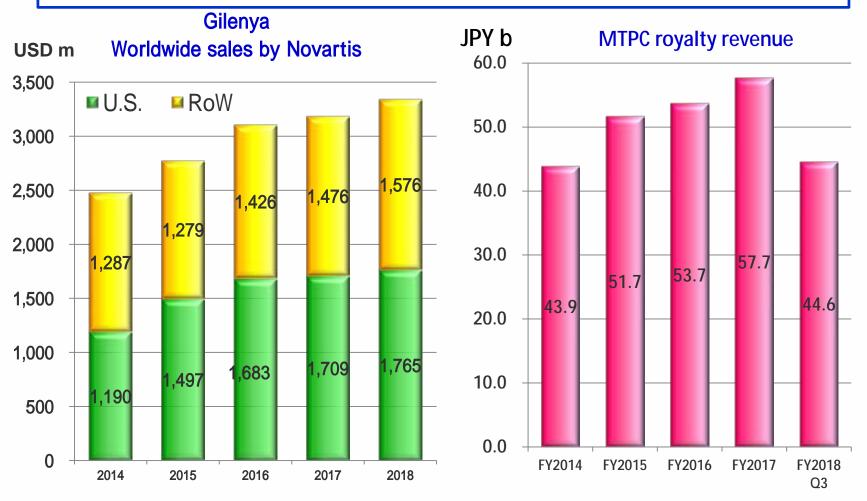




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Gilenya worldwide sales by Novartis in October to December, 2018 : \$836 m (\$825 m, the same period of previous year)

➡ MTPC royalty revenue in Q3 FY2018 (April to December, 2018) : ¥44.6 b



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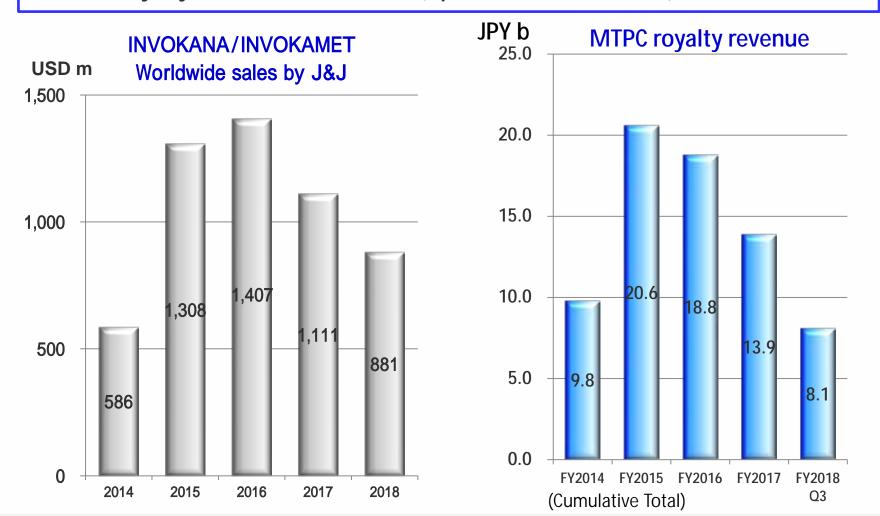
### Appendix INVOKANA/INVOKAMET



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 INVOKANA/INVOKAMET sales by Johnson & Johnson in October to December, 2018: \$228m (\$267m, the same period of previous year)
 MTPC royalty revenue in Q3 FY2018 (April to December, 2018) : ¥8.1b



### Appendix

### **Progress of Major Development Pipeline**





### **Domestic Late Stage Products**

Development Code	Indications (development stage)	Progress
MT-6548	Renal anemia (P3)	<ul> <li>P3 study is ongoing. Scheduled to filing in FY2019.</li> </ul>
MT-5547	Osteoarthritis (P2/3)	<ul> <li>P2/3 study is ongoing after redesigning protocol.</li> </ul>
TA-7284	Diabetic nephropathy (P3)	• P3 study is ongoing ahead of initial schedule.
MT-5199	Tardive dyskinesia (P2/3)	• P2/3 study is ongoing for FY2020 filing.

### Appendix

### **Pipeline Status**

#### Disease area

: Autoimmune disease : Diabetes and kidney disease : CNS disease : Other : Vaccines

### **Open Up** the Future

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### Red: Progress after the financial results for Q2 FY2018

MT-1303

MT-2990 Inflammatory diseases / Autoimmune diseases, etc. MP-124 Nervous system ND0701 Parkinson's disease MT-1186 ALS (Oral suspension) MT-6345 \*1

#### Nervous system

MT-7529 \*2

Prophylaxis of H7N9 influenza MT-5625 \*2 Prophylaxis of

rotavirus gastroenteritis

#### MT-0814

**Ophthalmologicals** MT-4129

Cardiovascular system, etc.

MT-7117 Erythropoietic protoporphyria (US) MP-513 Type2 diabetes mellitus (EU) MT-3995 Diabetic nephropathy (JP, EU) NASH (JP) MT-8554 Painful diabetic peripheral neuropathy (EU) Vasomotor symptoms associated with menopause (US) ND0612 Parkinson's disease (US, EU) MT-8972 \*2 Prophylaxis of H5N1 influenza (Canada)

Phase 3

Phase 2

Crohn's disease (JP, EU)

Multiple sclerosis, Psoriasis(EU)

Phase 3

MT-5547 Osteoarthritis (JP) TA-7284 **Diabetic nephropathy** (Global clinical study)\*3 **MP-513** Type2 diabetes mellitus (China) MT-6548 Renal anemia (JP) MT-5199 Tardive dyskinesia (JP) MT-2355 5 combined vaccine  $(4 \text{ combined} + \text{Hib}) (\text{JP})^{*4}$ 

MT-2271 \*2 Prophylaxis of seasonal influenza/ adults, elderly (US, EU, Canada, etc.)

Azanin Autoimmune hepatitis (JP) TA-7284

### As of February 4, 2019

Approved

**MCI-186** ALS (Switzerland)

Type2 diabetes mellitus (Indonesia)

**Filed** 

#### **MP-513**

Approved

(US)

Type2 diabetes mellitus (Indonesia, Singapore, Thailand, Malaysia) MCI-186 ALS (EU) **MP-214** Schizophrenia (Singapore, Thailand, Indonesia) **TAU-284** Allergic rhinitis, Urticaria (Thailand)

#### Major license-out products (post Phase 3)

**FTY720** Pediatric multiple sclerosis (EU) TA-7284 Reduce the composite risk of CV death, MI or stroke in type 2 diabetes with established cardiovascular disease (CANVAS/CANVAS-R)

\*1: Co-developed with Ube Industries(JP)

\*2: Medicago product (Canada)

\*3: Sponsor: Janssen Research & Development, LLC

\*4: Co-developed with The Research Foundation for Microbial Diseases of Osaka University (JP)

TA-7284 Diabetic nephropathy (Global clinical study)\*3 MT-210 Schizophrenia (US, EU) MT-4580

Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism (JP)

### **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.