

# Q1 FY2019 Business Results

(April - June, 2019)

July 29, 2019

Eizo Tabaru

Member of the Board, Managing Executive Officer

# Q1 FY2019 Business Results

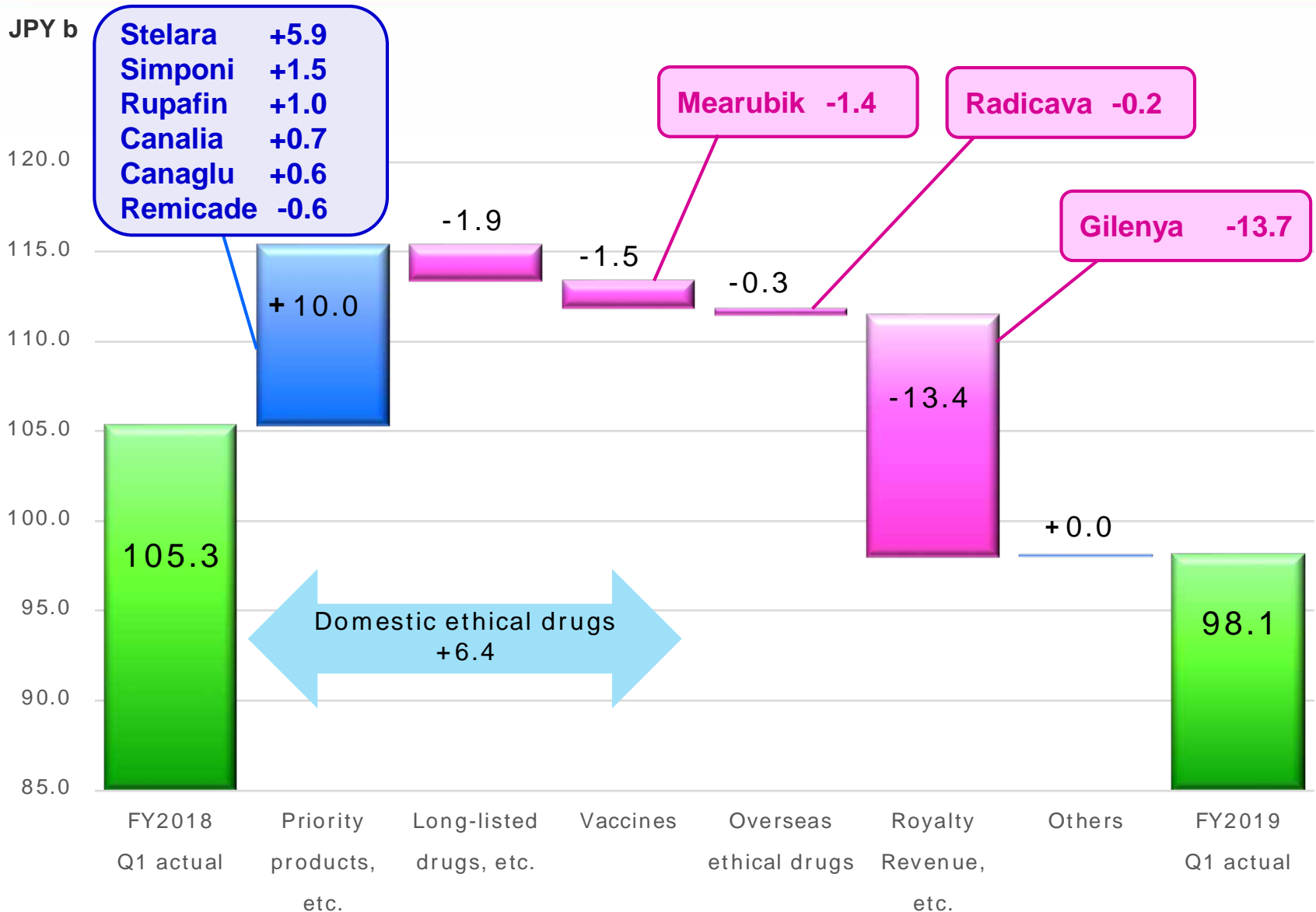


## Q1 FY2019 Financial Results

	FY2019	FY2018	Increase / Decrease		1H	Achieved
	Q1	Q1			Forecasts	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	98.1	105.3	(7.2)	(6.9)	187.0	52.5
(Domestic)	80.7	74.1	6.5	8.9	153.6	52.5
(Overseas)	17.3	31.1	(13.8)	(44.4)	33.3	52.1
Overseas sales ratio	17.7%	29.6%			17.8%	
Cost of sales	44.7	42.3	2.4	5.7	87.5	51.2
Sales cost ratio	45.6%	40.2%			46.8%	
Gross profit	53.3	63.0	(9.6)	(15.3)	99.5	53.6
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7
Operating profit	9.6	19.3	(9.6)	(50.2)	5.0	192.4
Net profit attributable to owners of the Company	6.8	13.9	(7.0)	(50.7)	4.0	172.0
Average exchange rate US\$	¥109.67	¥109.53			¥110.00	

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

# Revenue Trends



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

	FY2019	FY2018	Increase / Decrease		1H	Achieved
	Q1	Q1			Forecasts	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	98.1	105.3	(7.2)	(6.9)	187.0	52.5
Cost of Sales	44.7	42.3	2.4	5.7	87.5	51.2
Sales cost ratio	45.6%	40.2%			46.8%	
Gross profit	53.3	63.0	(9.6)	(15.3)	99.5	53.6
SG&A expense	22.9	23.1	(0.2)	(1.0)	49.0	46.8
R&D expense	19.9	19.6	0.2	1.4	44.5	44.8
Amortization of intangible assets associated with products	0.6	0.7	(0.0)	(11.9)	1.3	49.8
Other income and expense*	(0.0)	(0.1)	0.0	-	(0.2)	-
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7

\* Brackets indicate expense and loss.

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## Non-recurring items and Net Profit

	FY2019	FY2018	Increase / Decrease		1H	Achieved
	Q1	Q1			Forecasts	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	9.7	19.3	(9.5)	(49.5)	4.5	216.7
Non-recurring items <sup>*</sup>	(0.1)	-	(0.1)	-	0.5	-
Operating profit	9.6	19.3	(9.6)	(50.2)	5.0	192.4
Financial income	0.4	0.4	(0.0)	(12.6)		
Financial expense	0.8	0.0	0.7	-		
Net profit attributable to owners of the Company	6.8	13.9	(7.0)	(50.7)	4.0	172.0

\* Brackets indicate expense and loss.

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

# Development Pipeline



# Progress of Major Development Pipeline

## Progress Update

Progress since the announcement of fiscal 2018 results in May 10, 2019

Priority areas	Item	Development area	Indication	P1	P2	P3	Filed	Approved
Central nervous system	MCI-186	Global	ALS <sup>*1</sup>				China Singapore	
	MT-1186	Global	ALS <sup>*1</sup> /oral suspension					
	ND0612	Global	Parkinson's disease					
	MT-3921	Global	Spinal cord injury					
	MT-5199	Japan	Tardive dyskinesia					
	MT-8554	Global	Vasomotor symptoms associated with menopause					
Immuno-inflammation	MT-7117	Global	Erythropoietic protoporphyria					
	MT-2990	Global	Endometriosis					
	MT-5547	Japan	Osteoarthritis					
Diabetes and kidney	MT-6548	Japan	Renal anemia					
	MT-3995	Japan	Non-alcoholic steatohepatitis(NASH)					
	TA-7284	Japan	Diabetic nephropathy					
	MP-513	China	Type 2 diabetes mellitus					
Vaccines	MT-2271	Global	Seasonal influenza/VLP vaccine					
	MT-2355	Japan	5 combined vaccine <sup>*2</sup>					

\* 1: Amyotrophic lateral sclerosis

\* 2: Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants



## Status of Growth Drivers

### Radicava

Expanding market through preparation of application for approval in each country and region

- China: NDA filing accepted for review(April), priority review granted (June)
- Asia: NDA filed in Singapore(April)
- Europe: Withdrawal(May)

### MT-1186 (Radicava oral suspension)

- Agreed with FDA on submitting application for oral suspension using data of bioequivalence study (completed in May) and long-term safety study (scheduled to start in FY2019) for approval in FY2021.

### ND0612

- Accepted FDA's advice and finalized the P3 study design. Trial scheduled to start in August
- Study design presented at the World Parkinson Congress (June)

### MT-2271

- Scheduled to obtaining the results of the P3 study for the elderly (2Q FY2019) and planning to submit application in FY2019 for approval

## Vadadustat (MT-6548) / Profile

Filed in Japan in July 2019

Mechanism of Action	Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor
Indication	Renal Anemia
Origin	Akebia Therapeutics, Inc. Signed a collaboration agreement to development and commercialize Vadadustat in Japan and Asia in December 2015
Development Stage	Japan: filed (Reference) US, EU: P3
Expected Profile	<ul style="list-style-type: none"> <li>· Once-daily oral treatment</li> <li>· Treatment effect for anemia by stimulate endogenous erythropoietin production within physiological range</li> <li>· Easily to control hemoglobin level within target range</li> <li>· Maintain treatment effect by switching from the current standard treatment for renal anemia, injectable erythropoiesis stimulating agents (ESAs)</li> </ul>

## Positive results of efficacy and safety for anemia

The mean hemoglobin (Hb) level at week 20th and week 24th (g/dL)\*

	MT-6548 group	Darbepoetin Alfa group (DA group)	Difference (MT-6548 group - DA group)
J01 Trial [ NDD-CKD <sup>**</sup> ]	11.66 (11.49, 11.84)	11.93 (11.76, 12.10)	-0.26 (-0.50, -0.02)
J03 Trial [ HD-CKD <sup>***</sup> ]	10.61 (10.45, 10.76)	10.65 (10.50, 10.80)	-0.05 (-0.26, 0.17)

\*: LSMean (95%CI)

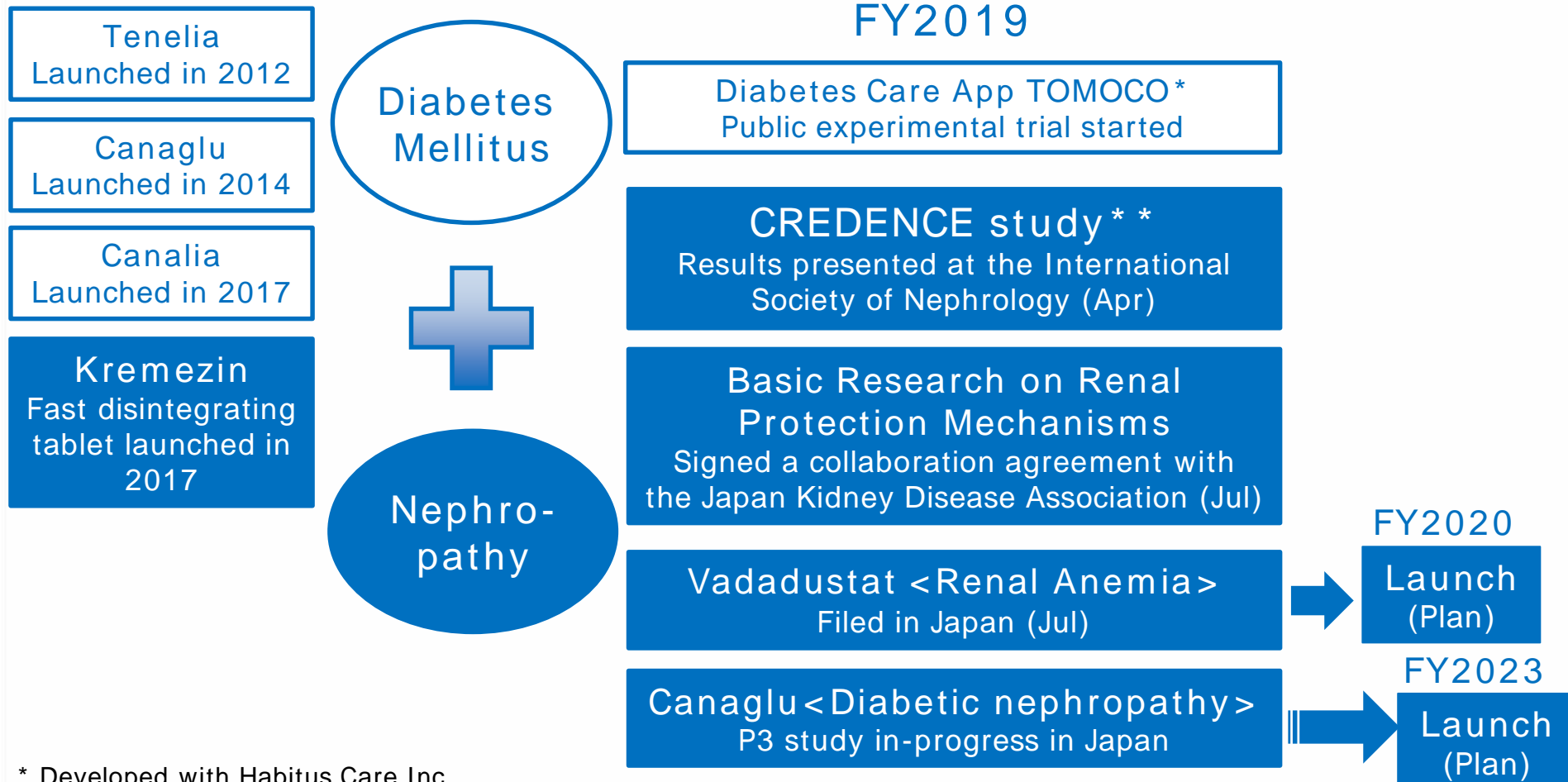
The differences in mean Hb was achieving the non-inferiority criteria (-0.75g/dL) in each clinical trial. Both pivotal studies met the primary endpoints.

\*\* : non-dialysis dependent chronic kidney disease

\*\*\* : hemodialysis dependent chronic kidney disease

## Diabetes and Kidney Products in Japan

Strengthen diabetes and renal development in Japan through launching new products, adding indications on existing products and developing evidence



\* Developed with Habitus Care Inc.

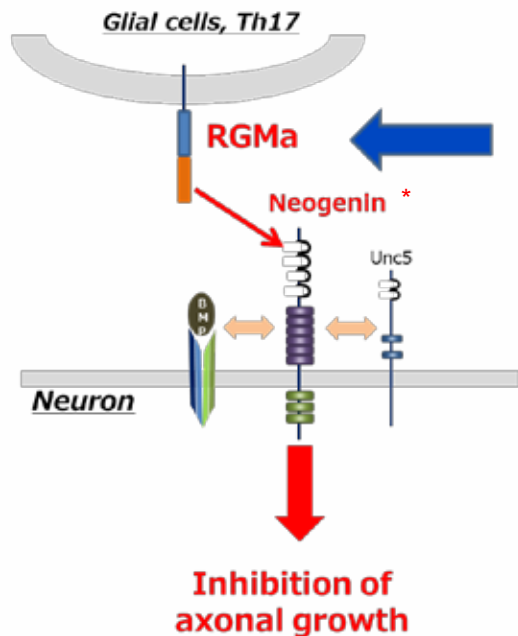
\*\* Clinical trials of canagliflozin testing the renal events in type 2 diabetic patients associated with chronic nephropathy<sup>11</sup> conducted by Janssen

# MT-3921: Next Growth Driver in CNS Area

## Initiation of clinical trial

MT-3921

- n Co-discovered **humanized anti-RGMa Ab** with Osaka University
- n Novel neurological drug with **neuroregeneration** and **anti-inflammatory** effect
- n Phase **I** clinical trial for healthy adults is on-going
- n **Traumatic spinal cord injury** is expected as target indication



Stimulate neuroregeneration by inhibiting RGMa-Neogenin\* binding

**MT-3921**  
(humanized anti-RGMa antibody)

**RGMa (Repulsive Guidance Molecule a)**

RGMa is expressed in glial cells, immune cells and neuron

- RGMa expression is induced after injury
- Binding with Neogenin inhibits neurite growth and affect regulates inflammation

\* : RGMa receptor. Expresses in neurons or T lymphocytes.

## Traumatic Spinal Cord Injury (SCI)

### High Medical Needs with no effective therapy

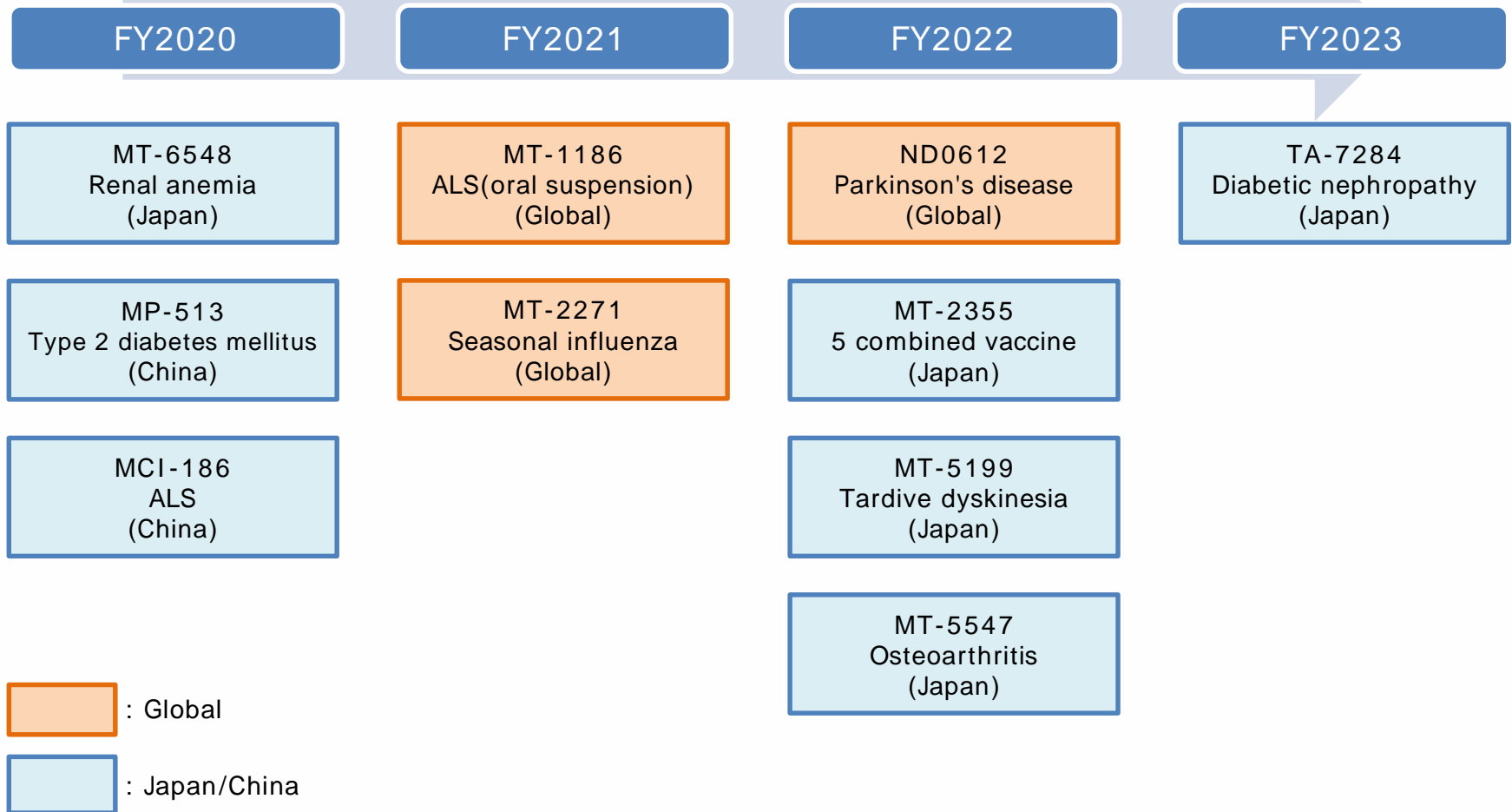
Annual injury	[US] Approx. 18,000 (chronic 300,000 ) [Japan] Approx. 4,000 ~ 5,000 ( chronic 100,000 ~ 200,000 )
Injured lesion	[US] cervical : thoracic : lumber = 55% : 45% : 10% (complicated injury included) [Japan] cervical : thoracic & lumber = 75% : 25%
Therapy	Surgical stabilization of the supine and intensive neurological rehabilitation (No regulatory approved drug for acute stage)
Medical needs	High need in AIS* A ~ C (complete lack of motor & sensory function - incomplete lack of motor function) Patients with lack of motor function hard to recover mobility even 1y after injury and need nursing care (increase caregiver cost, 14.5y reduction of life expectancy in US)

SCI patients with AIS\* A to C will be recruited in MT-3921 clinical trial

\*AIS: American Spinal Injury Association Impairment Scale

# Development and launch plan of major products to achieve management target

For Global products, indicate the first year of launch



# *Open Up the Future*

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





# Appendix



## Details of Revenue (Q1 FY2019, Cumulative Total)

	FY2019	FY2018	Increase / Decrease		1H	Achieved
	Q1	Q1			Forecasts	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	98.1	105.3	(7.2)	(6.9)	187.0	52.5
(overseas sales revenue)	17.3	31.1	(13.8)	(44.4)	33.3	52.1
Domestic ethical drugs	78.1	71.6	6.4	9.1	147.5	53.0
Overseas ethical drugs	12.5	12.9	(0.3)	(2.7)	24.1	52.2
Royalty revenue, etc.	5.0	18.5	(13.4)	(72.7)	9.8	51.5
OTC products	1.2	1.2	0.0	7.6	2.5	51.8
Others	1.0	1.0	(0.0)	(1.4)	2.9	34.3

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# Domestic Ethical Drugs

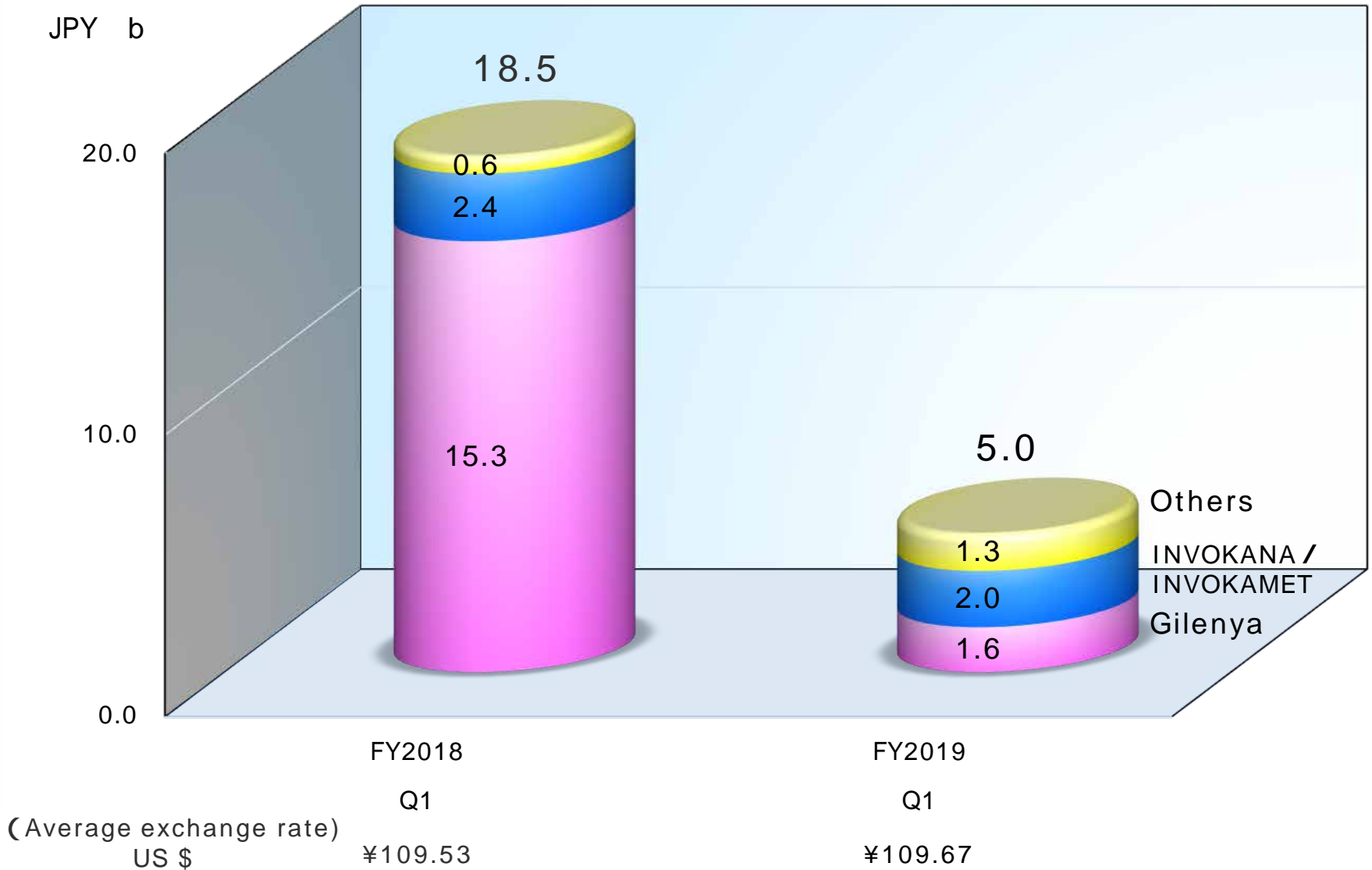
## Revenue of Priority Products and Vaccines

	FY2019	FY2018	Increase / Decrease		1H	Achieved
	Q1	Q1			Forecasts	
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	14.4	15.1	(0.6)	(4.6)	26.9	53.5
Simponi	10.5	9.0	1.5	16.7	21.2	49.5
Stelara	6.1	0.2	5.9	-	11.0	55.8
Imusera	1.1	1.1	0.0	0.4	2.2	51.7
Tenelia*	4.7	4.4	0.2	4.8	8.0	58.1
Canaglu	2.1	1.4	0.6	44.4	4.6	46.2
Canalia*	2.2	1.4	0.7	55.7	4.1	53.2
Lexapro	3.8	3.4	0.4	14.1	7.4	52.6
Rupafin	1.2	0.1	1.0	622.5	2.3	52.6
Total of priority products	46.5	36.4	10.0	27.5	88.2	52.7
Tetrabik	2.3	2.2	0.1	7.8	4.9	47.6
Mearubik	1.9	3.3	(1.4)	(42.6)	2.7	68.0
Varicella vaccine	1.2	1.4	(0.1)	(8.8)	2.6	48.4
JEBIK V	1.5	1.6	(0.1)	(8.7)	2.4	61.1
Influenza vaccine	0.0	(0.1)	0.0	(84.4)	1.0	(1.6)
Total of vaccines	7.3	8.8	(1.5)	(17.3)	14.4	50.7
Total of priority products and vaccines	53.8	45.3	8.4	18.7	102.6	52.4

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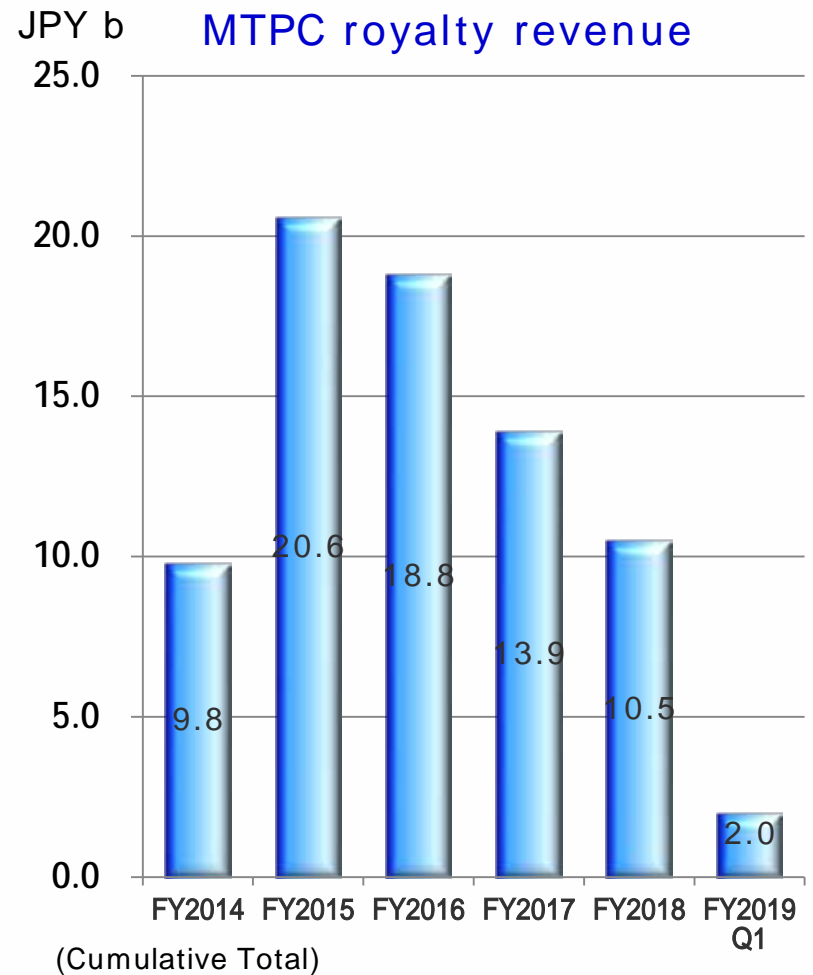
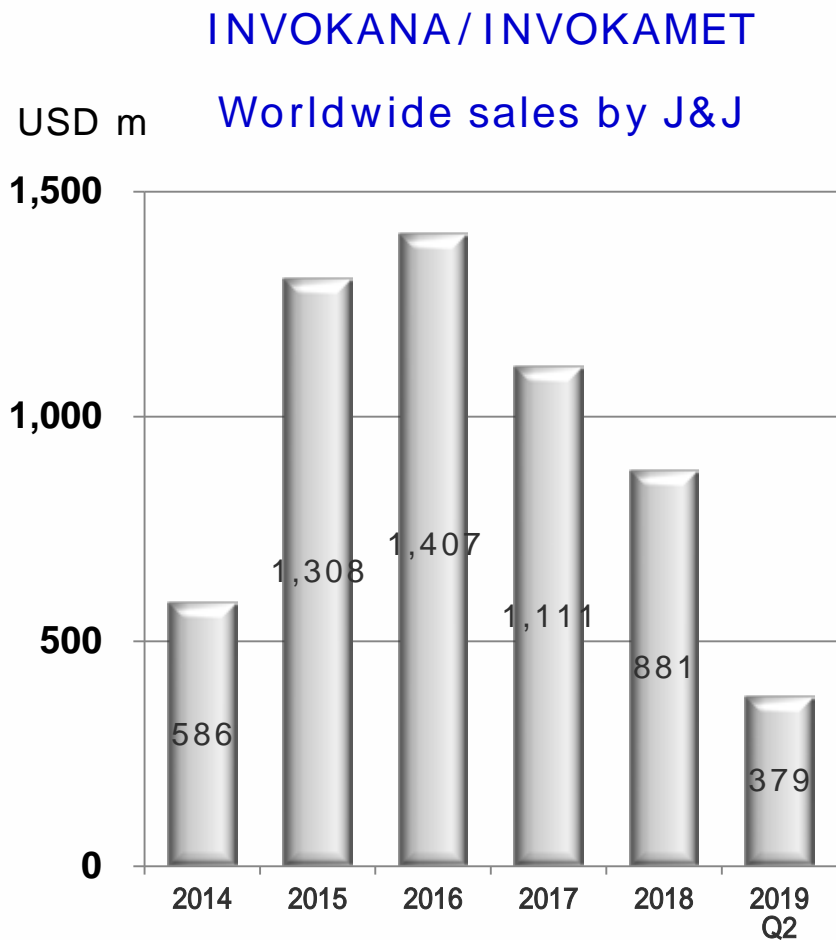
\*Tenelia and Canalia are co-promoted with our partner Daiichi Sankyo and sold by Daiichi Sankyo.  
The Company discloses revenue from the sale of both drugs by combining product supply to Daiichi Sankyo and the promotion fees.

# Royalty income, etc.



# INVOKANA/INVOKAMET

- I INVOKANA/INVOKAMET sales by Johnson & Johnson in April to June, 2019: \$177m (\$215m, the same period of previous year)
- I MTPC royalty revenue in Q1 FY2019 (April to June, 2019) : ¥2.0b



## 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.