Mitsubishi Tanabe Pharma Corporation

Q1 FY2018 Business Results

(April-June, 2018)

July 30, 2018

Eizo Tabaru
Board Director, Managing Executive officer

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Q1 FY2018 Business Results (April-June, 2018)

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Q1 FY2018 Financial Results

Although Radicava contributed, sales revenue declined because of the impact of NHI drug price revision on domestic ethical drugs, a decrease in royalty income, and the generic business transfer in FY2017.
Core operating profit declined due to an increase in R&D expenses.

	FY2018 Q1	FY2017 Q1	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	105.3	107.7	-2.3	-2.2	210.0	50.2
(overseas sales revenue)	31.1	25.6	+5.5	+21.7	64.2	48.5
Overseas sales ratio	29.6%	23.8%			30.6%	
Cost of sales	42.3	42.5	-0.2	-0.5	84.0	50.4
Sales cost ratio	40.2%	39.5%			40.0%	
Gross profit	63.0	65.1	-2.1	-3.3	126.0	50.0
Core operating profit	19.3	21.9	-2.6	-12.2	30.0	64.3
Operating profit	19.3	21.0	-1.7	-8.3	28.5	67.7
Net profit attributable to owners of the Company	13.9	16.9	-3.0	-17.8	19.5	71.6
Average exchange rate US$	¥109.53	¥111.42			¥105.00	

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

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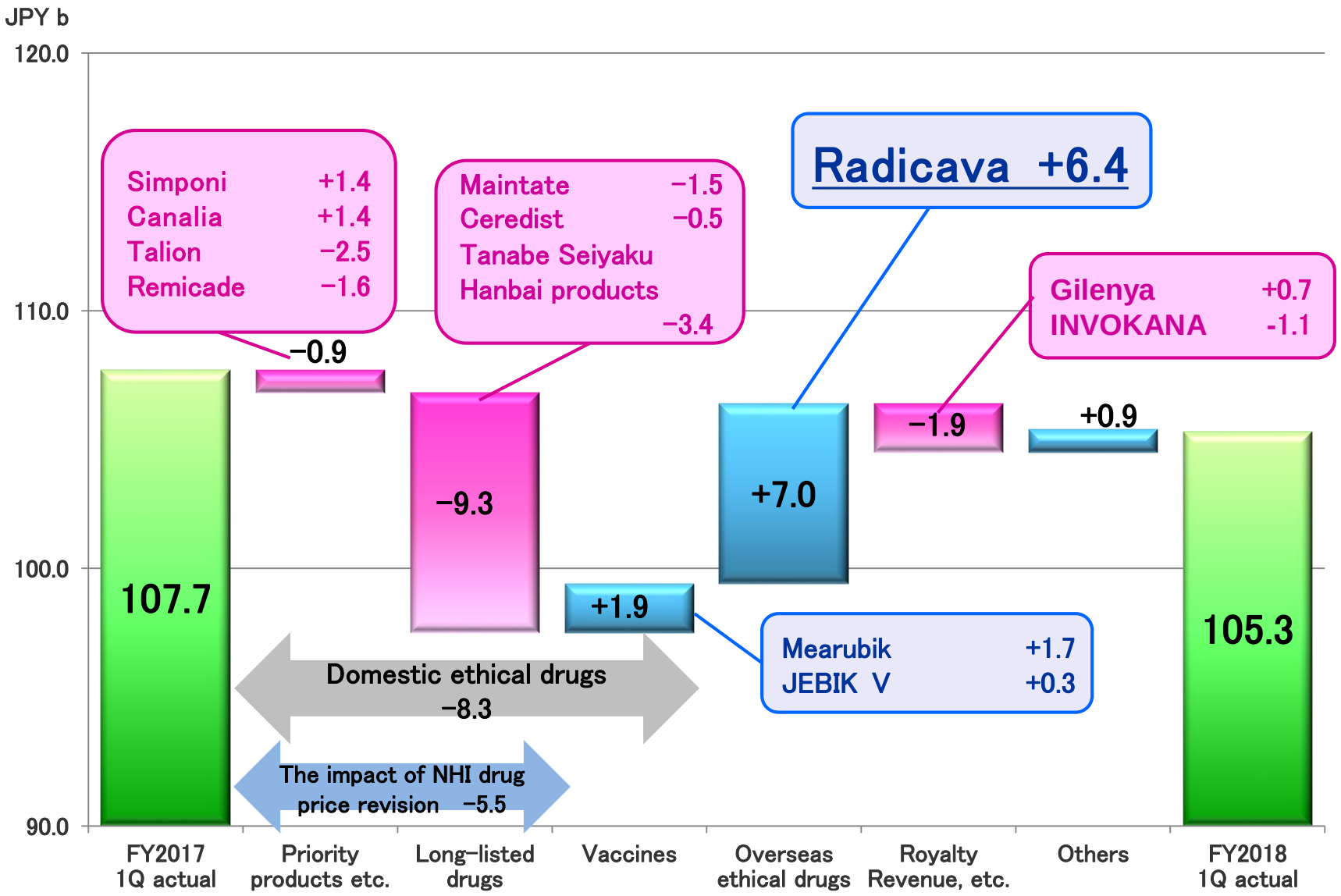
Revenue Trends



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Cost of Sales, SG&A Expenses, Core Operating Profit

The sales of cost ratio raised due to the impact of NHI drug price revision etc.
Core operating profit declined because R&D expenses increased due to progress in the late stage of development, etc.

	FY2018 Q1	FY2017 Q1	Increase/decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	105.3	107.7	-2.3	-2.2	210.0	50.2
Cost of Sales	42.3	42.5	-0.2	-0.5	84.0	50.4
Sales cost ratio	40.2%	39.5%			40.0%	
Gross profit	63.0	65.1	-2.1	-3.3	126.0	50.0
SG&A expense	23.1	24.4	-1.2	-5.0	50.0	46.4
R&D expense	19.6	18.0	+1.5	+8.6	44.5	44.2
Amortization of intangible assets associated with products	0.7	0.5	+0.2	+39.3	1.5	48.9
Other income and expense*2	-0.1	-0.1	-0.0	-	-	-
Core operating profit	19.3	21.9	-2.6	-12.2	30.0	64.3

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

*2: Negative signs (-) indicate expense and loss.

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Non-recurring items, Net Profit

	FY2018 Q1	FY2017 Q1	Increase/decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	19.3	21.9	-2.6	-12.2	30.0	64.3
Non-recurring items*2	-	-0.9	+0.9	-	-1.5	-
Operating profit	19.3	21.0	-1.7	-8.3	28.5	67.7
Financial income	0.4	1.0	-0.5	-52.9	-	-
Financial expense	0.0	0.0	-0.0	-37.9	-	-
Net profit attributable to owners of the Company	13.9	16.9	-3.0	-17.8	19.5	71.6

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

*2: Negative signs (-) indicate expense and loss.

Development Pipeline etc.

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Progress of Development Pipeline

Progress after the financial results for FY2017

As of July 27, 2018

Development code/ Product name (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed
MCI-186/ Radicava (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis)	EU				→
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Singapore				→
MT-7117	Dermatologicals, etc. (Erythropoietic protoporphyria)	US		→		
MT-5625	Plant-based VLP vaccine (Prophylaxis of rotavirus gastroenteritis)		→			

Changes of NeuroDerm Pipeline

Development code (Generic name)	Category (Indications)	Region	P1	P2	P3	Filed
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/patch pump (Parkinson's disease)	US, EU		→	consulting with authorities about Development Plan	
ND0801 (Nicotine / Opipramol)	Transdermal (CNS disease cognition disorders)	Israel		→	Discontinued	

＊The initial development plan of ND0612, “simultaneous NDA and EMA submission in FY2018 and its launch in FY2019” has been revised. As the investigation is ongoing, including consultation with the FDA.

Impact on Royalties

Gilenya（Novartis）

- MTPC's royalty based on sales of Gilenya continues for a certain period and at certain rate after compound patent expiration.
  (US: by Aug. 2019).
- The royalty rate is reduced after compound patent expiration.

Situation Summary

"In July, 2018, the PTAB issued a decision upholding the validity of the dosage regimen patent. A favorable resolution of the dosage regimen patent litigation may enable a longer period of US market exclusivity for Gilenya."

License-out product INVOKANA

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INVOKANA (Janssen (JNJ))

・Completion of FDA review on an additional indication for reducing the risks of cardiovascular events by the CANVAS Program is expected in October 2018.

・In July 2018, JNJ announced that CREDENCE clinical trial is being stopped early for positive efficacy findings. JNJ plans to file in the US in 1H 2019.

*1: CANVAS : CANagliflozin cardioVascular Assessment Study
*2: CREDENCE : Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation
*3: Reduction of the composite risk of CV death, MI or stroke in T2D with established, or risk for, CV disease.

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

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Appendix

Appendix

Details of Revenue (Q1 FY2018, Cumulative Total)

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	FY2018 Q1	FY2017 Q1	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	105.3	107.7	-2.3	-2.2	210.0	50.2
(overseas sales revenue)	31.1	25.6	+5.5	+21.7	64.2	48.5
Domestic ethical drugs	71.6	79.9	-8.3	-10.4	141.2	50.7
Overseas ethical drugs	12.9	5.9	+7.0	+118.1	29.2	44.3
Royalty revenue, etc.	18.5	20.4	-1.9	-9.6	35.4	52.2
OTC products	1.2	1.1	+0.0	+3.8	2.3	50.5
Others	1.0	0.1	+0.8	+537.3	1.6	62.2

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

Appendix

Sales Revenue of Domestic Ethical Drugs, Priority Products, etc.

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	FY2018 Q1	FY2017 Q1	Increase/decrease		1H Forecasts	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	15.1	16.8	−1.6	−9.9	28.4	53.2
Simponi	9.0	7.5	+1.4	+19.5	17.2	52.2
Tenelia	4.4	4.6	−0.1	−4.2	8.4	53.3
Stelara*	0.2	−	+0.2	−	4.9	4.2
Lexapro	3.4	3.1	+0.2	+9.2	6.4	52.9
Canaglu	1.4	1.4	+0.0	+2.8	3.6	40.9
Talion	1.4	4.0	−2.5	−64.3	3.5	40.6
Rupafin	0.1	−	+0.1	−	1.2	13.9
Imusera	1.1	1.2	−0.1	−11.4	2.5	45.1
Canalia	1.4	−	+1.4	−	2.1	65.5
Total of priority products	37.9	38.9	−0.9	−2.6	78.7	48.2
Tetrabik	2.2	2.3	−0.1	−5.9	4.5	48.9
Mearubik	3.3	1.5	+1.7	+110.3	2.9	114.2
Varicella vaccine	1.4	1.4	−0.0	−2.5	2.8	50.0
JEBIK V	1.6	1.3	+0.3	+27.0	2.3	70.4
Influenza vaccine	−0.1	−0.0	−0.0	−	1.3	−
Total of vaccines	8.8	6.8	+1.9	+29.1	14.3	61.5
Total of priority products and vaccines	46.7	45.7	+0.9	+2.2	93.0	50.2

* MTPC & Janssen have updated the agreement for STELARA to transfer domestic distribution from Janssen to MTPC on June 27, 2018. Sales forecast of FY2018: 4.9 JPY b for 1H ; 15.1JPY b for full year (Total sales forecast announced on May 9, 2018 includes this sales.)

Royalty income, etc.

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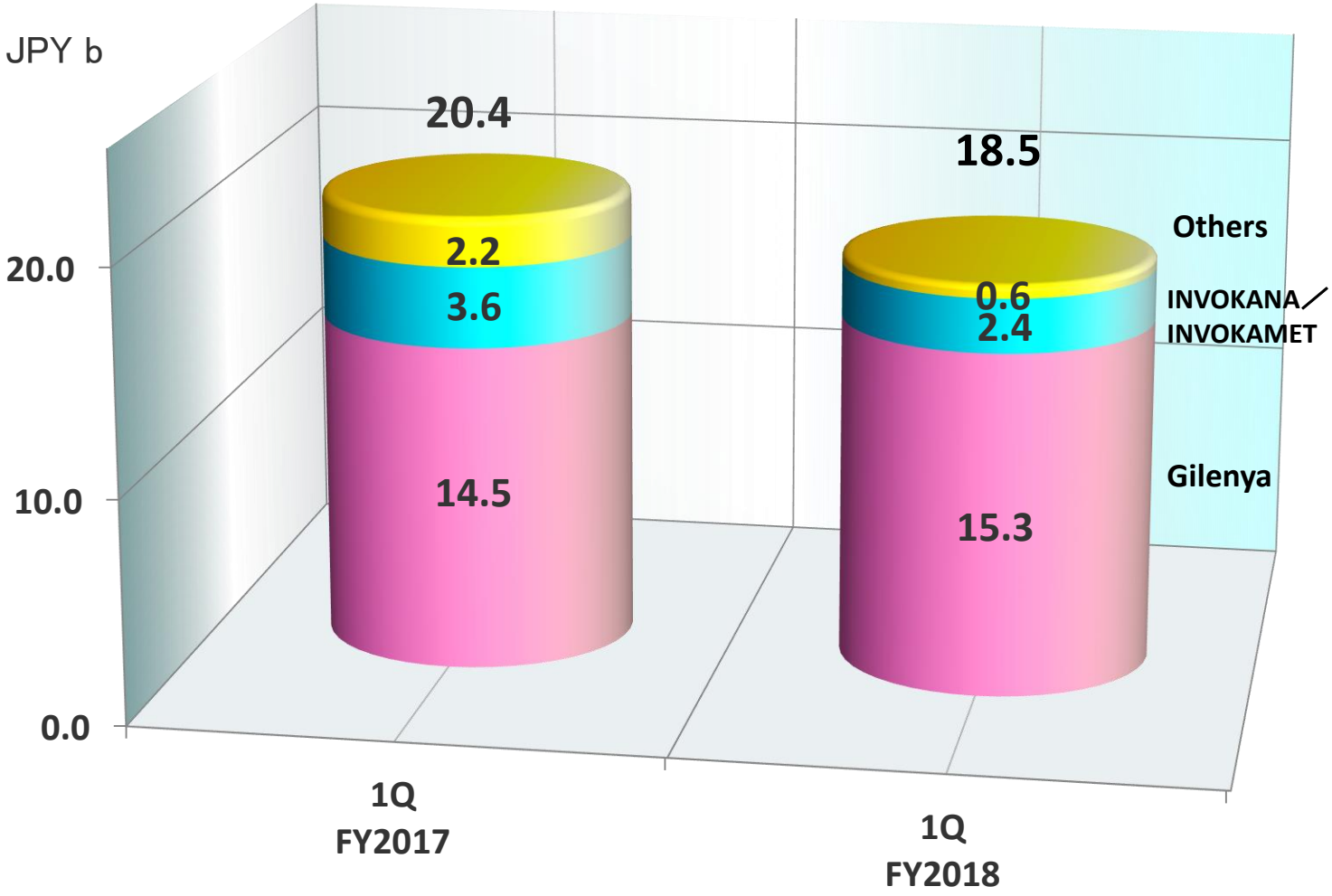

（Average exchange rate）		
US$	¥111.42	¥109.53

Gilenya

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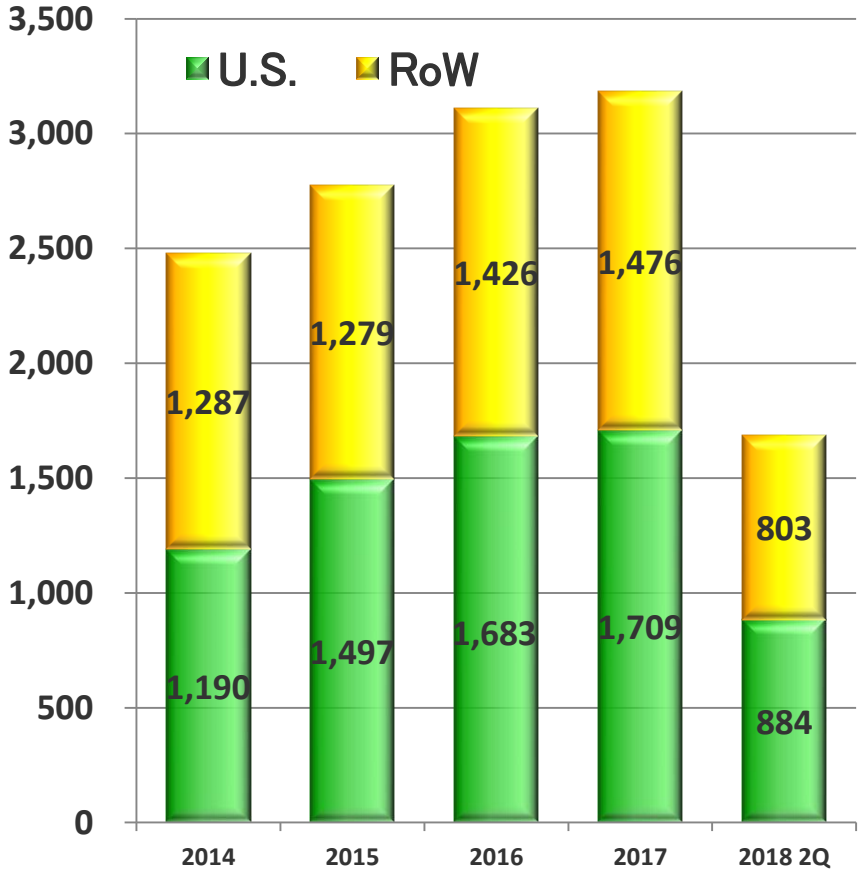
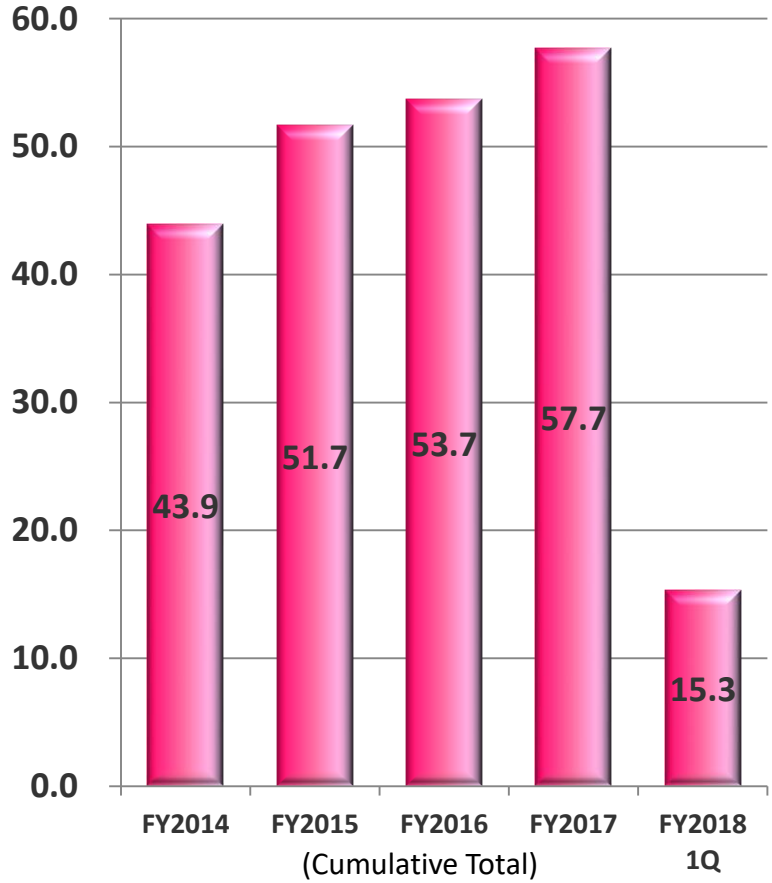
- Gilenya worldwide sales by Novartis in April to June, 2018 : $866 m ($837m, the same period of previous year)
- MTPC royalty revenue in Q1 FY2018 (April to June, 2018) : ¥15.3 b

Gilenya worldwide sales by Novartis



MTPC royalty revenue



Appendix

INVOKANA/INVOKAMET

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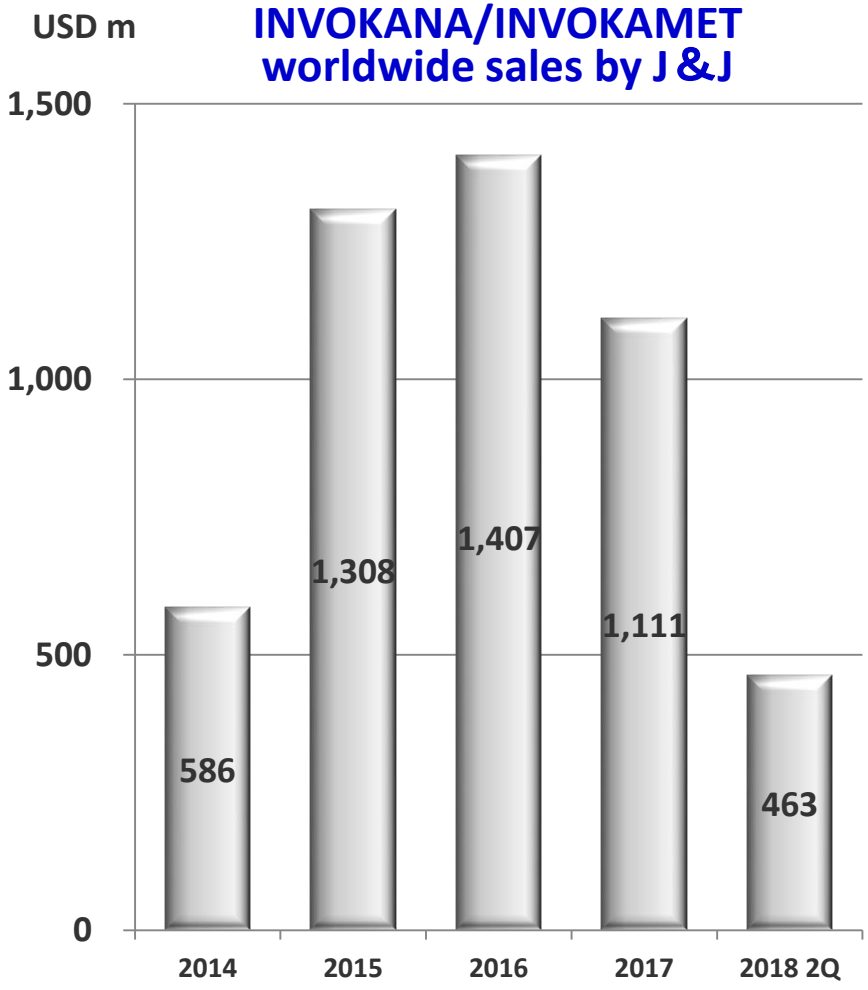
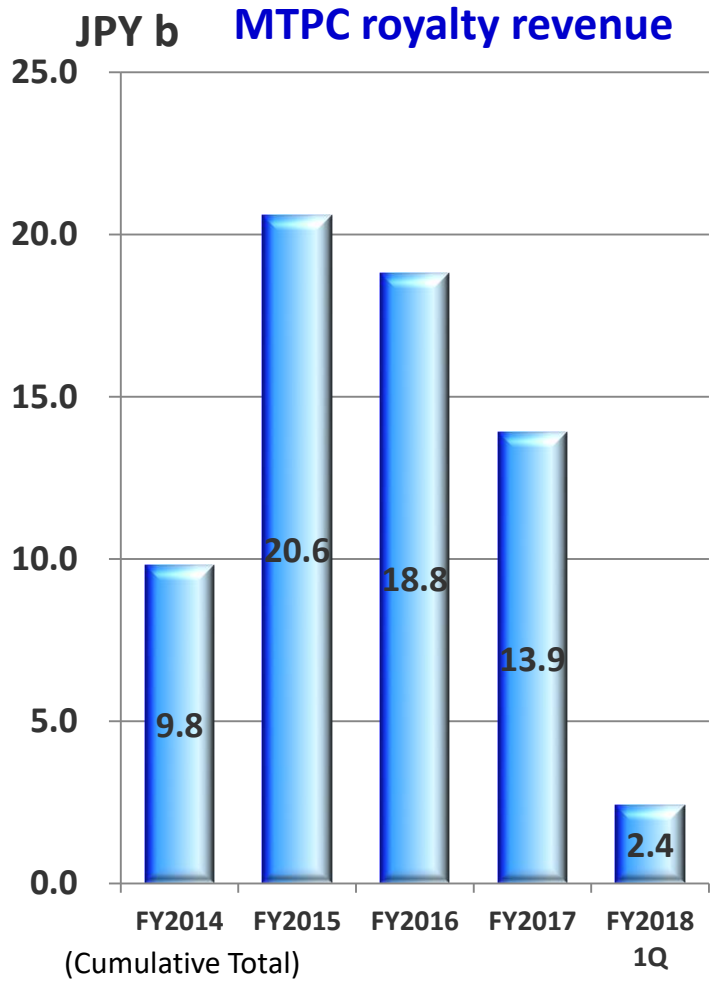
- INVOKANA/INVOKAMET sales by Johnson & Johnson in April to June, 2018: $215m ($295m, the same period of previous year)
- MTPC royalty revenue in Q1 FY2018 (April to June, 2018) : ¥2.4b





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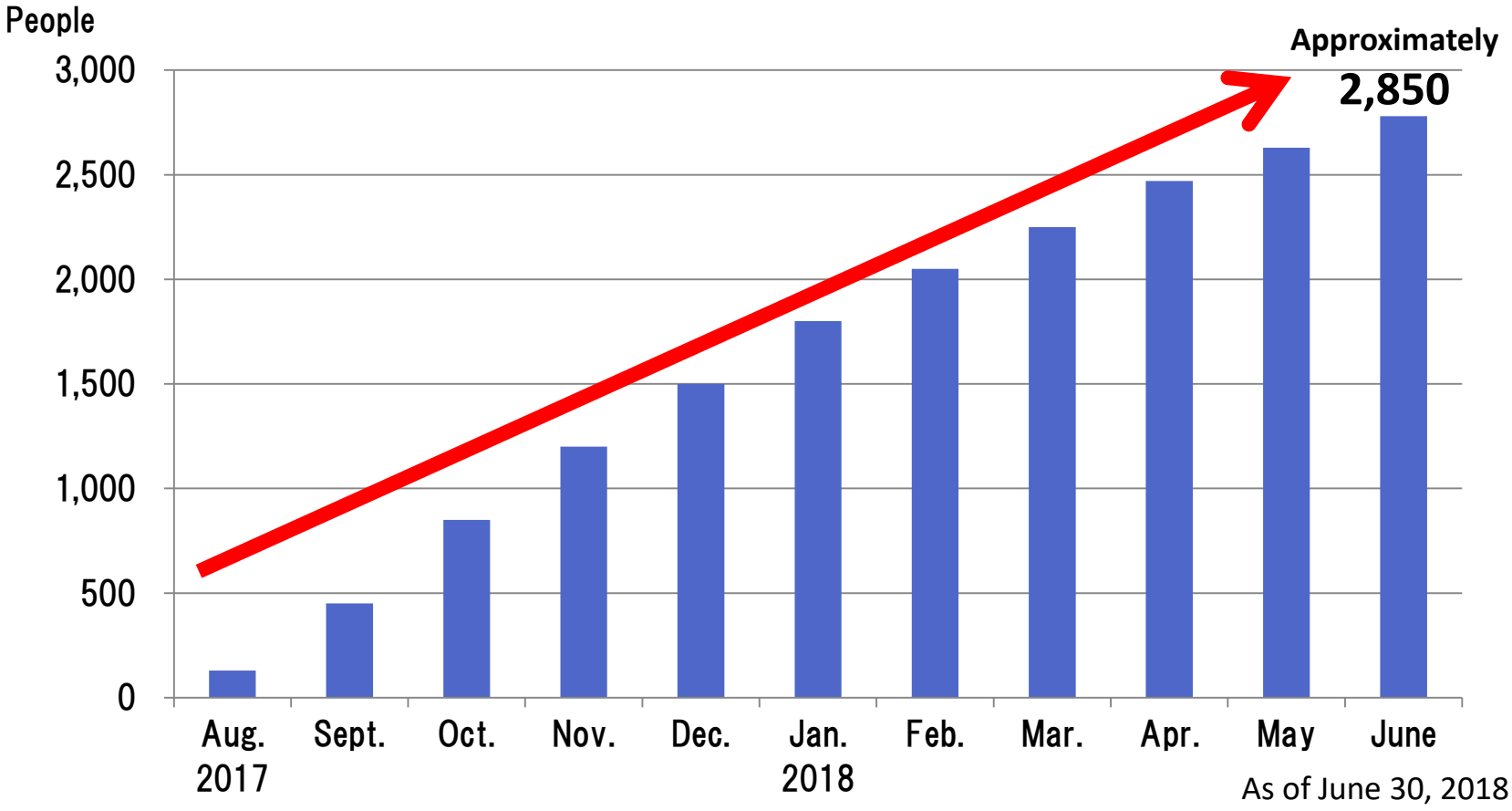
Number of Patients on Radicava (Cumulative)



Sales Revenue in April to June, 2018 : 6.4 JPY b

Number of Patients (Cumulative) : approximately 2,850
Number of patients（Continuous administration）: approximately 2,000

Appendix

Pipeline Status

Disease area
■ : Autoimmune disease ■ : Diabetes and kidney disease
■ : CNS disease ■ : Vaccines ■ : Other

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Red: Progress after the financial results for FY2017

As of July 27, 2018

Phase 1

- **MT-2990**
  Inflammatory diseases / Autoimmune diseases , etc.
- **MP-124**
  Nervous system
- **ND0701**
  Parkinson's disease
- **MT-1186**
  Amyotrophic lateral sclerosis (New administration route)
- **MT-7529**
  Prophylaxis of H7N9 influenza
- **MT-5625**
  Prophylaxis of rotavirus gastroenteritis
- **GB-1057**
  Blood and blood forming organs
- **MT-0814**
  Ophthalmologicals
- **MT-4129**
  Cardiovascular system, etc.
- **MT-2765** *1
  Cardiovascular system, etc.

Phase 2

- **MT-1303**
  Multiple sclerosis, Psoriasis(EU)
  Crohn's disease (JP, EU)
- **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**
  Prophylaxis of H5N1 influenza (Canada)

Phase 3

- **MT-5547**
  Osteoarthritis (JP)
- **Canaglu**
  Diabetic nephropathy (Global clinical study)*2
- **MP-513**
  Type2 diabetes mellitus (China)
- **MT-6548**
  Renal anemia (JP)
- **MT-5199**
  Tardive dyskinesia (JP)
- **MT-2355**
  5 combined vaccine (4 combined + Hib) (JP) *3
- **MT-2271**
  Prophylaxis of seasonal influenza (US, EU, Canada, etc.)

Filed

- **TA-7284**
  Type2 diabetes mellitus (Indonesia)
- **MP-513**
  Type2 diabetes mellitus (Indonesia)
- **MCI-186**
  Amyotrophic lateral sclerosis (Switzerland, Canada, EU)
- **MP-214**
  Schizophrenia (Korea, Taiwan, Singapore)
- **Valixa**
  Prevention of cytomegalovirus disease in pediatric organ transplant patients (Japan)

Approved

- **Jublia**
  Anti-fungal Agent (Taiwan)

Major license-out products (post Phase 3)

Phase 3

- **TA-7284**
  Diabetic nephropathy (Global clinical study)*2
- **MT-210**
  Schizophrenia (US, EU)
- **MT-4580**
  Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism (JP)

Approved

- **FTY720**
  Pediatric multiple sclerosis (US)

Filed

- **FTY720**
  Pediatric multiple sclerosis (EU)
- **TA-7284**
  Reduce the risk of death in Type 2 diabetes with established, or risk for, cardiovascular disease (CANVAS/CANVAS-R) (US, EU)

*1: Co-researched with Shanghai Pharmaceuticals Holding (China)
*2: Sponsor: Janssen Research & Development, LLC
*3: Co-developed with The Research Foundation for Microbial Diseases of Osaka University (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.