Mitsubishi Tanabe Pharma Corporation

FY2018 Business Results
(April, 2018 - March, 2019)

May 13, 2019

Masayuki Mitsuka
President and Representative Director

Open Up the Future

FY2018 Business Results

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Regarding Gilenya Royalty

- As Mitsubishi Tanabe Pharma Corporation (hereinafter, “MTPC”) announced on April 24, 2019 in the "Revision to Consolidated Financial Forecasts for Fiscal Year Ending March 31, 2019", MTPC is currently in the arbitration proceedings with Novartis Pharma AG (hereinafter "Novartis"), and among the “GILENYA® Royalty” amounts that MTPC is going to receive from Novartis, MTPC has decided not to recognize some of those amounts, which correspond to the clauses in the 1997 License Agreement of which Novartis has protested the validity, as our revenue because such payments do not satisfy one of the requirements under IFRS15, *i.e.*, “Revenue under contract with customers”.

- MTPC maintains it is entitled to receive the full royalty amounts due according to the 1997 License Agreement with Novartis, and MTPC will rigorously pursue its rights in the arbitration.

- As for the amounts among the “GILENYA® Royalty” amounts which will not be recognized as sales revenue, those will be recognized as revenue at the end of the arbitration, depending on the outcome of the arbitration.

FY2018 Financial Results

- **Sales revenue declined as a result of a decrease in revenue of domestic ethical drugs despite an increase in overseas.**
- **Core operating profit declined with the increase of R&D expenses.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	424.7	433.8	(9.0)	(2.1)	435.0	97.6
(Domestic)	307.7	320.8	(13.1)	(4.1)	304.7	101.0
(Overseas)	117.0	112.9	4.0	3.6	130.2	89.9
Overseas sales ratio	27.6%	26.0%			29.9%	
Cost of sales	180.6	169.7	10.8	6.4	176.0	102.6
Gross profit	244.1	264.1	(19.9)	(7.6)	259.0	94.3
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8
Operating profit	50.3	77.2	(26.9)	(34.9)	67.0	75.1
Net profit attributable to owners of the Company	37.3	57.9	(20.5)	(35.5)	47.0	79.5
Average exchange rate US$	¥111.07	¥110.70			¥105.00	

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

Revenue Trends

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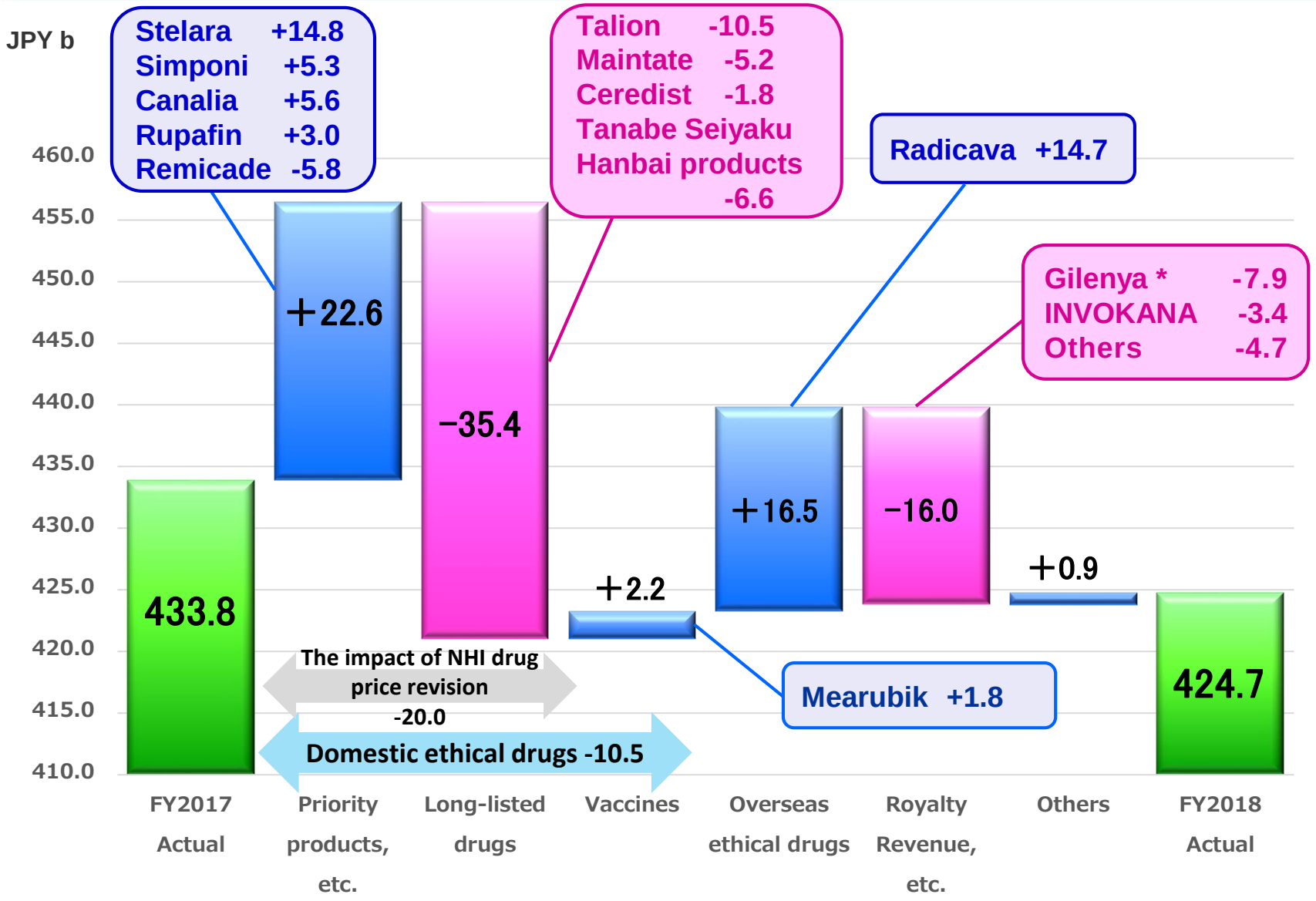

* including a decline in sales as for the amounts among the “GILENYA® Royalty” amounts which will not be recognized as sales revenue during arbitration proceedings

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

- **SG & A expenses reduced due to the operational productivity reform, etc.**
- **R&D expenses increased due to the progress of the late-stage global development.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	424.7	433.8	(9.0)	(2.1)	435.0	97.6
Cost of Sales	180.6	169.7	10.8	6.4	176.0	102.6
Sales cost ratio	42.5%	39.1%			40.5%	
Gross profit	244.1	264.1	(19.9)	(7.6)	259.0	94.3
SG&A expense	98.2	104.0	(5.8)	(5.6)	101.0	97.3
R&D expense	86.5	79.0	7.4	9.4	84.5	102.4
Amortization of intangible assets associated with products	2.9	2.4	0.4	19.7	3.0	97.8
Other income and expense*2	(0.5)	0.0	(0.6)	-	(0.5)	-
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8

※1: Announced on May 9, 2018 in the financial results of FY2017 ※2: Brackets indicate expense and loss.

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Non-recurring items and Net Profit

- **Non-recurring item increased with the impairment loss due to the decision to close Toda Office, etc.**

	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	55.8	78.5	(22.7)	(28.9)	70.0	79.8
Non-recurring items※2 [Toda Office impairment loss]	(5.5) [(5.2)]	(1.2)	(4.2)	-	(3.0)	-
Operating profit	50.3	77.2	(26.9)	(34.9)	67.0	75.1
Financial income and expense	0.1	1.4	(1.3)	(90.8)		
Net profit attributable to owners of the Company	37.3	57.9	(20.5)	(35.5)	47.0	79.5

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

※2: Brackets indicate expense and loss.

FY2019 Business Forecasts

Forecasts of FY2019

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	FY2019 Forecasts	FY2018 Actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	376.0	424.7	(48.7)	(11.5)
(Domestic)	308.3	307.7	0.6	0.2
(Overseas)	67.6	117.0	(49.3)	(42.2)
Overseas sales ratio	18.0%	27.6%		
Cost of sales	178.5	180.6	(2.1)	(1.2)
Gross profit	197.5	244.1	(46.6)	(19.1)
Core operating profit	10.0	55.8	(45.8)	(82.1)
Operating profit	11.5	50.3	(38.8)	(77.1)
Net profit attributable to owners of the Company	5.0	37.3	(32.3)	(86.6)
Average exchange rate（USD）	¥110.00	¥111.07		

Revenue Trends

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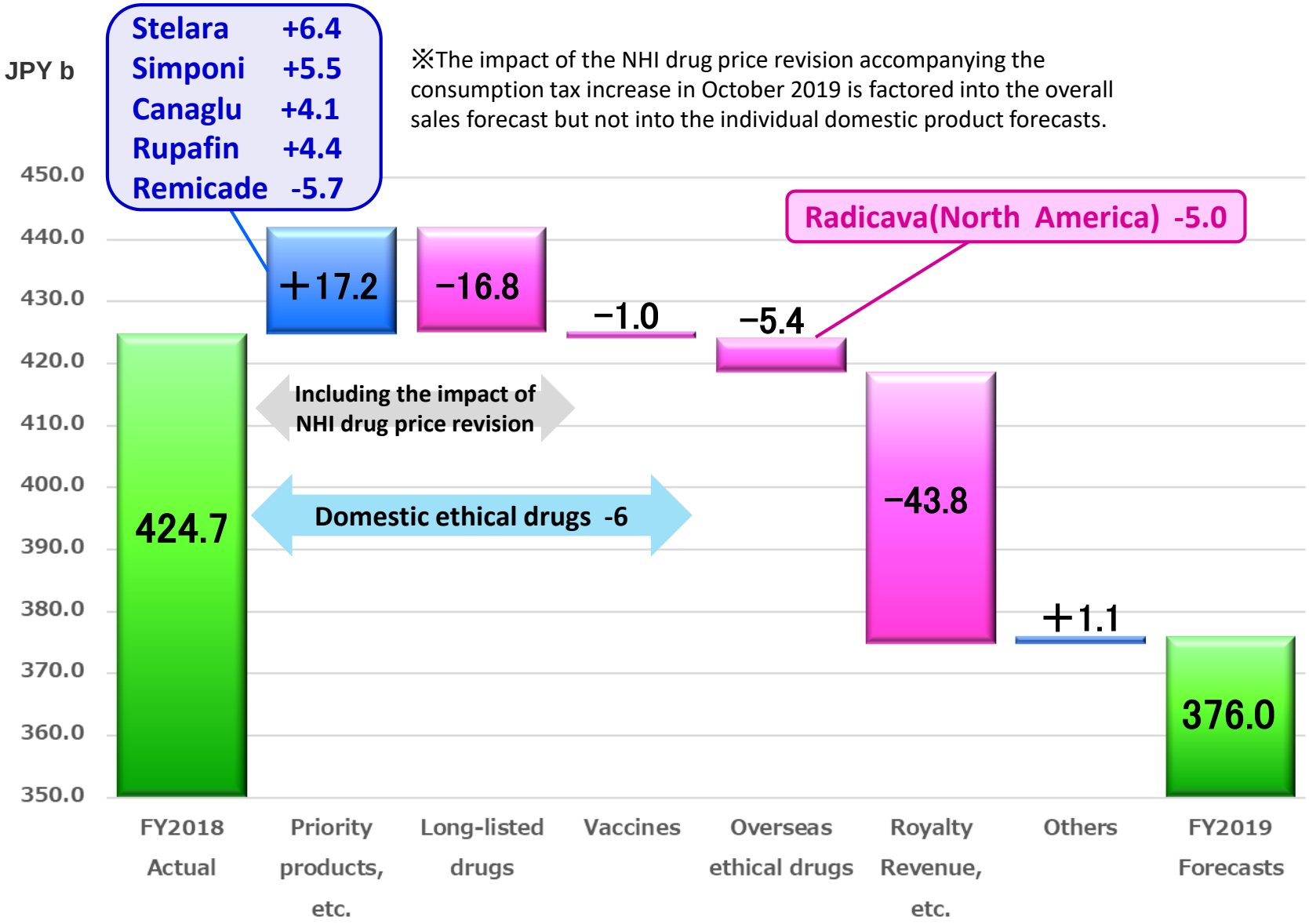

Royalty revenue, etc.

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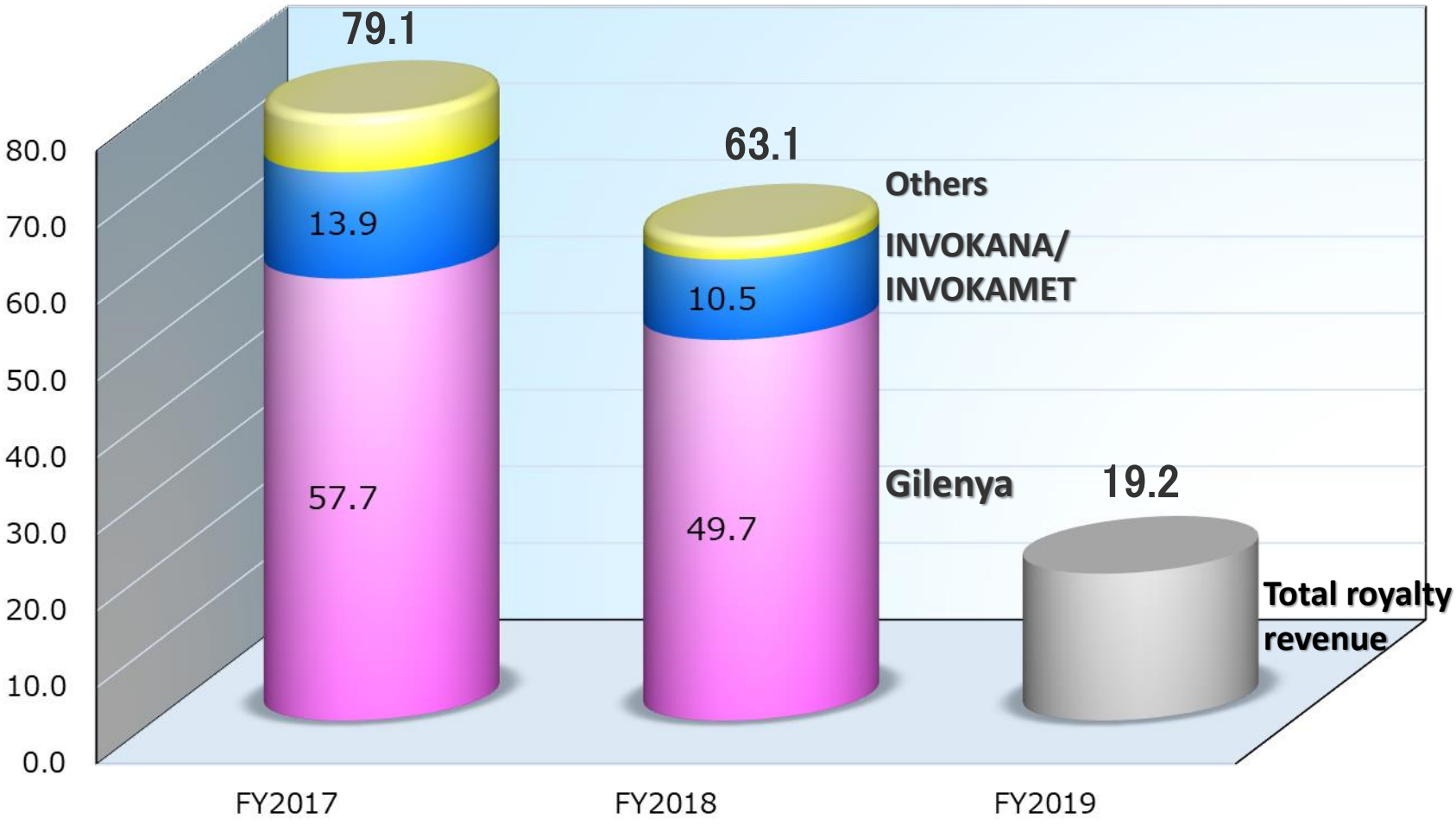

<Average exchange Rate (USD)>

FY2017	FY2018	FY2019 Forecast
¥110.70	¥111.07	¥110.00

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

- **R&D expenses will remain at the level of FY2018 as the progress of global products development.**

	FY2019 Forecasts	FY2018 Actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Revenue	376.0	424.7	(48.7)	(11.5)
Cost of Sales	178.5	180.6	(2.1)	(1.2)
Sales cost ratio	47.5%	42.5%		
Gross profit	197.5	244.1	(46.6)	(19.1)
SG&A expense	99.0	98.2	0.7	0.8
R&D expense	85.5	86.5	(1.0)	(1.2)
Amortization of intangible assets associated with products	2.5	2.9	(0.4)	(14.8)
Other income and expense*	(0.5)	(0.5)	0.0	-
Core operating profit	10.0	55.8	(45.8)	(82.1)

*Brackets indicate expense and loss.

Strategy for Restoring Business Growth

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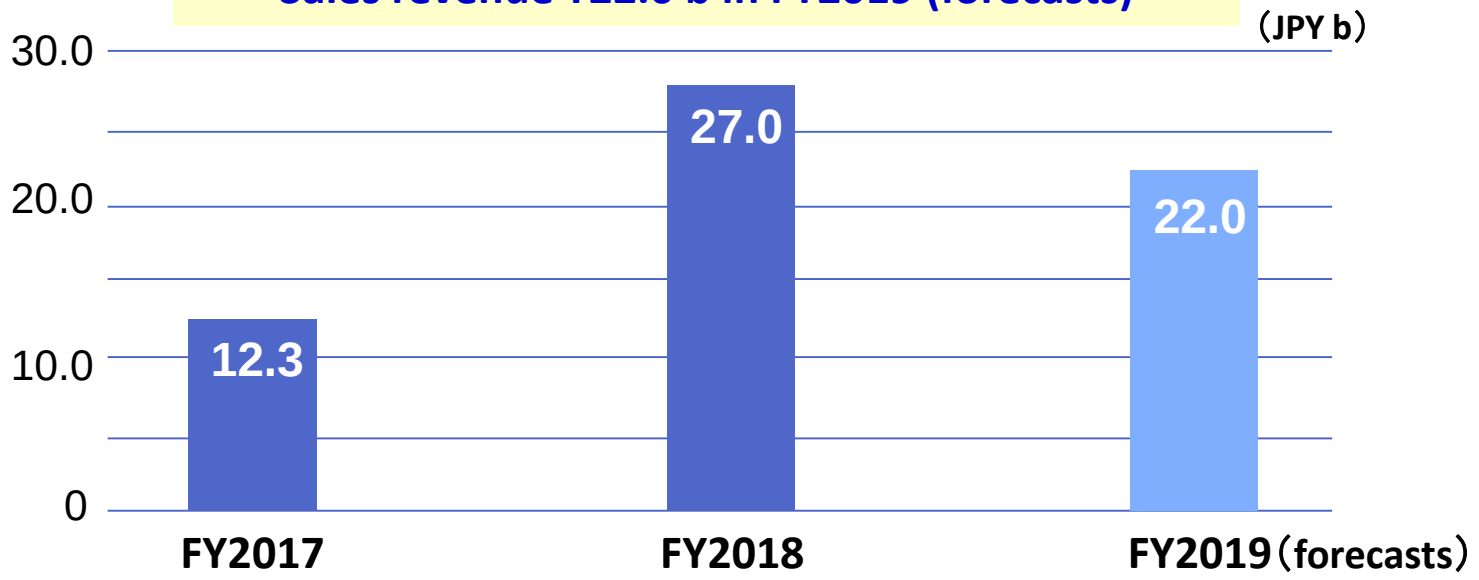
Radicava : Sales in North America

Sales revenue ¥22.0 b in FY2019 (forecasts)



- Administration to patients who waited for treatment has been almost completed.
- Some of new patients will be enrolled into clinical trials for oral suspension development.

Future Strategy :

- accelerate development of oral suspension.
- encourage early administration to new patients.
- improve the rate of continuous administration of Radicava.

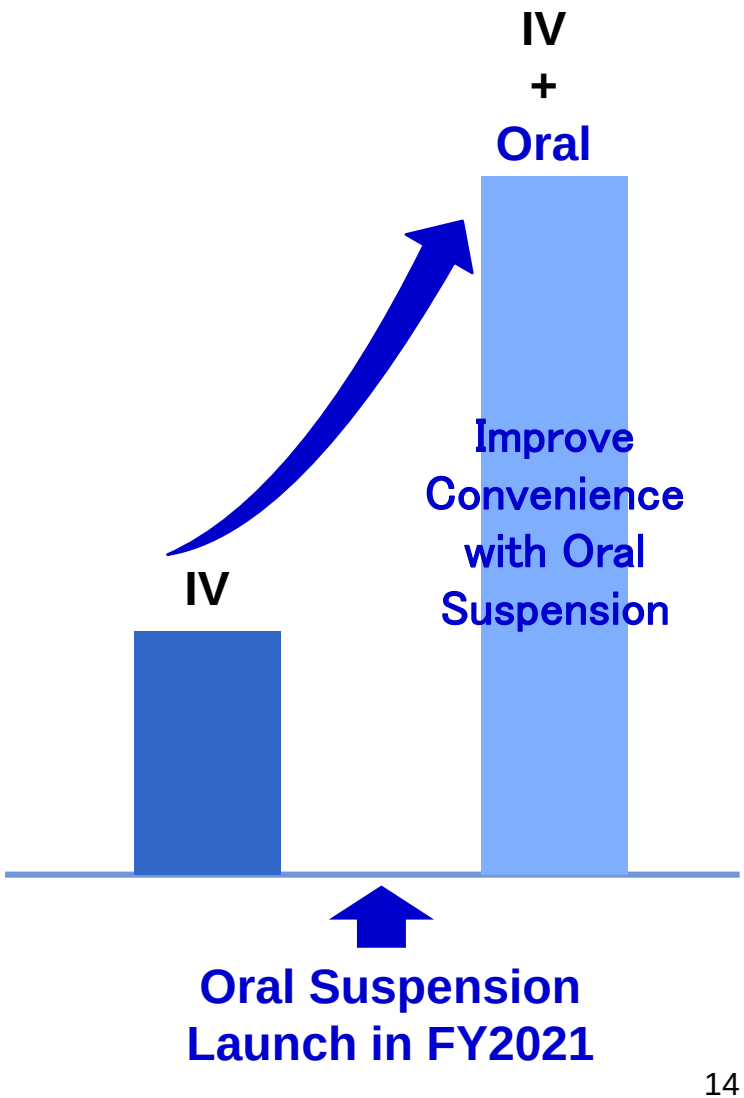
Radicava : Accelerate Oral Suspension Development (MT-1186)

Aim for launch of oral suspension in FY2021

Under discussion on regulatory path with US FDA

- Filing strategy : conduct PK comparison with intravenous (IV) Radicava and long-term safety trial for early launch
- Development strategy : conduct post-marketing commitments* of IV Radicava by using oral suspension with developing new dosing regimen

*Post-marketing Commitment : clinical study to be conducted in post-marketing, which has been agreed with US FDA



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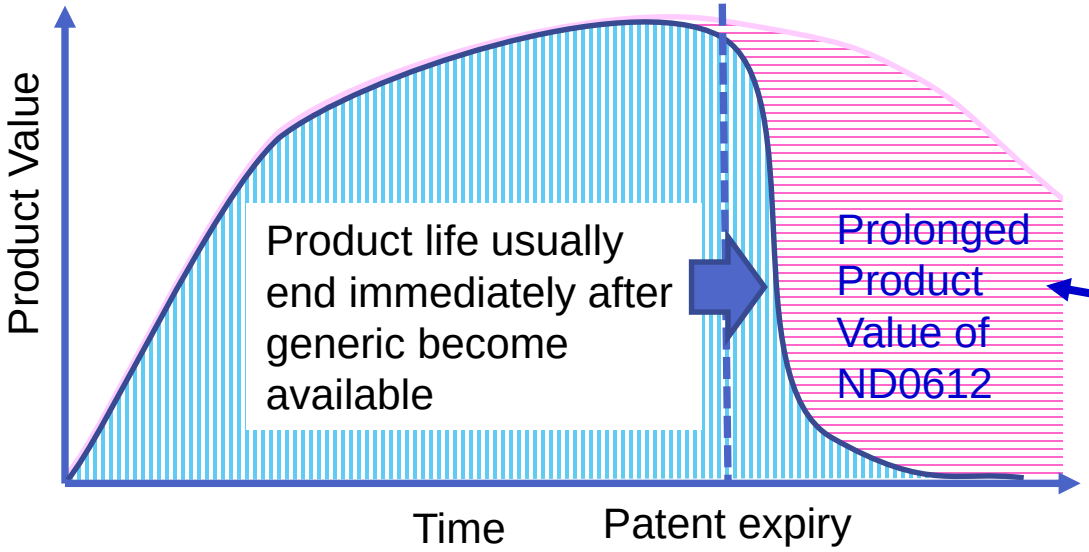
ND0612 : Simultaneous NDA Submission in US & EU

Change of Clinical Development Plan and Schedule

	FY2019	FY2020	FY2021～
US/EU	P2 Study：Safety P3 Study：Efficacy ■FY2019/Q2 Start P3 Study		■FY2021 NDA/MAA ■FY2022 Launch

Continuously Maximize the Value of Combination Product



- High barrier for generic entry caused by the nature of drug-device combination product
- Market value is expected to maintain even after patent expiry

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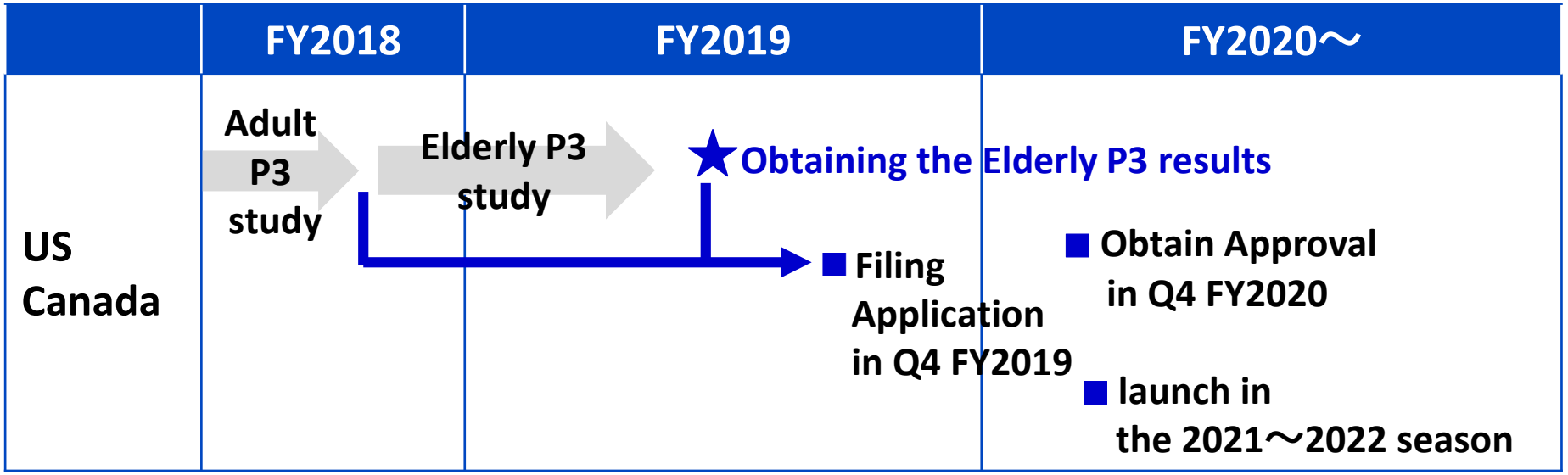
MT-2271 : Medicago Seasonal Influenza Plant-based VLP Vaccine

Features	■ Reduce time for manufacture ■ No egg adaptation
Strategy	■ Aim for achieving 10% share at the peak in growing non-egg based vaccines market. ■ Quebec new plant (scheduled for operation in FY2023) will cover the demand of 20 million doses.



＊North Carolina Plant will supply the product upon launch.

New growth drivers ①

■ MT-1303（amiselimod）

✓ Licensing Agreement（April, 2019）

- MTPC grants Bausch Health Companies Inc. ("Bausch Health") (Canada) exclusive rights to develop and commercialize MT-1303 worldwide except for Japan and certain other countries in Asia.

  (excluding neurology, rheumatology and certain rare dermatology diseases)

- Salix Pharmaceuticals* ("Salix") plans to initiate development of MT-1303 in ulcerative colitis.

* a wholly owned subsidiary of Bausch Health

✓ Future MTPC Initiatives

- MTPC has the right to file applications for approval and commercialize in our territory by using data from the global clinical trials conducted by Salix.
- MTPC will continue to global development of MT-1303 for indications in neurology and rheumatology.

New growth drivers ②

■ Products targeted for late-stage develop

Product	Indication	Unmet Medical Needs	Plans for FY2019
MT-8554	Vasomotor symptoms (VMS)	The safety issues of hormone replacement therapy has been reported, and an effective and safe drug is desired.	P2 study completed. Under consulting with FDA for P3 study.
MT-3995	Non-alcoholic steatohepatitis (NASH)	A multifactorial disease that may eventually lead to cirrhosis and liver cancer, but there are no therapeutic agents launched.	The results of P2 study are scheduled to be acquired in Q2 FY2019.
MT-7117*	Erythropoietic protoporphyria (EPP)	Neither standard treatment nor oral agent has been developed in US. Only prophylaxis to avoid sun exposure is available.	The results of P2 study are scheduled to be acquired in Q3 FY2019.

＊FDA fast-track designated

Domestic ethical drugs
Priority Areas ① Immuno-inflammatory

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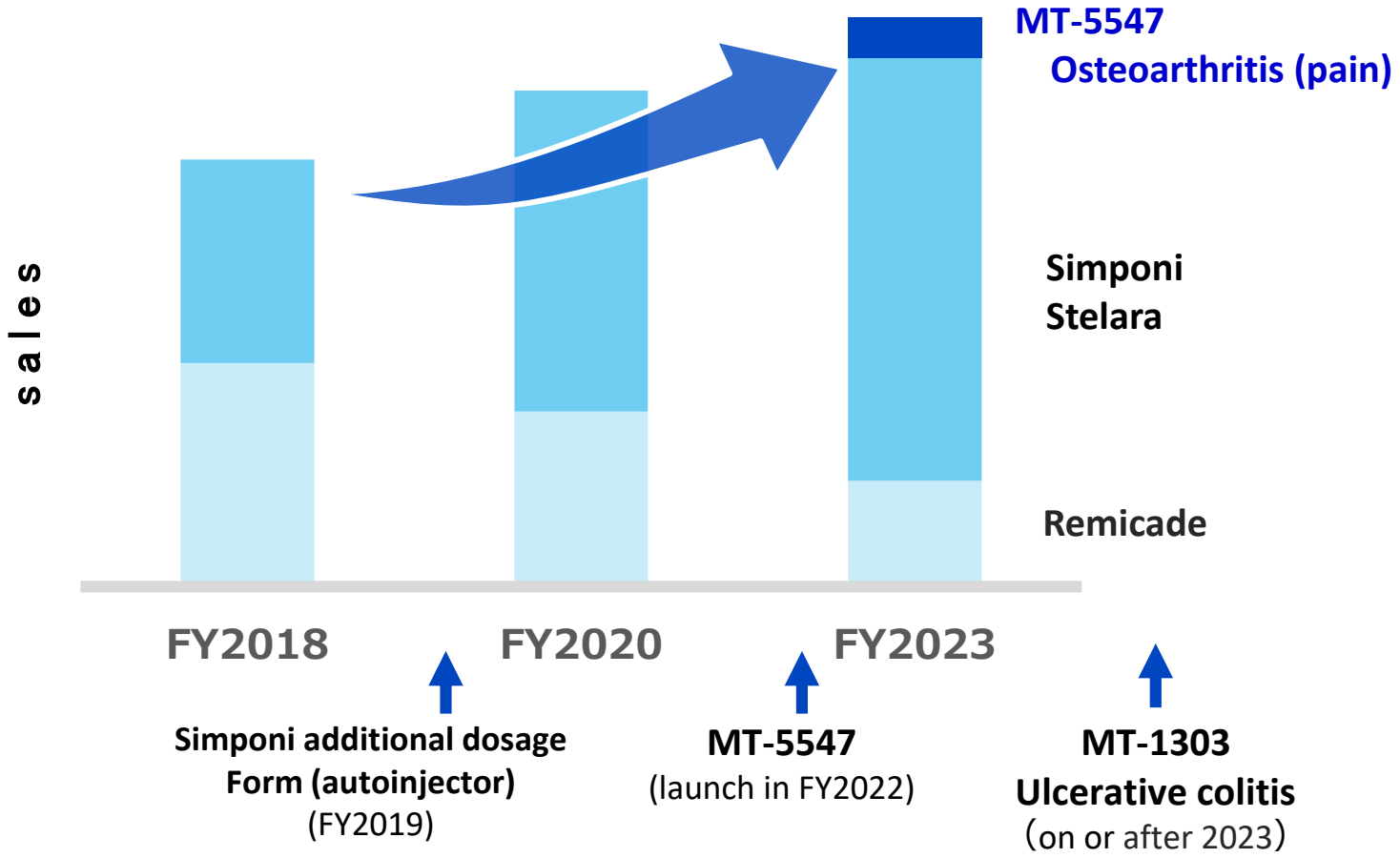
Aim for future sales of ¥150 billion by proposing optimal Bio treatments for each disease state/stage and maintaining 40% or more share of the Bio market in the field of immuno-inflammatory



Domestic ethical drugs
Priority Areas ② Diabetes and kidney

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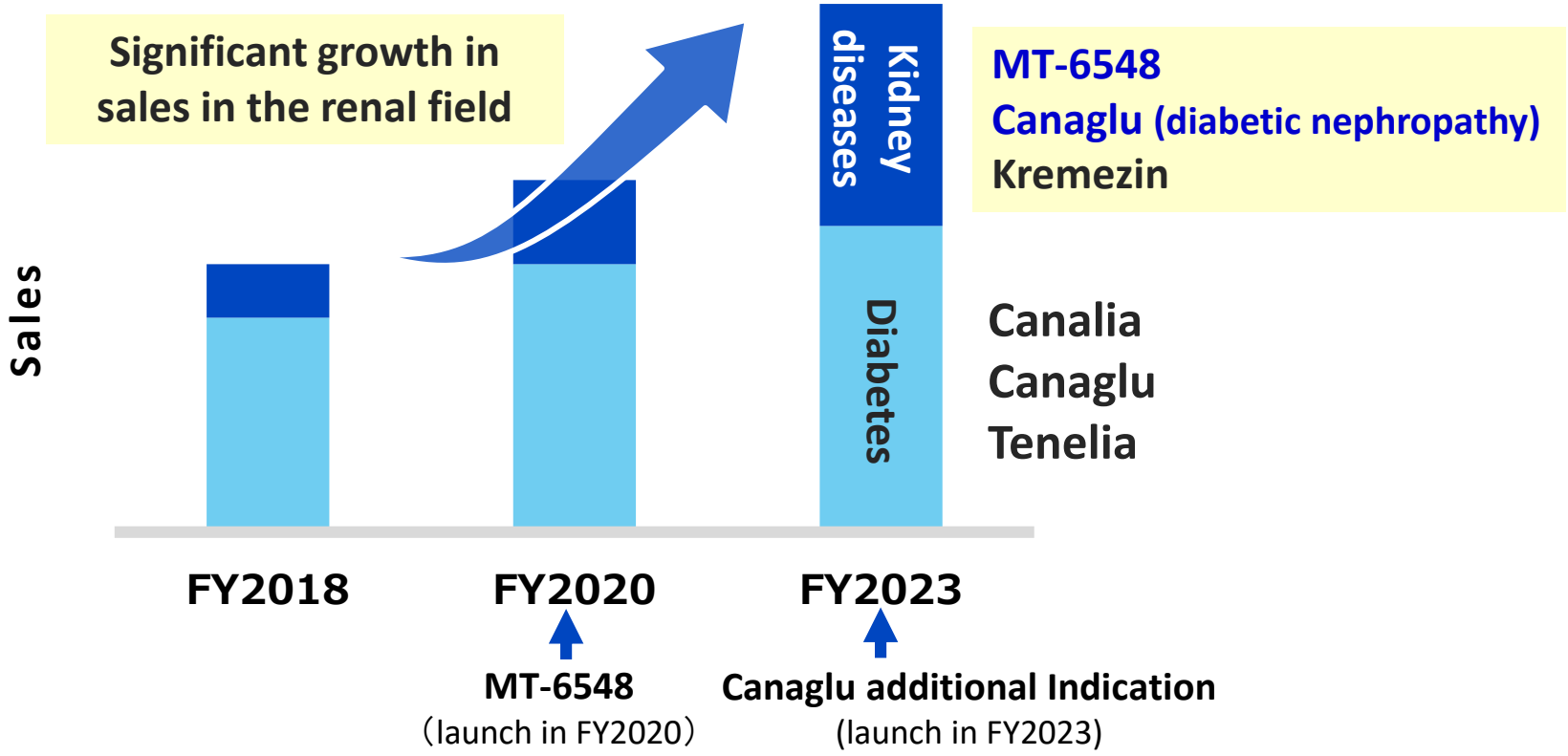
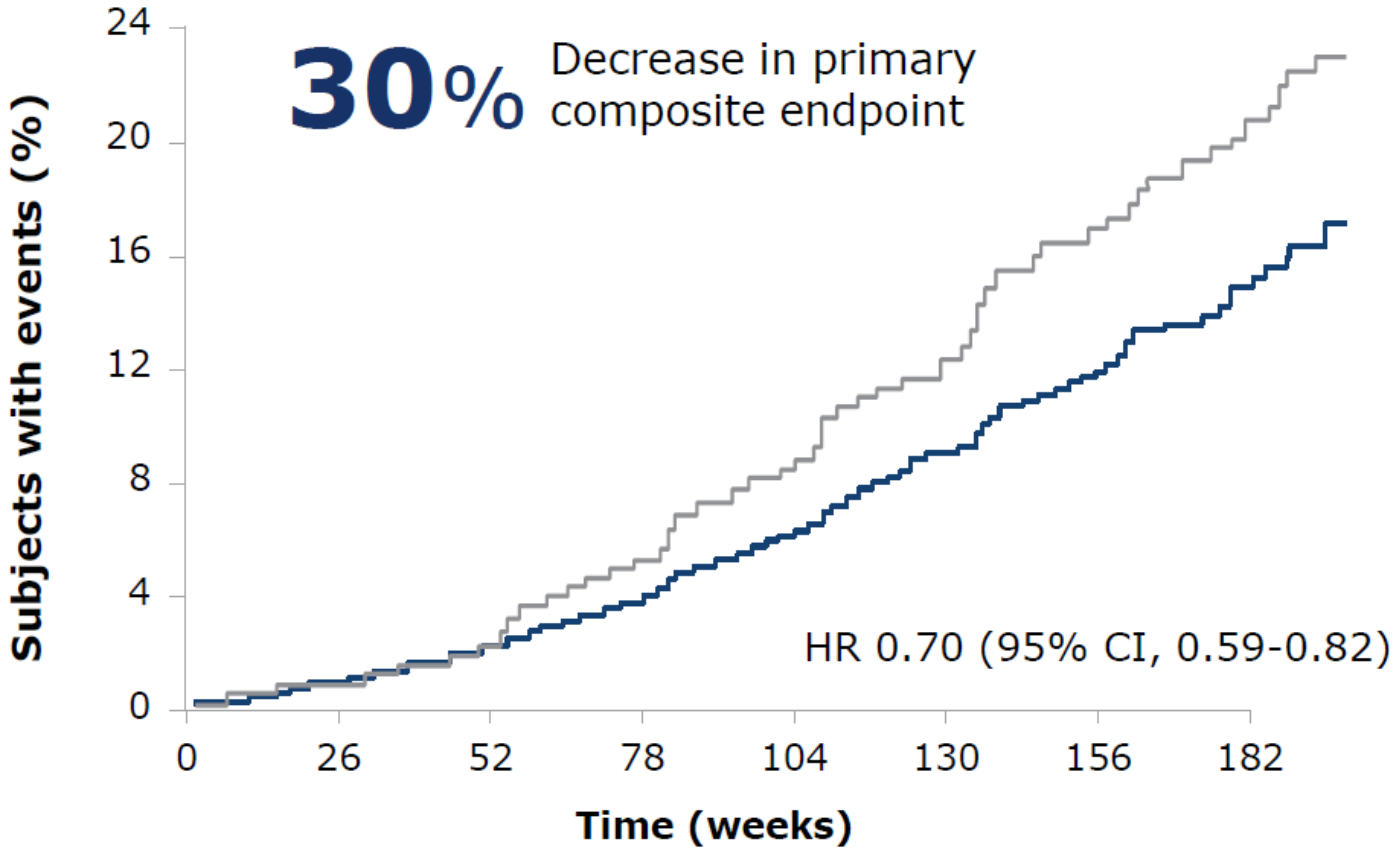
Aim for future sales of ¥100 billion by expanding market share of 3 antidiabetic products, launching MT-6548 and adding indication of diabetic nephropathy of Canaglu

Canaglu： In addition to the CANVAS *1 study, the CREDENCE *2 study published in April 2019 demonstrated a variety of effects on the heart and kidneys

*1 CANVAS study： Clinical trials of canagliflozin testing the cardiovascular and renal safety
*2 CREDENCE study： Clinical trials of canagliflozin testing the renal events in diabetic patients with overt nephropathy



The CREDENCE Study



No. at risk								
Canagliflozin	2202	2181	2145	2081	1786	1211	646	196
Placebo	2199	2178	2132	2047	1725	1129	621	170

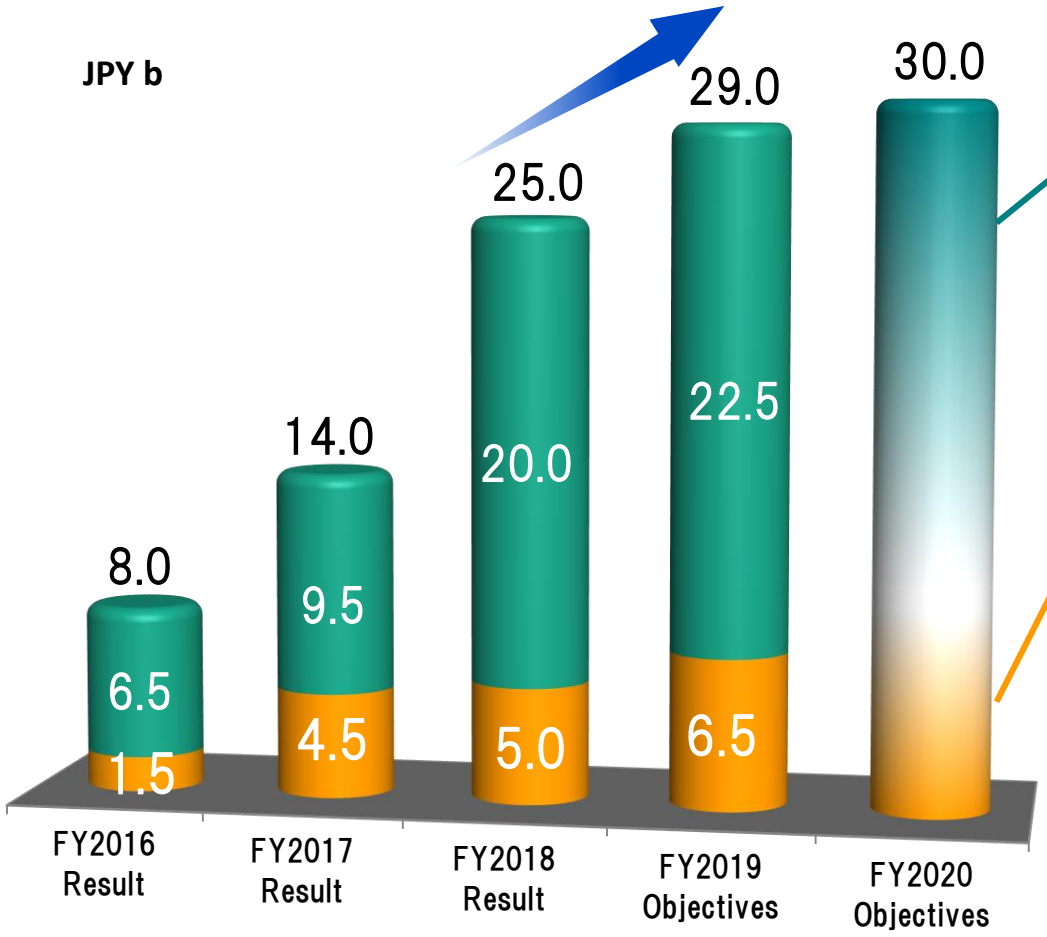
CREDENCE: Phase 3 Data

Primary composite endpoint composed of: End-stage Kidney Disease (ESKD), Doubling of Serum Creatinine, Renal or CV Death

1. *New England Journal of Medicine, April 14, 2019.* Available at https://www.nejm.org/doi/full/10.1056/NEJMoa1811744?query=recirc_curatedRelated_article

Reforming Operational Productivity

- **FY2018 Result : Reduced ¥25.0 b including fixed R&D expenses**
- **FY2019 Plan : Aim for reducing ¥29.0 b by additional fixed expenses reductions**



SG&A expenses / R&D expenses

- Reducing companywide fixed expenses
- Achieved a 5,000-person domestic workforce two years ahead of schedule through reduction of work and reevaluation of duplicated functions

Cost of sales

- Reevaluating procurement methods for pharmaceutical ingredients
- Increasing productivity by improving production technologies

Reinvestment in growth strategies

* Benchmark: fiscal 2015

Shareholders Return

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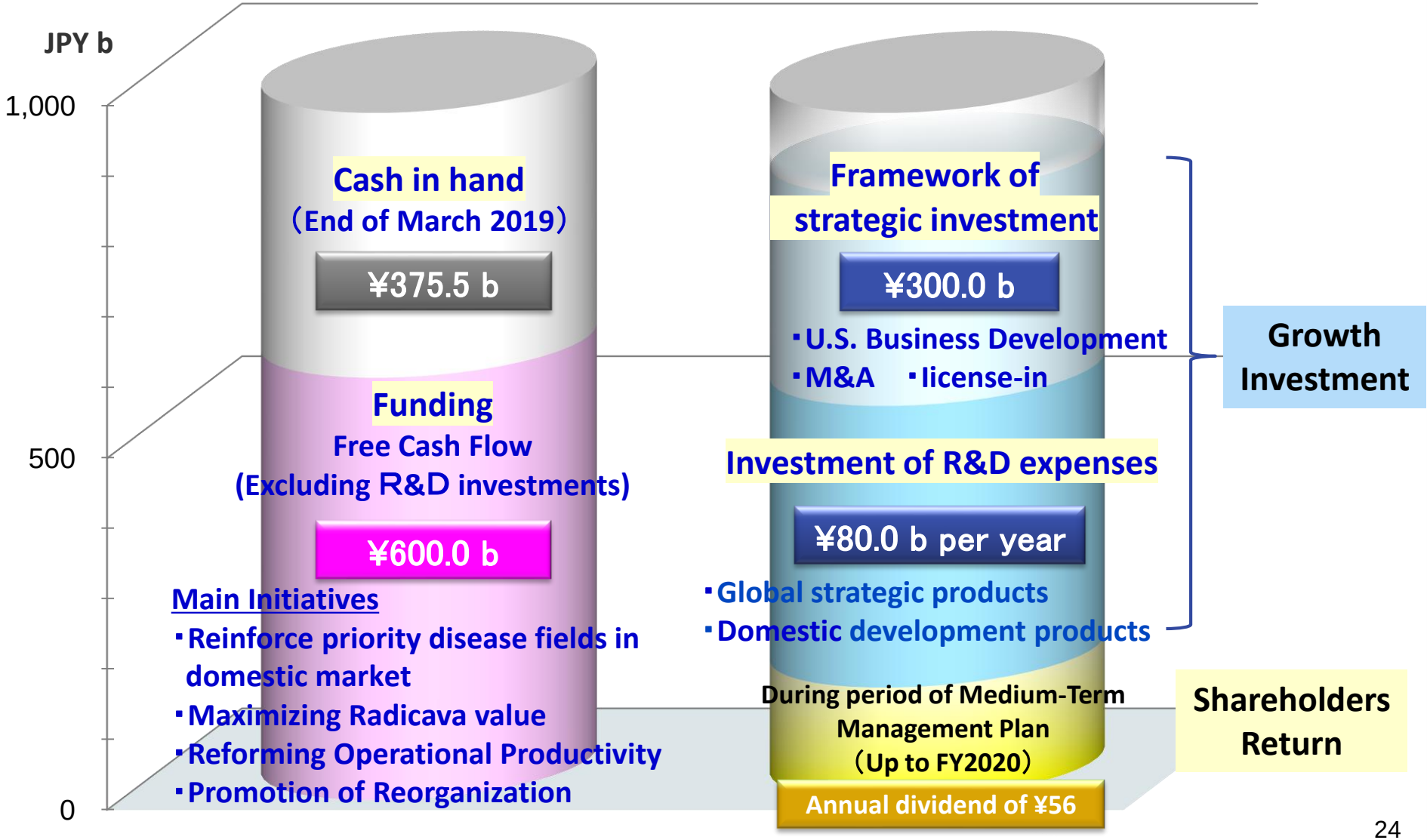
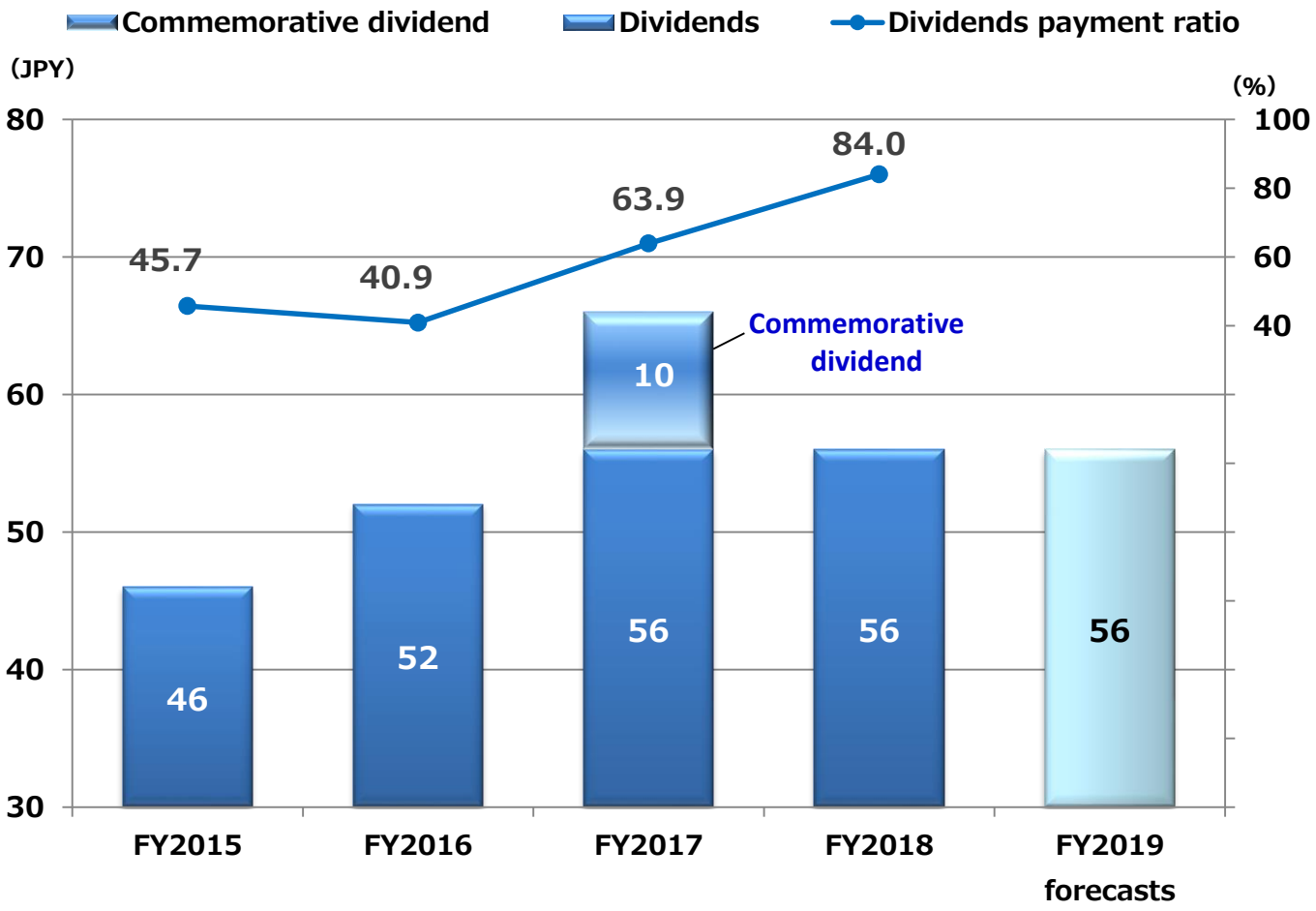
Growth Investment and Shareholders Return(FY2019-FY2023)



Dividends Trends

- Enhance stable, continuous return to shareholders
- Maintain current amount of dividends (annual dividend of ¥56) during period of Medium-Term Management Plan 16-20



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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

Details of Revenue

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	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales revenue	424.7	433.8	(9.0)	(2.1)	435.0	97.6
(overseas sales revenue)	117.0	112.9	4.0	3.6	130.2	89.9
Domestic ethical drugs	298.7	309.3	(10.5)	(3.4)	296.2	100.9
Overseas ethical drugs	55.1	38.5	16.5	42.9	61.1	90.2
Royalty revenue, etc.	63.1	79.1	(16.0)	(20.3)	69.8	90.3
OTC products	3.7	3.7	0.0	1.0	4.3	86.6
Others	3.9	3.0	0.9	30.9	3.3	118.3

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

Appendix

Domestic Ethical Drugs
Revenue of Priority Products and Vaccines

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	FY2018	FY2017	Increase / Decrease		FY2018 Forecasts※	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	58.8	64.6	(5.8)	(9.1)	55.5	105.8
Simponi	37.4	32.1	5.3	16.7	35.0	106.9
Tenelia	15.2	17.5	(2.3)	(13.3)	17.0	89.2
Stelara	15.2	0.3	14.8	-	15.1	100.5
Lexapro	14.0	12.7	1.2	9.7	13.1	106.4
Canalia	7.4	1.8	5.6	310.8	3.2	228.8
Canaglu	6.7	5.6	1.1	19.9	7.6	87.9
Rupafin	3.4	0.4	3.0	-	6.8	50.3
Imusera	4.3	4.7	(0.3)	(8.2)	4.9	87.1
Total of priority products	162.6	140.0	22.6	16.1	158.7	102.5
Influenza vaccine	10.2	9.9	0.3	3.1	11.2	91.4
Tetrabik	8.5	8.7	(0.1)	(2.1)	9.1	93.9
Mearubik	6.8	5.0	1.8	37.0	5.5	123.3
JEBIK V	5.5	5.2	0.3	5.8	4.3	127.5
Varicella vaccine	5.1	5.2	(0.1)	(3.5)	5.5	92.6
Total of vaccines	37.3	35.0	2.2	6.4	36.5	102.1
Total of priority products and vaccines	200.0	175.1	24.8	14.2	195.2	102.4

※: Announced on May 9, 2018 in the financial results of FY2017
※: Talion has been excluded from priority products since FY2018

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Domestic Ethical Drugs
Forecasts of Revenue of Priority Products and Vaccines

	FY2019 Forecasts	FY2018 Actual	Increase / Decrease	
	Billion yen	Billion yen	Billion yen	%
Remicade	53.1	58.8	(5.7)	(9.7)
Simponi	43.0	37.4	5.5	14.8
Stelara	21.6	15.2	6.4	42.4
Tenelia	16.1	15.2	0.8	5.9
Lexapro	15.2	14.0	1.2	9.2
Canaglu	10.9	6.7	4.1	62.1
Rupafin	7.8	3.4	4.4	128.9
Canalia	7.6	7.4	0.2	3.7
Imusera	4.2	4.3	(0.0)	(1.4)
Total of priority products	179.9	162.6	17.2	10.6
Influenza vaccine	10.7	10.2	0.5	5.1
Tetrabik	10.0	8.5	1.4	17.4
Varicella vaccine	5.1	5.1	0.0	1.7
Mearubik	4.8	6.8	(2.0)	(29.9)
JEBIK V	4.5	5.5	(0.9)	(16.6)
Total of vaccines	36.2	37.3	(1.0)	(2.9)
Total of priority products and vaccines	216.2	200.0	16.1	8.1

※: Talion has been excluded from priority products since FY2018

※: The full year forecast for sales of individual domestic ethical drugs for FY2019 does not include the impact of the NHI price revision following the consumption tax increase in October 2019.

INVOKANA/INVOKAMET

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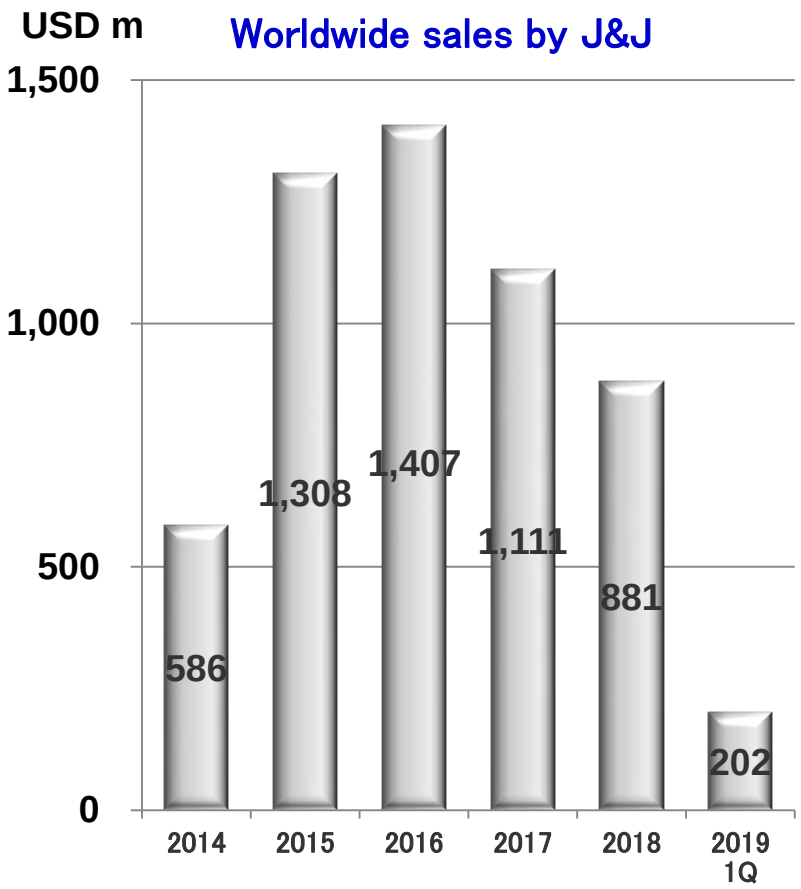
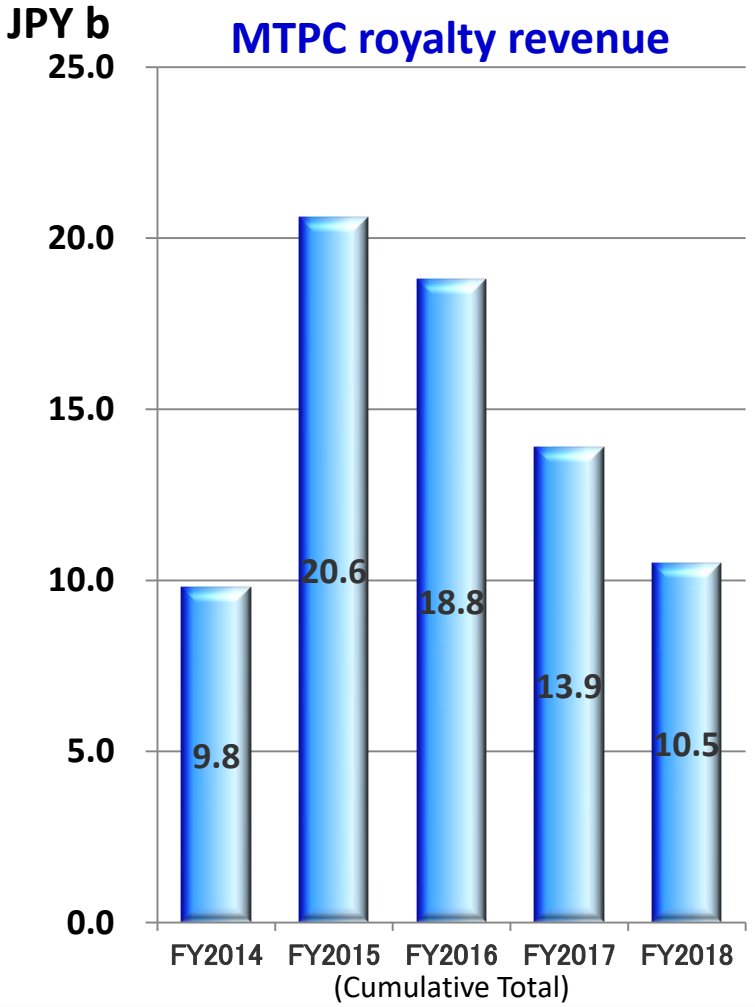
- INVOKANA/INVOKAMET sales by Johnson & Johnson
  in January to March, 2019: $202m ($248m, the same period of previous year)
- MTPC royalty revenue in FY2018 : ¥10.5b





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 Q3 FY2018

As of April 30, 2019

Phase 1

- **MT-2990**
  Seasonal Allergic Rhinitis
- **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-4129**
  Cardiovascular system, etc.

Phase 2

- **MT-1303**
  Multiple sclerosis (EU)
  Crohn's disease (JP)
- **MT-7117**
  Erythropoietic protoporphyria (Global)
- **MT-2990**
  Endometriosis (Global)
- **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 (Global)
- **ND0612**
  Parkinson's disease (Global)
- **MT-8972** *2
  Prophylaxis of H5N1 influenza (Canada)

Phase 3

- **MT-5547**
  Osteoarthritis (JP)
- **TA-7284**
  Diabetic nephropathy (JP)
- **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** *2
  Prophylaxis of seasonal influenza/ adults, elderly (US, EU)

Filed

- **TA-7284**
  Type2 diabetes mellitus (Asia)
- **MP-513**
  Type2 diabetes mellitus (Asia)
- **MCI-186**
  ALS (EU, China, Asia)
- **MP-214**
  Schizophrenia (Asia)
- **TAU-284**
  Allergic rhinitis, Urticaria (Asia)

Approved

- **Azanin**
  Autoimmune hepatitis (JP)

※ Asia: excluding Japan and China

*1: Co-developed with Ube Industries(JP)
*2: Medicago product (Canada)
*3: Co-developed with The Research Foundation for Microbial Diseases of Osaka University (JP)

Major license-out products (post Phase 3)

Approved

Filed

- **TA-7284**
  Diabetic nephropathy (US)
- **MT-4580**
  Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism (JP)

Phase 3

- **MT-210**
  Schizophrenia (US, EU)

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.