



# **Q2 FY2016 Business Results**

## **(April-September, 2016)**

**November 1, 2016**

**Eizo Tabaru**

**Board Director, Managing Executive officer  
General Manager of Finance & Accounting Dept.**

## **Q2 FY2016 Business Results**

**The Company has voluntarily applied IFRS from FY2016 and discloses based on IFRS from Q1 FY2016.**

**Amounts less than ¥100 million are rounded down.**

## Overview

<b>Revenue</b>	¥ 204.1 billion	+1.0%, year-on-year
<b>Core operating profit</b>	¥ 47.9 billion	- 3.5%, year-on-year
<b>Net profit attributable to owners of the Company</b>	¥ 36.2 billion	+ 1.6%, year-on-year

## Topics

- Revenue was increased by 1.0%, y-on-y. In domestic ethical drugs, main products revenue was increased by 17.3%, y-o-y, due to the growth of Simponi and vaccines.
- Forecast of net profit attributable to owners of the Company in FY2016: ¥64.0b increased by 8%, y-o-y, hit a new record high
- MCI-186 for ALS: NDA was accepted in the US in Aug.
- Conclusion of a licensing agreement of Invossa, a cell therapy drug, with Kolon Life Science in Nov.
- MT-2412(Canaglu+Tenelia) for T2DM: filed in Japan in Aug.
- Announcement of sales collaboration regarding Sun Pharma products in Sep.
- Announcement of execution of basic agreement for sales anti-allergy agent, Rupatadine in Oct.
- Biogen announced the termination of the development of MT-1303 in Oct.

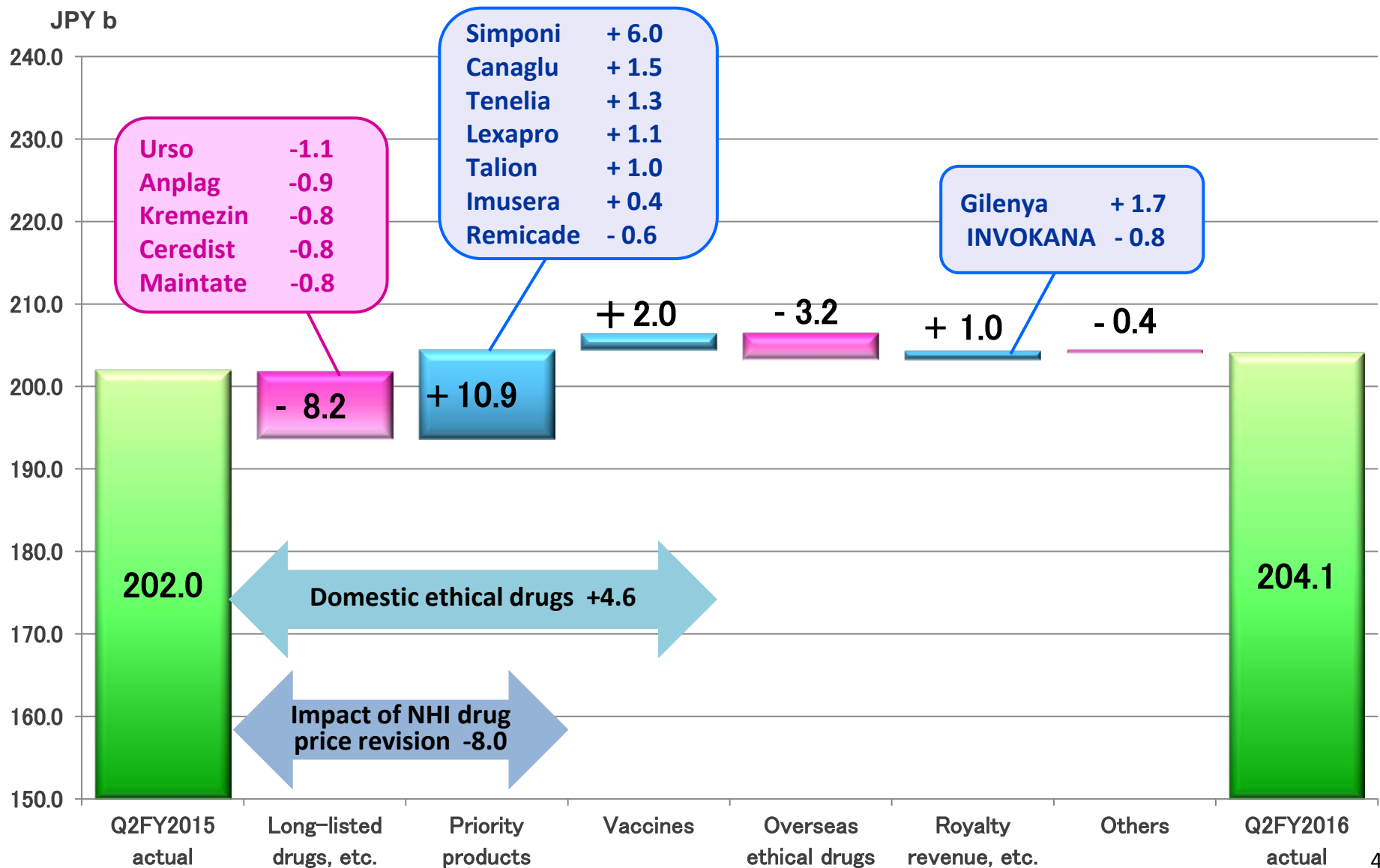
## Q2 FY2016 Financial Results

	FY2016	FY2015	Increase/decrease		1H forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	204.1	202.0	+2.0	+ 1.0	193.0	105.8
(Overseas sales revenue)	48.6	50.8	-2.1	-4.3	48.1	
Overseas sales ratio	23.9%	25.2%		-1.3	24.9%	
Cost of sales	78.3	73.1	+5.2	+7.2	72.5	108.1
Sales cost ratio	38.4%	36.2%			37.6%	
Gross profit	125.7	128.9	-3.2	- 2.5	120.5	104.4
Core operating profit	47.9	49.7	-1.7	- 3.5	38.0	126.2
Net profit attributable to owners of the Company	36.2	35.7	+0.5	+1.6	28.5	127.4
Average exchange rate (USD)	1H FY2016 ¥105.39	1H FY2015 ¥121.73			1H FY2016 forecast ¥110.00	

\*: Announced on May 11, 2016 in the financial results of FY2015. The Company revised the forecasts of sales revenue, operating profit and net profit attributable to owners of the Company



## Sales Revenue Trends

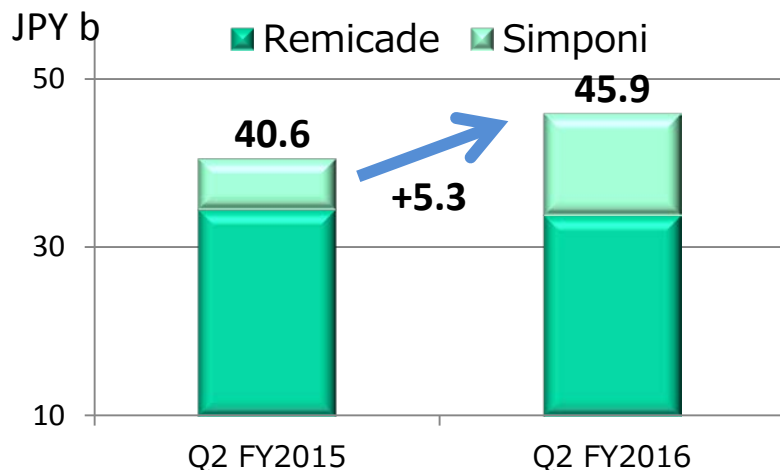




## Growth in Priority Areas

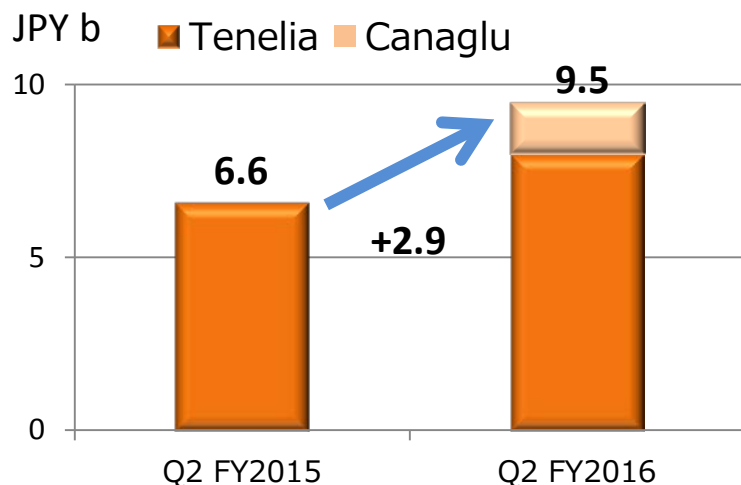
### (1) Autoimmune Diseases, Diabetes and Kidney Diseases

#### 【Autoimmune diseases】



- ◆ Revenue of Remicade and Simponi were increased by ¥5.3b, y-o-y
- ◆ Remicade+Simponi: 39% share in this area in 1H FY2016
- ◆ Simponi: Synergy effect by enforcement of collaboration scheme with Janssen Pharma
- ◆ Remicade: Revenue is maintained by wide indications and lineup of Simponi
- Keep the No.1 share by maximizing the value of i.v. product(Remicade) and s.c. product(Simponi)

#### 【Diabetes and kidney diseases】

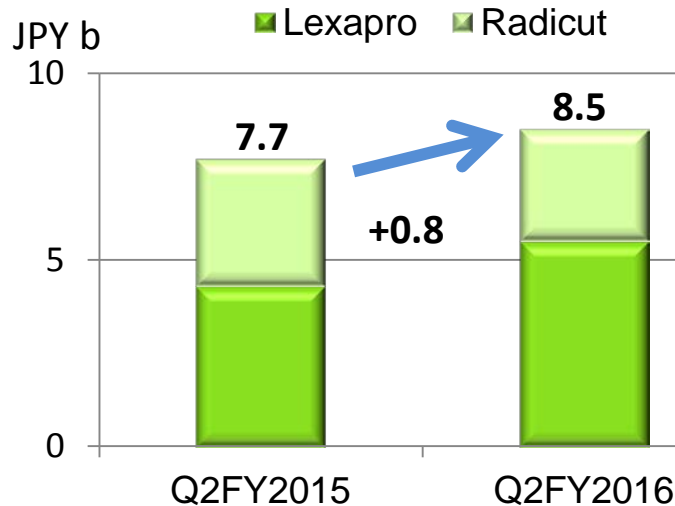


- ◆ Revenue of Tenelia and Canaglu were increased by ¥2.9b, y-o-y
- ◆ Tenelia: 10% share in DPP-4 inhibitors in 1H FY2016, it is No.1 growth, y-o-y. Penetrated among the patient with weak kidney and the elderly based on collaboration with Daiichi Sankyo.
- ◆ Canaglu: 13% share in SGLT2 inhibitors in 1H FY2016  
Establishment of the base in the market with lifting of the ban on long-term prescription
- Aim for further growth towards launch of MT-2412 in FY2017 and announcement of new evidence of Canaglu



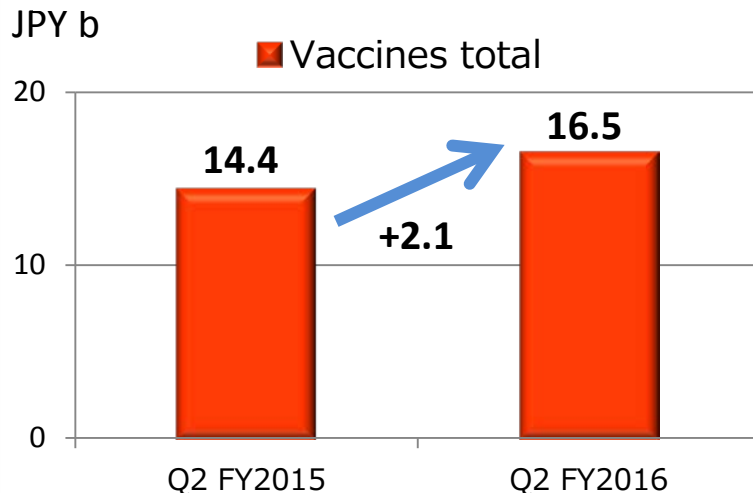
## Growth in Priority Areas (2) CNS diseases and Vaccines

### 【CNS】



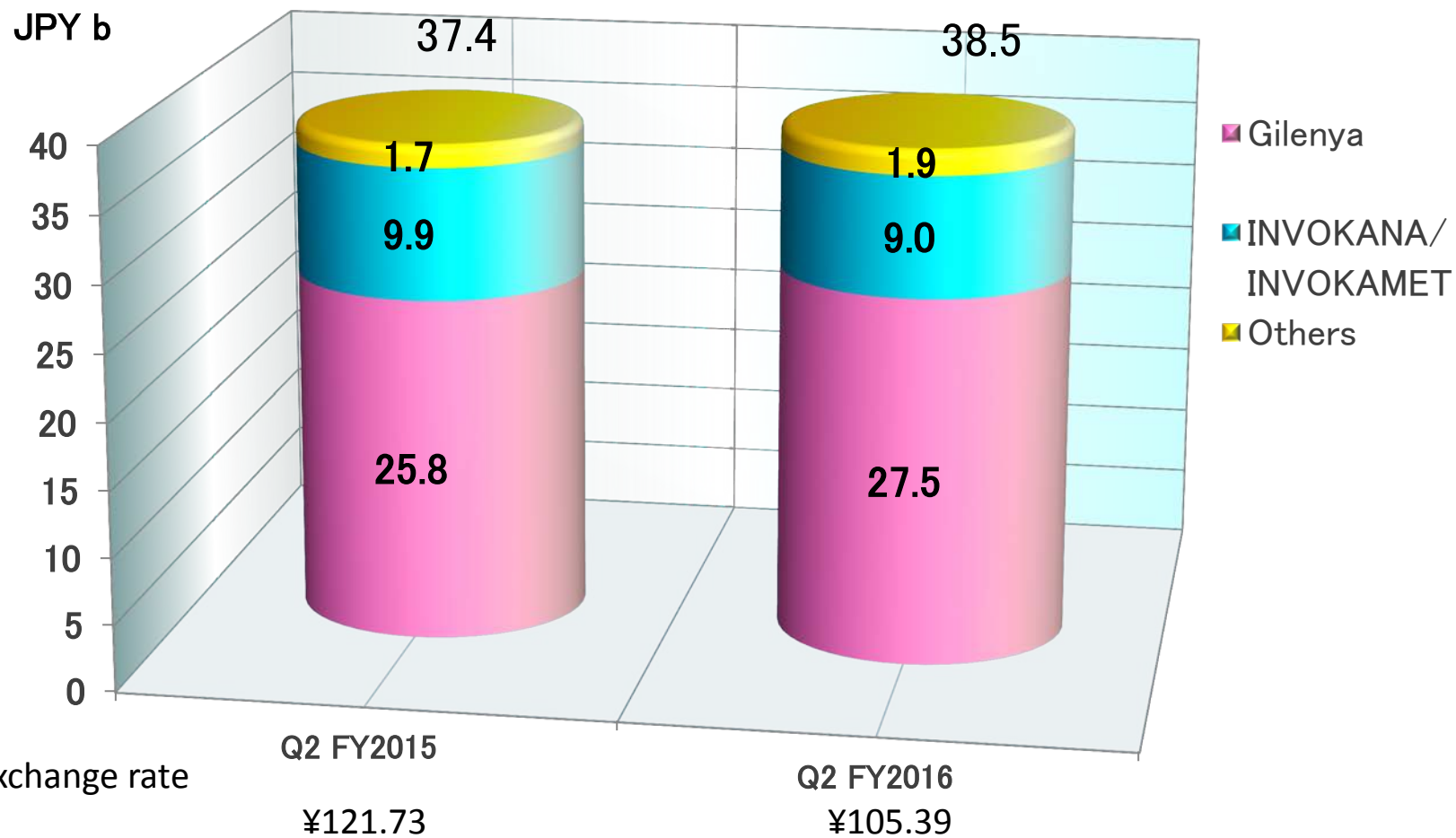
- ◆ Revenue of Lexapro and Radicut were increase by ¥0.8b, y-o-y
- ◆ Lexapro: 37% share in SSRI in 1H FY2016  
Penetrated among the patients with anxiety by additional indication of SAD
- ◆ Radicut  
Administration for about 1,800 patients with ALS
- Aim for No.1 share in anti-depressant by improvement of efficacy evaluation of Lexapro and enforcement of collaboration with Mochida Pharmaceutical and Yoshitomiyakuhin

### 【Vaccines】



- ◆ Revenue of vaccines were increased by ¥2.1b due to the growth of Tetrabik and Mearubik
- ◆ Top class share in vaccines: 24% in 1H FY2016  
Stable supply is top priority based on the collaboration with BIKEN
- ◆ Keep the stable supply based on the collaboration with BIKEN and establish the market base towards new combination vaccines

# Royalty revenue, etc.







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

	1H FY2016	1H FY2015	Increase/decrease		Forecasts *1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	204.1	202.0	+2.0	+1.0	193.0	105.8
Cost of Sales	78.3	73.1	+5.2	+7.2	72.5	108.1
Sales cost ratio	38.4%	36.2%			37.6%	
Gross profit	125.7	128.9	-3.2	-2.5	120.5	104.4
SG&A expense	46.6	46.3	+0.3	+0.6	48.0	97.3
R&D expense	30.3	31.8	-1.5	-4.9	33.5	90.5
Amortization of intangible assets associated with products	0.7	0.7	-0.0	-0.1	0.7	105.3
Other income and expense*2	-0.0	-0.2	+0.1	-	-0.3	-
Core operating profit	47.9	49.7	-1.7	-3.7	38.0	126.2
Total labor costs	35.7	39.7	-3.9	-10.1	37.5	95.4

\*1: Announced on May 11, 2016 in the financial results of FY2015. The Company revised the forecasts of sales revenue, operating profit and net profit attributable to owners of the Company

\*2: Negative signs indicate expense and loss.

## Non-recurring items, Net Profit

	1H FY2016	1H FY2015	Increase/decrease		Forecasts* <sup>1</sup>	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Core operating profit	47.9	49.7	-1.7	-3.5	38.0	126.2
Non-recurring items* <sup>2</sup>	-0.1	-0.4	+0.2	-	-	-
Operating profit	47.8	49.2	-1.4	-3.0	38.0	125.8
Financial income	1.8	1.5	+0.3	+25.1	-	-
Financial expense	0.2	1.0	-0.7	-72.8	-	-
Net profit attributable to owners of the Company	36.2	35.7	+0.5	+1.6	28.5	127.4

\*1: Announced on May 11, 2016 in the financial results of FY2015. The Company revised the forecasts of sales revenue, operating profit and net profit attributable to owners of the Company

\*2: Negative signs indicate expense and loss.

# Forecasts for FY2016



## Revenue, Gross Profit and Core Operating Profit

	FY2016				FY2015		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*1	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Revenue	414.0	406.5	+7.5	+1.8	425.7	-11.7	-2.8
Cost of sales	163.0	159.0	+4.0	+2.5	155.8	+7.1	+4.6
Sales cost ratio	39.4%	39.1%			36.6%		
Gross profit	251.0	247.5	+3.5	+1.4	269.9	-18.9	-7.0
SG&A expense	97.9	98.5	-0.6	-0.6	96.3	+1.5	+1.6
R&D expense	66.0	70.0	-4.0	-5.7	64.6	+1.3	+2.1
Amortization of intangible assets associated with products	1.5	1.5	-	-	1.4	+0.0	+1.8
Other income and expense*2	-0.6	-0.5	-0.1	-	-0.5	-0.0	-
Core operating profit	85.0	77.0	+8.0	+10.4	106.9	-21.9	-20.5

\*1: Comparison to the revised forecasts announced on October 25, 2016. Previous forecasts were announced on May 11, 2016.

\*2: Negative signs indicate expense and loss.

	FY2016				FY2015		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Core operating profit	85.0	77.0	+8.0	+10.4	106.9	-21.9	-20.5
Operating profit	84.0	75.5	+8.5	+11.3	81.8	+2.1	+2.7
Profit before tax	86.0	77.0	+9.0	+11.7	83.2	+2.7	+3.3
Net profit attributable to owners of the Company	64.0	57.0	+7.0	+12.3	59.3	+4.6	+7.9

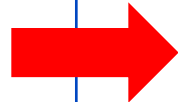
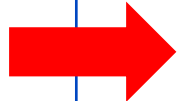


\*: Comparison to the revised forecasts announced on October 25, 2016. Previous forecasts were announced on May 11, 2016.

# Development Pipeline





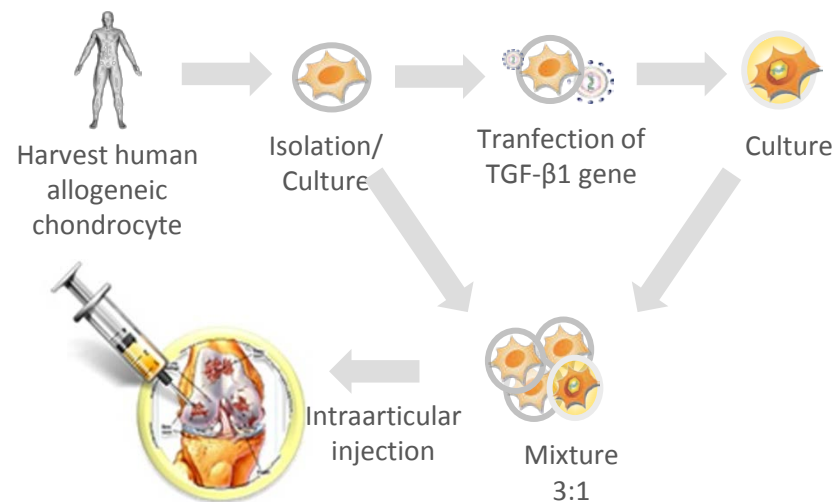
## Progress of Development Pipeline

Product name/ development code	MOA(indications)	Area	P1	P2	P3	Filed	Appro ved
<b>Valixa</b>	Anti-cytomegalovirus chemotherapeutic agent (Prevention of cytomegalovirus disease in organ transplant patients)	Japan					
<b>INVOKANA</b> (Licensee: Janssen Pharmaceuticals)	SGLT2 inhibitor (T2DM, fixed dose combination with metformin, XR)	US					
<b>Remicade</b>	Anti-human TNF $\alpha$ monoclonal antibody (Crohn's disease: shortened administration interval)	Japan					
<b>MT-2412</b>	Fixed-dose combination of DPP-4 inhibitor and SGLT2 inhibitor (T2DM)	Japan					

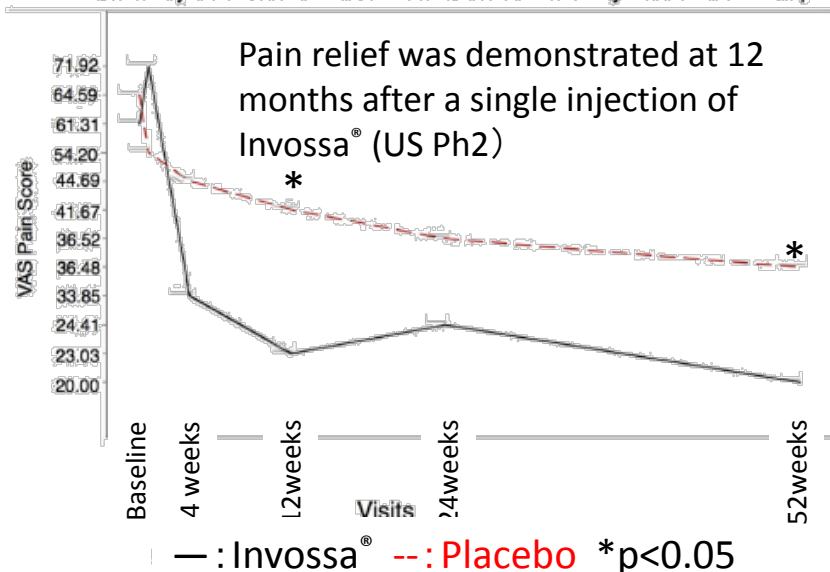
- MCI-186 for ALS: NDA was accepted by FDA in the US in Aug, 2016.

### Invossa®

- Cell therapy product discovered by TissueGene, Inc. (US), an affiliate of Kolon Life Science, Inc. (Korea)
  - Intraarticular injection of mixture of chondrocytes with/without TGF-β1 gene transfection
  - In addition to pain relief and functional improvement in OA patients, chondroprotective effect is expected
- Exclusive development and commercialization rights in Japan
  - Development stages: BLA submitted in Korea; Phase 3 in preparation in the US
- Expand autoimmune disease franchise that has been established by Remicade® and Simponi®
  - Expect synergy with MT-5547 (anti-NGF antibody) in OA treatment



Summary of Mean VAS Pain Scores Over Time by Treatment Group



\*TGF-β1, Transforming Growth Factor-β1; BLA, Biologics License Application .

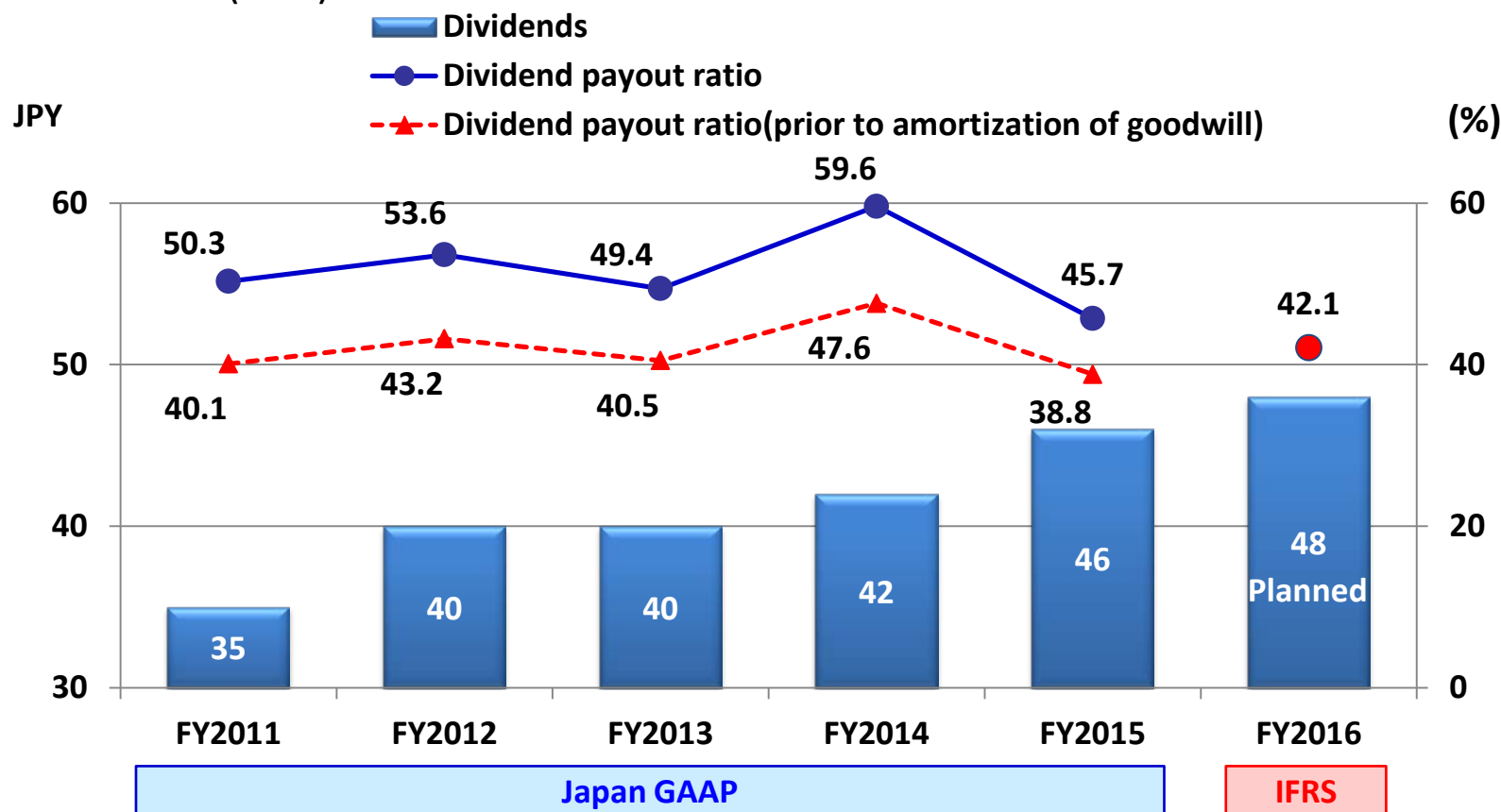


# Shareholders Return



# Dividends Trends

- MTPC's basic policy calls for providing a stable and continuous return to shareholders while striving to maximize enterprise value by aggressively investing in future growth.
- Under this medium-term management plan, implementation of dividends based on mid., long-term profit and the dividend policy of the consolidated dividend payout ratio to 50% (IFRS).



# *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 (1H FY2016)

	1H FY2016	1H FY2015	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Revenue	204.1	202.0	+2.0	+1.0	193.0	105.8
(Overseas ratio)	48.6	50.8	-2.1	-4.3	48.1	101.2
Domestic ethical drugs	151.9	147.3	+4.6	+3.2	141.1	107.6
Overseas ethical drugs	10.6	13.9	-3.2	-23.2	10.2	104.3
Royalty revenue, etc.	38.5	37.4	+1.0	+2.7	38.2	100.6
OTC	1.9	2.0	-0.1	-7.4	2.2	86.2
Others	0.9	1.2	-0.2	-20.0	1.0	95.3

\*: Previous forecasts announced on May 11, 2016. The Company announced the revised forecast of revenue on October 25, 2016.

	1H FY2016	1H FY2015	Increase/decrease		Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	33.8	34.5	-0.6	-1.9	31.6	106.9
Simponi	12.1	6.1	+6.0	+97.4	11.2	108.2
Tenelia	8.0	6.6	+1.3	+20.8	8.3	96.9
Talion	7.4	6.4	+1.0	+16.1	6.6	111.7
Lexapro	5.5	4.3	+1.1	+26.3	5.6	98.0
Imusera	2.4	1.9	+0.4	+24.9	2.2	111.1
Canaglu	1.5	0.0	+1.5	-	1.6	89.9
Total of priority products	71.0	60.1	+10.9	+18.2	67.4	105.3
Tetrabik	5.0	3.6	+1.4	+39.1	3.9	127.4
Mearubik	3.2	2.5	+0.7	+30.2	2.3	142.1
Varicella vaccine	2.8	3.3	-0.5	-15.2	2.9	96.7
JEBIK V	2.3	1.8	+0.5	+28.2	2.1	109.5
Influenza vaccine	2.5	2.7	-0.2	-9.2	2.0	123.7
Total of vaccines	16.5	14.4	+2.0	13.9	13.7	120.0
Total	87.5	74.6	+12.9	+17.3	81.2	107.8

\*: Previous forecasts announced on May 11, 2016. The Company announced the revised forecasts on October 25, 2016.

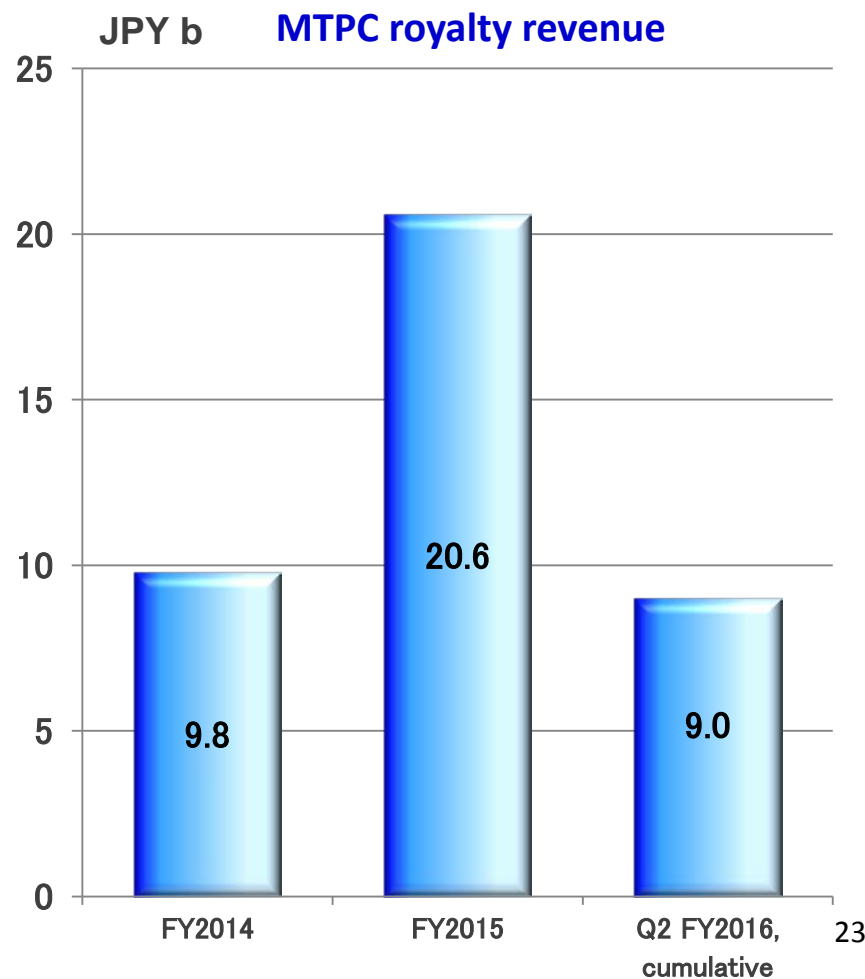
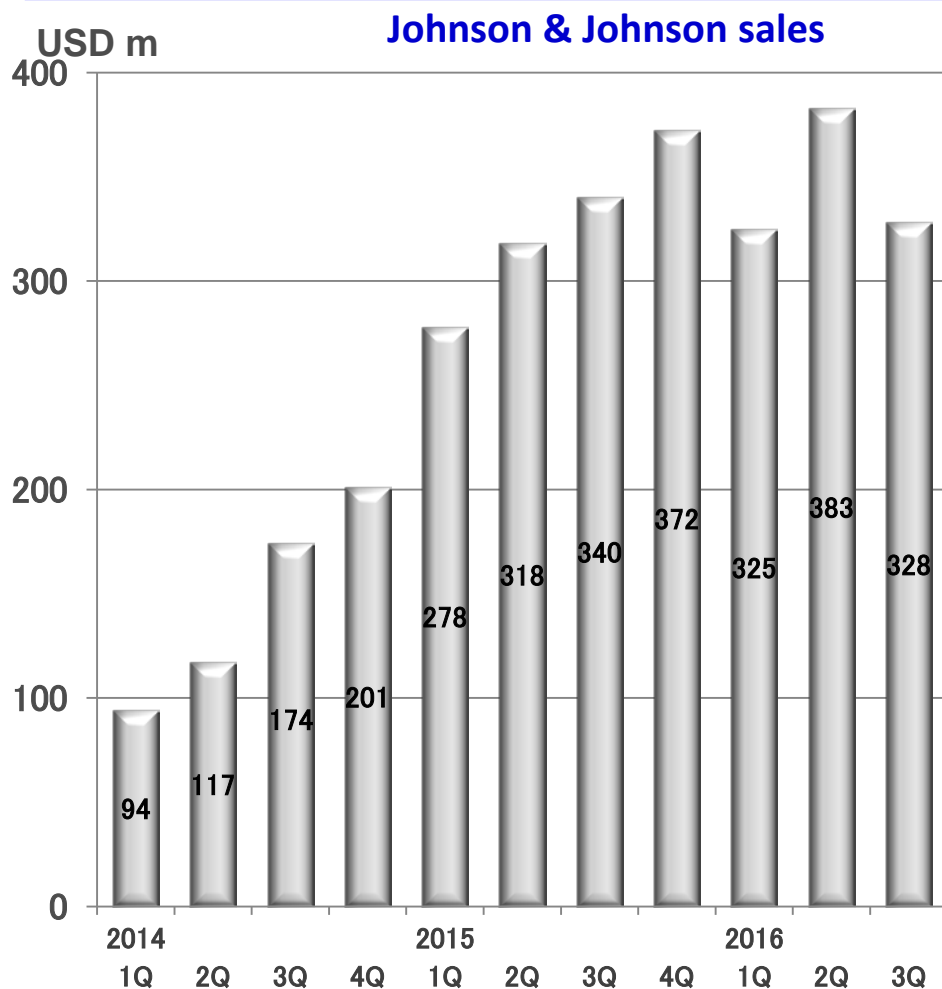
## Revenue of Main Products

	FY2016				FY2015		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Domestic ethical drugs	313.0	300.8	12.2	4.1	308.0	5.0	1.6
Total of priority products	149.1	141.6	+7.5	+5.3	127.5	+21.5	+16.9
Remicade	66.4	62.5	+3.8	+6.2	69.4	-3.0	-4.3
Simponi	25.4	23.3	+2.1	+9.1	12.9	+12.5	+97.4
Tenelia	17.4	17.4	-0.0	-0.3	14.1	+3.2	+23.2
Talion	19.1	17.3	+1.8	+10.4	16.8	+2.2	+13.4
Lexapro	12.5	12.6	-0.1	-0.8	9.5	+3.0	+31.8
Imusera	4.8	4.6	+0.1	+4.3	4.1	+0.7	+17.6
Canaglu	3.2	3.6	-0.3	-9.0	0.5	+2.7	+478.8
Vaccines	37.6	33.6	+4.0	+12.0	39.0	-1.4	-3.6
Influenza	12.0	11.1	+0.8	+7.9	13.7	-1.7	-12.8
Tetrabik	9.7	8.5	+1.1	+13.7	9.5	+0.2	+2.5
Varicella vaccine	5.5	5.5	-0.0	-0.6	6.3	-0.8	-13.4
Mearubik	5.4	4.0	+1.6	+40.4	4.9	+0.7	+9.1
JEVIK V	3.8	3.6	+0.2	+6.1	3.6	+0.1	+5.0
TSH products	14.4	14.2	+0.1	+0.8	13.8	+0.6	+4.4
Royalty revenue, etc.	74.1	77.9	-3.7	-4.9	86.6	-12.4	-14.4
Gilenya	-	-	-	-	51.7	-	-
INVOKANA	-	-	-	-	20.6	-	-

\*: Comparison to the revised forecasts announced on October 25, 2016. Previous forecasts were announced on May 11, 2016.

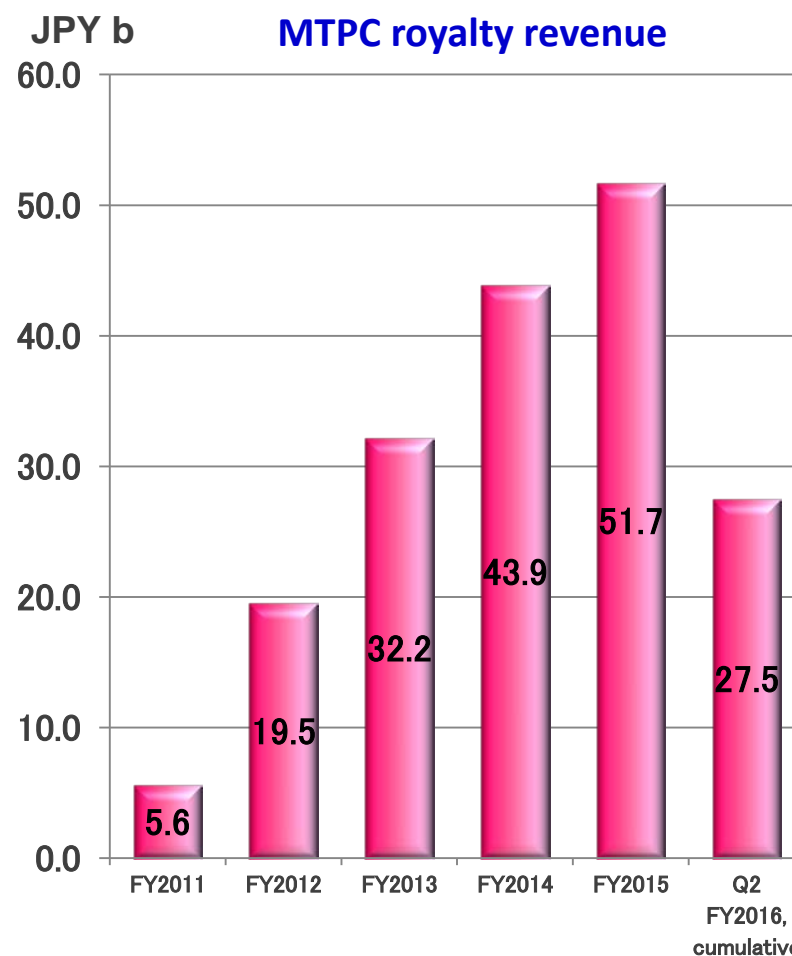
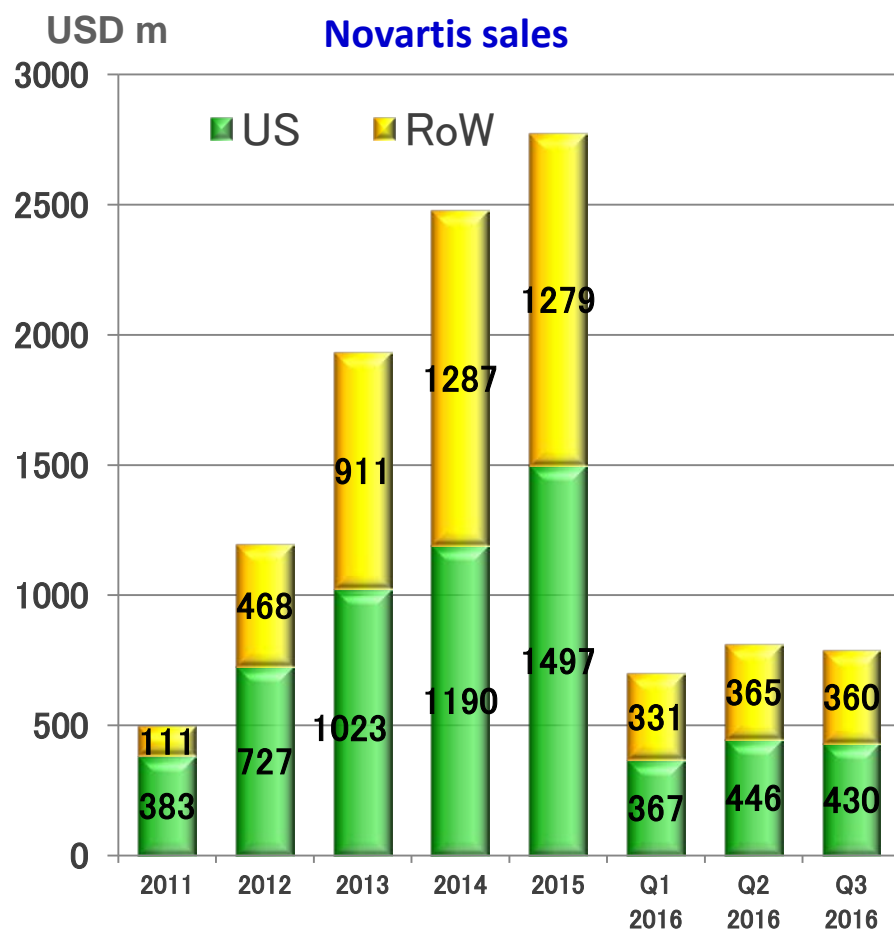
## INVOKANA/INVOKAMET

- ◆ Johnson & Johnson sales in July to September 2016: \$328m (the same period the last year: \$340m)
- ◆ INVOKANA/INVOKAMET TRx share 6.4% in defined U.S. T2D market
- ◆ MTPC royalty revenue in cumulative April to September, 2016: ¥9.0b





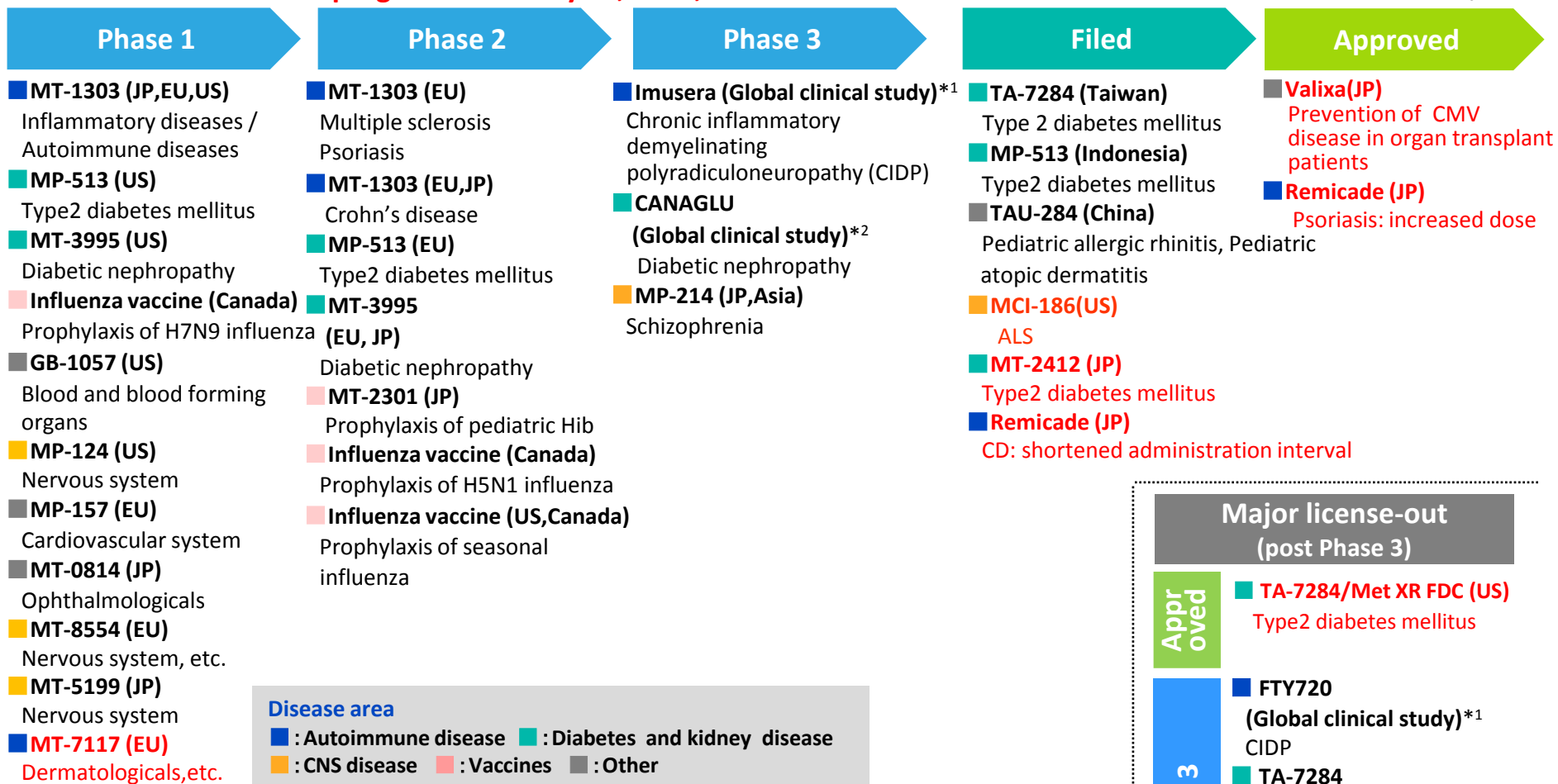
- ◆ Novartis worldwide sales in July to September, 2016: \$790m (\$696m, the same period of the last year)
- ◆ MTPC royalty revenue in cumulative April to September, 2016: ¥27.5b



# Pipeline Status

Red: progress after May 11, 2016, the financial results for FY2015

As of November 1, 2016



\*1: Global clinical study, co-developed with Novartis Pharma in Japan, licensed to Novartis overseas

\*2: Sponsor: Janssen Research & Development, LLC

### **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.**