

Mitsubishi Tanabe Pharma Corporation

# **2nd Quarter of FY2015 Business Results**

**(April – September, 2015)**

**October 30, 2015**

**Eizo Tabaru**

**Board Director,**

**Managing Executive officer**

**General Manager of**

**Finance & Accounting Dept.**



Mitsubishi Tanabe Pharma

# Q2 FY2015 Financial Results



# Overview of Q2 FY2015 Business Results

## Net sales

¥ 201.7 billion +1.4%, year-on-year

## Operating income

¥ 43.5 billion +24.5%, year-on-year

## Net income attributable to shareholders of the Company

¥ 29.1 billion -10.4%, year-on-year

## Topics

- Hit a record high in operating income of cumulative Q2
- Growth of royalty income from Gilenya and INVOKANA
- Conclusion of the license agreement on MT-1303 with Biogen in September
- Announcement of patent and know-how transfer for TA-8995 to Amgen in September
- Announcement of conclusion of collaboration agreement for fasinumab with Regeneron in October
- Allergan received the approval of cariprazin(MP-214) for manic or mixed episodes of bipolar I disorder and schizophrenia in U.S. in September
- Approval of REMICADE for additional indications for entero-, neuro-, and vasculo- Behcet's diseases in August
- Announcement of conclusion of strategic collaboration and licensing agreement for the Development of antibody drug conjugates to treat cancer with MedImmune in September

# Q2 FY2015 Financial Results

New **Value** Creation



	FY2015	FY2014	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	201.7	198.9	+2.8	+1.4	191.5	105.3
Cost of sales	73.2	78.2	-5.0	-6.4	70.5	103.8
Sales cost ratio	36.3%	39.3%			36.8%	
Gross profit	128.6	120.7	+7.9	+6.5	121.0	106.2
SG&A	85.0	85.8	-0.7	-0.8	93.0	91.4
Operating income	43.5	35.0	+8.6	+24.5	28.0	155.4
Ordinary income	43.3	35.5	+7.9	+22.2	28.0	154.7
Net income attributable to shareholders of the Company	29.1	32.5	-3.4	-10.4	19.0	153.4

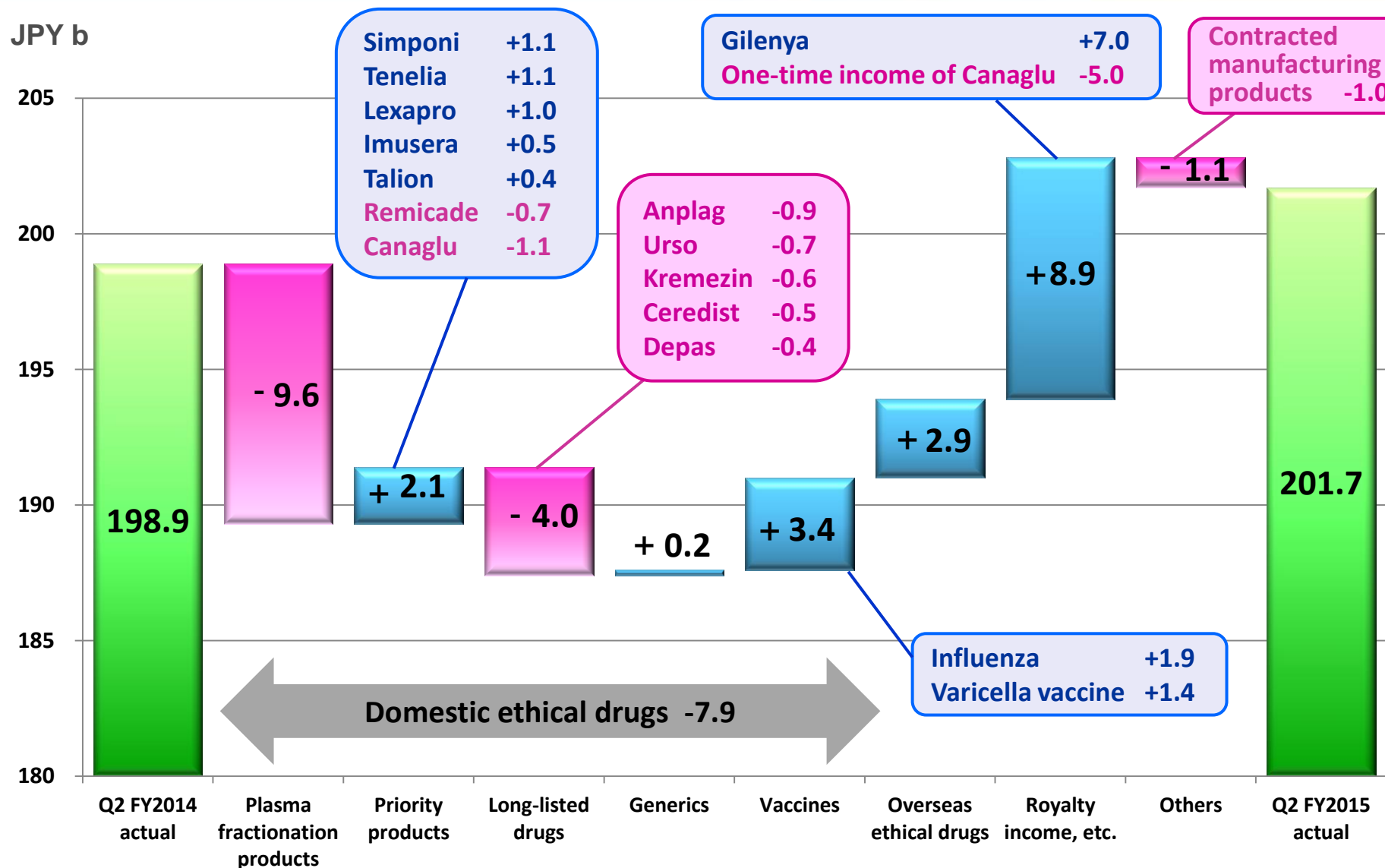
\*: Forecasts of sales, operating income, ordinary income, and net income attributable to shareholders of the Company were revised on September 30, 2015. Previous forecasts announced on May 8, 2015 in the financial results of FY2014 are shown in this slide.

# Sales Trends

New **Value** Creation



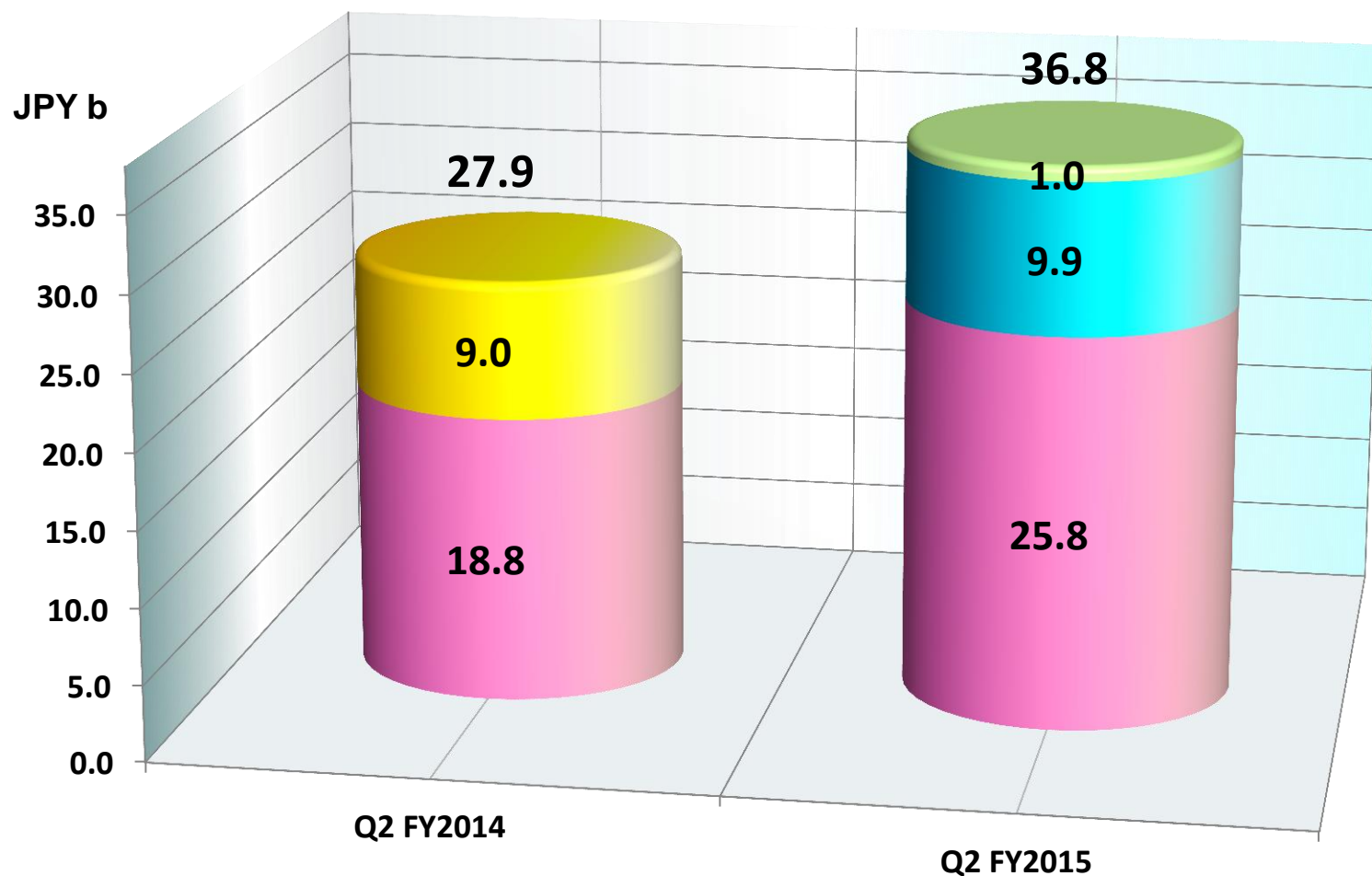
【Q2 FY2015 Business Results】



# Royalty income, etc.

【Q2 FY2015 Business Results】

New **Value** Creation



■ Gilenya

■ INVOKANA/INVOKAMET

■ Others including INVOKANA

■ Others

# Cost of Sales, SG&A

New **Value** Creation



## 【Q2 FY2015 Business Results】

	FY2015	FY2014	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	201.7	198.9	+2.8	+1.4	191.5	105.3
Cost of Sales	73.2	78.2	-5.0	-6.4	70.5	103.8
Sales cost ratio	36.3%	39.3%			36.8%	
Gross profit	128.6	120.7	+7.9	+6.5	121.0	106.2
SG&A	85.0	85.8	-0.7	-0.8	93.0	91.4
R&D expenses	33.3	31.9	+1.3	+4.2	39.5	80.8
Labor cost	23.0	23.0	-0.0	-0.1	23.0	100.0
Amortization of goodwill	5.3	5.4	-0.1	-2.5	5.3	99.2
Others	23.5	25.4	-1.9	-7.4	25.2	93.3
Operating income	43.5	35.0	+8.6	+24.5	28.0	155.4

\*: Forecasts of sales, operating income were revised on September 30, 2015. Previous forecasts announced on May 8, 2015 in the financial results of FY2014 are shown in this slide.

# Non-operating Income and Loss/Extraordinary Income and Loss

【Q2 FY2015 Business Results】

New *Value* Creation



	FY2015	FY2014	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Operating income	43.5	35.0	+8.6	+24.5	28.0	155.4
Non-operating income and loss	-0.2	0.5	-0.7	-140.1	-	
Ordinary income	43.3	35.5	+7.9	+22.2	28.0	154.7
Extraordinary income	0.5	13.6	-13.1	-96.4		
Gain on sales of property, plant and equipment	0.3	11.9				
Gain on sales of investment in securities	0.2	1.1				
Gain on sales of shares of subsidiaries and affiliates	-	0.6				
Extraordinary loss	0.7	2.7	-2.0	-74.0		
Impairment loss	0.7	0.9				
Loss on valuation of investment in securities	-	0.1				
Loss on liquidation of subsidiaries and affiliates	-	1.4				
Others	-	0.2				
Net income attributable to shareholders of the Company	29.1	32.5	-3.4	-10.4	19.0	153.4

\*: Forecasts of operating income, ordinary income, and net income were revised on September 30, 2015. Previous forecasts announced on May 8, 2015 in the financial results of FY2014 are shown in this slide.



# FY2015 Full Year Forecasts



# Revised Forecasts for Full Year FY2015

## Sales, Gross Operation Profit, Operating Income

New **Value** Creation



	FY2015				FY2014		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Sales	418.0	396.0	+22.0	+5.6	415.1	+2.9	+0.7
Cost of sales	150.0	147.0	+3.0	+2.0	169.6	-19.6	-11.6
Sales cost ratio	35.9%	37.1%			40.9%		
Gross operation profit	268.0	249.0	+19.0	+7.6	245.5	+22.5	+9.2
SG&A expenses	186.0	181.5	+4.5	+2.5	178.4	+7.6	+4.3
R&D expenses	76.0	74.0	+2.0	+2.7	69.6	+6.4	+9.2
Labor cost	47.0	46.0	+1.0	+2.2	46.8	+0.2	+0.5
Amortization of goodwill	10.5	10.5	-	-	10.9	-0.4	-3.8
Others	52.5	51.0	+1.5	+2.9	51.1	+1.4	+2.7
Operating income	82.0	67.5	+14.5	+21.5	67.1	+14.9	+22.1

\*: Compared with the previous forecasts

# Revised Forecasts for Full Year FY2015

## Sales of Main Products

	FY2015				FY2014		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*1	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Ethical drugs domestic sales	296.6	294.6	+2.0	+0.7	323.9	-27.4	-8.4
Total of priority products*2	117.8	127.6	-9.8	-7.7	115.7	+12.0	+10.4
Remicade	67.7	70.7	-3.0	-4.3	70.6	-3.0	-4.2
Talion	16.9	17.1	-0.2	-1.4	16.0	+0.9	+5.4
Tenelia(previous scheme)	3.7	9.6	-5.9	-61.7	6.2	-2.6	-41.0
Tenelia(new scheme)	9.9	Undisclosed	-	-	Undisclosed	-	-
Simponi	12.6	13.3	-0.7	-5.5	10.5	+2.1	+20.2
Lexapro	10.4	10.5	-0.1	-0.5	8.0	+2.5	+30.9
Imusera	4.1	3.8	+0.3	+7.9	3.2	+0.9	+26.7
Canaglu	2.5	2.6	-0.1	-4.7	1.2	+1.3	+114.4
Vaccines	32.6	26.9	+5.7	+21.3	30.3	+2.4	+7.9
Influenza	11.2	7.9	+3.3	+42.0	7.4	+3.8	+51.9
Tetrabik	7.4	7.1	+0.3	+4.3	7.5	-0.1	-1.6
Varicella vaccine	6.1	4.4	+1.7	+39.3	7.2	-1.0	-14.4
Generics	14.0	14.4	-0.4	-2.7	13.6	+0.4	+3.0
Royalty income, etc.	89.6	70.2	+19.4	+27.7	60.4	+29.3	+48.5
Gilenya	Undisclosed	Undisclosed	-	-	43.9	-	-
INVOKANA	Undisclosed	Undisclosed	-	-	9.8	-	-

\*1: Compared with the previous forecasts , \*2: Total amount excluding "Tenelia(new scheme)"

# Revised Forecasts for Full Year FY2015

## Operating Income ~ Net Income Attributable to Shareholders of the Company

New **Value** Creation

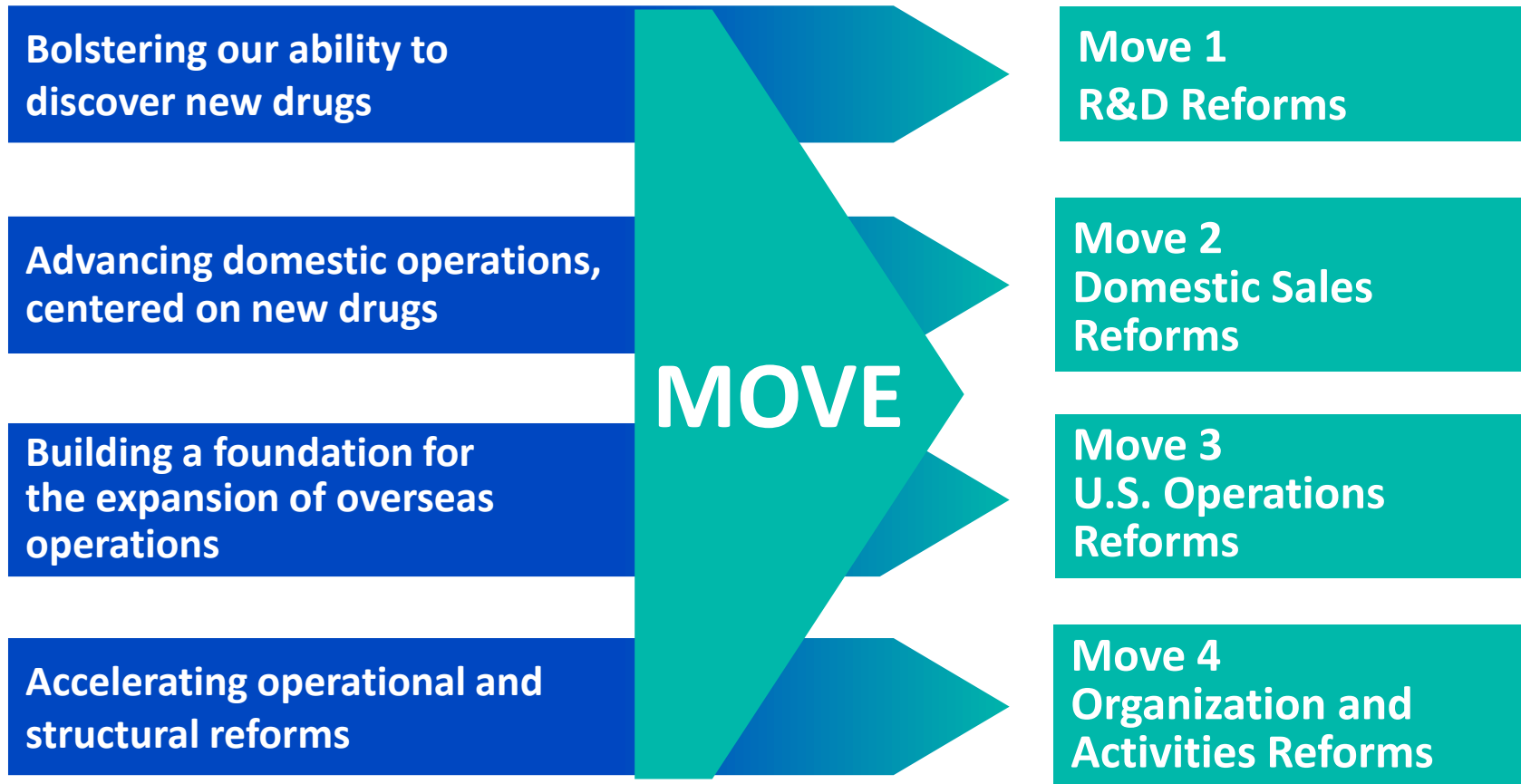


	FY2015				FY2014		
	Revised forecasts	Previous forecasts	Increase/decrease		Actual	Increase/decrease*	
	Billion yen	Billion yen	Billion yen	%	Billion yen	Billion yen	%
Operating income	82.0	67.5	+14.5	+21.5	67.1	+14.9	+22.1
Non-operating income/loss	-1.0	-0.5	-0.5		0.5		
Ordinary income	81.0	67.0	+14.0	+20.9	67.7	+13.3	+19.7
Extraordinary income/loss	-13.5	-7.5	-6.0		-5.0		
Net income attributable to shareholders of the Company	46.0	40.5	+5.5	+13.6	39.5	+6.5	+16.4

\*: Compared with the previous forecasts

# Progress of Challenges in FY2015

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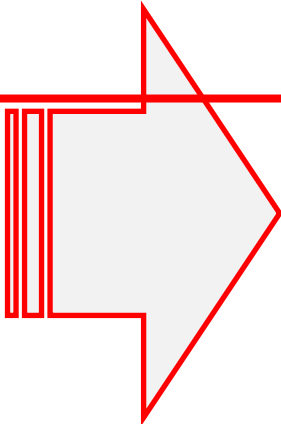
**Move forward**, working together to plot a course through  
**uncharted territory**

# Move 1: Reforms of R&D

## Development pipeline (Progress in 1H FY2015)

**Filed and approved**

Product name (indication)	Stage as of May 8 (region)	Progress
Talion (Pediatric usage)	Passed the committee in Apr., 2015 (Japan)	Approved in May
Radicut (ALS)	Filed (Japan)	Approved in June Preparing for filing in U.S.
Remicade (Entero-, neuro-, and vasculo-Behcet's disease)	Filed (Japan)	Approved in Aug.
Remicade (Refractory Kawasaki disease)	P3 (Japan)	Filed in May



**Orphan drug designated, “First to deliver unique value”**

## Development pipeline (Progress in 1H FY2015)

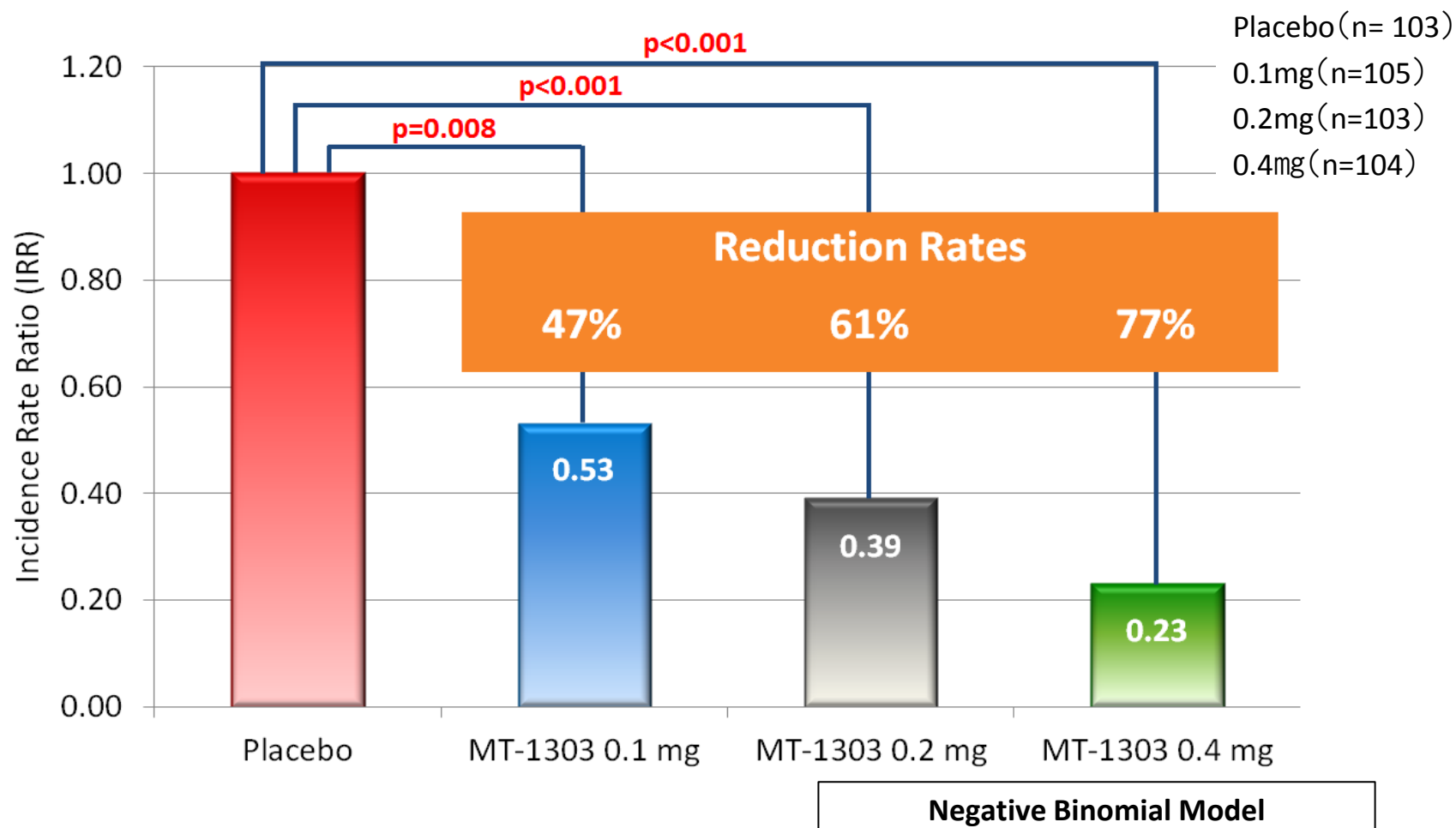
## Under clinical studies

Development code/ (indication)	Stage as of May 8 (region)	Progress/target
MT-4666 (AD)	P3 (Global clinical trial)	Discontinuation of global clinical P3
MP-214 (Schizophrenia)	P2b/3 (Japan, Asia)	Completion of enrollment in FY2015
MT-2412 (Type 2 diabetes mellitus)	P3 (Japan)	Completion of enrollment in FY2015
MT-3995 (Diabetic nephropathy)	P2 (Japan, Europe)	Acquisition of POC at an early date
MT-1303 (MS)	P2 (Europe)	Licensed to Biogen, except for Japan and Asia
MT-1303 (Inflammatory disease, autoimmune diseases)	P1 (Japan, Europe, U.S.)	Start of P2 for Crohn's disease(Japan, EU) Licensed to Biogen, except for Japan and Asia
Seasonal influenza vaccine	P2 (U.S., Canada)	Promotion of development toward start of P2b in FY2015



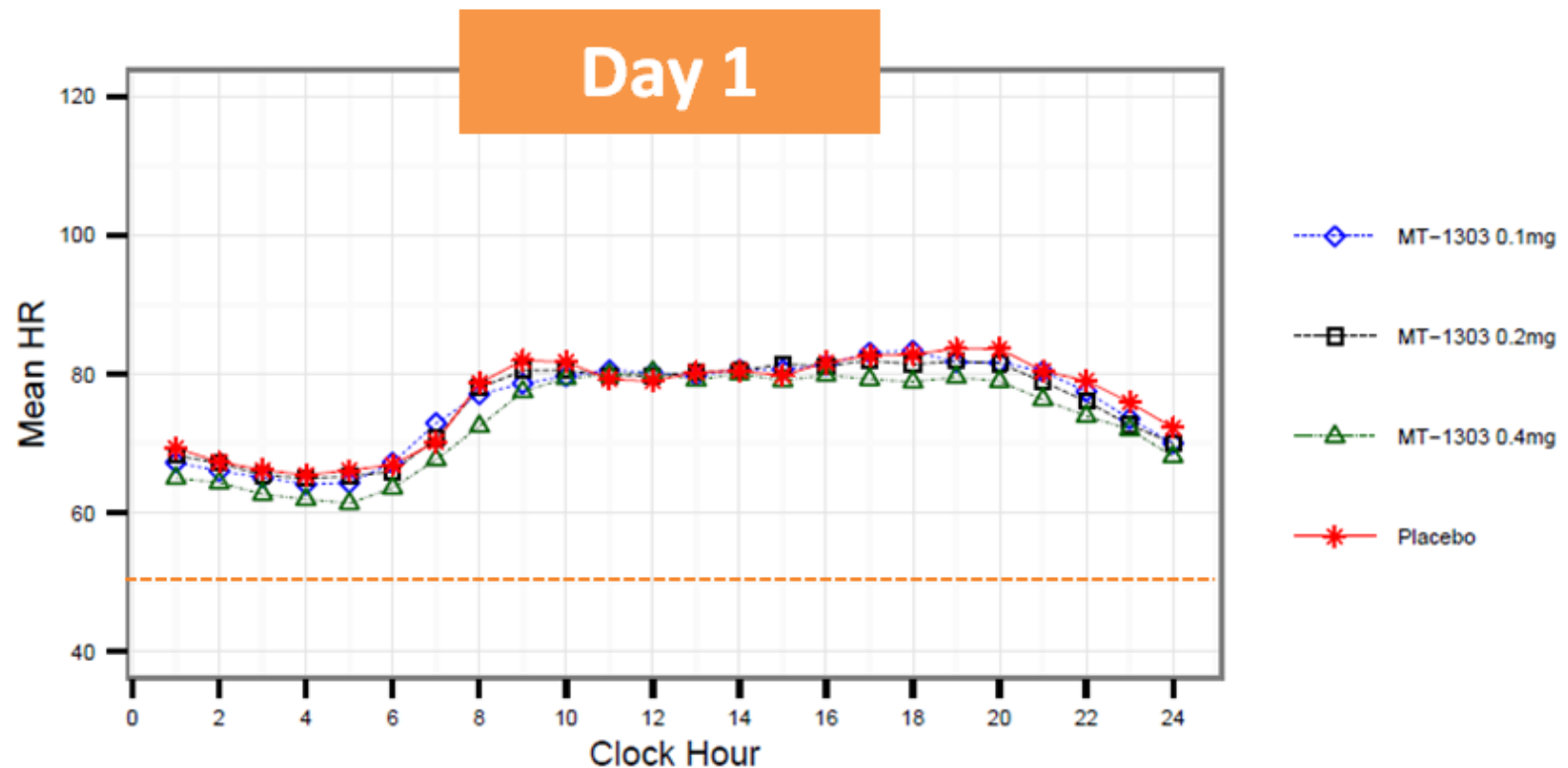
# Topics <MT-1303 Phase2 data>

## Total Number of Gd(+) T1-W Lesions (Weeks 8-24)



## Topics <MT-1303 Phase2 data>

### Holter ECG – Mean Hourly Heart Rate



## Topics < Collaboration with Regeneron >

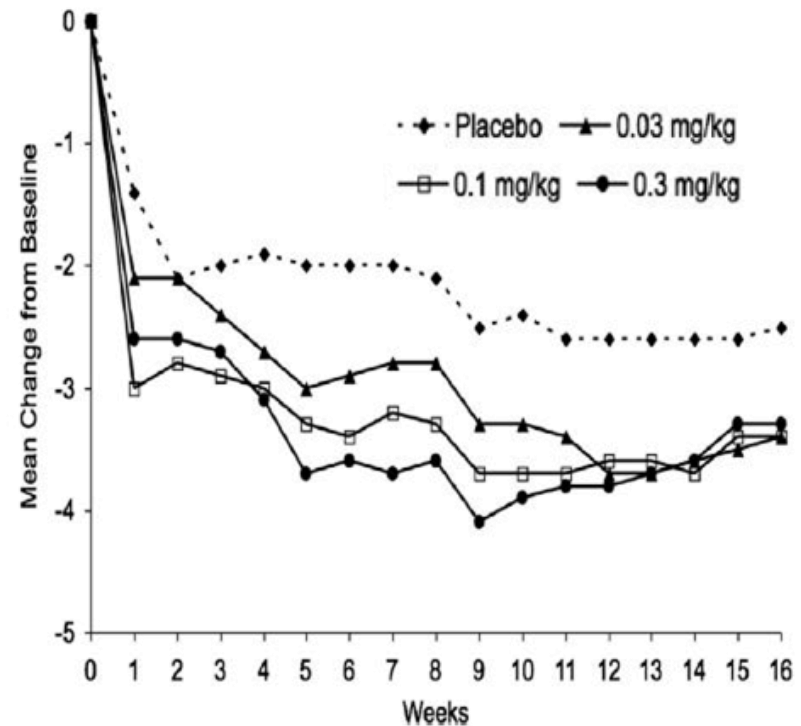
### MT-5547 Anti-NGF Antibody

Fully-human antibody that binds to NGF and ameliorates pain caused by NGF

Moving ahead with the development for indications of osteoarthritis pain and chronic low back pain

Strengthening Franchise in orthopedics/ rheumatology following Remicade/Simponi

Clinical study data (Ph2 in US)

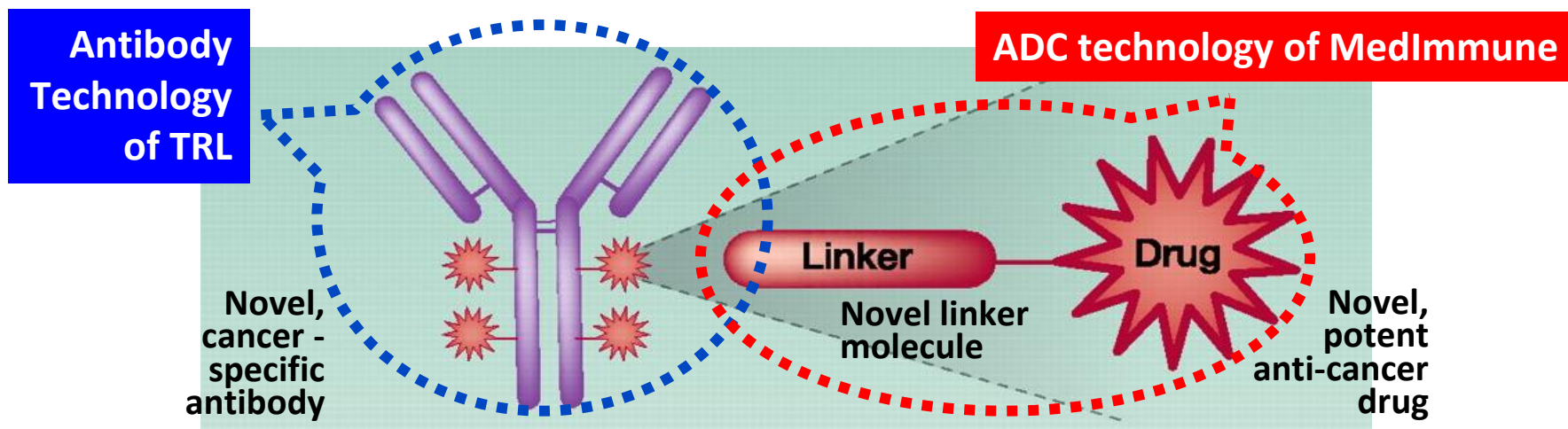


MT-5547, fasinumab, was associated with a significant reduction in walking knee pain.

PAIN 155 (2014) 1245–1252

### Challenge to a New Area by Expansion of Biologics Technology

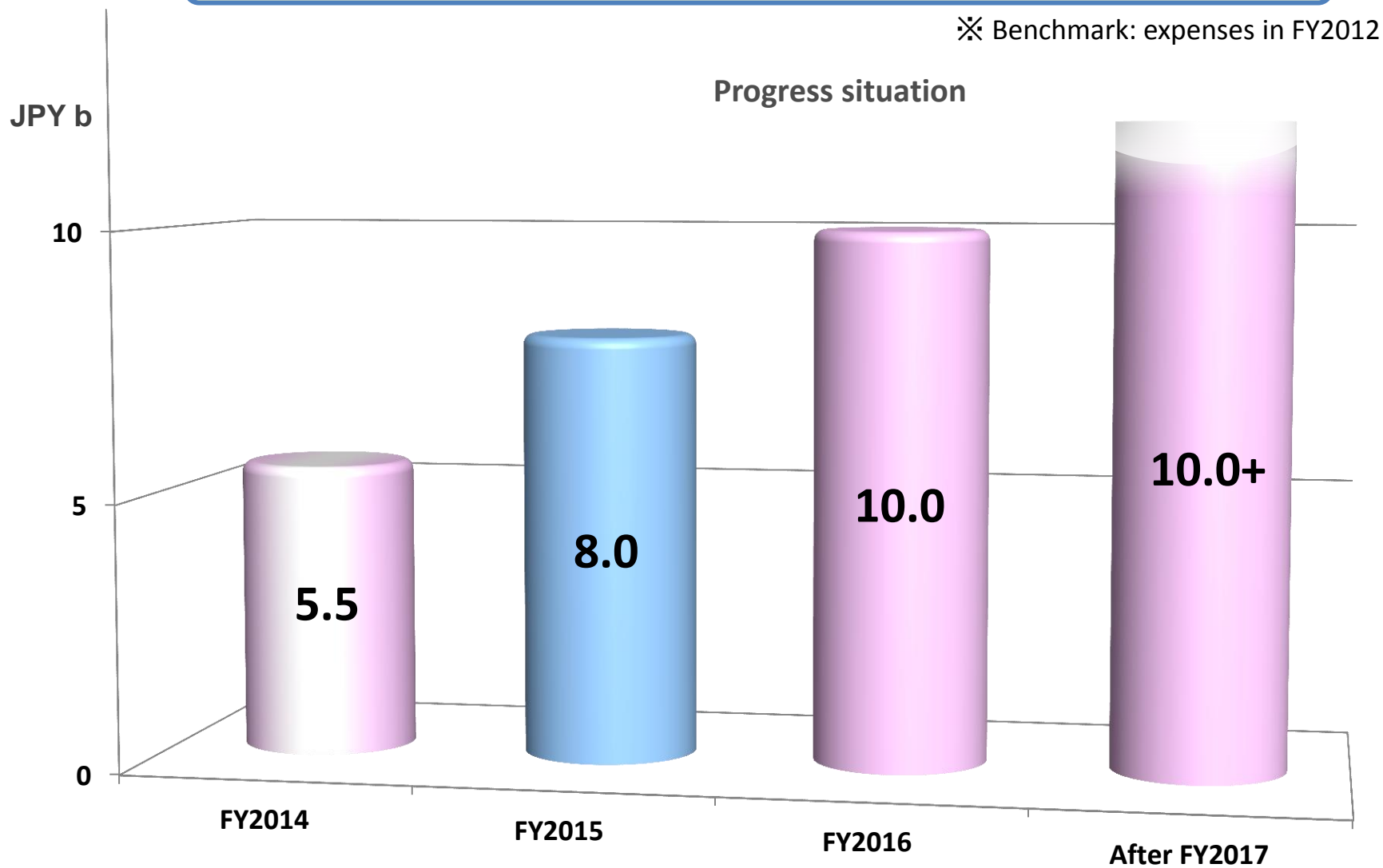
- MedImmune, the biologics research and development arm of AstraZeneca, and TRL, MTPC's research base specialized in biologics, have started research collaborations on anti-cancer drugs using antibody-drug conjugate (ADC).
- Incorporating excellent technologies by open innovation
- Considering possibilities of collaborations with MedImmune after certain developmental stage such as Ph1b.



*Teicher B A , and Chari R V Clin Cancer Res 2011;17:6389-6397*

Aim at creation of new drugs combined ADC technologies of MedImmune and antibody drug technologies and skills of MTPC/TRL which are accumulated in autoimmune disease area

In FY2015, steady progress toward cost cut of JPY 80b

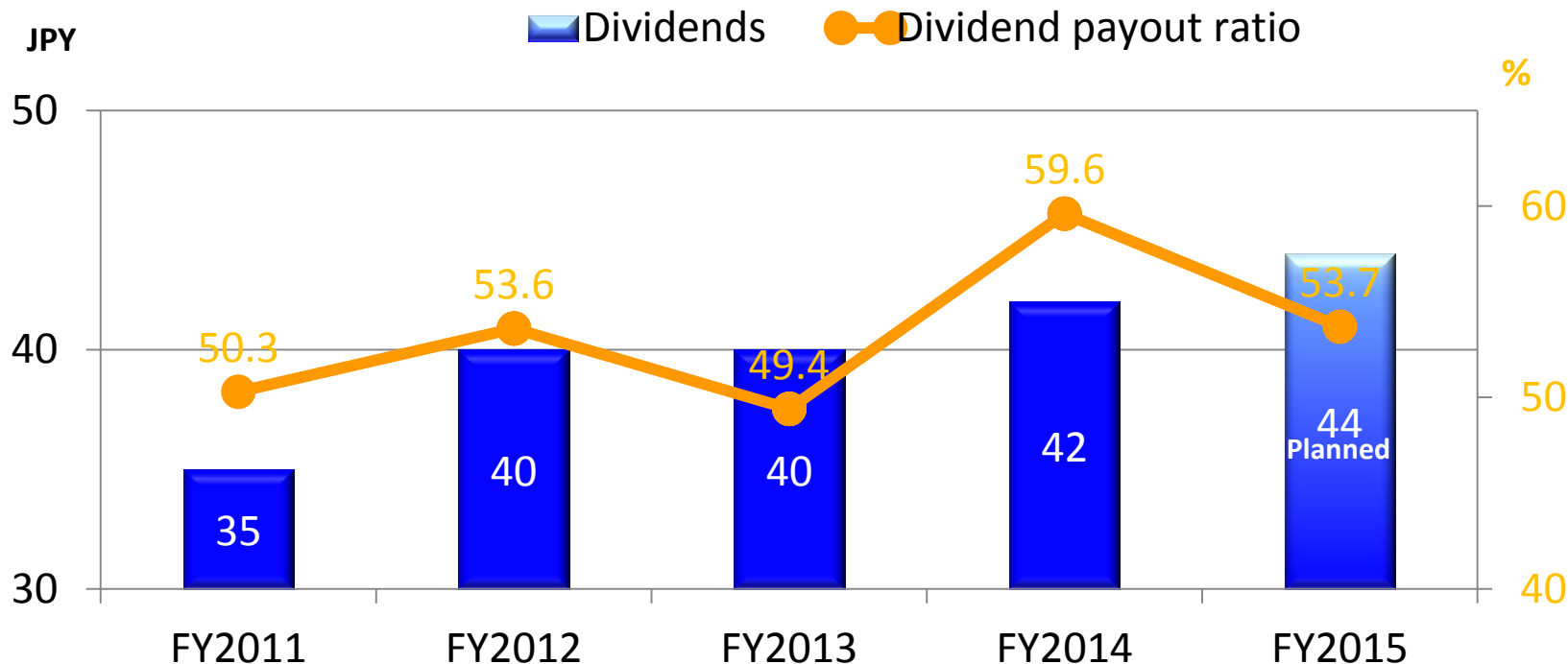


# Shareholders Return

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## ■ Policy

- 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, in addition to profit growth, the basic for the dividend payout ratio is 50% (that prior to amortization of goodwill is 40%), and MTPC will work to provide an enhanced return to shareholders.



# *New **Value** Creation*

**Becoming a “Company that Can Continue to Create New Value”**



# Appendix



# Sales by Business Segment

New **Value** Creation

【Q2 FY2015 Business Results, appendix】



	FY2015	FY2014	Increase/decrease		1H Forecasts*	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Sales	201.7	198.9	+2.8	+1.4	191.5	105.3
(Overseas)	(50.9)	(33.9)	(+17.0)	(+50.2)	( 47.2 )	(107.8)
Pharmaceuticals	201.5	198.7	+2.9	+1.4	191.3	105.4
Domestic ethical drugs	147.3	155.2	-7.9	-5.1	140.8	104.6
Royalty income, etc.	36.8	27.9	+8.9	+32.1	33.9	108.5
Overseas ethical drugs	14.3	11.3	+2.9	+25.8	13.4	106.4
OTC products	2.1	2.2	-0.1	-3.8	2.1	100.0
Contracted manufacturing products	1.1	2.1	-1.0	-49.4	1.1	95.7
Others	0.2	0.2	0.0	-14.8	0.2	95.0

\*: Forecasts of sales were revised on September 30, 2015. Previous forecasts announced on May 8, 2015 in the financial results of FY2014 are shown in this slide.

# Ethical Drugs Domestic Sales

## Priority Products and Vaccines

【Q2 FY2015 Business Results, appendix】

New **Value** Creation



Mitsubishi Tanabe Pharma

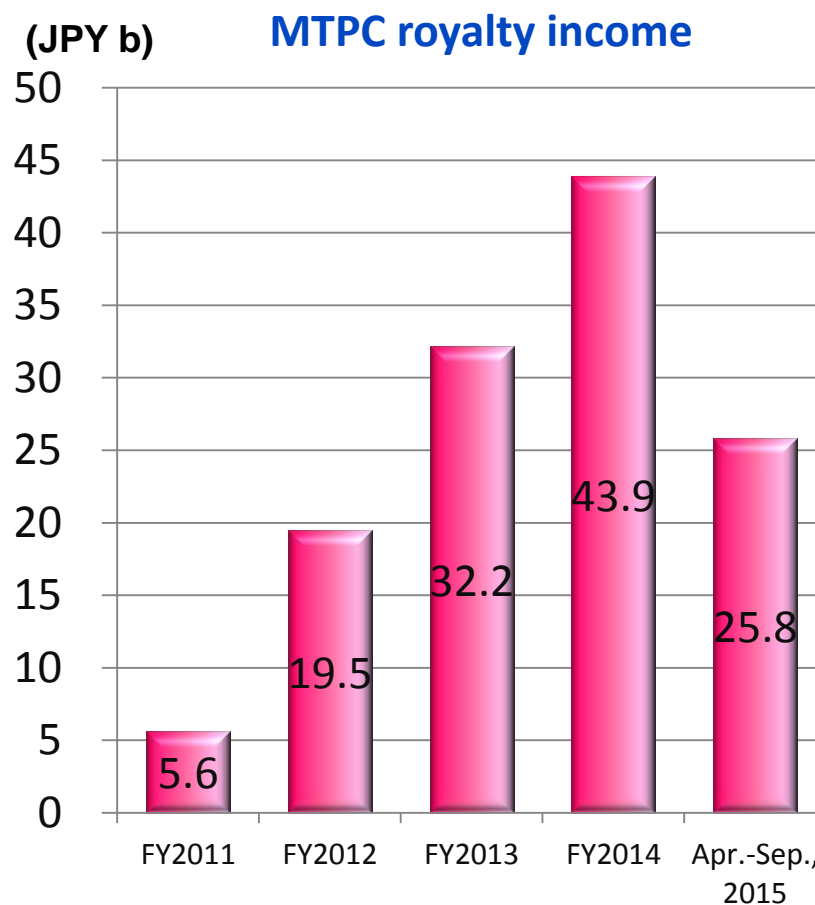
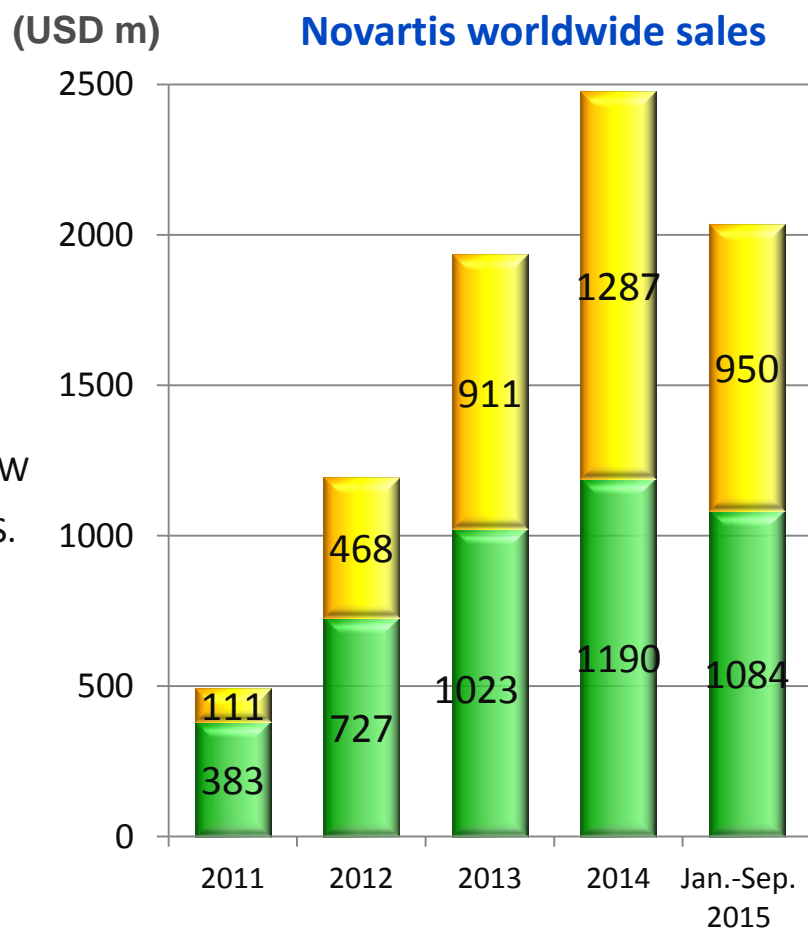
	FY2015	FY2014	Increase/decrease		1H Forecasts*1	Achieved
	Billion yen	Billion yen	Billion yen	%	Billion yen	%
Remicade	34.5	35.3	-0.7	-2.1	35.6	96.9
Talion	6.4	6.1	+0.4	+5.8	6.4	100.5
Simponi	6.2	5.0	+1.1	+22.5	6.2	99.5
Lexapro	4.4	3.4	+1.0	+28.5	4.1	107.0
Tenelia (previous scheme)	3.7	2.7	+1.1	+40.2	4.5	83.1
Tenelia (new scheme)	2.9	Undisclosed	-	-	Undisclosed	-
Imusera	2.0	1.5	+0.5	+32.1	1.8	108.9
Canaglu	0.0	1.1	-1.1	-	0.8	-
Total of priority products*2	57.2	55.1	+2.1	+3.9	59.4	96.3
Tetrabik	3.7	3.6	+0.1	+2.5	3.4	107.5
Varicella vaccine	3.3	1.9	+1.4	+73.0	2.3	144.8
Influenza	2.8	0.9	+1.9	+212.7	0.6	462.3
Total of vaccines	14.5	11.1	+3.4	+30.6	10.6	136.8
Total of priority products and vaccines*2	71.7	66.1	+5.5	+8.4	70.0	102.4

\*1: Forecasts announced on May 8, 2015 in the financial results of FY2014

\*2: Total amount excluding "Tenelia(new scheme)"

## 【Q2 FY2015 Business Results, appendix】

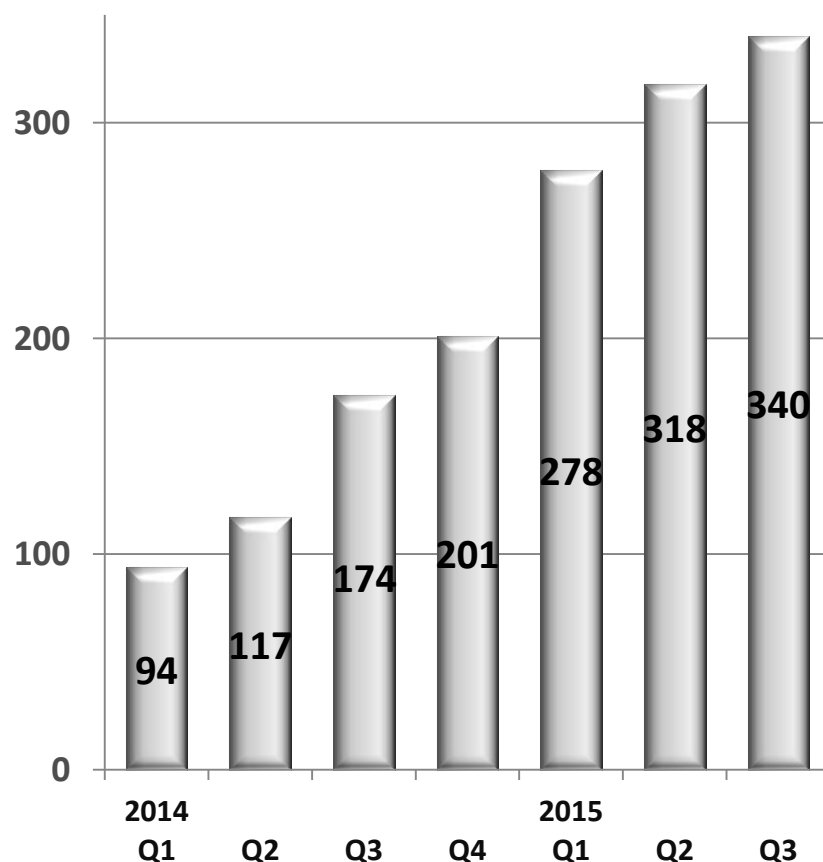
- ◆ Novartis worldwide sales in Jan. to Sep., 2015: \$ 2,034 m, + 22%, y-o-y
- ◆ MTPC royalty income in Q1 to Q2 FY2015: ¥ 25.8 b



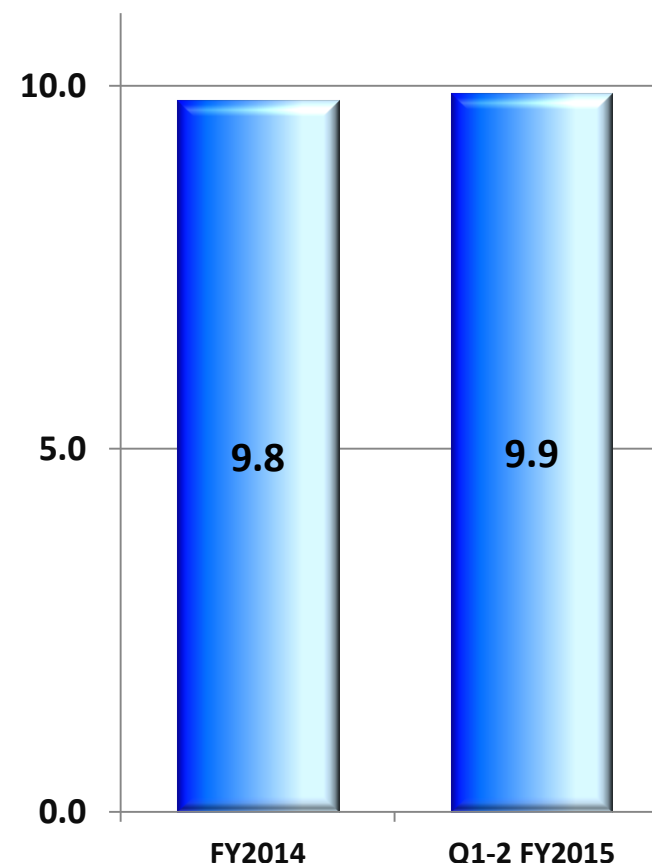
## 【Q2 FY2015 Business Results, appendix】

- ◆ Johnson & Johnson sales in Jan.-Sep., 2015: \$ 936m (+ \$ 385m, y-o-y)
- ◆ Achieved ~6.3% in defined U.S. T2DM market and ~13% share with endocrinologists
- ◆ MTPC royalty income in Q1 to Q2 FY2015: ¥ 9.9b

(USD m) **Johnson & Johnson sales**



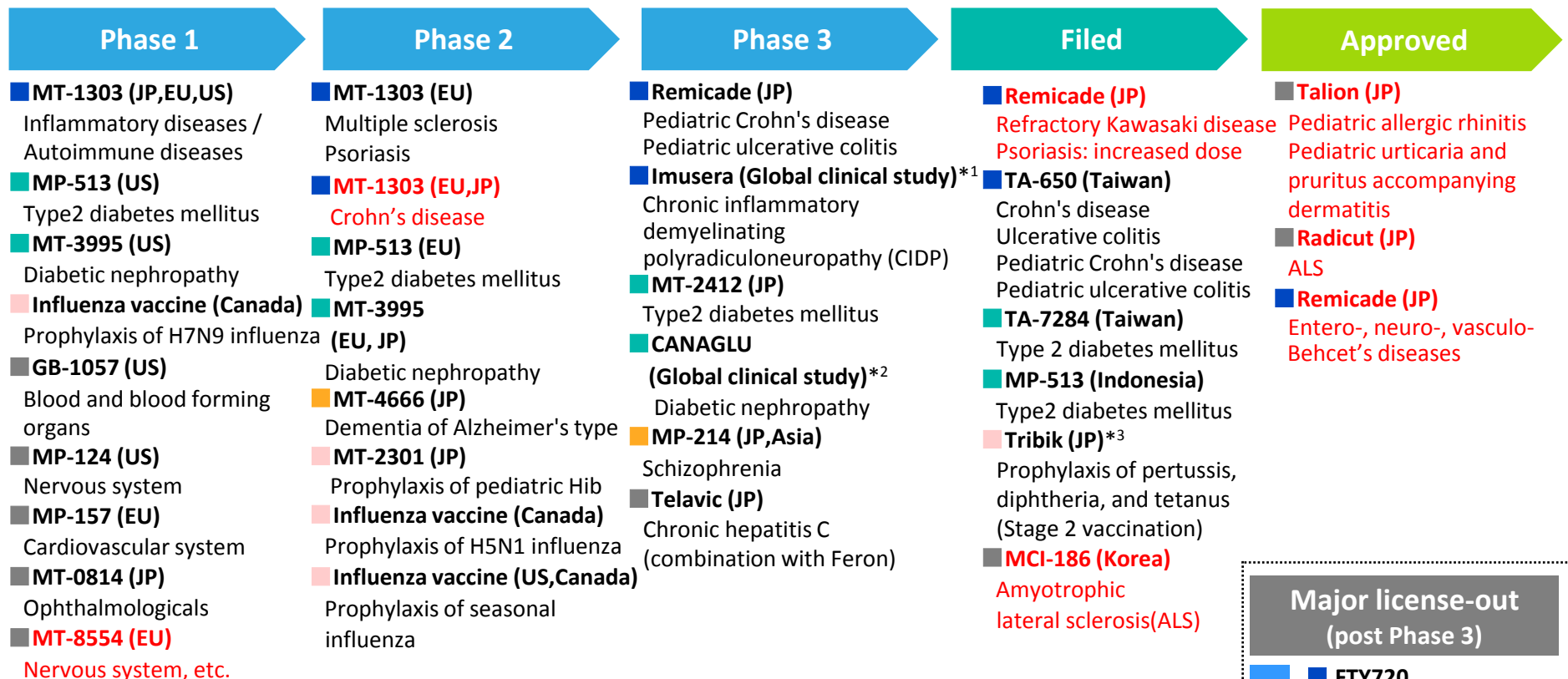
(JPY b) **MTPC royalty income**



# Pipeline Status(New Drugs, Additional Indications)

Red: progress after May 8, 2015, the financial results for FY2014

As of October 30, 2015



## Disease area

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

## Major license-out (post Phase 3)

**Phase 3**  
■ **FTY720 (Global clinical study)\*1**  
CIDP  
■ **TA-7284/Met XR FDC (US)**  
Type2 diabetes mellitus  
■ **TA-7284 (Global clinical study)\*2**  
Diabetic nephropathy

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

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

\*3: Co-developed with BIKEN

### **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.**