

# Mitsubishi Tanabe Pharma Corporation Information Meeting

## Becoming a “Company that Can Continue to Provide New Value”

February 21, 2013

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President and  
Representative Director



Mitsubishi Tanabe Pharma

## Medium-Term Management Plan 11-15: Results in the First Two Years

## Initiatives Targeting Sustained Growth toward 2015:

### Issues for the Next Three Years

- Growth strategies for Remicade and Simponi
- Growth of Gilenya/Imusera
- Taking on challenges in the diabetes area (Tenelia, TA-7284)
- Strategy for nurturing new products / priority products (Lexapro, Talion, Telavic)
- Promising pipeline (MT-1303, MP-214, MT-4666, MT-3995, MT-9938)

### Other Initiatives

- Operational and Structural Reforms
- Contributing to *KAITEKI* Society by orchestrating

# Medium-Term Management Plan 11-15: Results in the First Two Years



# Operating Environment in the Pharmaceutical Industry

## Maturation of Medicine

- Increase in patients by the aging society
- Advances in medicine



Control of health care expenditures because of growth in health care spending

- Promotion of use of generics
- Revisions of NHI drug price and NHI drug system



## Maturation of pharmaceutical market

- Intensifying competition among companies
- Increase in log-listed drugs
- Increase in R&D expenses due to the decline in development success rate



Decline in earning power

- Expansion of operational scale of companies by M&A and cooperation
- Selection and concentration on business activities



# Medium-Term Management Plan 11-15

## Success in These Two Years

New Value Creation



**Bolstering Our Ability to Discover New Drugs**

**Advancing Domestic Operations, Centered on New Drugs**

**Building a Foundation for the Expansion of Overseas Operations**

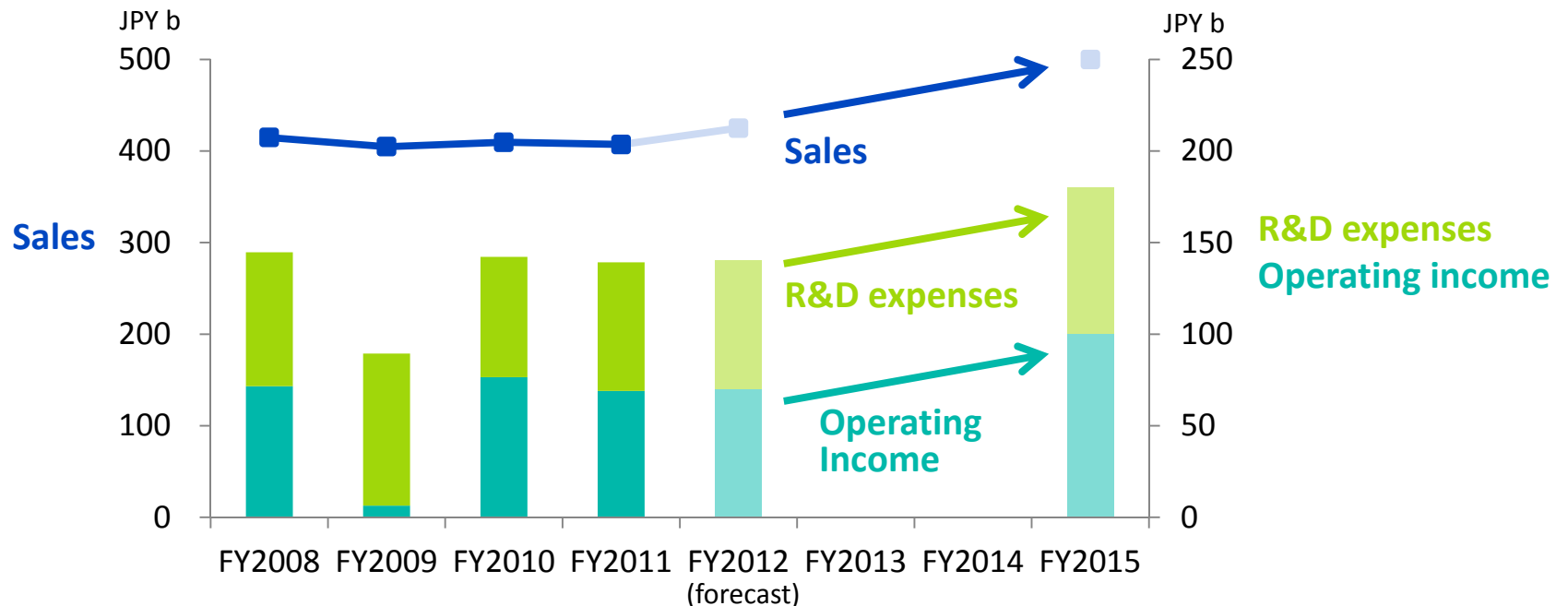
**Accelerating Operational and Structural Reforms**

### Success to Date

- ◆ Launched 6 new drugs (Lexapro, Simponi, Telavic, Imusera, Tenelia, Tetrabik)
- ◆ Taking on challenges in diabetes field (Launch of Tenelia, strategic joint sales agreement with Daiichi Sankyo)
- ◆ Steadily implementing LCM (Remicade, Maintate, others)
- ◆ Progress in domestic and overseas development pipelines  
P3: TA-7284 (Japan), P2b/3: MP-214 (Japan)  
P2: MT-4666 (Japan), MT-9938 (US), MT-3995 (Europe)  
In preparation for P2: MT-1303 (Europe)
- ◆ Progress in development by out-licensing partners  
Gilenya: Grow to blockbuster  
TA-7284: NDAs filed in Europe and US, approval recommended in US  
TA-1790: NDAs filed in Europe and US, approval received in US
- ◆ Progress with in-house development  
Argatroban: Launched in increasing number of markets (11 countries)  
MCI-196: Approved in Europe; Talion: Launched in China, Indonesia
- ◆ Integrated plasma fractionation operations with the Japanese Red Cross Society
- ◆ Transferred fine chemical operations
- ◆ Outsourced logistics operations

# FY2015 Numerical Targets

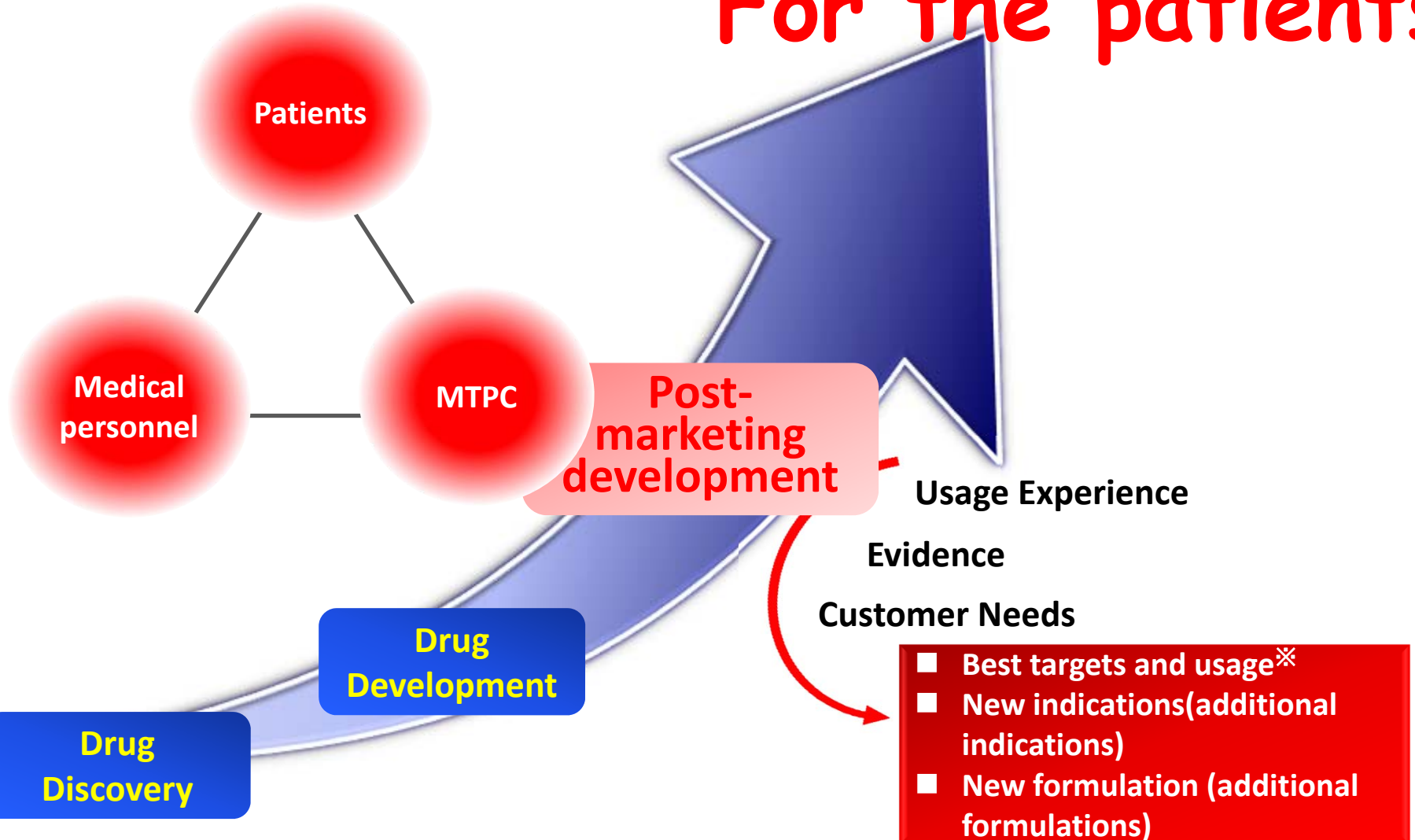
	FY2011 actual	FY2012 forecast	FY2015 objectives
<b>Sales</b>	<b>¥ 407.1 billion</b>	<b>¥ 425.0 billion</b>	<b>¥ 500.0 billion</b>
<b>Operating income</b>	<b>¥ 69.0 billion</b>	<b>¥ 70.0 billion</b>	<b>¥ 100.0 billion</b>
<b>Overseas sales ratio</b>	<b>7.0%</b>	<b>9.6%</b>	<b>15% +</b>



# Initiatives Targeting Sustained Growth toward 2015: Issues for the Next Three Years



## For the patients



\*Maximize effects, minimize side effects

# Future Marketing Strategy that Reflects System Reforms

## Priority drugs and new drugs

Early maximization of product value  
[Targeting First in category / Only one in category]

Generics

## Mature products\*

Expected to generate earnings  
as foundation business

- Active cooperative initiatives: Maximizing sales capabilities
  - Co-marketing
  - Co-promotion
  - Reinforcing the partnership with wholesalers
- Advancing LCM:
  - Evidence
  - Additional indications/formulations
- Information provision: Maximizing product value
  - T-Shaped Marketing system
- Group cooperative initiatives and strategic alliances
- Utilizing multiple channels

\*Mature products: Long-listed drug except for priority products

# Growth strategies for Remicade and Simponi



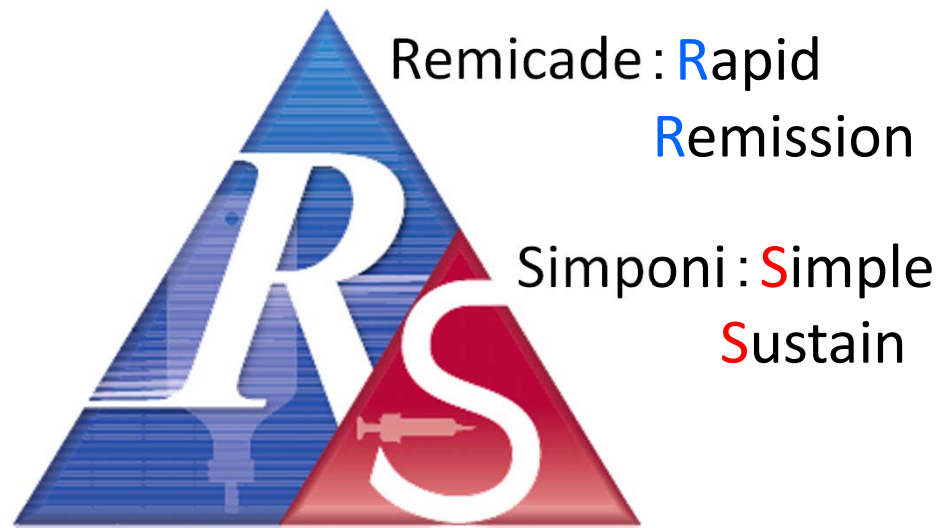
# Remicade & Simponi: Advantages

## ■ Advantages of the one-company, two-drug approach

- Can provide large quantity of information accumulated
- Can propose drugs to meet patient needs and lifestyles (intravenous injection, subcutaneous injection)
- Can be the first to identify patients for whom one of the drugs was not effective.

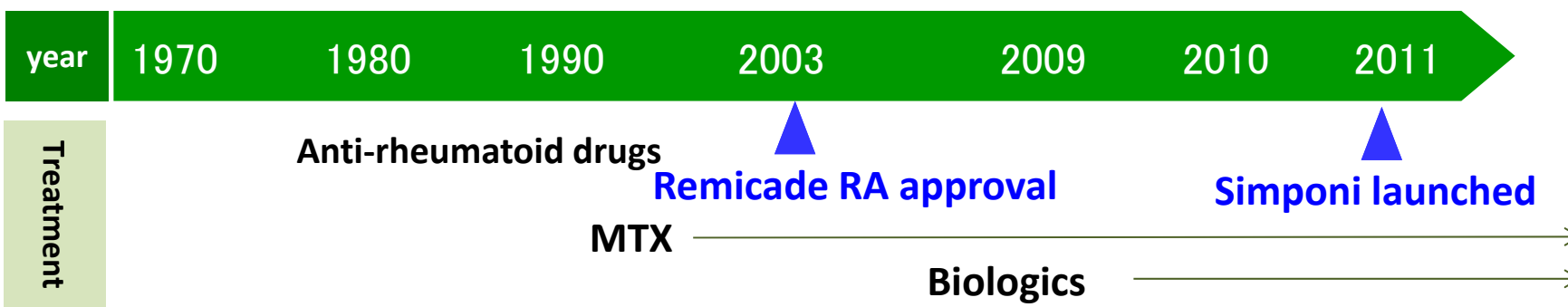
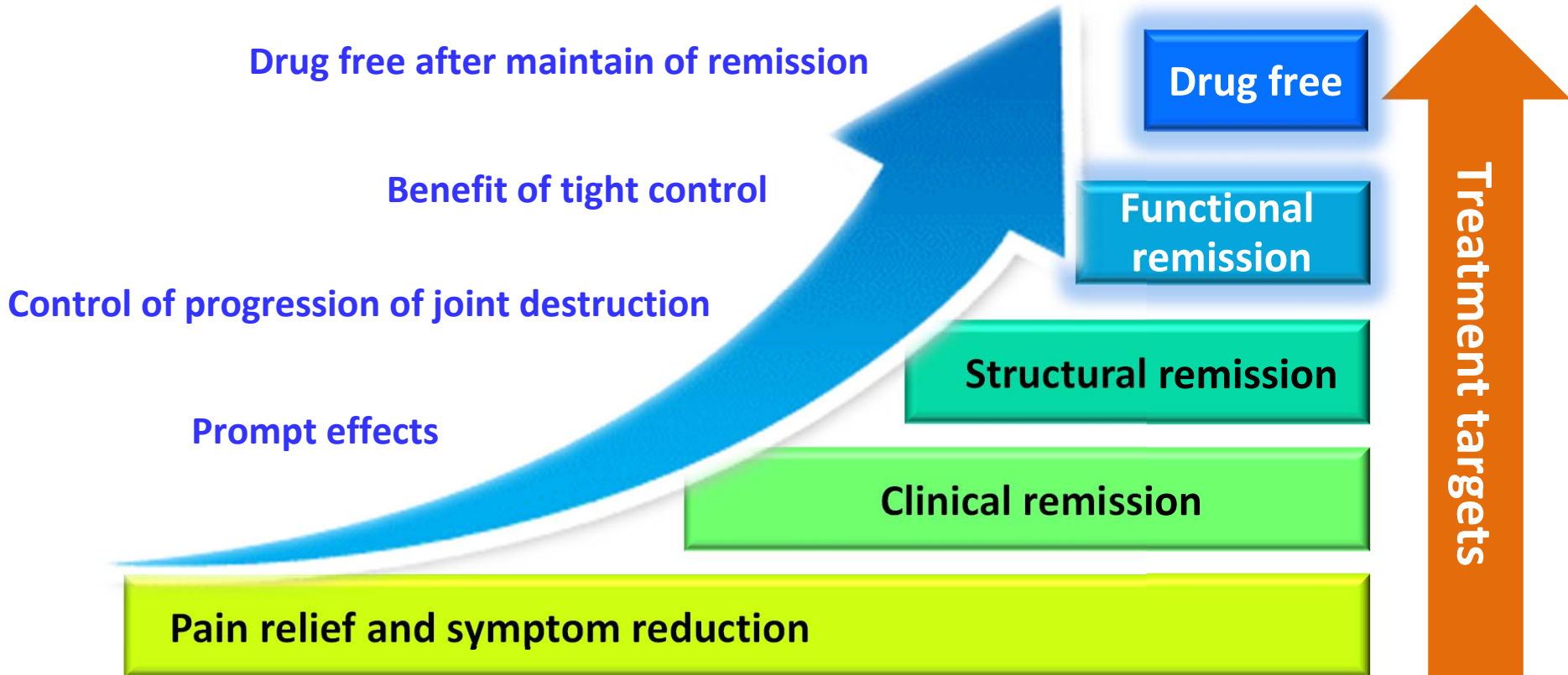
## ■ Advantages shared by both drugs

- Both target TNF
- Both can be tightly controlled (setting dosage to obtain maximum effect)  
(possible to increase dosage)

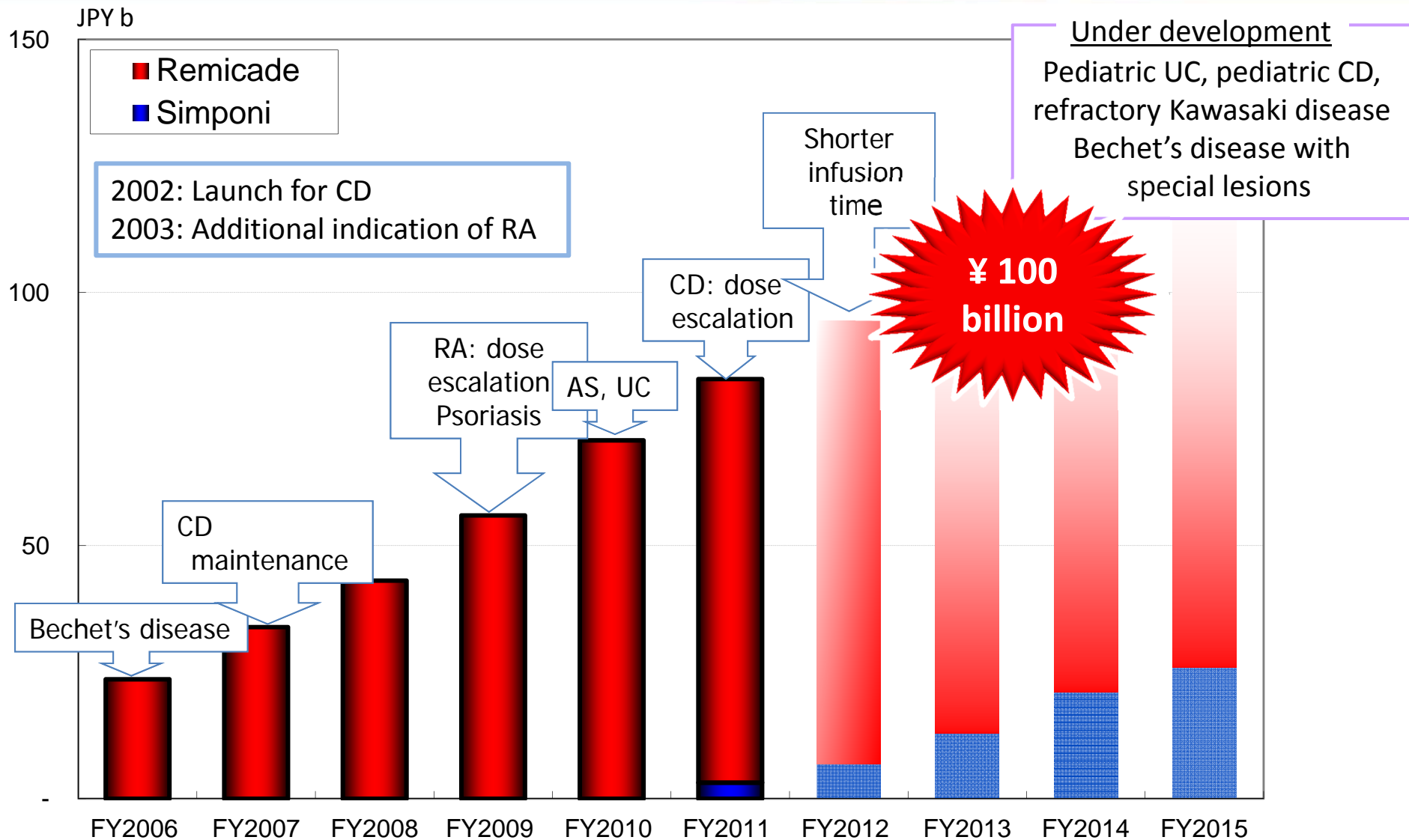


# Remicade & Simponi: Meeting the Next Treatment Needs in RA

New Value Creation



# Remicade & Simponi: ¥ 100 billion of Sales in FY2013

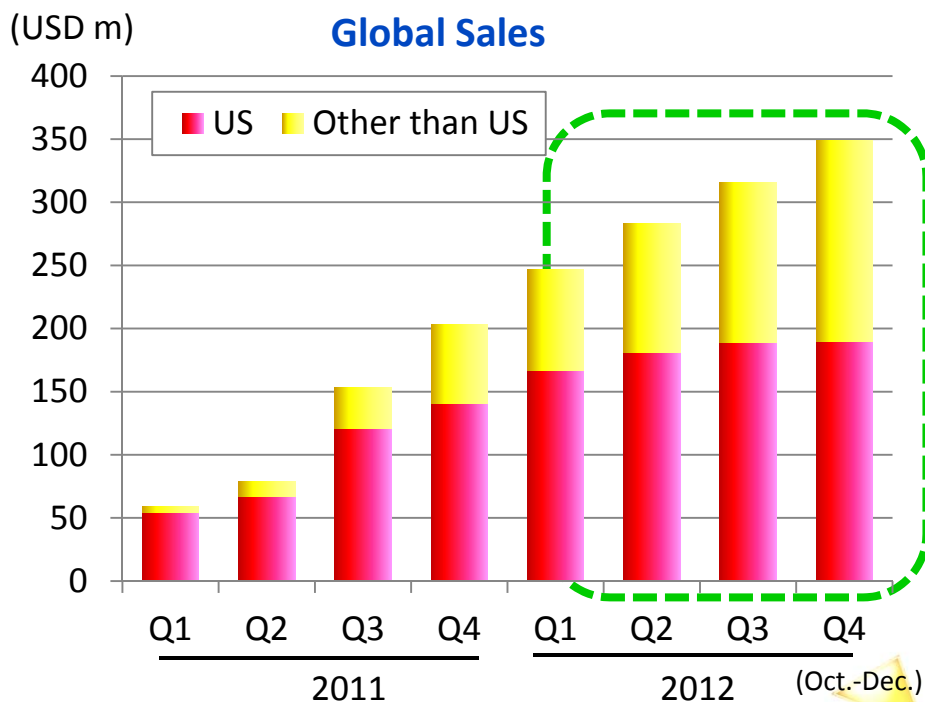


CD: Crohn's disease, RA: rheumatoid arthritis, AS: ankylosing spondylitis, UC: ulcerative colitis

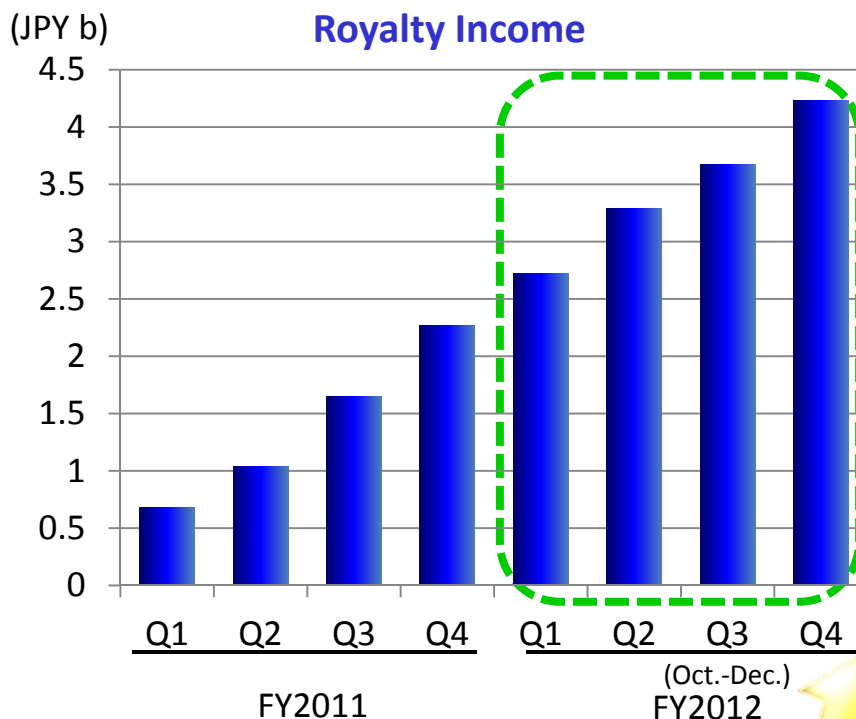
# Growth of Gilenya/Imusera

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- ◆ Novartis 2012 global sales: about \$1.2 billion
- ◆ Approved in more than 65 countries, used in the treatment of more than 53,000 patients after marketing



**Global Sales**  
**About \$1.2 billion**

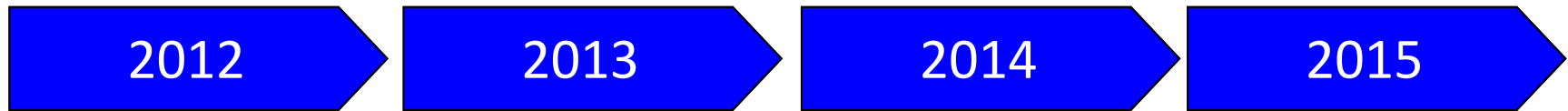


**Royalty Income**  
**¥13.9 billion**

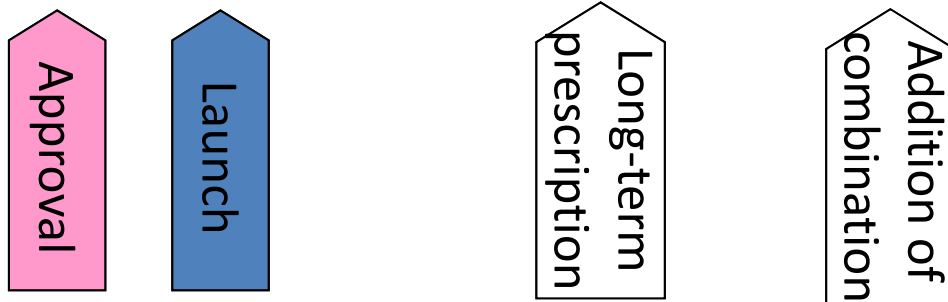
# Taking on Challenges in the Diabetes Area (Tenelia, TA-7284)

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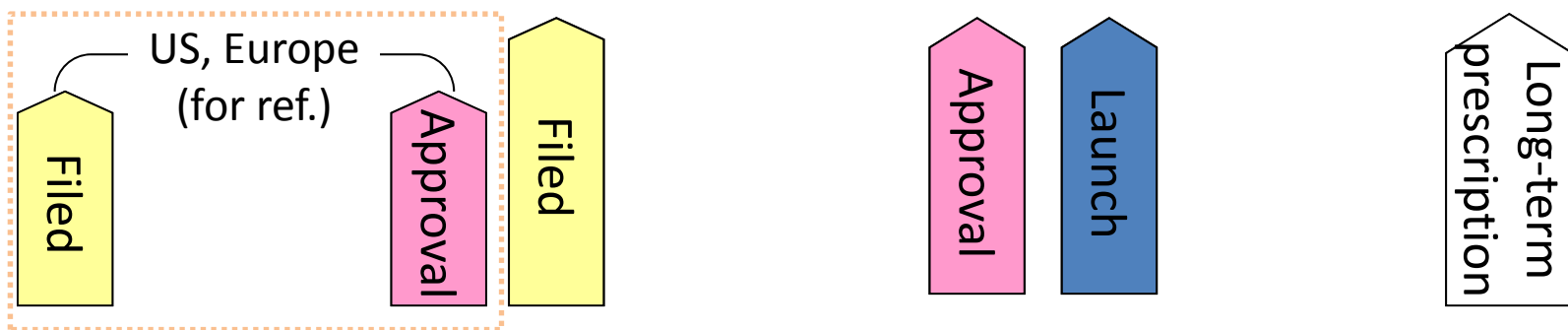
# Schedule of MTPC's Diabetic Drugs in Japan



## Tenelia (DPP-4 inhibitor)



## TA-7284/Canaglifrozin (SGLT2 inhibitor)



# Tenelia: Priority Issues

Priority Issues		Measures
Short-term	Promote rapid spread of product profile	<ul style="list-style-type: none"> <li>➤ Strengthen cooperation and activities among 4,000 MRs</li> <li>➤ Emergence of unmet needs in diabetes treatment</li> </ul>
Short to long term	Maximize product value	<ul style="list-style-type: none"> <li>➤ Establish evidence <ul style="list-style-type: none"> <li>✓ Special post-marketing surveillance in 10,000 patients (RUBY trials)</li> <li>✓ Anti-arteriosclerosis (endothelial cell function), others</li> </ul> </li> <li>➤ Meticulous preparations for change in usage, long-term administration</li> </ul>
	Promote spread of MTPC brand	<ul style="list-style-type: none"> <li>➤ Advance patient support program</li> <li>➤ Strengthen system for support of diabetes research</li> <li>➤ Deepen T-Shaped system</li> </ul>

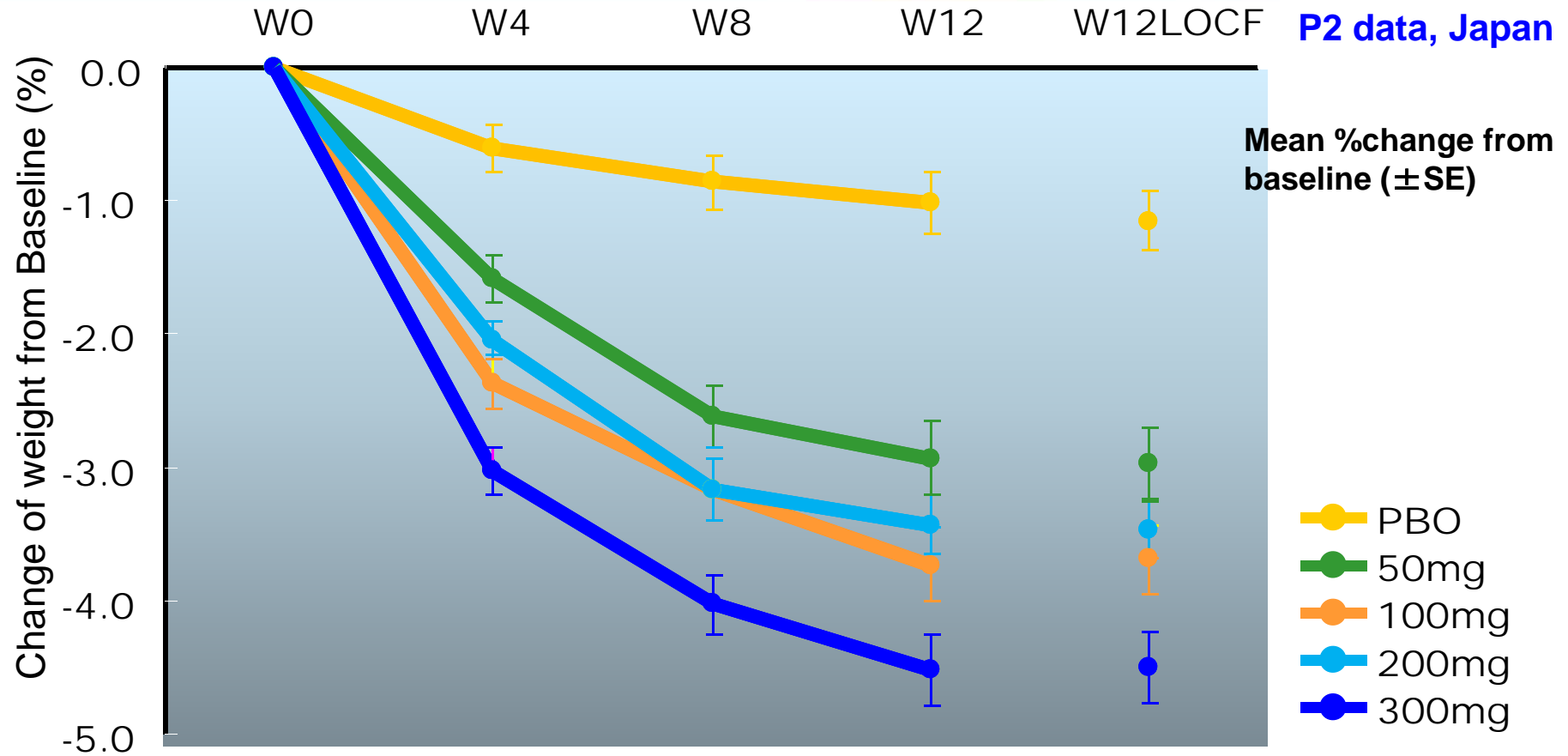
**Tenelia & TA-7284**

**Top tier presence in domestic market (diabetes field)**

# TA-7284 (SGLT2 inhibitor): Distinctive Features

<b>Mechanism of action</b>	<b>SGLT2 inhibitor</b>
<b>Indication</b>	<b>Type2 diabetes mellitus</b>
<b>Development stage</b>	<b>Japan: Phase 3 (planning 1<sup>st</sup> half of FY2013) US, Europe: Filed (by Janssen Pharmaceuticals)</b>
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ <b>Abundant clinical data from Japan and overseas (more than 12,000)</b></li><li>➤ <b>Efficacious without regard to insulin status</b></li><li>➤ <b>Low risk of hypoglycemia</b></li><li>➤ <b>Weight reduction effect</b></li></ul>

# TA-7284(SGLT2 inhibitor): Body Weight Reduction

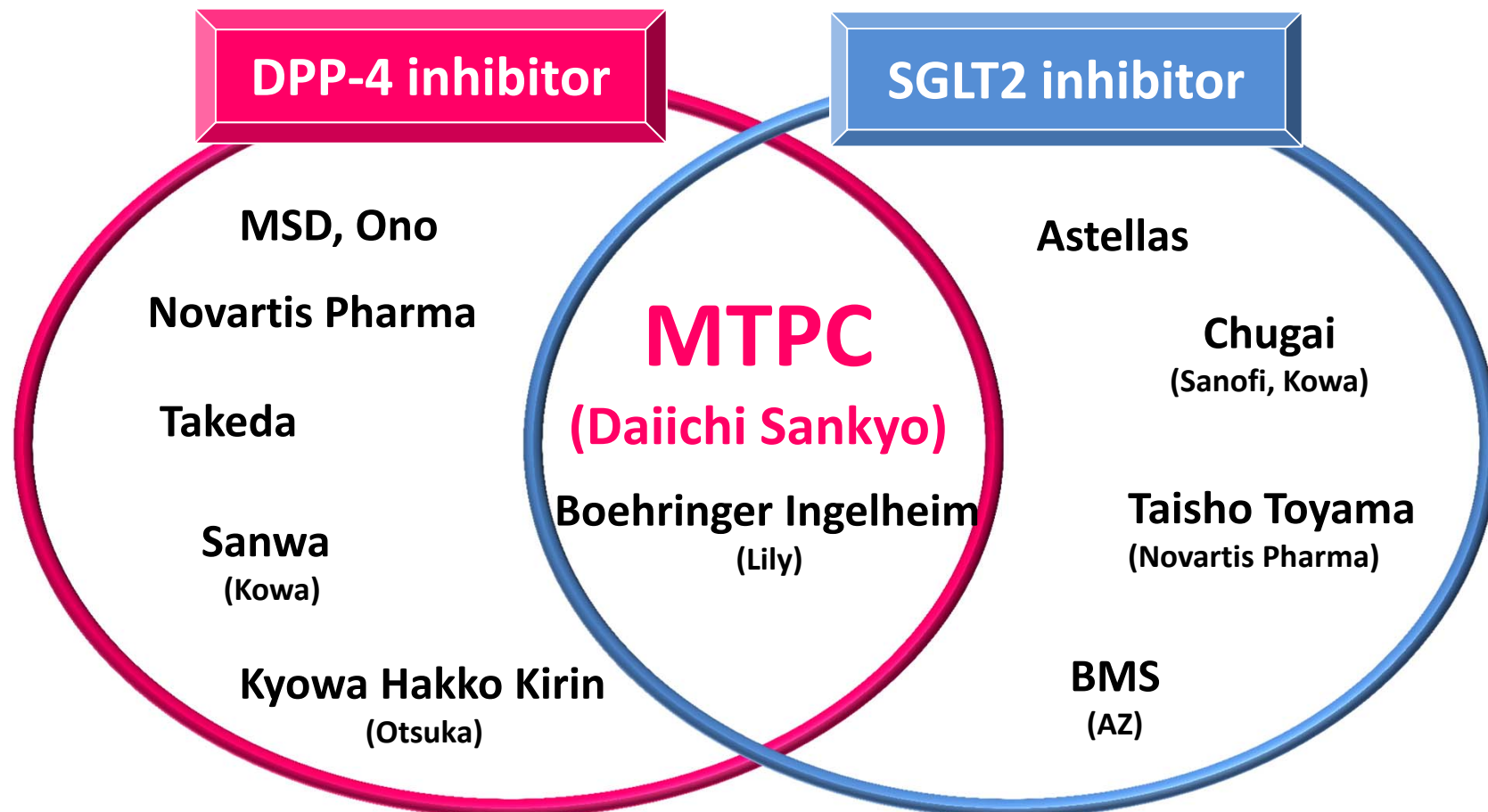


	PBO	50mg	100mg	200mg	300mg
n	75	82	74	76	75
BW at BL (kg)	72.56 $\pm$ 15.36	65.77 $\pm$ 13.56	68.61 $\pm$ 14.86	68.97 $\pm$ 14.50	71.30 $\pm$ 12.19

# Advantage in Diabetic Area

■ Major marketing authorization holders

( ): Co-marketing or co-promotion

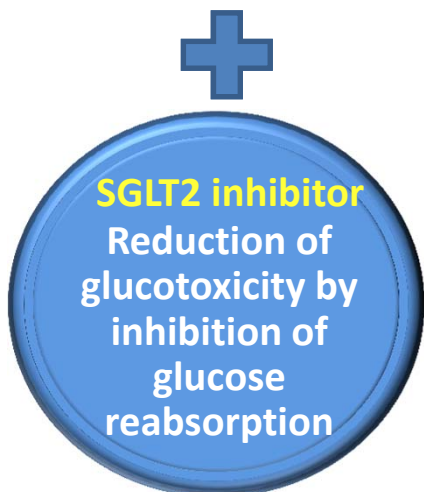
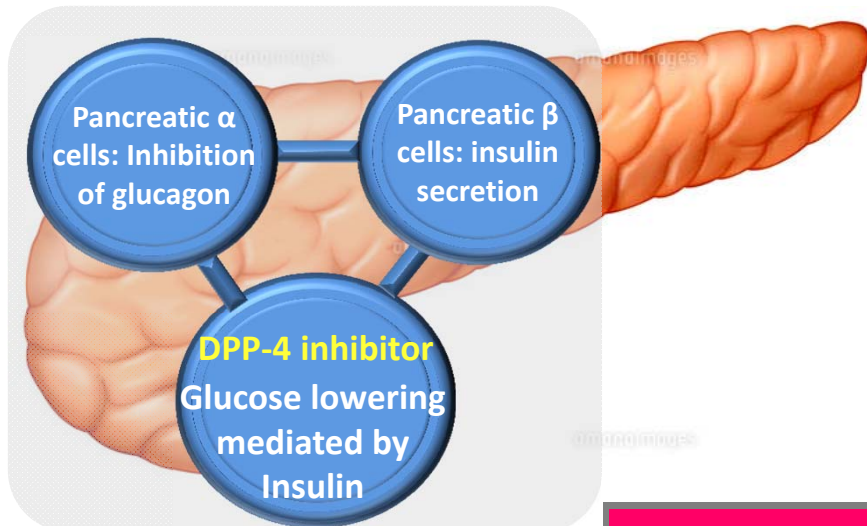


**MTPC and Boehringer Ingelheim  
are the originators having both drugs**

# Ideal Diabetic Treatment brought about by Two Mechanisms of Action

## Gentle treatment for pancreatic $\beta$ cells

Physiological insulin secretion by incretin



## Reduction of CV risks by TENELIA<sup>®</sup> and canagliflozin

### Requirements to inhibit CV events

1. Adequate control of blood glucose
2. No hypoglycemia
3. No body weight gain
4. Influence on blood pressure

TENELIA <sup>®</sup>
Improvement of postprandial hyperglycemia
Fewer hypoglycemia by monotherapy
No body weight increase
No influence on blood pressure



TA-7284
Improvement of fasting hyperglycemia
Fewer hypoglycemia by monotherapy
Body weight loss
Blood pressure decrease

# Medium- to Long-term Expansion in Diabetic Area

New *Value Creation*



2012

2014

DPP-4  
inhibitor  
TENELIA

SGLT2 inhibitor  
TA-7284/  
canagliflozin

Proposal of  
combination  
drug  
(DPP-4 inhibitor +  
SGLT2 inhibitor)

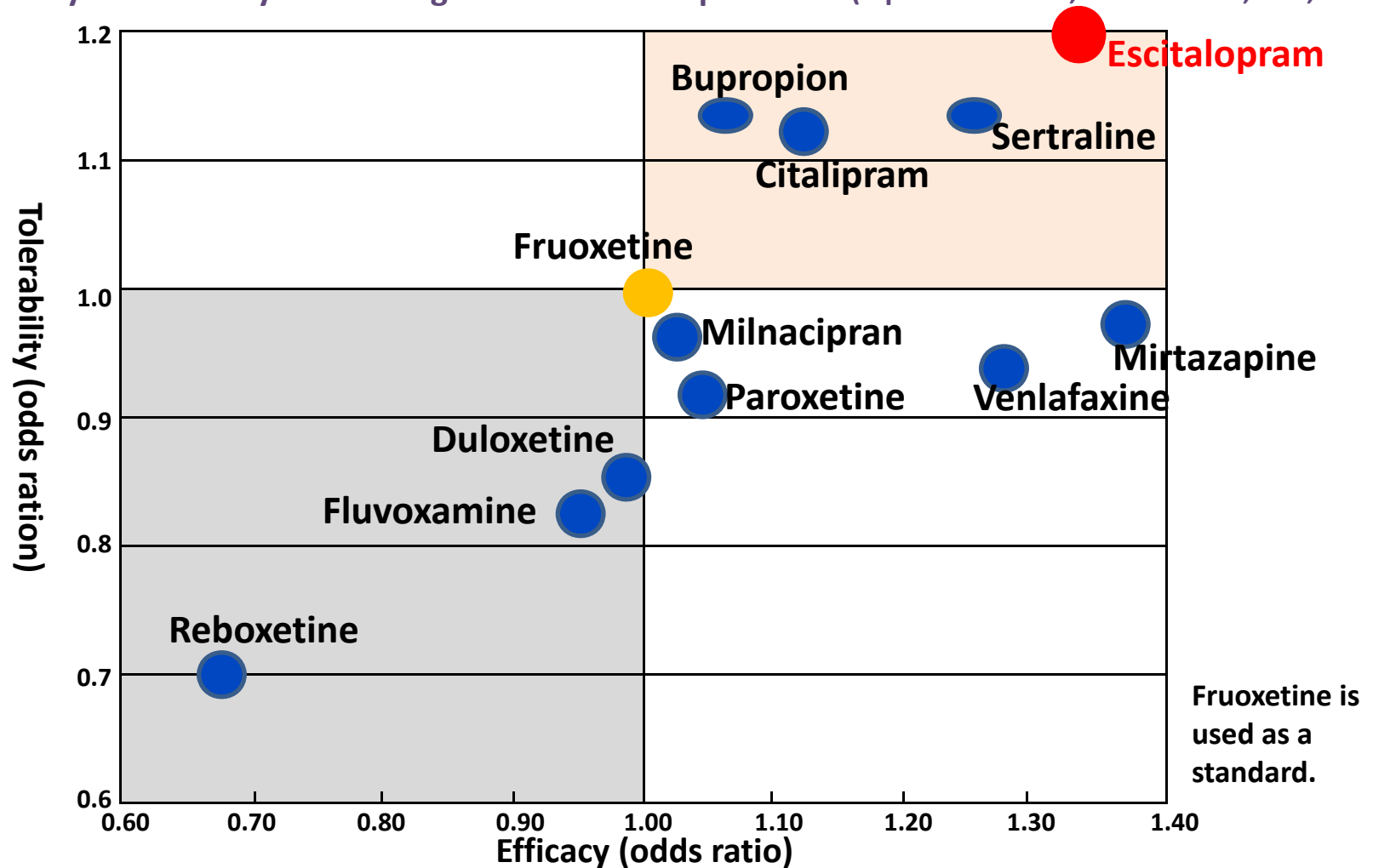
# Strategy for Nurturing New Products / Priority Products (Lexapro, Talion, Telavic)



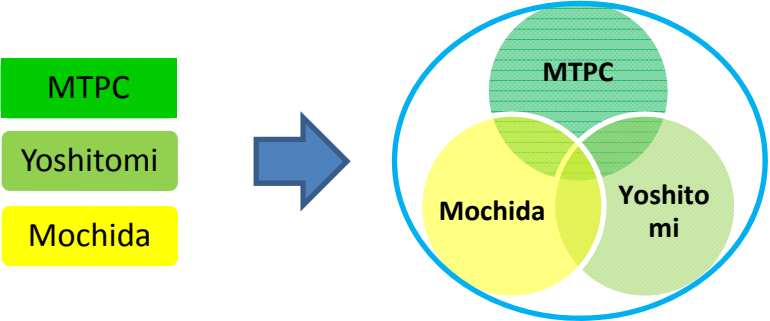
## No.1 in MANGA study, famous for meta-analysis of antidepressants

### Efficacy and Tolerability of antidepressants

MANGA Study: Meta-analysis of new generation antidepressants (Cipriani A. et al., Lancet 2009; 373, 746-758)



# Lexapro: Priority Issues

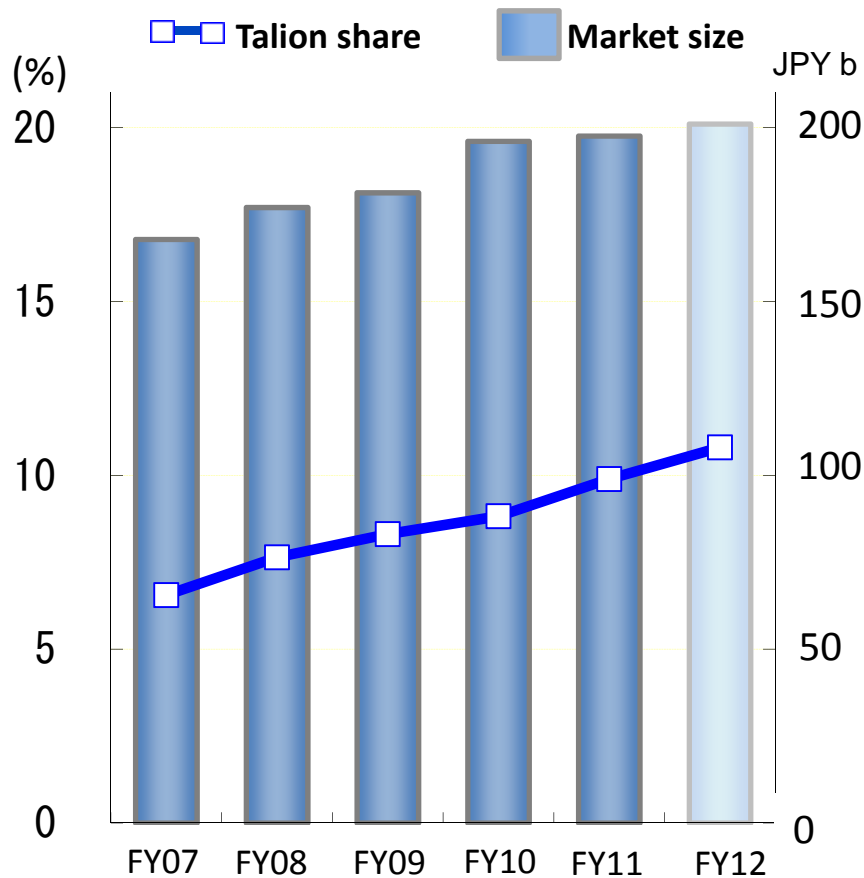
Priority issues		Measures
Short-term	Penetration of the product concept	<ul style="list-style-type: none"> <li>➤ Strengthening of the marketing information provision system(single visit ⇒ multi visits)</li> </ul> 
Med.-to long-term	Maximization of the product value	<ul style="list-style-type: none"> <li>➤ Evidence in Japan</li> <li>➤ Additional indication: Social anxiety disorder</li> </ul>



**Toward No.1 share in antidepressants**

# Talion: Current Status

Market size and share trend of Talion




Market has grown to ¥200 billion per year by increasing hay fever patients.

Talion is expanding its market share year by year.

A spate of patent off;  
In FY2012, GEs of Allegra and Allelock are launched.

Products.	Alesion	Zyrtec	Ebastel	Claritin	Allelock	Allegra
GE launch	2002 Jul.	2007 Jul.	2008 Jul.	2011 Nov.	2012 Dec.	2013 Jan.

# Talion: Priority Issues

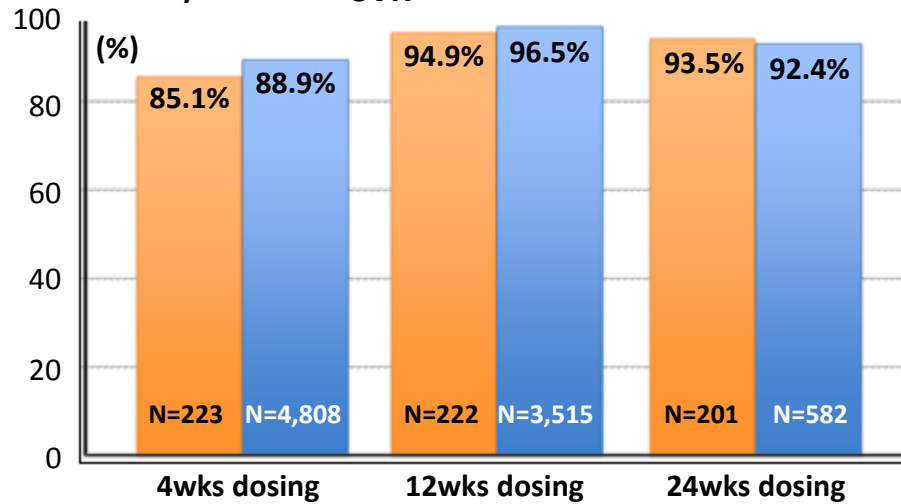
Priority Issues	Measures
<p><b>Increase promotional impact</b></p>	<p>➤ Continually provide evidence from Japanese patients and strengthen product key message, as domestically produced antihistamine.</p>  <p>The diagram shows two parallel timelines. The top timeline for 'Dermatological problems' includes 'ACROSS' (2010), 'UPDATE' (2013), and 'Proactive therapy' (2015). The bottom timeline for 'Hay fever' includes 'ACTION' (2007), 'ACTION II' (2011), and 'ACTION III' (2012). Both timelines end with arrows pointing to the right.</p>
<p><b>Develop new market</b></p>	<p>➤ Preparations to obtain additional indication in pediatric field</p>
<p><b>Capture share in existing market</b></p>	<p>➤ Establish product position through evidence from Japanese patients and encourage switch to Talion from long-term listed products (1st generation products, etc.).</p>



**Develop to sales of ¥30 billion/year**

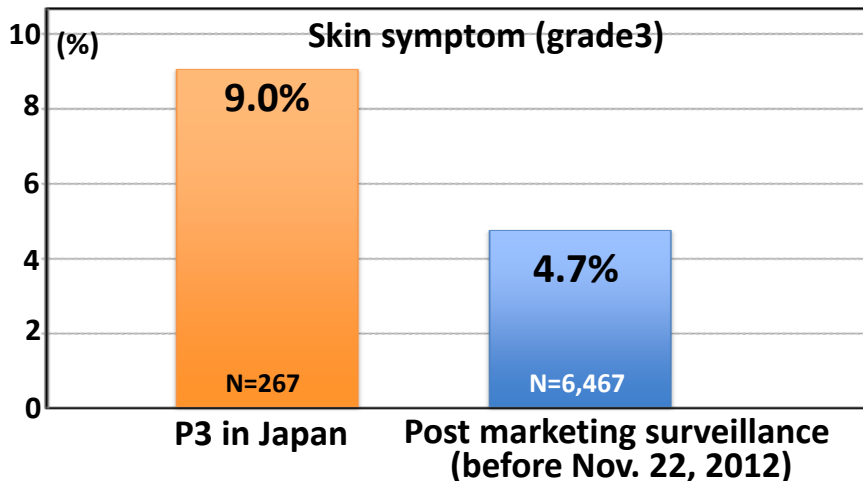
# Telaviv: Current Status

## ■ Efficacy



■ P3 in Japan ■ Post marketing surveillance (before Nov. 22, 2012)

## ■ Safety

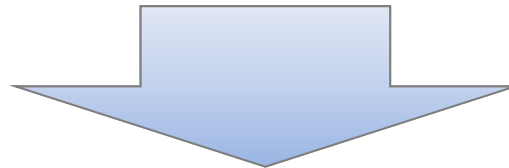


Note: 1,500 mg dosage cases are included in PMS

# Telavic:

## Priority Issues and Measures

Priority Issues		Measures
All-patient surveillance underway	Safety confirmation/usage establishment	➤ Early completion of all-patient surveillance by speeding up the information collection and analysis
After completion of all-patient surveillance	Foster spread of usage method	<ul style="list-style-type: none"> <li>➤ Rapidly expand number of institutions [gastroenterologists] (continued links with dermatology)</li> <li>➤ Disseminate knowledge about usage methods through Doctor to Doctor* communications</li> </ul>
	Develop new market	➤ Additional indications (genotype 2, etc.)



\* At presentations and other venues, have doctors who are opinion leaders provide information to other doctors who have not used it yet or are not well acquainted with it.

**Strive to expand sales based on the established safety evidence after the approval conditions are lifted**

# Promising Pipeline

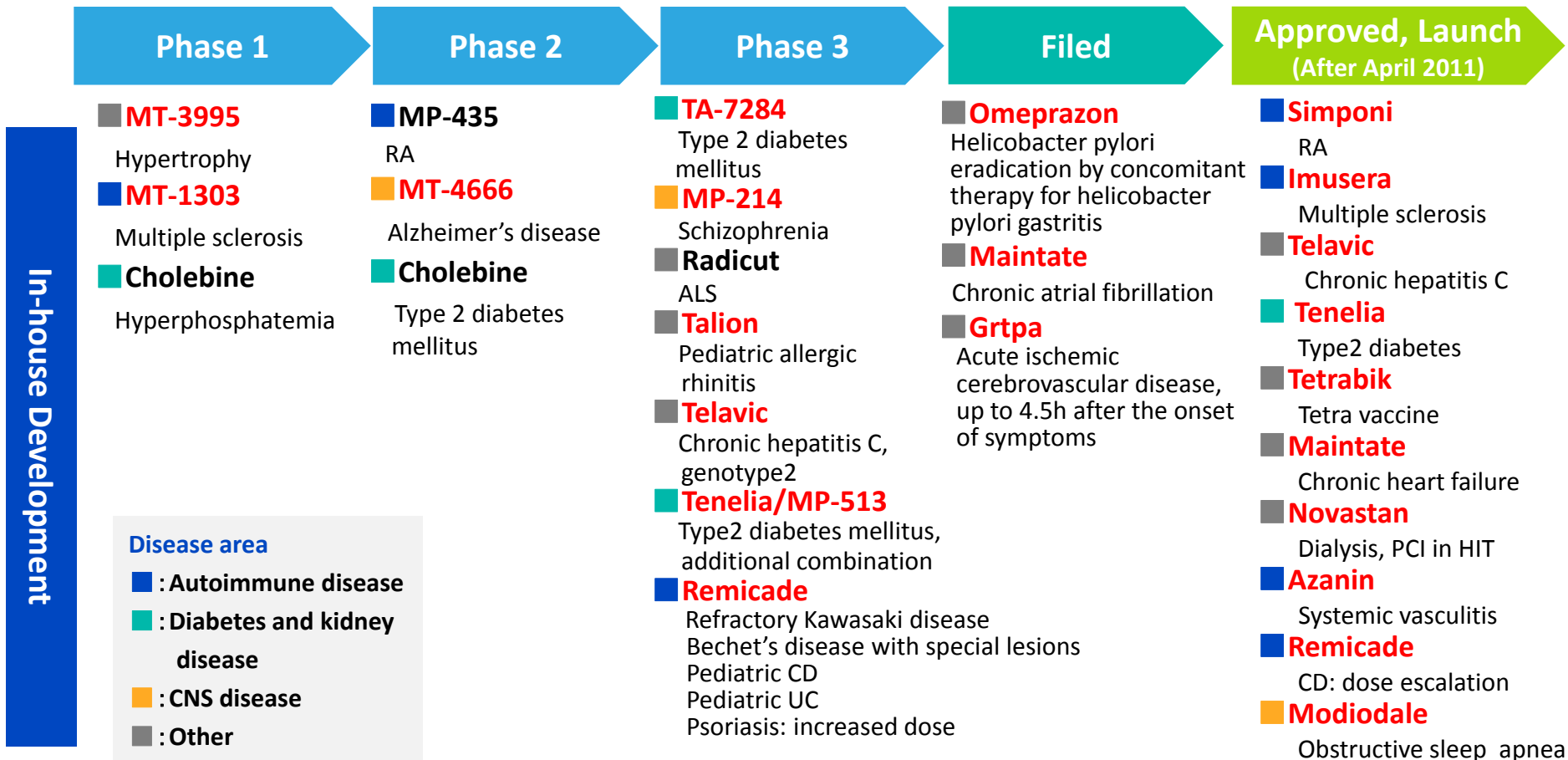
(MT-1303, MP-214, MT-4666, MT-3995, MT-9938)

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# Pipeline Status (Japan)

Red: progress after April 2011

As of Feb. 1, 2012



Major license-out

# Pipeline Status (Overseas)

Red: progress after April 2011

As of Feb. 1, 2012



In-house Development

- |  |   |  |  |  |
|--|---|--|--|--|
| <ul style="list-style-type: none"> <li>■ <b>MT-1303 (Europe)</b><br/>Multiple sclerosis</li> <li>■ <b>MP-513 (US)</b><br/>Type2 diabetes mellitus</li> <li>■ <b>MT-7716 (US)</b><br/>Alcohol-use disorder</li> <li>■ <b>MP-124 (US, Canada)</b><br/>Acute ischemic stroke</li> <li>■ <b>MT-3995 (Europe)</b><br/>Hypertension →P2 start in Diabetes nephropathy</li> <li>■ <b>MP-157 (Europe)</b><br/>Hypertention</li> <li>■ <b>GB-1057 (US)</b><br/>Stabilizing agent</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>MT-9938 (US)</b><br/>Refractory pruritus</li> <li>■ <b>MP-513 (Europe)</b><br/>Type2 diabetes mellitus</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>MP-146(US, Europe)</b><br/>Chronic kidney disease</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>MP-424 (Taiwan)</b><br/>Chronic hepatitis C</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>Talion (China, Indonesia)</b><br/>Allergic disease</li> <li>■ <b>Simponi (Taiwan, Indonesia)</b><br/>RA, ankylosing spondylitis</li> <li>■ <b>Livalo (Indonesia)</b><br/>Primary hyperlipidemia , mixed dyslipidemia</li> <li>■ <b>Livalo (Taiwan)</b><br/>Primary hypercholesteremia, mixed dyslipidemia</li> <li>■ <b>Exembol (UK)</b><br/>HIT type II</li> <li>■ <b>BindRen (Europe)</b><br/>Hyperphosphatemia</li> </ul> |
|--|---|--|--|--|

Major license-out

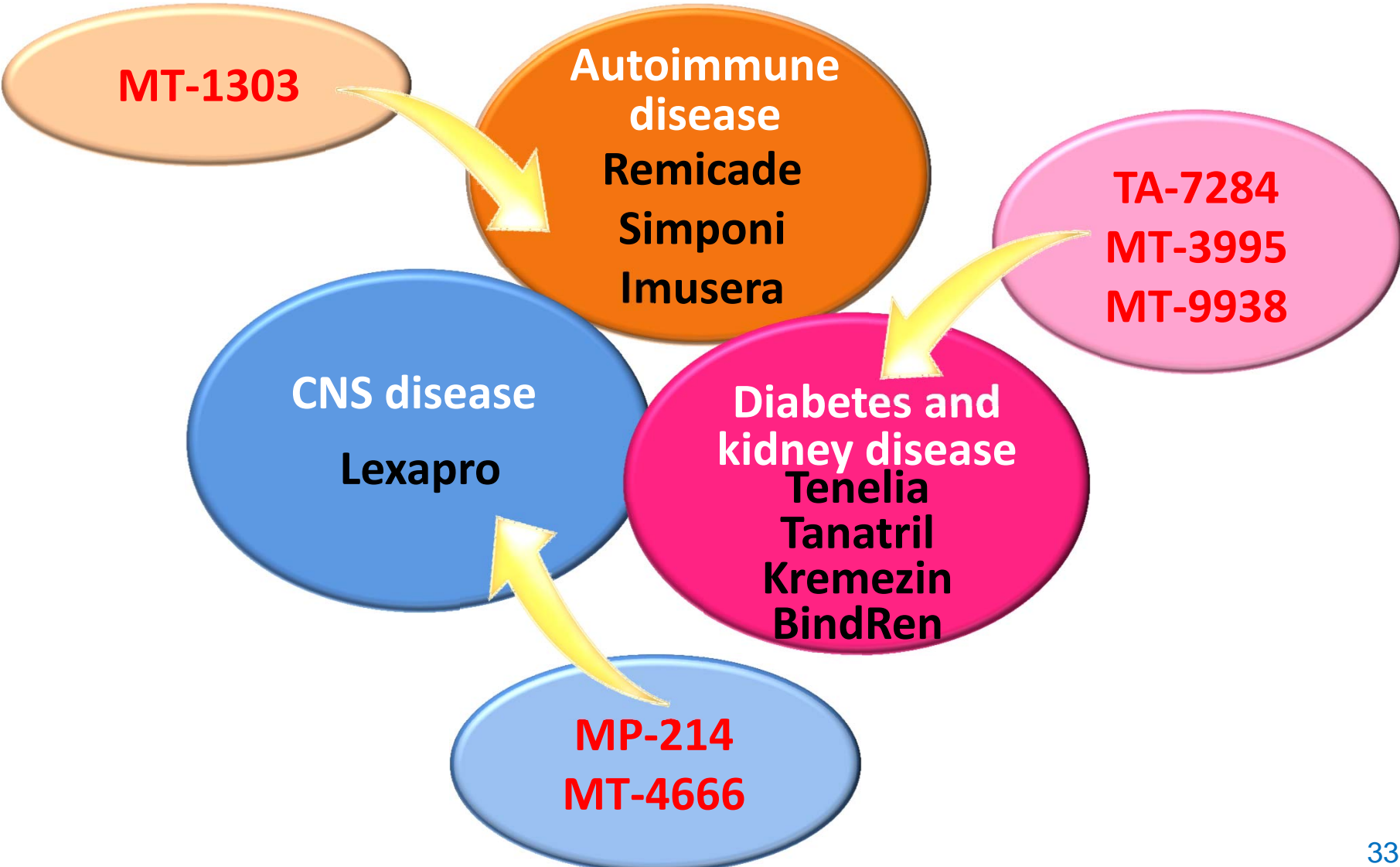
**Disease area**

- : Autoimmune disease
- : Diabetes and kidney disease
- : CNS disease
- : Other

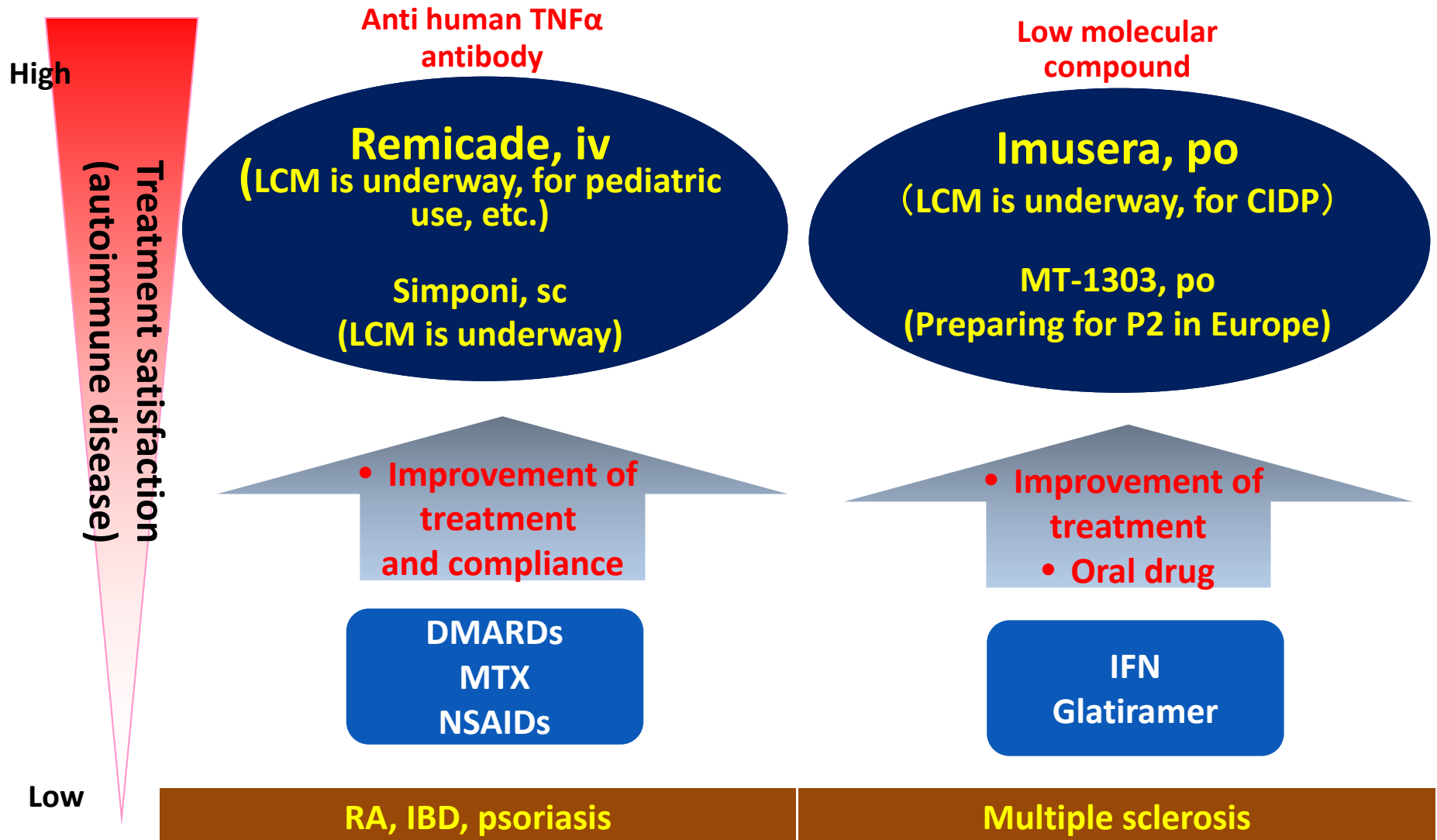
- |   |   |   |   |
|---|---|---|---|
| <ul style="list-style-type: none"> <li>■ <b>TA-7284 (US, Europe)</b><br/>Obesity</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>MP-513 (Korea)</b><br/>Type2 diabetes mellitus</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>TA-7284 (US, Europe)</b><br/>Type2 diabetes mellitus</li> <li>■ <b>TA-1790 (Europe)</b><br/>ED</li> </ul> | <ul style="list-style-type: none"> <li>■ <b>TA-1790 (Korea, US)</b><br/>ED</li> </ul> |
|---|---|---|---|

# Nurturing of Three Disease Areas:

Autoimmune disease, Diabetes and Kidney Disease, CNS disease

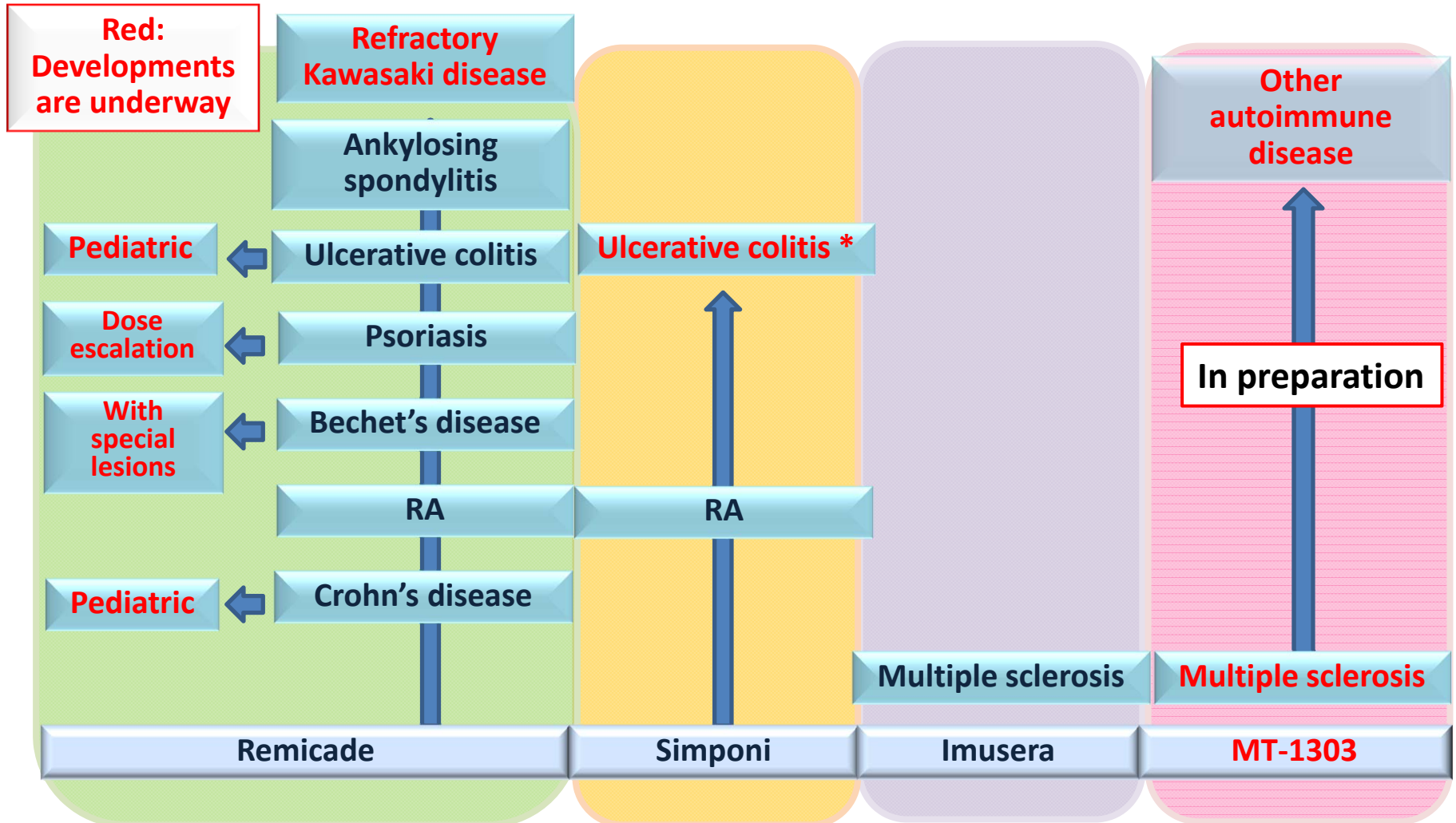


# Nurturing of Autoimmune Disease Area



# Nurturing of Autoimmune Disease Area

## Expansion of indication based on Remicade experiences



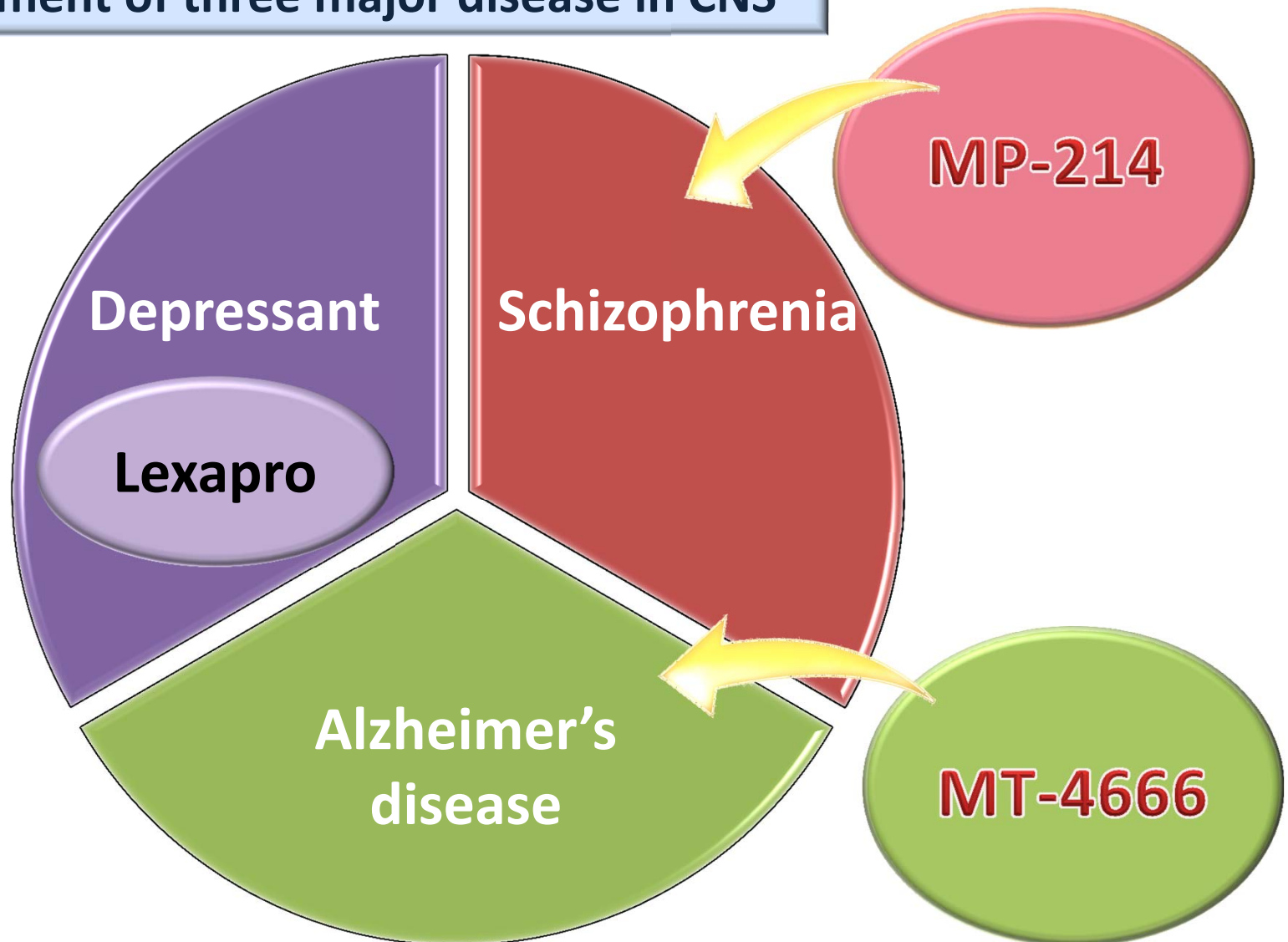
\*: developed by Janssen Pharmaceutical

# MT-1303 for Multiple Sclerosis

<b>Mechanism of action</b>	<b>S1P receptor functional antagonist</b>
<b>Indication</b>	<b>Multiple sclerosis and other autoimmune disease</b>
<b>Development stage</b>	<b>Japan: Phase1 Europe: preparing for Phase2b</b>
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ <b>Equivalent efficacy to FTY720 (Imusera)</b></li><li>➤ <b>Circulatory system side effects have been eliminated, and the high level of safety that is better than others</b></li><li>➤ <b>Using FTY720 (Imusera) development know-how</b></li><li>➤ <b>Are now considering development for indications other than MS, using Remicade development know-how</b></li></ul>

# Nurturing of CNS Disease Area

## Complement of three major disease in CNS



## CNS disease area

**Alzheimer's  
disease**

Clinical symptom,  
for example: problem  
behavior

Cognition  
disorder

**Schizophrenia**

Negative symptom  
Positive symptom

**MT-4666**

(P2b in Japan)

**MP-214**

(P2b/3 in Japan,  
Korea and Taiwan)

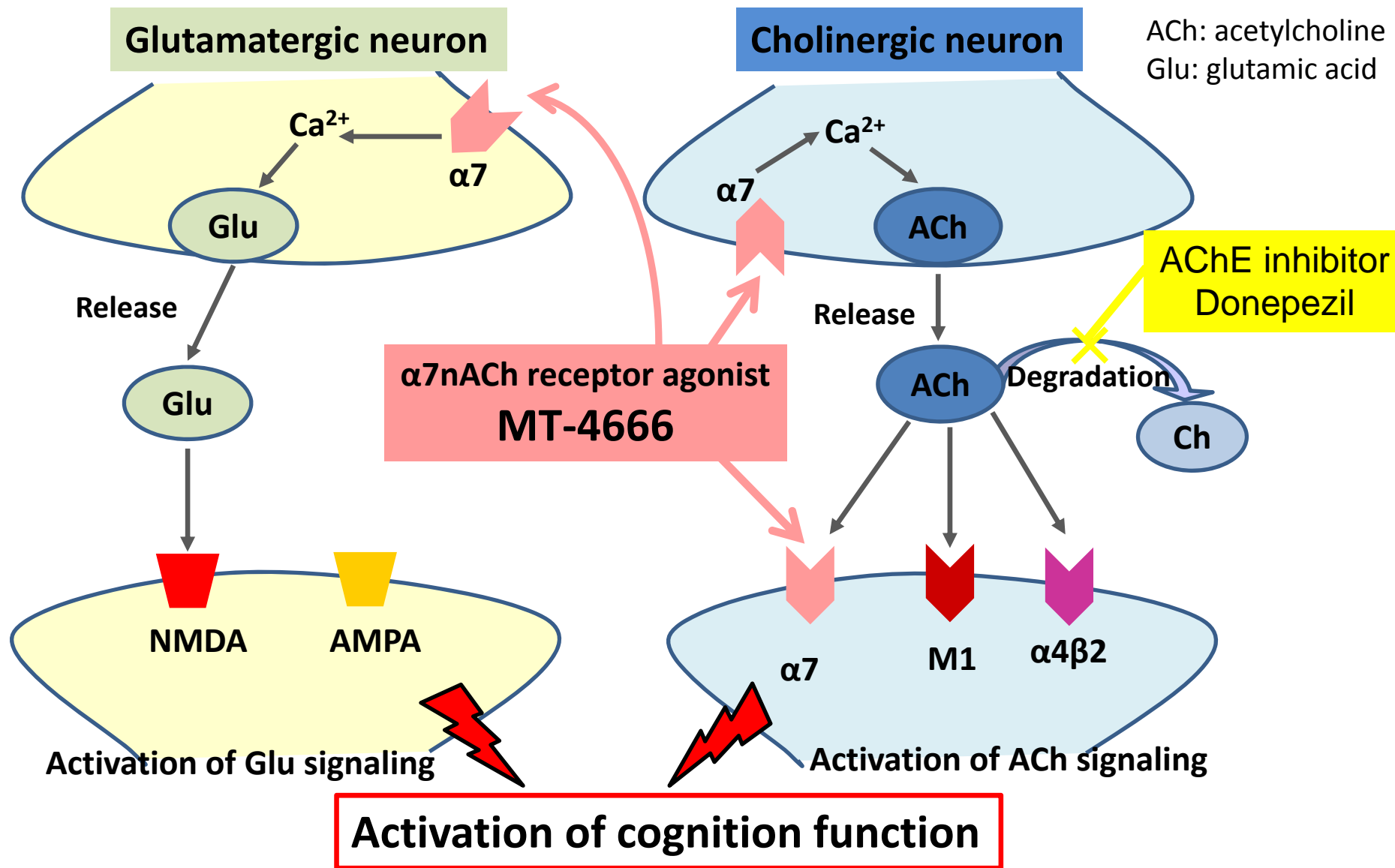
# MP-214 (cariprazin) for Schizophrenia

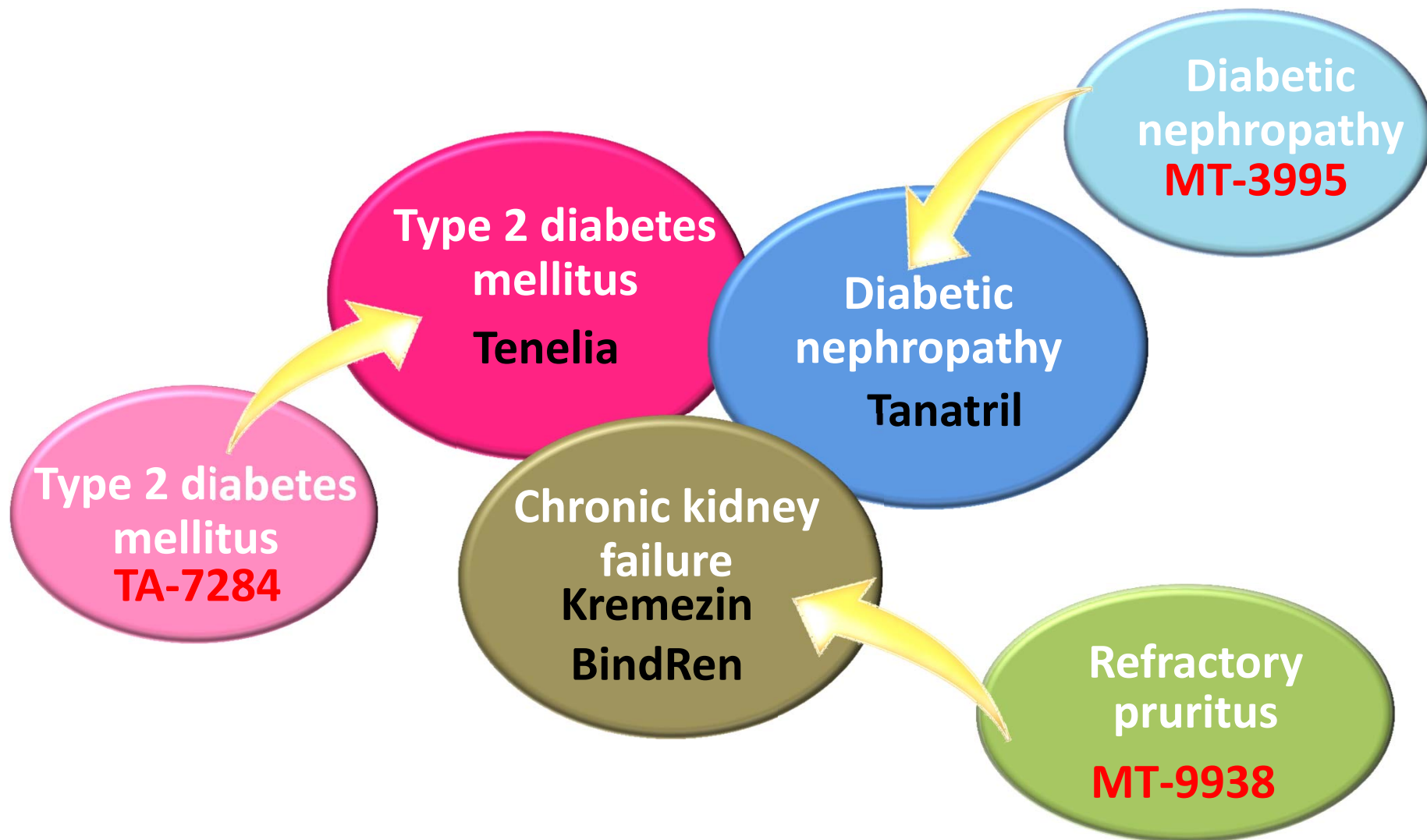
<b>Mechanism of action</b>	D3/D2 receptor partial agonist
<b>Indication</b>	Schizophrenia
<b>Development stage</b>	Japan, Korea, Taiwan: Phase2b/3
<b>Originator</b>	Gedeon-Richter (Hungary)
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ <b>Expected to show efficacy for both positive symptoms and negative symptoms</b></li><li>➤ <b>With limited side effects, it is expected to be suitable for long-term use</b></li><li>➤ <b>P3 results in Europe and the U.S. for schizophrenia show results equivalent to or better than aripiprazole.</b></li></ul>

# MT-4666 for Alzheimer's Disease

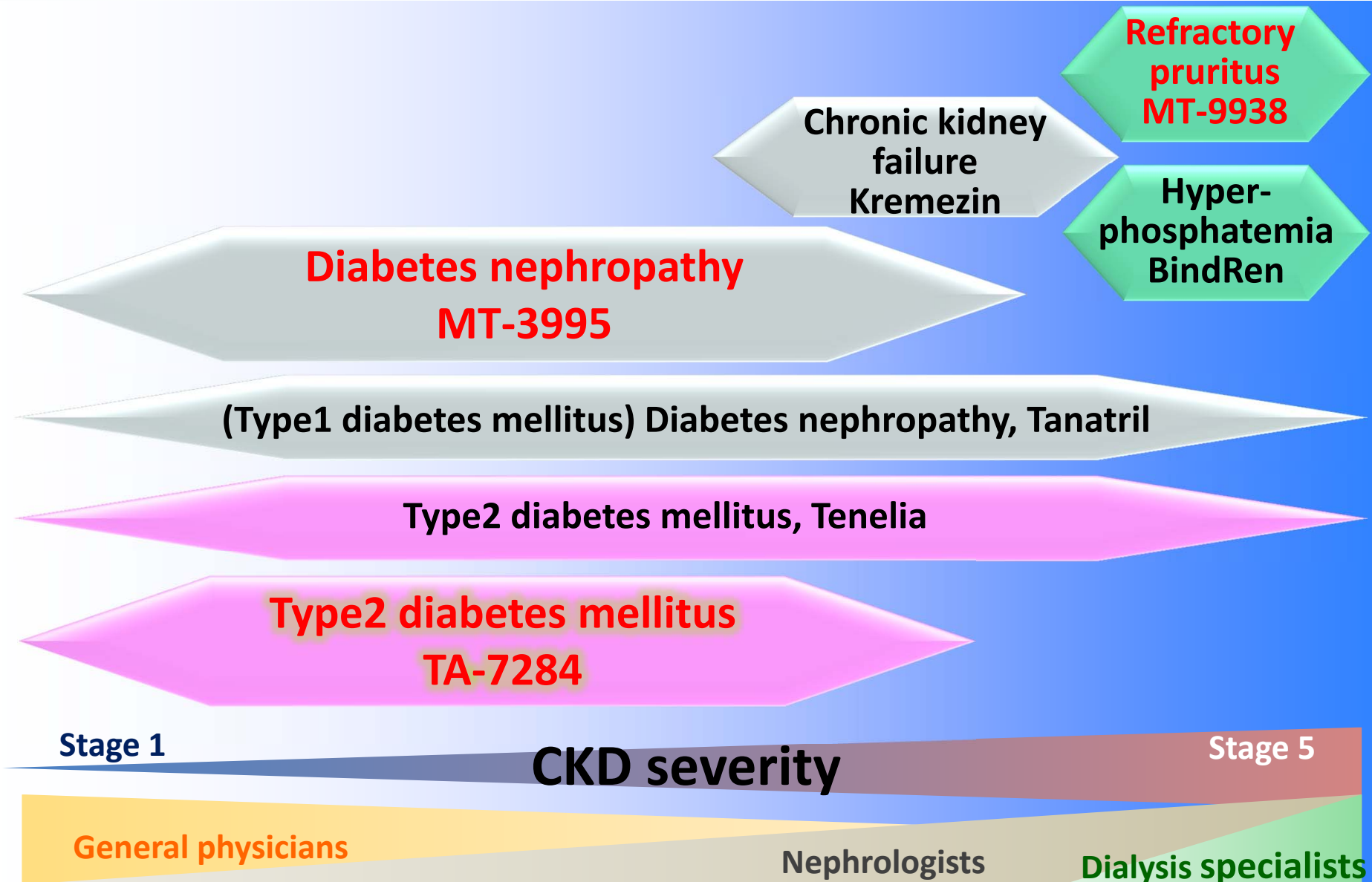
<b>Mechanism of action</b>	$\alpha 7$ nACh receptor agonist
<b>Indication</b>	Japan: Alzheimer's disease
<b>Development stage</b>	Japan: Phase2b
<b>Originator</b>	EnVivo (US)
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ In phase 2b trials overseas (in vivo), it had good results in improving cognitive function and clinical symptoms in Alzheimer's (expected to be first in class).</li><li>➤ Expected to be used concomitantly with such drugs as donepezil, rivastigmine, and galantamine</li></ul>

# MT-4666, Treatment for Alzheimer's disease





# Nurturing of Diabetes and Kidney Disease Area



# MT-3995 for Diabetes Nephropathy

<b>Mechanism of action</b>	<b>Selective mineralocorticoid receptor antagonist</b>
<b>Indication</b>	<b>Diabetes nephropathy</b>
<b>Development stage</b>	<b>Japan: Phase1 Europe: Phase2 (Feb. 2012)</b>
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ <b>In pre-clinical trials, anti-albuminuria effects confirmed</b></li><li>➤ <b>Has non-steroid structure, avoids sex hormone related side effects.</b></li><li>➤ <b>As a new generation mineralocorticoid receptor antagonist, phase 2 trials have begun for diabetic nephropathy.</b></li></ul>

# MT-9938 for Refractory Pruritus

<b>Mechanism of action</b>	<b><math>\kappa</math>-opioid receptor agonist</b>
<b>Indication</b>	<b>Refractory pruritus (for hemodialysis patients)</b>
<b>Development stage</b>	<b>US: Phase2b</b>
<b>Distinctive features</b>	<ul style="list-style-type: none"><li>➤ <b>Fewer physical and mental addiction, compared with morphine</b></li><li>➤ <b>Action on CNS and inhibition of pruritus independent from histamine, liver and kidney failure</b></li><li>➤ <b>Expected to be first in class</b></li></ul>

# Other Initiatives: Operational and Structural Reforms

A decorative horizontal bar with a blue-to-teal gradient, starting as a solid blue bar on the left and fading into a light teal gradient on the right.

## Vaccine Business Policy

- In addition to the discovery and provision of drugs to treat diseases, by supplying vaccines we will also contribute to improving the QOL of patients in the area of disease prevention.
  - We will bolster our domestic foundation, centered on our relationship with BIKEN.
    - We will take steps to contribute to maximizing value as the top domestic brand, such as offering an influenza vaccine, a Japanese encephalitis vaccine, and a combination vaccine for four diseases.
    - Launch of Tetra vaccine, Tetrabik
  - We will independently in-license competitive products and technologies, develop and provide new products, with consideration for global use
    - Build a system that is suitable for production and development in cooperation with Medicago
    - Consider cooperative activities with a view to global development

## Generics Business Policy

- Provide “Reliable Generics” that leverage the strengths of the Group’s organizational foundation (new drugs, specialized areas)

### <Environmental Changes>

- Market growth due to progress in measures to promote the use of generics
- Intensifying competition due to new market entrants and bolstered operations



- Response to major drugs coming off patent
- Strengthen the earning power using the group marketing foundation at a maximum (not only Tanabe Seiyaku Hanbai but also MTPC and Yoshitomiya-kuhin)
- Targeting the FY2015 sales objective of ¥50.0 billion, we will further enhance our presence, with consideration for strategic tie-ups.

# Bolstering of Major Base Function

## Medium-Term Management Plan 11-15

### Bolstering of Major Base Function

#### Research facilities

- **Research Headquarters: Completed transfer/consolidation of research functions at Yokohama and Toda.**
- **CMC Research Center: Bolstered CMC research facilities at Kashima.**

#### Head office, etc.

- **Completed reorganization / relocation of Tokyo head office building (Nihonbashi, Sanbancho)**
- **Construction / relocation of Osaka head office building**
- **Constructed Kashima office building**

# Bolstering Production Bases

**New drug production building at Tianjin Tanabe**  
(Start construction in 2013, finish in 2015)



(Tianjin, China)

**Bolster production capacity to accommodate demand growth in China and Asia.**

**New drug production building at P.T. Tanabe Indonesia**  
(Start construction in 2013, finish in 2014)



(Bandung, Indonesia)



**New drug production building at Yoshitomi Plant (Fukuoka Prefecture)**  
(Start construction in 2014, finish in 2016)



**Enhance new drug supply system and achieve optimal production system**

**New drug production building at Onoda Plant (Yamaguchi Prefecture)**  
(Start construction in 2014, finish in 2016)



**During the period covered by the current medium-term management plan, we will invest a total of about ¥20.0 billion to build new plants to global standards at production bases in Japan and overseas. In addition, we will strengthen the clinical drug facility function.**

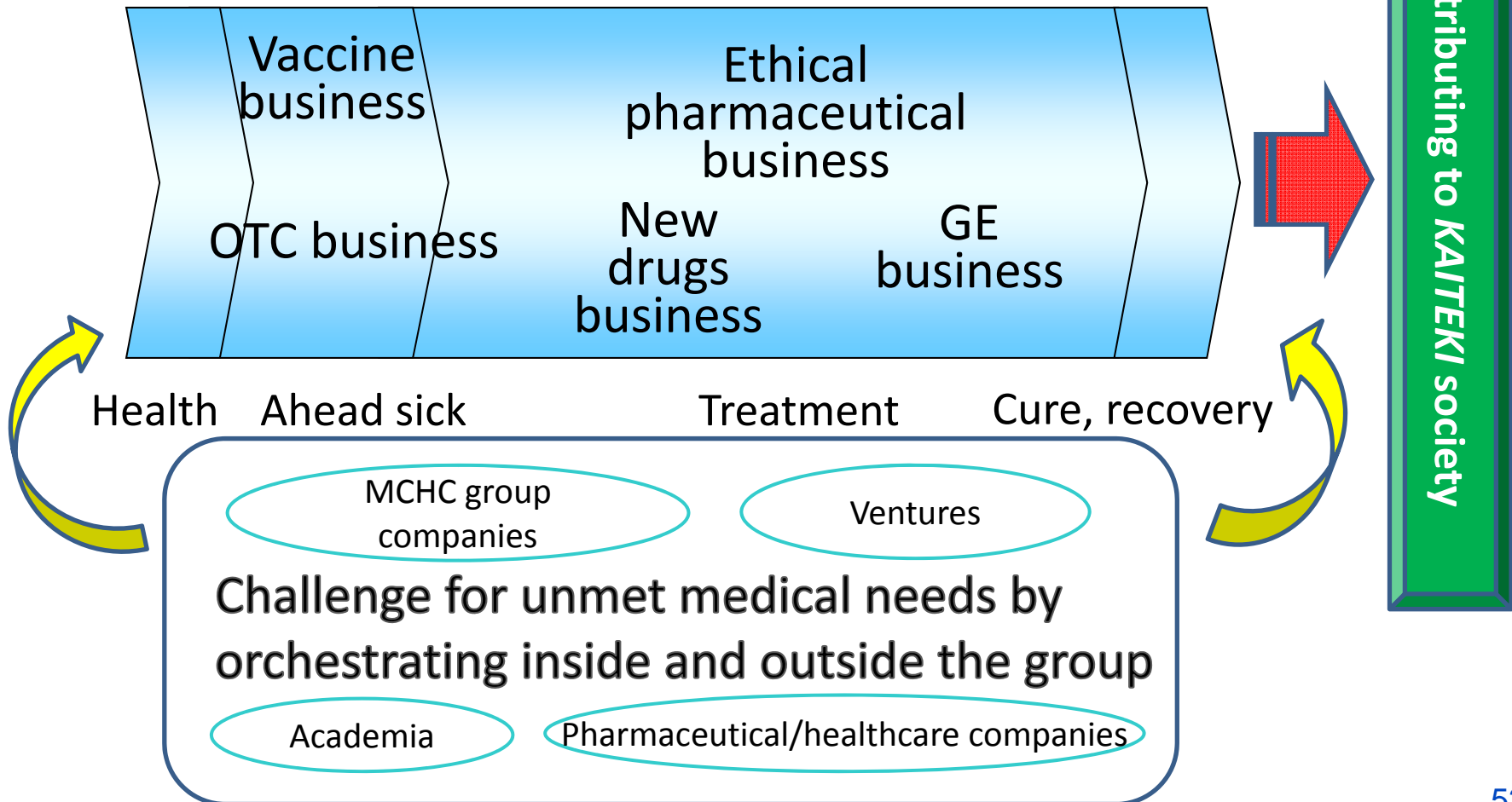
## Other Initiatives

Contributing to *KAITEKI* Society by orchestrating



# Contributing to *KAITEKI* Society by orchestrating

Creation and provision of the drugs meeting unmet medical needs



# Toward Achievement of FY2015 Targets



# Growth Drivers in the Future

Creating a sustained growth by increasing revenues from home and abroad

Launch of the promising pipeline

MT-1303	MP-214	MT-4666
MT-3995	MT-9938	

Overseas: Expansion of royalty income

Gilena TA-7284

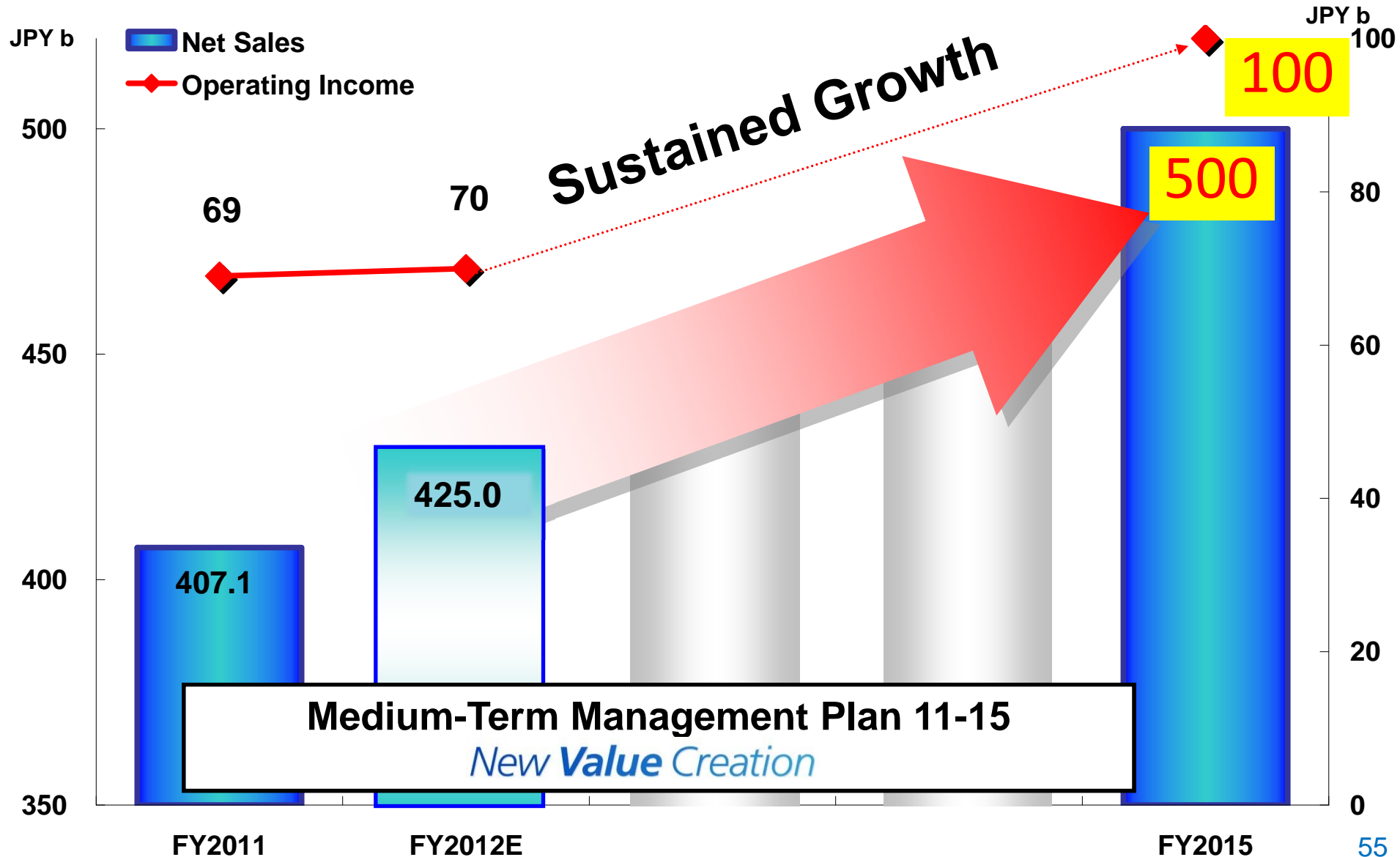
Japan: Nurturing of new products and priority products

Remicade, Talion, Simponi, Lexapro, Telavic, Imusera, Tenelia, Tetrabik, TA-7284 (under development)

Medium-Term Management Plan 11-15 (-FY2015)

FY2016-

# Toward Achievement of FY2015 Targets



# *New Value Creation*

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

## **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.**