

Mitsubishi Tanabe Pharma Corporation Information Meeting

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

February 21, 2013

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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

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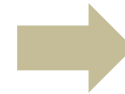
Operating Environment in the Pharmaceutical Industry

New **Value** Creation



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

New **Value** Creation

Success in These Two Years



**Bolstering Our
Ability to
Discover New
Drugs**

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

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

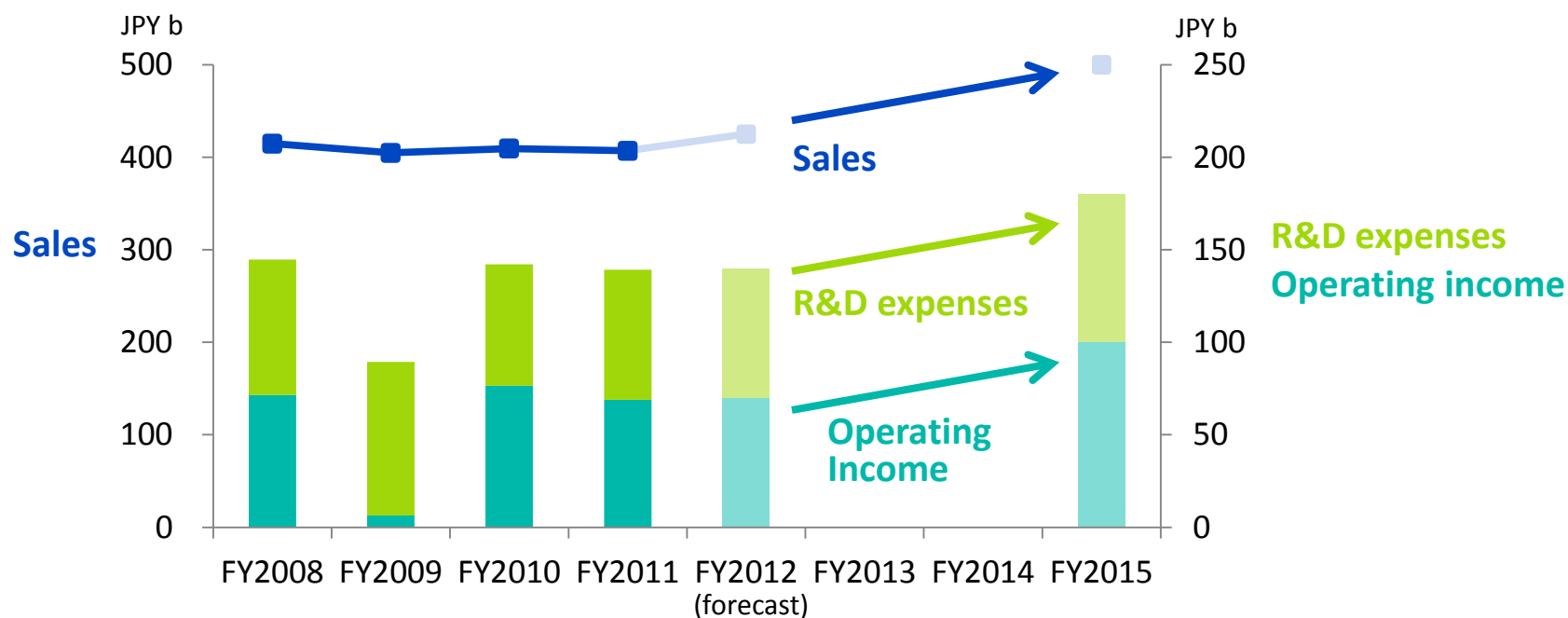
**Accelerating
Operational
and Structural
Reforms**

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
Sales	¥ 407.1 billion	¥ 425.0 billion	¥ 500.0 billion
Operating income	¥ 69.0 billion	¥ 70.0 billion	¥ 100.0 billion
Overseas sales ratio	7.0%	9.6%	15% +



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



For the patients –the improvements of health and treatment satisfaction-

For the patients



Future Marketing Strategy that Reflects System Reforms

New **Value** Creation



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

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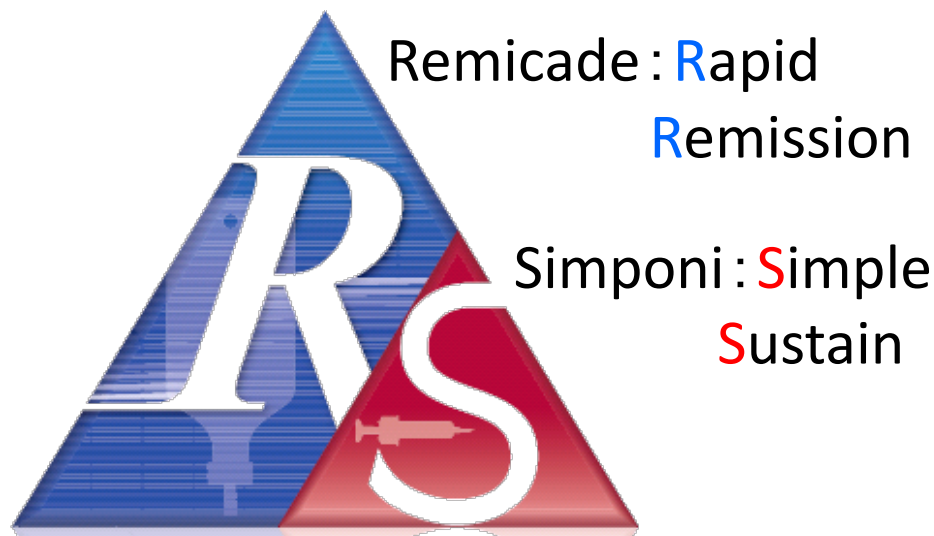
Remicade & Simponi: Advantages

■ 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.

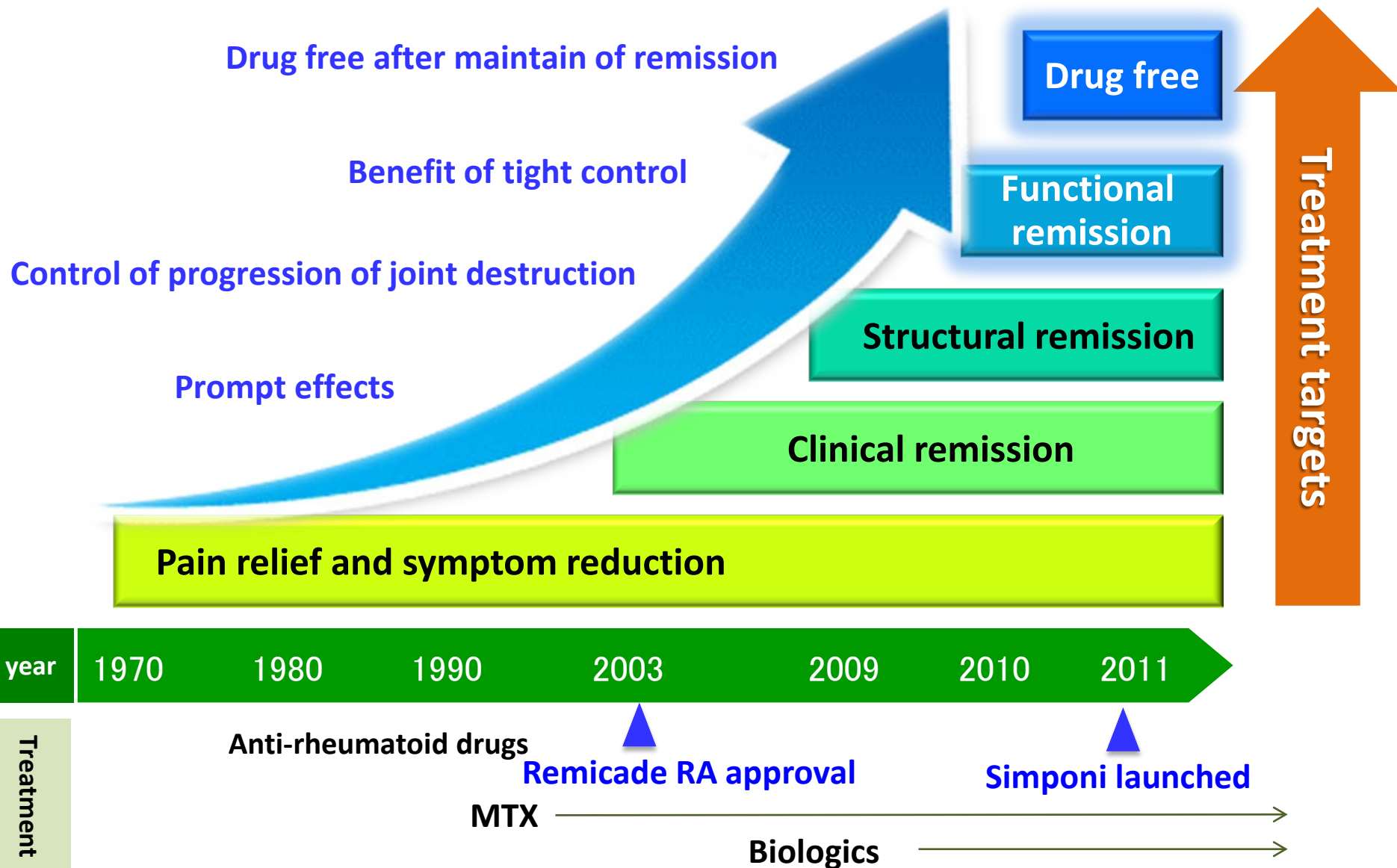
■ Advantages shared by both drugs

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



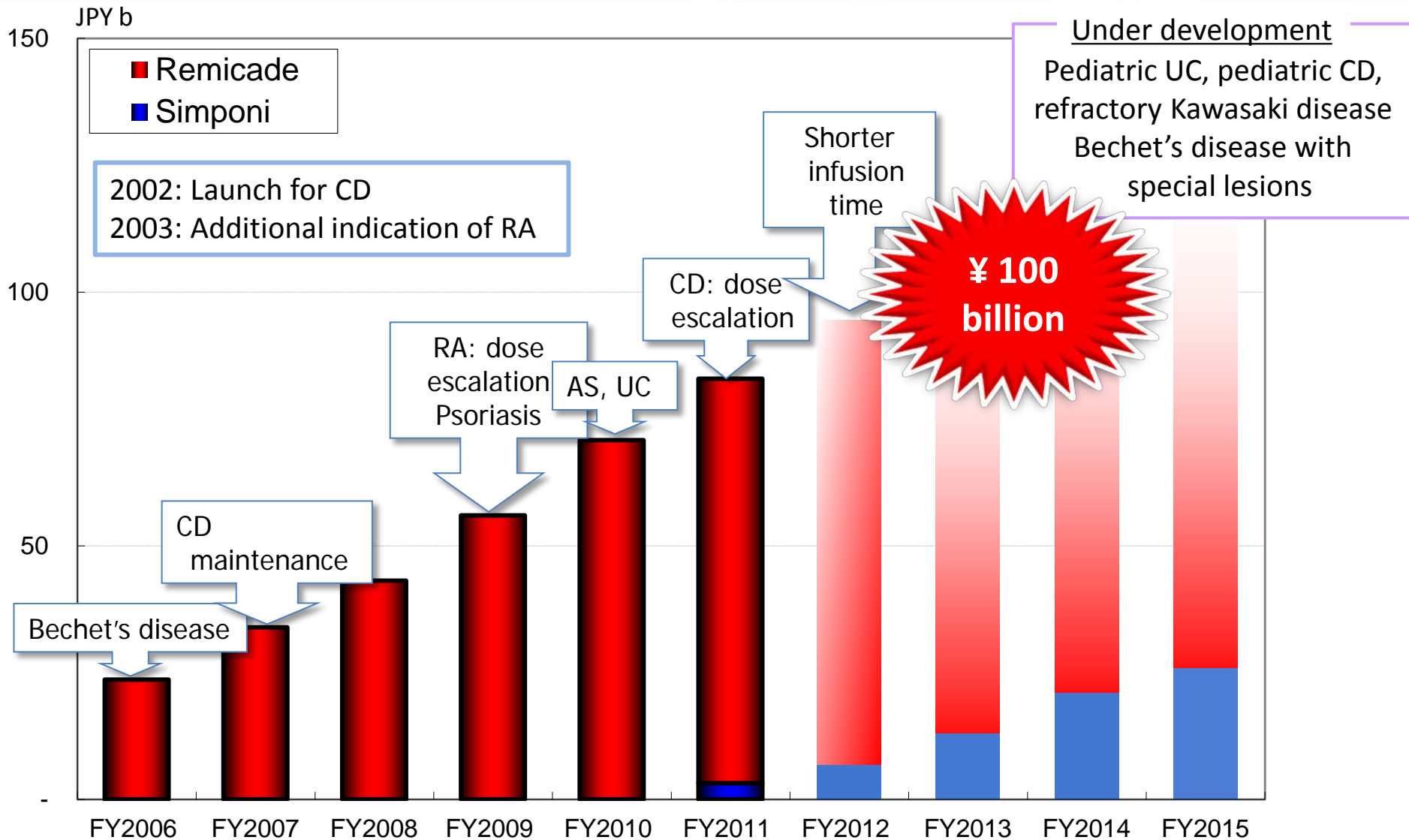
Remicade & Simponi: Meeting the Next Treatment Needs in RA

New **Value** Creation



Remicade & Simponi: ¥ 100 billion of Sales in FY2013

New Value Creation

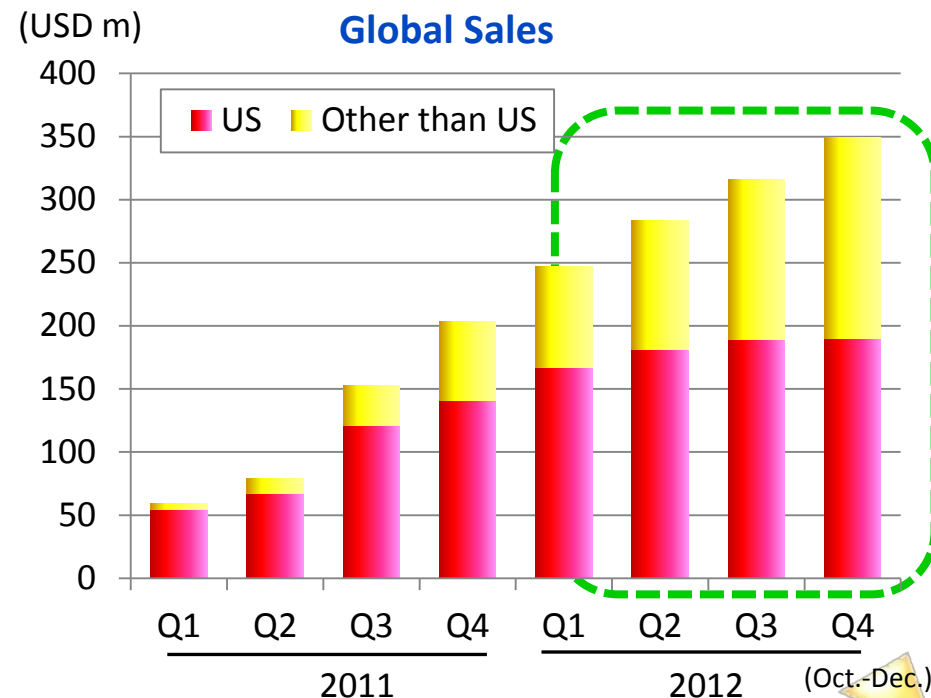


CD: Crohn's disease, RA: rheumatoid arthritis, AS: ankylosing spondylitis, UC: ulcerative colitis

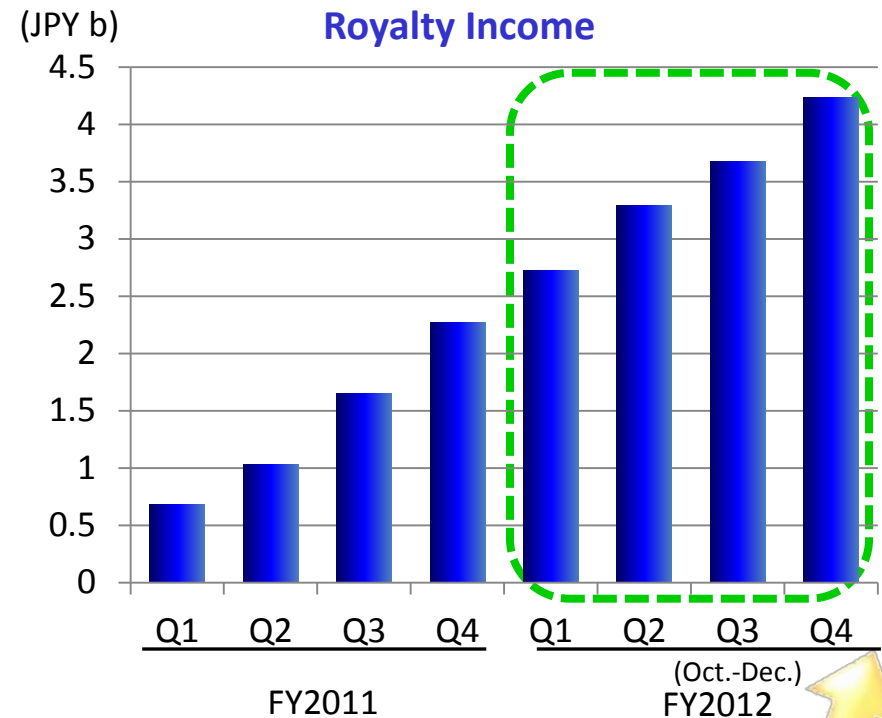
Growth of Gilenya/Imusera

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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



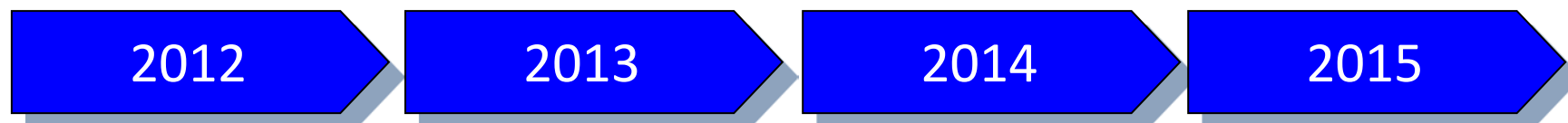
Royalty Income
¥13.9 billion

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

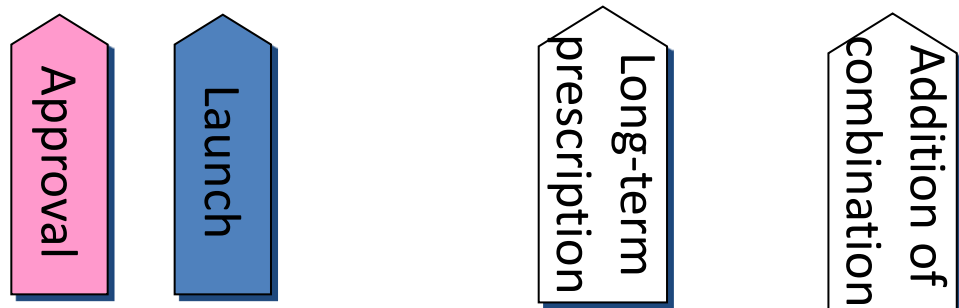


Schedule of MTPC's Diabetic Drugs in Japan

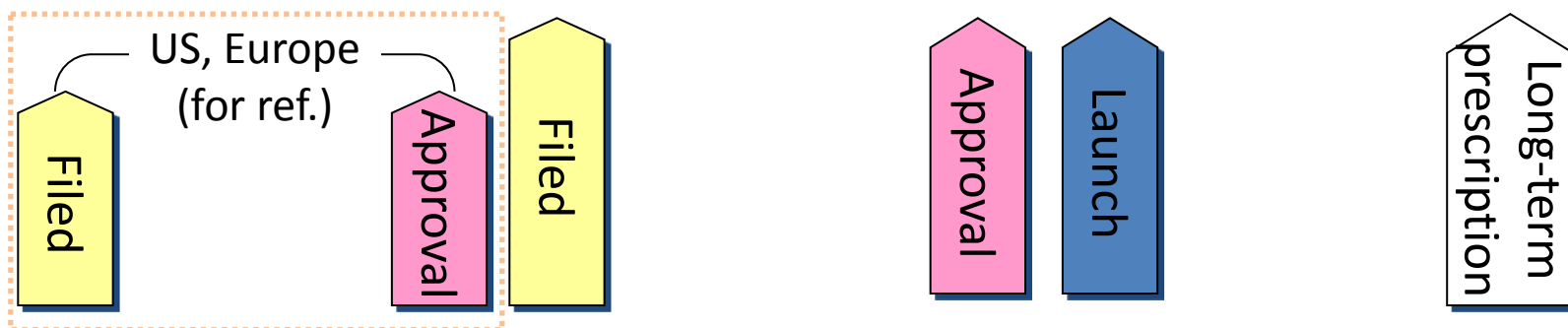
New **Value** Creation



Tenelia (DPP-4 inhibitor)



TA-7284/Canagliflozin (SGLT2 inhibitor)



Tenelia: Priority Issues

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

Tenelia & TA-7284

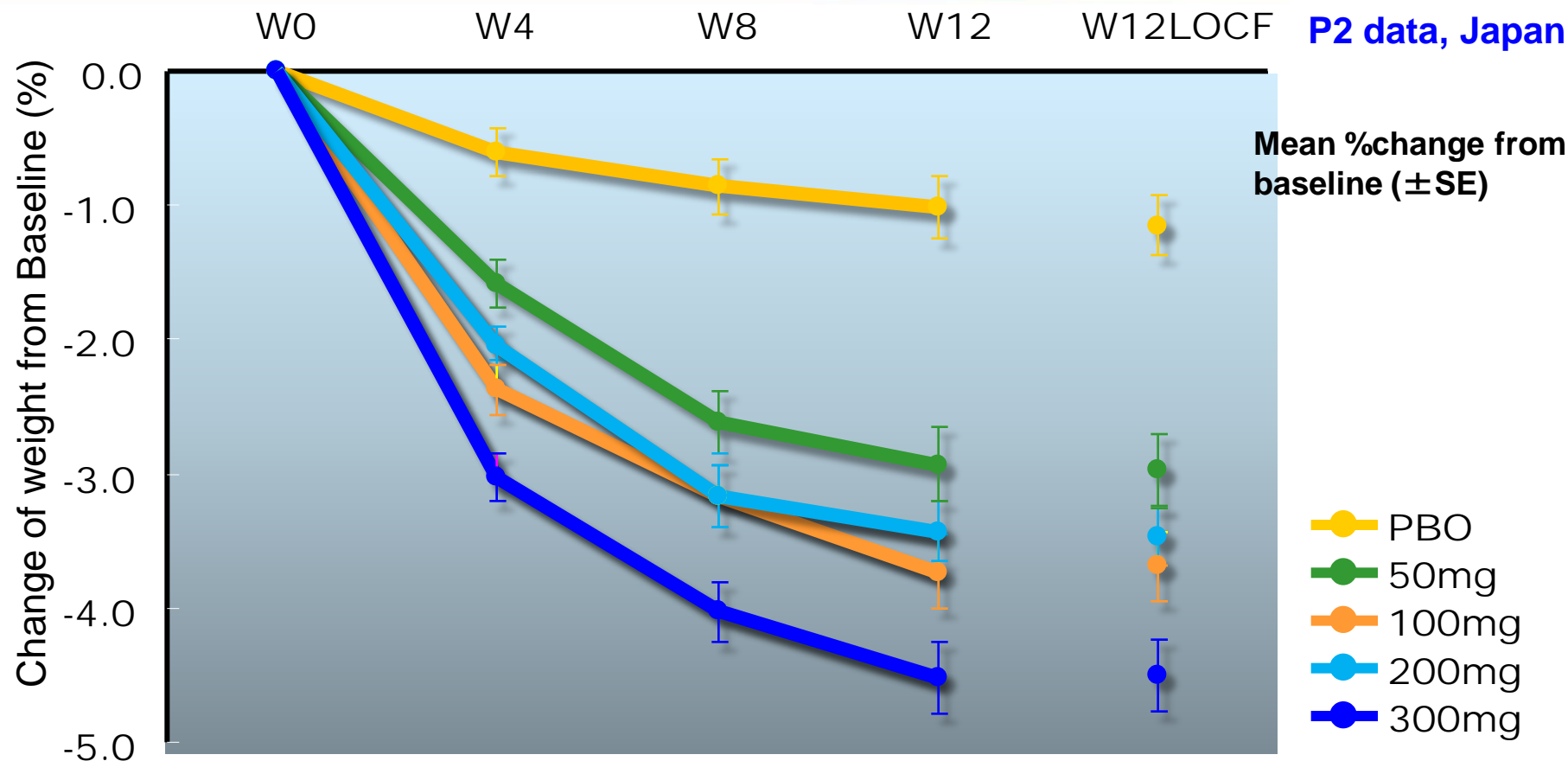
Top tier presence in domestic market (diabetes field)

TA-7284 (SGLT2 inhibitor): Distinctive Features

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

TA-7284(SGLT2 inhibitor): Body Weight Reduction

New **Value** Creation

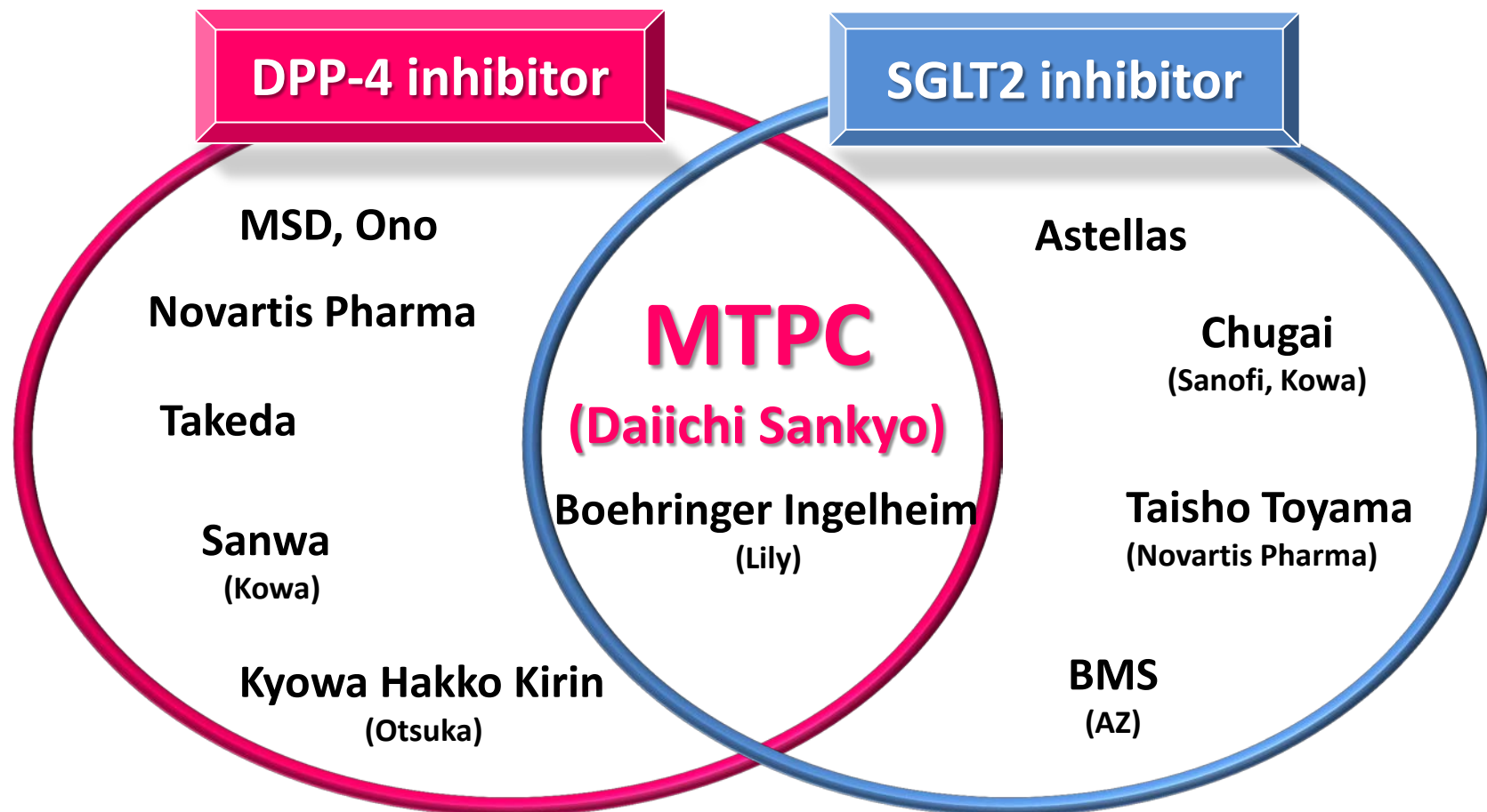


	PBO	50mg	100mg	200mg	300mg
n	75	82	74	76	75
BW at BL (kg)	72.56 \pm 15.36	65.77 \pm 13.56	68.61 \pm 14.86	68.97 \pm 14.50	71.30 \pm 12.19

Advantage in Diabetic Area

■ Major marketing authorization holders

(): Co-marketing or co-promotion

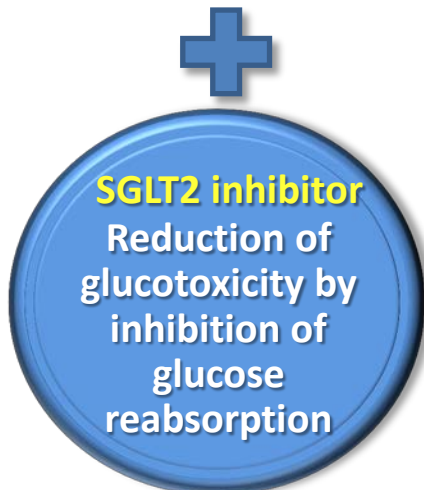
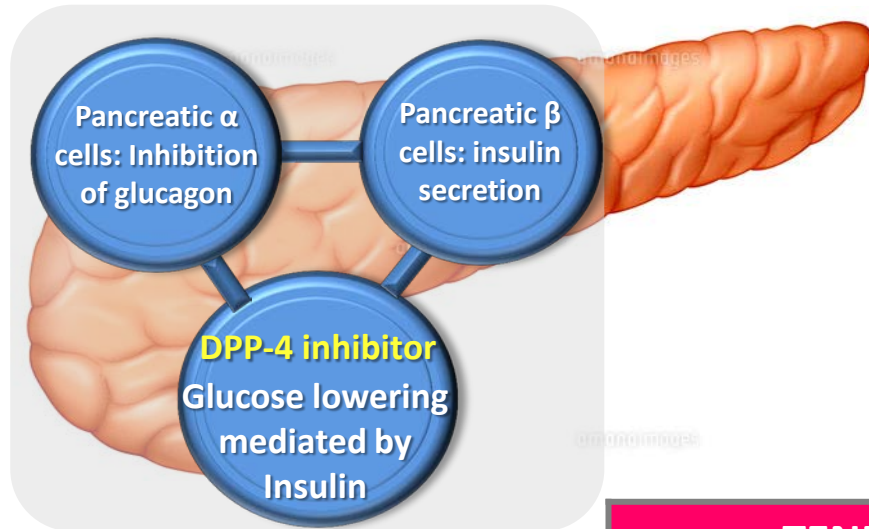


**MTPC and Boehringer Ingelheim
are the originators having both drugs**

Ideal Diabetic Treatment brought about by Two Mechanisms of Action

Gentle treatment for pancreatic β cells

Physiological insulin secretion by incretin



Reduction of CV risks by TENELIA® 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®
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)

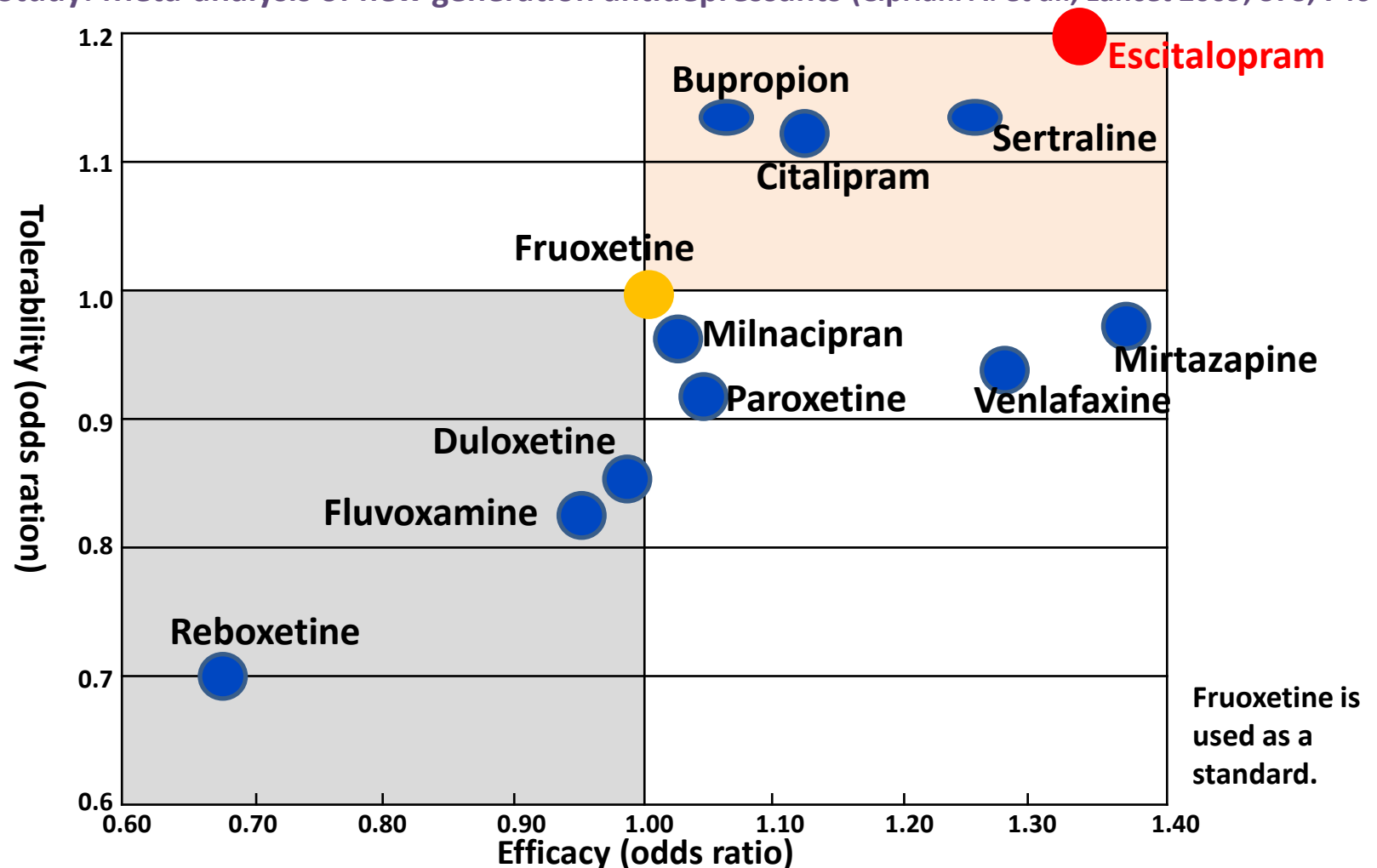
Strategy for Nurturing New Products / Priority Products (Lexapro, Talion, Telavic)



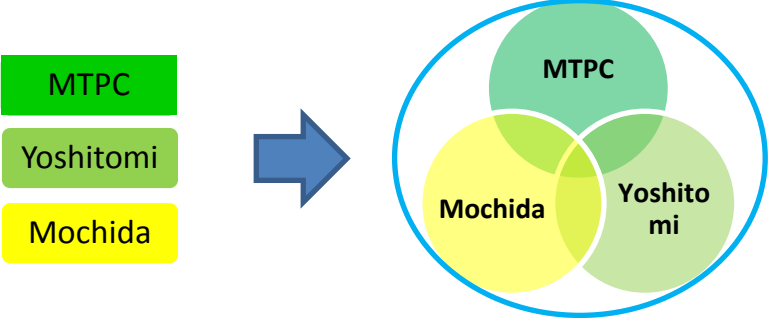
No.1 in MANGA study, famous for meta-analysis of antidepressants

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

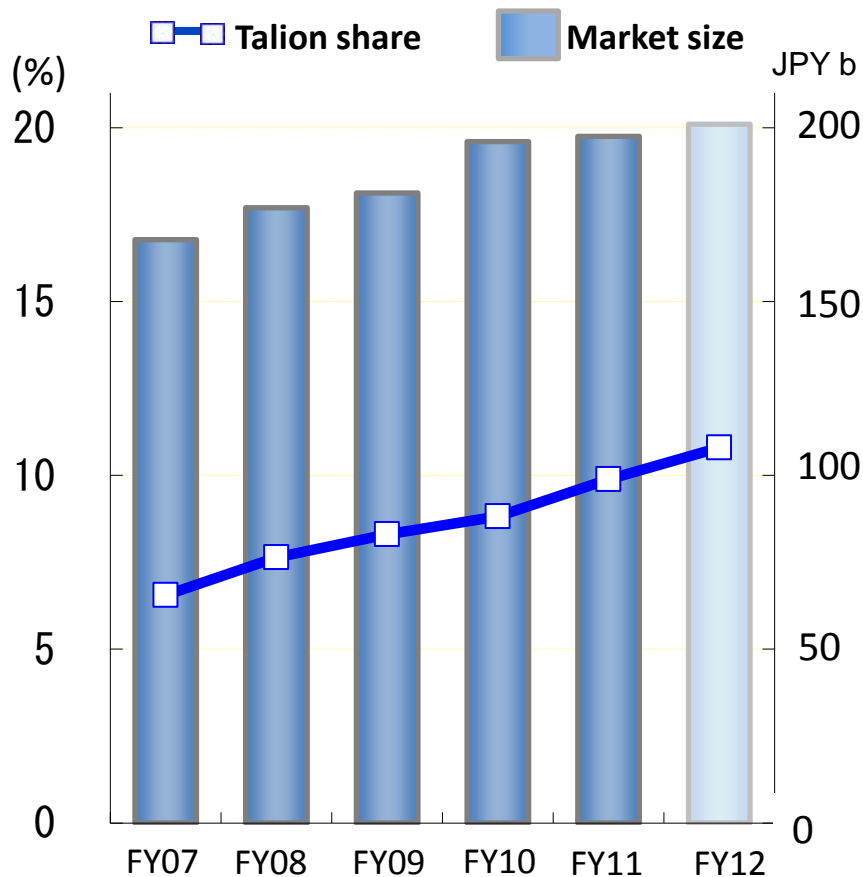
Priority issues		Measures
Short-term	Penetration of the product concept	<p>➤ Strengthening of the marketing information provision system(single visit ⇒ multi visits)</p> 
Med.-to long-term	Maximization of the product value	<p>➤ Evidence in Japan</p> <p>➤ Additional indication: Social anxiety disorder</p>



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.

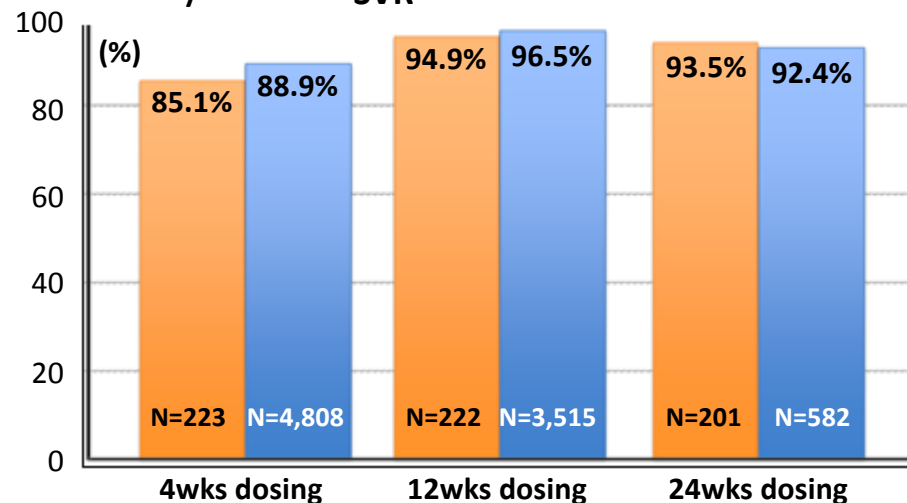
Talion: Priority Issues

Priority Issues	Measures
Increase promotional impact	<p>➤ Continually provide evidence from Japanese patients and strengthen product key message, as domestically produced antihistamine.</p> 
Develop new market	<p>➤ Preparations to obtain additional indication in pediatric field</p>
Capture share in existing market	<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

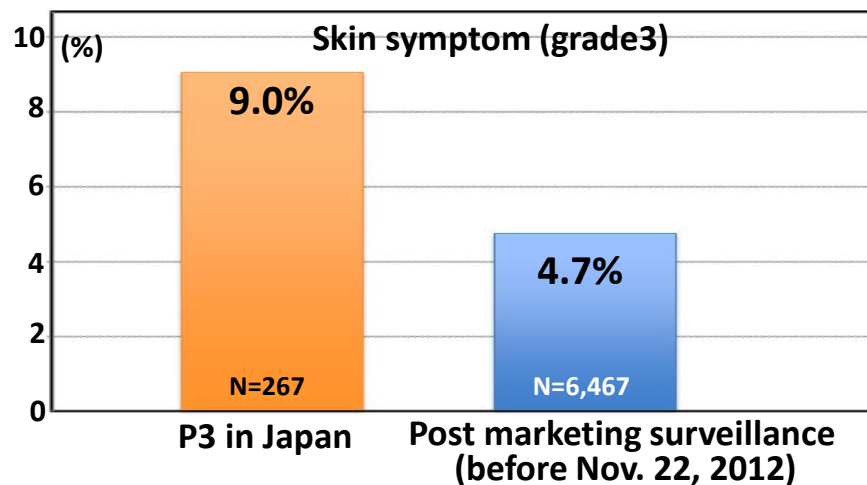
Telaviv: Current Status

■ Efficacy



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

■ Safety

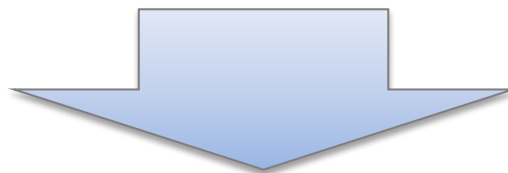


Note: 1,500 mg dosage cases are included in PMS

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	➤ Rapidly expand number of institutions [gastroenterologists] (continued links with dermatology) ➤ Disseminate knowledge about usage methods through Doctor to Doctor* communications
	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

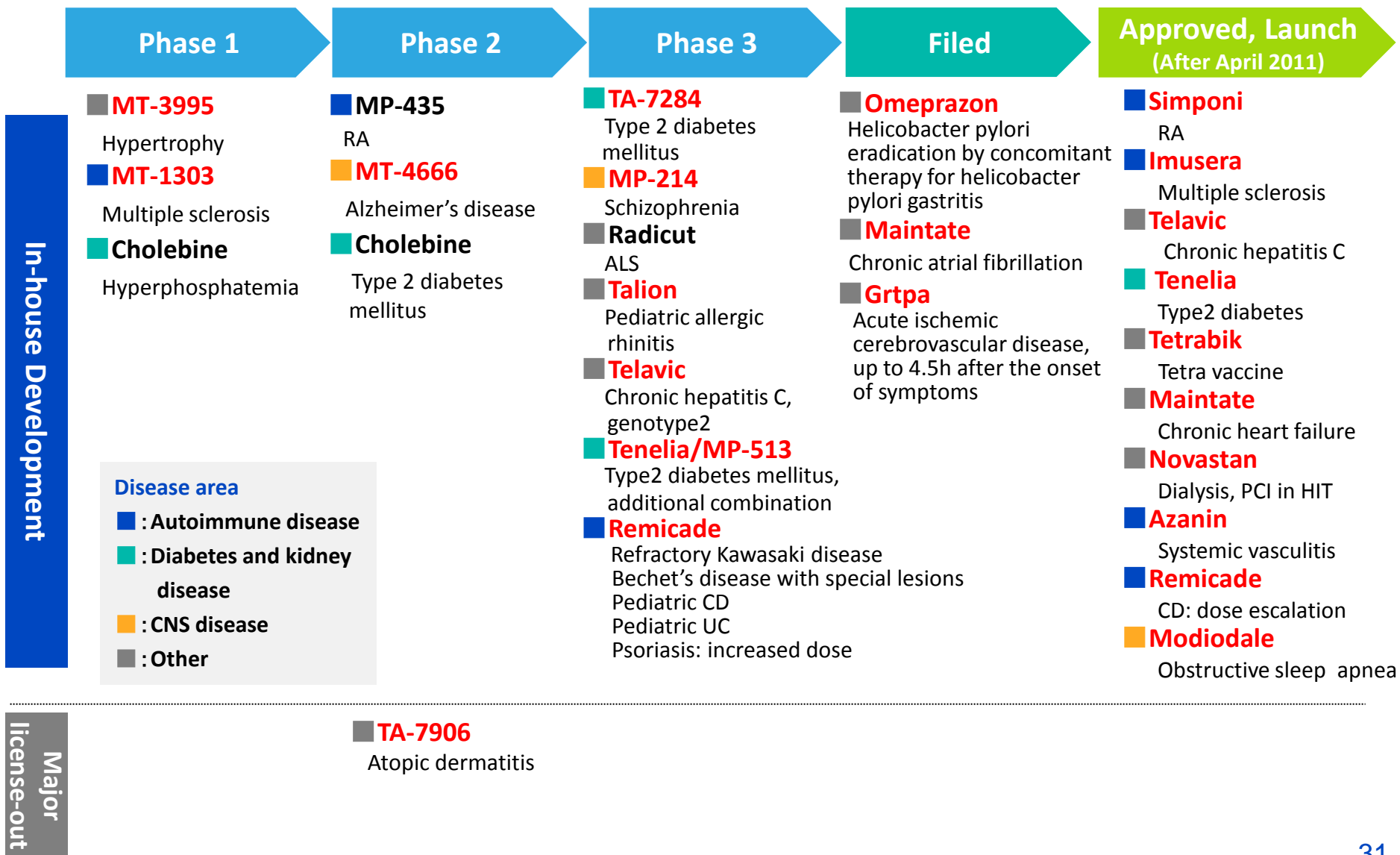
Promising Pipeline (MT-1303, MP-214, MT-4666, MT-3995, MT-9938)

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Pipeline Status (Japan)

Red: progress after April 2011

As of Feb. 1, 2012



Pipeline Status (Overseas)

Red: progress after April 2011

As of Feb. 1, 2012

Phase 1

Phase 2

Phase 3

Filed

Approved, Launch
(After April 2011)

In-house Development

■ **MT-1303 (Europe)**

Multiple sclerosis

■ **MP-513 (US)**

Type2 diabetes mellitus

■ **MT-7716 (US)**

Alcohol-use disorder

■ **MP-124 (US, Canada)**

Acute ischemic stroke

■ **MT-3995 (Europe)**

Hypertension → P2 start in Diabetes nephropathy

■ **MP-157 (Europe)**

Hypertention

■ **GB-1057 (US)**

Stabilizing agent

■ **MT-9938 (US)**

Refractory pruritus

■ **MP-513 (Europe)**

Type2 diabetes mellitus

■ **MP-146(US, Europe)**

Chronic kidney disease

■ **MP-424 (Taiwan)**

Chronic hepatitis C

■ **Talion (China, Indonesia)**

Allergic disease

■ **Simponi (Taiwan, Indonesia)**

RA, ankylosing spondylitis

■ **Livalo (Indonesia)**

Primary hyperlipidemia ,
mixed dyslipidemia

■ **Livalo (Taiwan)**

Primary hypercholesteremia,
mixed dyslipidemia

■ **Exembol (UK)**

HIT type II

■ **BindRen (Europe)**

Hyperphosphatemia

Disease area

■ : Autoimmune disease

■ : Diabetes and kidney disease

■ : CNS disease

■ : Other

■ **TA-7284 (US, Europe)**
Obesity

■ **MP-513 (Korea)**
Type2 diabetes mellitus

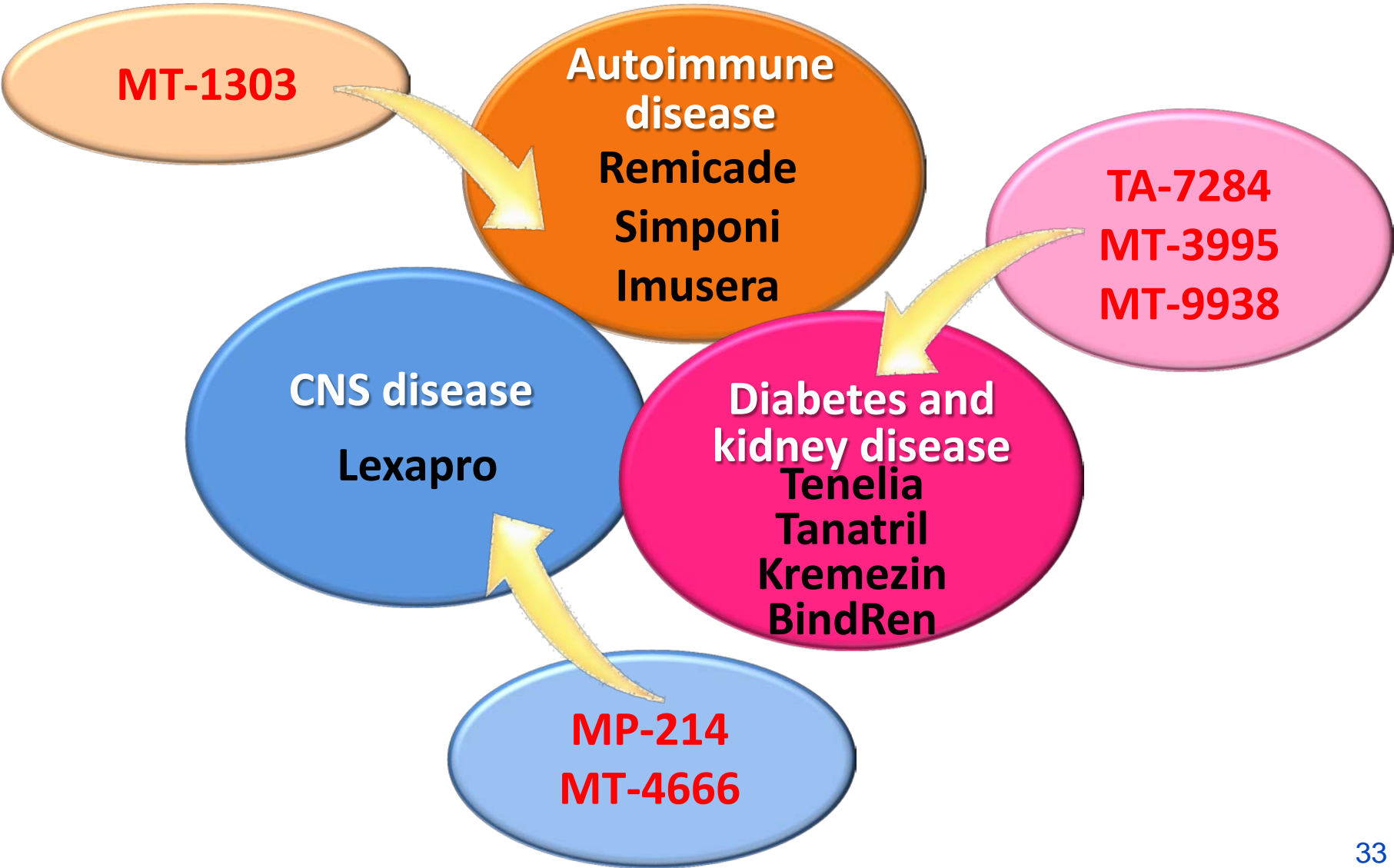
■ **TA-7284 (US, Europe)**
Type2 diabetes mellitus
■ **TA-1790 (Europe)**
ED

■ **TA-1790 (Korea, US)**
ED

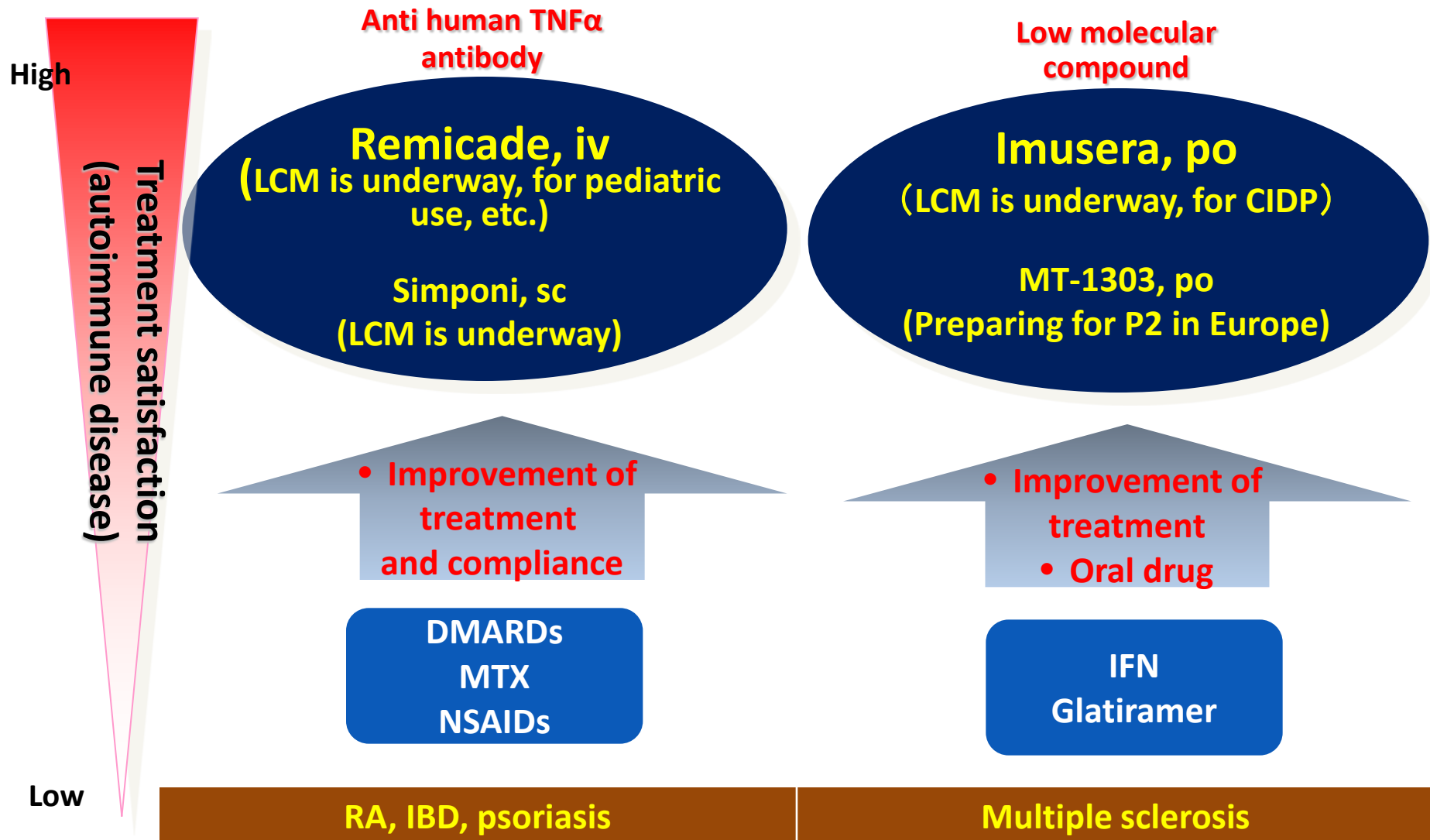
Major
license-out

Nurturing of Three Disease Areas:

Autoimmune disease, Diabetes and Kidney Disease, CNS disease

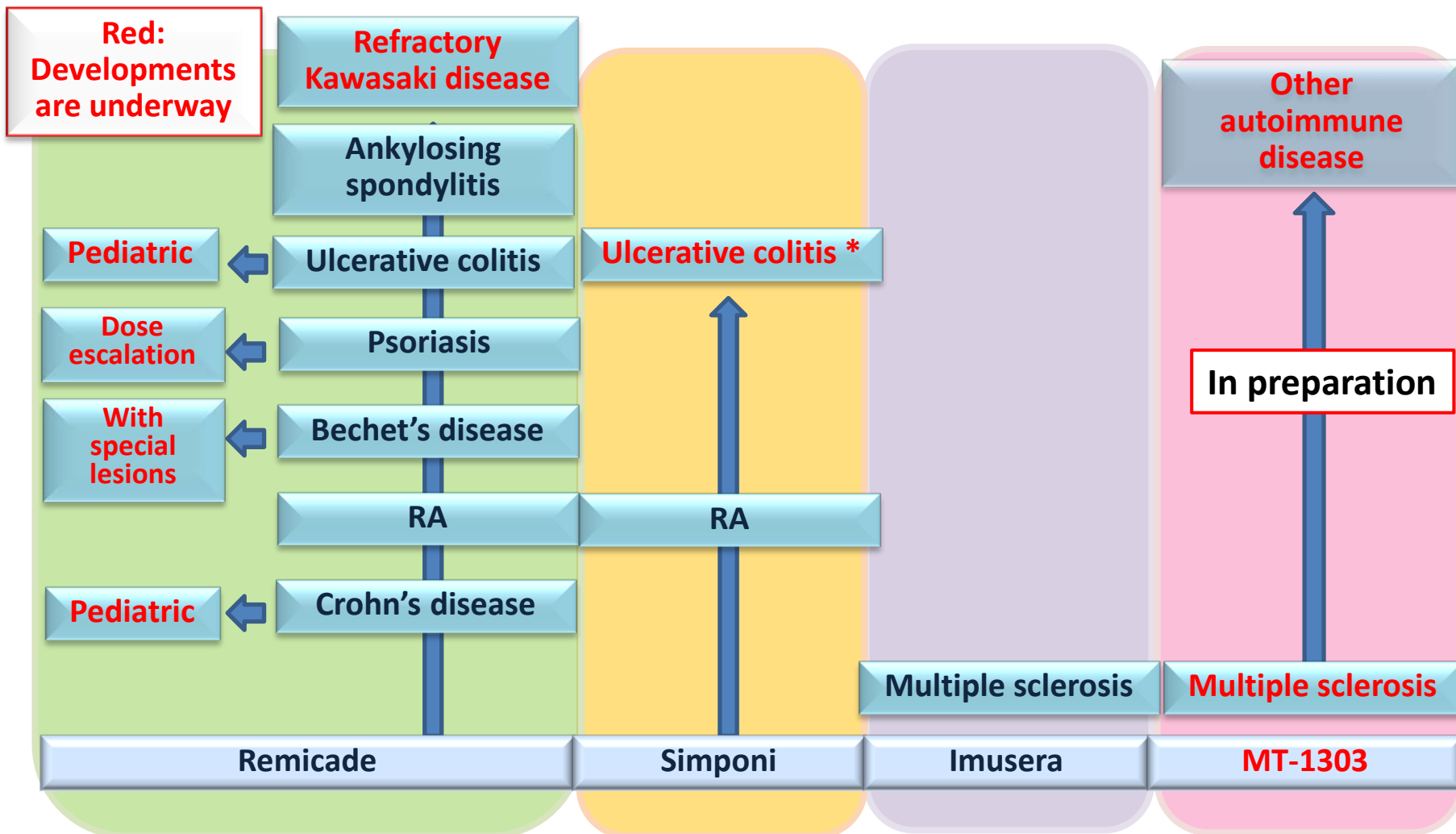


Nurturing of Autoimmune Disease Area



Nurturing of Autoimmune Disease Area

Expansion of indication based on Remicade experiences



*: developed by Janssen Pharmaceutical

MT-1303 for Multiple Sclerosis

New **Value** Creation



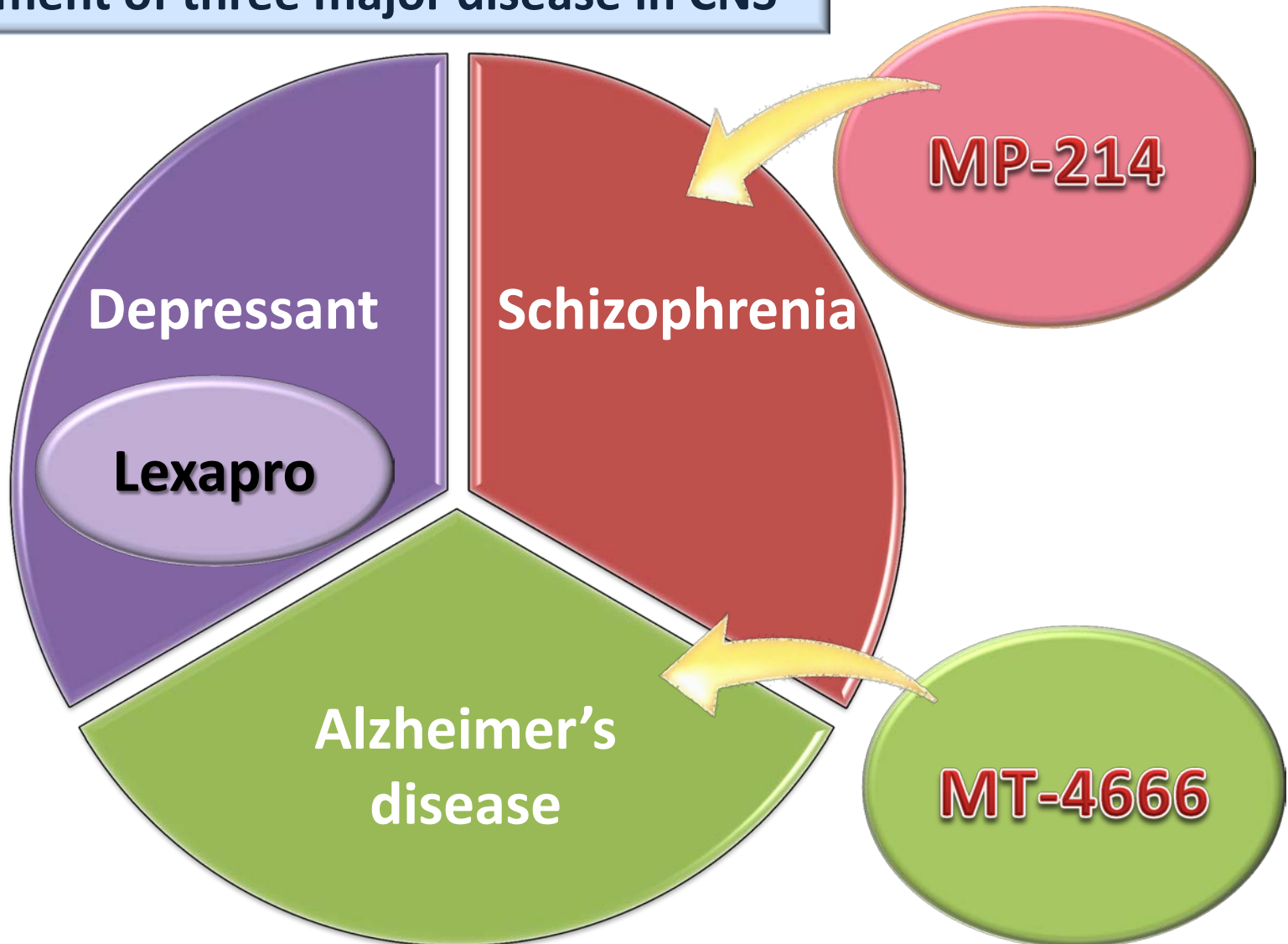
Mechanism of action	S1P receptor functional antagonist
Indication	Multiple sclerosis and other autoimmune disease
Development stage	Japan: Phase1 Europe: preparing for Phase2b
Distinctive features	<ul style="list-style-type: none">➤ Equivalent efficacy to FTY720 (Imusera)➤ Circulatory system side effects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

Nurturing of CNS Disease Area

New **Value** Creation



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)

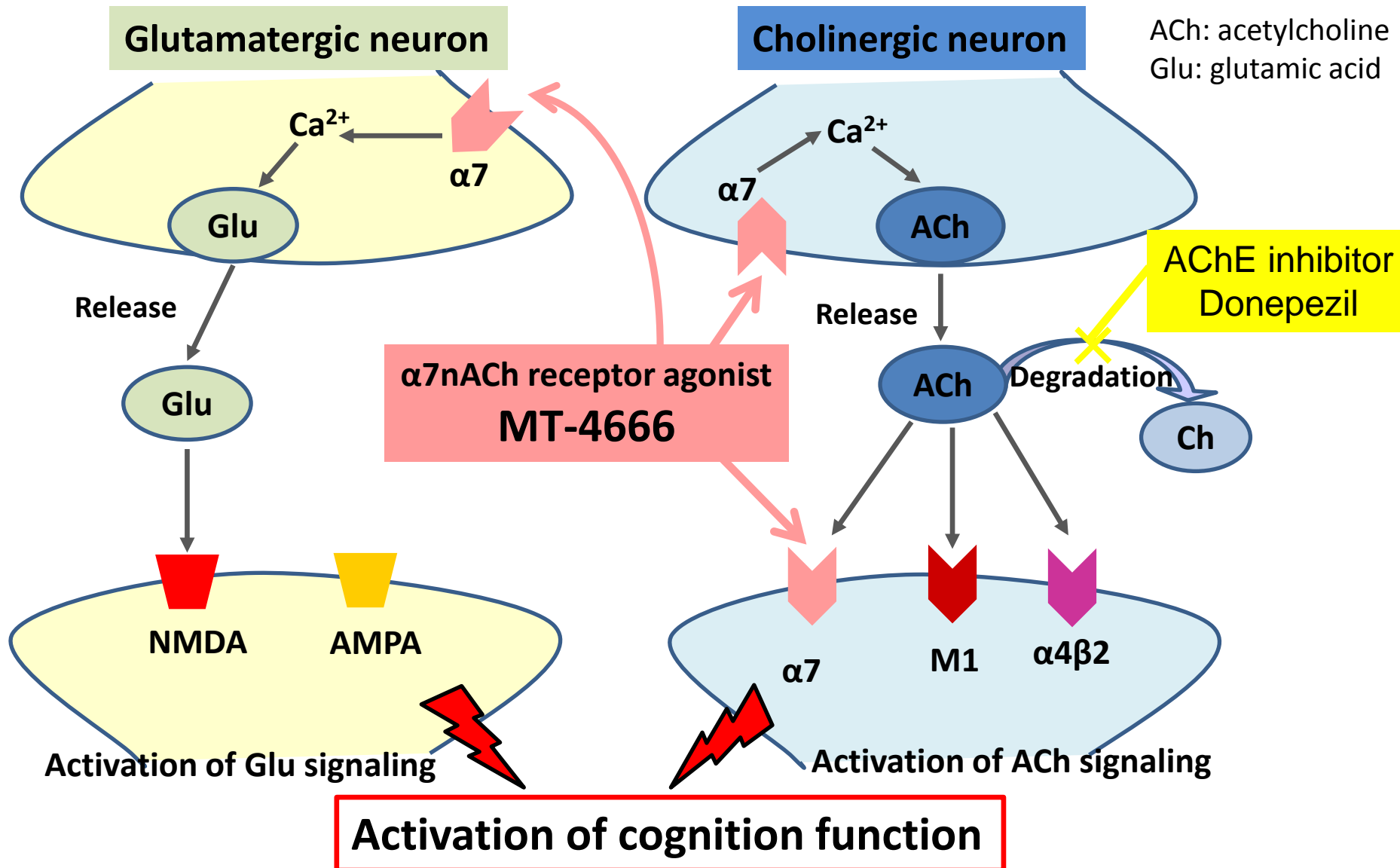
MP-214 (cariprazin) for Schizophrenia

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

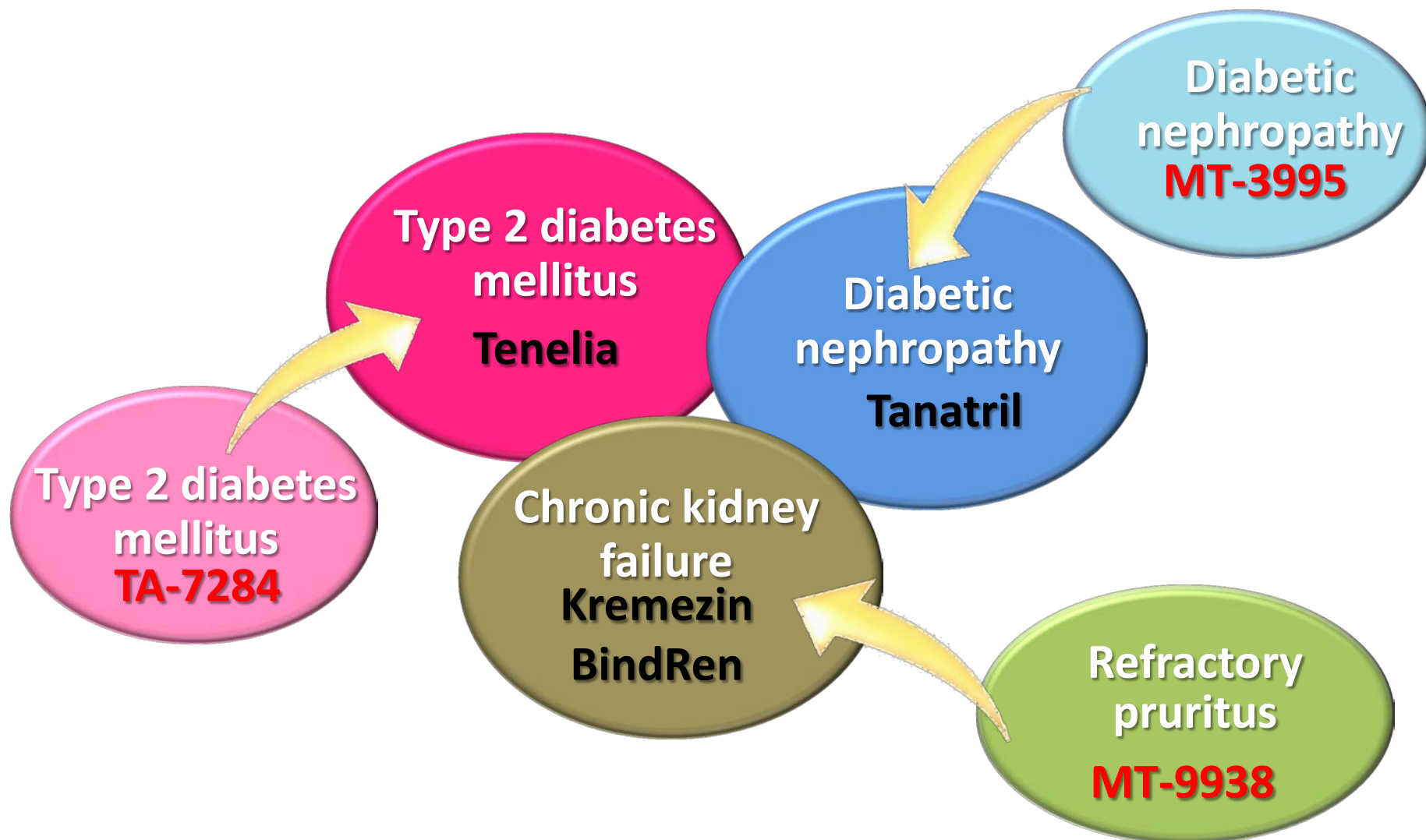
MT-4666 for Alzheimer's Disease

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

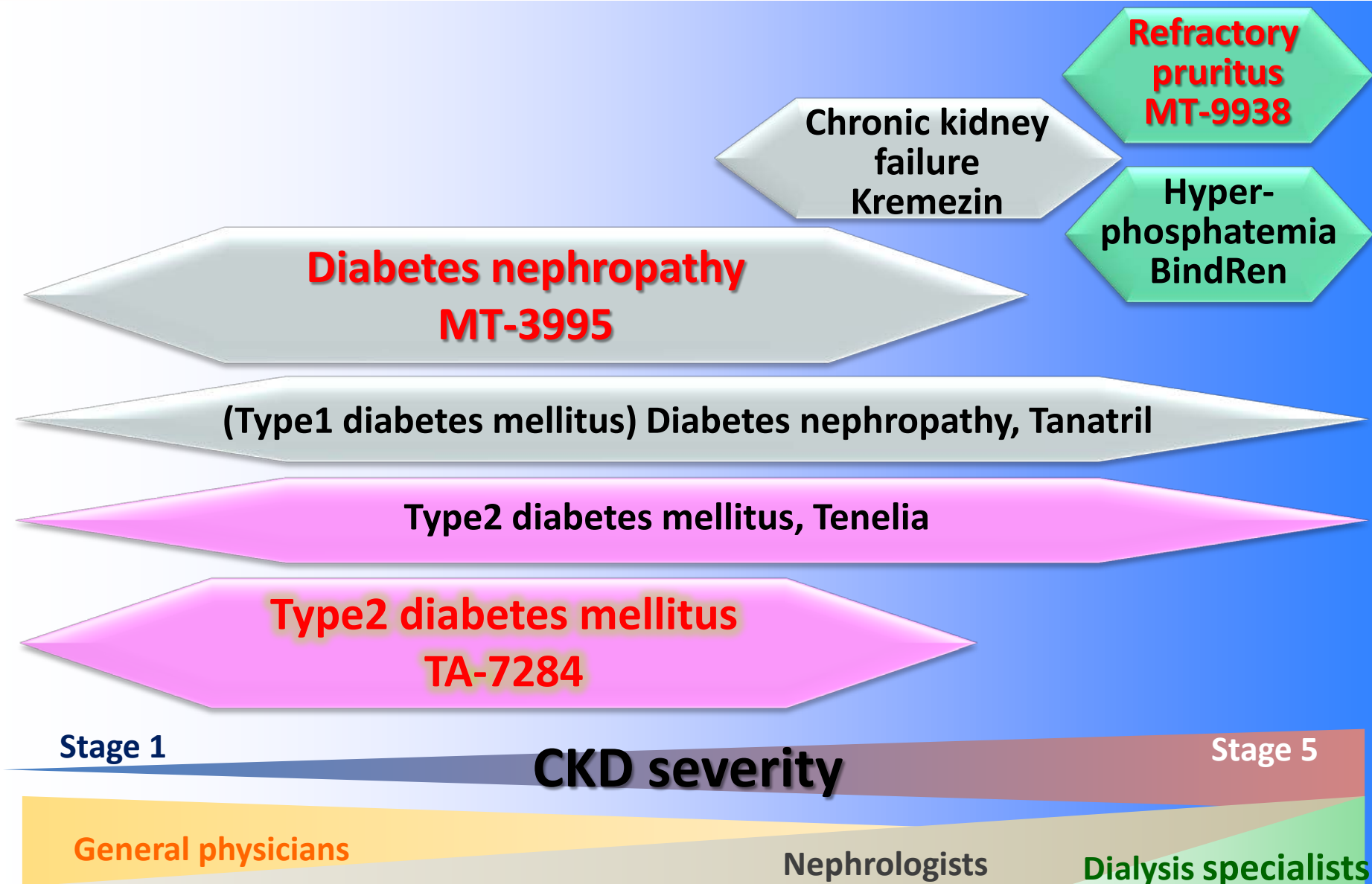
MT-4666, Treatment for Alzheimer's disease



Nurturing of Diabetes and Kidney Disease Area



Nurturing of Diabetes and Kidney Disease Area



MT-3995 for Diabetes Nephropathy

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

MT-9938 for Refractory Pruritus

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

Other Initiatives: Operational and Structural Reforms

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Strengthening and Expanding the Vaccine Business

New **Value** Creation



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**

Strengthening and Enhancing the Generic Business

New **Value** Creation



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 Yoshitomiyakuhin)
- 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

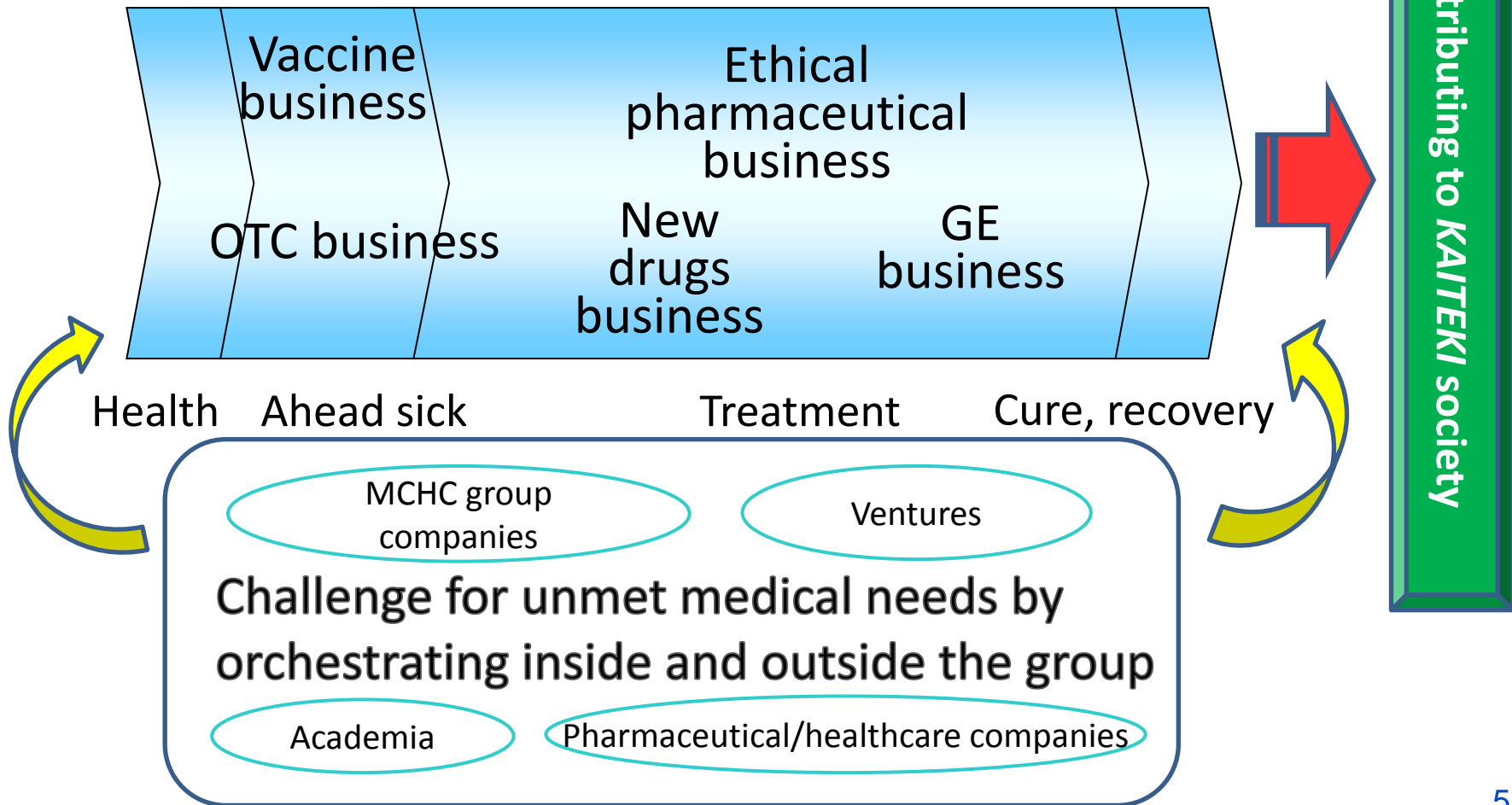


Contributing to *KAITEKI* Society by orchestrating

New *Value* Creation



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

Gilenya TA-7284

Japan: Nurturing of new products and priority products

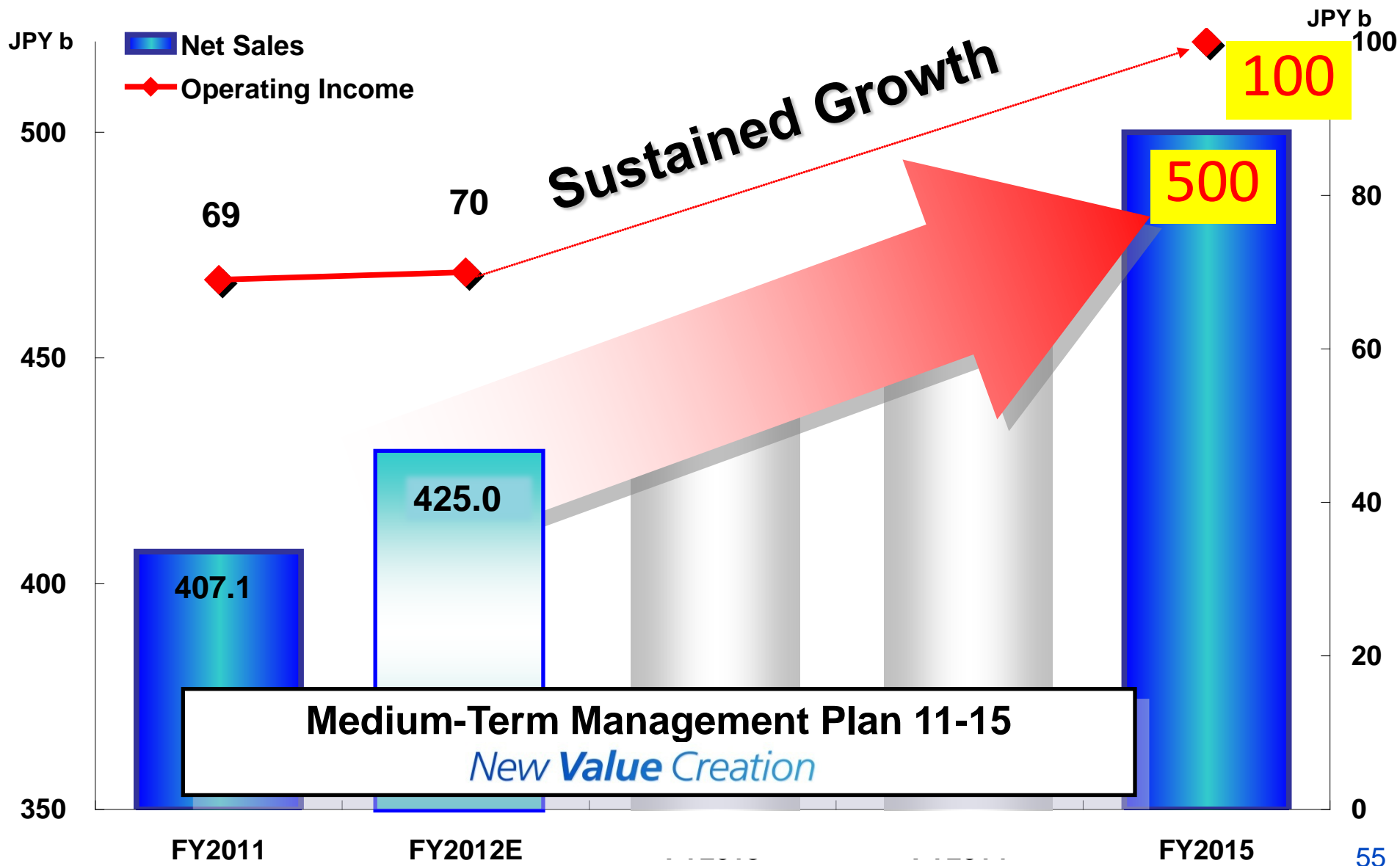
Remicade, Talion, Simponi, Lexapro, Telavic, Imusera, Tenelia, Tetrabik, TA-7284 (under development)

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

FY2016-

Toward Achievement of FY2015 Targets

New *Value* Creation



*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.