Mitsubishi Tanabe Pharma Corporation

Progress and Future of Development Pipeline

Deutsche Securities Inc.
Japan Pharmaceutical Conference 2010
September 29, 2010
Hotel Seiyo Ginza/Tokyo

Masayuki Mitsuka, Ph.D.
Board Director,
Executive Officer
Head of Global Product Strategy

Corporate Strategy in R&D

Mitsubishi Tanabe Pharma

- **Clearly product distinction in Japan/the U.S. and Europe**
  - **Specialty and primary in Japan**
  - **Specialty in the U.S. and Europe**

- **Good balance between self-development products and licensing-in/out products**
  - **Create the robust pipeline using alliances**

- **Reviw of our priority fields**
  - **Current priority fields: metabolism and circulation**
    (especially diabetes and cerebral infarction)
  - **⇒ Reviewing of the priority fields in looking back on the Medium-Term Management Plan 08-10**

Reviewing the 08-10 Medium-Term Period (Domestic)

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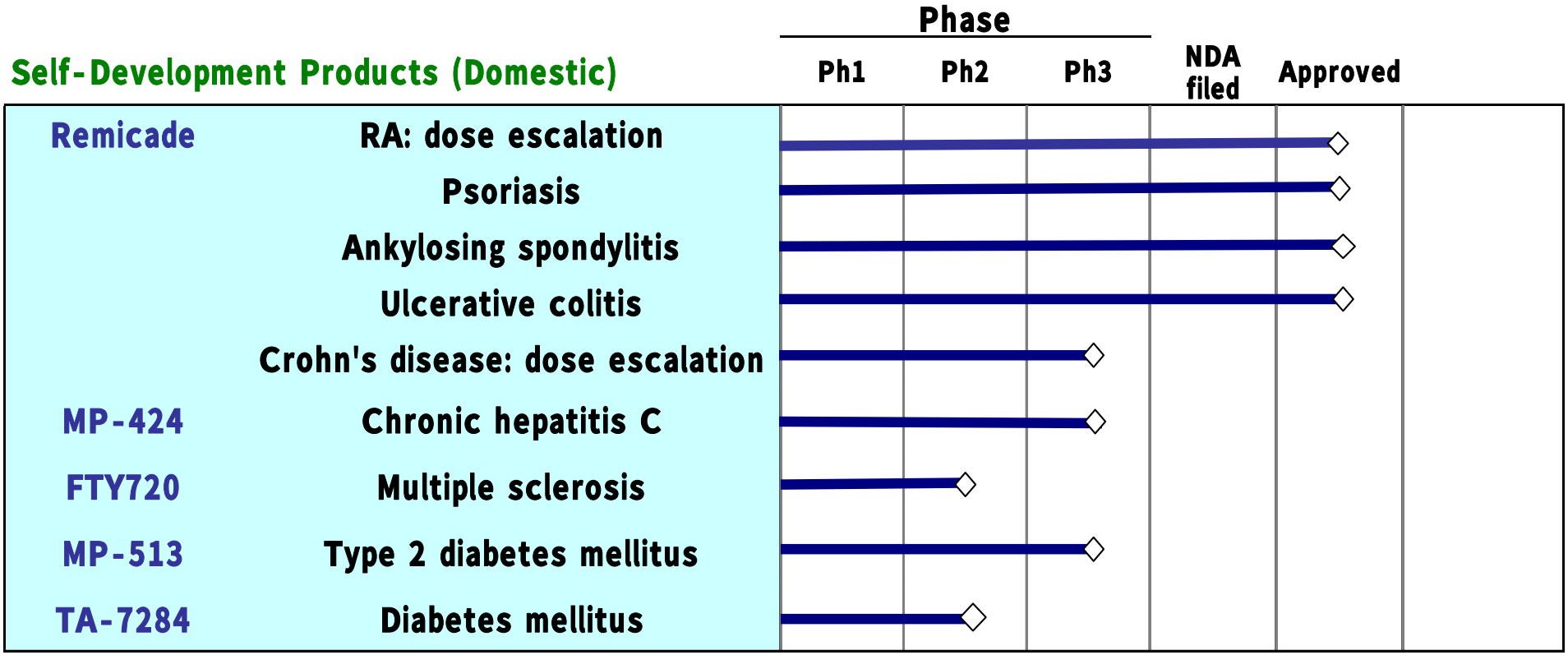
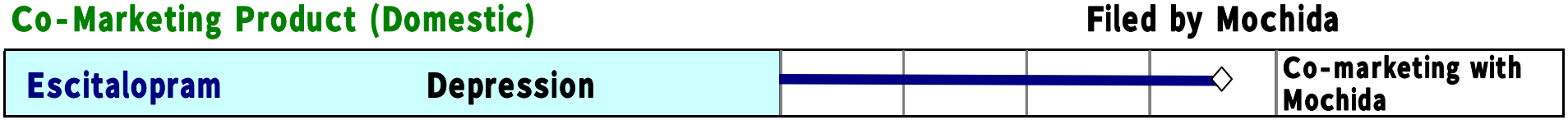
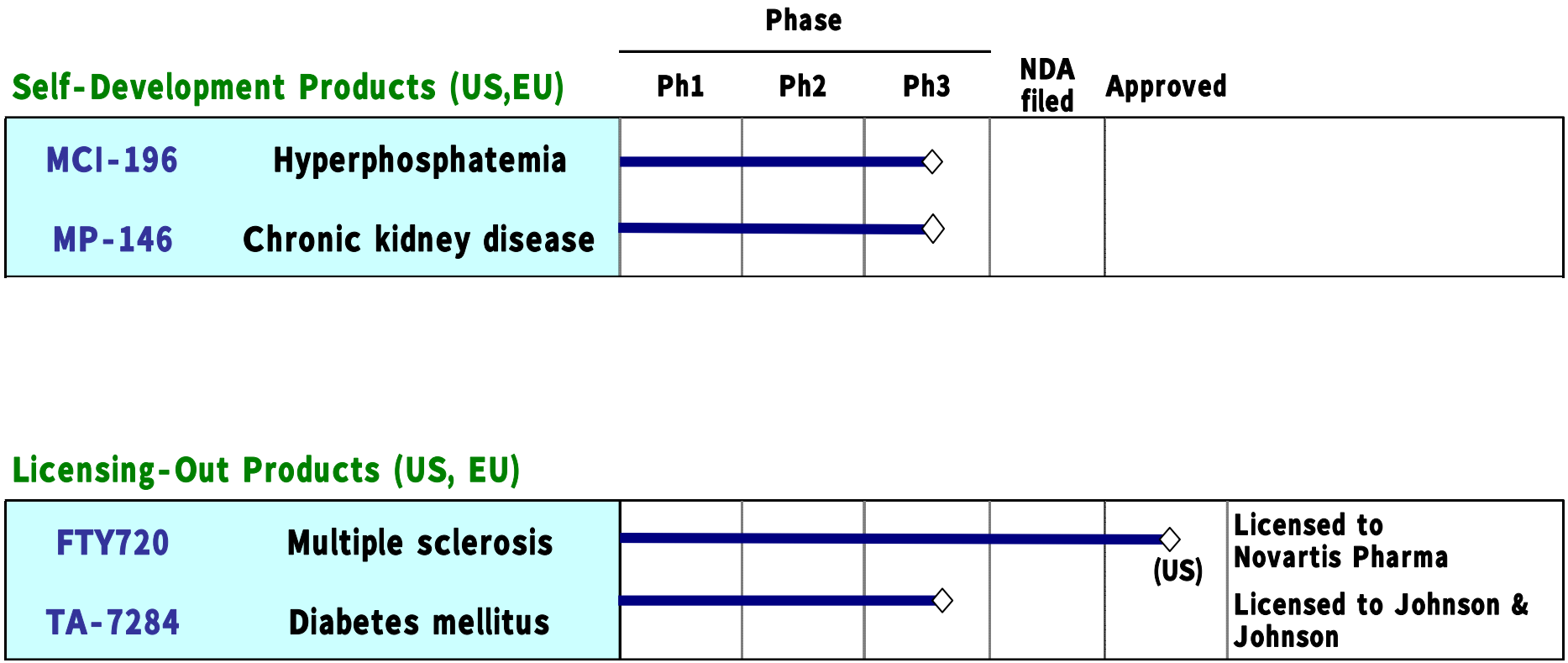
Self-Development Products (Domestic)



Co-Marketing Product (Domestic)



Reviewing the 08-10 Medium-Term Period (Overseas)



Immunology & Inflammation

Remicade
MP-424 (Chronic hepatitis C)
FTY720 (Multiple sclerosis)

Remicade Infliximab (Anti-TNFα monoclonal antibody)

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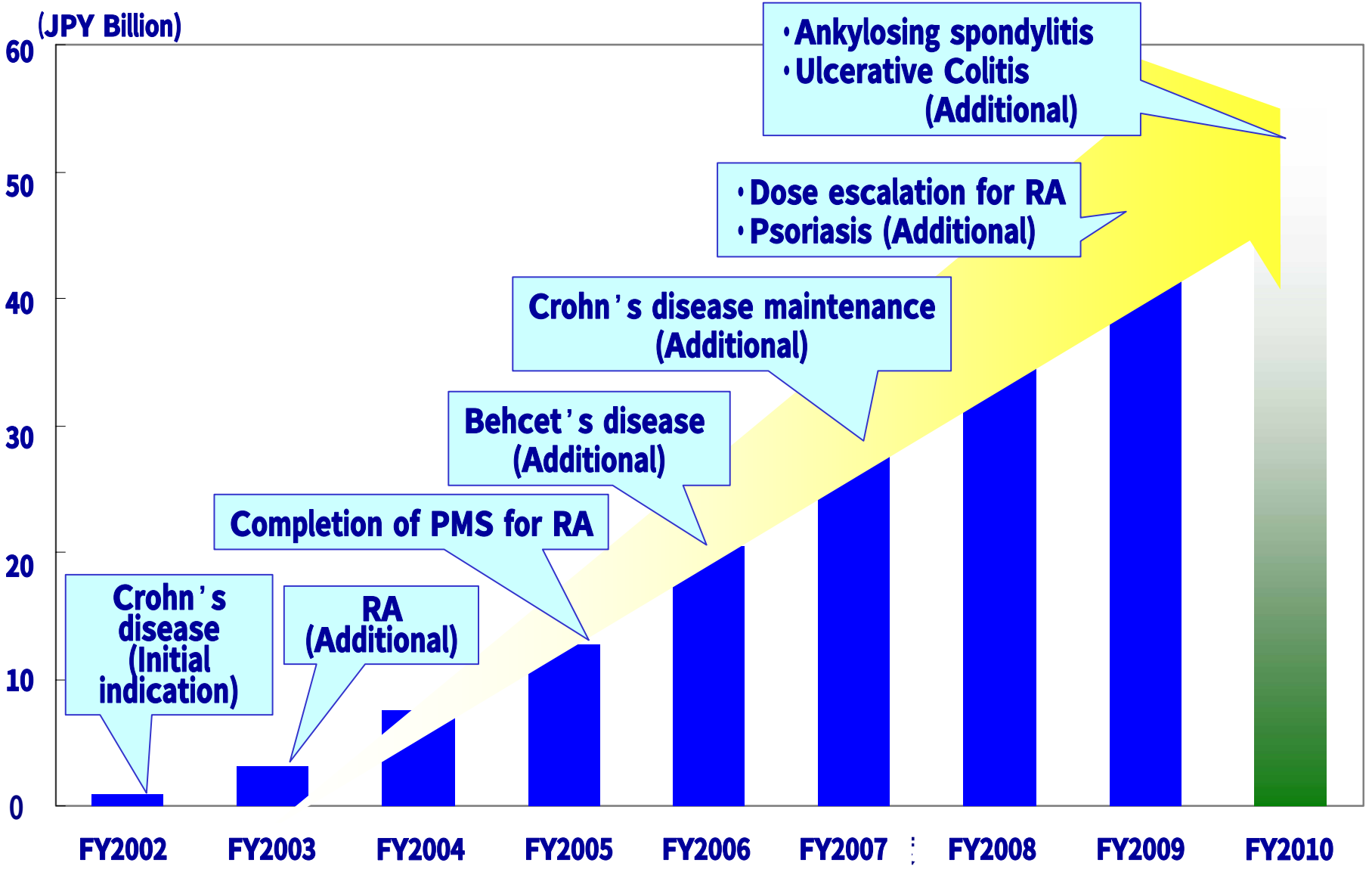
Project	Contents			
Remicade (Infliximab)	Mechanism	Anti-TNFα monoclonal antibody		
	Stage	Domestic	RA: dose escalation	Approved in July 2009
			Psoriasis	Approved in Jan. 2010
			Ankylosing spondylitis	Approved in Apr. 2010
			Ulcerative colitis	Approved in June 2010
			Crohn's disease: dose escalation	Ph3
	Profile	• Fast-acting and strong effect • Effective for 2 months by a single dose		

Remicade: Sales Growth & LCM



Remicade: Market Potential (Domestic)

Indications	Number of Patients	Other Major Biologics
RA	700,000 (MTX 200,000)	Launch: Enbrel Humira Actemura Orencia Under development: Golimumab Cimzia
Anlylosing spondylitis	2,000	Under development: Humira
Psoriasis	82,000	Launch: Humira Under development: Ustekinumab
Crohn's disease	27,000	Under development: Humira Cimzia
Ulcerative colitis	97,000	Under development: Golimumab Humira

Remicade: Comparison with Other Biologics

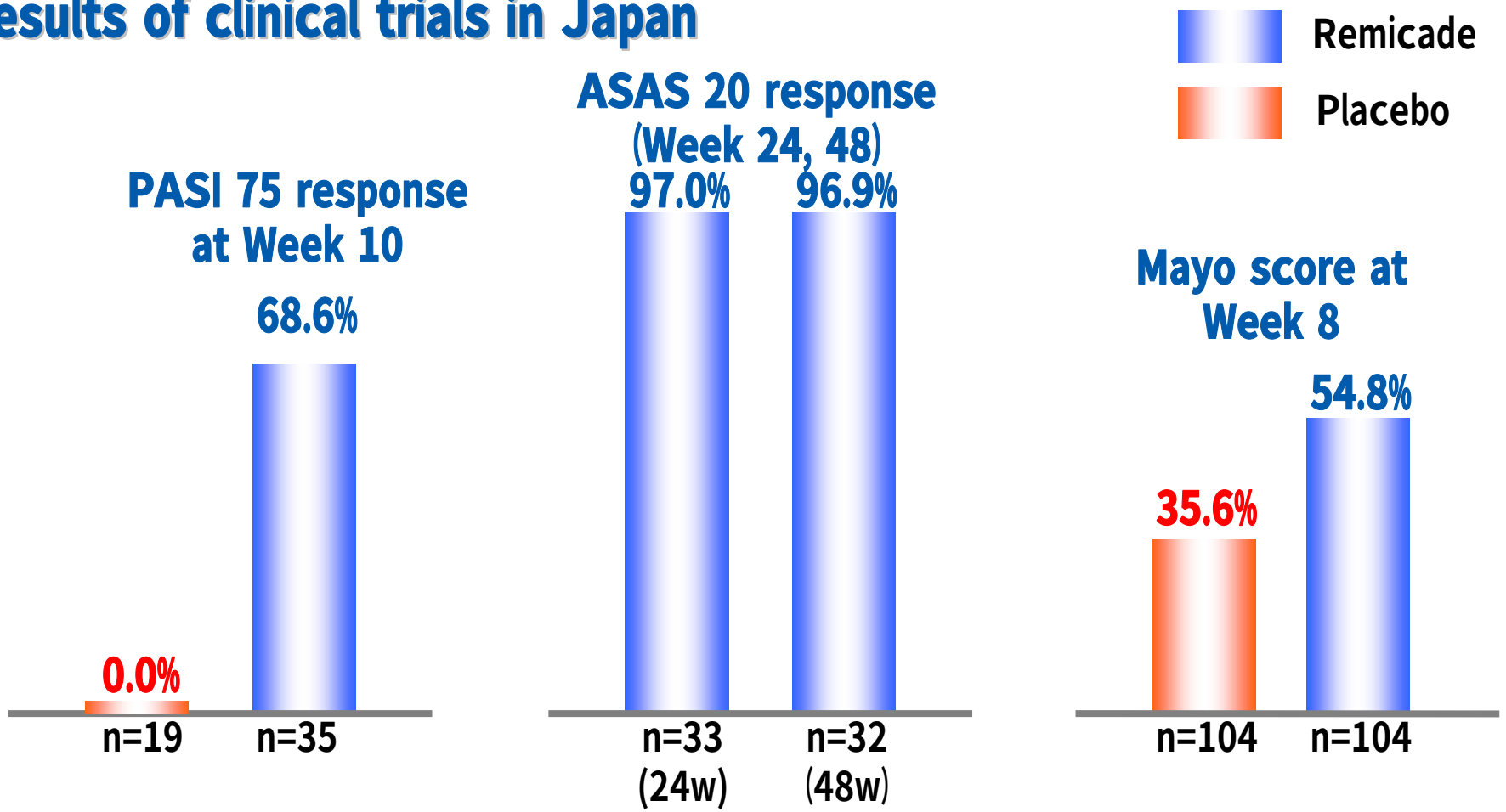
	Anti-TNFα antibody					Anti-IL-6 receptor antibody	CTLA4-Ig
Product name	Remicade	Enbrel	Humira	Golimumab	Cimzia	Actemra	Orencia
RA approval	2003	2005	2008	Under development	Under development	2008	2010
Company	MTPC	Takeda /Pfizer	Abbott /Eisai	Janssen /MTPC	UCB /Otsuka	Chugai	BMS
Indications	RA, CD BD, Ps AS, UC	RA JIA	RA, Ps (CD, AS UC, JIA)	(RA, UC)	(RA、CD)	Castleman, RA, JIA	RA
Administration method	IV	SC	SC	SC	SC	IV	IV
Administration interval	Every 8 weeks	Once or twice-weekly	Every 2 weeks	Every 4 weeks	Every 4 weeks	Every 4 weeks	Every 4 weeks

RA Rheumatoid Arthritis
CD Crohn's disease
BD Behcet's disease
Ps Psoriasis
AS Ankylosing Spondylitis
UC Ulcerative Colitis
JIA Juvenile Idiopathic Arthritis

( ) Under development
IV : Intravenous Injection
SC :Subcutaneous Injection

Remicade: New indications

Results of clinical trials in Japan



Psoriasis
Approved in Jan. 2010

Anlylosing spondylitis
Approved in Apr. 2010

Ulcerative colitis
Approved in June 2010

MP-424 (Telaprevir) /VX-950

Project	Contents			
MP-424 (Telaprevir)	Licensed from Vertex Pharmaceuticals			
	Mechanism	Inhibition of HCV NS3-4A serine protease		
	Stage	Chronic Hepatitis C	Domestic	Ph3
			Overseas (Vertex) (Tibotec)	US, EU: Ph3
	MTPC territory	15 Asian countries including Japan and China		
	Features	• High efficacy compared with existing therapy • Oral drug		

Current Treatment for HCV in Japan

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Estimated number of patients

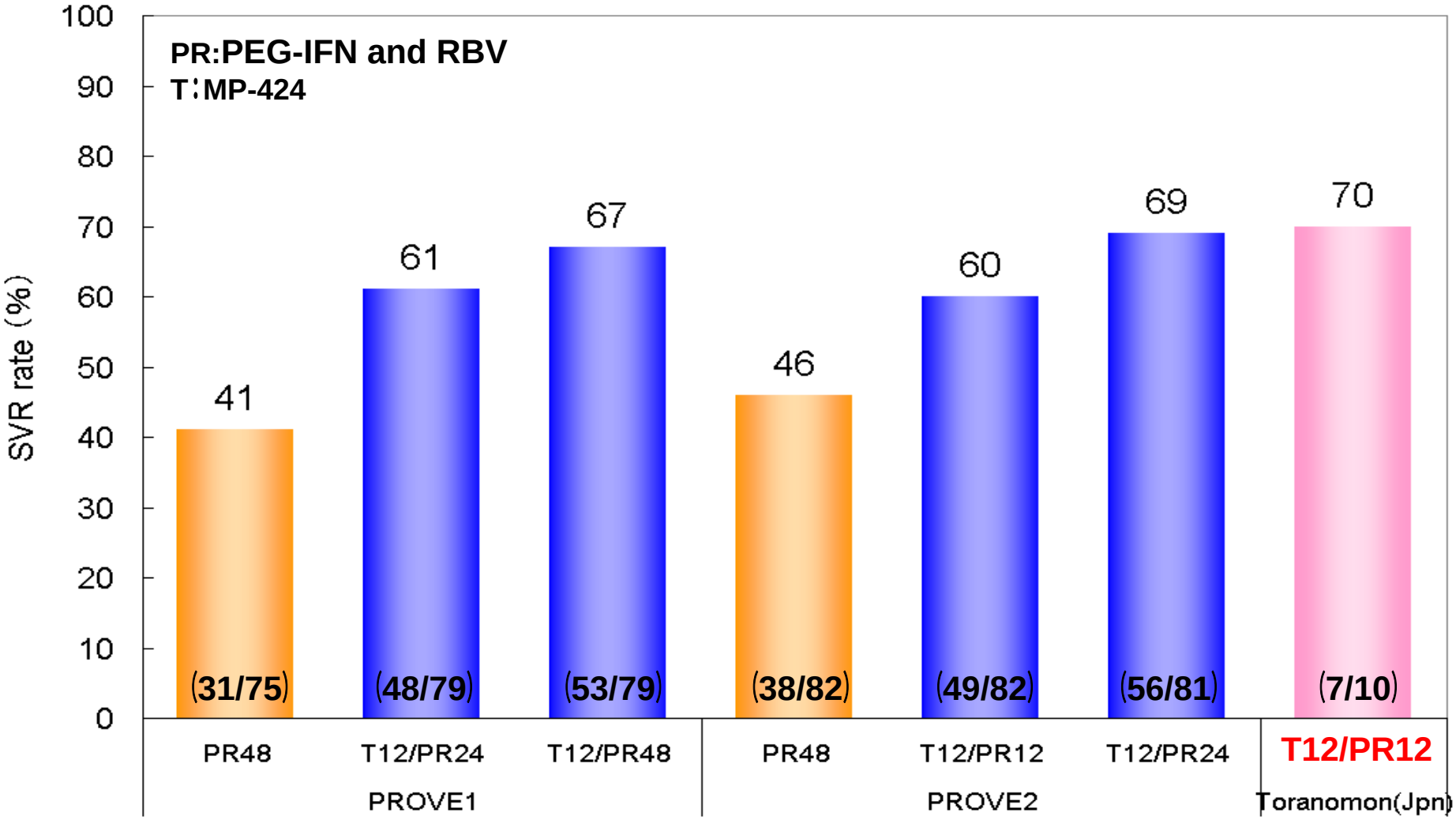
- Asymptomatic HCV carriers: 1.5 - 2 million
- Patients who visit doctors: 400,000 - 500,000 patients/year
- Patients on IFN: 30,000 - 50,000 patients/year

Treatment Options

- Current standard of therapy (antiviral therapy)
  Peginterferon + Ribavirin (48 weeks)
  Price for one course of therapy: approx. JPY 2.1 million
- New treatment with MP-424
  MP-424 + Peginterferon + Ribavirin (24 weeks)
  Treatment period of MP-424: 12 weeks

MP-424: Clinical Results -1 <Naive Patients>

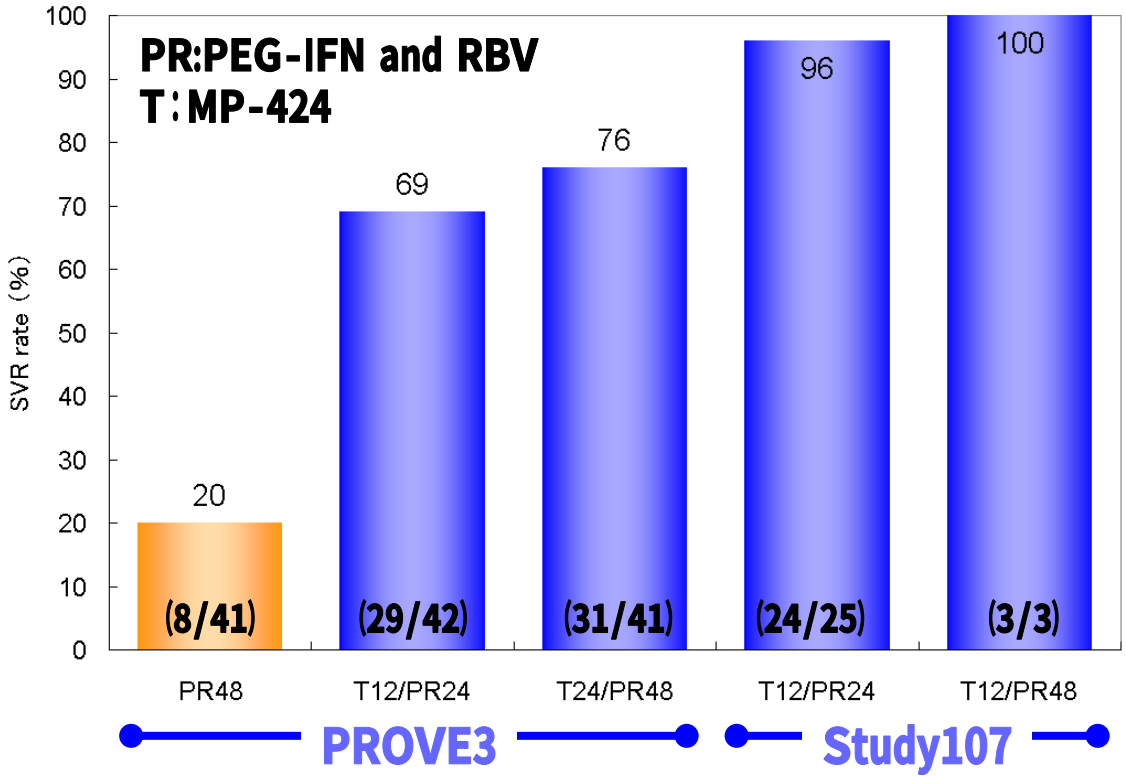
SVR Rate for Telaprevir in Treatment-Naive Patients



N Engl J Med 360:1827, April 30, 2009（PROVE1）, N Engl J Med 360:1839, April 30, 2009（PROVE2）
Annual report2010, grant-in-aid from the Ministry of Health, Labor and Welfare, Japan. (Toranomon)

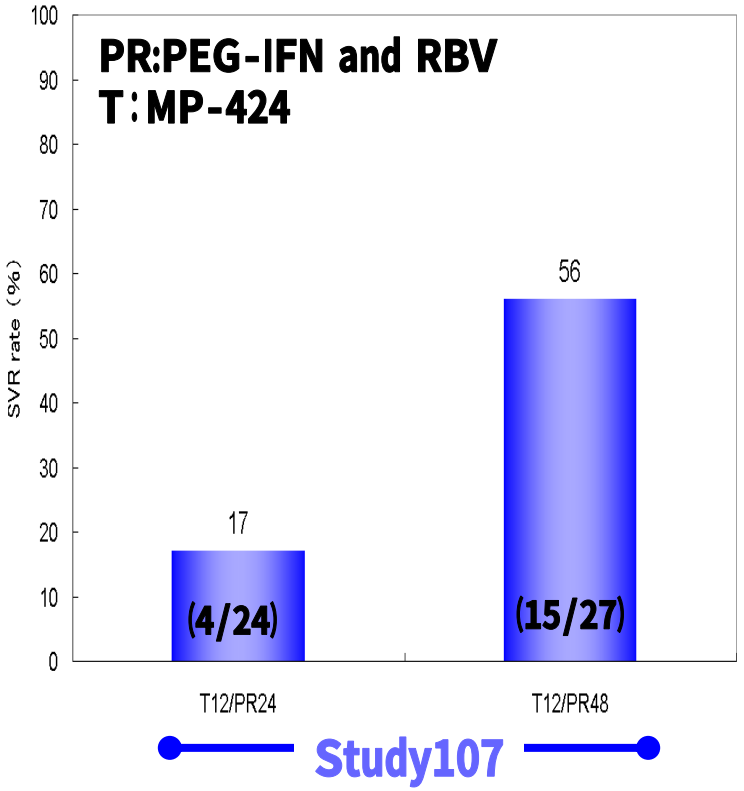
Clinical Results -2 <Experienced Patients>

SVR Rate in Treatment -Experienced Patients ; Prior Relapsers



N Engl J Med 362:1292, April 8, 2010 (PROVE3) , Berg T, EASL2010 (Study 107)

SVR Rate in Treatment -Experienced Patients; Prior Null Responders



Berg T, EASL2010 (Study 107)

Development Products for HCV

■Protease inhibitor

Telaprevir (Vertex/Tibotec/Mitsubishi Tanabe)

The most advanced protease inhibitor
Ph3 in US and EU, three times daily
Expected NDA for FDA in 2010

Boceprevir (Merck)

The second most advanced protease inhibitor
Ph3 in US and EU、three times daily
Expected NDA for FDA in 2010

TMC435 (Medivir/Tibotec/Janssen)

Strong protease inhibitor, once-daily, Ph2 in US ,EU, Japan

■Polymerase inhibitor, others

RG7128 (Pharmasset/Roche)

One of the most advanced polymerase inhibitor, twice-daily
Ph2 in US and EU

BMS-790052(BMS)

Strong NS5A inhibitor, Ph2 in US and EU

FTY720 (Fingolimod hydrochloride)

Project	Contents			
FTY720 (Fingolimod hydrochloride)	Mechanism	Modulation of sphingosine 1-phosphate (S1P) receptor		
	Stage	Multiple sclerosis (MS)	Domestic (Co-development with Novartis Pharma K.K.)	Ph2
			Overseas (Licensed to Novartis Pharma)	US: Approved in Sep. 2010
				EU: Filed in Dec. 2009
	Profile	・More effective than interferon ・World's first oral MS drug		

World Distribution of the MS Patients

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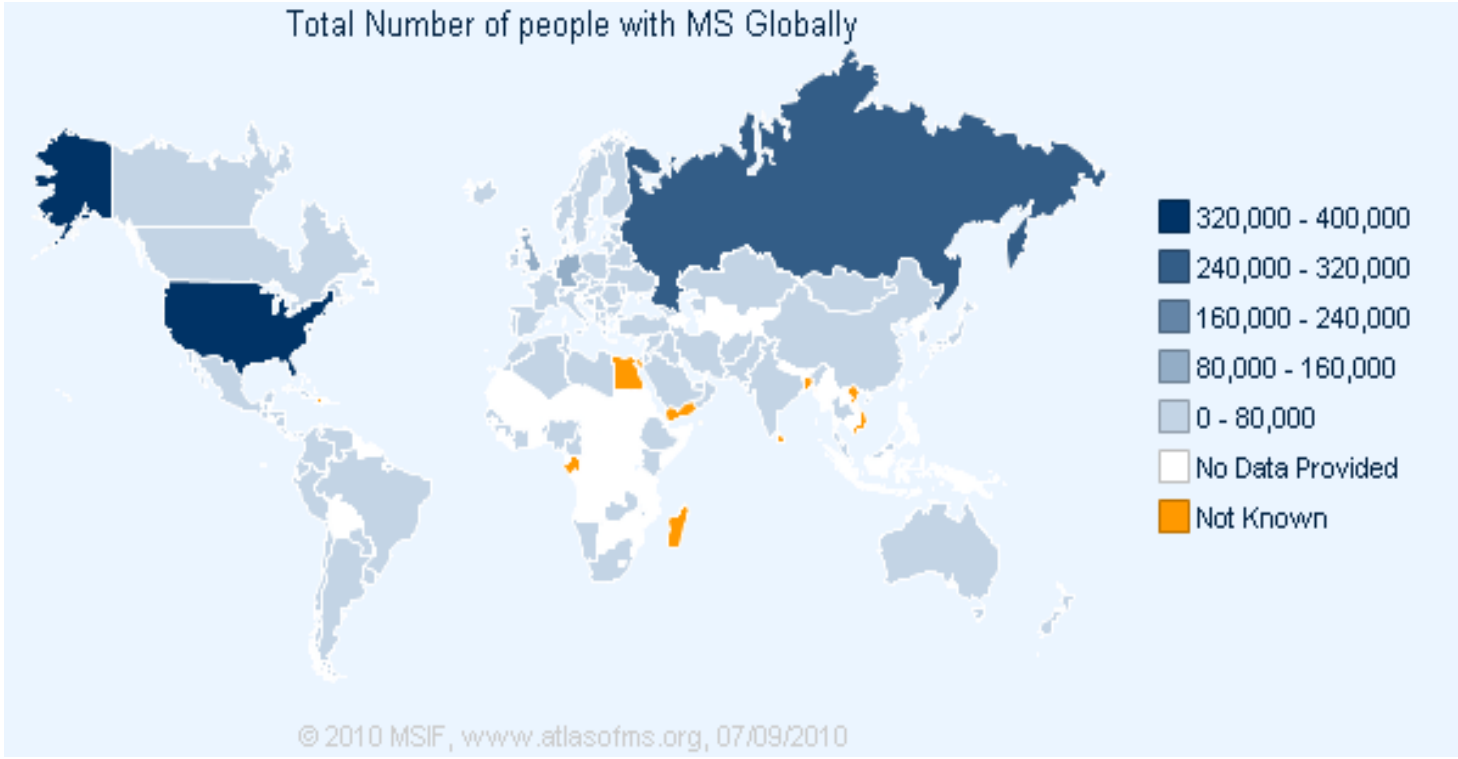
◆Multiple Sclerosis (MS)

Multiple sclerosis (MS) is caused by demyelination in central nervous system. MS presents acute attacks of diverse neurological dysfunction followed by remission of functions.

◆Number of Patients

2,500,000	
U.S.A.	**400,000**
Russia	**250,000**
Canada	**50,000**
U.K.	**85,000**
France	**80,000**
Germany	**122,000**
Italy	**54,000**
Spain	**40,000**
Japan	**10,000**



MSIF: Multiple Sclerosis International Federation

FTY720

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- **Status**

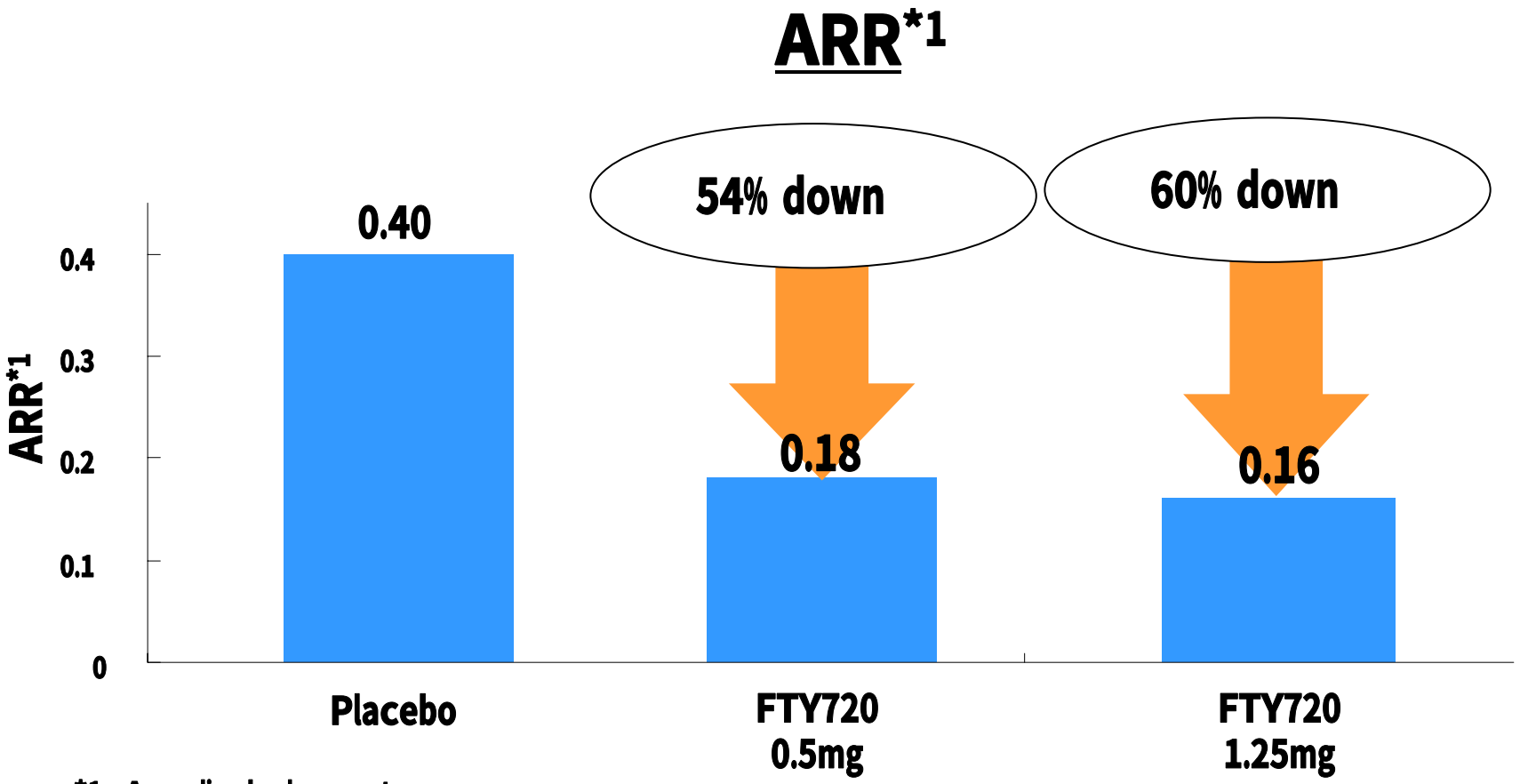
  Overseas : Licensed to Novartis Pharma
  Approved in US and Russia in September 2010
  Filed in US and EU in December 2009
  by Novartis Pharma
  Domestic : Co-development with Novartis Pharma K.K.
  Expected to be filed in 2010
  Mechanism : Facilitation of lymphocyte homing

- **Competitive product**

  Cladribine
  Approved in Russia in July 2010
  in Australia in September 2010
  Filed in US in July 2010 (Result is expected in 4Q.)
  Mechanism : Cytotoxic effect against lymphocyte

FTY720 (Placebo-controlled study)

Dose: 0.5 or 1.25 mg, once a day

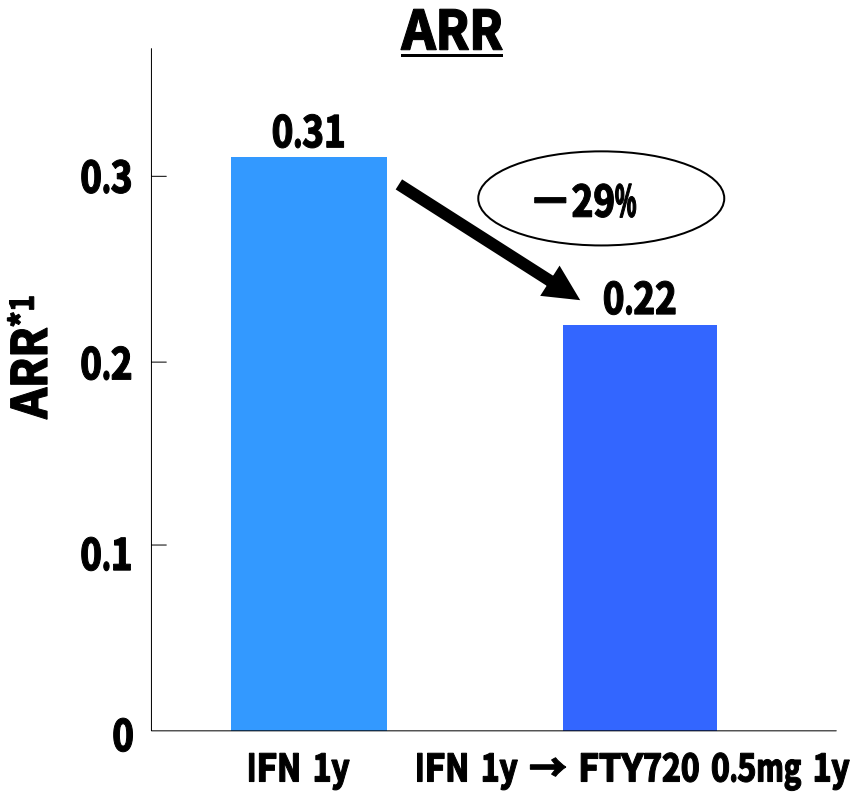


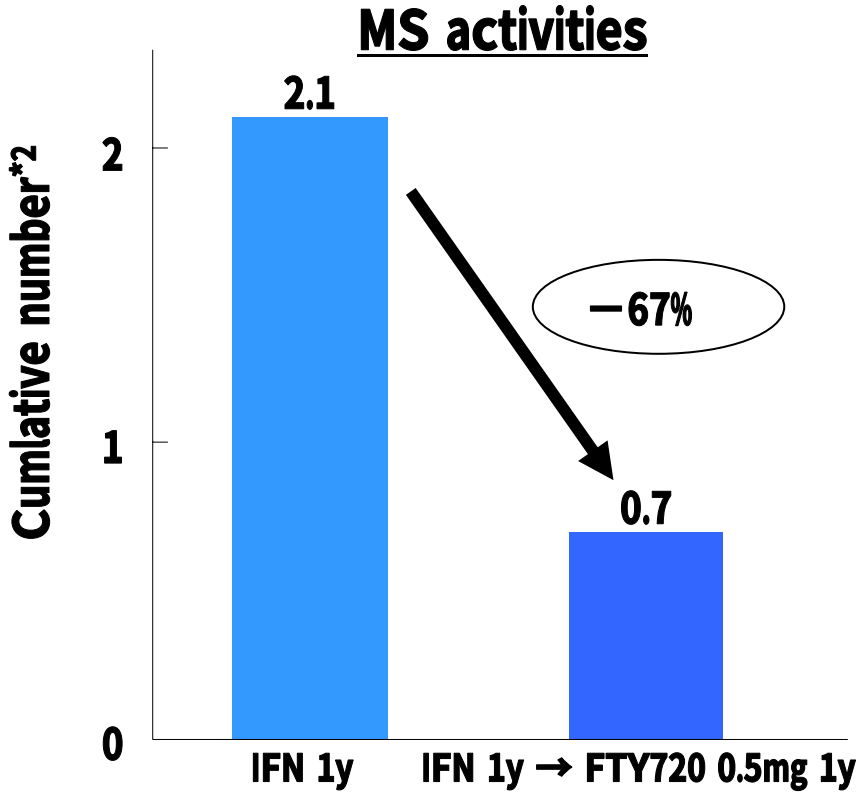
*1 : Annualized relapse rate

N Engl J Med 2010;362:387-401.

FTY720 (Comparative trial with IFN)

[Poster presentaion at AAN in Apr. 2010]
TRANSFORMS extension study





*1 : Annualized relapse rate

*2 : Cumlative number of new/newly enlarged T2 lesions

Diabetes

TA-7284
MP-513

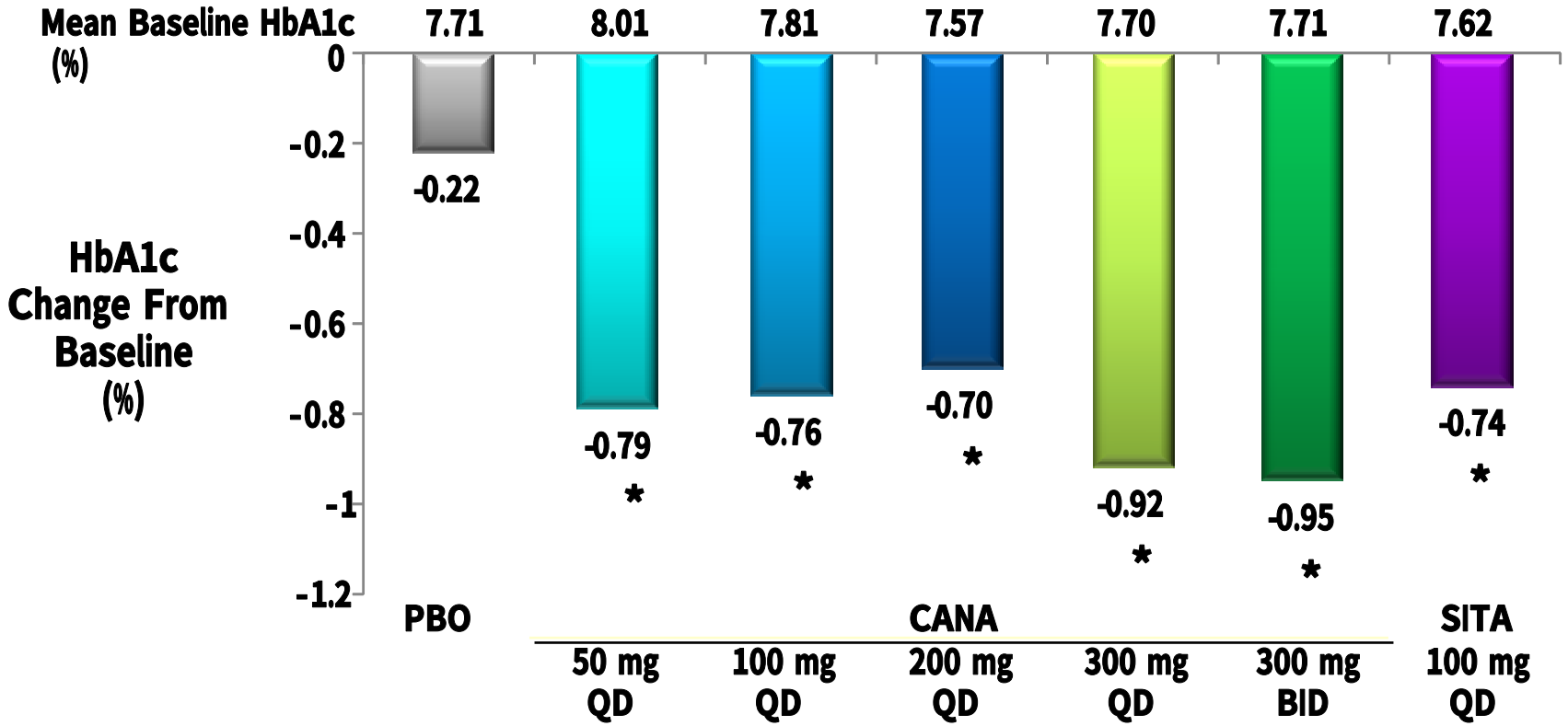
Major Development Project (Diabetes)

Project	Contents		
TA-7284 (Canagliflozin)	Mechanism	Inhibition of SGLT2	
	Stage	Domestic	Ph2
		Overseas (Johnson & Johnson*)	Ph3
	Profile	Low risk of hypoglycemia, body weight reduction	
MP-513 (Teneligliptin)	Mechanism	Inhibition of DPP4	
	Stage	Domestic	Ph3
		Overseas	Ph2
	Profile	Superior inhibitory activity, long-acting effect and renal excretion & hepatic metabolism	

*Ortho-McNeil-Janssen Pharmaceutical

Canagliflozin (JNJ-28431754/TA-7284) Overseas Ph2b Study: HbA1c

SGLT2 Inhibition for Type 2 DM: MET + Canagliflozin Dose-Ranging Study

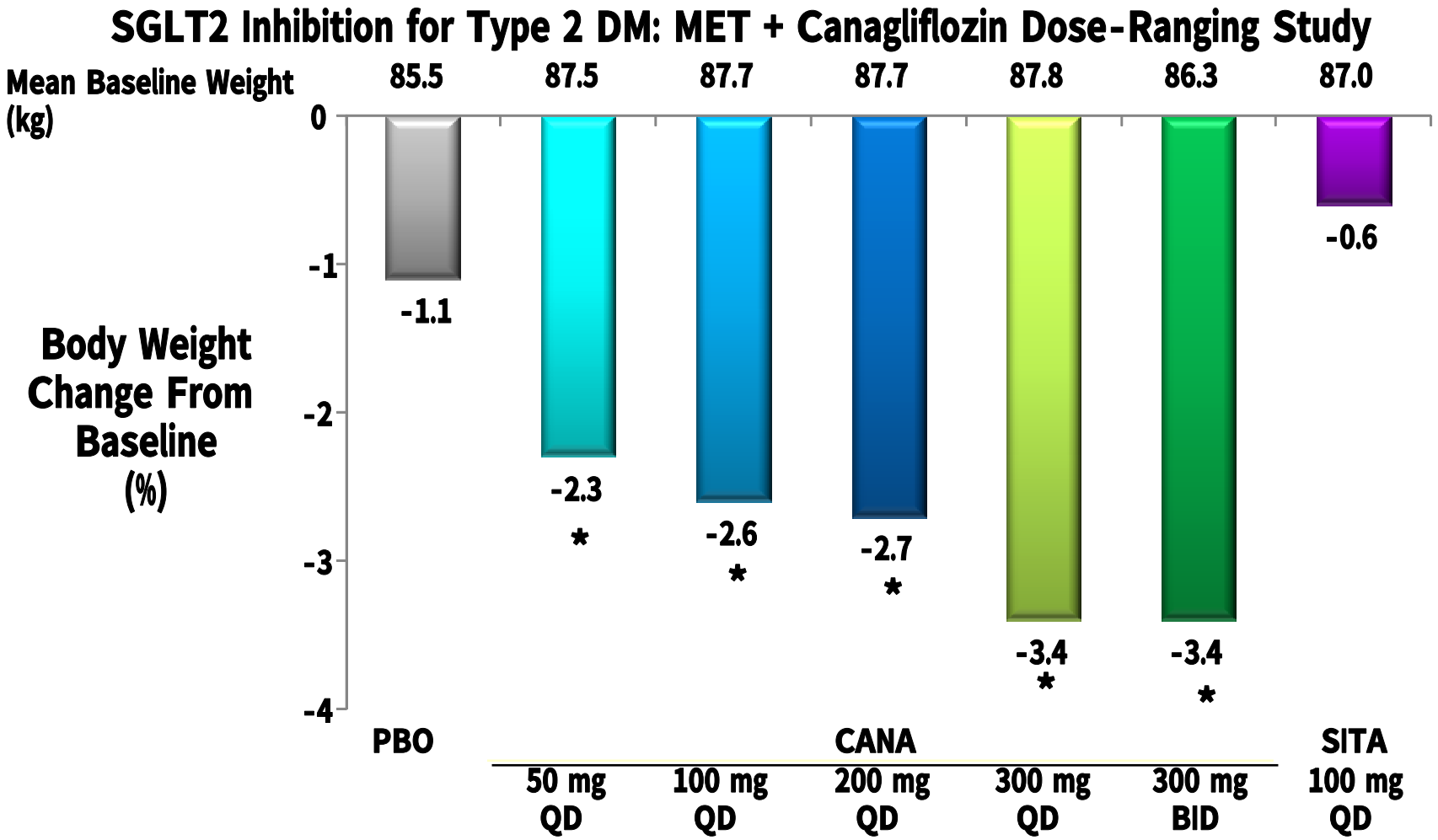


*$P<0.001$ vs placebo calculated using LS means.

"Canagliflozin is being developed by Johnson & Johnson Pharmaceutical Research and Development, LLC in collaboration with Mitsubishi Tanabe Pharma Corporation."

Source: Presentation slides at ADA on June 26, 2010 by Dr. Julio Rosenstock (partially modified)

Canagliflozin (JNJ-28431754/TA-7284) Overseas Ph2b Study: Body Weight

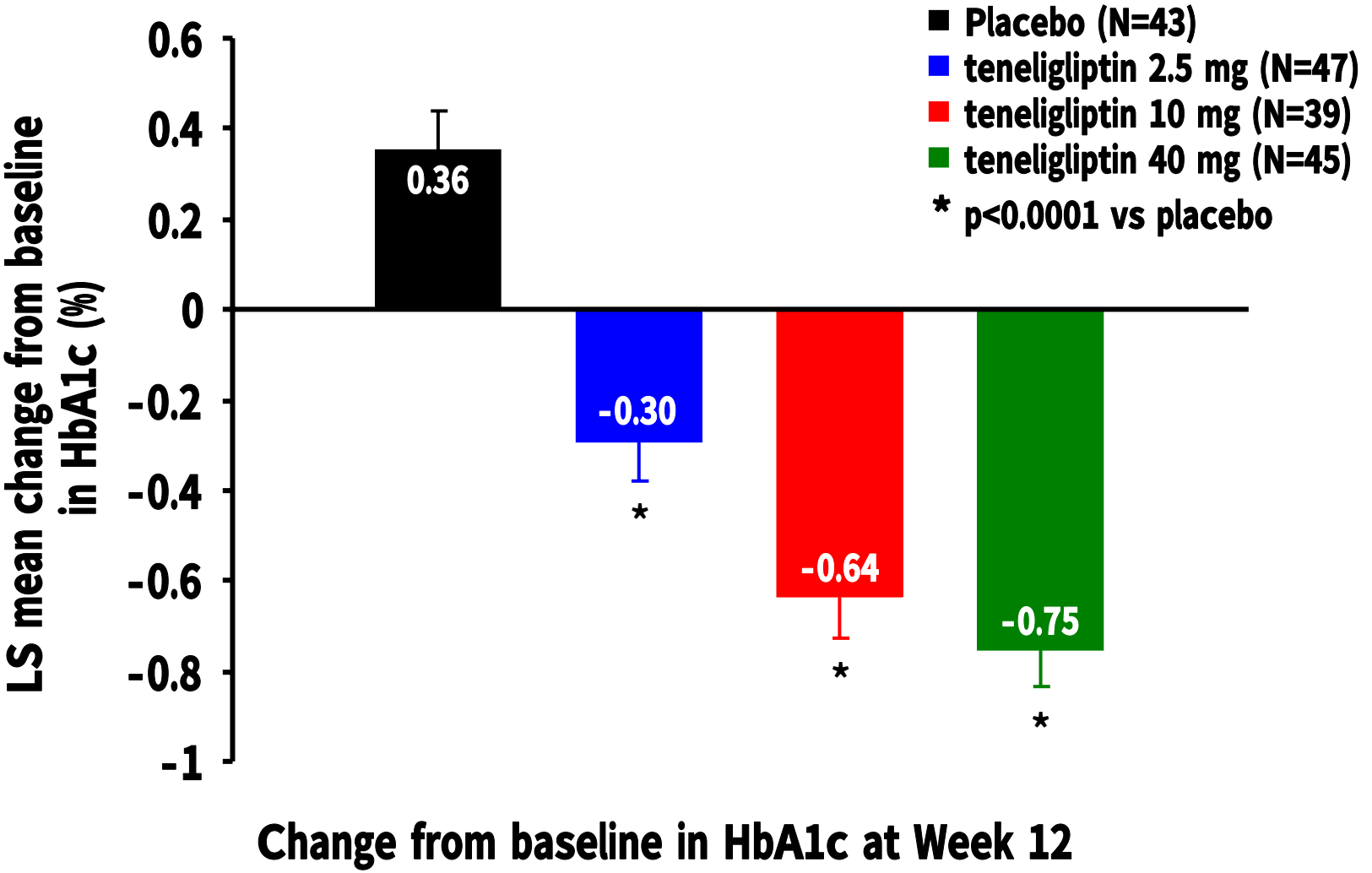


*P<0.01 vs placebo calculated using LS means.

"Canagliflozin is being developed by Johnson & Johnson Pharmaceutical Research and Development, LLC in collaboration with Mitsubishi Tanabe Pharma Corporation."

Source: Presentation slides at ADA on June 26, 2010 by Dr. Julio Rosenstock (partially modified)

MP-513 (teneligliptin) Japanese Ph2a Study: HbA1c



*The data are expressed as LS mean values±S.E.

Source: Presentation slides at Japan Diabetes Society in May, 2010 by Dr. Takashi Kadowaki (partially modified)

Competition: SGLT2 Inhibitors

Company Name	Product Name/Generic Name	Development Stage (Overseas)
Bristol-Myers Squibb/AstraZeneca	Dapagliflozin (BMS512148)	US/EU: Ph3
Johnson & Johnson	Canagliflozin (JNJ-28431754/TA-7284)	US/EU: Ph3
Boehringer Ingelheim	BI-10773	US/EU: Ph3
Roche	RG7201 (CSG452)	US/EU: Ph2b
Astellas	ASP-1941	US/EU: Ph2b
Lexicon	LX4211	US/EU: Ph2a
Pfizer	PF-04971729	US/EU: Ph2a
ISIS	ISIS 388626	EU: Ph1
Company Name	**Product Name/Generic Name**	**Development Stage (Japan)**
Astellas	ASP-1941	Ph3
Chugai	CSG452 (RG7201)	Ph2/3
Mitsubishi Tanabe	Canagliflozin (TA-7284/JNJ-28431754)	Ph2b
Bristol-Myers Squib/AstraZeneca	Dapagliflozin (BMS512148)	Ph2b
Taisho	TS-071	P2
Boehringer Ingelheim	BI-10773	Ph2

Source: Companies' Website/Investor Relations

Competition：DPP4 Inhibitors

Company Name	Product Name/Generic Name	Development Stage (Overseas)
Merck	Januvia® (sitagliptin)	US/EU：Launched
Novartis	Galvus® (vildagliptin)	EU：Launched, US：Not Approved
Bristol-Myers Squibb/AstraZeneca	Onglyza® (saxagliptin)	US/EU：Launched
Takeda	Alogliptin (SYR-322)	US/EU：Ph3
Boehringer Ingelheim	Linagliptin (BI-1356/Ondero®)	US/EU：Ph3
Mitsubishi Tanabe	Teneligliptin (MP-513)	EU：Ph2, US：Ph1
Dainippon Sumitomo	DSP-7238	EU：Ph1
Company Name	**Product Name/Generic Name**	**Development Stage (Japan)**
Banyu	Januvia® (sitagliptin)	Launched (December, 2009)
Ono	Glactiv® (sitagliptin)	
Novartis	Equa® (vildagliptin)	Launched (April, 2010)
Takeda	Nesina® (alogliptin)	Launched (June, 2010)
Mitsubishi Tanabe	Teneligliptin (MP-513)	Ph3
Boehringer Ingelheim	Linagliptin (BI 1356)	Ph3
Sanwa Kagaku	Anagliptin (SK-0403)	Ph3
Otsuka	Saxagliptin (OPC262)	Ph2/3

Source: Companies' Website/Investor Relations

Others

Escitalopram (Depression)

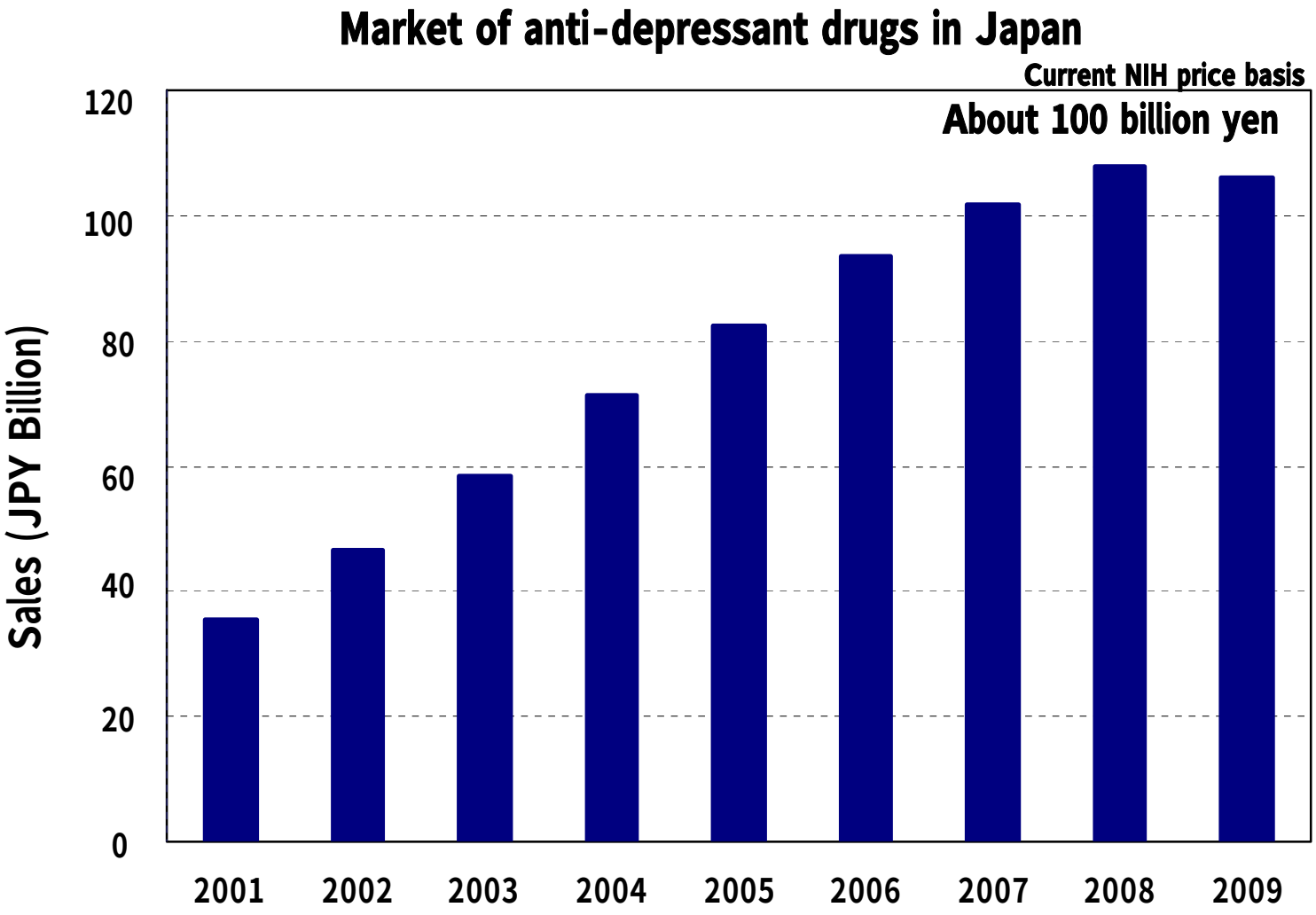
TA-1790 (ED)

Escitalopram
(Selective Serotonin Reuptake Inhibitors SSRI)

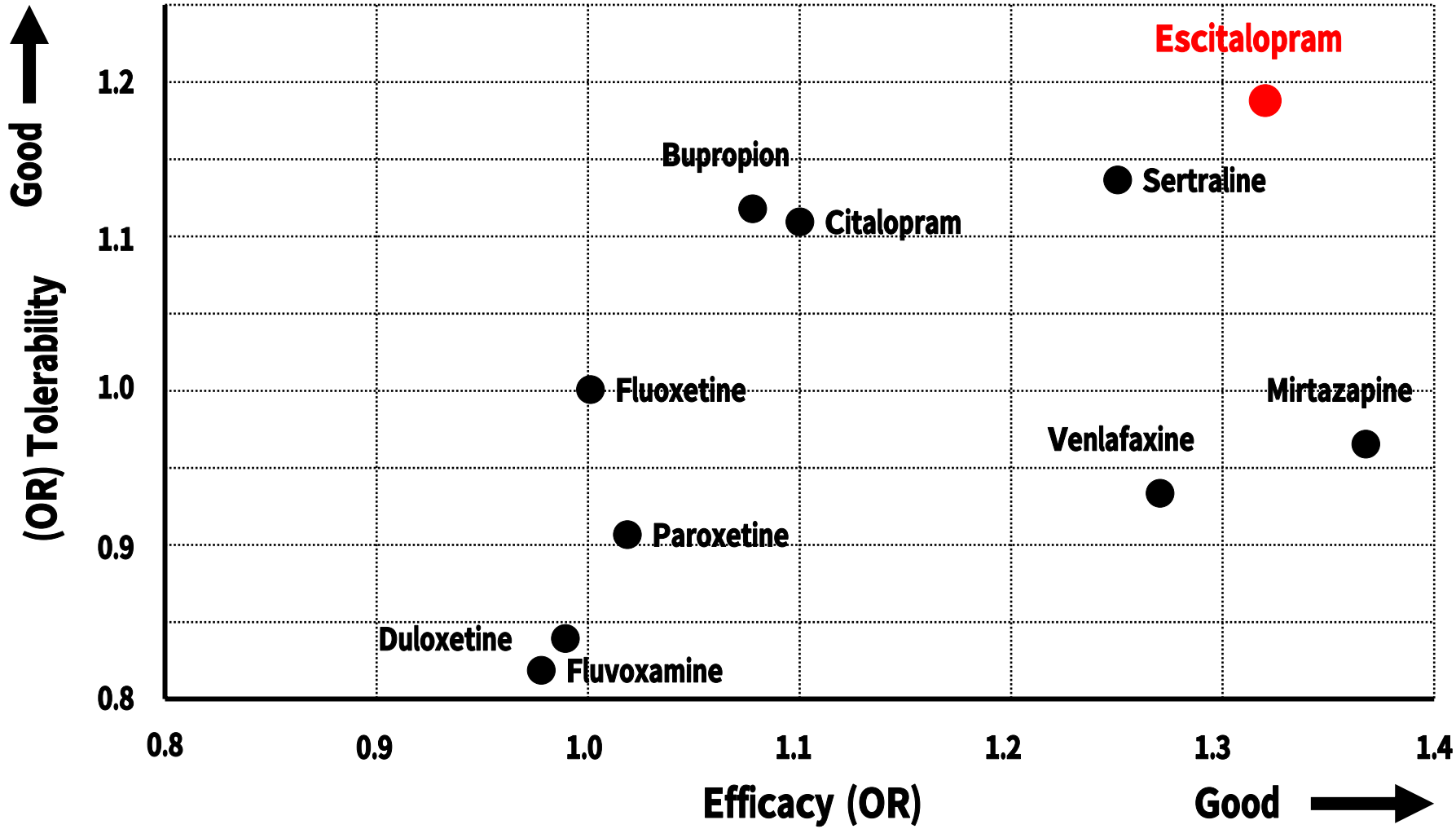
Project	Contents			
Escitalopram	Mechanism	Selective Serotonin Reuptake Inhibitors (SSRI)		
	Stage	Depressants	Japan (Mochida)	Filed by Mochida ※Co-marketing with Mochida* ＊Co-promotion with Yoshitomiyakuhin at psychiatric institution
	Features	• Highest selective SSRI • High efficacy and tolerability • Low drug interaction • W/W Sales 3,845M $**		

**Uto Brain 2009/07

Sales of Anti-Depressant Drugs



Efficacy and Tolerability of Escitalopram



Meta-analysis demonstrated that escitalopram possesses high efficacy and tolerability.

Source: Lancet(2009)

TA-1790 (Avanafil)

Project	Contents			
TA-1790 (Avanafil)	Mechanism	Inhibition of PDE5		
	Stage	Erectile Dysfunction	US (VIVUS)	Ph3
			Korea (Choongwae)	Ph3
	Features	High potency, good safety, rapid onset		

TA-1790 (Avanafil) Clinical Data

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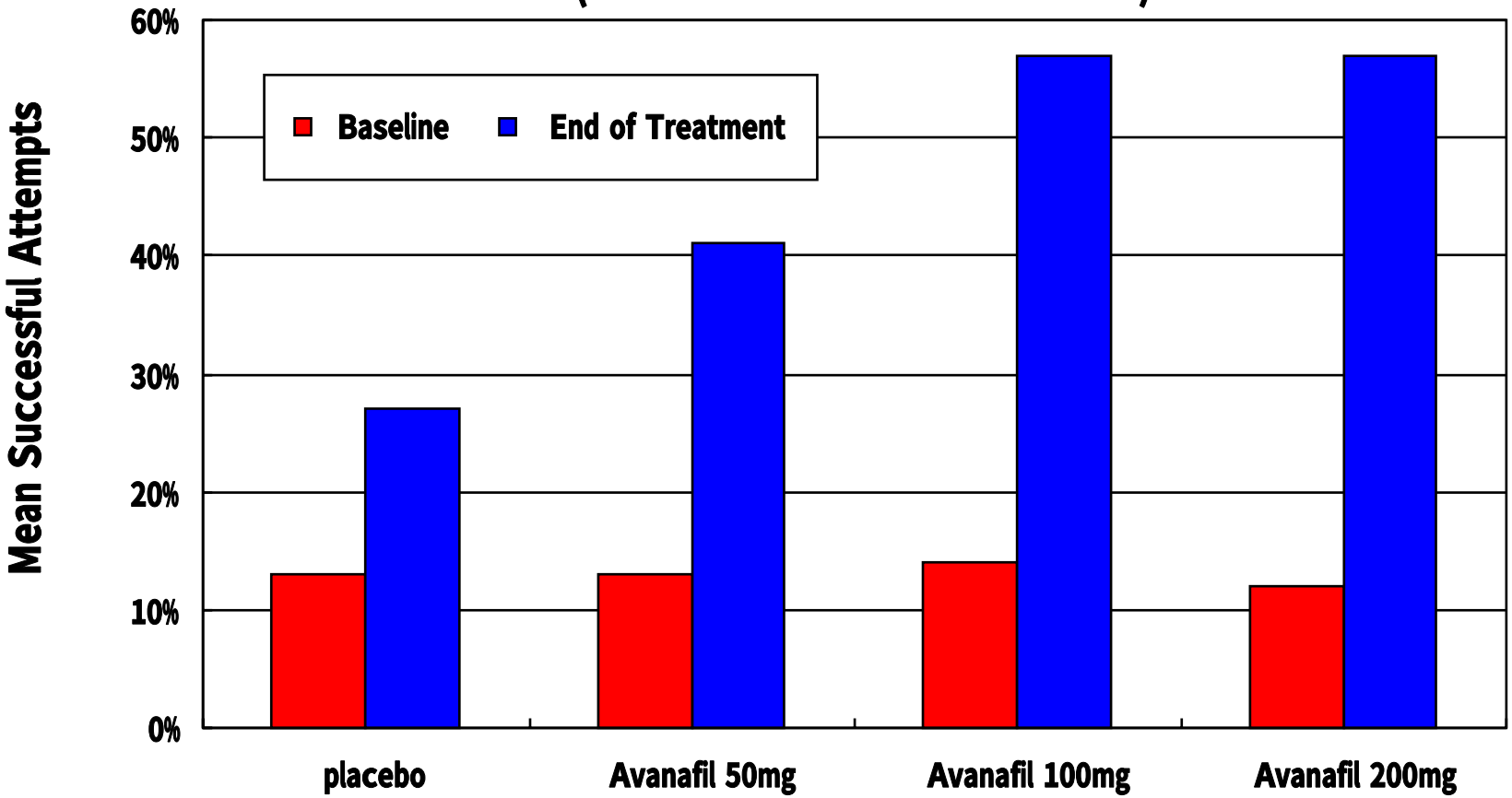
Co-primary SEP 3: Percent of successful sexual attempts (SEP:Sexual Encounter Profile)



*p<0.001 active vs. placebo change from baseline

Resource: Press release by VIVUS on Nov. 18, 2009

Others (Filed and Approved) ①

New Molecular Entities

Development code (Generic name)	Category	Indications	Phase
CNTO148 (Golimumab)	Anti-TNFα monoclonal antibody	RA	Filed in June 2010 (filed by Janssen Pharma, co-development Janssen Pharma)
TA-8317/Acref (Fentanyl citrate)	Narcotic analgestic	Breakthrough cancer pain: oral transmucosal	Filed in Aug. 2008
BK-4SP	Vaccine	Prophylaxis of pertussis diphteria, tetanus, an poliomyelitis	Co-development (BIKEN*)

* The research Foundation for Microbial of Osaka University

Others (Filed and Approved) ②

Additional Indications

Development code (Generic name)	Category	Indications	Phase
Venoglobulin IH (Polyethlene glycol-treated human normal immunoglobulin)	Human immunoglobulin G	Polymyositis, Dermatomyositis	Filed in May 2003
		Hypo and gammagloblinemia: additional dose	Approved in May 2010
		Systemic sclerosis	
		Myasthenia gravis	
Modiodal (Modafinil)	Psychoneurotic agent	Obstructive sleep apnea	Filed in May 2010
Pazucross (Pazufloxacin mesilate)	New quinolone antibacterial agent	Severe or intractable case: additional dose,septis, pneumococcus	Approved in July 2010

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. Actual financial results may differ materially from these forecasts depending on a number of important factors.