

Product Strategy & Development Pipeline

May 14, 2010
FY2009 Business Results Briefing
LEVEL XXI, Tokyo Kaikan

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Development Division

Agenda

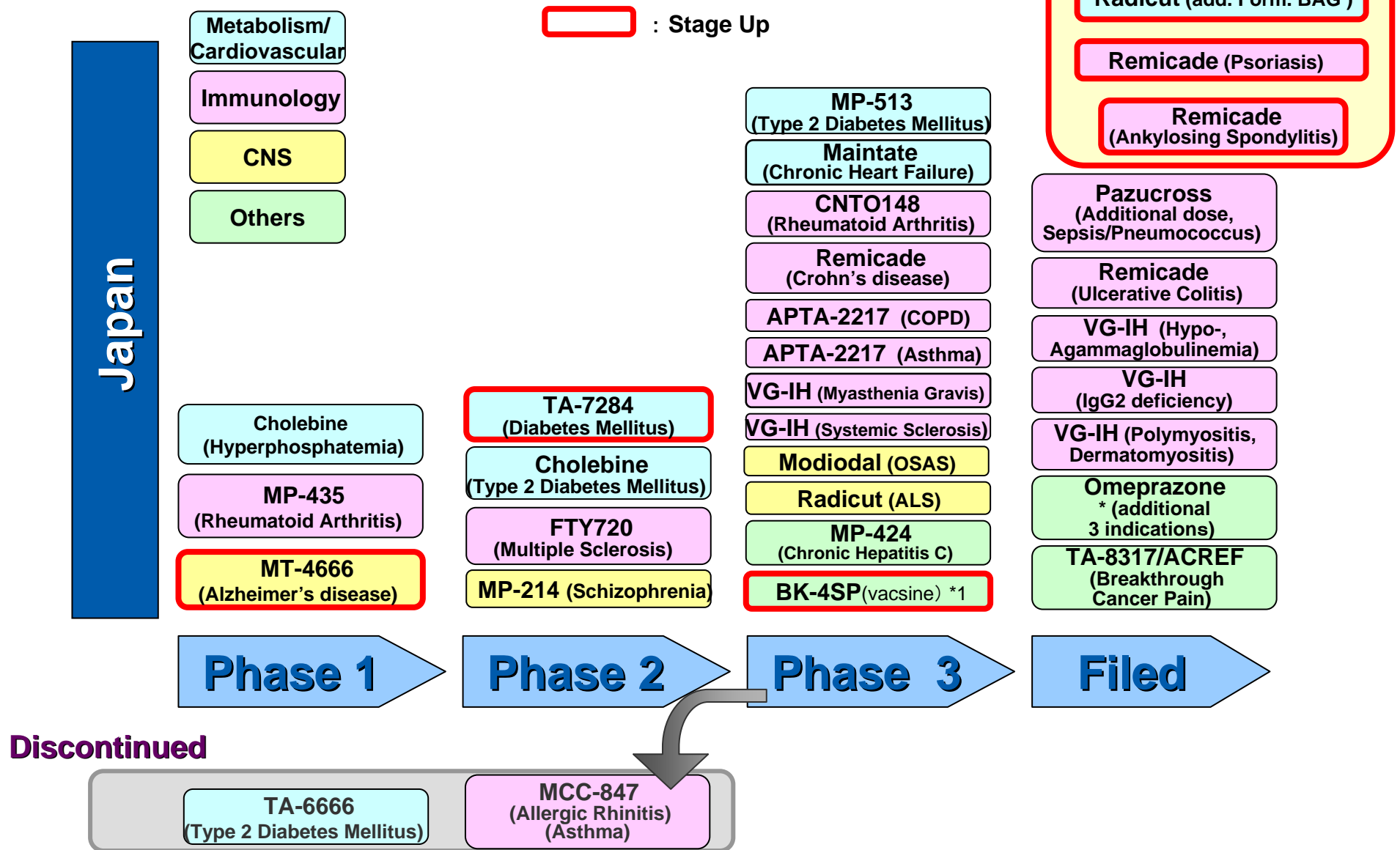


- 1. Development Pipeline Status**
- 2. Major Development Projects**
 - **Overseas Development Status**
 - **Diabetes**
 - **Autoimmune disease**
 - **Others**

1. Development Pipeline Status

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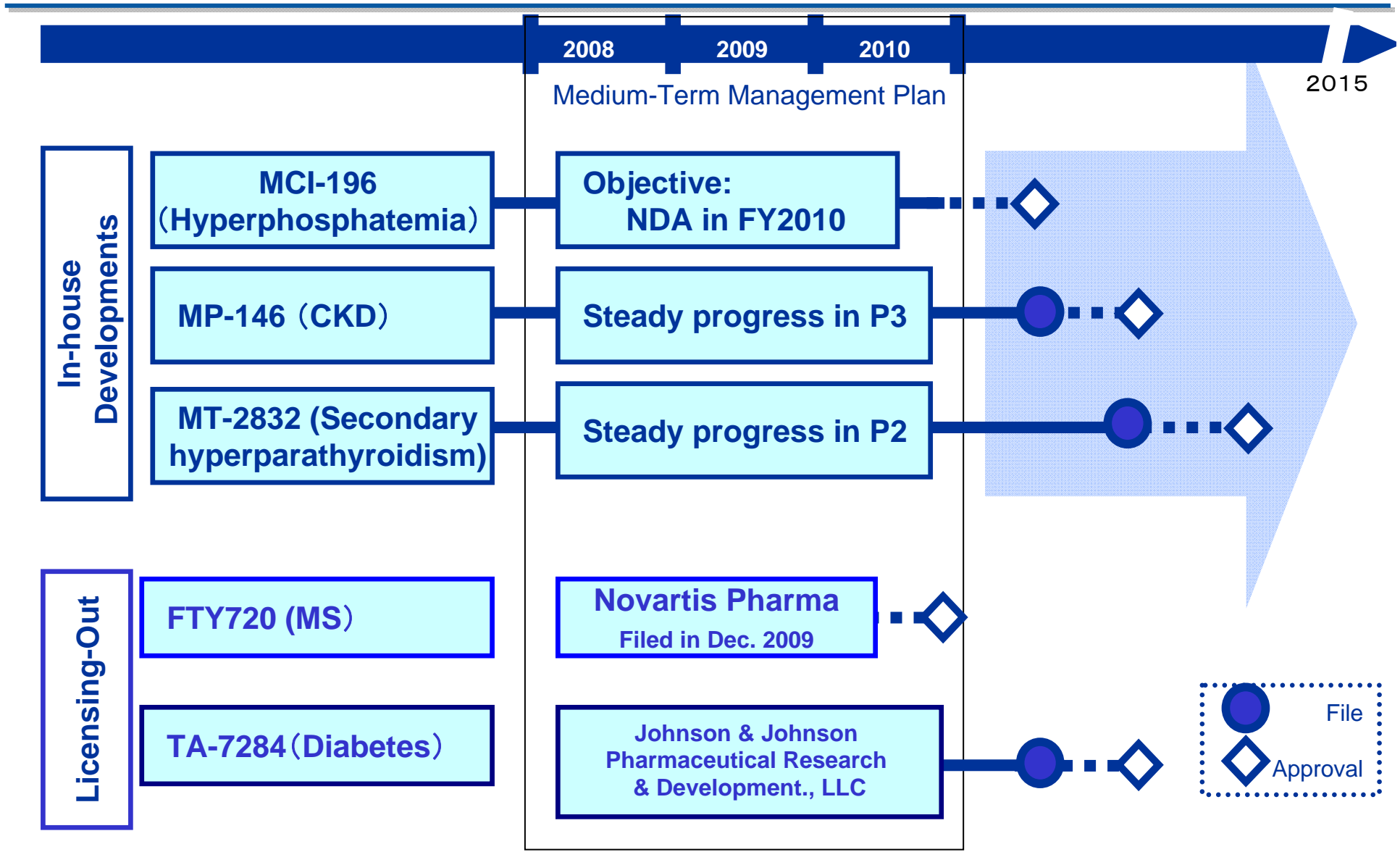
< Japan >



2. Major Development Products

Overseas Development Status

Major Development Projects [Overseas]

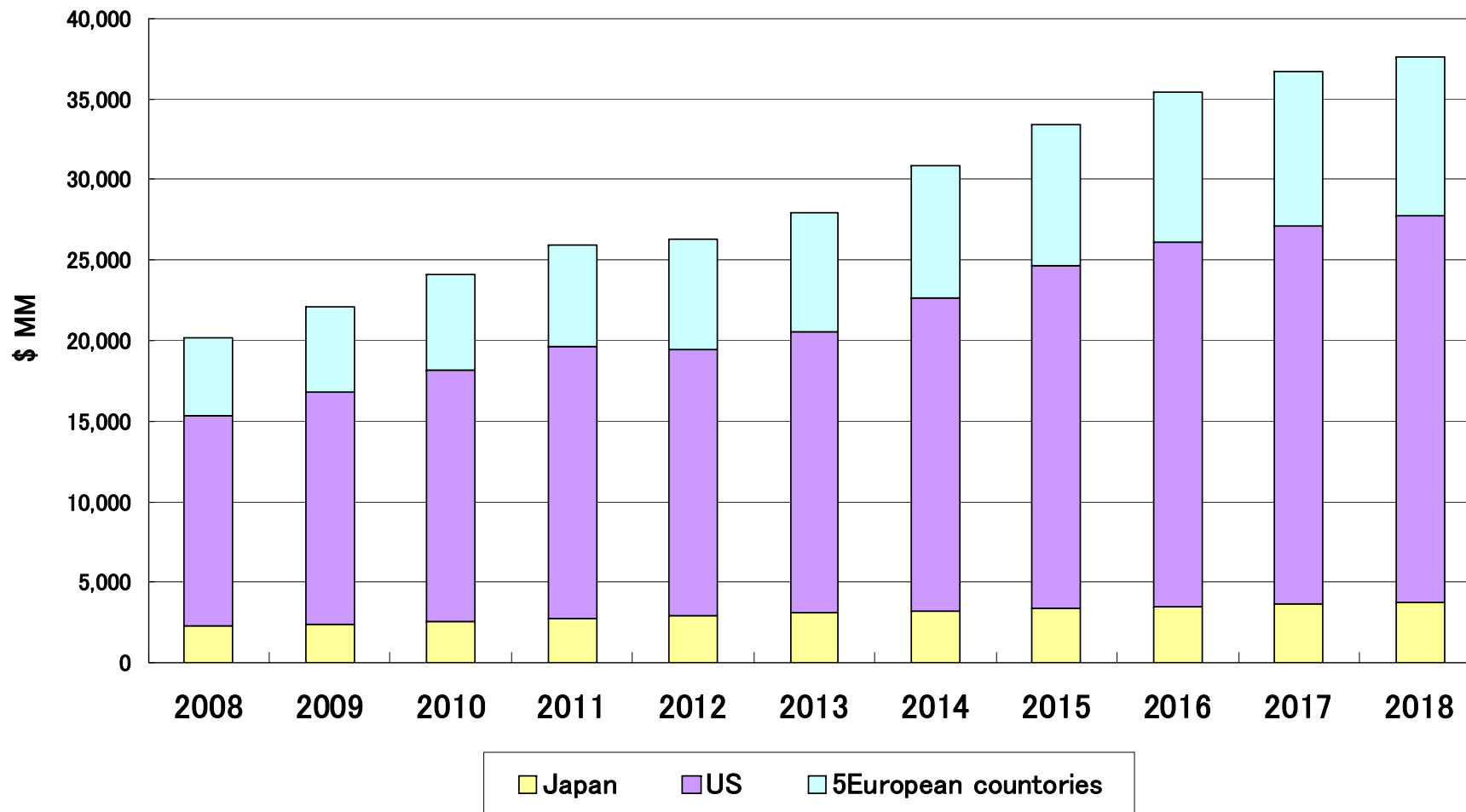


Diabetes

Oral Antidiabetic Agent Market



Increasing sales forecasts in major countries



Data Source; Data Monitor

“Commercial Insight: Antidiabetics Forecast Data Summary, IMHC0297, 09/2009”

MP-513 (Teneligliptin)



【Status of Development】

Japan: Phase 3

US/Europe: Phase 2

- Under negotiation for licensing

■ Competitors in Japan

Launched	Sitagliptin, Vildagliptin
Approved	Alogliptin
Phase 3	Linagliptin Teneligliptin (MTPC) SK0403 Saxagliptin

■ Characteristics

- May improve hyperglycemia with an oral once daily low dose
- Low excretion rate from kidneys (possible potential no dosage adjustment is required on the patients with low kidney functions)

■ Results of Clinical Trials

Japan Diabetes Society (May)

American Diabetes Association (June)

TA-7284 (Canagliflozin)



【Status of Development】

Japan: Phase 2 by MTPC

US/Europe: Phase 3, licensed out

Development by Johnson & Johnson Pharmaceutical Research & Development, LLC (Planned filing 2012)

■ SGLT2 inhibitors under development

(Japan)

Phase 3	ASP-1941
Phase 2	Dapagliflozin RG7201/CSG452 Canagliflozin (MTPC) BI10773

(Overseas)

Phase 3	Dapagliflozin TA-7284/Canagliflozin
Phase 2	BI10773 RG7201/CSG452 ASP1941

■ Characteristics

Potent blood glucose lowering + weight reduction

Insulin-independent mechanism

■ Results of Clinical Trials

: Japan Diabetes Society (May)

: American Diabetes Association (June)

Autoimmune disease

FTY720 (Multiple Sclerosis)



【Status of Development】

- Overseas: Licensing-out to Novartis, NDA filed last December in US and Europe
- Japan: Co-development with Novartis K.K, NDA filing to be planned at the end of 2010*1

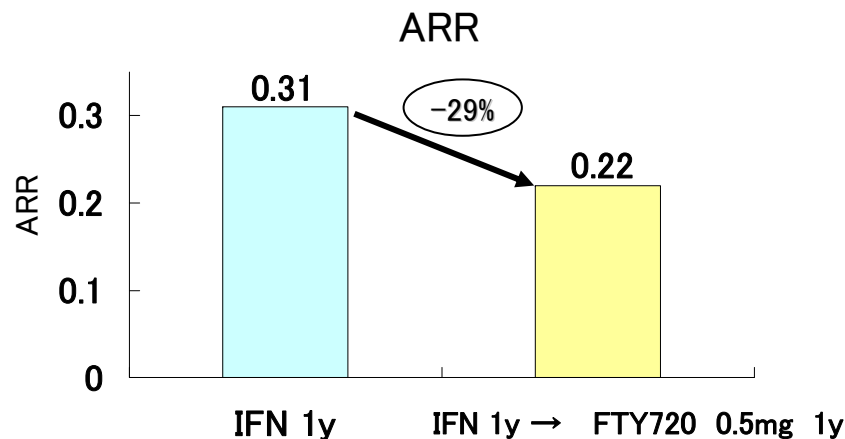
*1: when results of Phase 2 studies yield expected outcomes

【Competitors】

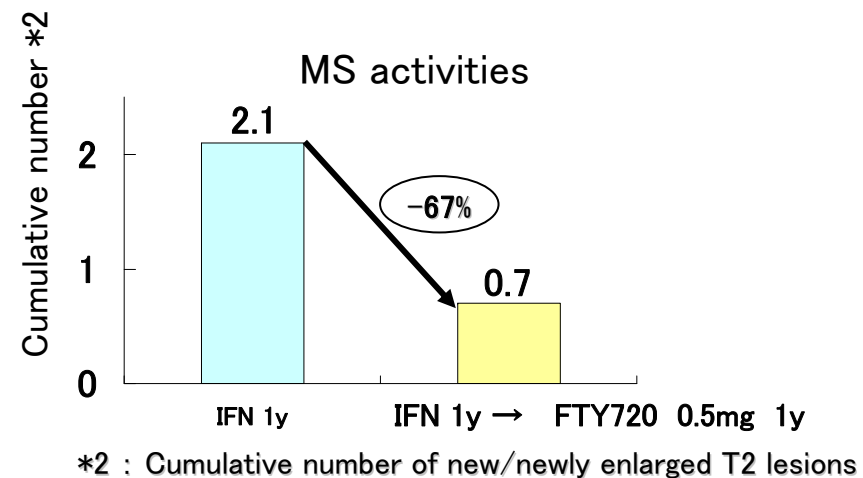
- Current treatment (injection only)

Drug name	Avonex	Rebif	Betaferon	Copaxone (glatiramer acetate)	Tysabri (natalizumab)
Dosage, Administration	IM 1/week	SC 3/week	SC Alternate-day	SC 1/day	IV 1/month

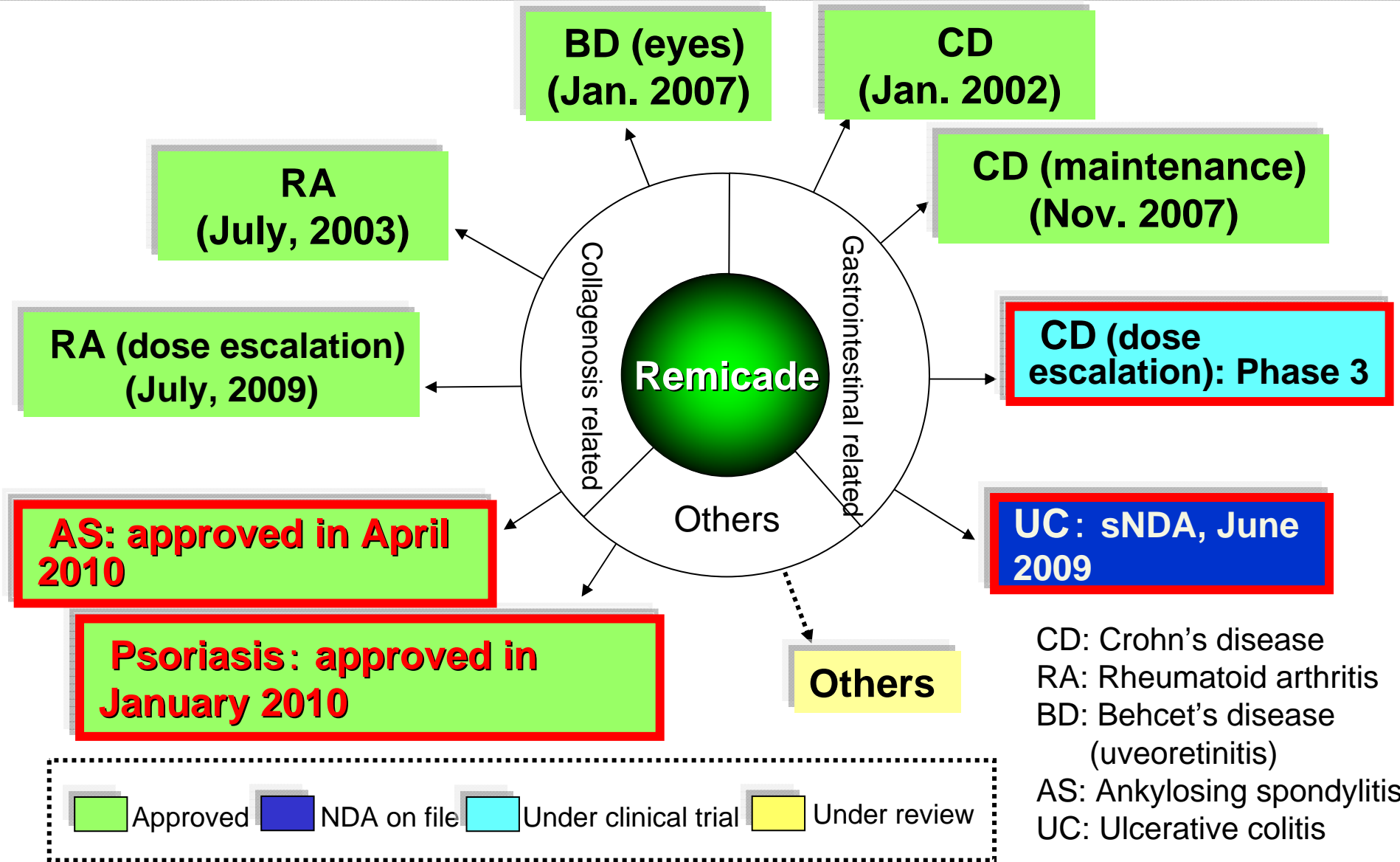
【AAN, Apr. 2010】



TRANSFORMS extension study



Remicade (Life Cycle Management)

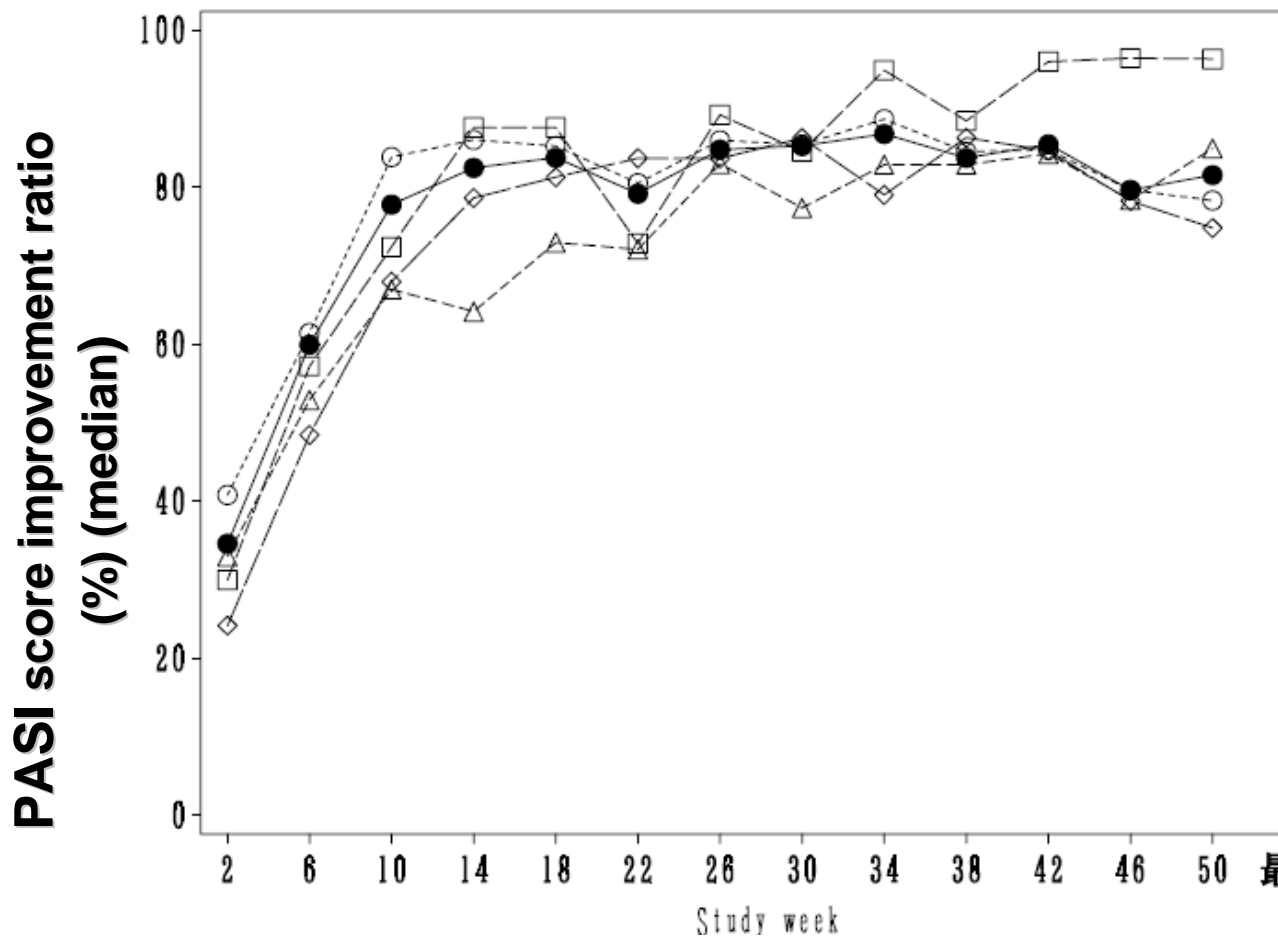


Remicade (Psoriasis) Approved in January 2010

Results of P3 clinical trial in Japan



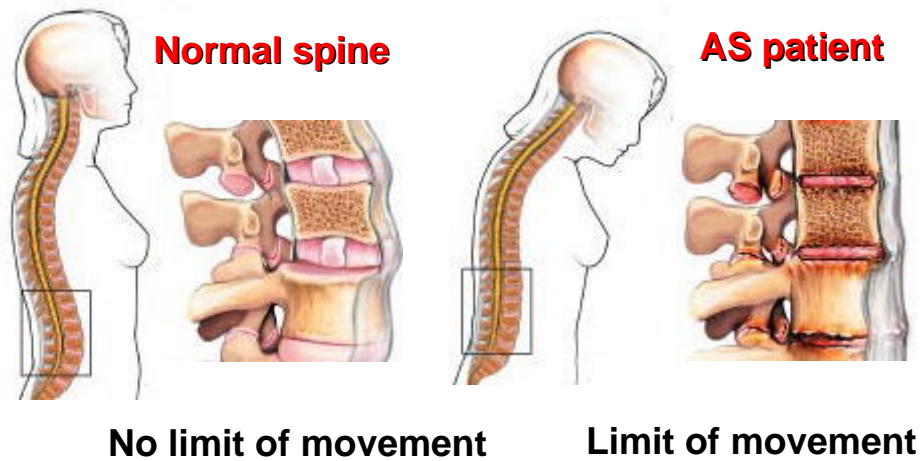
PASI score improvement ratio of each PS subtype (Results of a Long term trial)



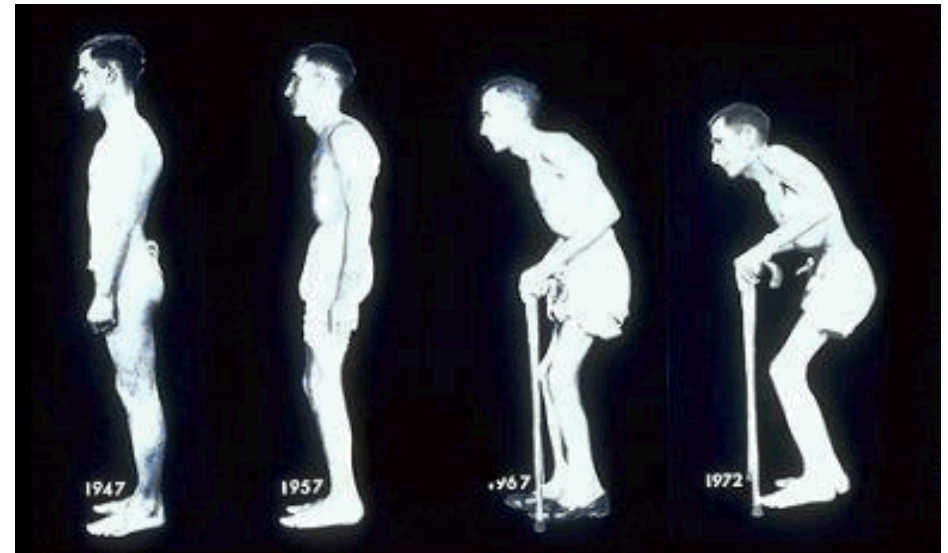
●:Overall ○:plaque psoriasis (n=37) △:psoriasis arthropathica (n=12)
□:pustular psoriasis (n=7) ◇:erythrodermic psoriasis (n=8)

Approved in April 2010

Remicade (Ankylosing Spondylitis)



from <http://www.nurs.or.jp/~academy/igaku/s9/s9521.htm>

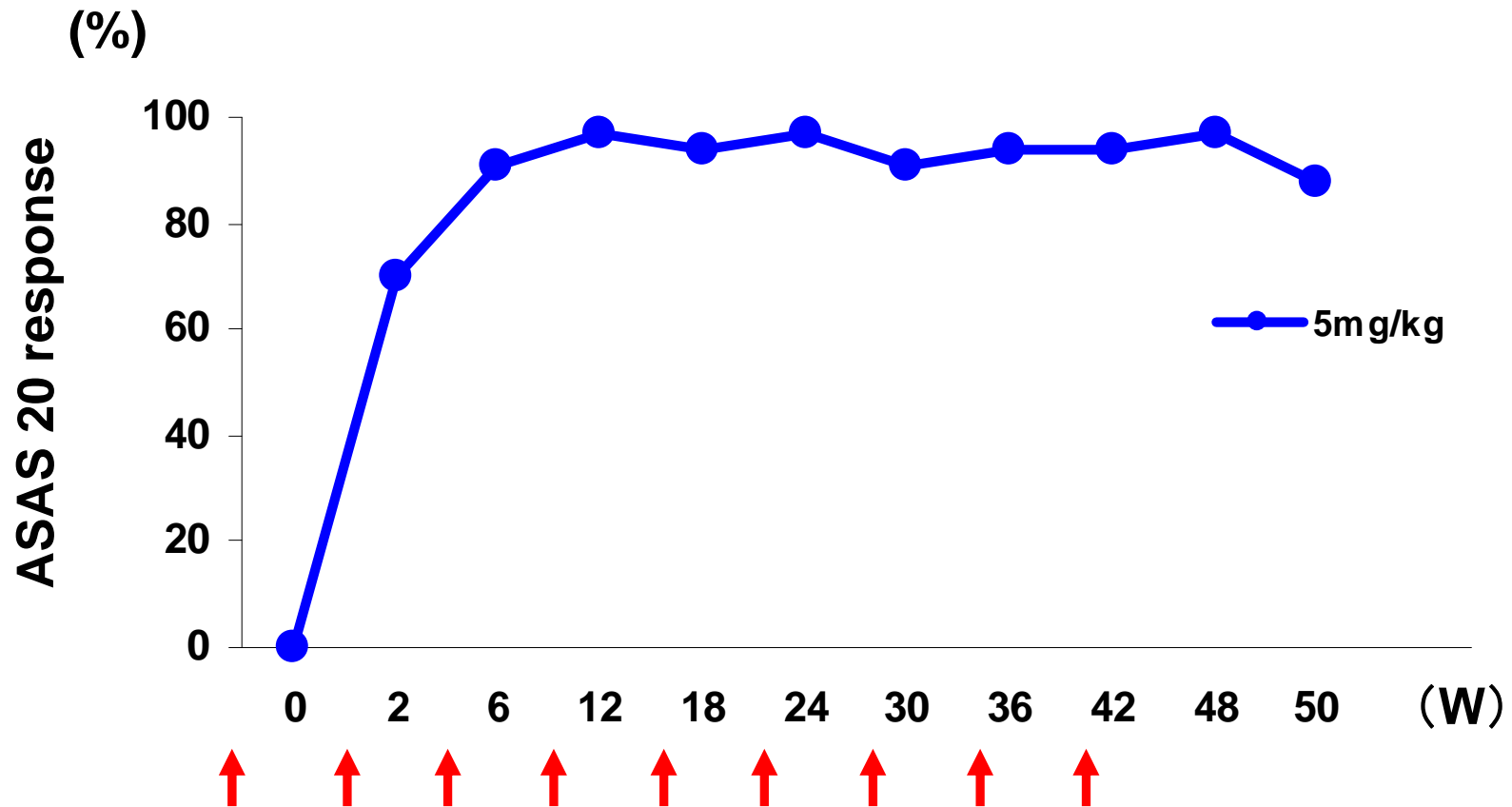


from Little H. et al. Am J. Med 1976
<http://basdai.com/>

Indication for Ankylosing Spondylitis was approved in May, 2003 in Europe and December, 2004 in the US

Remicade (Ankylosing Spondylitis)

Results of Phase3 clinical trial in Japan



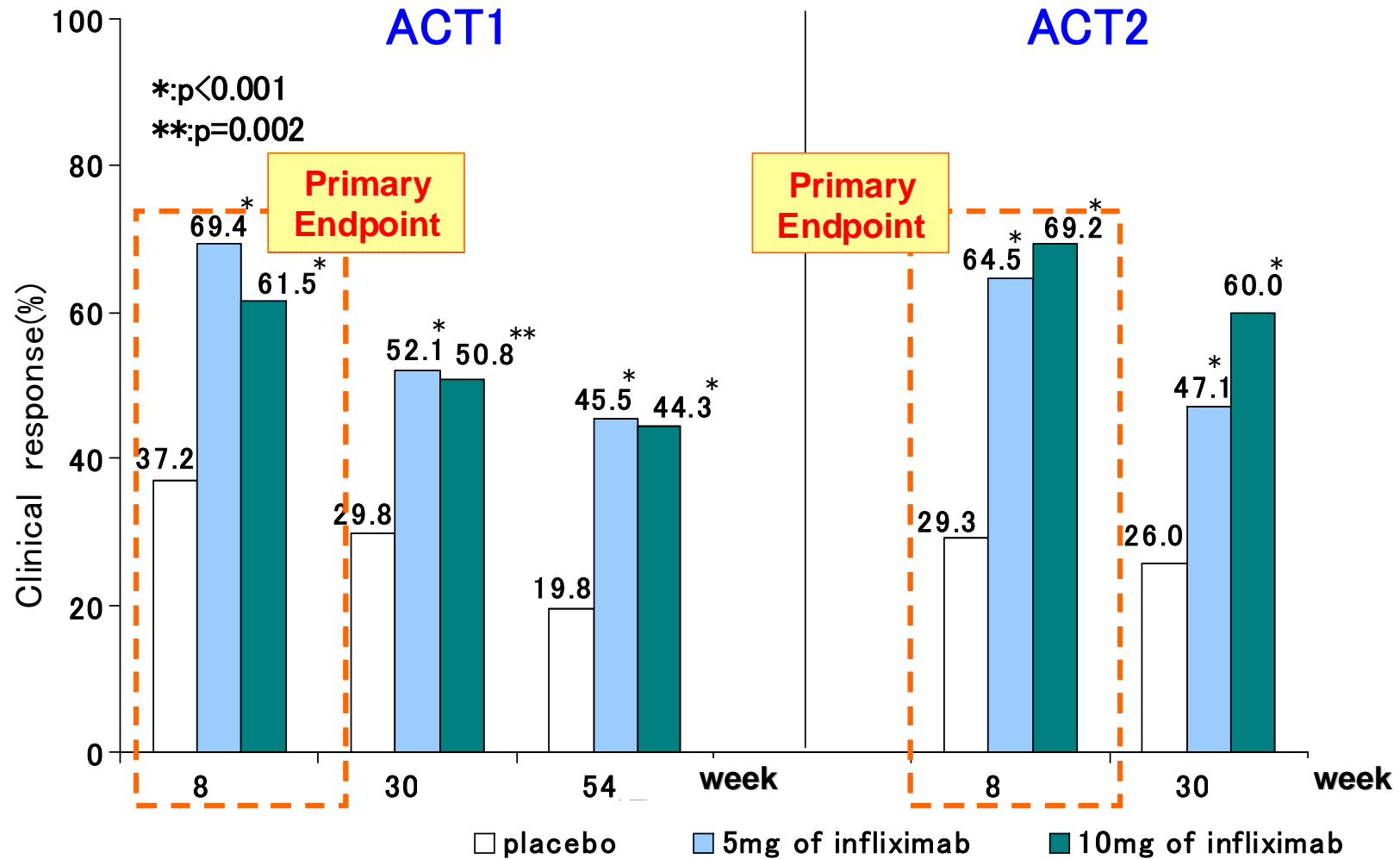
ASAS components: global patient assessment, spinal pain, physical function, morning stiffness/inflammation

Remicade (Ulcerative Colitis)

Results of Phase3 clinical trial Overseas



【Filed】 June, 2009



Modified from “Rutgeerts P et al., NEJM. 2005:323(23):2462-2476”

Competitor's of Remicade in Japan

CD: Crohn's disease
 RA: Rheumatoid arthritis
 BD: Behcet's disease
 (uveoretinitis)
 AS: Ankylosing spondylitis
 UC: Ulcerative colitis
 PS: Psoriasis
 JIA: Juvenile idiopathic arthritis

Product name	Remicade	Enbrel	Humira
Development	MTPC	Wyeth (Pfizer) / Takeda	Eisai/ Abbott
Indications	<ul style="list-style-type: none"> • CD • RA • BD • PS • AS 	<ul style="list-style-type: none"> • RA • JIA 	<ul style="list-style-type: none"> • RA • PS
Filed/ Development	Filed: UC P3: CD (dose escalation)		Filed: CD, AS P2/3: UC, JIA

Product name	Actemra	Orencia	Cimzia
Development	Chugai	BMS	UCB/Otsuka
Indications	<ul style="list-style-type: none"> • RA • JIA • Castleman's disease 	—	—
Filed/ Development	P1/2: RA (SC administration)	Filed: RA (April 2010: Division deliberation)	P3: CD, RA

CNTO148 (Rheumatoid Arthritis)



【Development Status】

- **Japan: Co-development (Janssen Pharma)**
Phase 2/3, preparations for NDA filing
- **Overseas: Launched in Europe and US**
(by Johnson and Johnson/MSD)

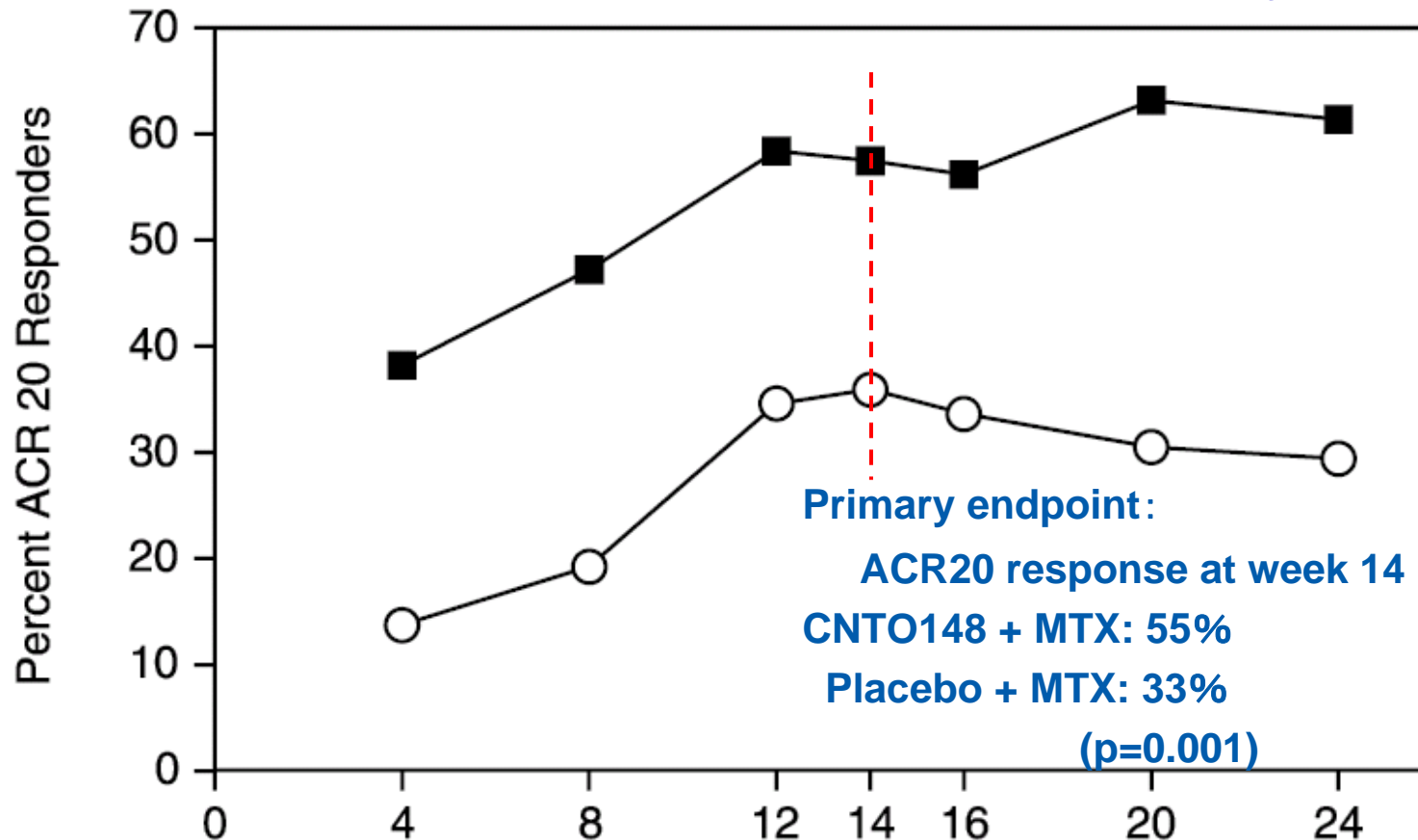
【Mechanism·Product profile】

- **Anti-TNF α monoclonal antibody**
- **Injection solution for subcutaneous use**
- **Once per month**

(GO-FORWARD trial) ~Percent of Patients Achieving ACR20 Response Results of P3 clinical trial Overseas



In Active Rheumatoid Arthritis Despite Methotrexate Therapy



—■— : CNTO148 50 mg +MTX
—○— : Placebo + MTX

Time (Weeks)

Partly modified from:
E C Keystone et al., Ann Rheum Dis 2009;68:789-796

MP-435 (Rheumatoid Arthritis)

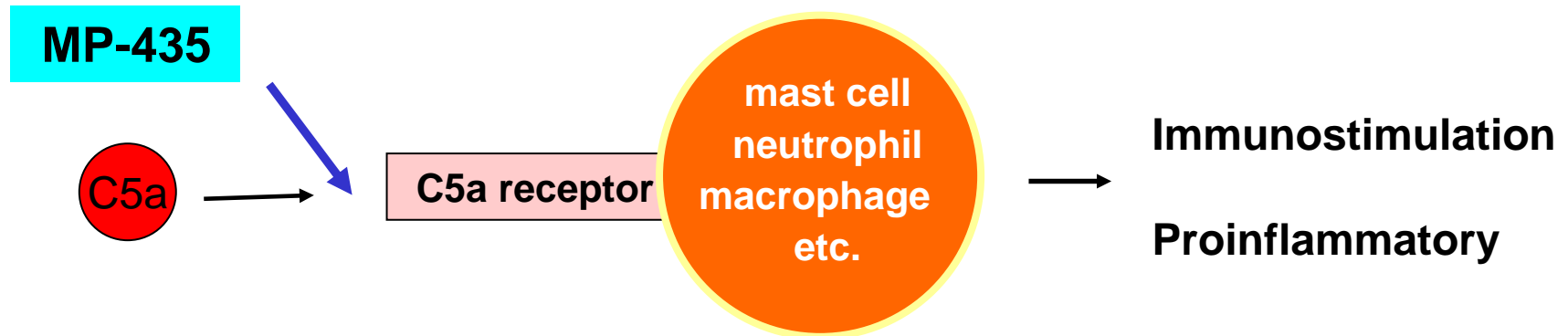


【Status of Development】

- Japan: Own development, will stage up to Phase 2 soon
- Overseas: Licensing-out to Jansen Pharmaceutica

【Mechanism of Action】

Anti immunosuppression and anti inflammatory action by C5a receptor antagonism

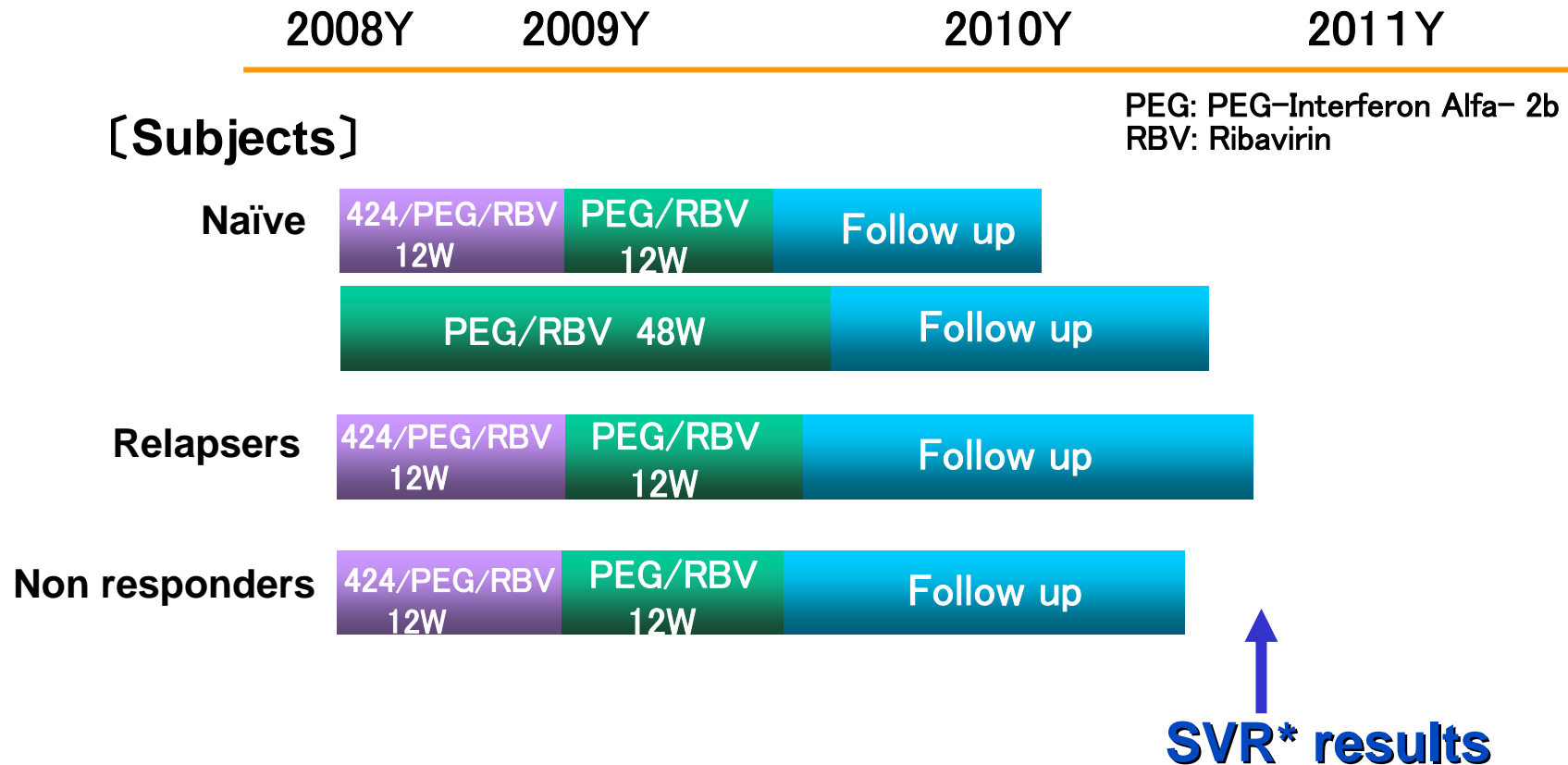


Others

MP-424 (Chronic Hepatitis C)



< Phase 3 schedule >



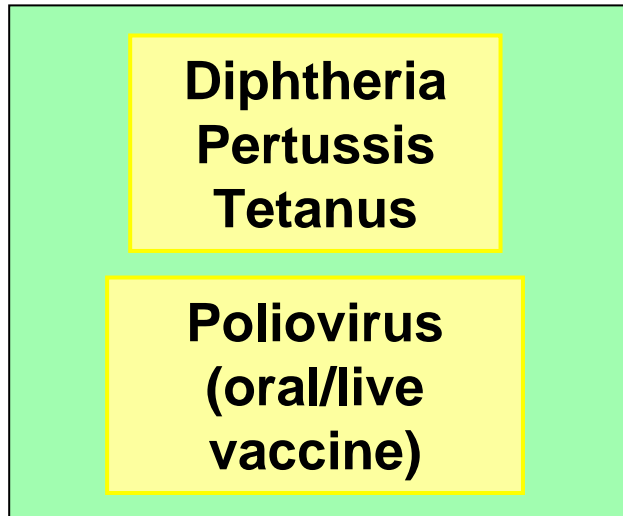
Japan : Priority advice designated product (February 2008)

* : Sustained Viral Response

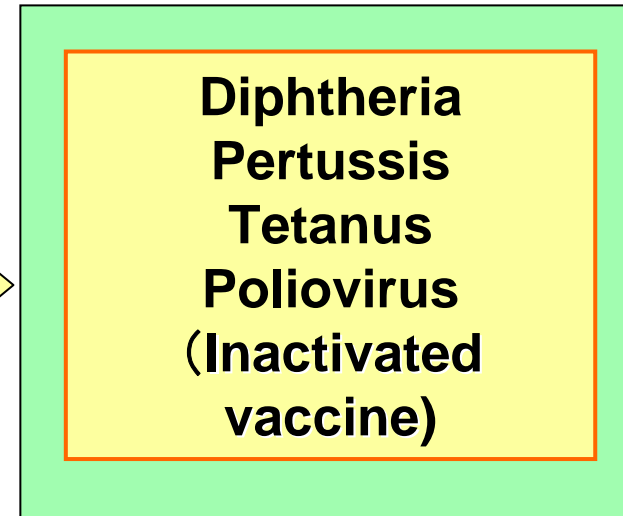
BK-4SP (Combined Vaccine)



Present



New Development



- Use inactivated poliovirus
 - possible prevention of side reactions (paralysis) and secondary infection
- Reduce patients burden by simultaneous inoculation

【Development Status】

Started Phase 3 co-development with The Research Foundation for Microbial Diseases of Osaka University

Cautionary Statement

The statements contained in this presentation are based on a number of assumptions and beliefs in light of the information currently available to the management of the company and is subject to significant risks and uncertainties.