

Mitsubishi Tanabe Pharma Corporation

2Q of FY2013 Business Results

Development Pipeline

November 1, 2013

Masayuki Mitsuka

Board Director , Managing Executive Officer

Development Division Manager



Mitsubishi Tanabe Pharma

- **Pipeline Development Status**
- **Current Status of Main Products**
 - **MT-4666/EVP-6124**
 - **MP-214 (Cariprazine)**
 - **Gilenya/Imusera**

Pipeline Development Status

→ : Changes since July 31, 2013

		Mode of Action (Indications)	Region	P1	P2	P3	NDA	Approval
New Molecular Entities in-house	MT-1303	S1P receptor functional antagonist (Inflammatory bowel disease)	Europe	→				
		(Psoriasis)	Europe	→				
	MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Japan	→				
	MT-4666	α7 nACh receptor agonist (Alzheimer's disease)	Japan	→	→	→	→	Preparing for P3
Out-licensed Products	MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan (Kyowa Hakko Kirin)	→				
	TA-7284/ INVOKANA™	SGLT2 inhibitor (Type 2 diabetes mellitus)	Europe (Janssen Pharmaceuticals)	→	→	→	→	Recommendation of approval
	MP-513	DPP-IV inhibitor (Type 2 diabetes mellitus)	Korea (Handok Pharmaceuticals)	→	→	→	→	

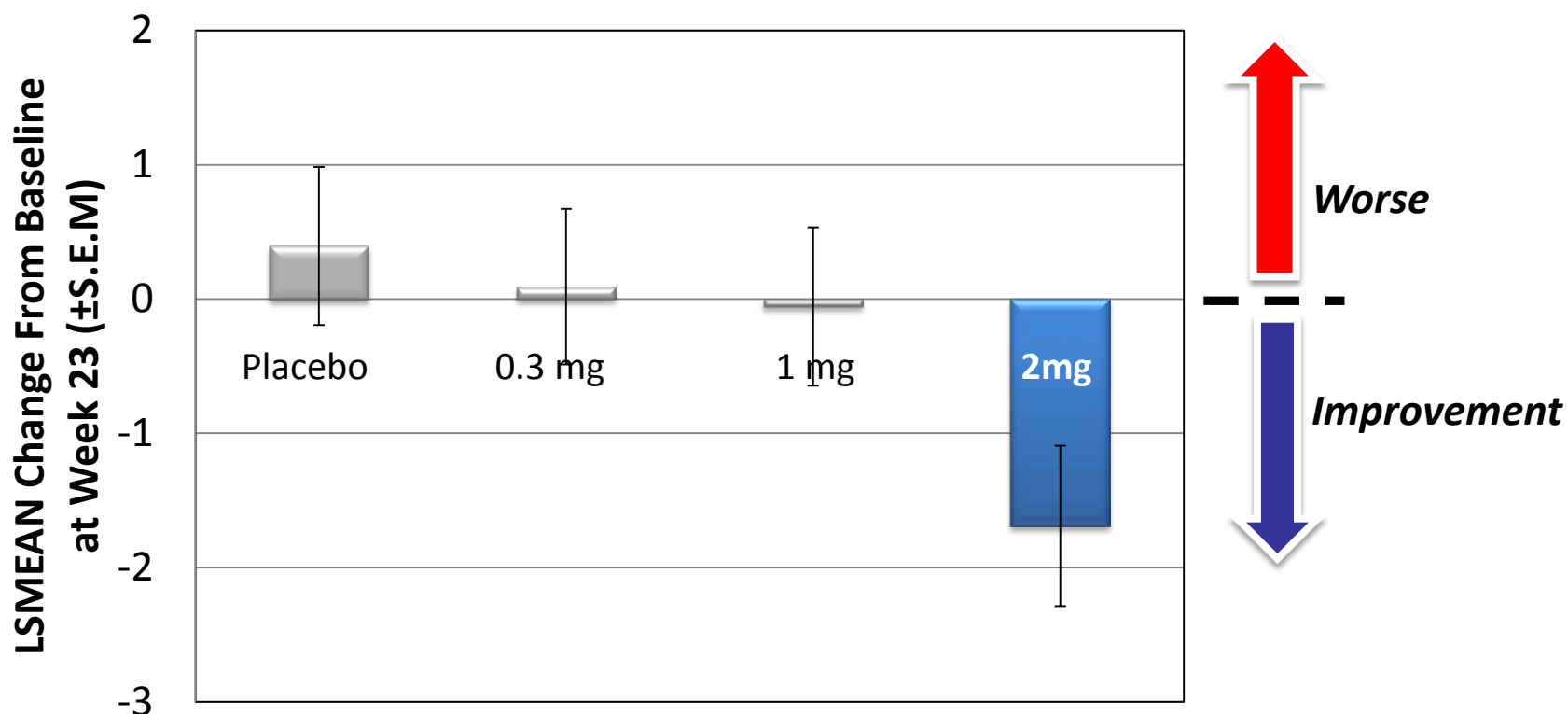
MT-4666/EVP-6124

Mode of action	α 7 nicotinic acetylcholine receptor agonist
Indications	Alzheimer's Disease
Origin	EnVivo (US)
Development regions	Japan
Current stage	Phase 2
Distinctive features	<ul style="list-style-type: none">• Overseas phase 2b trials (conducted by EnVivo), indicated positive results on improving cognition and clinical symptoms in Alzheimer's patients (expected first in class).• Expected to be used concomitantly with drugs such as donepezil, rivastigmine, and galantamine.

Participation in Global Ph3 studies and aiming for early approval in Japan

《Cognition: ADAS Cog-13》

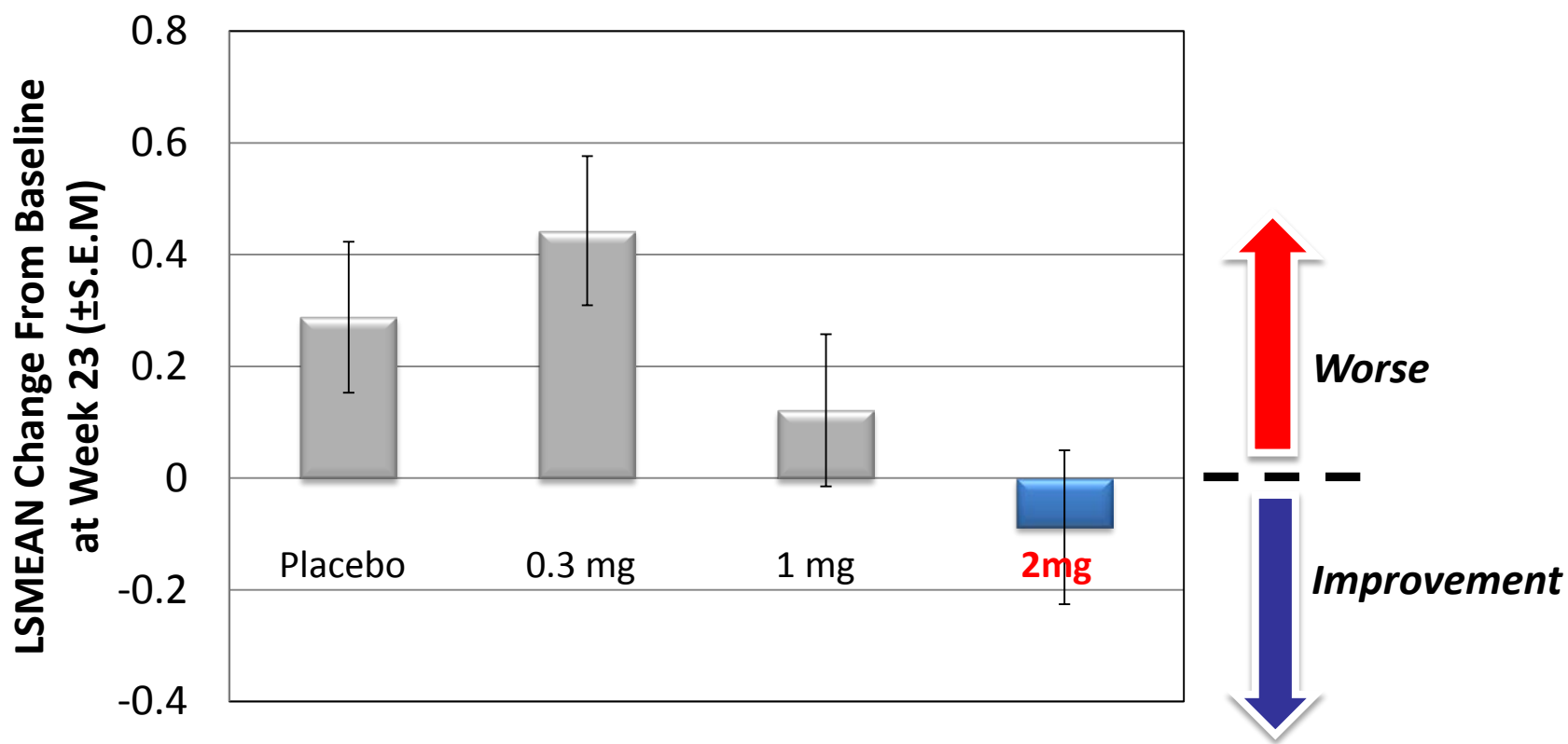
- Effects on cognition (ADAS Cog-13) in mild to moderate Alzheimer's disease patients.
- EVP-6124, 2 mg dose showed statistically significant improvement in cognition.



EVP-6124 2 mg vs. Placebo
Week 23: P-value = 0.0189
Effect Size = 0.39

« Clinical Function: CDR-SB »

- Effects on clinical function (CDR-SB) in mild to moderate Alzheimer's disease patients.
- EVP-6124, 2 mg dose showed statistically significant improvement in clinical function.



EVP-6124 2 mg vs. Placebo
Week 23: P-value = 0.0253
Effect Size = 0.31

Global Alzheimer's Disease Drug Development

(As of October, 2013)

Classification	Drug	Mode of Action	Company	Dosage Form	Stage
Symptomatic Drugs	MT-4666/EVP-6124	α 7R agonist	MTPC EnVivo	Oral	Ph2
	ABT-126	α 7R agonist	AbbVie	Oral	Ph2
	AZD-1446	α 4 β 2R agonist	AstraZeneca	Oral	Ph2 (discontinued)
	Lu AE58054	5-HT6R antagonist	Otsuka Lundbeck	Oral	Ph3
	ORM-12741	α 2cAR antagonist	Orion Pharma	Oral	Ph2
Disease Modifying Drugs	LY2062430 (solanezumab)	A β (mAb)	Eli Lilly	Injection	Ph3
	MK-8931	BACE inhibitor	Merck	Oral	Ph2/3
	RG1450	A β (mAb)	Roche	Injection	Ph2
	BAN2401	Protofibril (mAb)	Eisai	Injection	Ph2
	ACC-001 (vanutide cridificar)	A β vaccine	Pfizer Janssen AI	Injection	Ph2 (discontinued)
	BMS-708163	γ -secretase inhibitor	BMS	Oral	Ph2 (discontinued)
	LY2886721	BACE inhibitor	Eli Lilly	Oral	Ph2 (discontinued)
	T-817MA	Neurotrophic agent	Toyama Chemical	Oral	Ph2

MP-214, Cariprazine

Mode of action	Dopamine D3/D2 receptor partial agonist
Indications	Schizophrenia
Originator	Gedeon Richter (Hungary)
Development regions	Japan, Korea, Taiwan: Phase2b/3
Current stage	Phase2b/3
Distinctive features	<ul style="list-style-type: none">• Represents a new treatment option for schizophrenia• Shows favorable safety and pharmacokinetic profile• Has novel mechanism of action

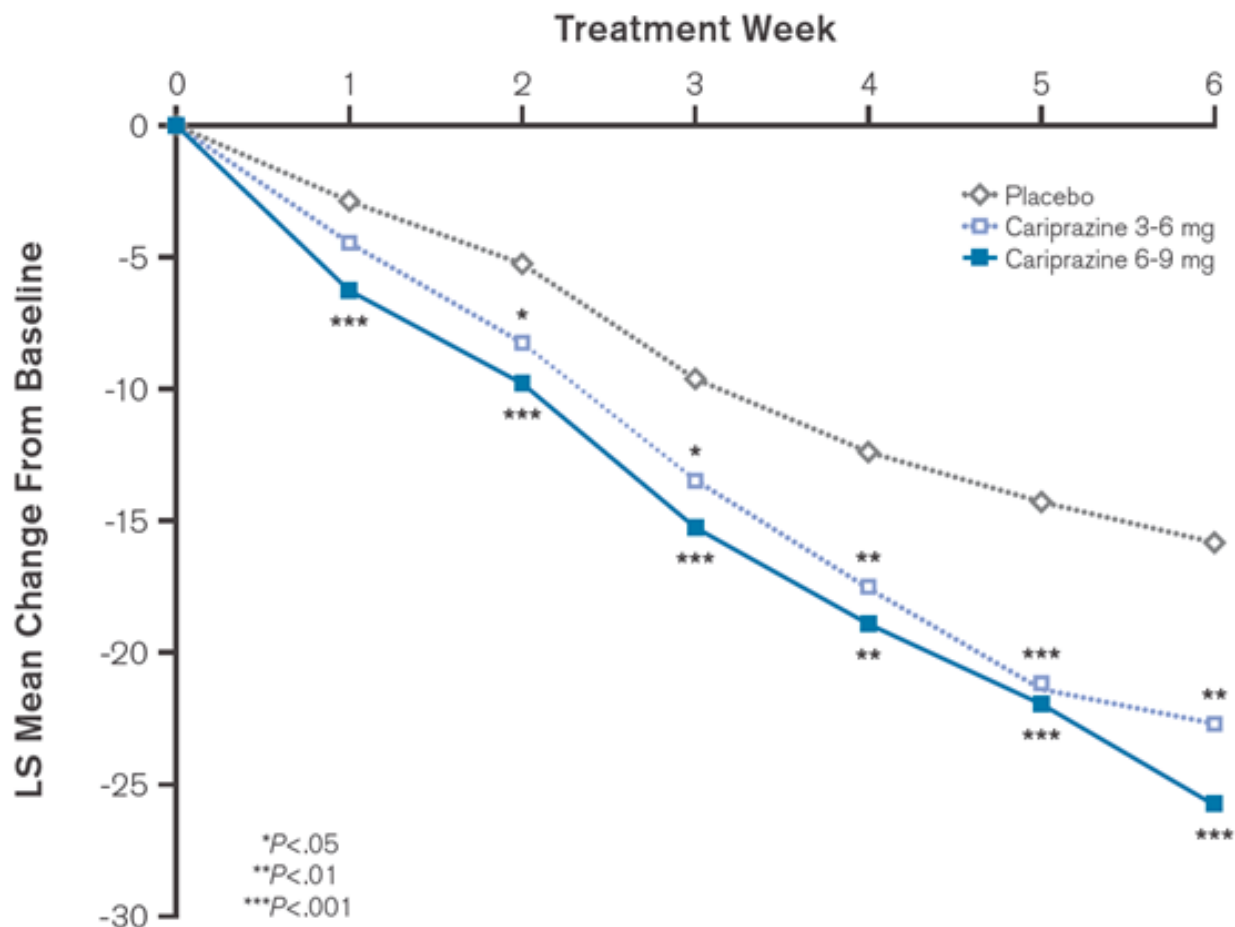
Promoting Asian Ph2b/3 studies

Phase 3 Trial in Schizophrenia (Forest)

《PANSS* Total Score》

*: Positive and Negative Symptom Scale

- MP-214 (Cariprazine), 3-6 and 6-9 mg/day, in acute exacerbation of schizophrenia.
- Change in PANSS total score from baseline to week 6 (MMRM, ITT population).
- Significant improvement vs. placebo seen in both MP-214 groups.



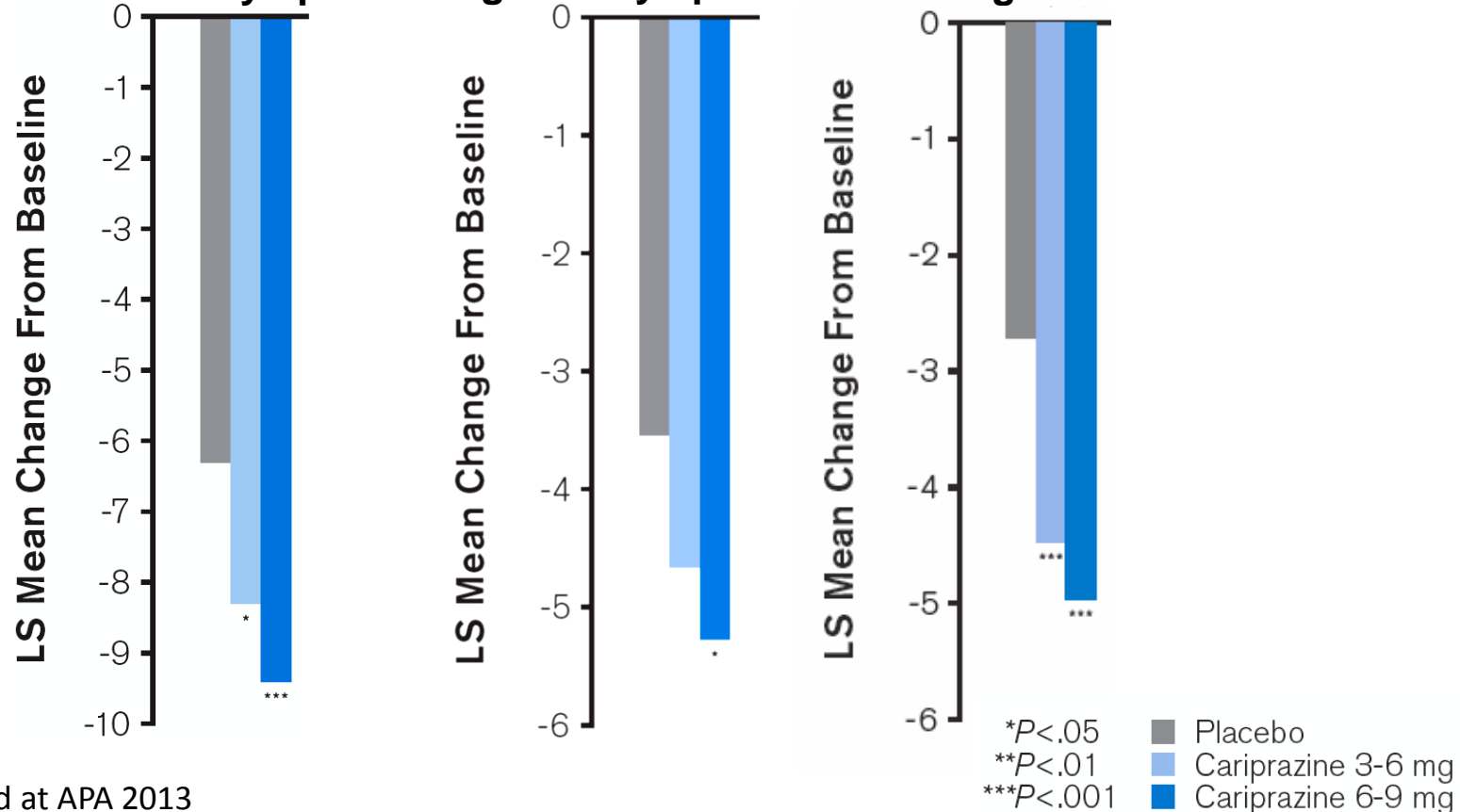
Post Hoc Results from P3 Trial in Schizophrenia New Value Creation



《PANSS Subscales》

- MP-214 (Cariprazine), 3-6 and 6-9 mg/day, in acute exacerbation of schizophrenia.
- LS mean change at week 6 for PANSS subscales (MMRM, ITT population).
- M-214 showed demonstrated efficacy on both positive and negative symptoms.

Marder Factors: Positive Symptom Negative Symptom Cognitive



Gilenya/Imusera

Mode of action	S1P receptor functional antagonist
Indications	Multiple sclerosis (MS) Chronic inflammatory demyelinating polyneuropathy (CIDP)
Origin	In-house
Current stage	MS ; Launched (Overseas: Novartis, Domestic: MTPC & Novartis) CIDP ; Phase 3 (Multinational Study*)
The latest topics	<ul style="list-style-type: none">• Continuous Gilenya treatment (4 years) reduced brain atrophy; confirm relationship between brain atrophy disability in MS patients.• Treatment with Gilenya reduced the annual relapse rate and risk of relapse by approximately 50% compared to standard interferon or glatiramer acetate treatment.

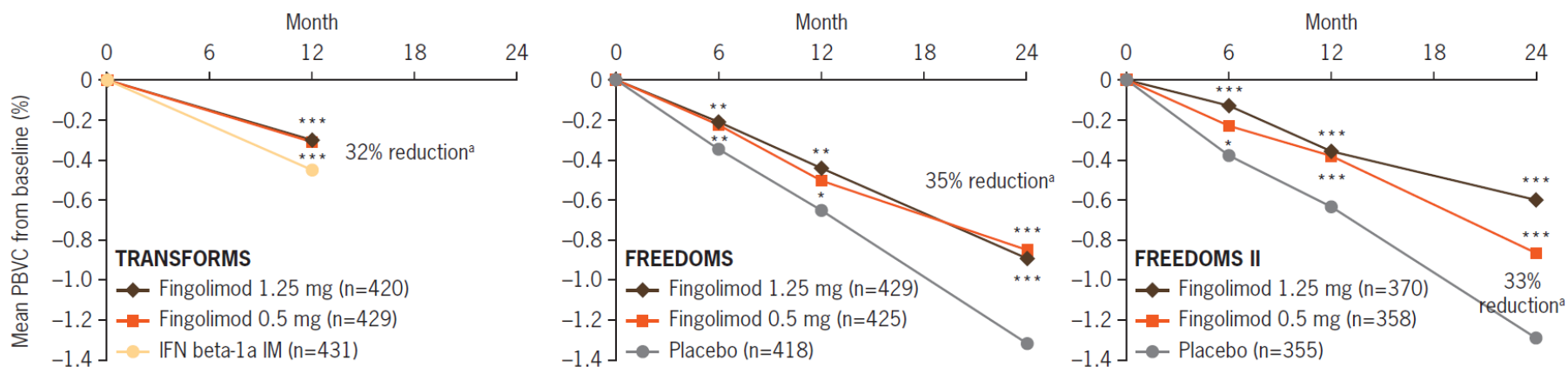
*: Multinational study, co-developed with Novartis Pharma in Japan, licensed to Novartis overseas

Gilenya's superiority in MS treatment compared with standard therapies has been shown.

Gilenya reduces rate of brain atrophy in MS patients

- In an analysis of over 3,600 patients from three large Phase III studies (TRANSFORMS, FREEDOMS and FREEDOMS II), Gilenya showed a significant reduction in the rate of brain atrophy vs. a comparator.

PBVC: percentage brain volume change



*** $p < 0.001$ versus IFN beta-1a; p values calculated using Wilcoxon rank-sum test.

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ versus placebo; p values calculated using rank analysis of covariance adjusted for treatment, region and baseline normalized BV.

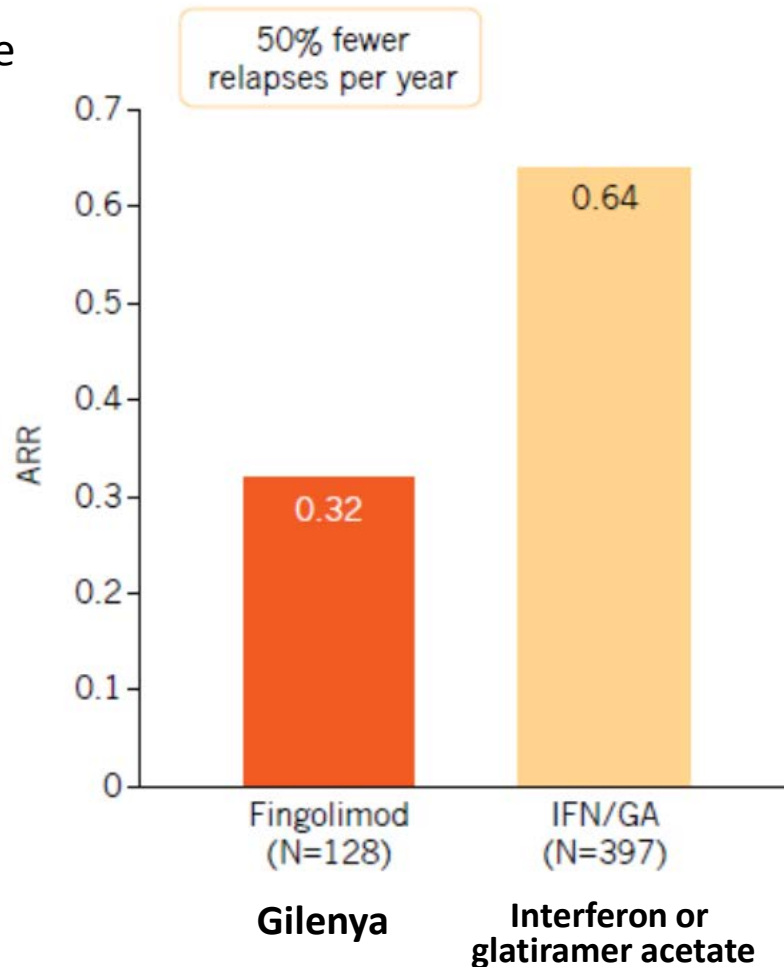
^aFingolimod 0.5 mg versus placebo.

Patient numbers shown are for the intent-to-treat population.

Treatment with Gilenya reduced the annualized relapse rate compared with standard therapies

- The real world treatment with Gilenya reduced the annual relapse rate by approximately 50% compared to standard interferon or glatiramer acetate treatment

ARR; Annualized relapse rate



New Value Creation

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

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 are subject to significant risks and uncertainties.