R&D Meeting

March 28, 2007

Dainippon Sumitomo Pharma Co., Ltd.

Drug Research Overview

Dainippon Sumitomo Pharma Co. Ltd.

Executive Director, Drug Research

Yuichi Yokoyama, Ph.D.

28th March, 2007

DAINIPPON SUMITOMO PHARMA

1. **Mid-Term Business Plan (FY 2007-2009), Drug Research**

2. **Progress in Drug Research**

Mid-Term Business Plan (FY 2007-2009)

Strengthen Our Business Foundation for the First Step to Become a Global Corporation

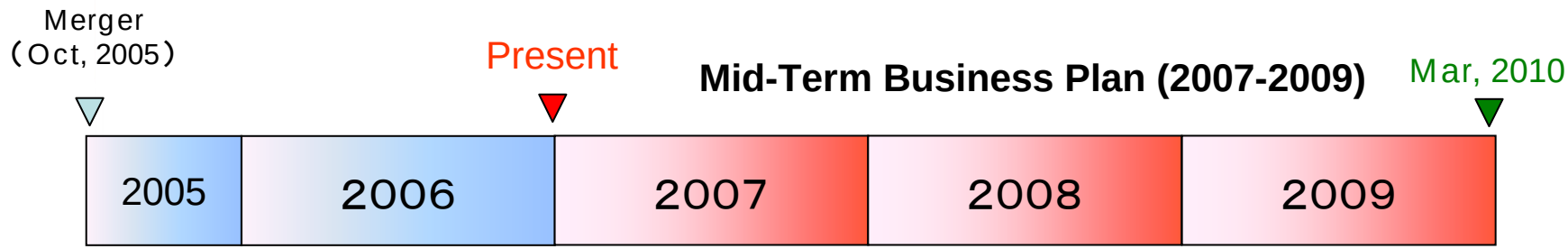
1. **Strengthen Our Domestic Business Foundation**
2. Strengthen Our R&D Organization for Strong Flow of the Pipeline Products
3. **Preparing International Operation Structure**
4. **Strengthening Strategic Partnership**
5. **Striving for Efficient Management and for Efficient and Profitable Cooperate Structure**
6. **Establishment of “DSP Management”**

Mid-Term Business Plan (FY 2007-2009), Drug Research

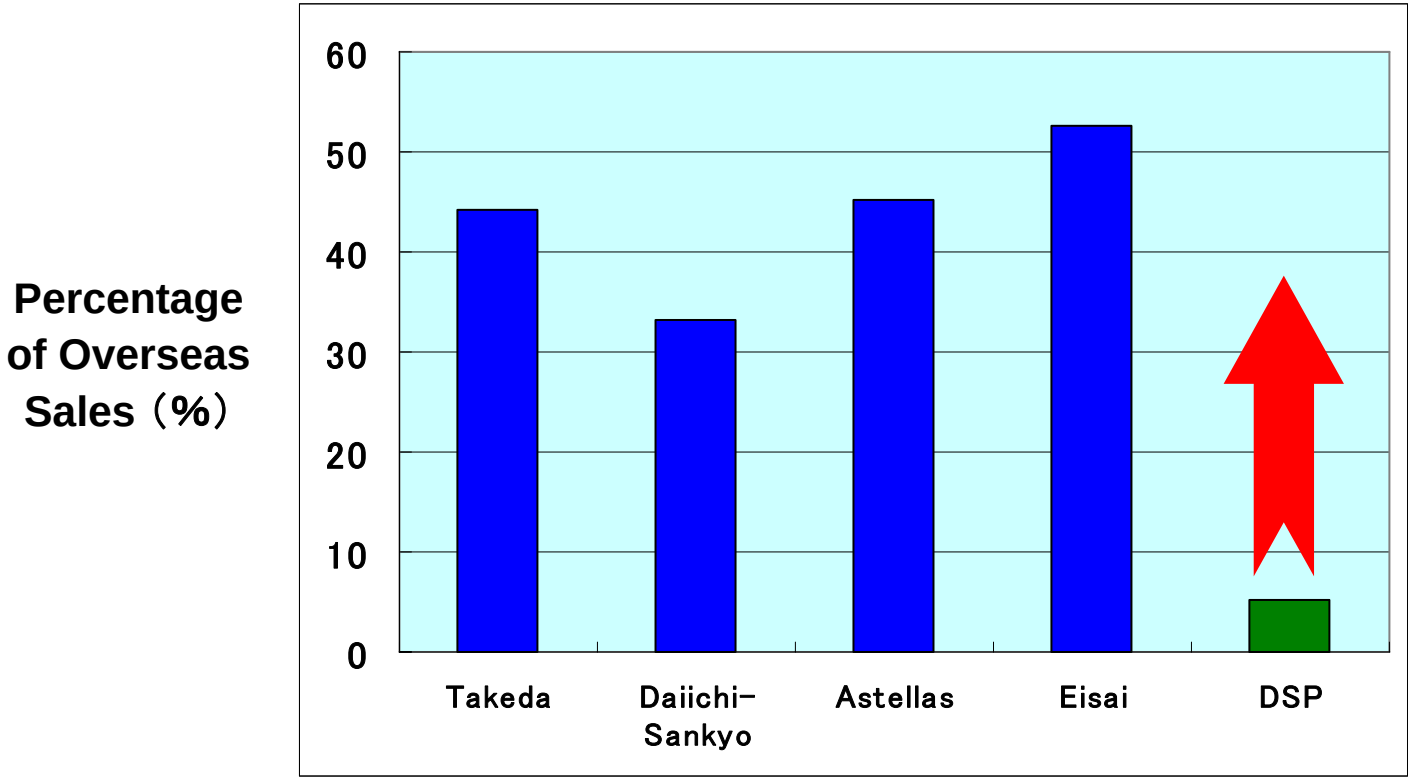
＜Basic Strategies for 3 years＞

Strengthen Our Research Organization

for Strong Flow of the Pipeline for Global Products



Discovery Capability that Generates Internationally-Competitive Drugs that Can Enhance Overseas Sales



Based on data of FY ending in March, 2006

Strengthen Our R&D Capability to Create New Compounds

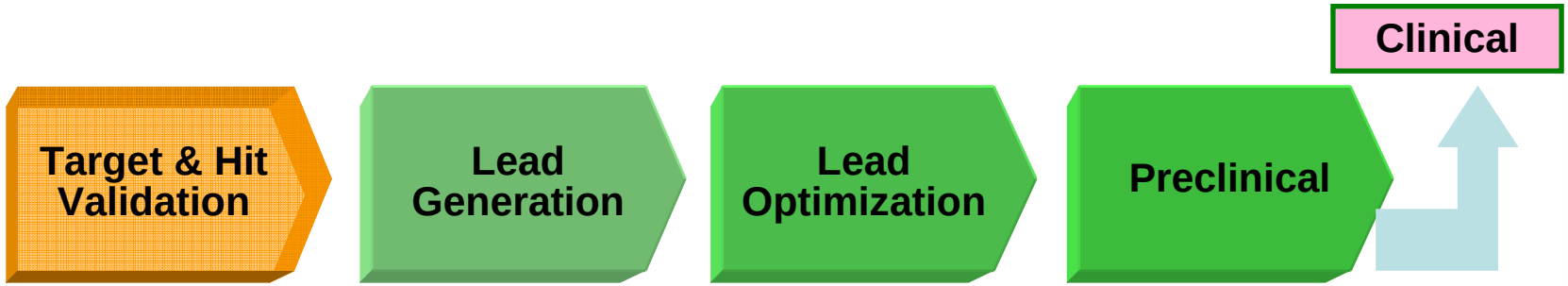
◆Three Focused Research Areas

- Diabetes/Cardiovascular
- CNS
- Inflammatory/Allergy

◆Three Strategic Plans

1. Enrich Early-Stage Discovery Programs
2. Strengthen Proprietary and Platform Technologies to Improve Research Efficiency
3. Cultivate and Activate Human Capital that Achieves Generation of Internationally-Competitive Drugs

Strengthen Our R&D Capability to Create New Compounds



Enhance number of discovery targets

1. Enrich Discovery Programs

2. Establish Proprietary and Platform Technologies

3. Cultivate and Activate Human Capital

1. Enrich Early-Stage Discovery Programs

- **Enhance Promising Research Projects**
  - We will value innovative concepts and ideas for novel therapeutics and encourage our scientists to pursue the research projects to “Target & Hit Validations” stage.

- **Strengthen Research Pipelines through Partnering and In-licensing**
  - Currently, Ongoing in CNS Area

    KASPAC: Karolinska Inst./DSP

    Drug Discovery in Alzheimer's Disease

（KASPAC）

  - Explore Further Opportunities for Collaborations with Domestic/Overseas Biopharmas and Academia

    CNS, Inflammation/Allergy, Diabetes/CV areas

2. Strengthen Platform Technologies

- **Seeds-Discovery of Promising Drug Targets**
  - Genomics, Proteomics, Metabolomics, HTS
- **Efficient Lead Optimization**
  - Protein crystallography
  - Simulation Studies to predict PK profiles in Humans
- **Improve Predictability of Efficacy in Human and Increase Probability of Success**
  - Pharmacological/Pharmacokinetic/Toxicological evaluations using target molecules/cells derived from human samples

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Application of X-ray Crystallography for Drug Discovery

Structure Analysis of Protein-Compound Complex Leads to a Design of Promising Small Compounds

- Acceleration of Structure-Based Drug Design -

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Protein crystallography

Ⅰ. Production of protein

- Gene to protein

Ⅱ. Crystallization of protein-compound complex

- Protein to crystal

Ⅲ. X-ray data collection and analysis

- Crystal to structure

- Technology Refinement to the Level Applicable to Drug Discovery
- Efficient and Effective Applications of This Technology are Essential for Structure-Based Drug Design

Procedure of X-ray crystallography

Expression of Proteins

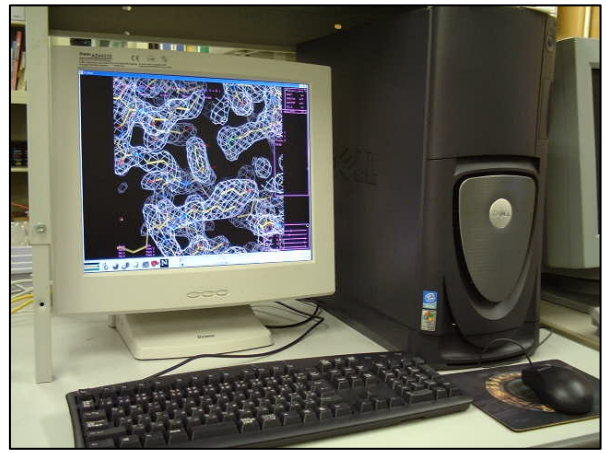
Purification of Proteins

Crystallization of Protein-Compound Complex

Large Synchrotron Radiation Facility

SPring-8
(Hyogo Prefecture)

X-ray data collection

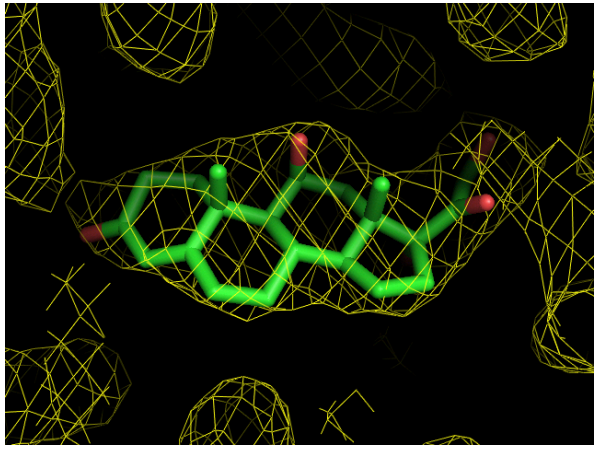


Three-Dimensional Structure Analysis

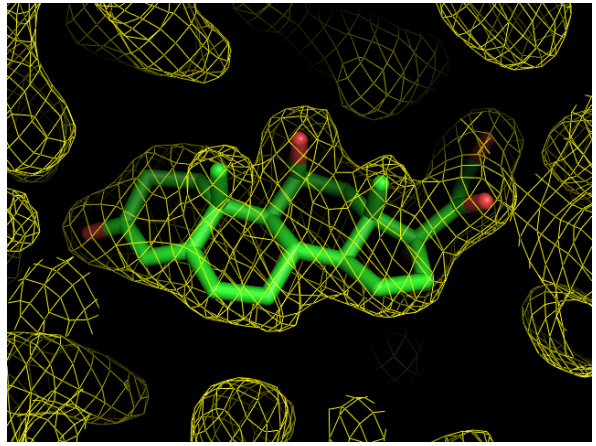
Application of structure data for drug discovery

	In-house	Spring-8
Crystal size	**0.2 mm**	**0.05 mm**
Exposure time	**30 minutes**	**1 second**
Total data collection time	**90 hours**	**3 minutes**
Resolution	**3 Å**	**2 Å**

3 Å



2 Å

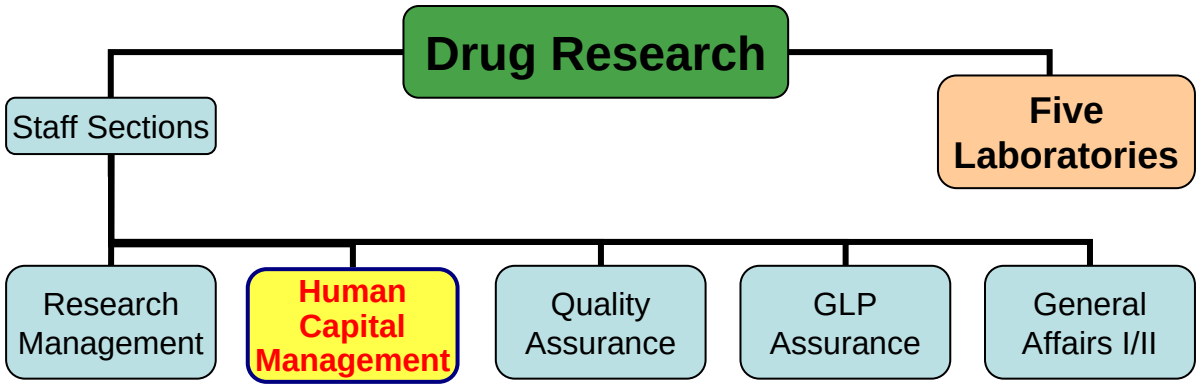


Predicted structures of protein-compound complex were analyzed using our drug candidates, which gives information on structure-activity relationship including their specificity that enabled us to find promising compounds.

3. Maximize Human Capital Management

◆ "Human Capital Management"

- Newly-organized Office that is dedicated to Strategic HRM for scientists/staff of Drug Research
- Translation of Research Strategies into HR practices to maximize the R&D performance, including Personnel Placement, Performance/ Development Planning, Career Innovation, and Recruiting



DAINIPPON SUMITOMO PHARMA

1. **Mid-Term Plan (FY 2007-2009), Drug Research**

2. **Progress in Drug Research**

Diabetes/Cardiovascular

	Main Indication Mechanism of Action			Products	Development	Research
Metabolic Syndrome-related Diseases	Diabetes	Insulin Secretagogue	Sulfonyl Urea	GLIMICRON		◎
			Rapid-acting Insulin Secretagogue		SMP-508 (repaglinide)	
		Insulin Sensitizer		MELBIN	SMP-862 (metformin)	◎
		Glucose absorption Inhibitor		SEIBULE		◎
		Complication Drug			AS-3201 (ranirestat)	○
		Antiobesity Drug				○
	CV	Hypertension		AMLODIN CETAPRIL ALMARL	Irbesartan	○
		Hyperlipidemia		LIPOCLIN		○

◎: **proceeded to preclinical stage**

Oral Antidiabetics

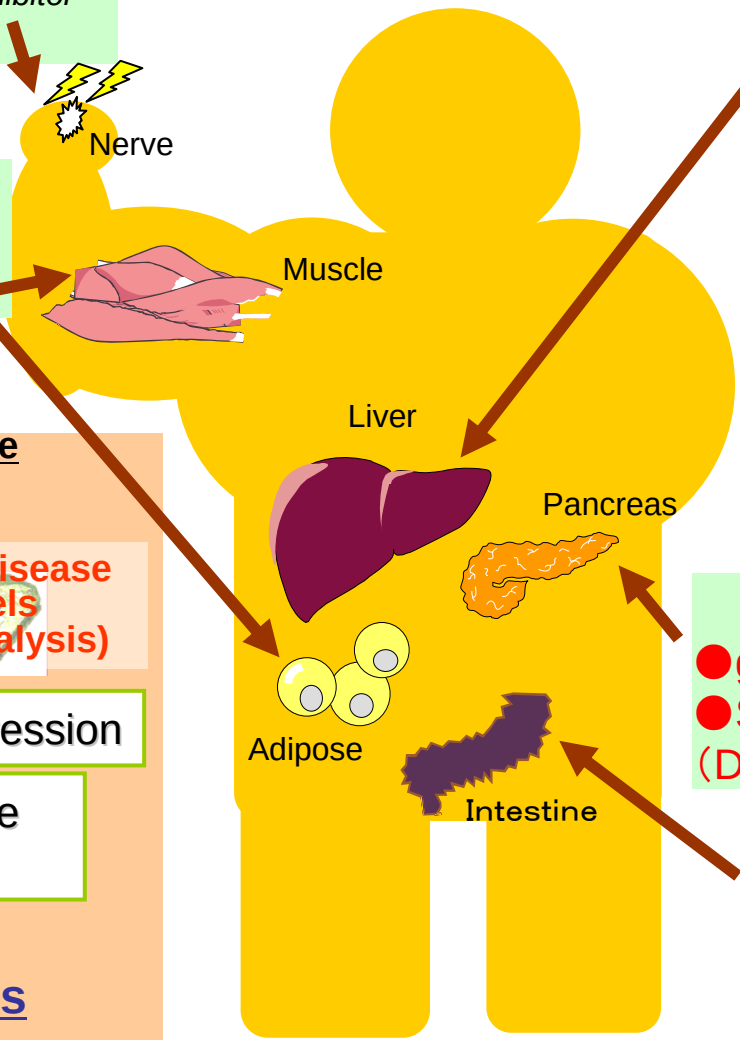
Complication Drug
Neural Sorbitol Accumulation Inhibitor
●AS-3201（Development）

Insulin Sensitizer
Glucose Uptake Accelerator
Muscle, Adipose

Biguanide
Hepatic Gluconeogenesis Inhibitor
●metformin
（SMP-862: Development）

DNA chip Analysis

Novel Drug Targets



Gene Expression Profile

GeneLogic DB
（Human Data）

Animal Disease Models
(Chip Analysis)

Tissue Specific Gene Expression

Disease-specific Gene Expression

Target Candidates

Insulin Secretagogue
●gliglazide (GLIMICRON)
●SMP-508（repaglinide）
（Development）

Glucose absorption Inhibitor
●miglitol（SEIBULE）

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CNS

Main Indication Mechanism of Action		Products	Development	Research
Functional	Schizophrenia	LULLAN SERENACE HALOMONTH	AD-5423 （blonanserin） SM-13496 （lurasidone）	○
	Depression	NORITREN ABILIT		
	Anxiety	SEDIEL ERISPAN		
Organic	Dementia		AC-3933	○
	Parkinson's Disease	DOPS AKINETON	AD-810N （zonisamide）	
	Epilepsy	EXCEGRAN MYSTAN		
Pain		Morphine		○

Seeking potential partners for novel research seeds in CNS area.

KASPAC Project（2000.8～）

KASPAC: Karolinska Institute (KI) + Dainippon Sumitomo Pharma (DSP)
Karolinska Institute Sumitomo Pharmaceuticals Alzheimer Center

Target-Discovery for Alzheimer's Disease

KI → KASPAC ← DSP

Basic Research
Clinical Expertise
Human Samples

Drug Discovery
Genomic Research

Inflammatory/Allergy

Main Indication Mechanism of Action	Products	Development	Research
Inflammation（RA）	–	SMP-114	○
Allergy （Respiratory）	QVAR EBASTEL	SMP-028	◎

◎：proceeded to preclinical stage

Drug Development Overview

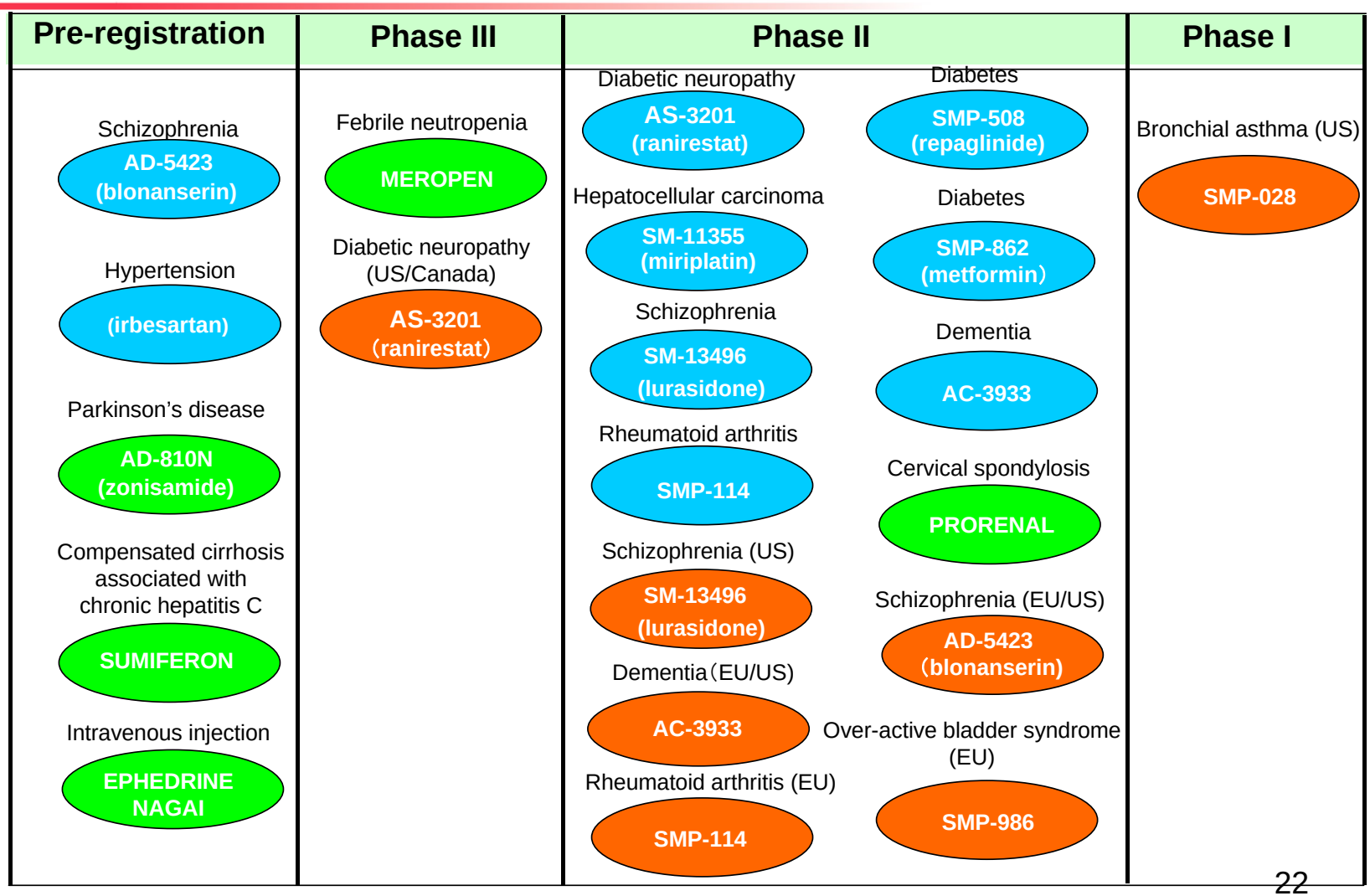
Dainippon Sumitomo Pharma Co. Ltd.

Executive Director, Drug Development

Keiichi Ono, Ph.D.

28th Match, 2007

R&D Pipeline



Development in Japan (New Chemical Entity) Development in Japan for new indication etc. Overseas development

Pre-registration

Product code	Generic name	Target disease	Formulation
AD-5423	Blonanserin	Schizophrenia	Tablet Powder
	Irbesartan	Hypertension	Tablet
AD-810N	Zonisamide	Parkinson's disease (New indication)	Tablet
SUMIFERON	Interferon-alfa	Compensated cirrhosis associated with chronic hepatitis C (New indication)	Injection
EPEDRIN NAGAI	Ephedrine hydrochloride	Hypotension under anesthesia (New administration route)	Injection

Outline of Lurasidone

Target Indication	Schizophrenia
Pharmacology	High affinities for D_2, 5-HT_2, 5-HT_7 and 5-HT_{1A} receptors
Formulation	Tablet
Origin	Dainippon Sumitomo
Clinical Phase	P2b in Japan Preparation for P3 in the US

Clinical Studies of Lurasidone

1. P2a Study in Japan
2. PET Study in the US
3. P2 Studies in the US
4. P2b Study in Japan
5. Thorough QTc Study in the US
6. Comparative Tolerability Study
7. Summary

P2a Study in Japan

- Patient

  Schizophrenics

- Design

  Open-label, Non-controlled, Flexible dose study

- Dosage and Administration

  Once daily after breakfast

  8-week treatment

  Starting dose is 20 mg followed by flexible dosing at the range of 20 to 80 mg

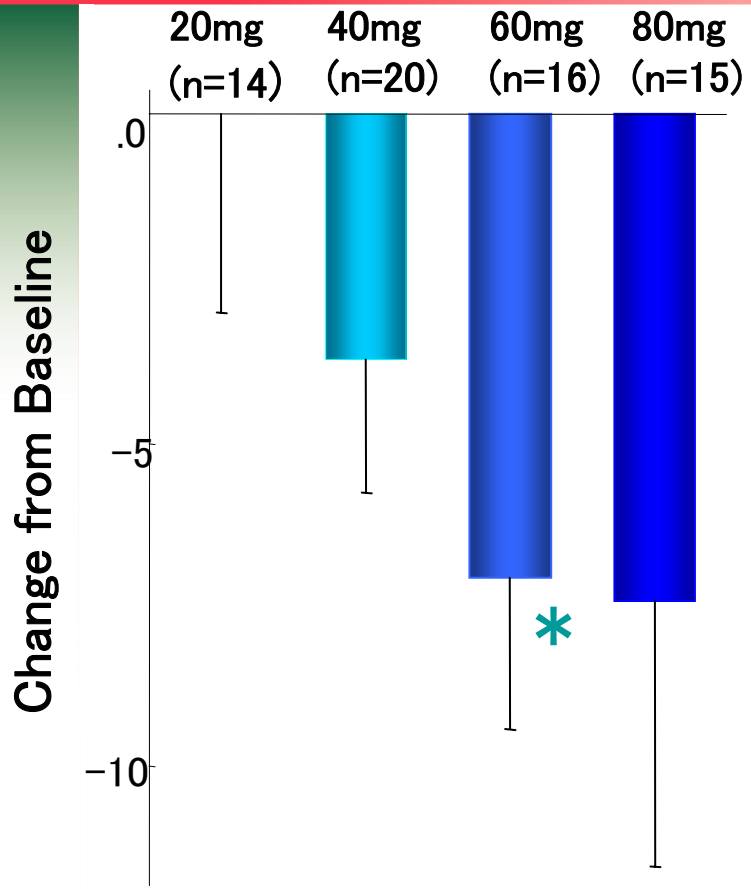
- Planned sample size
  60 patients

- Assessments

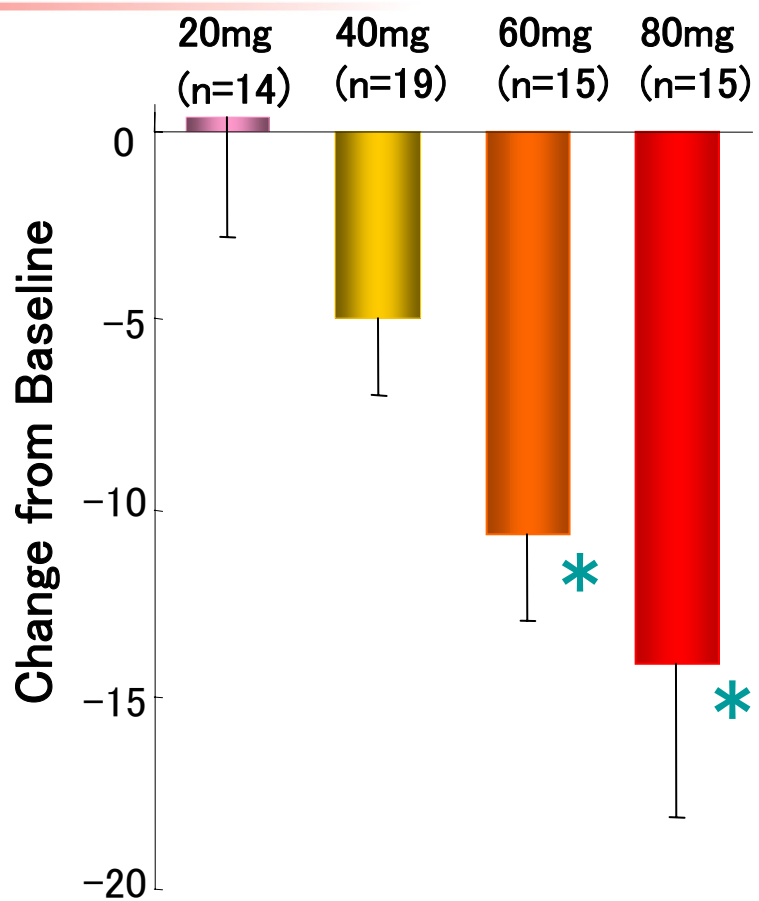
  BPRS, PANSS, Global Improvement Rating (GIR), DIEPSS(EPS scale), AEs, etc

Efficacy

BPRS#



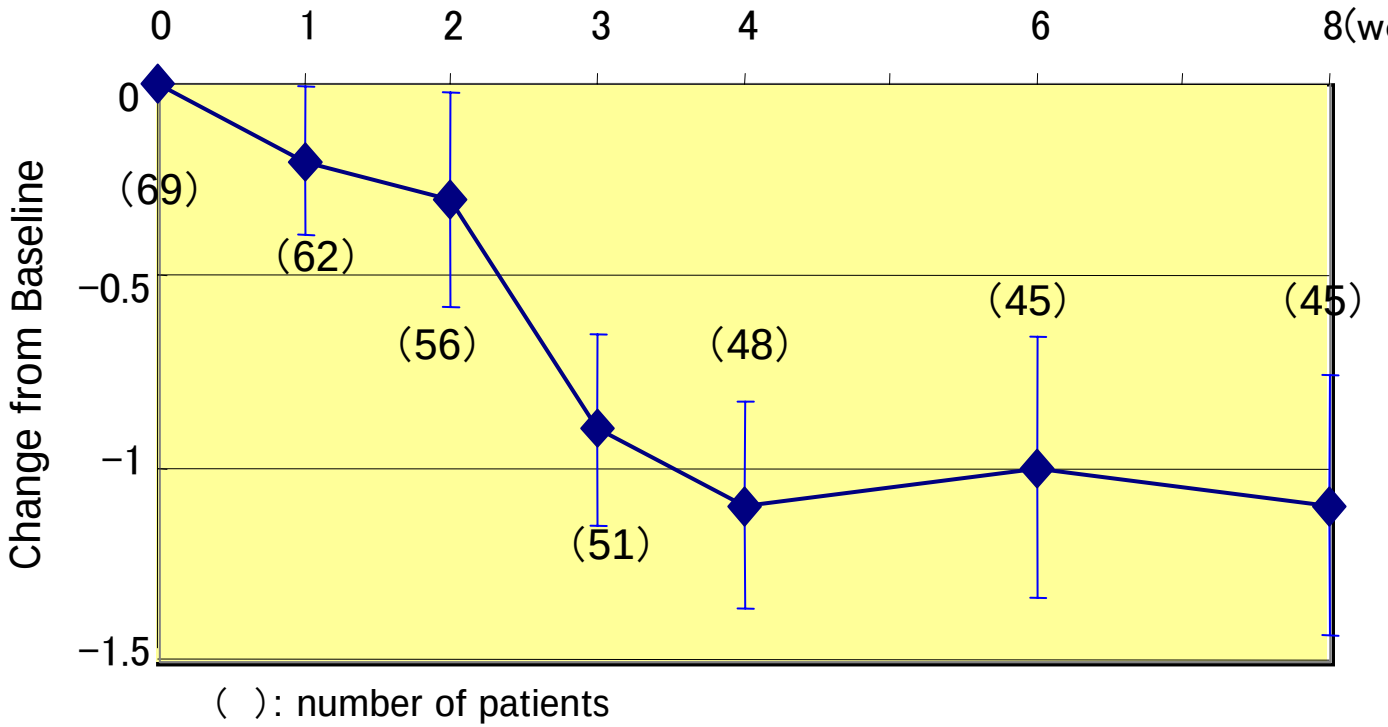
PANSS#



＊: Significant change (P<0.05) from baseline
#: Sub-analysis by most frequently used dose
Mean±SEM
BPRS=Brief Psychiatric Rating Scale,
PANSS=Positive and Negative Syndrome Scale

Safety

Change in EPS score（DIEPSS*）

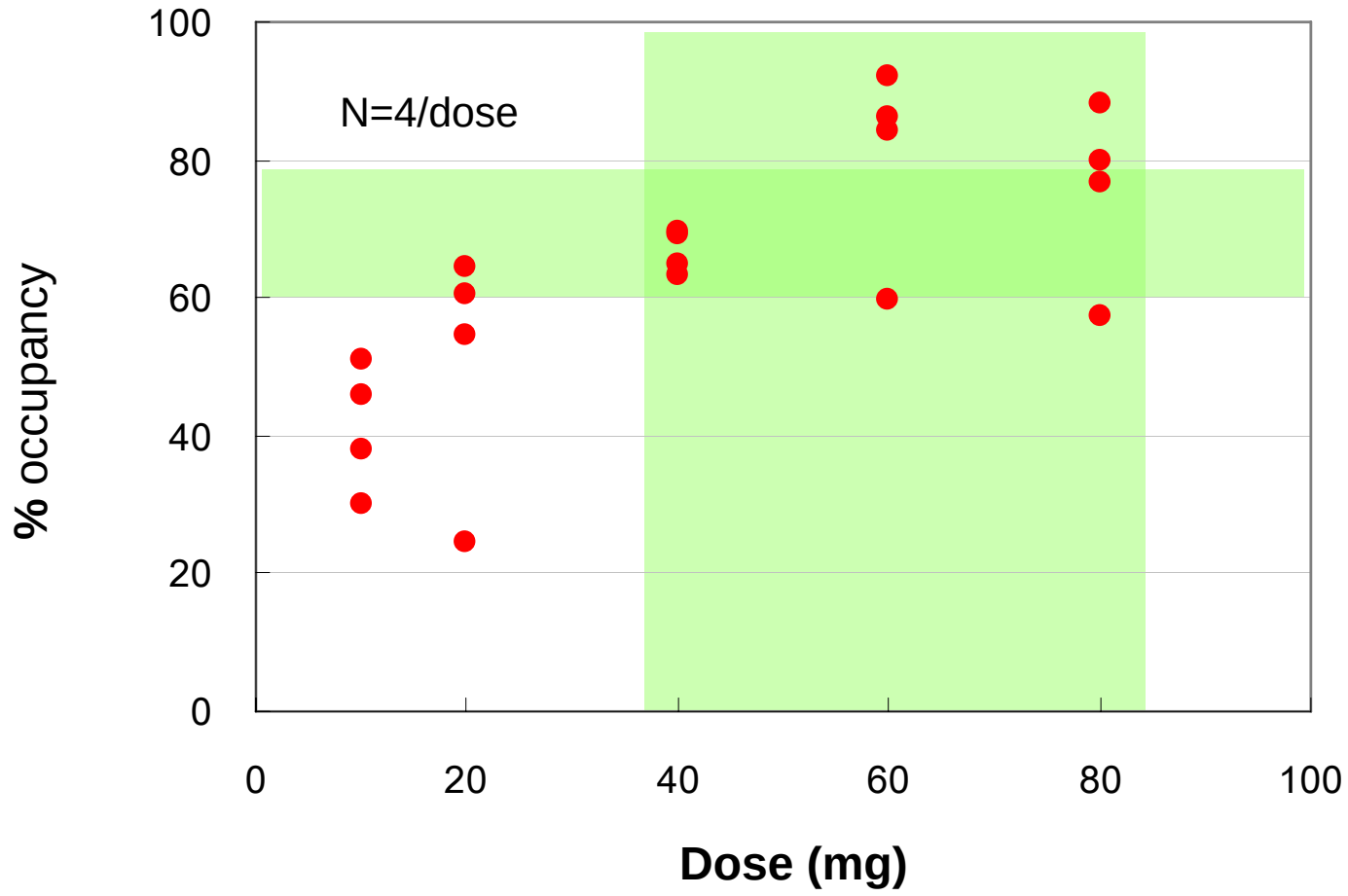


( ): number of patients

* Drug Induced Extra-Pyramidal Symptoms Scale

PET Study in the US

D2 receptor occupancy in Striatum in human（Ligand: C^{11}-Raclopride）



P2 Studies in the US

- Patient

  Schizophrenics
- Design

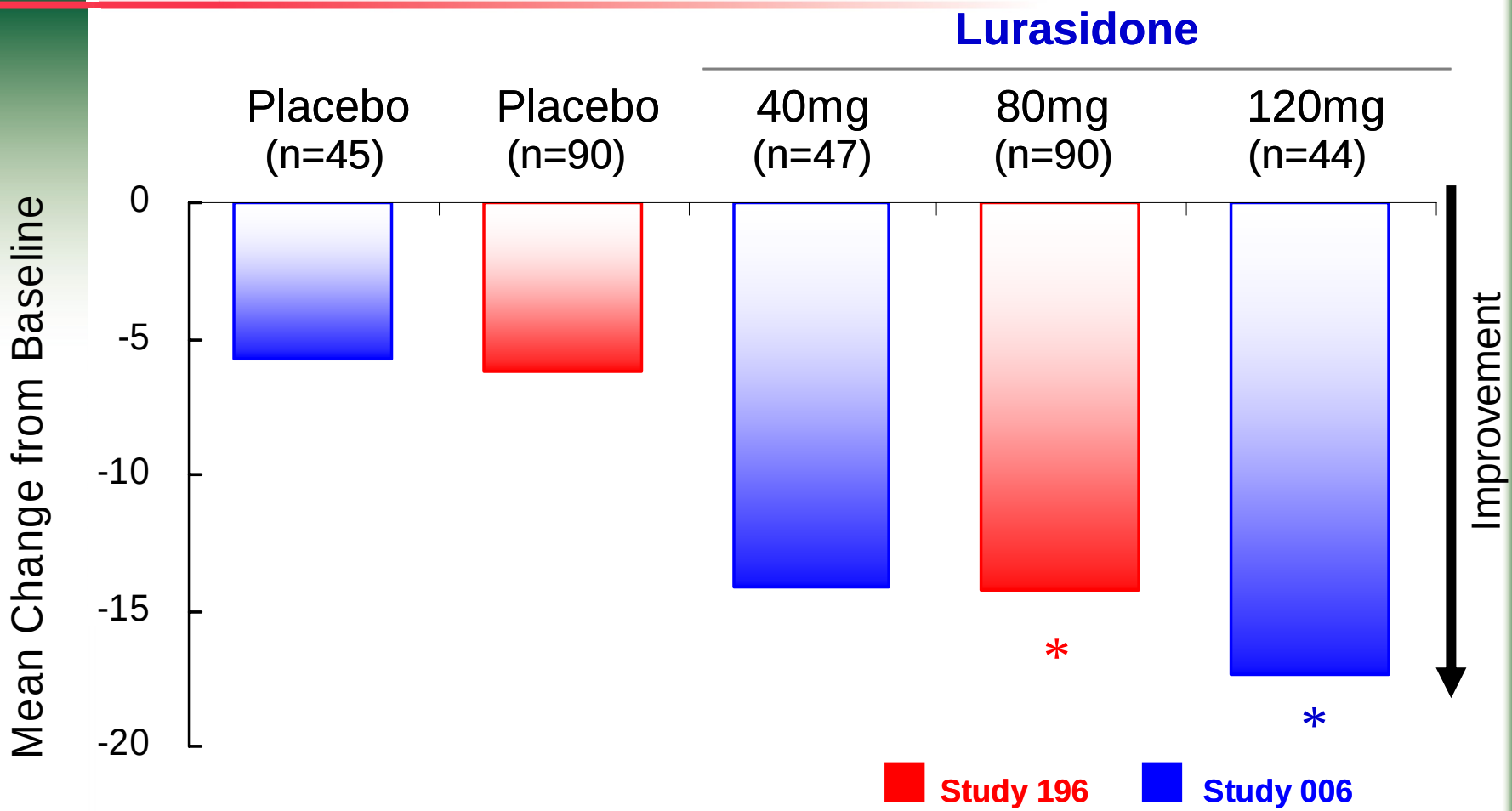
  Randomized, Double-blind, Parallel-group, Placebo-controlled study
- Dosage and Administration

  Once daily after breakfast

  6-week treatment
  Study 006: lurasidone 40mg and 120mg or placebo
  Study 196: lurasidone 80mg or placebo
- Planned Sample Size
  Study 006: 50 patients per group
  Study 196: 80 patients per group
- Assessment

  BPRS, PANSS, EPS, AEs, etc

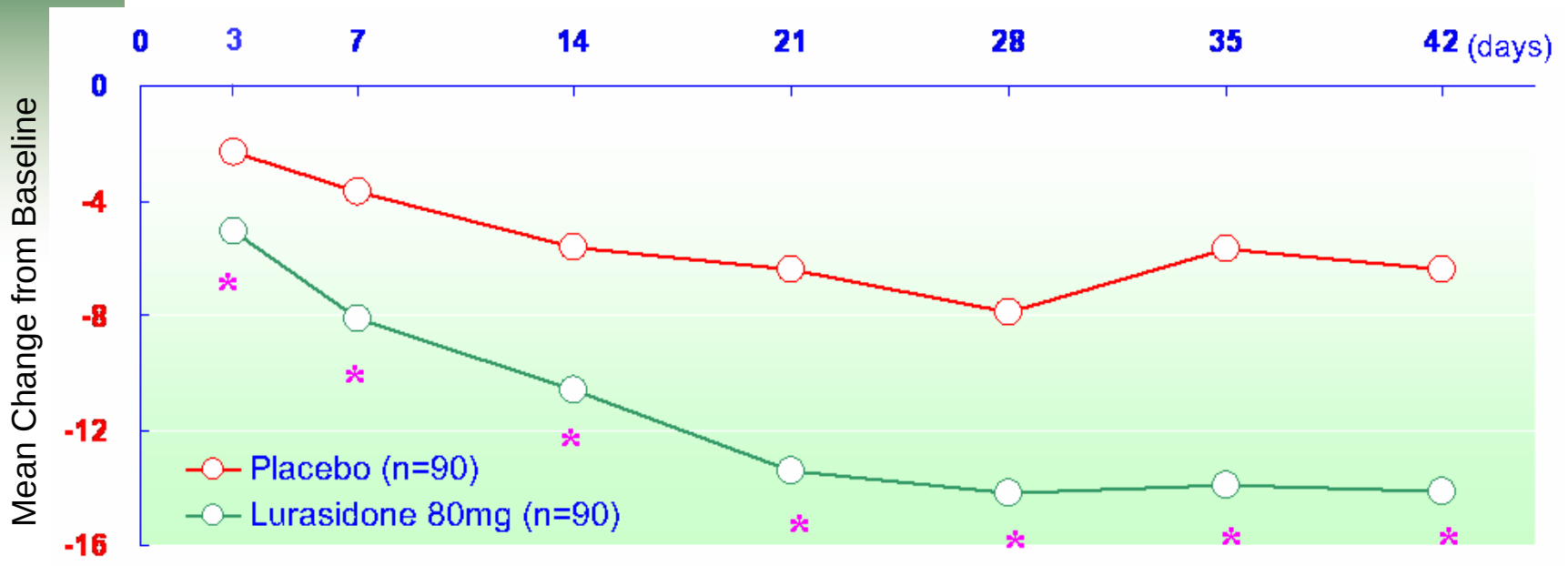
Efficacy (1)



Mean change from baseline at end point (LOCF analysis)
*: p<0.05 vs corresponding placebo group

Efficacy (2)

PANSS Total Score



Study 196
Baseline: Placebo 96.0, Lurasidone 94.4
LOCF analysis
*: statistically different ($p<0.05$) from placebo at each time point using ANCOVA.

Presented at 2007 ICOSR, Colorado, USA.

P2b Study in Japan

- Patient

  Schizophrenics

- Design

  Open-label, Double-blinded for dose, Non-controlled, Parallel-group, Fixed-dose Study

- Dosage and Administration

  Once daily after breakfast

  8-week treatment

  Three doses of lurasidone 20 mg, 40 mg and 80 mg

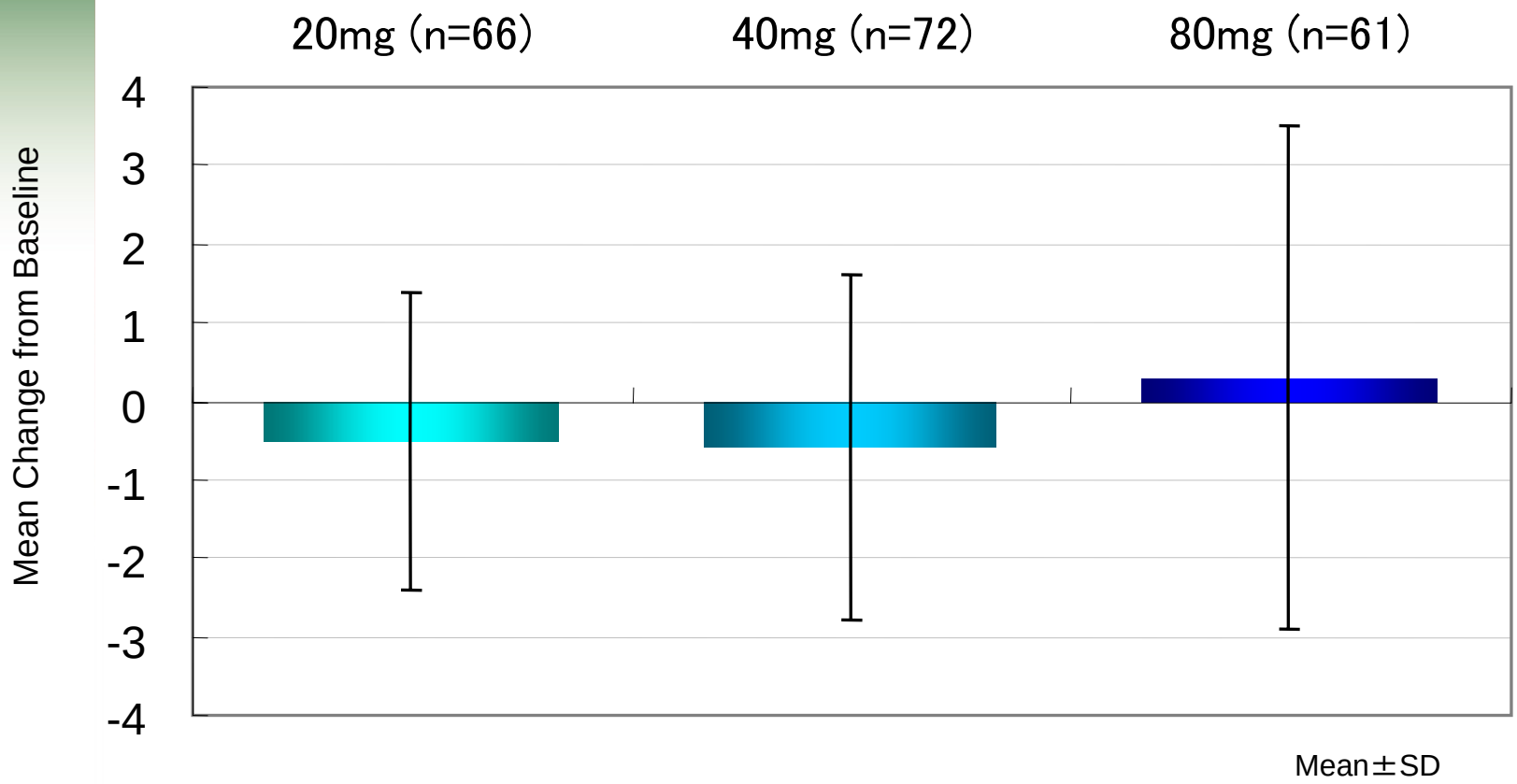
- Planned sample size
  65 patients

- Assessments

  BPRS, PANSS, Global Improvement Rating (GIR), DIEPSS (EPS scale), AEs, etc

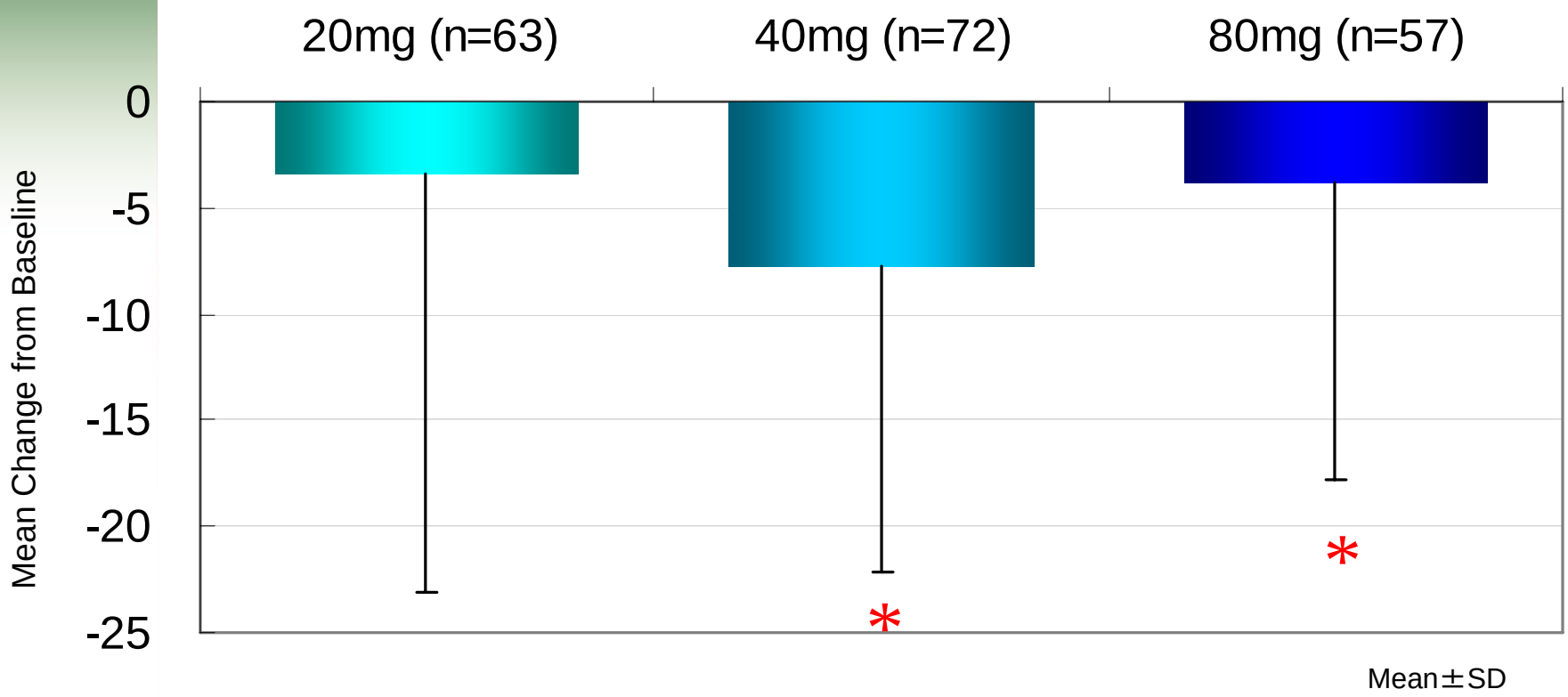
Safety

DIEPSS



Efficacy (1)

PANSS total score



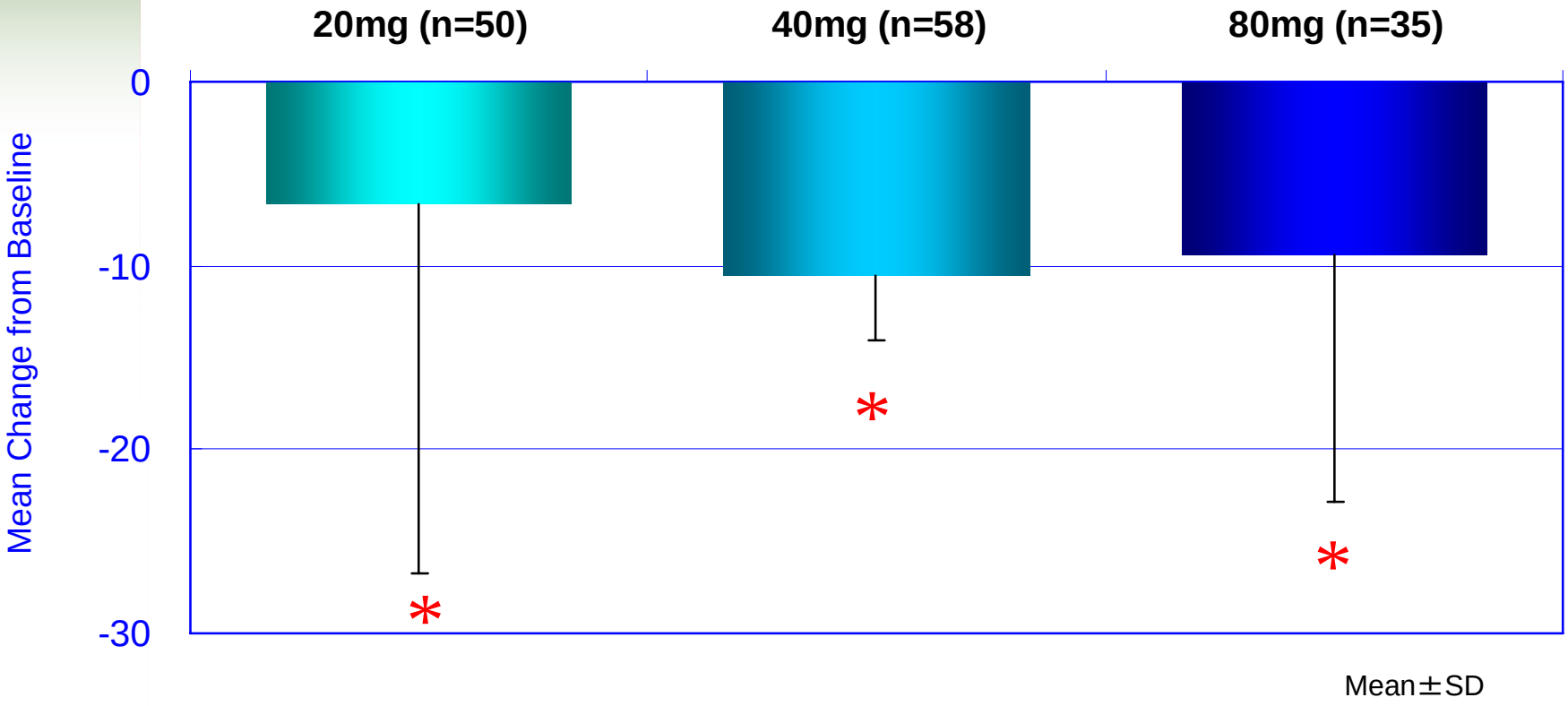
Mean±SD

* p<0.05 vs Placebo

Efficacy (2)

PANSS total score

Patients who received treatment for more than 29 days

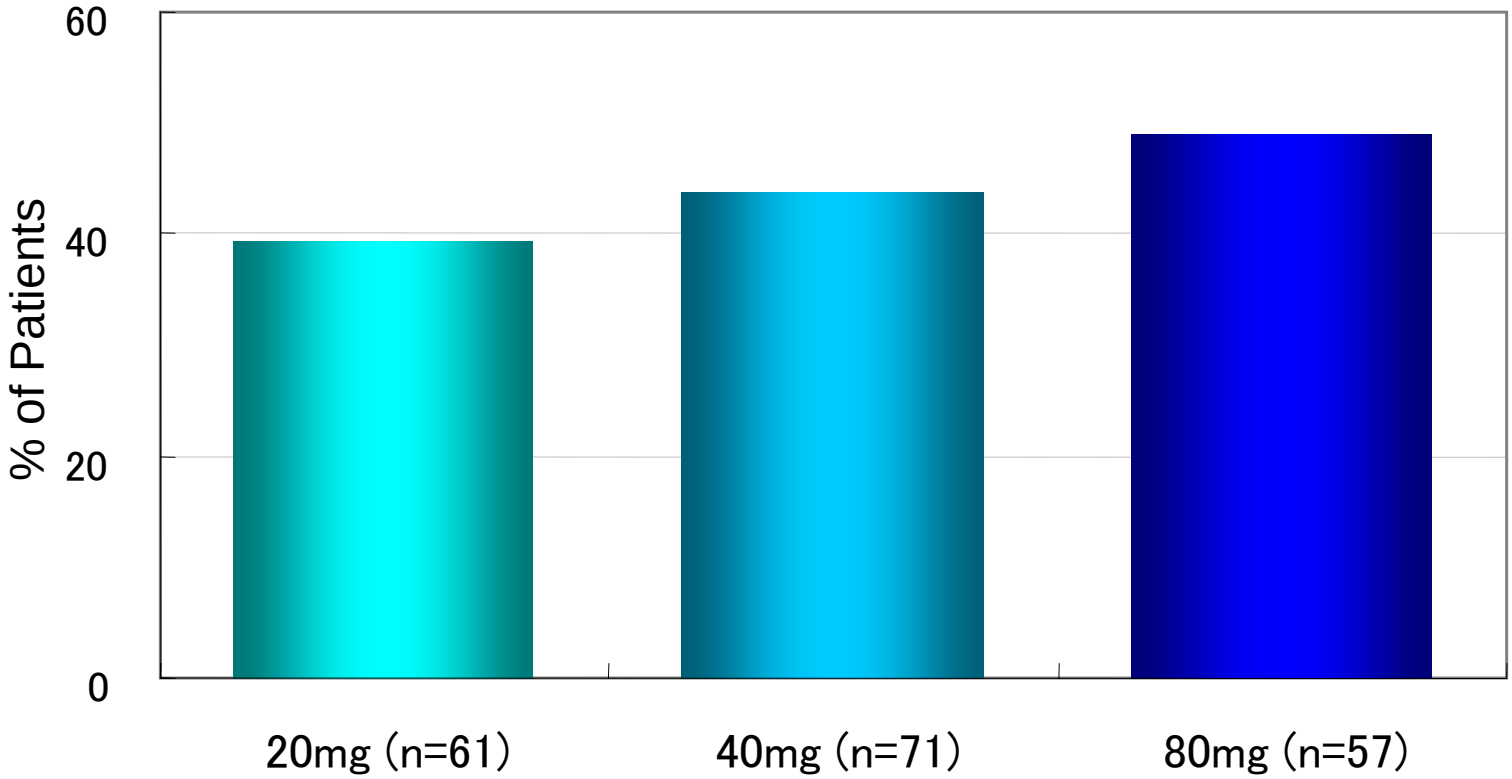


Mean±SD

* p<0.05 vs Placebo

Efficacy (3)

Global Improvement Rating (GIR) *



*: % of patients with moderate or marked improvements at Week 8 (LOCF)

Thorough QTc Study in the US

- Patients

  Schizophrenics
- Study Design

  Randomized, Double-Blind, Parallel Assignment
- Dosage and Administration

  1) Lurasidone 120mg/day, once daily

  2) Lurasidone 600mg/day (Dose titration method), once daily

  3) Ziprasidone 160mg/day (80mg, bid)

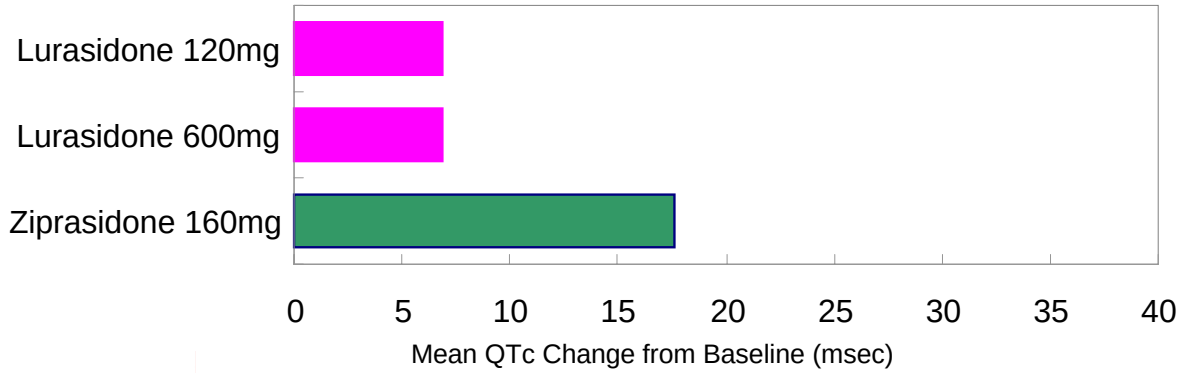
  Total treatment period: 11 days
- Enrollment

  25 patients / group
- Outcomes

  ECG data analysis at Tmax on Day 0 (Baseline) and Day 11

QTc Results

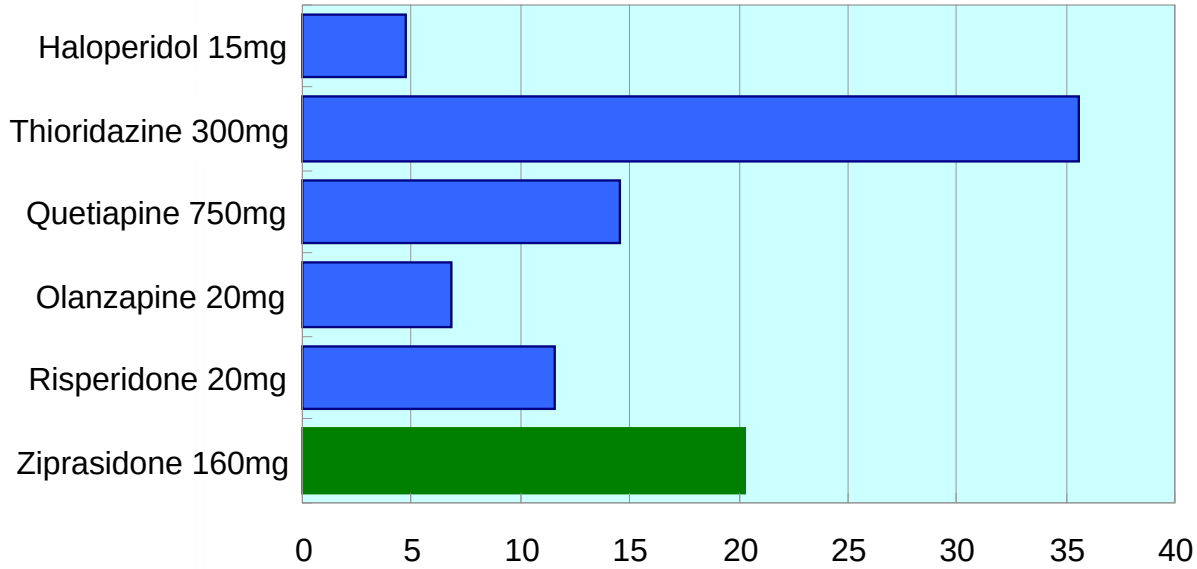
QTc Prolongation – Mean QTc Changes at Tmax (Ziprasidone: at 4 hr)



Individual Data Analysis

	Lurasidone		Ziprasidone
	120mg	600mg	160mg
n	23	22	26
QTc Prolongation: >60 msec	0	0	1
n	25	22	26
QTc: >500 msec	0	0	0

QTc Prolongation Compared with Antipsychotics*



*Ziprasidone Study 054:
FDA Psychopharmacological Drugs Advisory Committee, 19 July 2000

Comparative Tolerability Study in the US

- Patients

  Schizophrenics
- Study Design

  Randomized, Double-Blind, Parallel Assignment
- Dosage and Administration

  1) Lurasidone 120mg/day, once daily

  2) Ziprasidone 160mg/day (80mg, bid)

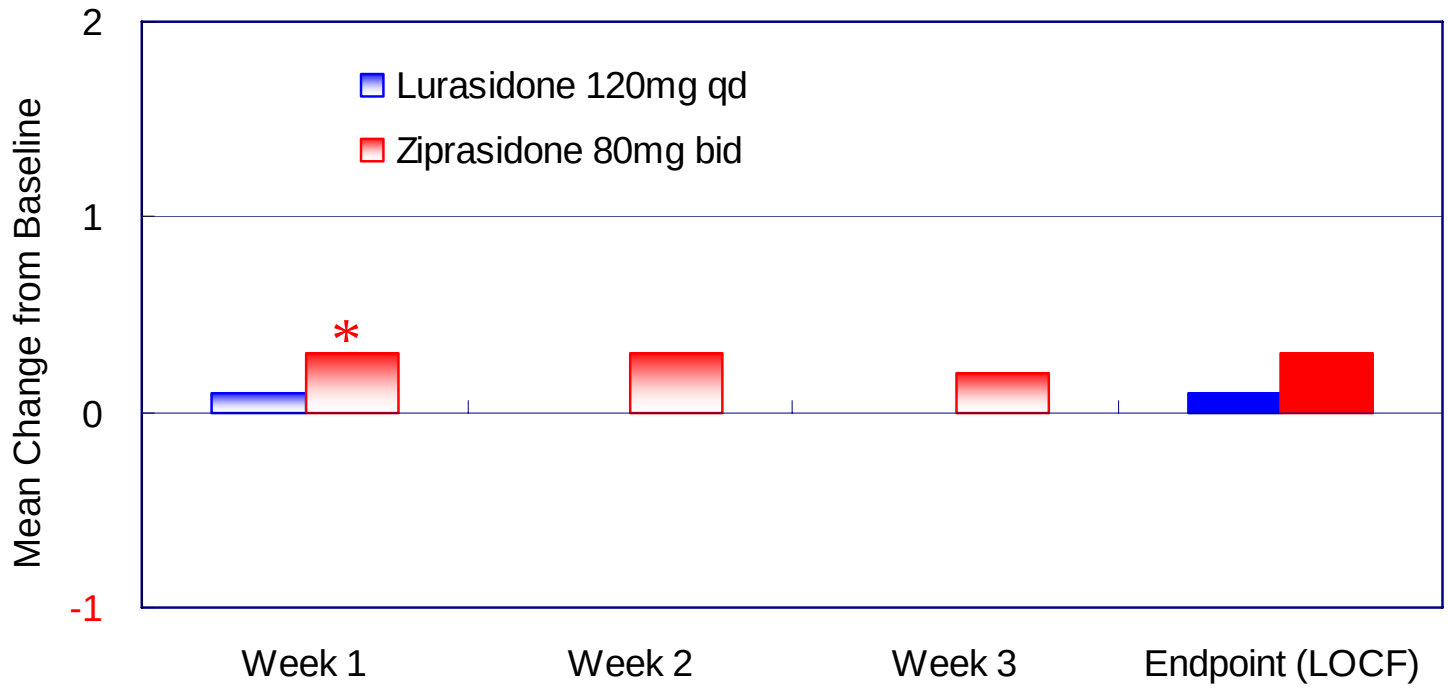
  Total treatment period: 3 weeks
- Enrollment

  160 patients / group
- Outcomes

  PANSS, EPS Scales (BAS, AIMS, SAS), AEs, etc.

Safety (1)

Barnes Akathisia Rating Scale (BAS)

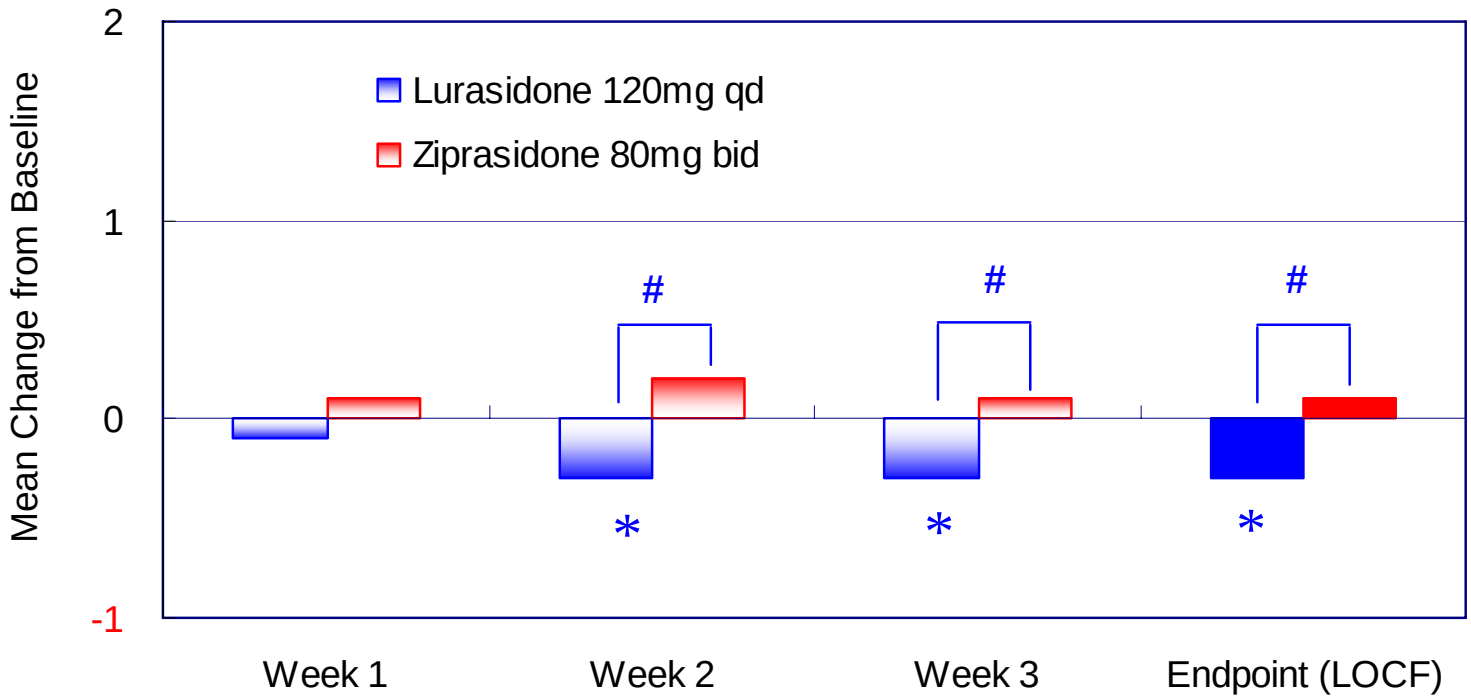


n= (Lura. / Zipra.)	(141/143)	(121/123)	(100/103)	(132/139)

*Significant change (95% CI) from baseline

Safety (2)

Abnormal Involuntary Movement Scale (AIMS)

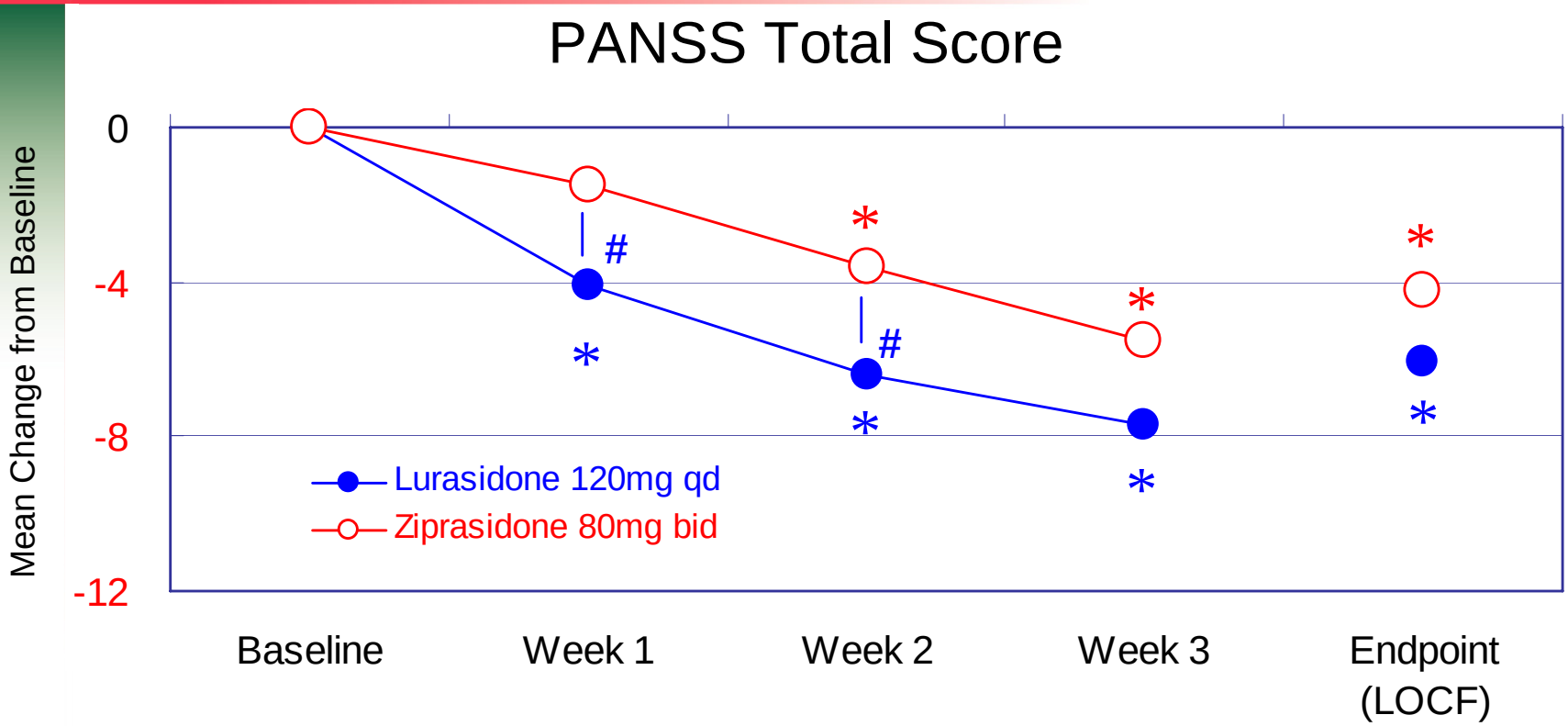


n= (Lura. / Zipra.) (141/144) (121/123) (100/103) (132/139)

*Significant change (95% CI) from baseline

#Significant difference (95% CI) between the groups

Efficacy



	Baseline	Week 1	Week 2	Week 3	Endpoint (LOCF)
n= (Lura. / Zipra.)	(149/150)	(140/142)	(121/125)	(101/103)	(131/138)

* * Significant change (95% CI) from baseline

#Significant difference (95% CI) between the groups

Lurasidone Phase 2: Efficacy

- JP P2 Studies:
  - Lurasidone was effective in patients with schizophrenia at the daily dose range from 20 mg to 80 mg.
- US P2 Studies:
  - PET study showed that lurasidone should be effective in the dose range from 40 mg to 80mg.
  - Lurasidone was effective in the dose range of 40 mg to 120mg in the P2 studies.
  - PANSS total score was improved significantly on and after Day 3 in 80 mg dose group.
- JP P2b Study:
  - PANSS total score was improved significantly in 40 mg and 80 mg dose groups. However, dose dependency was not demonstrated.
  - The percentage of patients with moderate to marked improvements of GIR score increased dose-dependently in the dose rage from 20 mg to 80 mg.
- Comparative Tolerability Study with Ziprasidone:
  - Lurasidone demonstrated the comparative efficacy with ziprasidone (approved drug).

Lurasidone Phase 2: Safety

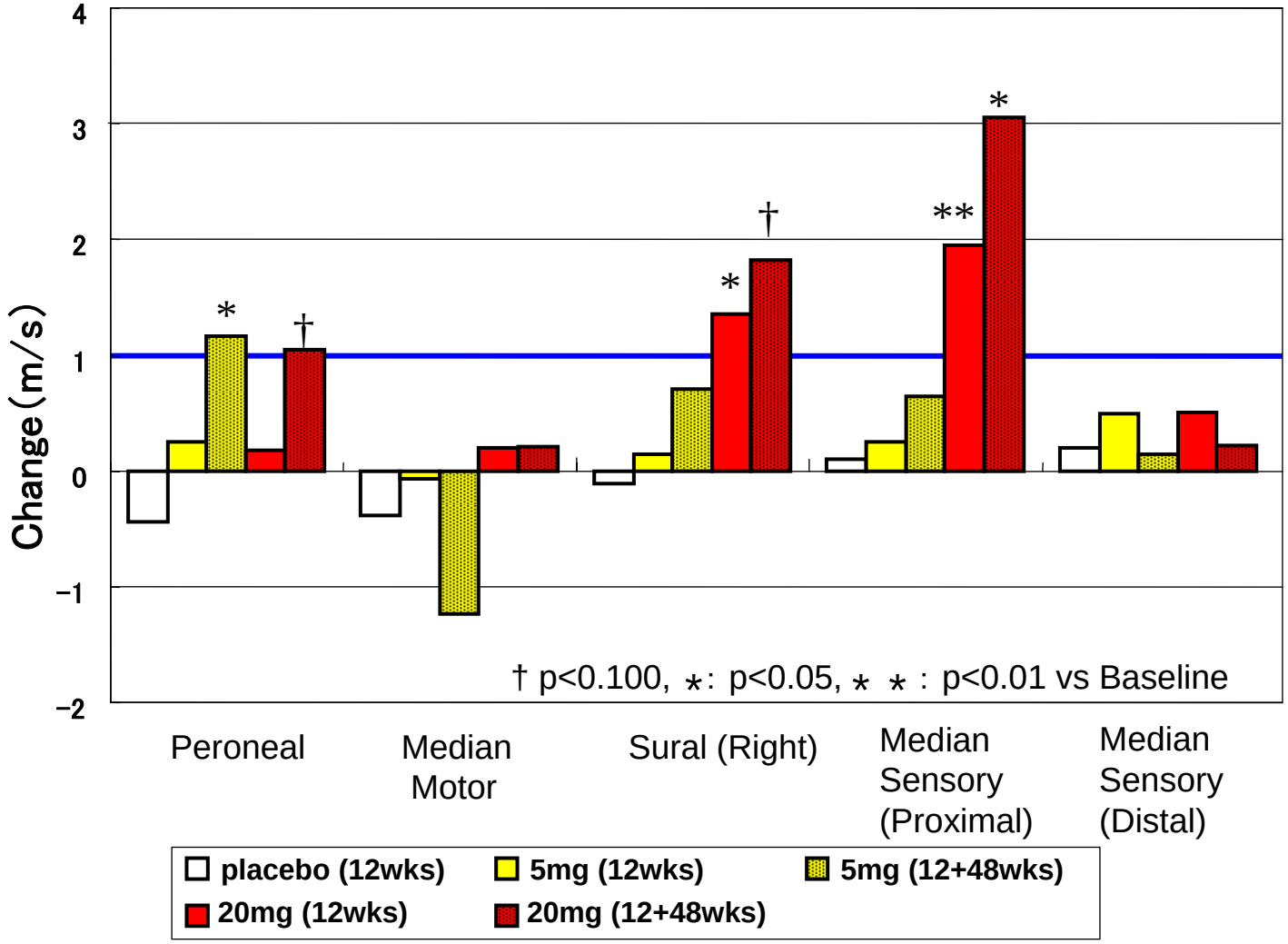
- US QTc Study:
- QTc interval prolongation of more than 5 msec, a threshold suggested in the guideline, was observed both at the highest daily clinical dose (120mg) and the 5 fold dose (600mg).
- There were no patients with QTc interval prolongation of >60msec or QTc of >500msec.
- US Comparative Tolerability Study with Ziprasidone:
- It was confirmed that the akathisia score in 120 mg of lurasidone was lower than ziprasidone dose group at all assessed points.
- JP and US Phase 2 Studies:
- Abnormal involuntary movement score was significantly decreased by dosing lurasidone.
- It was suggested that lurasidone causes minimal EPS.
- Lurasidone was generally safe and well tolerated without any significant abnormalities in metabolic parameters including blood sugar and lipid levels.

Outline of ranirestat

Indication	Diabetic Sensorimotor Polyneuropathy (DSP)
Pharmacology	Inhibition of Aldose Reductase, resulting in prevention and improvement of DSP
Formulation	Tablet
Origin/License	Dainippon Sumitomo/Licensed out to Eisai
Stage	Phase 2a (Japan: Co-development with Kyorin） Phase 3（North America）

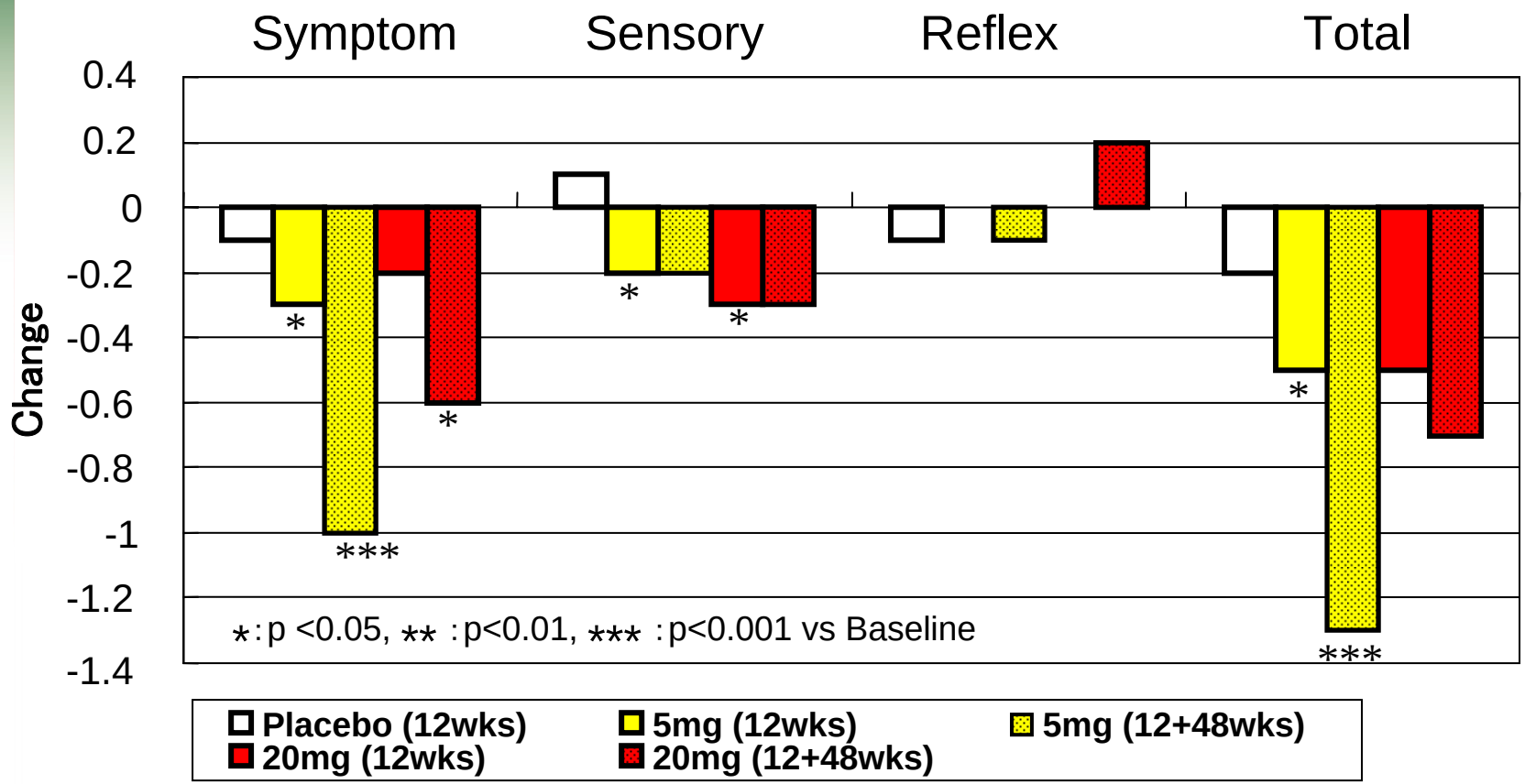
Phase IIa/Extension in North America

Improvement in Nerve Conduction Velocities (NCV) -Change from baseline



Phase IIa/Extension in North America

Change in Toronto Clinical Neuropathy Score



Ranirestat Clinical Trials

1. Phase 2a in Japan

2. Phase 3 in North America

P2a in Japan

- Patients
  Diabetic patients with clinical signs and symptoms of symmetrical distal Diabetic Sensorimotor Polyneuropathy (DSP)

- Design
  Multicenter, randomized, double blind, placebo-controlled study

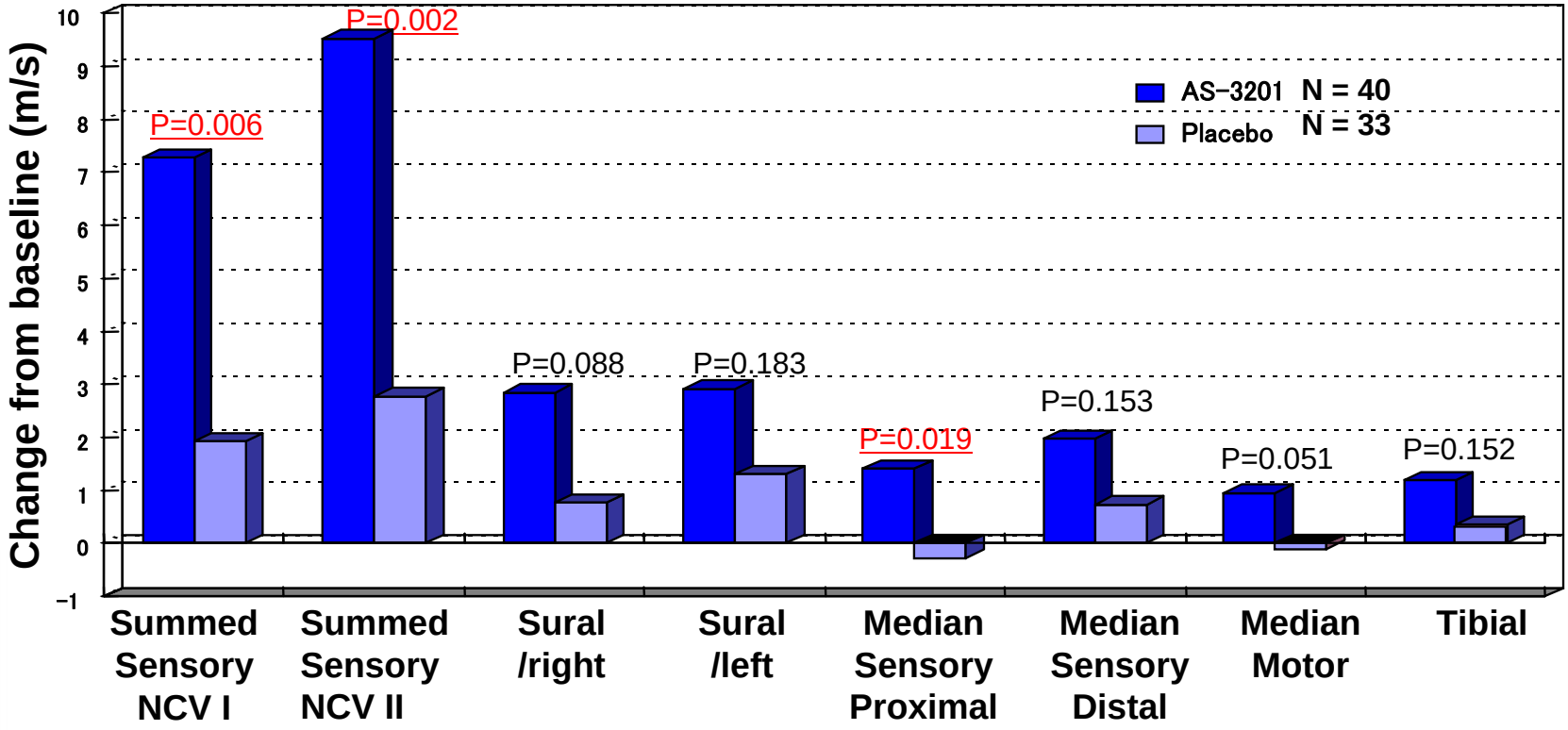
- Dosage Regimen
  Ranirestat 20mg or Placebo, Oral, Once daily for 26 weeks

- Sample Size: 30 patients/arm

- Efficacy Parameters
  Summed sensory nerve conduction velocity,
  modified Toronto Clinical Neuropathy Score（mTCNS） etc.

Efficacy(1)

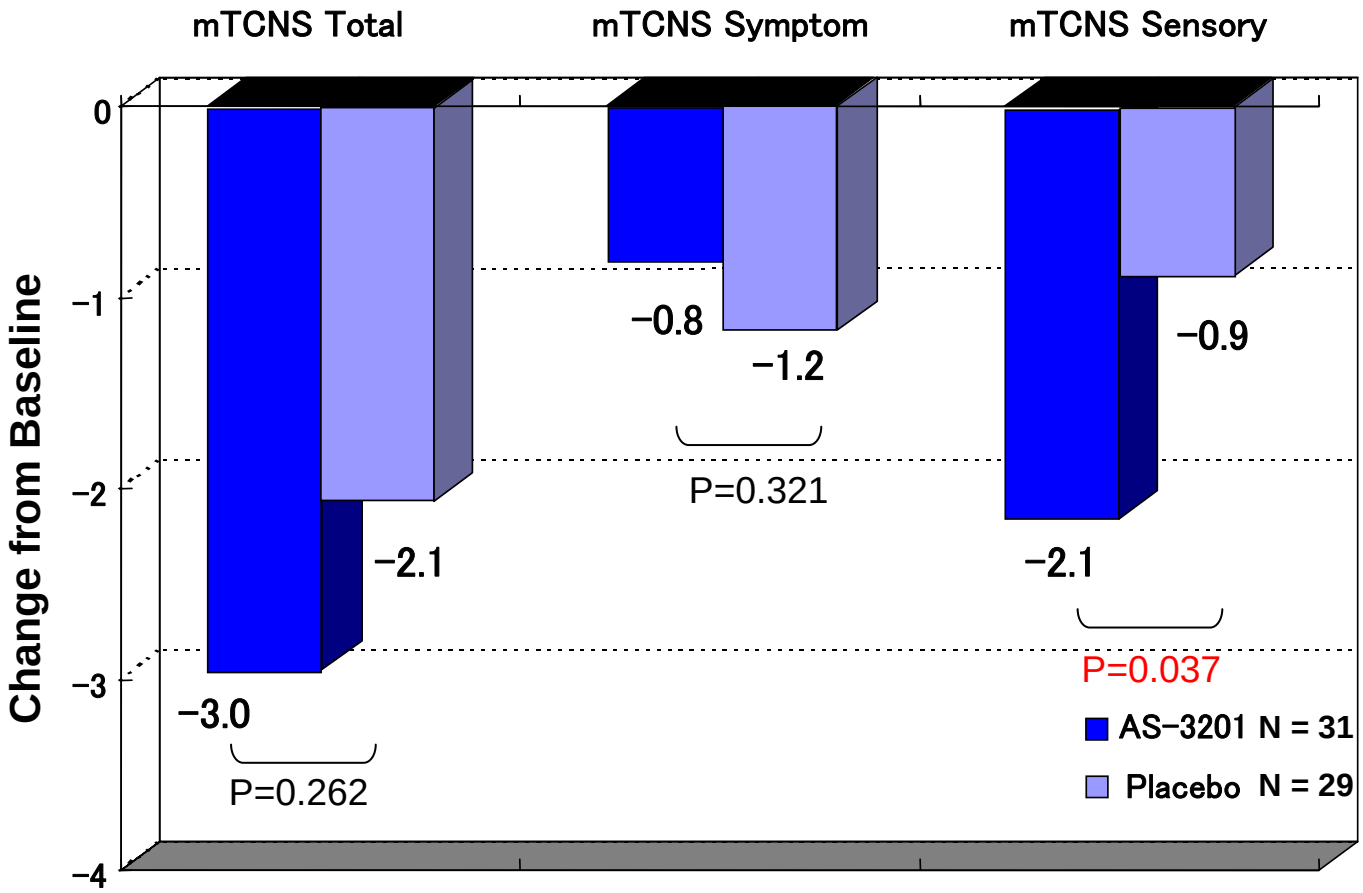
Nerve Conduction Velocities (NCV)



AS-3201=ranirestat

Efficacy(2)

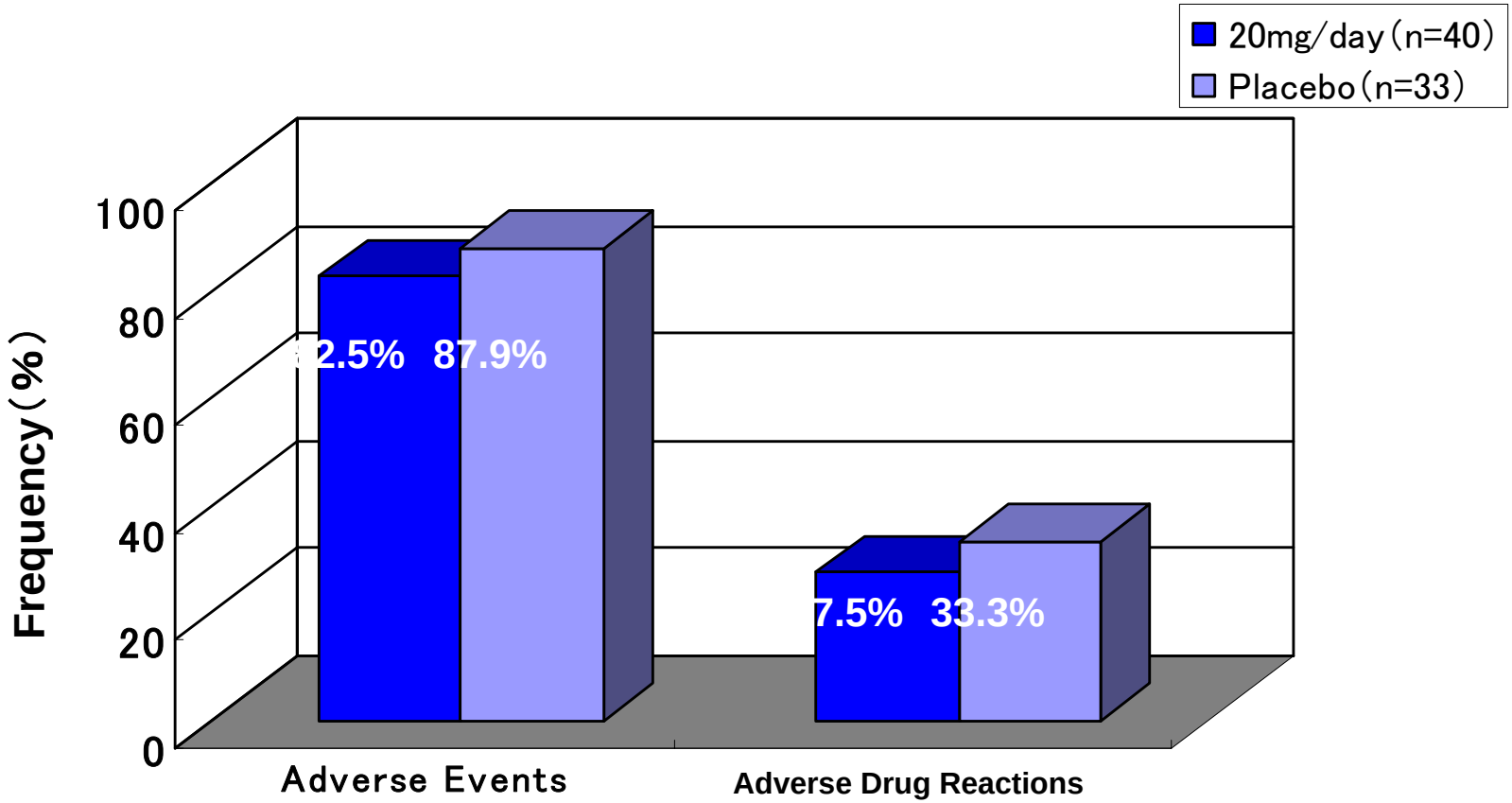
Clinical：Change from baseline in mTCNS (without population in “No Neuropathy” categorized by TCNS)



AS-3201=ranirestat

Safety

Adverse Events / Adverse Drug reactions



Summary of Phase 2a in Japan

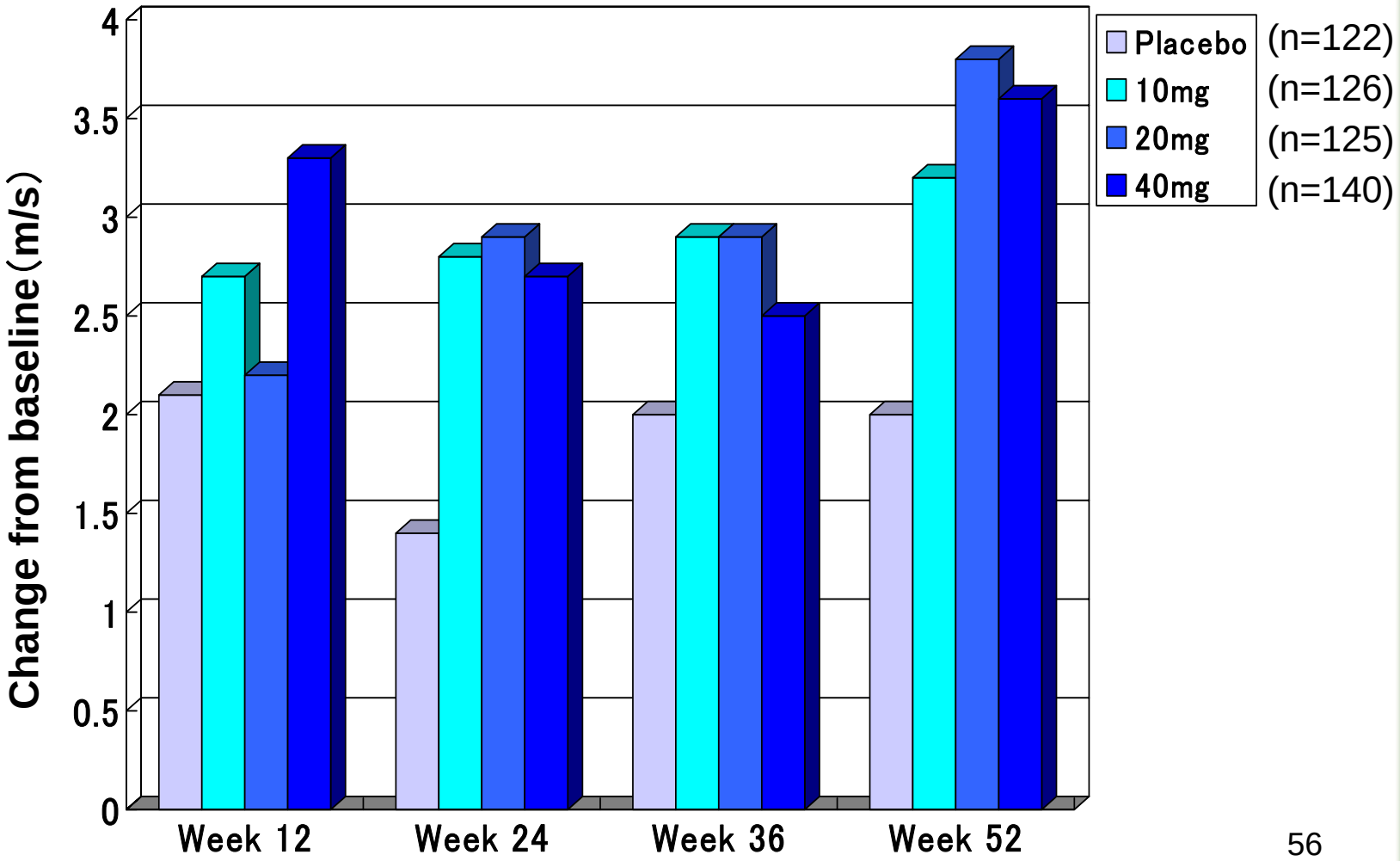
- Ranirestat at the dose of 20mg/day showed significant improvement in summed SNCV in comparison with placebo.
- Ranirestat demonstrated significant improvement in sensory score of mTCNS in mild to severe population.
- Ranirestat was generally safe and well tolerated without any significant abnormalities.

Phase 3 in North America

- Patients
  Diabetic patients with clinical signs and symptoms of symmetrical distal DSP
- Design
  Multicenter, randomized, double blind, placebo-controlled study
- Dosage Regimen
  Ranirestat 10mg, 20mg, 40mg or Placebo, Oral, Once daily for 52 weeks
- Sample Size: 120 patients/arm
- Efficacy Parameters
  Summed sensory nerve conduction velocity,
  modified Toronto Clinical Neuropathy Score（mTCNS） etc.

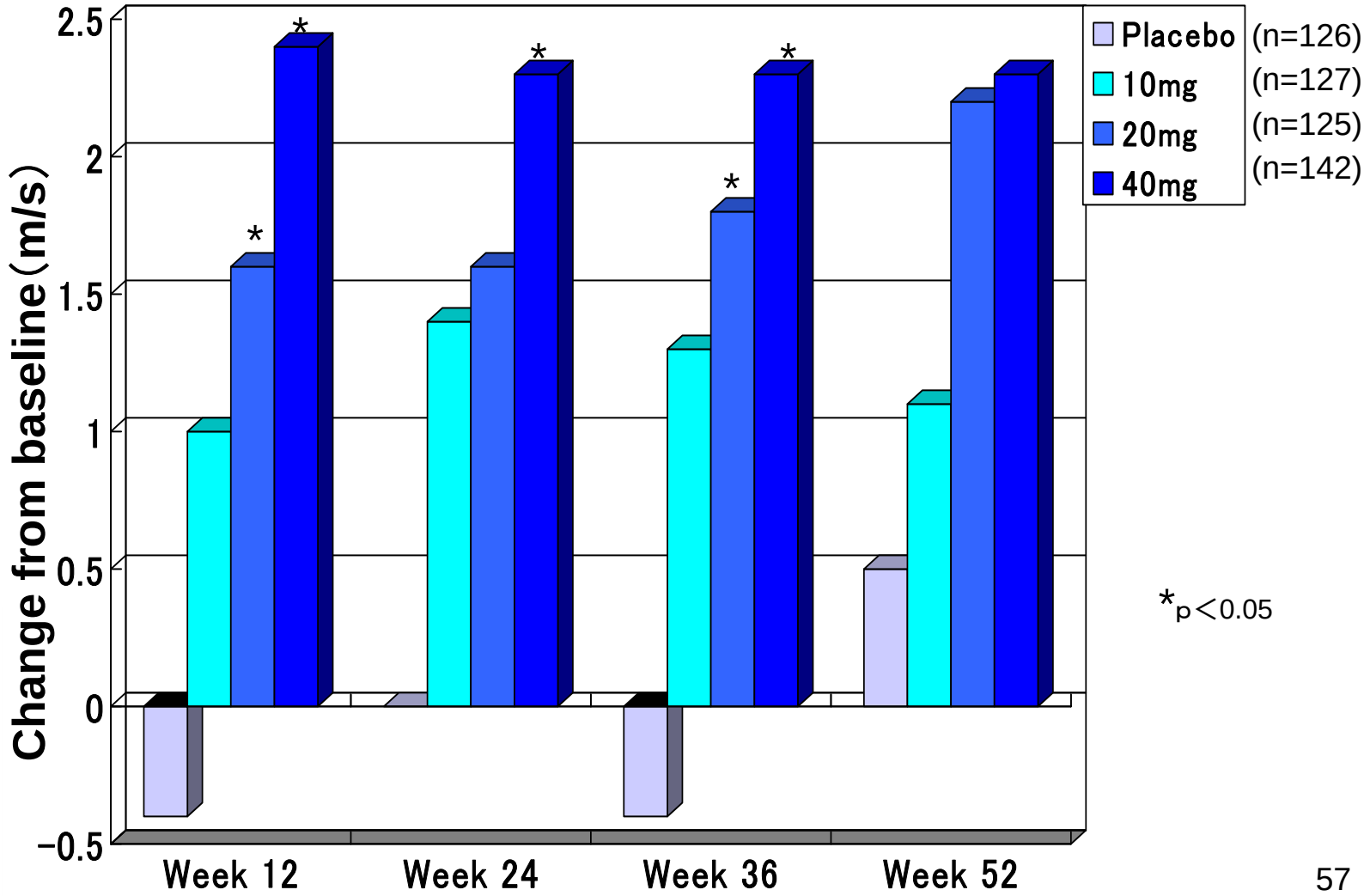
Efficacy(1)

Summed Sensory Nerve Conduction Velocities



Efficacy(2)

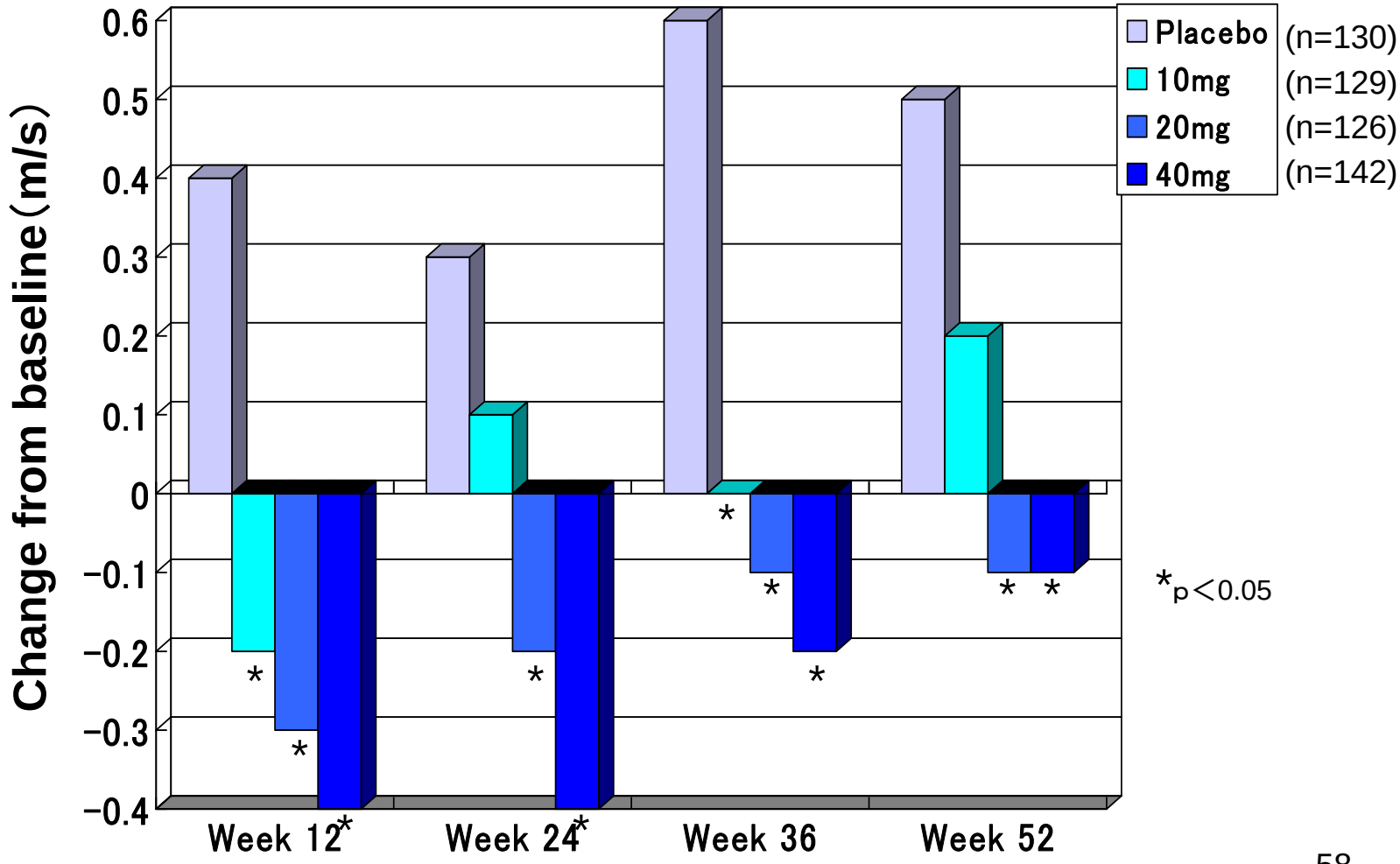
Summed Motor Nerve Conduction Velocities



*$p < 0.05$

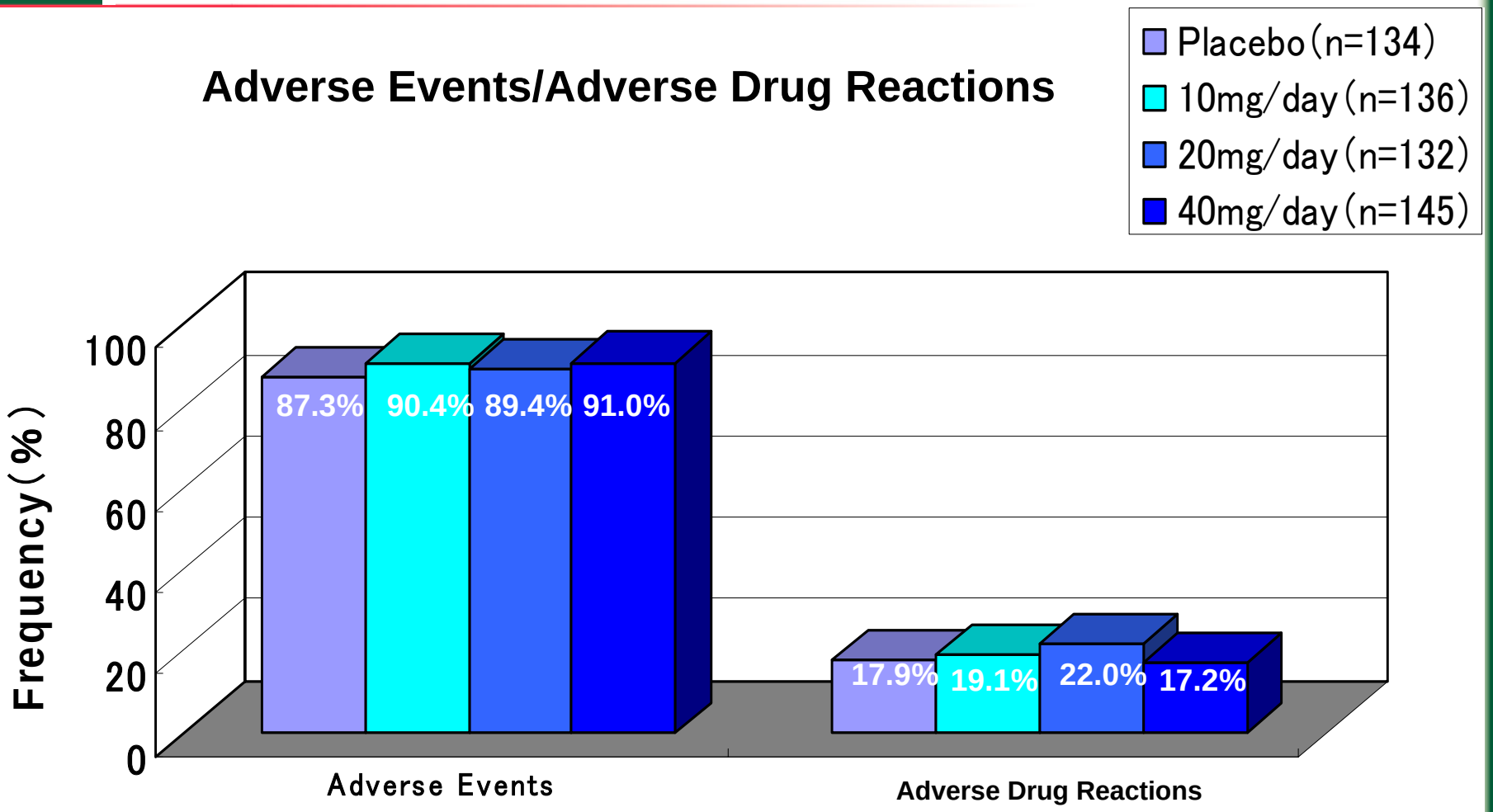
Efficacy（3）

F-Wave minimum latency in Median motor nerve



Safety

Adverse Events/Adverse Drug Reactions



Summary of Phase 3 in North America

- No significant differences in summed SNCV were observed between ranirestat group and placebo group. This unclear study result may be attributed to the changes in placebo group which were much higher than expected.
- Ranirestat showed somewhat improvement in MNCV and F-wave latencies.
- No significant differences in mTCNS, a critical clinical parameter, between ranirestat group and placebo group were observed. This unclear study result may be attributed to the unexpected high improvement in the placebo group.
- Ranirestat was generally safe and well tolerated without any significant abnormalities

Outline of SMP-862（metformin）

Indication	Type 2 Diabetes
Pharmacology	Suppression of hepatic gluconeogenesis and improvement of insulin sensitivity
Formulation	Tablet
In-house/Licensed	Licensed from Merck Sante
Stage	Phase 2b

P2b

- Indication

  Type 2 diabetes mellitus

- Design

  Placebo-controlled, double-blind, parallel group comparative study (dynamic allocation)

- Dosage Regimen: 750mg/day and 1500mg/day

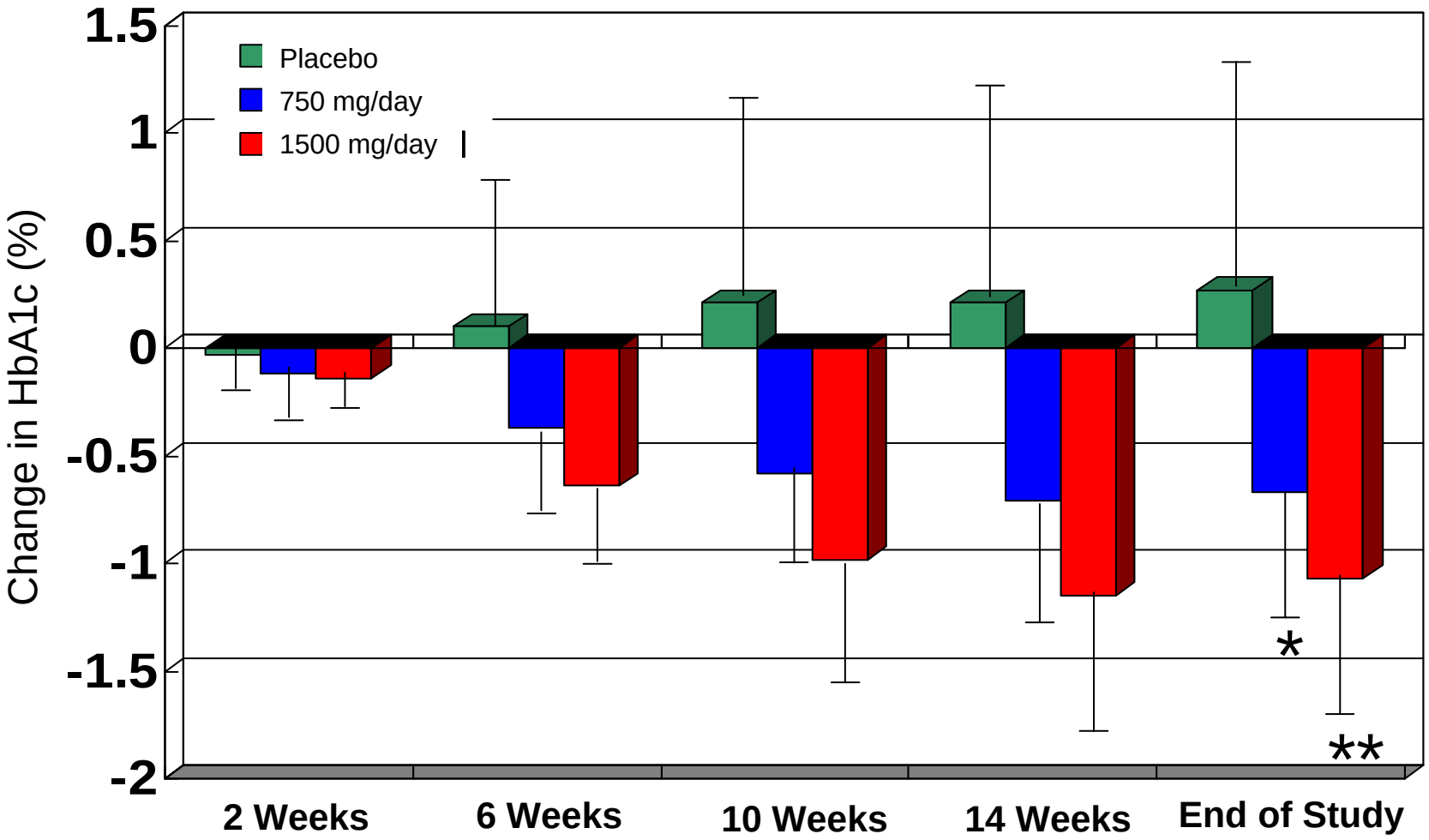
- Sample Size

  100 patients/SMP-862 dosing group (50 patients/placebo group)

- Endpoint: Change in HbA1c from baseline

Efficacy

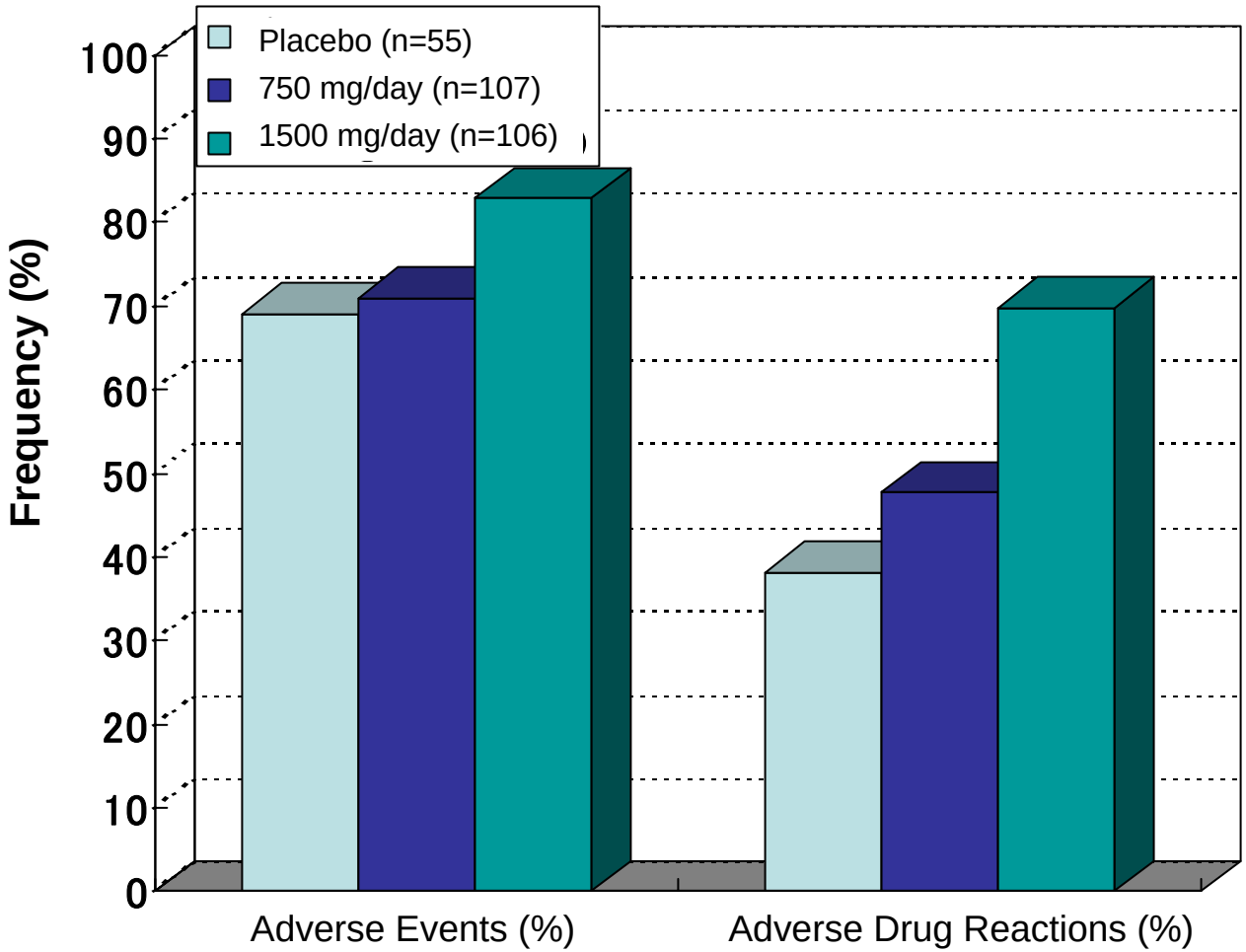
Change in HbA1c



* p<0.001 vs Placebo
** p<0.001 vs Placebo and 750 mg/day

Safety

Adverse Events / Adverse Drug reactions



Summary of P2b Monotherapy Study

- HbA1c was decreased dose-dependently in 14-week administration of 750 mg/day of SMP-862, 1500 mg/day of AMP-862 and placebo.
- HbA1c was significantly decreased in the group of 1500 mg/day compared to 750 mg/day, currently approved as daily dose for metformin chloride.
- No change in lactic acid level an no other significant findings in safety

DAINIPPON SUMITOMO PHARMA

Outline of repaglinide

Indication: Type 2 diabetes mellitus

Pharmacology: Rapid insulin secretagogue characterized by rapid absorption and rapid metabolism

Formulation: Tablet

In-house/License: Licensed from Novo Nordisk

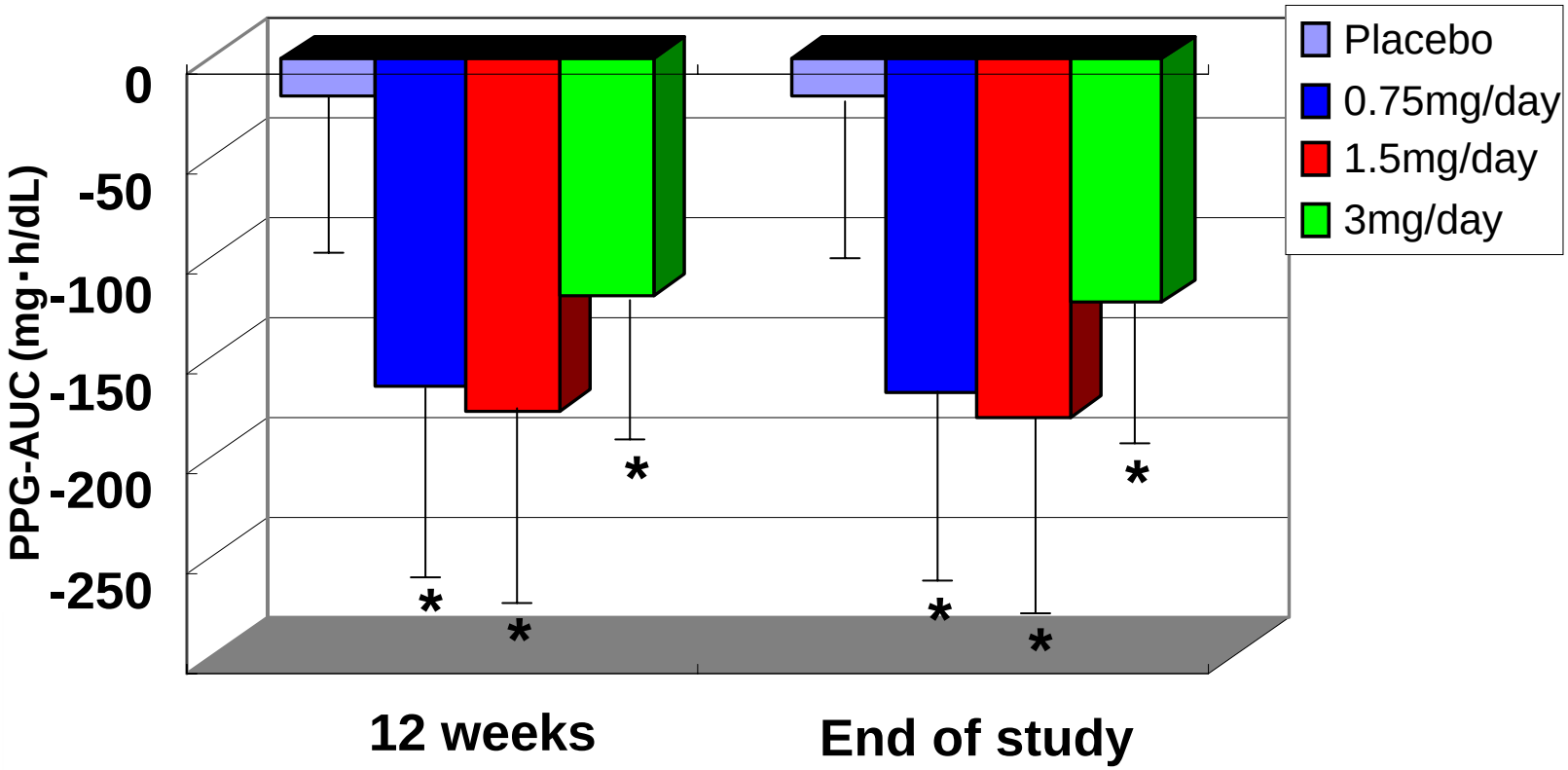
Stage: P2b

P2b clinical study

- Patients: Type 2 diabetes mellitus
- Design: Placebo-controlled, random allocation, double-blind, comparative study
- Dosage Regimen: Placebo, repaglinide 0.75, 1.5, 3mg/day
- Sample size: 30 patients/group
- Primary Endpoint: Change in Postprandial Plasma Glucose (PPG) AUC 0-3h

P2b monotherapy clinical study

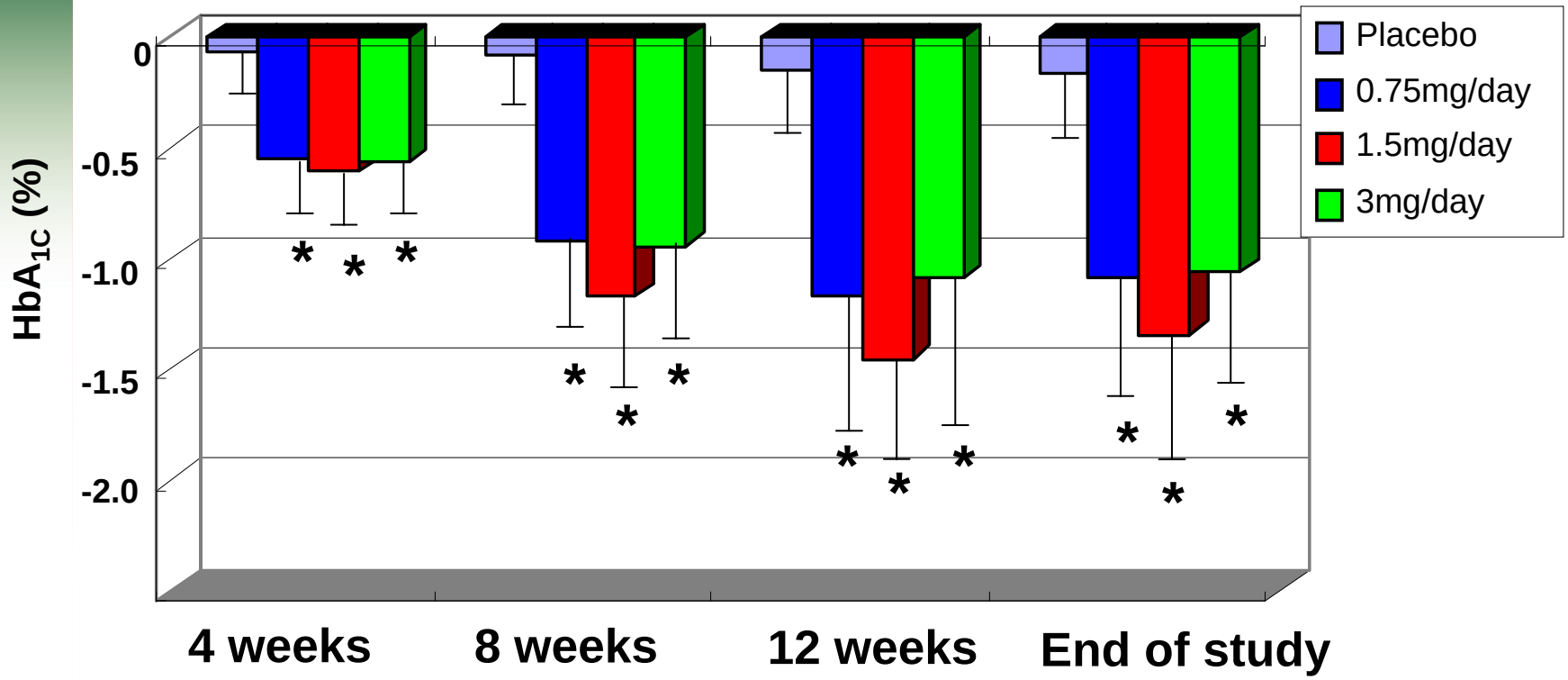
Change in PPG $AUC_{0\text{-}3h}$



*: vs placebo, p<0.001

P2b monotherapy clinical study

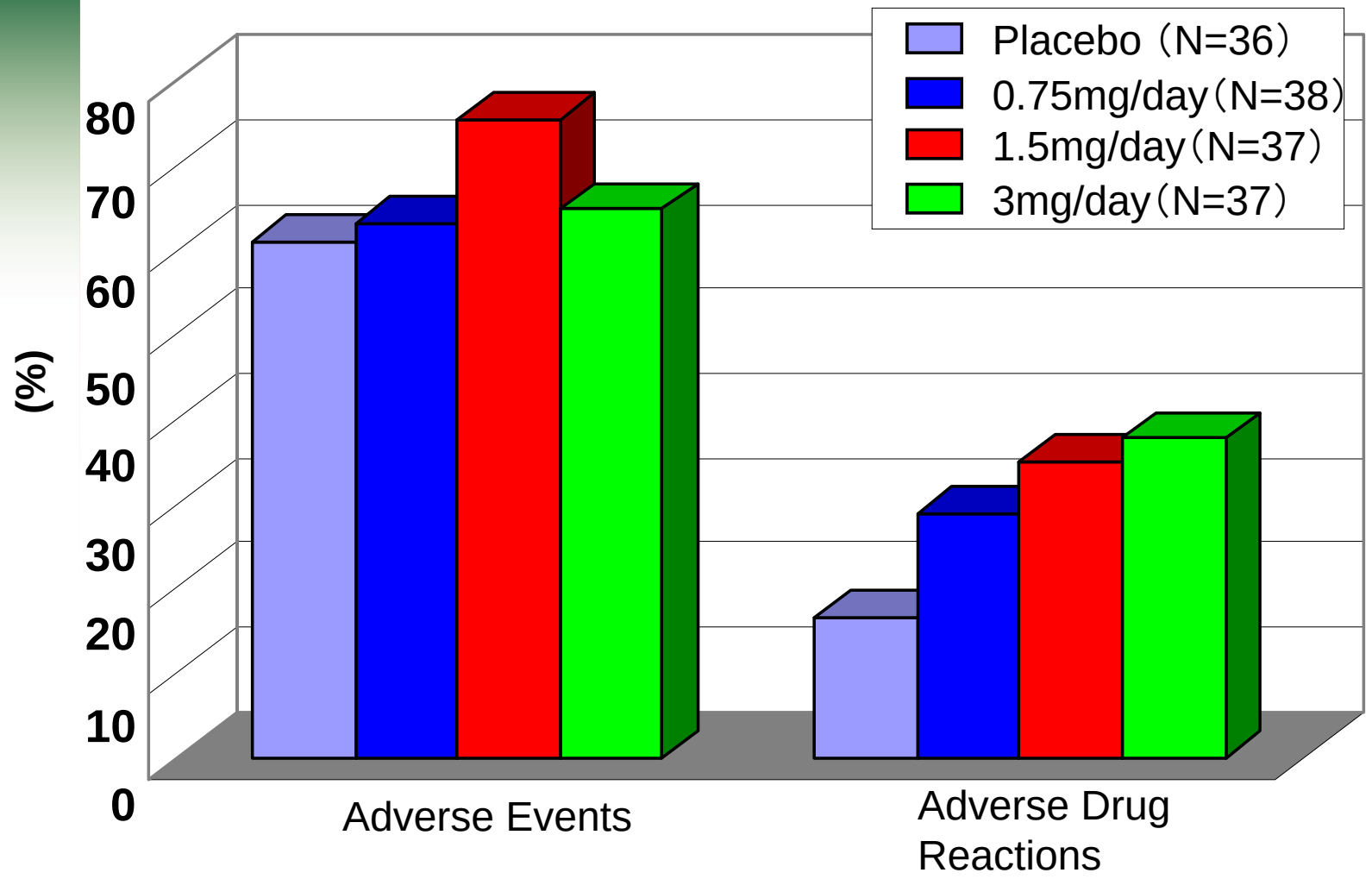
Change in HbA_{1C}



*: vs placebo, p<0.001

Safety

Adverse Events and Adverse Drug Reactions



P2b monotherapy clinical study: Conclusions

- Repaglinide at dose levels of 0.75, 1.5 and 3 mg/day showed significant reduction in PPG-AUC and HbA1C in comparison with placebo.
- The optimal dose level of repaglinide to control blood glucose level was 1.5 mg/day.
- Repaglinide was generally safe and well tolerated without any significant abnormalities

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Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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