

Passion for Innovation.  
Compassion for Patients.™




# Top Management Presentation

Financial Results for 2Q Fiscal 2012 (April 1 - September 30, 2012)

Thursday, November 1, 2012

Joji Nakayama, President and CEO



1st Half FY2012 proceeded roughly to plan  
Absolutely committed to achieve full-year targets:  
Net sales ¥980.0 billion Operating income ¥100.0 billion



Steady progress in major development projects

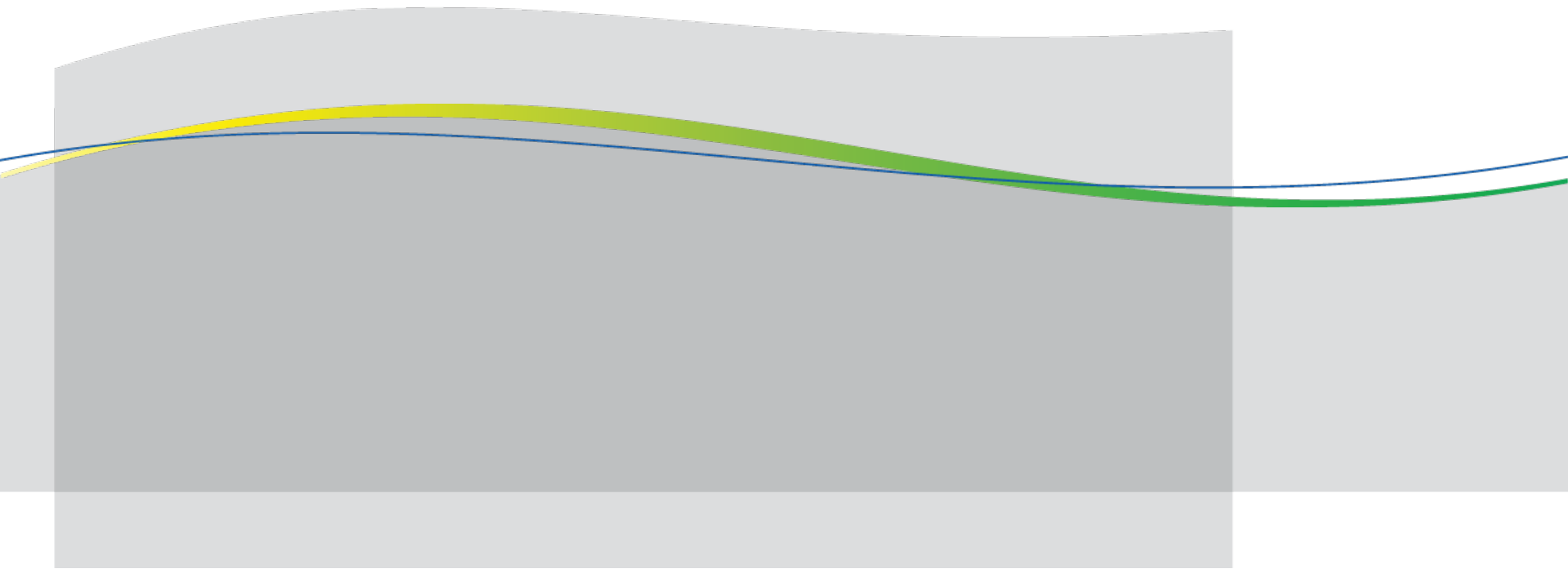


Ranbaxy's continuous growth and ongoing contribution to profit



Maintenance of ¥60 annual dividend

# Financial Overview



# Overview of FY2012 2Q Results

## - compared with FY2011 2Q results -

### Consolidated Income Statement

	FY2011 2Q Results	FY2012 2Q Results	FY2012	
			Forecast	Progress
Net Sales	456.0	484.2	980.0	49%
Cost of Sales	128.9	143.8	302.0	48%
SG&A Expenses	265.0	283.3	578.0	49%
R&D Expenses	84.1	87.2	188.0	46%
Other Expenses	180.9	196.1	390.0	50%
Operating Income	62.2	57.1	100.0	57%
Ordinary Income	66.3	49.9	100.0	50%
Net Income	37.0	24.4	50.0	49%

Currency Rate	USD/JPY (average)	79.81	79.42	80.00
	EUR/JPY (average)	113.78	100.64	100.00

### Ranbaxy Group

Note : Figures of Ranbaxy are pre-adjusted before consolidation

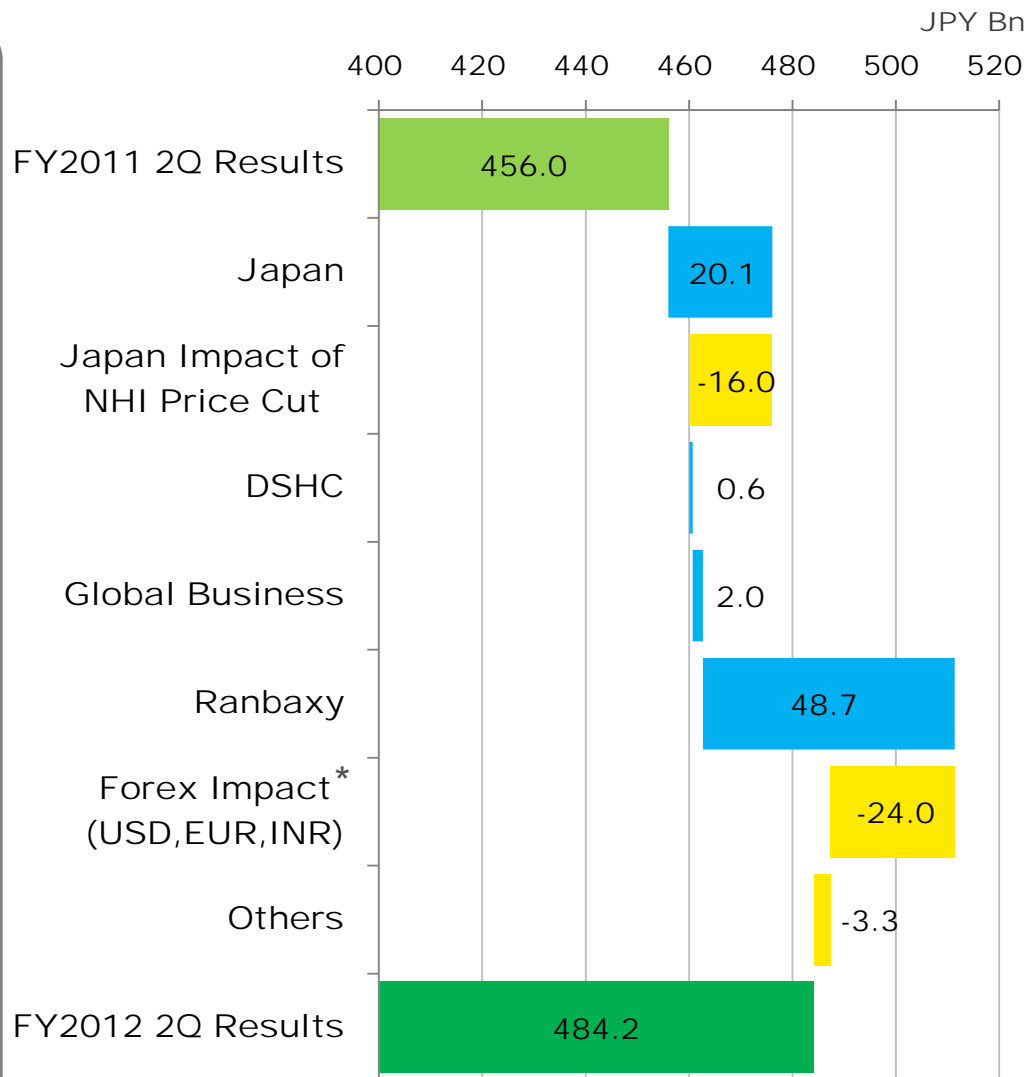
FY2011 (Jan-Jun) Results	FY2012 (Jan-Jun) Results	FY2012 (Jan-Dec)	
		Plan	Progress
78.6	107.7	179.0	60%
39.5	40.9		
32.2	47.4		
4.7	4.1		
27.5	43.2		
6.9	19.4		
10.0	12.0		
10.3	8.1		

JPY Bn

# Overview of FY2012 2Q Results

## - compared with FY2011 2Q results -

Net Sales factors



### Japan

- New products:  
Memary +6.9, Nexium +1.8, Ranmark +1.7
- Current products:  
Olmetec•Rezaltas•Calblock -2.1  
Mevalotin -4.1

### Global business

- Daiichi Sankyo Inc. (DSI) +4.6
- Luitpold Pharmaceuticals, Inc. (LPI) -2.9
- Daiichi Sankyo Europe GmbH (DSE) -1.0
- Asia, South and Central America (ASCA) +1.4

### Ranbaxy (RLL)

- Contribution of Atorvastatin etc.

### Others

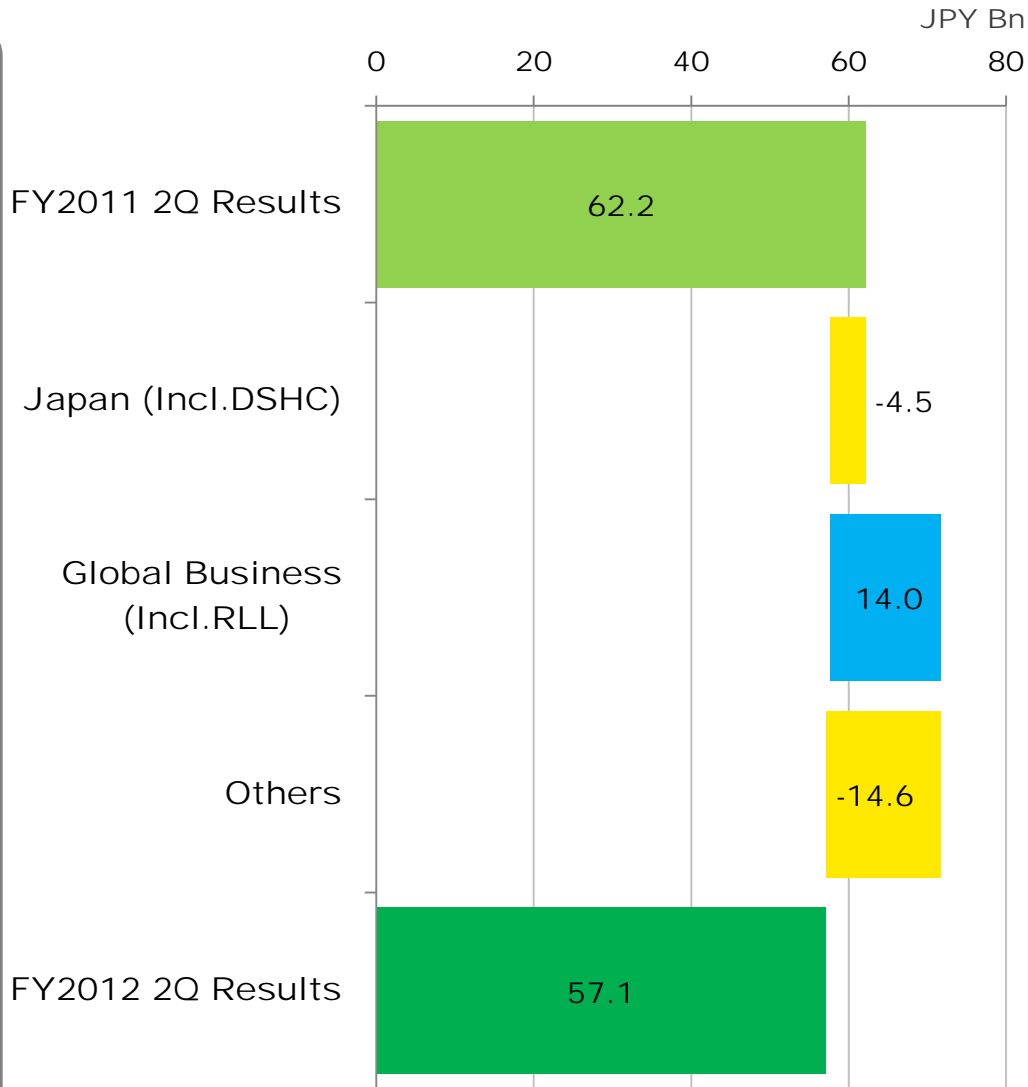
- Plexxikon revenue decline etc.

	FY2011 2Q Results	FY2012 2Q Results
*Currency Rate		
USD/JPY (average)	79.81	79.42
EUR/JPY (average)	113.78	100.64
INR/JPY (average)	1.83	1.54

# Overview of FY2012 2Q Results

- compared with FY2011 2Q results -

Operating Income factors



### Japan

- Enhanced promotion of new products
- Negative impact on NHI price cut

### Global business

- Increase factors:
  - RLL; Contribution of Atorvastatin +12.5 DSI
- Decrease factors:
  - LPI and DSE

### Others

- Increase in RD expenses
- Decrease in export of Levofloxacin
- Plexxikon revenue decline

# Overview of FY2012 2Q Results

## - compared with FY2011 2Q results -

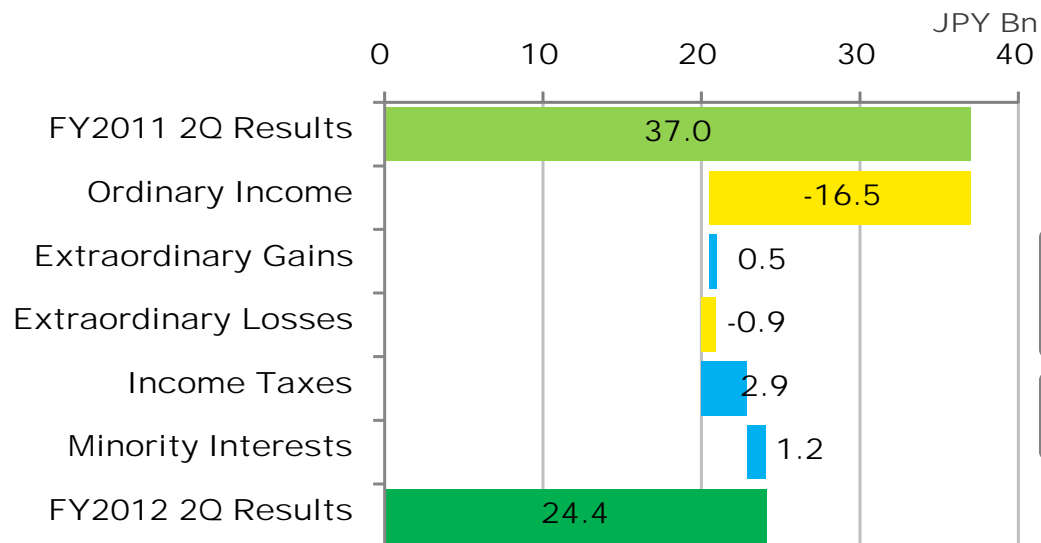
### Ordinary Income factors



**Non-operating income/expenses**

- Increases in forex losses and loss on valuation of derivatives of RLL

### Net Income factors



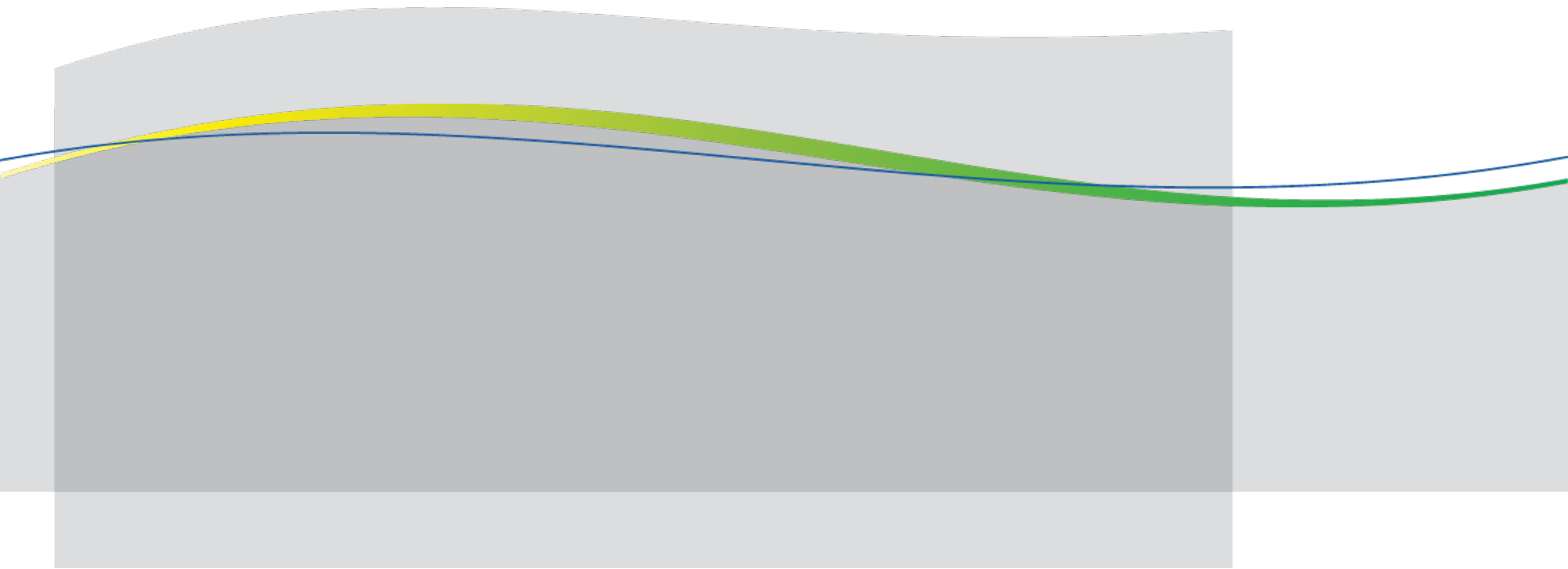
**Extraordinary gains/losses**

- Gain on sales of non-current assets
- Impairment loss (DSE Evista)

**Corporation tax and others:**

- Decrease in pretax income

# Business Highlights





## Steady achievement of existing mainstay product targets

- **Olmetec**
  - 46% of annual target achieved
  - Highest share growth rate in mono therapy market.
  - Continue to stronger prescription with lower dosage or higher dosage, and appeal its efficacy and durability by using evidence with Japanese patients
  
- **Rezaltas**
  - Sales 34% higher than 2Q FY2011.  
Focus will be catch up from a delay in the annual target progress.
  - Accelerate for the patients with less effective by mono therapy to be introduced to prescribe
  
- **Other mainstays (Loxonin, Cravit, Mavalotin, etc.)**
  - Progress in 1st half is mostly according to plan.
  - Continuous and steady activities as current promotions

## Realize earlier popularization of new products

- **Memary**
  - 41% of annual target achieved
  - Accelerate promotion post the cancellation of dosage restriction period
  - Raise rates of combined treatment with Donepezil by strengthening approach towards specialists, speed up acquisition of prescriptions.
  
- **Nexium**
  - Higher competition among general practitioner market
  - Corresponding with the cancellation of dosage restriction period from Oct. , promote with extensive pharmaceuticals information to speed up the switch of prescriptions from PPI.
  
- **Ranmark**
  - Sales results and number of adopting hospitals are progressing as planned.
  - Continually promote safety, efficacy, convenience of use.
  
- **Tenelia**
  - Using comprehensive sales capabilities, including distribution strategies, to ensure the market release smoothly.
  - Appealing to the once-a-daily dosage, early market penetration is planned.

## Daiichi Sankyo Inc. (DSI)

- **Olmesartan franchise**
  - 65% of annual target was achieved.
  - Prevent competing generics from encroaching by improved patients' supporting program
- **Welchol**
  - This year's annual target is more than 14% higher than FY2011, and 50% has been achieved in the 1st half. Aiming to surely achieve the annual target.
- **Effient**
  - Aiming to maximize sales, strong efforts will be continued. And by maximum using the acquired evidence, differentiate competing drugs among ACS-PCI patients and maximize the sales

## Luitpold Pharmaceuticals Inc. (LPI)

- **Venofer**
  - 47% of annual target was achieved.
  - The aggressive sales of competitor, and the entry of competing generics have created a severe market, but we are absolutely committed to achieve the annual target
- **Other**
  - Aiming to quickly resolve the GMP issue and obtain approval of Injectafar

## Daiichi Sankyo Europe (DSE)

- **Olmesartan franchise**
  - In the 1st half, 44% of annual target was achieved, which was within the expected range
  - Aggressive expansion of prescription for combination drugs as Sevikar and Sevicar HCT

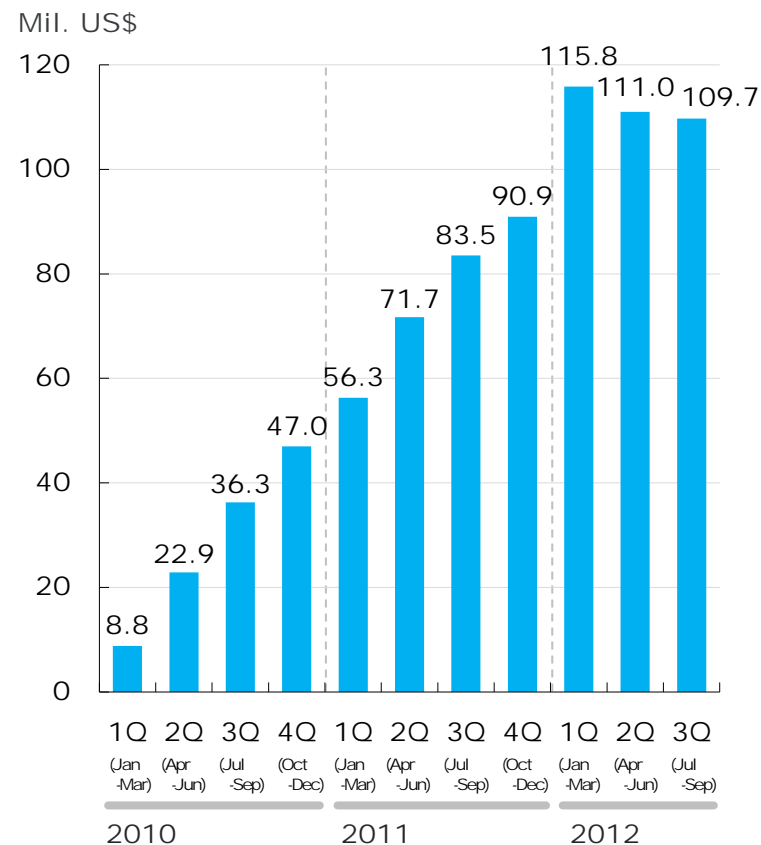
# Sales of Major Products

JPY Bn

		FY2011 2Q Results	FY2012 2Q Results	FY2012	
				Forecast	Progress
Global	Olmesartan	123.8	120.8	237.0	51%
	Prasugrel (alliance revenue)	4.5	6.5	-	-
Japan	Loxonin	30.1	29.7	62.0	48%
	Cravit	16.8	16.5	37.0	45%
	Nexium	2.6	4.4	29.0	15%
	Memary	3.9	10.8	26.0	41%
	Mevalotin	17.4	13.3	26.0	51%
	Artist	12.4	11.2	21.0	54%
	Omnipaque	11.9	10.2	18.0	57%
	Calblock	6.4	5.5	13.0	43%
	Urief	5.4	5.4	11.0	50%
U.S.	Welchol	13.6	15.5	31.0	50%
	Venofer	12.9	10.7	23.0	46%

Currency Rate	USD/JPY (average)	79.81	79.42	80.00
	EUR/JPY (average)	113.78	100.64	100.00

## Prasugrel Global Sales



\*Source: financial announcements of Lilly

## RANBAXY

### Response to U.S. FDA and U.S. Department of Justice

- Taking solid steps under a consent decree conducted with FDA
- Taking steps to finalize issues raised by DOJ. Settlement expenses to be within \$500 million provided for reserve thereof in FY2011

### Achievements of FY2012

- Maximization of value of Atorvastatin
- Entered market with pioglitazone Authorized Generic
- Smooth operational startup and of newly built Mohali plant in India

### Future measures

- To enter market with Valsartan FTF and others
- Shrinking derivatives position
- To smoothly enter market in U.S. with dermatology products

## Edoxaban (DU-176b)

### Aiming for Best in Class FXa inhibitor

- Steady progress in ENGAGE AF-TIMI 48 study, HOKUSAI VTE phase 3 study

## Prasugrel (CS-747)

### Expectations of commercial release in Japan

- Acute Coronary Patients undergoing PCI
  - For coronary heart disease patients undergoing elective PCI
  - Ischemic cerebrovascular disease
- } Estimated filing in FY2013

## Tivantinib (ARQ 197)

### Speed up measures to secure indication

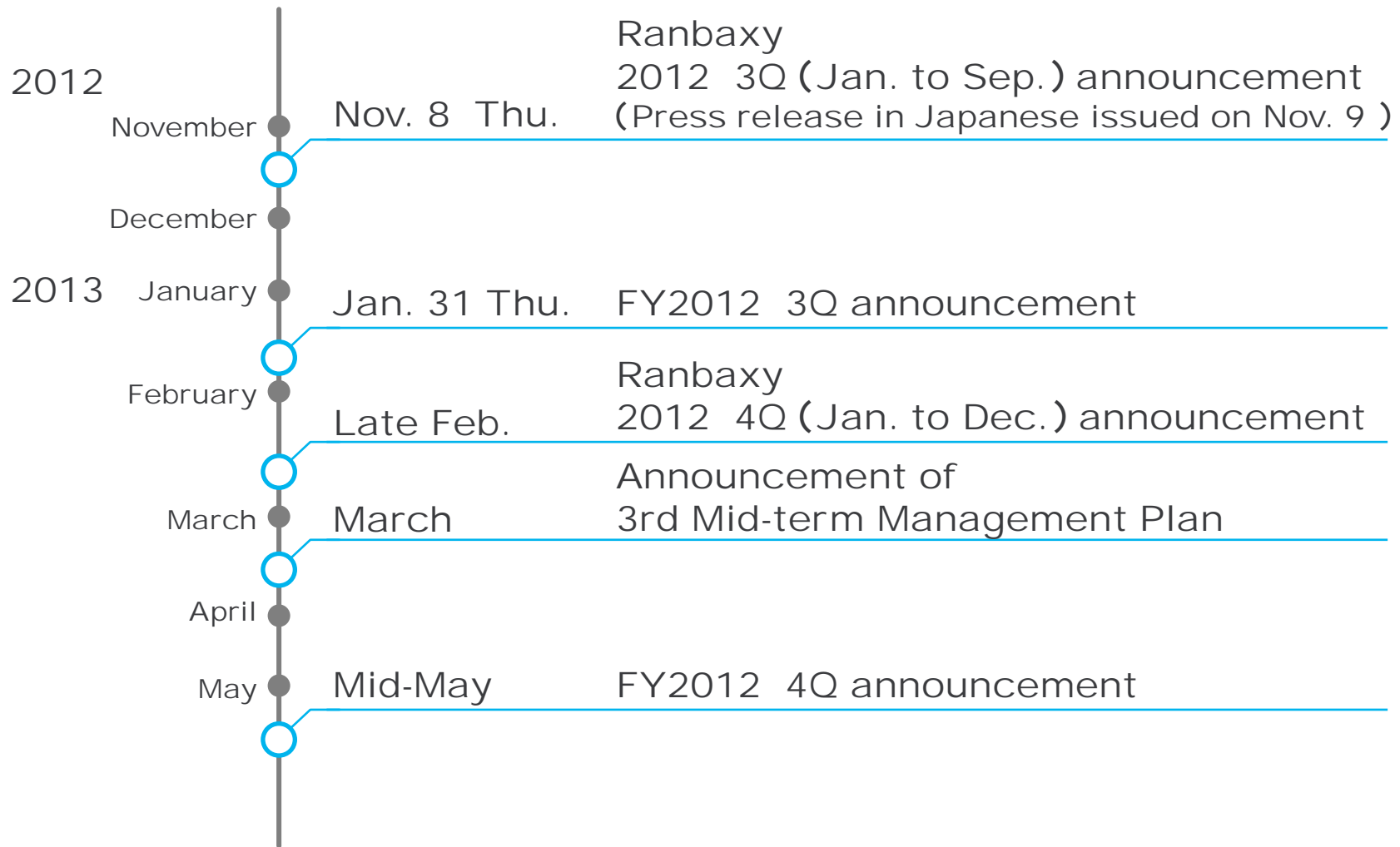
- Preparing phase 3 study for liver-cell cancer patients
- Proceeding with phase 2 study for colon cancer patients

## Denosumab (AMG 162)

### Osteoporosis, bound for approval and launch

- Japanese submission in March, 2012
- Studies for other indication ongoing
  - Breast cancer adjuvant, Rheumatoid arthritis, Giant cell tumor

# Future Schedule





Passion for Innovation.  
Compassion for Patients.™



# Global Research & Development

Thursday, November 1, 2012

Glenn Gormley MD PhD

Global Head of R&D  
Senior Executive Officer




# Major R&D Pipeline

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	<ul style="list-style-type: none"> <li>■ DS-7309 (Anti-diabetes / Glucokinase activator)</li> <li>■ DS-6930 (Anti-diabetes / Selective PPAR-gamma modulator)</li> <li>■ DS-8500 (Anti-diabetes / GPR119 agonist)</li> <li>■ DS-1442 (Dyslipidemia / CETP inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ CS-747 (US) (Prasugrel / Sickle cell disease / anti-platelet agent)</li> <li>■ CS-3150 (JP) (Anti-hypertensive / MR antagonist)</li> <li>■ DS-7250 (JP) (Anti-diabetes / DGAT1 inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ DU-176b (Global) (Edoxaban / AF / oral factor Xa inhibitor)</li> <li>■ DU-176b (Global) (Edoxaban / VTE / oral factor Xa inhibitor)</li> <li>■ CS-747 (Global*) (Prasugrel / ACS-MM / anti-platelet agent)</li> <li>■ CS-747 (JP) (Prasugrel / PCI / anti-platelet agent)</li> <li>■ CS-747 (JP) (Prasugrel / ischemic stroke / anti-platelet agent)</li> </ul>	
Oncology	<ul style="list-style-type: none"> <li>■ U3-1565 (US/JP) (Anti-HB-EGF antibody)</li> <li>■ DS-2248 (US) (HSP90 inhibitor)</li> <li>■ DS-7423 (US/JP) (PI3K/mTOR inhibitor)</li> <li>■ ARQ 092 (US) (Akt inhibitor)</li> <li>■ DS-3078 (US/EU) (mTOR inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ ARQ 197 (US/EU) (Tivantinib / Met inhibitor)</li> <li>■ CS-1008 (Global) (Tigatuzumab / anti-DR5 antibody)</li> <li>■ DE-766 (JP) (Nimotuzumab / anti-EGFR antibody)</li> <li>■ CS-7017 (US/EU) (Efatutazone / PPAR-gamma agonist)</li> <li>■ U3-1287 (US/EU) (Anti-HER3 antibody)</li> <li>■ PLX4032 (US/EU) (Vemurafenib / BRAF inhibitor)</li> <li>■ PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ ARQ-197 (Global*) (Tivantinib / NSCLC / Met inhibitor)</li> <li>■ AMG 162 (JP) (Denosumab / breast cancer adjuvant / Anti-RANKL antibody)</li> </ul>	
Others	<ul style="list-style-type: none"> <li>■ CS-8958 (Laninamivir / anti-influenza / Outlicensing with Biota)</li> <li>■ DS-8587 (Anti-bacterial)</li> <li>■ CS-4771 (Anti-sepsis)</li> <li>■ PLX5622 (Rheumatoid arthritis)</li> <li>■ CS-0777 (Immunomodulator)</li> <li>■ ASB17061 (Atopic Dermatitis)</li> <li>■ DS-7113 (Narcotic analgesic)</li> </ul>	<ul style="list-style-type: none"> <li>■ AMG 162 (JP) (Denosumab / rheumatoid arthritis / anti-RANKL anti-body)</li> <li>■ DS-5565 (Global) (Chronic pain / α2δ ligand)</li> <li>■ SUN13837 (US) (Spinal cord injury / Modulator of bFGF signaling system)</li> </ul>	<ul style="list-style-type: none"> <li>■ CS-8958 (JP) (Laninamivir / anti-influenza, prophylactic / Neuraminidase inhibitor)</li> <li>■ DD-723-B (JP) (Perflubutane / Contrast-enhanced ultrasonography for prostate tumor / ultrasound-contrast agent)</li> <li>■ DR-3355 (JP) (Levofloxacin / anti-infection / new quinolone)</li> </ul>	<ul style="list-style-type: none"> <li>■ DD-723-B (JP) (Perflubutane / Contrast enhanced ultrasonography for breast lesions / ultrasound contrast agent)</li> <li>■ AMG 162 (JP) (Denosumab / osteoporosis / Anti-RANKL antibody)</li> </ul>

The most advanced stages are described here in oncology area

# Edoxaban (DU-176b) : Once Daily Oral Factor Xa Inhibitor

Development by Daiichi Sankyo globally

Indication	Summary
<p><b>AF: ENGAGE AF-TIMI 48</b> Prevention of thromboembolic event in atrial fibrillation</p> 	<p>Phase 3 study, enrollment completed in Nov 2010</p> <p>Study to be completed by FY2012-end (Mar 2013)</p>
<p><b>VTE: HOKUSAI VTE</b> Acute treatment and long-term prevention of thromboembolic event in patient with DVT*/PE**</p> 	<p>Phase 3 study, enrollment completed in Oct 2012</p> <p>Study to be completed by FY2012-end (Mar 2013)</p>
<p><b><i>DVT-OS</i></b> <i>Prevention of post-surgical thromboembolic event</i></p>	<p><i>Launched in Japan on Jul 19, 2011</i></p> 

\*DVT : Deep Vein Thrombosis  
\*\*PE : Pulmonary Embolism

# Edoxaban (DU-176b) : Competitive advantage

- The best dose-finding study in Phase 2
  - Ensures the best balance in efficacy and safety
- The best Phase 3 studies in FXa class
  - The largest phase 3 studies
    - ENGAGE AF-TIMI 48 with over 21,000
    - HOKUSAI VTE with over 8,250
  - 2 doses in ENGAGE AF-TIMI 48 (30mg, 60mg Once a daily) to provide flexible treatment options for patients
- The best design for study closing for ENGAGE AF-TIMI 48
- Accumulated safety data of about 70,000 from DVT-OS patients post launch of Lixiana in Japan

# Prasugrel (CS-747) : Anti-platelet agent

Co-development with Ube Industries in Japan, with Eli Lilly outside of Japan

Indication	Summary
<p><b>Japan domestic Phase 3 studies</b></p> <ul style="list-style-type: none"><li>-ACS-PCI*:PRASFIT-ACS</li><li>-Elective-PCI</li><li>-Ischemic stroke</li></ul>	<p>Top line results of PRASFIT-ACS was announced in Sep 2012</p> <p>Elective-PCI study to be completed by the end of FY2012</p> <p>Application planned in PCI in FY2013</p> <p>Ischemic stroke study to be completed in FY2014</p>
<p><b>Sickle Cell Disease in Pediatric Participants</b></p>	<p>Phase 2 study, started in Nov 2011</p>
<p><b><i>ACS-MM** : TRILOGY ACS</i></b> <i>Reduction of thrombotic cardiovascular events in acute coronary syndromes without PCI</i></p>	<p><i>Results presented at ESC in Aug 2012</i></p>

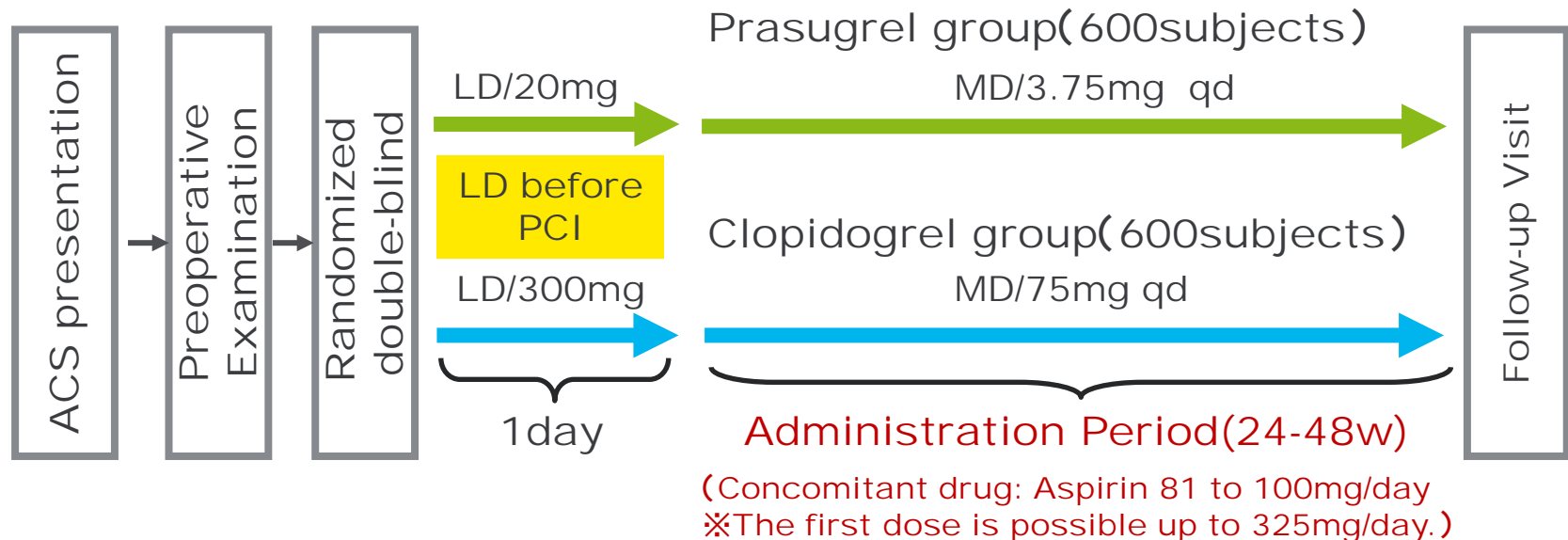
\*PCI : Percutaneous Coronary Intervention

\*\*MM : Medical Management

# Prasugrel ACS-PCI Phase 3 in Japan

## PRASFIT - ACS

- Multicenter, randomized, double-blind, double-dummy, parallel group study
- Evaluation of efficacy and safety of prasugrel in patients with ACS(UA, NSTEMI, STEMI)



Co-development with ArQule globally, except Japan, Asia

Indication	Summary
HCC (Hepatocellular Carcinoma)	Results presented at ASCO in June 2012 Phase 3 study is currently being planned
CRC (Colorectal Cancer)	Phase 2 study ongoing
<i>NSCLC (Non-Small Cell Lung cancer): MARQUEE</i>	<i>Study has just been stopped based on the recommendation from Data Monitoring Committee, that the study will not reach its primary endpoint.</i>

# Denosumab (AMG 162) : Anti- RANKL Antibody



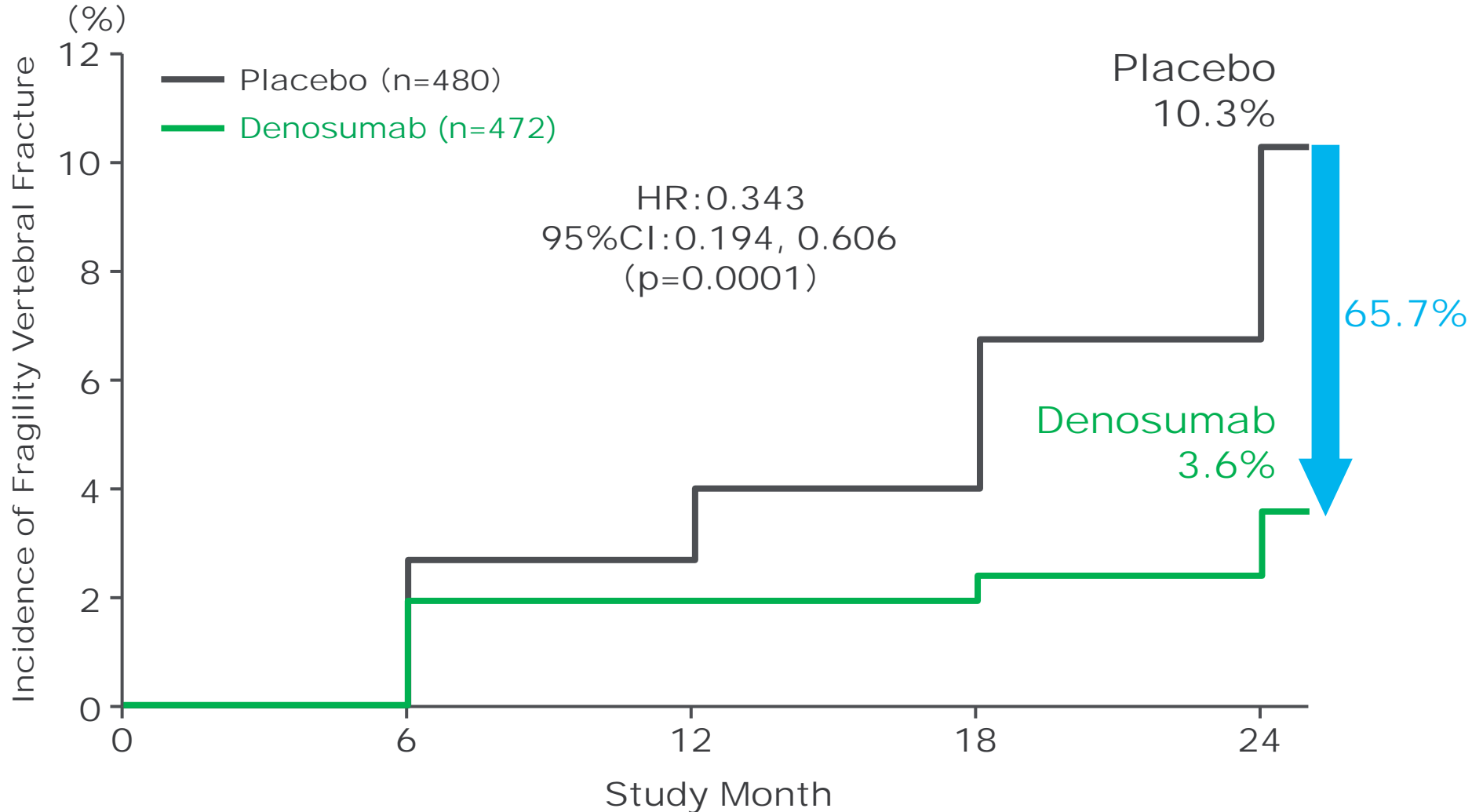
Development by Daiichi Sankyo in Japan

Indication	Summary
Osteoporosis: DIRECT	NDA filed in Japan in Mar 2012 Results presented at ASBMR in Oct 2012
Breast cancer adjuvant	Phase 3 study ongoing
Rheumatoid arthritis	Phase 2 study ongoing
Giant cell tumor	Phase 2 study ongoing
<i>Bone metastasis</i>	<i>Launched in Japan on Apr 17, 2012</i> <b>RANMARK</b> (denosumab)



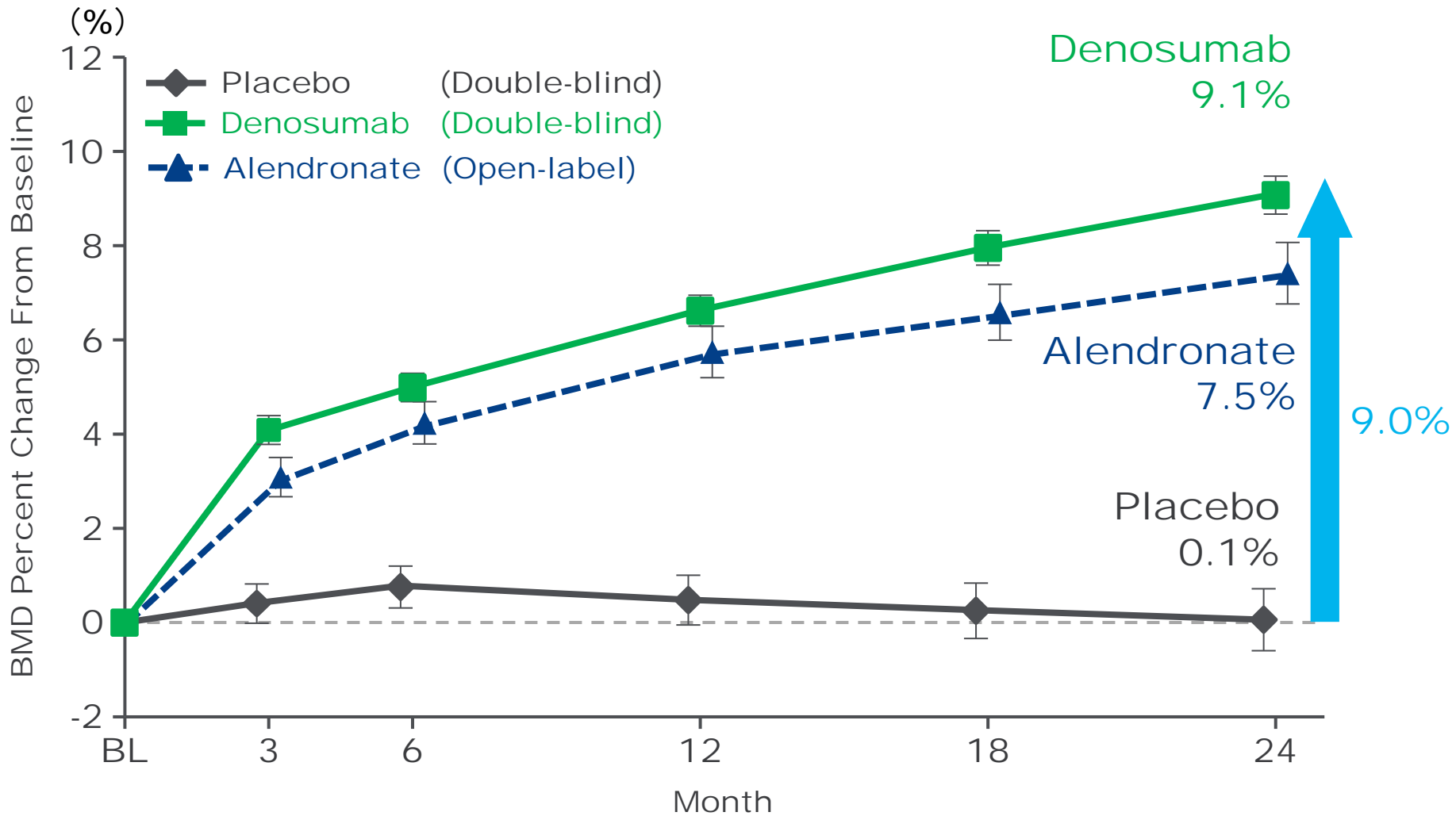
# Denosumab: DIRECT Study

## Incidence of New or Worsening vertebral fractures



# Denosumab: DIRECT Study

## Lumbar Spine BMD Levels



# Denosumab: DIRECT Study

## Summary of Adverse Events

Adverse Event	Double-blind		Open-label
	Placebo (N=481) n (%)	Denosumab (N=475) n (%)	Alendronate (N=242) n (%)
All	446 (92.7)	448 (94.3)	229 (94.6)
Serious	68 (14.1)	66 (13.9)	30 (12.4)
Death	5 (1.0)	5 (1.1)	0 (0.0)
Leading to study discontinuation	2 (0.4)	5 (1.1)	2 (0.8)
Leading to discontinuation of IP	31 (6.4)	23 (4.8)	18 (7.4)
AEs of interest			
Hypocalcemia	0 (0.0)	2 (0.4)	2 (0.8)
Cellulitis	3 (0.6)	6 (1.3)	0 (0.0)
Infection	269 (55.9)	286 (60.2)	131 (54.1)
Cardiovascular disorder	63 (13.1)	68 (14.3)	21 (8.7)
Malignancy	11 (2.3)	9 (1.9)	2 (0.8)
Serious AEs of interest			
Cellulitis	0 (0.0)	0 (0.0)	0 (0.0)
Infection	7 (1.5)	5 (1.1)	3 (1.2)
Cardiovascular disorder	7 (1.5)	6 (1.3)	2 (0.8)
Malignancy	10 (2.1)	7 (1.5)	2 (0.8)

## Contact address regarding this material

Daiichi Sankyo Co., Ltd.  
Corporate Communications Department

TEL: +81-3-6225-1126

Each numerical value regarding the future prospect in this material is derived from our judgment and assumptions based on the currently available information and may include risk and uncertainty. For this reason, the actual performance data, etc. may differ from the prospective value.