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

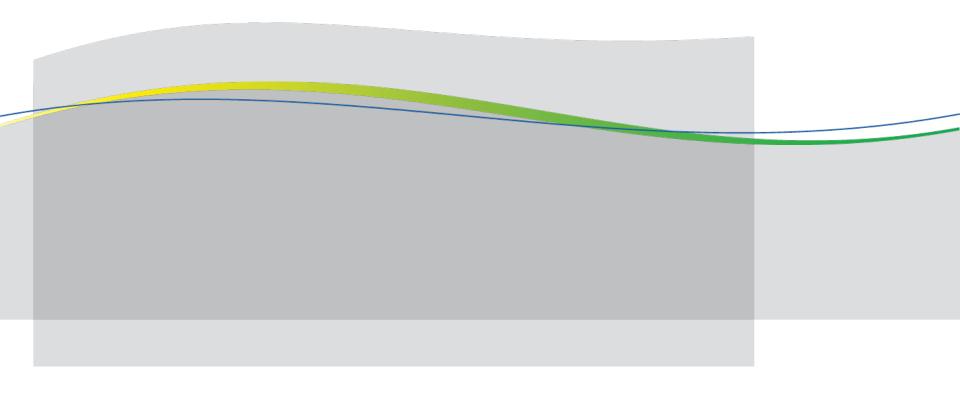
**Steady progress in major development projects** 

Ranbaxy's continuous growth and ongoing contribution to profit

Maintenance of ¥60 annual dividend

## **Financial Overview**

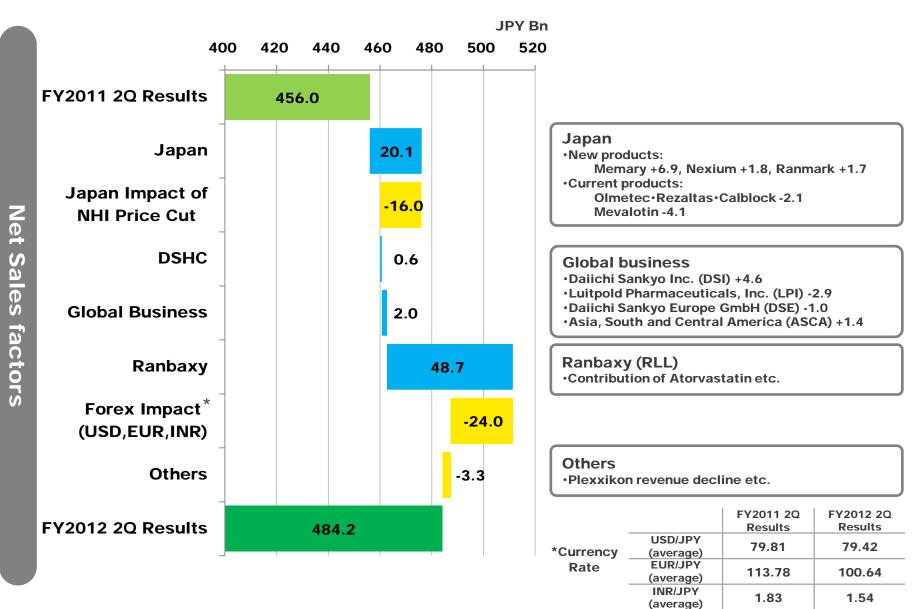




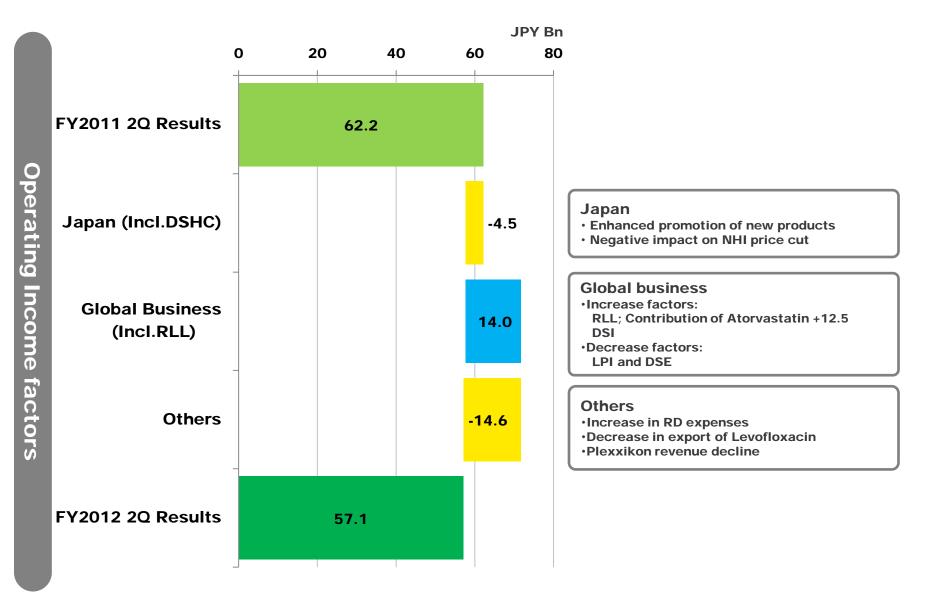


| Consolidated Income Statement |                      |              |              |          | Ranbaxy Group |                     |                     |                  |          |
|-------------------------------|----------------------|--------------|--------------|----------|---------------|---------------------|---------------------|------------------|----------|
|                               |                      | FY2011<br>2Q | FY2012<br>2Q | FY2012   |               | FY2011<br>(Jan-Jun) | FY2012<br>(Jan-Jun) | FY2012 (Jan-Dec) |          |
|                               |                      | Results      | Results      | Forecast | Progress      | Results             | Results             | Plan             | Progress |
| Net Sa                        | ales                 | 456.0        | 484.2        | 980.0    | <b>49%</b>    | 78.6                | 107.7               | 179.0            | 60%      |
| Cost of Sales                 |                      | 128.9        | 143.8        | 302.0    | 48%           | 39.5                | 40.9                |                  |          |
| SG&A Expenses                 |                      | 265.0        | 283.3        | 578.0    | 49%           | 32.2                | 47.4                |                  |          |
| R&<br>Exp                     | D<br>penses          | 84.1         | 87.2         | 188.0    | 46%           | 4.7                 | 4.1                 |                  |          |
| Oth<br>Exp                    | her<br>penses        | 180.9        | 196.1        | 390.0    | 50%           | 27.5                | 43.2                |                  |          |
| Operating<br>Income           |                      | 62.2         | 57.1         | 100.0    | 57%           | 6.9                 | 19.4                |                  |          |
| Ordinary<br>Income            |                      | 66.3         | 49.9         | 100.0    | 50%           | 10.0                | 12.0                |                  |          |
| Net Income                    |                      | 37.0         | 24.4         | 50.0     | 49%           | 10.3                | 8.1                 |                  |          |
| Currency                      | USD/JPY<br>(average) | 79.81        | 79.42        | 80.00    |               |                     |                     |                  | JPY Bn   |
| Rate                          | EUR/JPY<br>(average) | 113.78       | 100.64       | 100.00   |               |                     |                     |                  | 4        |

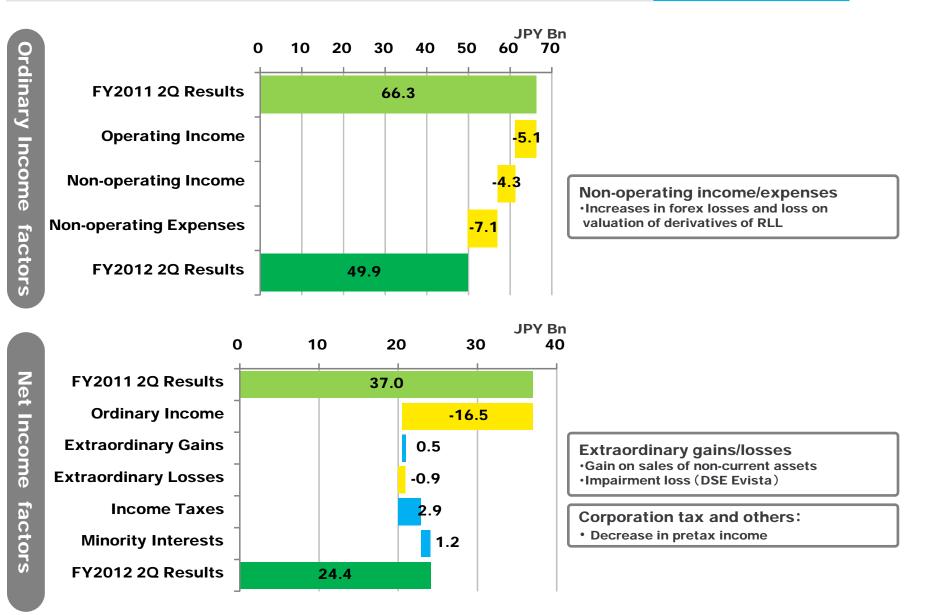






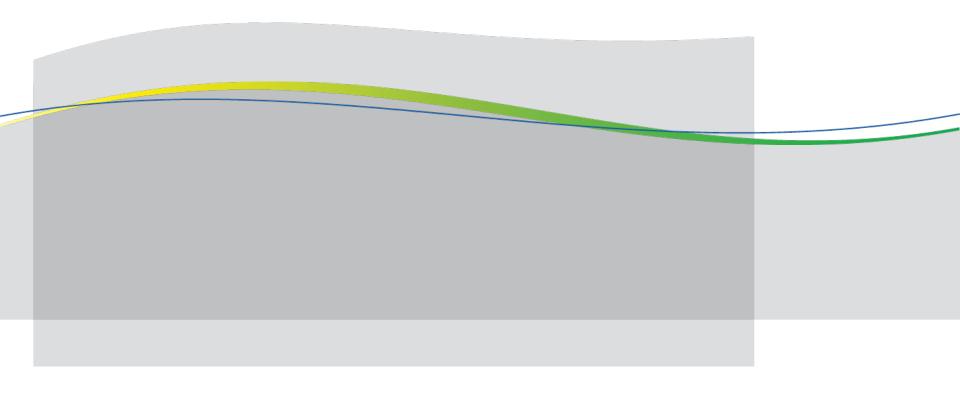






# **Business Highlights**





## **Highlights Japan**



## 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

## Highlights Japan



## **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.

Highlights North America & Europe



### Daiichi Sankyo Inc. (DSI)

| Olmesartan | <ul> <li>65% of annual target was achieved.</li> </ul> |
|------------|--|
| fuenchies  | · Provent competing generics from encroaching          |

- franchise 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

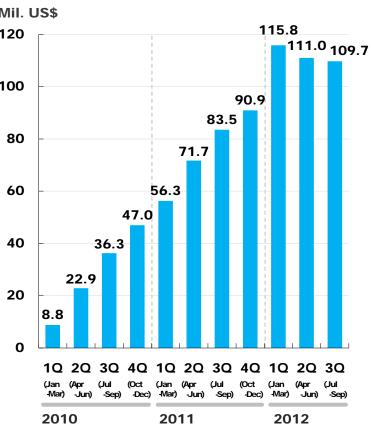
## **Sales of Major Products**



|                           | JPY Bn                          |               |               |          |          |   |
|---------------------------|---------------------------------|---------------|---------------|----------|----------|---|
|                           |                                 | FY2011        | FY2012        | FY2012   |          |   |
|                           |                                 | 2Q<br>Results | 2Q<br>Results | Forecast | Progress |   |
| GIO                       | Olmesartan                      | 123.8         | 120.8         | 237.0    | 51%      |   |
| Global                    | Prasugrel<br>(alliance revenue) | 4.5           | 6.5           | -        | -        | N |
|                           | Loxonin                         | 30.1          | 29.7          | 62.0     | 48%      | 1 |
|                           | Cravit                          | 16.8          | 16.5          | 37.0     | 45%      | 1 |
|                           | Nexium                          | 2.6           | 4.4           | 29.0     | 15%      |   |
| ر                         | Memary                          | 3.9           | 10.8          | 26.0     | 41%      |   |
| Japan                     | 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%      |   |
| S.                        | Venofer                         | 12.9          | 10.7          | 23.0     | 46%      |   |
| Cu                        | USD/JPY<br>rrency (average)     | 79.81         | 79.42         | 80.00    |          |   |
| Rate EUR/JPY<br>(average) |                                 | 113.78        | 100.64        | 100.00   | ]        |   |

#### **Prasugrel Global Sales**

IDV D.



\*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
- Estimated filing in FY2013

Ischemic cerebrovascular disease



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

## Denosmab (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-<br>Metabolics | / Selective PPAR-gamma modulator)   | <ul> <li>CS-747 (US)         <ul> <li>(Prasugrel / Sickle cell disease / anti-platelet agent)</li> <li>CS-3150 (JP)</li></ul></li></ul>  | <ul> <li>DU-176b (Global)<br/>(Edoxaban / AF / oral factor Xa inhibitor)</li> <li>DU-176b (Global)<br/>(Edoxaban / VTE / oral factor Xa inhibitor)</li> <li>CS-747 (Global*)<br/>(Prasugrel / ACS-MM / anti-platelet agent)</li> <li>CS-747 (JP)<br/>(Prasugrel / PCI / anti-platelet agent)</li> <li>CS-747 (JP)<br/>(Prasugrel / ischemic stroke<br/>/ anti-platelet agent)</li> </ul> |  |
| Oncology                      | <ul> <li>U3-1565 (US/JP)<br/>(Anti-HB-EGF antibody)</li> <li>DS-2248 (US)<br/>(HSP90 inhibitor)</li> <li>DS-7423 (US/JP)<br/>(PI3K/mTOR inhibitor)</li> <li>ARQ 092 (US)<br/>(Akt inhibitor)</li> <li>DS-3078 (US/EU)<br/>(mTOR inhibitor)</li> </ul>   | <ul> <li>ARQ 197 (US/EU)</li> <li>(Tivantinib / Met inhibitor)</li> <li>CS-1008 (Global)</li> <li>(Tigatuzumab / anti-DR5 antibody)</li> <li>DE-766 (JP)</li> <li>(Nimotuzumab / anti-EGFR antibody)</li> <li>CS-7017 (US/EU)</li> <li>(Efatutazone / PPAR-gamma agonist)</li> <li>U3-1287 (US/EU)</li> <li>(Anti-HER3 antibody)</li> <li>PLX4032 (US/EU)</li> <li>(Vemurafenib / BRAF inhibitor)</li> <li>PLX3397 (US)</li> <li>(Fms/Kit/Flt3-ITD inhibitor)</li> </ul> | <ul> <li>ARQ-197 (Global*)<br/>(Tivantinib / NSCLC / Met inhibitor)</li> <li>AMG 162 (JP)</li> <li>(Denosumab / breast cancer adjuvant / Anti-RANKL antibody)</li> </ul>   |  |
| Others                        | <ul> <li>CS-8958</li> <li>(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> <li>AMG 162 (JP)</li> <li>(Denosumab / rheumatoid arthritis / anti-RANKL anti-body)</li> <li>DS-5565 (Global)</li> <li>(Chronic pain / α2δ ligand)</li> <li>SUN13837 (US)</li> <li>(Spinal cord injury / Modulator of bFGF signaling system)</li> </ul>   | <ul> <li>CS-8958 (JP)</li> <li>(Laninamivir / anti-influenza, prophylactic / Neuraminidase inhibitor)</li> <li>DD-723-B (JP)</li> <li>(Perflubutane / Contrast enhanced -ultrasonography for prostate tumor / ultrasound contrast agent)</li> <li>DR-3355 (JP)</li> <li>(Levofloxacin / anti-infection / new quinolone)</li> </ul>   | <ul> <li>DD-723-B (JP)</li> <li>(Perflubutane / Contrast enhanced<br/>ultrasonography for breast lesions<br/>/ ultrasound contrast agent)</li> <li>AMG 162 (JP)</li> <li>(Denosumab / osteoporosis<br/>/ 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  |
|---|--|
| AF: ENGAGE AF-TIMI 48<br>Prevention of thromboembolic event                   | Phase 3 study, enrollment<br>completed in Nov 2010 |
| in atrial fibrillation<br>Engage AF<br>TIMI 48                                | Study to be completed by FY2012-end (Mar 2013)     |
| VTE: HOKUSAI VTE<br>Acute treatment and long-term                             | Phase 3 study, enrollment completed in Oct 2012    |
| prevention of thromboembolic event<br>in patient with DVT*/PE**<br>HokusaiVTE | Study to be completed by FY2012-end (Mar 2013)     |
| <b>DVT-OS</b><br>Prevention of<br>post-surgical thromboembolic event          | Launched in Japan<br>on Jul 19, 2011               |

## 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



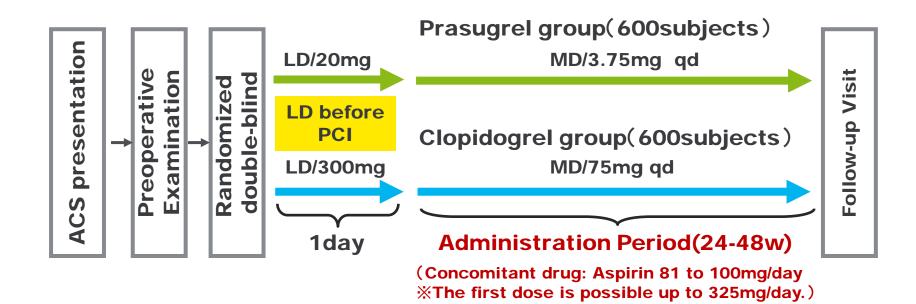
# Co-development with Ube Industries in Japan, with Eli Lilly outside of Japan

| Indication  | Summary   |
|---|---|
| Japan domestic Phase 3 studies  | Top line results of PRASFIT-ACS was announced in Sep 2012 |
| -ACS-PCI*:PRASFIT-ACS<br>-Elective-PCI<br>-Ischemic stroke  | Elective-PCI study to be completed by the end of FY2012   |
|   | Application planned in PCI in FY2013                      |
|   | Ischemic stroke study to be completed in FY2014           |
| Sickle Cell Disease in<br>Pediatric Participants  | Phase 2 study, started in Nov 2011                        |
| <b>ACS-MM**: TRILOGY ACS</b><br>Reduction of thrombotic<br>cardiovascular events in acute<br>coronary syndromes without PCI | Results presented at ESC in Aug 2012                      |

\*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)



Daiichi-Sankyo



## Co-development with ArQule globally, except Japan, Asia

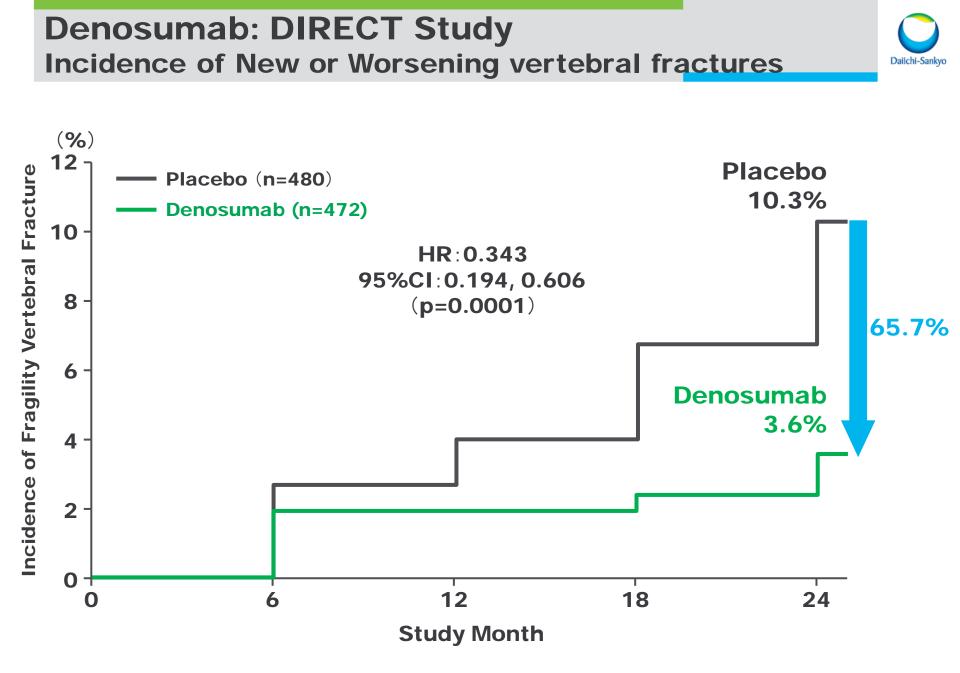
| Indication   | Summary  |
|--|--|
| HCC<br>(Hepatocellular Carcinoma)                          | Results presented at ASCO in<br>June 2012<br>Phase 3 study is currently being<br>planned   |
| CRC<br>(Colorectal Cancer)                                 | Phase 2 study ongoing  |
| <i>NSCLC<br/>(Non-Small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

Denosumab (AMG 162) : Anti- RANKL Antibody



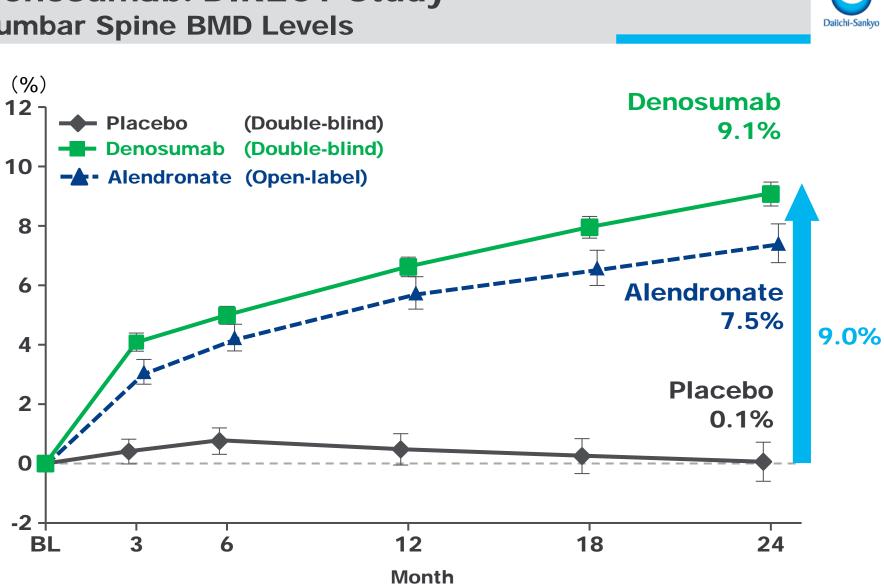
## Development by Daiichi Sankyo in Japan

| Indication             | Summary   |  |  |
|------------------------|---|--|--|
|                        | NDA filed in Japan in Mar 2012                              |  |  |
| Osteoporosis: DIRECT   | 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                                       |  |  |
| Bone metastasis        | Launched in Japan on Apr 17, 2012<br>RANMARK<br>(denosumab) |  |  |



## **Denosumab: DIRECT Study** Lumbar Spine BMD Levels

**BMD Percent Change From Baseline** 





|                                  | Doub                        | Open-label                    |                                 |
|----------------------------------|-----------------------------|-------------------------------|---------------------------------|
| Adverse Event                    | Placebo<br>(N=481)<br>n (%) | Denosumab<br>(N=475)<br>n (%) | Alendronate<br>(N=242)<br>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** 

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