



JP Morgan Healthcare Conference 2013

An Update from Daiichi Sankyo

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George Nakayama, President and CEO



Passion for Innovation. Compassion for Patients.™

Daiichi-Sankyo

- One of the Top pharmaceutical companies in Japan
- Ranked among the top 20 global pharmaceutical companies
- Worldwide Presence:
 - Ground presence in more than 50 countries
 - Manufacturing locations in 13 countries
 - R&D locations in Japan, US, Germany, UK, India, and etc.
- Consolidated net sales JPY 938.7 Bn (FY2011) = 11.73 Bn US\$ *
- >31,000 employees globally represented by 50 nationalities
- Business model encompassing; Innovative and Established pharmaceuticals, OTC, and Vaccines

Our innovation history



The innovation of Taka-diastase by Dr. Jokichi Takamine, 1st president of ex-Sankyo, continues today

 Pravastatin : HMG-CoA inhibitor Anti-cholesterol launched in 1989 licensed to BMS Pravachol



 Levofloxacin : Broad spectrum anti-biotic quinolone launched in 1993 licensed to J&J Levaquin



Our innovation history

- Olmesartan : Angiotensin Receptor Blocker (ARB) Anti-hypertensive launched in 2002 Benicar[®], Benicar HCT[®] Azor[®], Tribenzor[®]
- Prasugrel : ADP receptor inhibitor Anti-platelet launched in 2009 co-promotes with Eli Lilly Effient[®]
 - Edoxaban : FXa inhibitor Anti-coagulant launched in Japan in July, 2011 Lixiana[®] Two P3 global studies ongoing



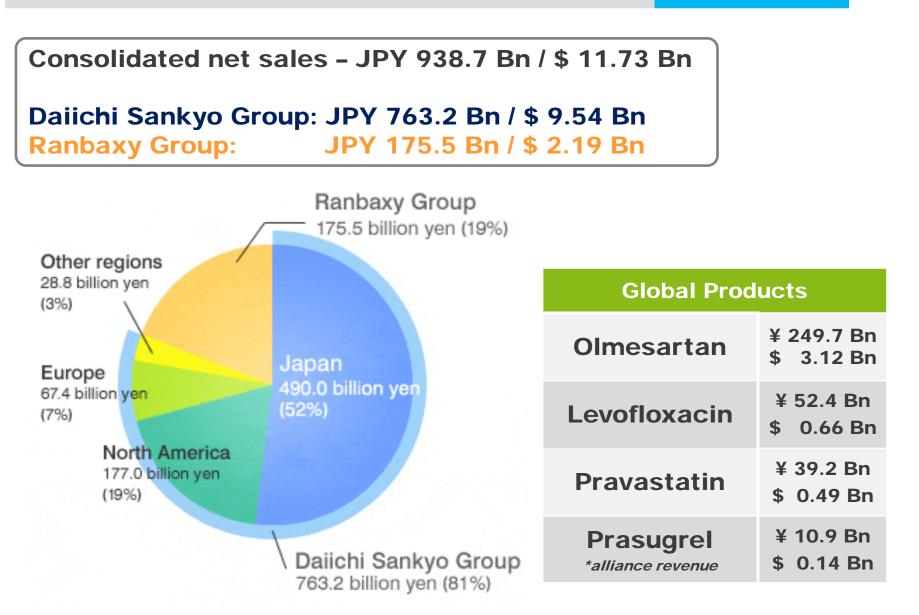






Global Sales Splits (FY2011)







1st Half FY2012 results on trackCommitted to achieve full-year targets:Net sales¥ 980.0 Bn / \$ 12.3 BnOperating income¥ 100.0 Bn / \$ 1.25 Bn

Steady progress in major development projects

Ranbaxy's continuous base business growth and ongoing contribution to profit

Overview of FY2012 2Q Results



JPY Bn

Consolidated Income Statement

		FY2012		
		Forecast	End of 2Q	Progress
Net Sales		980.0	484.2	49%
Cost of Sales		302.0	143.8	48%
SG&A Expenses		578.0	283.3	49%
	R&D Expenses	188.0	87.2	46%
	Other Expenses	390.0	196.1	50%
Operating Income		100.0	57.1	57%
Ordinary Income		100.0	49.9	50%
Net Income		50.0	24.4	49%

Currency rate : JPY/USD=80.0 JPY/EUR=100.0

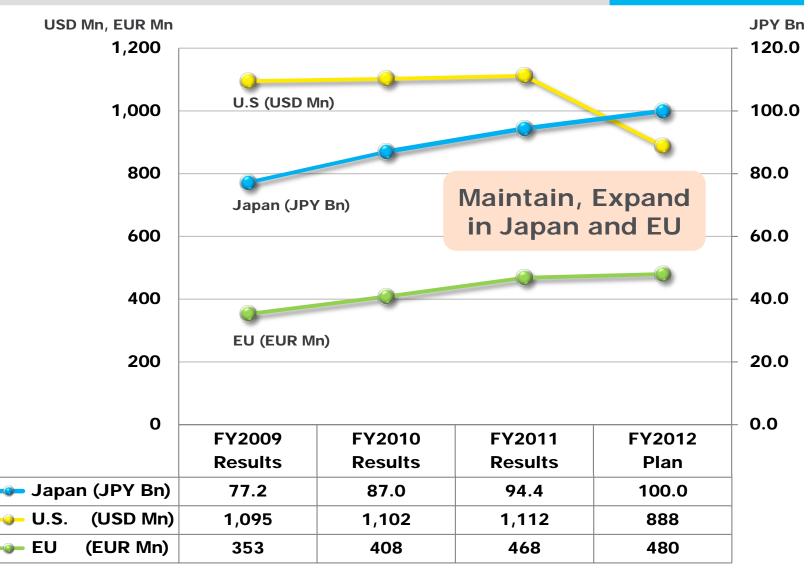
Ranbaxy Group

FY2012 (Jan-Dec)			
Plan	End of 2Q	Progress	
179.0	107.7	60%	
	40.9		
	47.4		
	4.1		
	43.2		
	19.4		
	12.0		
	8.1		

Note : Figures of Ranbaxy are pre-adjusted before consolidation

Sales of Olmesartan (Local Currency Basis)





Breakdown for Olmesartan

Japan: Olmetec, Rezaltas

U.S.: Benicar, Benicar HCT, Azor, Tribenzor

Europe: Olmetec, Olmetec Plus, Sevikar, Sevikar HCT

Set for growth in Japan (1)



- Potential flagship products growing
 - Memary[®]

Treatment for Alzheimer Launched in June 2011



- Nexium[®] Proton Pump Inhibitor Launched in Sep. 2011



- New launches in 2012
 - Ranmark[®]

Treatment for bone metastasis, launched in April

- Tenelia®

Treatment for anti type 2 diabetes, DPP 4 inhibitor Launched in September, licensed from Mitsubishi Tanabe First step for expanding the diabetes franchise

 Japan Vaccine Co. Ltd., joint venture with GSK, established in 2012



- Denosumab licensed from Amgen
 - Investigational treatment for Osteoporosis, anti-RANKL antibody
 - NDA filed in March 2012
 - Anticipated approval and launch in 1H, 2013
- Prasugrel
 - Oral anti platelet (OAP), treatment for ischemic diseases
 - OAP market in Japan growing to 150 billion JPY or over
 - Anticipated NDA filing of the treatment for PCI patients or ischemic stroke patients in FY2013 or FY2014, respectively
- Inavir[®]
 - Long acting neuraminidase inhibitor
 - Launched in Oct. 2010, treatment for influenza
 - Additional NDA filing in Nov. 2012, influenza prevention

Ranbaxy Laboratories Limited

Among the top global generic companies





- Strong presence in Emerging Markets
- Synergies with Daiichi Sankyo through the Hybrid Business Model



- Demonstrated NDDS capabilities
- Manufacturing:
 - DF & API across 8 countries



- Amongst the top global Gx companies
- Sales in over 150

countries

 Ground presence in 43 countries

Daiichi Sankyo currently holds 64% equity stake in the company





RANBAXY

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

- Progress on Consent Decree with the FDA progressed per plan
- **\$500 Mn settlement expenses with the DOJ, in FY 2011**

Achievements of FY2012

- Successful launch of Atorvastatin
- Smooth operational startup and of newly built Mohali plant in India
- Entered market with pioglitazone Authorized Generic
- Launch of Absorica™ (Isotretinoin) for recalcitrant nodular acne

Future measures

- Confident of monetizing important FTF opportunities including Valsartan, Esomeprazole and others
- Address impact of now reduced open derivatives position
- Accelerate focus on differentiated opportunities in brand markets, including U.S. dermatology space

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



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

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

Edoxaban (DU-176b) : Competitive advantage



Dose-finding study in Phase 2

• Ensures the best balance in efficacy and safety

Phase 3 studies in FXa class

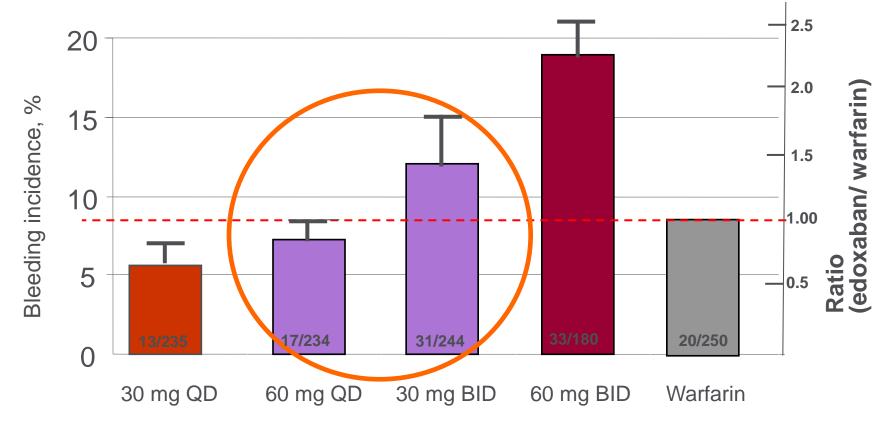
- The largest NOAC phase 3 studies
 - ENGAGE AF-TIMI 48 with over 21,000 enrollments
 - HOKUSAI VTE with over 8,250 enrollments
- 2 doses in ENGAGE AF-TIMI 48 (30mg, 60mg Once a day) to provide flexible treatment options for patients
- Design for study closing for ENGAGE AF-TIMI 48
- Accumulated safety data from about 70,000 DVT-OS patients post launch of Lixiana in Japan



	Edoxaban	Dabigatran	Rivaroxaban	Apixaban
Trial Name	ENGAGE AF TIMI 48	RE-LY	ROCKET AF	ARISTOTLE
Enrollment	21,107	18,113	14,264	18,201
Principle Dose	30 mg QD 60 mg QD	110 mg BID 150 mg BID	20 mg QD	5 mg BID

Edoxaban Phase 2b Study in AF -All Bleeds for Edoxaban Relative to Warfarin-





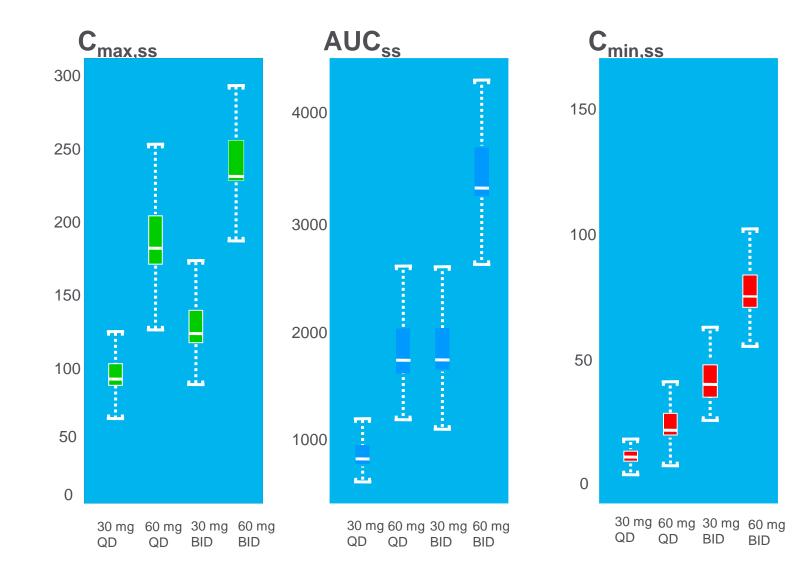
For the same total daily dose of 60 mg, higher bleeding observed for 30 mg BID compared with 60 mg QD

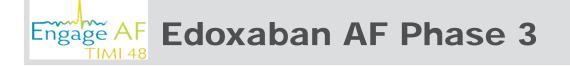
Weitz, J. et al. Thromb Haemostas. 2010;104:633-641.

Edoxaban Phase 2b Study in AF

- $C_{min,ss}$ follows a similar pattern to that observed in edoxaban bleeding -



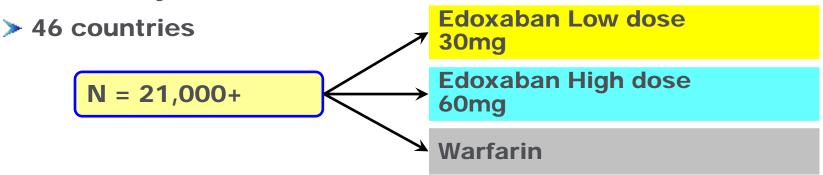






Effective Anticoagulation With Factor Xa Next Generation in Atrial Fibrillation

- Randomized, Double-Blind, Double-Dummy, Parallel Group, Multi-Center, Multi-National
- Evaluation of efficacy and safety of edoxaban in AF patients in comparison with those of warfarin
- > Once daily



Primary efficacy endpoint: stroke, systemic embolism Secondary efficacy endpoint: stroke, systemic embolism, all-cause mortality Safety endpoint: major bleeding, clinically relevant bleeding



Expectations of commercial release in Japan

Indication	Summary
Japan domestic Phase 3 studies -ACS-PCI*:PRASFIT-ACS -Elective-PCI -Ischemic stroke	PRASFIT-ACS study was completed in 2012 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 Pediatric Participants	Phase 2 study, started in Nov 2011

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

*PCI : Percutaneous Coronary Intervention **MM : Medical Management



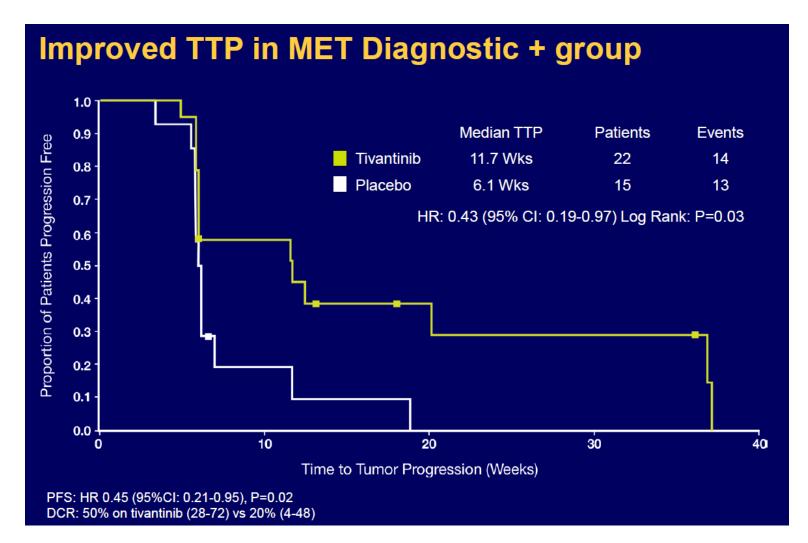
Speed up measures to secure indication

Indication	Summary	
HCC (Hepatocellular Carcinoma)	Results presented at ASCO in June 2012 Preparation for Phase 3 study	
CRC (Colorectal Cancer)	Phase 2 study ongoing	
Co-development with ArQule globally,		

Co-development with ArQule globally, except for select Asian countries including Japan **Tivantinib HCC Phase 2:** Time to Progression Hepatocellular Carcinoma(HCC) with Met high



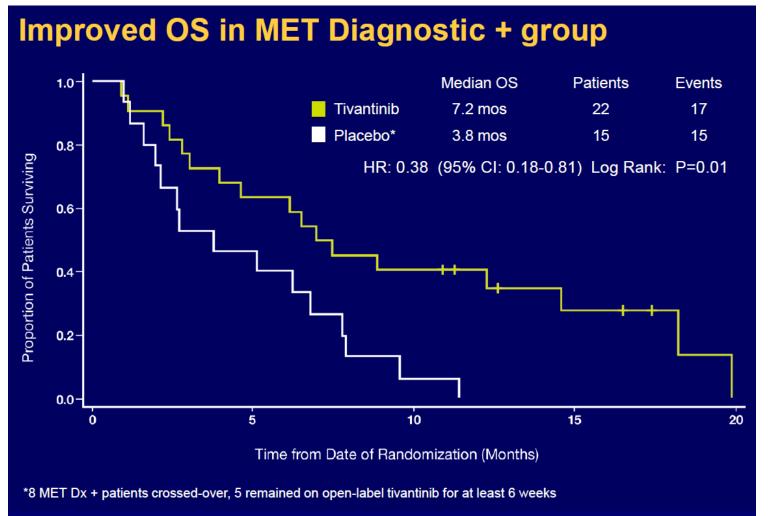
- > HCC is the most common primary liver cancer and on the rise worldwide
- There is no currently approved standard of care in 2nd line HCC



Tivantinib HCC Phase 2: Overall Survival Hepatocellular Carcinoma(HCC) with Met high



- Liver cancer is the 3rd leading cause of cancer-related death(Globally ~700 thousands/ year)
- Phase 3 study is currently being planned



Major R&D Pipeline (as of Dec. 2012)



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	 DS-7309 (Anti-diabetes / Glucokinase activator) DS-6930 (Anti-diabetes / Selective PPAR-gamma modulator) DS-8500 (Anti-diabetes / GPR119 agonist) DS-1442 (Dyslipidemia / CETP inhibitor) 	 CS-747 (US) (Prasugrel / Sickle cell disease / anti-platelet agent) CS-3150 (JP) (Anti-hypertensive / MR antagonist) DS-7250 (JP) (Anti-diabetes / DGAT1 inhibitor) 	 Edoxaban (Global) (DU-176b / AF / oral factor Xa inhibitor) Edoxaban (Global) (DU-176b / VTE / oral factor Xa inhibitor) Prasugrel (JP) (CS-747/ PCI / anti-platelet agent) Prasugrel (JP) (CS-747/ ischemic stroke / anti-platelet agent) 	
Oncology	 U3-1565 (US/JP) (Anti-HB-EGF antibody) DS-2248 (US) (HSP90 inhibitor) DS-7423 (US/JP) (Pl3K/mTOR inhibitor) ARQ 092 (US) (Akt inhibitor) DS-3078 (US/EU) (mTOR inhibitor) 	 Tivantinib (US/EU) (ARQ 197 / Met inhibitor) CS-1008 (Global) (Tigatuzumab / anti-DR5 antibody) DE-766 (JP) (Nimotuzumab / anti-EGFR antibody) CS-7017 (US/EU) (Efatutazone / PPAR-gamma agonist) U3-1287 (US/EU) (Anti-HER3 antibody) PLX4032 (US/EU) (Vemurafenib / BRAF inhibitor) PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor) 	AMG 162 (JP) (Denosumab / breast cancer adjuvant / Anti-RANKL antibody)	
Others	 CS-8958 (Laninamivir / anti-influenza / Outlicensing with Biota) DS-8587 (Anti-bacterial) CS-4771 (Anti-sepsis) PLX5622 (Rheumatoid arthritis) CS-0777 (Immunomodulator) ASB17061 (Atopic Dermatitis) DS-7113 (Narcotic analgesic) 	 AMG 162 (JP) (Denosumab / rheumatoid arthritis / anti-RANKL anti-body) DS-5565 (Global) (Chronic pain / α2δ ligand) SUN13837 (US) (Spinal cord injury / Modulator of bFGF signaling system) 	DR-3355 (JP) (Levofloxacin / anti-infection / new quinolone)	 AMG 162 (JP) (Denosumab / osteoporosis / Anti-RANKL antibody) CS-8958 (JP) (Laninamivir / anti-influenza, prophylactic / Neuraminidase inhibitor)

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