

Passion for Innovation.
Compassion for Patients.™



JP Morgan Healthcare Conference 2014

An Update from Daiichi Sankyo

January 13, 2014 San Francisco, CA, USA

George Nakayama, President and CEO

Passion for Innovation.
Compassion for Patients.™

- One of the Top pharmaceutical companies in Japanese market
- 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 997.9 Bn (FY2012) = 9.9 Bn US\$ *
- Business model encompassing;
Innovative and Established pharmaceuticals, OTC, and Vaccines
- >32,000 employees globally represented by 50 nationalities
- Common objective "Passion for Innovation. Compassion for Patients."

*Currency rate : JPY/USD=100.0

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
launch in Japan this year
Effient[®]
- Edoxaban : FXa inhibitor
Anti-coagulant
launched in Japan
in July, 2011 ***Lixiana[®]***
NDA globally

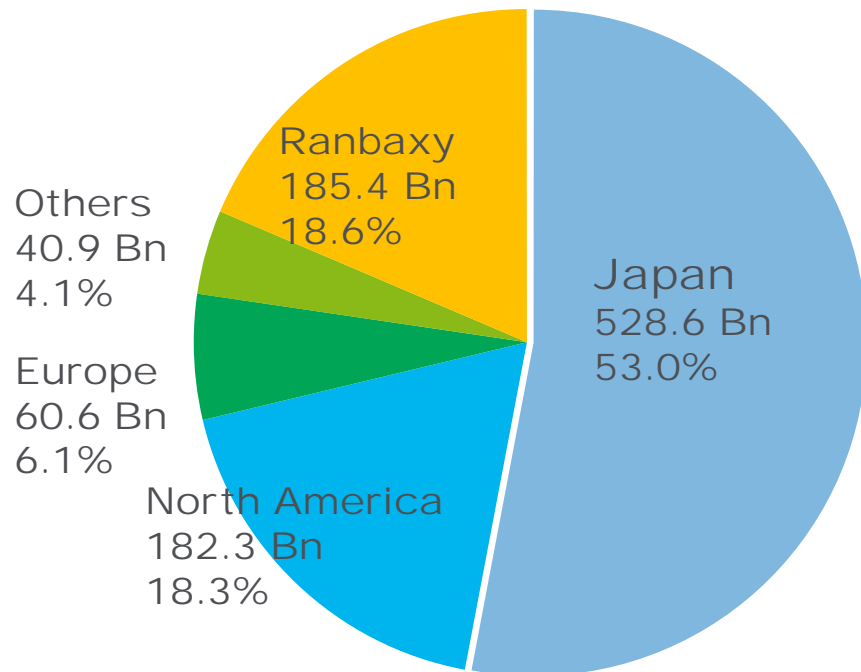


Global Sales Splits (FY2012)

Consolidated net sales – JPY 997.9 Bn / \$ 9.98 Bn

Daiichi Sankyo Group: JPY 812.4 Bn / \$ 8.12 Bn

Ranbaxy Group: JPY 185.4 Bn / \$ 1.85 Bn



Global Products Sales	
Olmesartan	¥ 258.9 Bn
Levofloxacin	¥ 49.7 Bn
Pravastatin	¥ 32.3 Bn
Prasugrel <i>*alliance revenue</i>	¥ 16.2 Bn

*Currency rate : JPY/USD=100.0

FY2013 revised consolidated forecast

JPY Bn

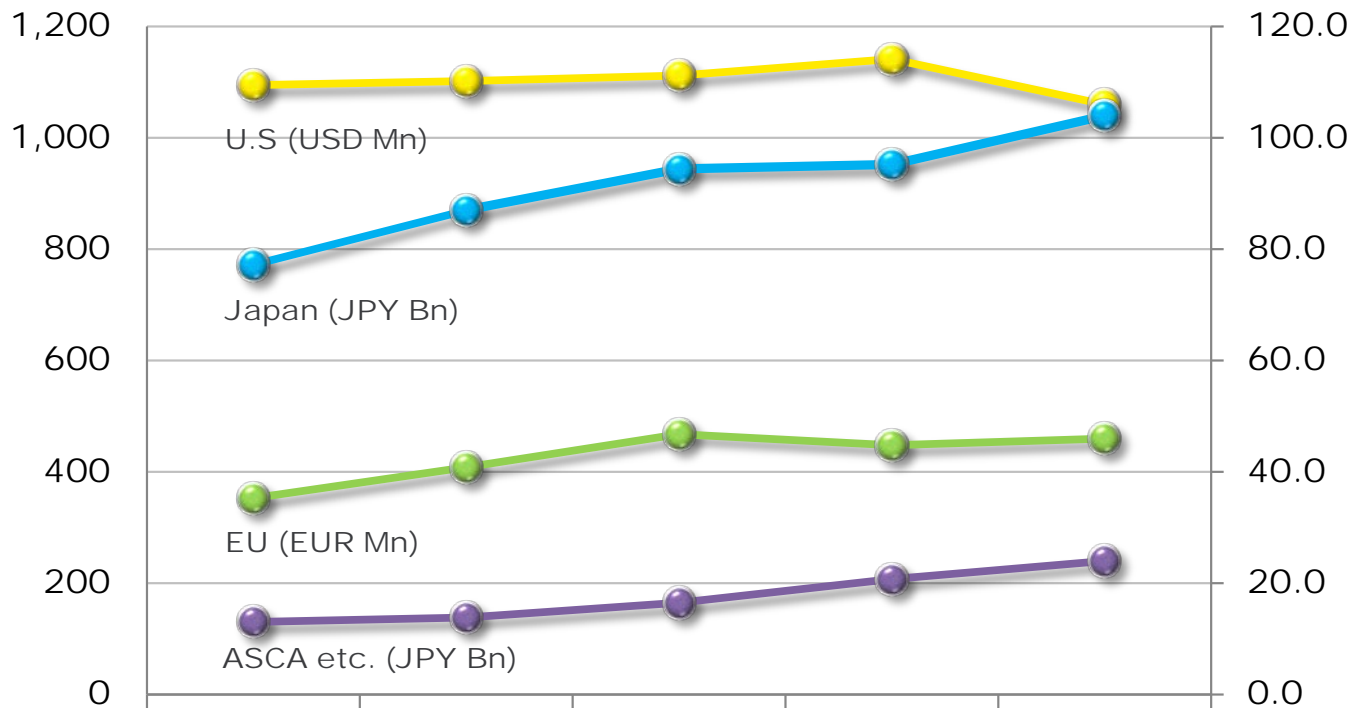
	FY 2013 Forecast (July)	FY 2013 Revised Forecast (October)	change
Net Sales	1080.0	1110.0	+30.0
(From Ranbaxy) (INR/JPY)	(217.0) (1.75)	(224.0) (1.66)	(+7.0)
Cost of Sales	355.0	376.0	+21.0
SG&A Expenses	615.0	629.0	+14.0
R&D Expenses	187.0	191.0	+4.0
Other Expenses	428.0	438.0	+10.0
Operating Income	110.0	105.0	-5.0
Ordinary Income	100.0	90.0	-10.0
Net Income	65.0	65.0	-

Currency Rate	USD/JPY (average)	95.94	96.93
	EUR/JPY (average)	125.99	130.01

Sales of Olmesartan(Local currency basis)

USD Mn, EUR Mn

JPY Bn



Japan (JPY Bn)	77.2	87.0	94.4	95.2	104.0
U.S. (USD Mn)	1,095	1,102	1,112	1,142	1,060
EU (EUR Mn)	353	408	468	448	460
ASCA etc. (JPY Bn)	13.1	13.9	16.5	20.7	24.0

Breakdown for Olmesartan

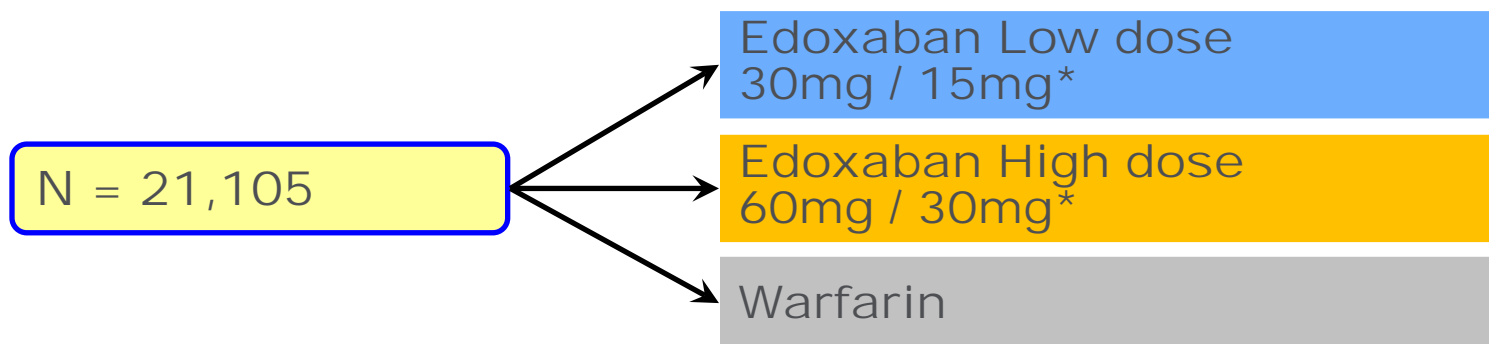
Japan: Olmetec, Rezaltas

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

Europe: Olmetec, Olmetec Plus, Sevikar, Sevikar HCT

- Dose-finding study in Phase 2
 - Ensures the best balance in efficacy and safety
- Phase 3 studies in FXa class
 - The largest Oral Anti Coagulant phase 3 studies
 - ENGAGE AF-TIMI 48 with 21,105 patients
 - Hokusai-VTE with 8,292 patients
 - 2 dose regimens in ENGAGE AF-TIMI 48 (30mg/15mg, 60mg/30mg Once daily) to provide flexible treatment options for patients
- Design for study closing for ENGAGE AF-TIMI 48
- In Japan, Edoxaban was launched in July 2011 as the brand name of LIXIANA with accumulated safety data from almost 135,000 DVT-OS patients post launch

- Randomized, Double-Blind, Multi National Study
- Evaluation of efficacy and safety of edoxaban in AF patients in comparison with those of warfarin
- Once daily
- 46 countries

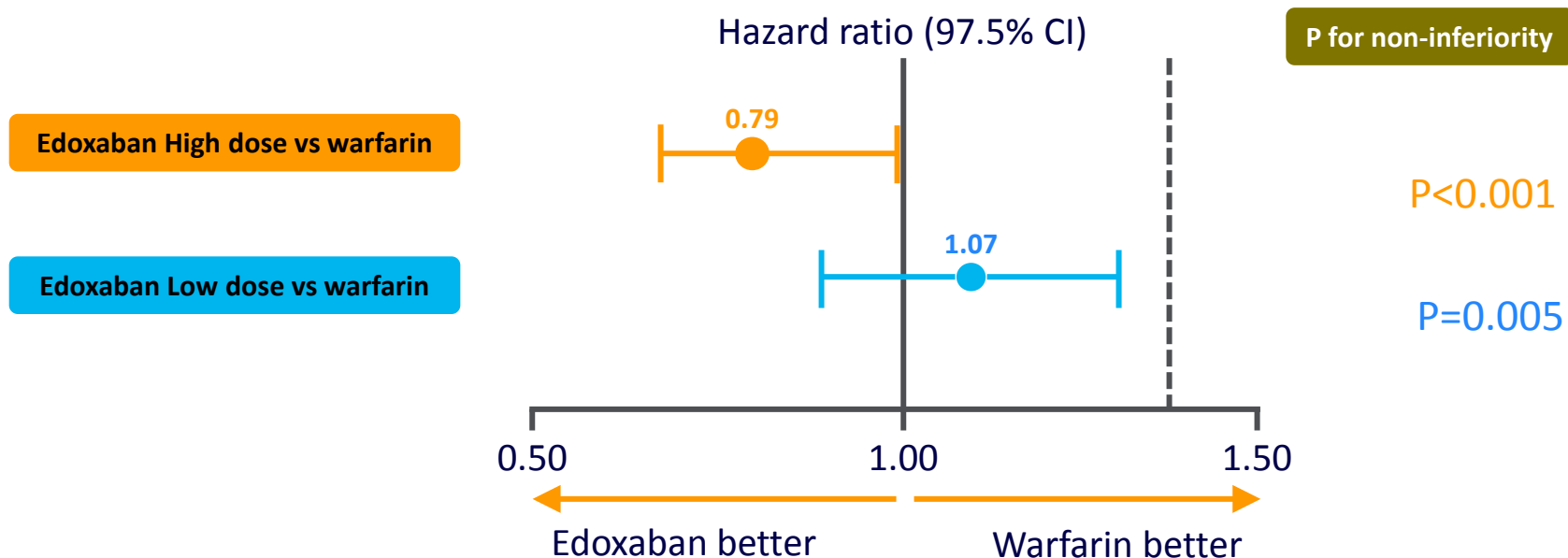


Primary efficacy endpoint:	Stroke, systemic embolism
Secondary efficacy endpoint:	Stroke, systemic embolism, CV mortality
Principle Safety endpoint:	Major bleeding

*dose reduction for low CrCl, low body weight, P-gp inhibitors

Edoxaban versus warfarin

Treatment	N	n	Incidence (%/yr)	HR (97.5% CI)	P for non-inferiority
Warfarin (median TTR 68.4%)	7,012	232	1.50	-	-
Edoxaban High dose (60mg / 30mg)	7,012	182	1.18	0.79 (0.63–0.99)	<0.001
Edoxaban Low dose (30mg / 15mg)	7,002	253	1.61	1.07 (0.87–1.31)	0.005



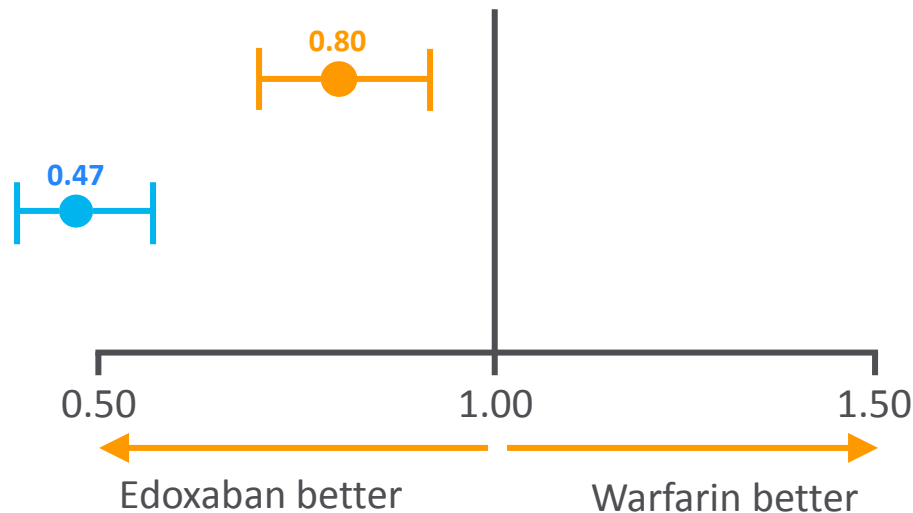
Edoxaban versus warfarin

Treatment	N	n	Incidence (%/yr)	HR (95% CI)	P value
Warfarin	7,012	524	3.43	-	-
Edoxaban High dose (60mg / 30mg)	7,012	418	2.75	0.80 (0.71–0.91)	<0.001
Edoxaban Low dose (30mg / 15mg)	7,002	254	1.61	0.47 (0.41–0.55)	<0.001

Hazard ratio (95% CI)

Edoxaban High dose vs warfarin

Edoxaban Low dose vs warfarin



P for superiority

P<0.001









P<0.001

- ◆ Compared to well-managed warfarin (TTR 68.4%)
Once daily Edoxaban:
 - Non-inferior for stroke/SEE* (High dose / Low dose regimens)
 - High dose lower stroke/SEE on Rx (trend ITT)
 - Both regimens significantly reduced:
 - Major bleeding
(HD vs warfarin : 20% / LD vs warfarin : 53%)
 - ICH (53% / 70%)
 - Hem. stroke (46% / 67%)
 - CV death (14% / 15%)
 - Superior net clinical outcomes
No excess in stroke or bleeding during transition
→ oral anticoagulant at end of trial

*SEE= Systemic Embolic Event

Edoxaban





Global NDA / Launch Schedule

Target Indications	FY2013		FY2014				FY2015 ~
	2013 4Q	2014 1Q	2014 2Q	2014 3Q	2014 4Q	2015 1Q	
Prevention of stroke and systemic embolic events in patients with atrial fibrillation 							
Acute treatment and long-term prevention of thromboembolic event in patient with DVT*/PE** 							

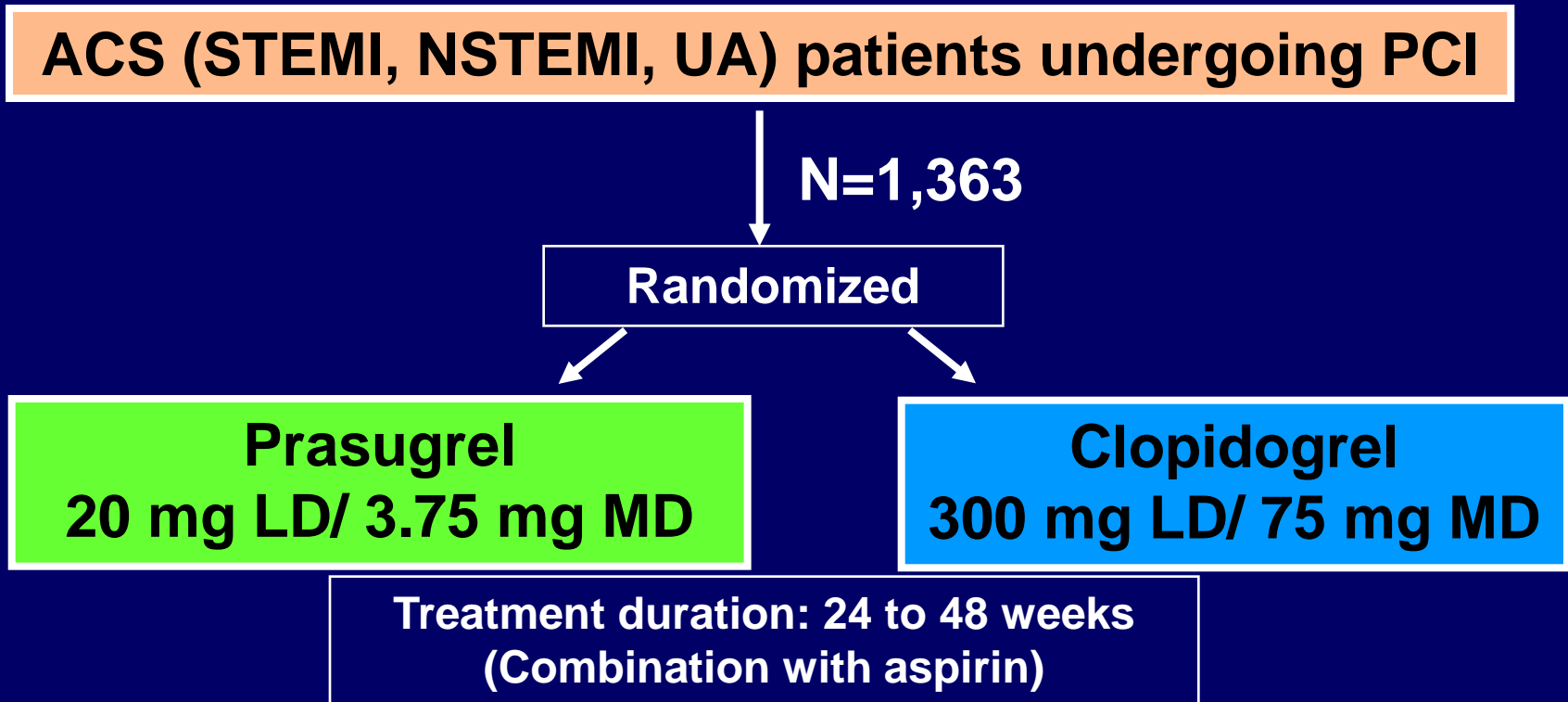
*DVT : Deep Vein Thrombosis

**PE : Pulmonary Embolism

Anti-platelet agent Prasugrel: Japan launch schedule

Target Indications	FY2013		FY2014				FY2015	FY2016
	2013 4Q	2014 1Q	2014 2Q	2014 3Q	2014 4Q	2015 1Q		
Coronary Artery Disease undergoing PCI* <i>PRASFIT-ACS</i> <i>PRASFIT-Elective</i>								
Ischemic Stroke <i>PRASTRO-I</i>								

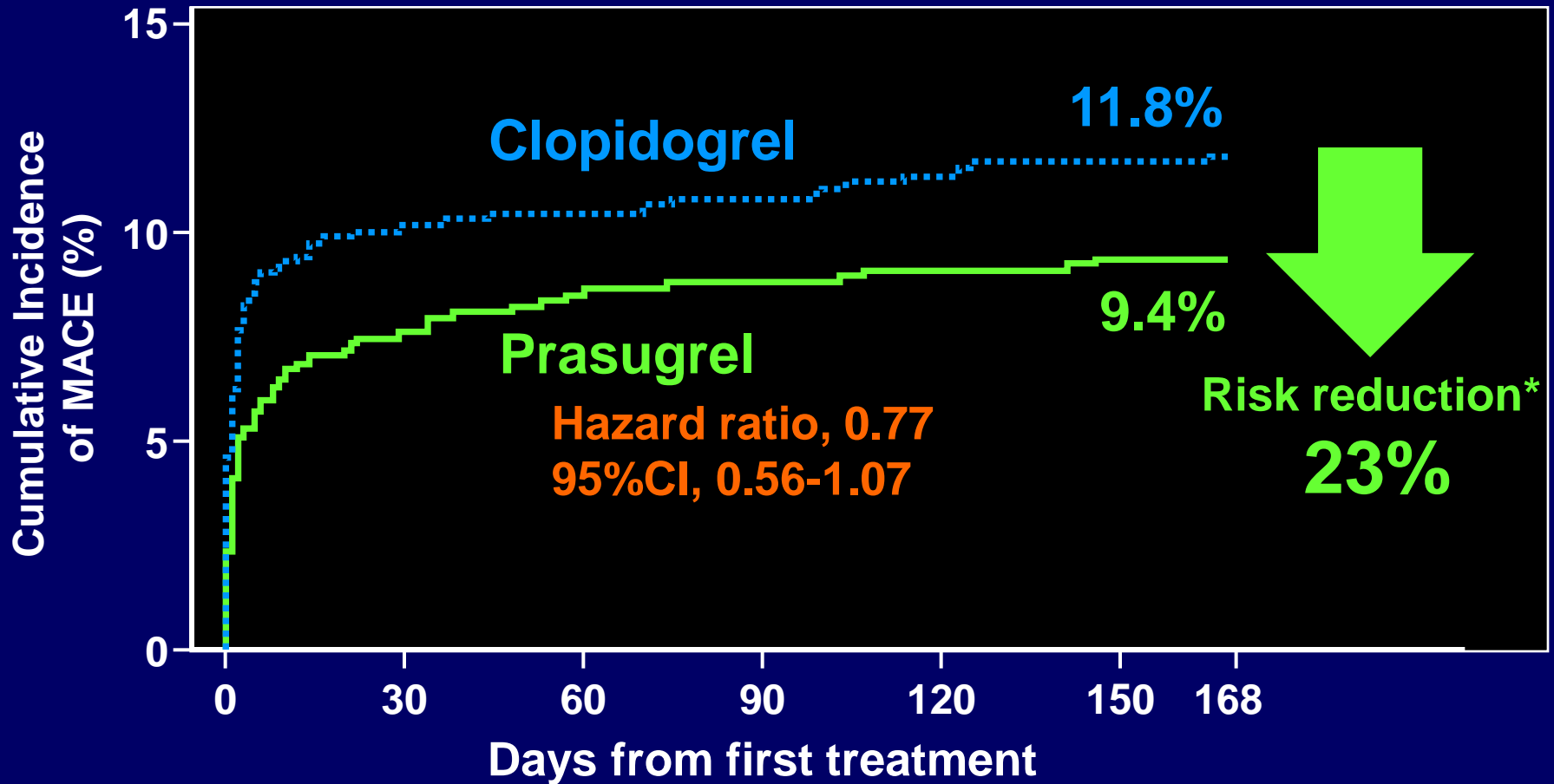
*PCI : Percutaneous Coronary Intervention



Primary Efficacy Endpoint: Major Adverse Cardiovascular Events (MACE)
Cardiovascular(CV) death, Nonfatal MI and Nonfatal ischemic stroke during 24 week follow-up period

Safety Endpoints:
Non-CABG TIMI major, TIMI minor or clinically relevant bleeding

Primary Efficacy Endpoint (MACE at 24 weeks)



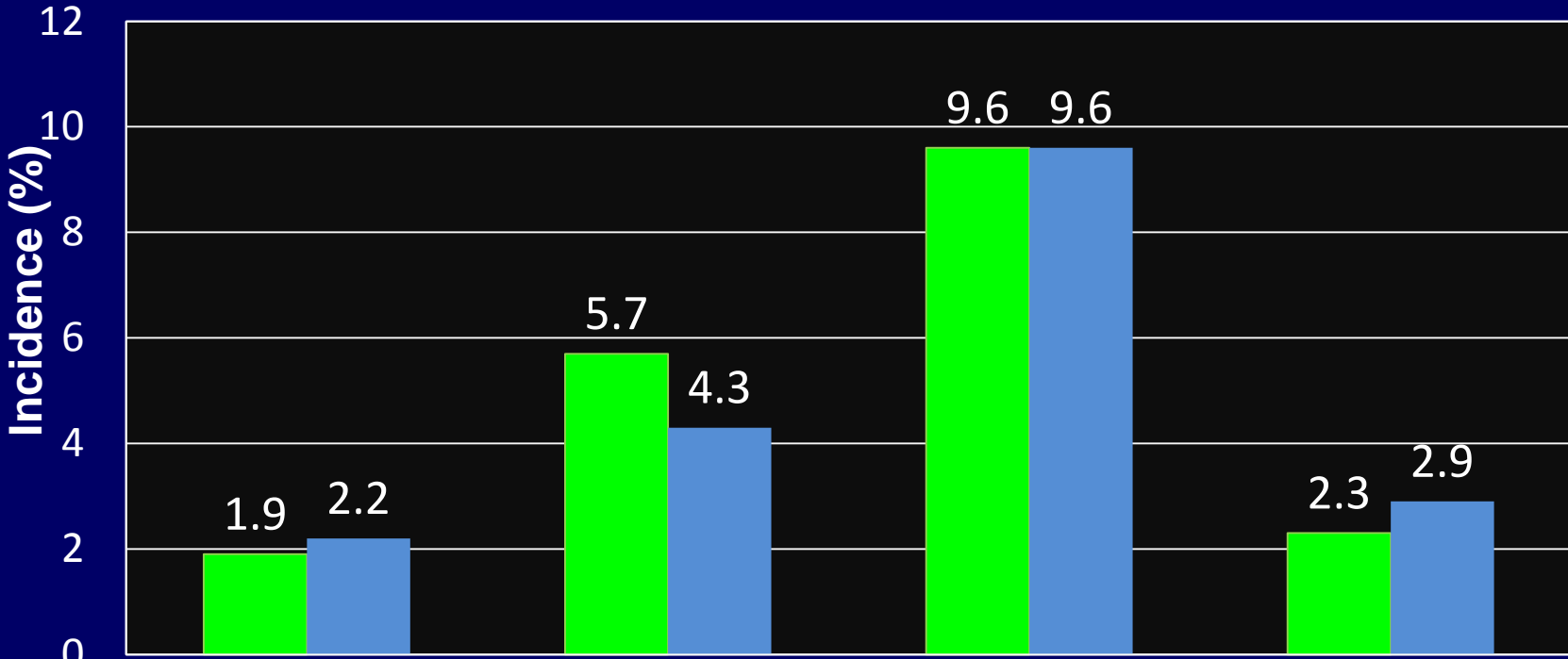
Based on Full Analysis Set

*Risk reduction: 1-HR (Hazard ratio)

Non-CABG Clinically Important Bleeding Events



■ Prasugrel (n=685) ■ Clopidogrel(n=678)



	TIMI Major	TIMI Major or Minor	TIMI Major or Minor or Clinically relevant	Bleeding events leading to discontinuation
Hazard Ratio	0.82	1.30	0.98	0.76
P-value	0.38	0.36	0.92	0.26

Based on Safety Analysis Set
Incidence: (n / n) x 100%

Major R&D Pipeline

As of Dec. 2013



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	<ul style="list-style-type: none"> ■ DS-7309 (Anti-diabetes / Glucokinase activator) ■ DS-8500 (Anti-diabetes / GPR119 agonist) ■ DS-1442 (Dyslipidemia / CETP inhibitor) ■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor) 	<ul style="list-style-type: none"> ■ CS-3150 (JP) (Anti-hypertensive/DM nephropathy / MR antagonist) 	<ul style="list-style-type: none"> ■ DU-176b (US/EU) (edoxaban / AF / oral factor Xa inhibitor) ■ DU-176b (US/EU) (edoxaban / VTE / oral factor Xa inhibitor) ■ CS-747 (JP) (prasugrel / ischemic stroke / anti-platelet agent) ■ CS-747 (US) (prasugrel / Sickle Cell Disease / anti-platelet agent) 	<ul style="list-style-type: none"> ■ CS-747 (JP) (prasugrel / PCI / anti-platelet agent) ■ DU-176b (JP) (edoxaban / AF / oral factor Xa inhibitor) ■ DU-176b (JP) (edoxaban / VTE / oral factor Xa inhibitor)
Oncology	<ul style="list-style-type: none"> ■ U3-1565 (US/JP) (Anti-HB-EGF antibody) ■ DS-2248 (US) (HSP90 inhibitor) ■ DS-7423 (US/JP) (PI3K/mTOR inhibitor) ■ DS-3078 (US/EU) (mTOR inhibitor) ■ DS-3032 (US) (MDM2 inhibitor) ■ PLX7486(US) (Fms/Trk inhibitor) 	<ul style="list-style-type: none"> ■ U3-1287 (US/EU) (patritumab / anti-HER3 antibody) ■ PLX4032 (US/EU) (vemurafenib / BRAF inhibitor) ■ PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor) 	<ul style="list-style-type: none"> ■ ARQ 197 (US/EU) (tivantinib / HCC / Met inhibitor) ■ AMG 162 (JP) (denosumab / breast cancer adjuvant / anti-RANKL antibody) ■ DE-766 (JP) (nimotuzumab / NSCLC / anti-EGFR antibody) ■ DE-766 (JP) (nimotuzumab / Gastric cancer / anti-EGFR antibody) 	<ul style="list-style-type: none"> ■ AMG 162 (JP) (denosumab / GCT of Bone / anti-RANKL antibody)
Others	<ul style="list-style-type: none"> ■ DS-8587 (Anti-bacterial / Topoisomerase inhibitor) ■ CS-4771 (Anti-sepsis / TLR4 inhibitor) ■ PLX5622 (Rheumatoid arthritis / FMS kinase inhibitor) ■ CS-0777 (Immunomodulator / S1P receptor modulator) ■ DS-1093 (Anemia of chronic kidney disease/HIF-PH inhibitor) 	<ul style="list-style-type: none"> ■ AMG 162 (JP) (denosumab / rheumatoid arthritis / anti-RANKL anti-body) ■ DS-5565 (Global) (Chronic pain / $\alpha 2\delta$ ligand) ■ SUN13837 (US/EU) (Spinal cord injury / Modulator of bFGF signaling system) ■ ASB17061 (US) (Atopic Dermatitis / chymase inhibitor) ■ CS-8958 (US/EU) (laninamivir / anti-influenza / Outlicensing with Biota) ■ DS-7113 (hydromorphone / Narcotic analgesic / opioid mu-receptor regulator) 	<ul style="list-style-type: none"> ■ DR-3355 (JP) (levofloxacin / anti-infection / New quinolone) 	

Contact address regarding this material

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