Current R&D Status of Daiichi Sankyo

Deutsche Securities Inc.
Japan Pharmaceutical Conference 2008

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Daiichi Sankyo R&D Pipeline

	Phase 1	Phase 2	Phase 3	Application
Cardiovascular diseases	CS-8080 DB-772d	DU-176b Olmetec/diuretic Combo (#)	CS-8635 Olmetec additional indication (#) <Diabetic nephropathy> Olmetec/Calblock Combo (#)	Prasugrel Sevikar (EU)
Glucose metabolic disorders		AJD101	Rivoglitazone	
Infectious diseases		CS-8958	Levofloxacin inj (#)	Levofloxacin high-dose (#)
Malignant neoplasm	CS-7017 Nimotuzumab (#) U3-1287	CS-1008		
Immunological allergic diseases	CS-0777 SUN13834			
Bone / joint diseases			Denosumab (#) Loxonin gel (#)	
Others		Human ghrelin	Memantine hydrochloride (#) Silodosin	Feron/Ribavirin combination therapy (#)
Total	7	6	9	4

: Developed only in JPN

- Only the most advanced stages are described for the projects under global development
- Projects with highest priority are underlined (blue)

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Status of Principal Development Projects

- *Effient*™ (Prasugrel, CS-747 : Anti-platelet)
  - 2008 1st indication (ACS-PCI) - US: FDA action date (September 26, 2008)
    - EU: Application made to EMEA (Feb-2008)
  - Jun-2008 New Phase 3 study TRILOGY ACS for 2nd indication (ACS-MM)
- DU-176b (Oral blood coagulation factor Xa inhibitor)
  - Sep-2008 Phase 2b results in VTE (venous thromboembolism) presented at ESC and APSTH
  - 2H - 2008 Phase 3 study in NVAF (nonvalvular atrial fibrillation) planned
- Denosumab (AMG 162 : Anti-RANKL antibody)
  - Jun-2008 Phase 3 study in osteoporosis in Japan
  - Phase 3 multinational studies including Japan in advanced breast cancer ongoing
- CS-8635 (Olmesartan + Amlodipine + Hydrochlorothiazide : Anti-hypertensive)
  - May-2008 Phase 3 study in US
  - 2009 NDA submission planned

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Effient™ (Prasugrel, CS-747)

- Platelet aggregation inhibitor
  - Higher IPA (inhibition of platelet aggregation)
  - Faster onset of IPA
  - More consistent IPA
- Nov-07 AHA (American Heart Association), proved superiority statistically over current benchmark treatments
- Dec-07 FDA filing for 1st indication (ACS-PCI)

ACS: acute coronary syndrome
PCI : percutaneous coronary intervention

- Feb-08 NDA filing in Europe (ACS-PCI)
- Jun-08 New Phase 3 Study TRILOGY ACS for 2nd indication (ACS-Medical Management)
- Sep 26, 2008 FDA action date for 1st indication (ACS-PCI)

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FDA Continues to Review Prasugrel NDA

Announced on September 26, 2008 (US time)

"This is a very large, complex submission, and it should not be surprising that delays occur.
The review is very far along, and we remain optimistic."

"We remain confident in the submission package for prasugrel and look forward to bringing this medication to the market for ACS patients who are being managed with PCI."

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Clinical Benefits of Prasugrel

Compared with Clopidogrel, Prasugrel significantly reduced the relative risk in patients with ACS who are managed with PCI by…

- 19% in the primary composite endpoint of non-fatal heart attack, non-fatal stroke or cardiovascular death
- 13% in the combined endpoint of all-cause death, heart attack, stroke and major bleeding
- 52% in stent thrombosis
- 30% in a subset of patients with diabetes
- 35% in recurrent cardiovascular events

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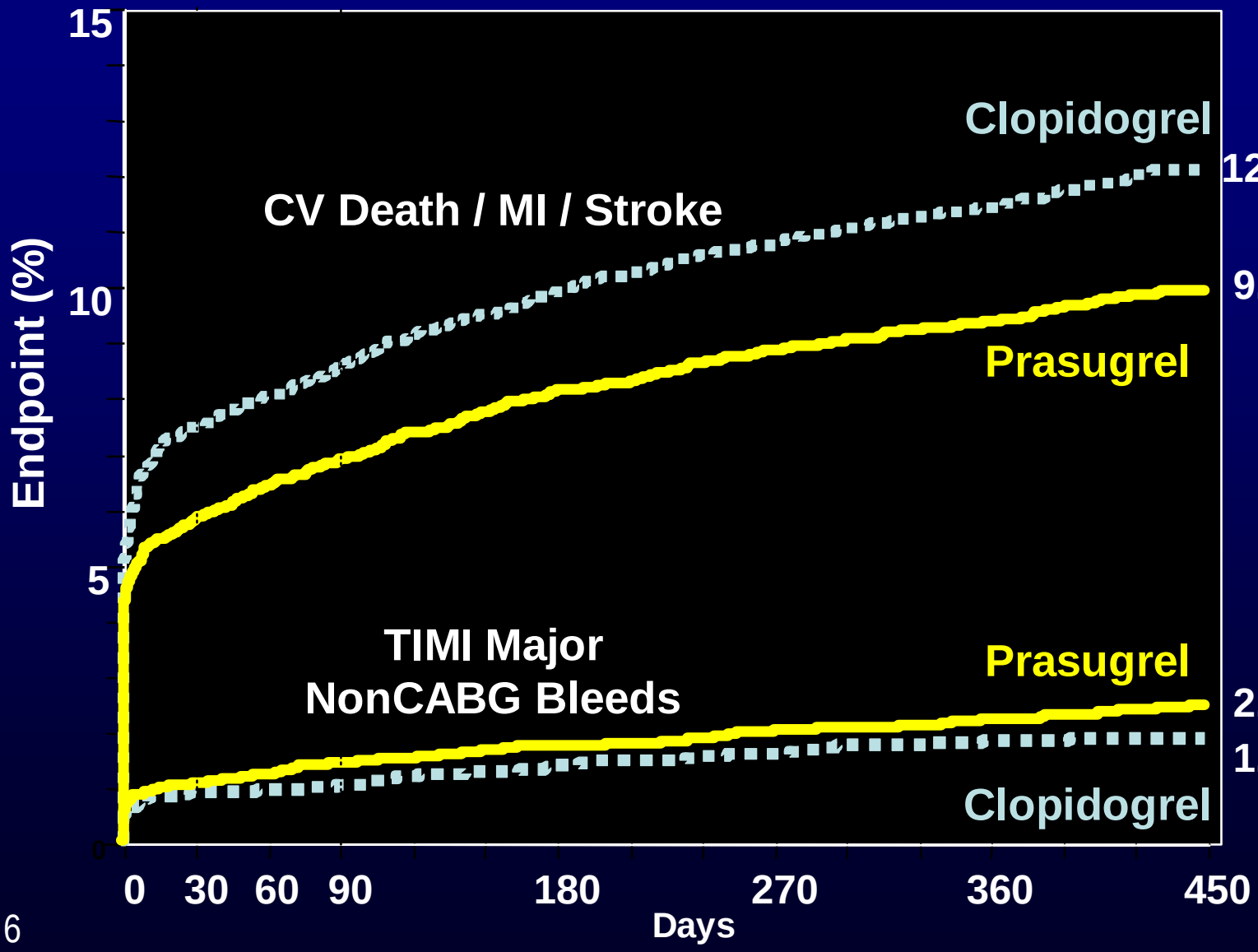
TRITON TIMI-38

Balance of Efficacy and Safety



↓ 138 events

HR 0.81
(0.73-0.90)
P=0.0004

NNT = 46

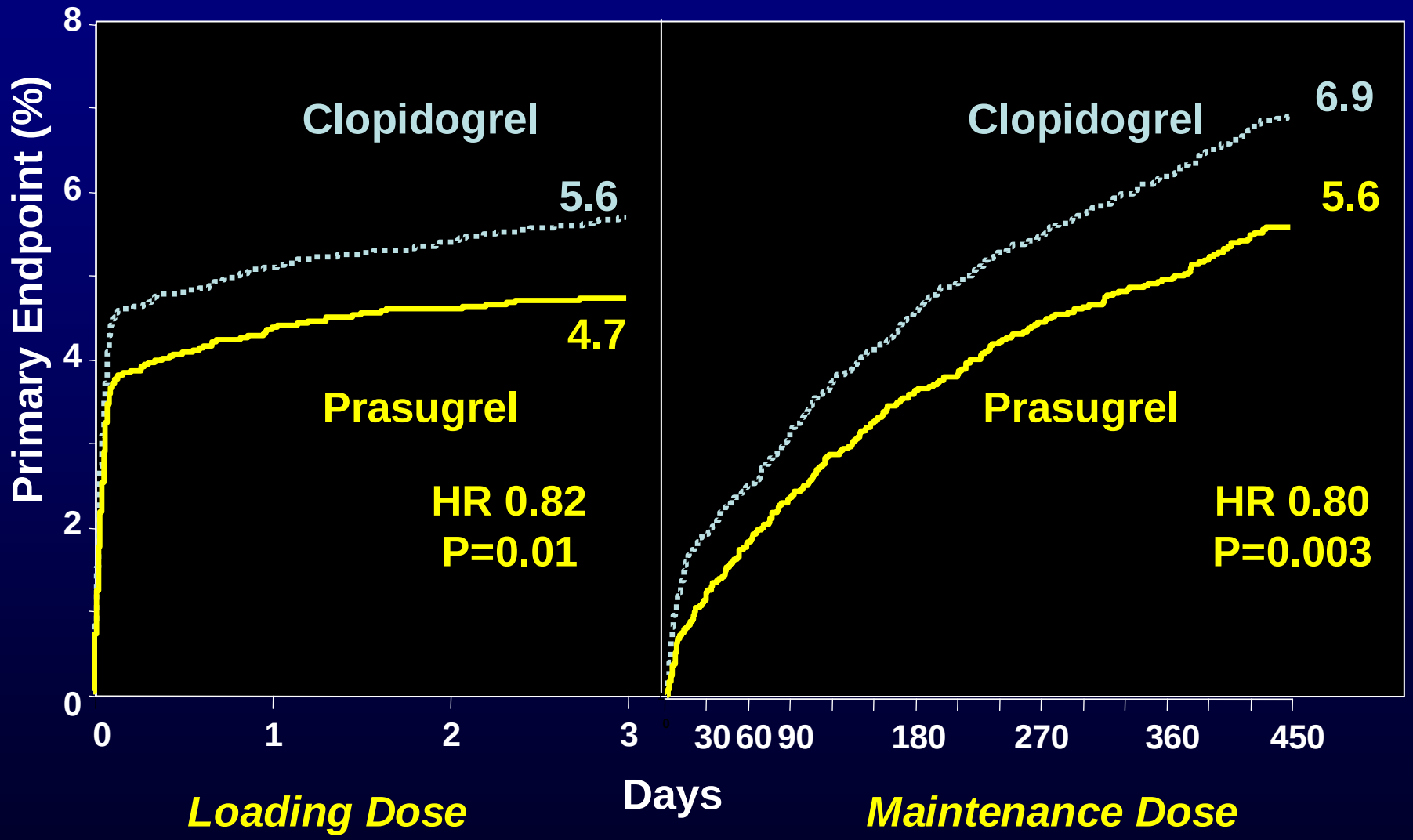
↑ 35 events

HR 1.32
(1.03-1.68)
P=0.03

NNH = 167

TRITON TIMI-38

Timing of Benefit (Landmark Analysis)



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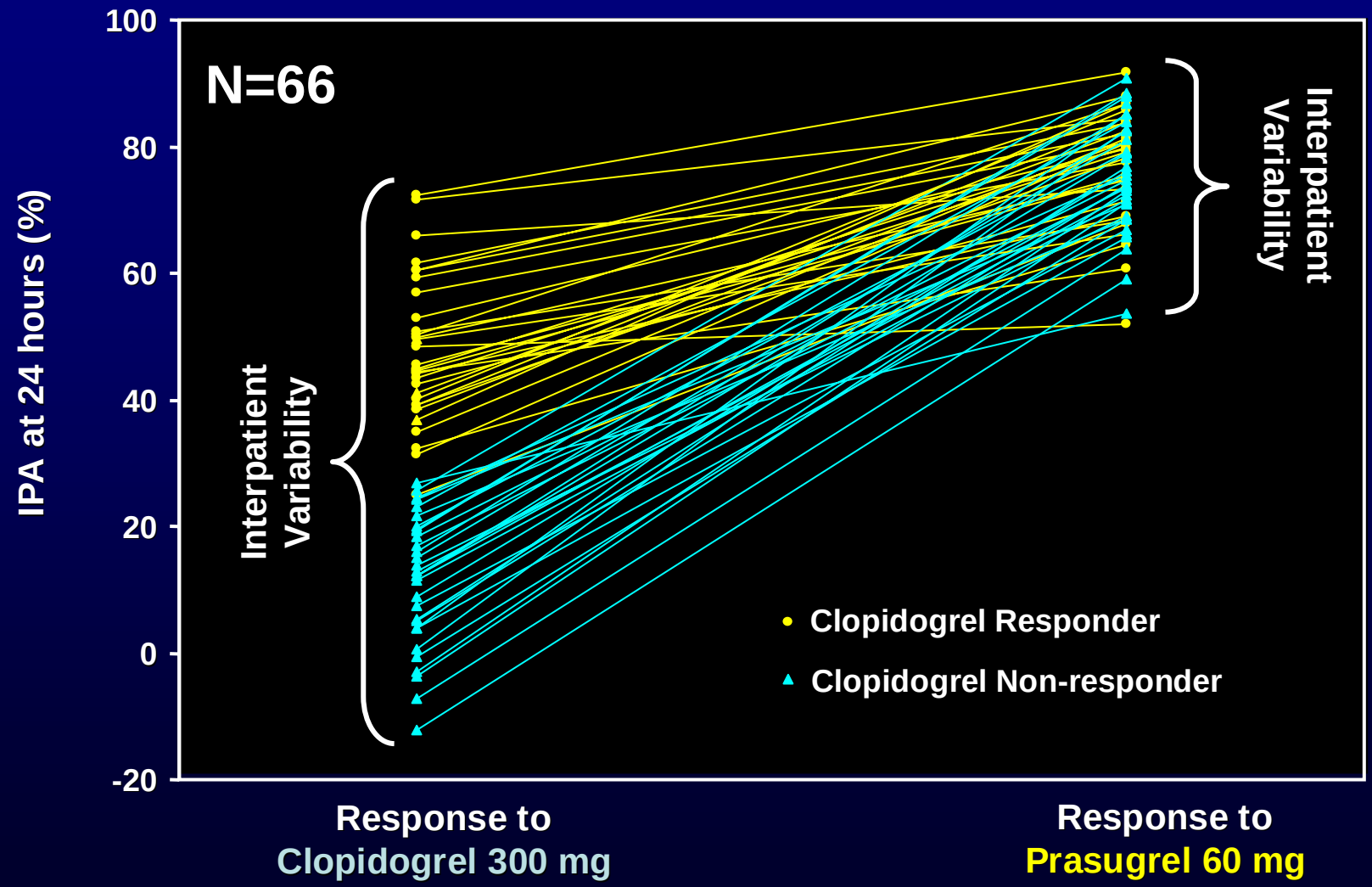
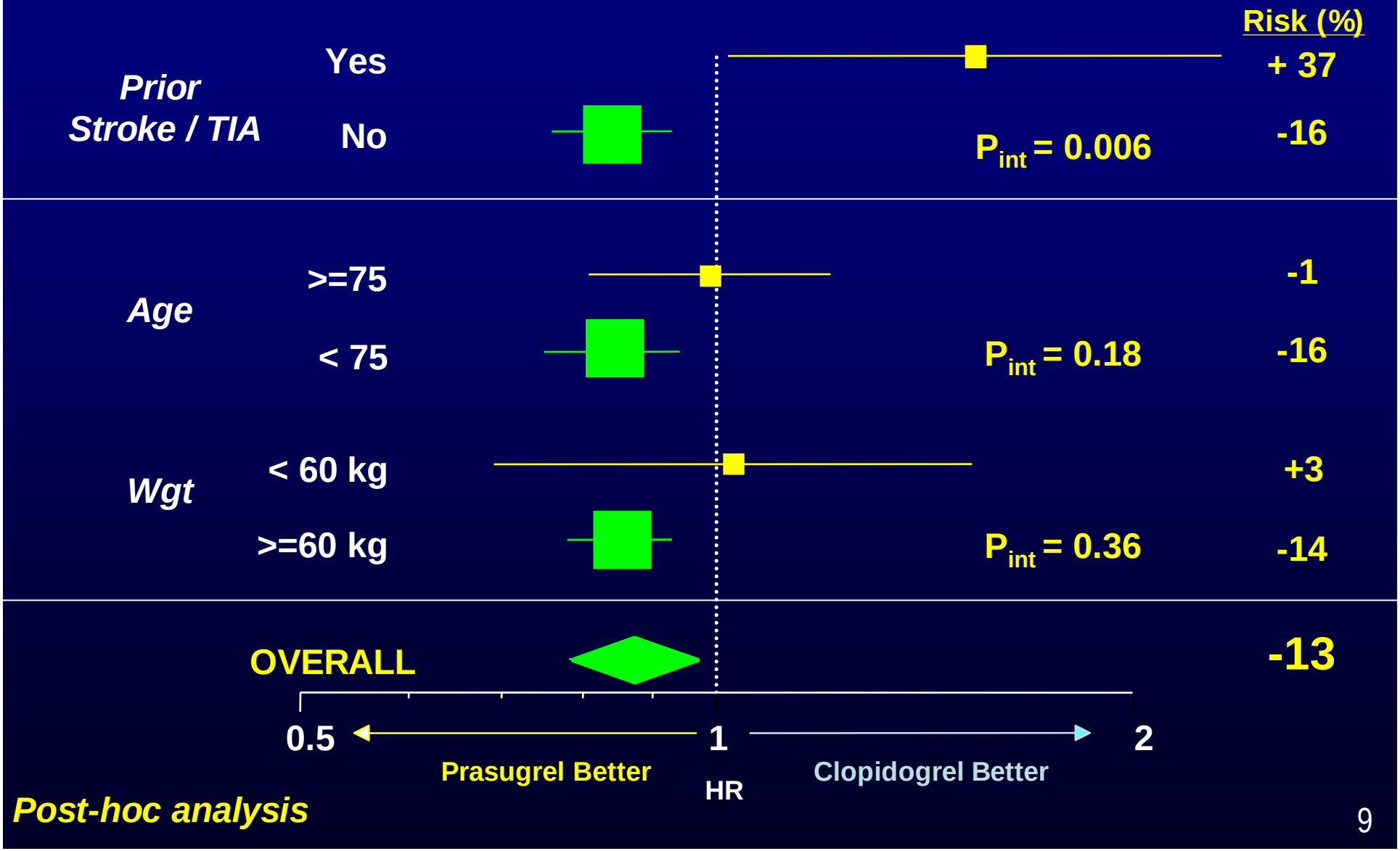
Healthy Volunteer Crossover Study



From Brandt JT AHJ 153: 66e9,2007

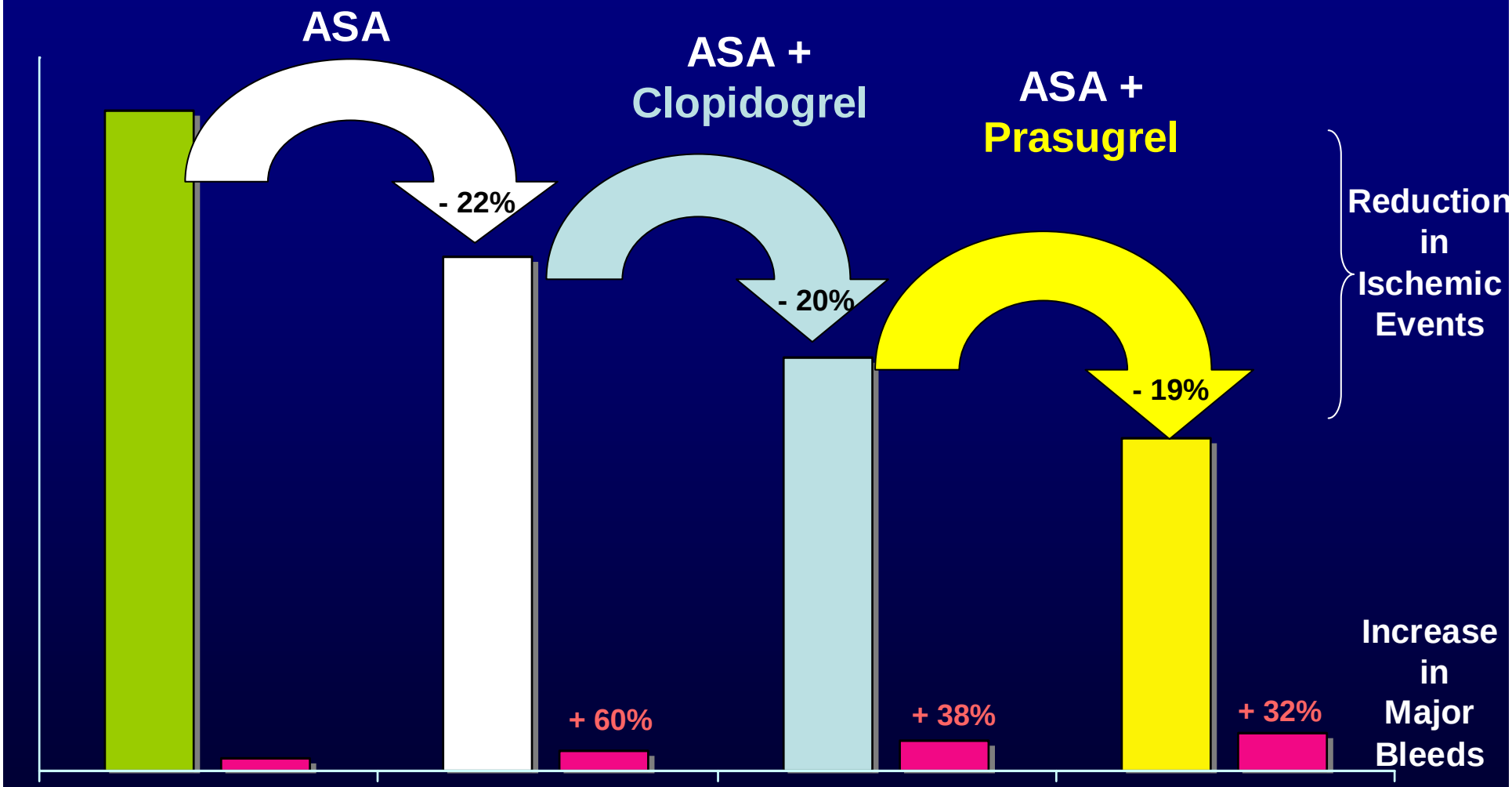
TRITON TIMI-38

Net Clinical Benefit
Bleeding Risk Subgroups



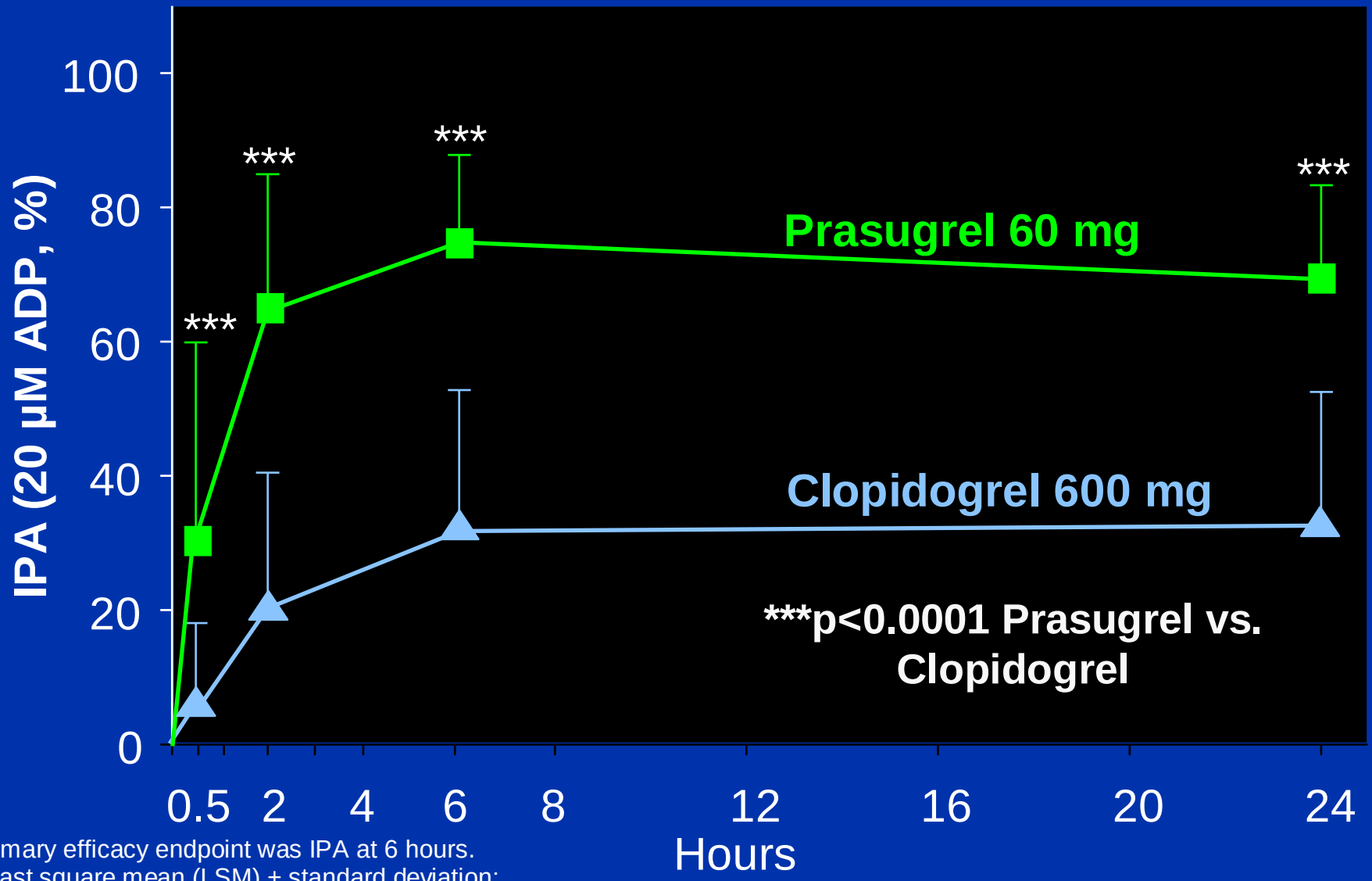
Post-hoc analysis

Antiplatelet Therapy in ACS



Primary Endpoint: Loading Dose Phase IPA

Highly significant differences emerged throughout the LD phase

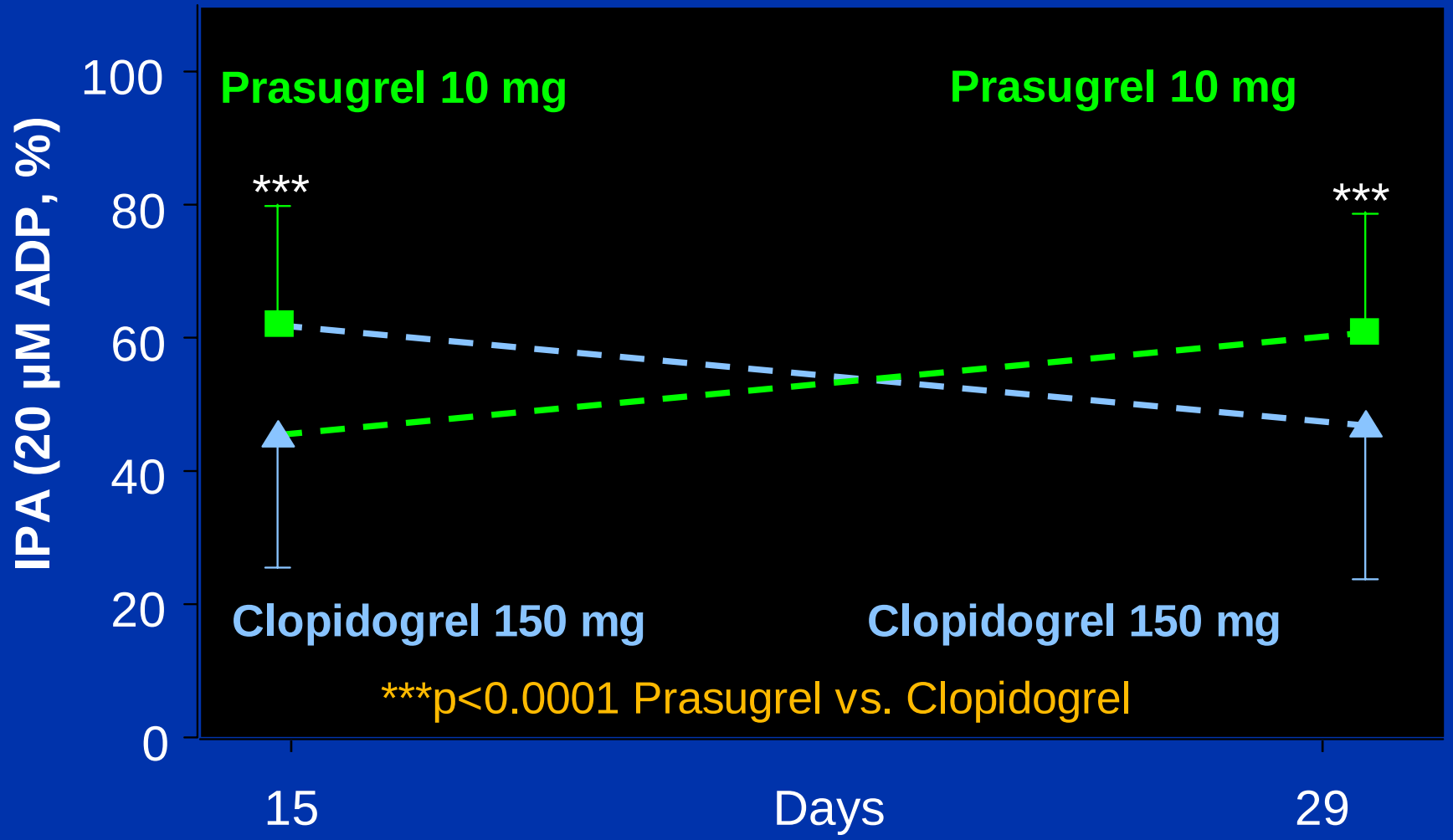


Primary efficacy endpoint was IPA at 6 hours.
Least square mean (LSM) + standard deviation;
IPA=inhibition of platelet aggregation

Wiviott SD et al. *Circulation* 2007;116:2923-2932

Maintenance Dose Phase IPA

Substantially and statistically significantly greater platelet inhibition with prasugrel



Least square mean (LSM) + standard deviation; IPA=inhibition of platelet aggregation

- Well-tolerated and no TIMI major bleeds observed in either treatment arm during the study period.

Wiviott SD et al. *Circulation* 2007;116:2923-2932

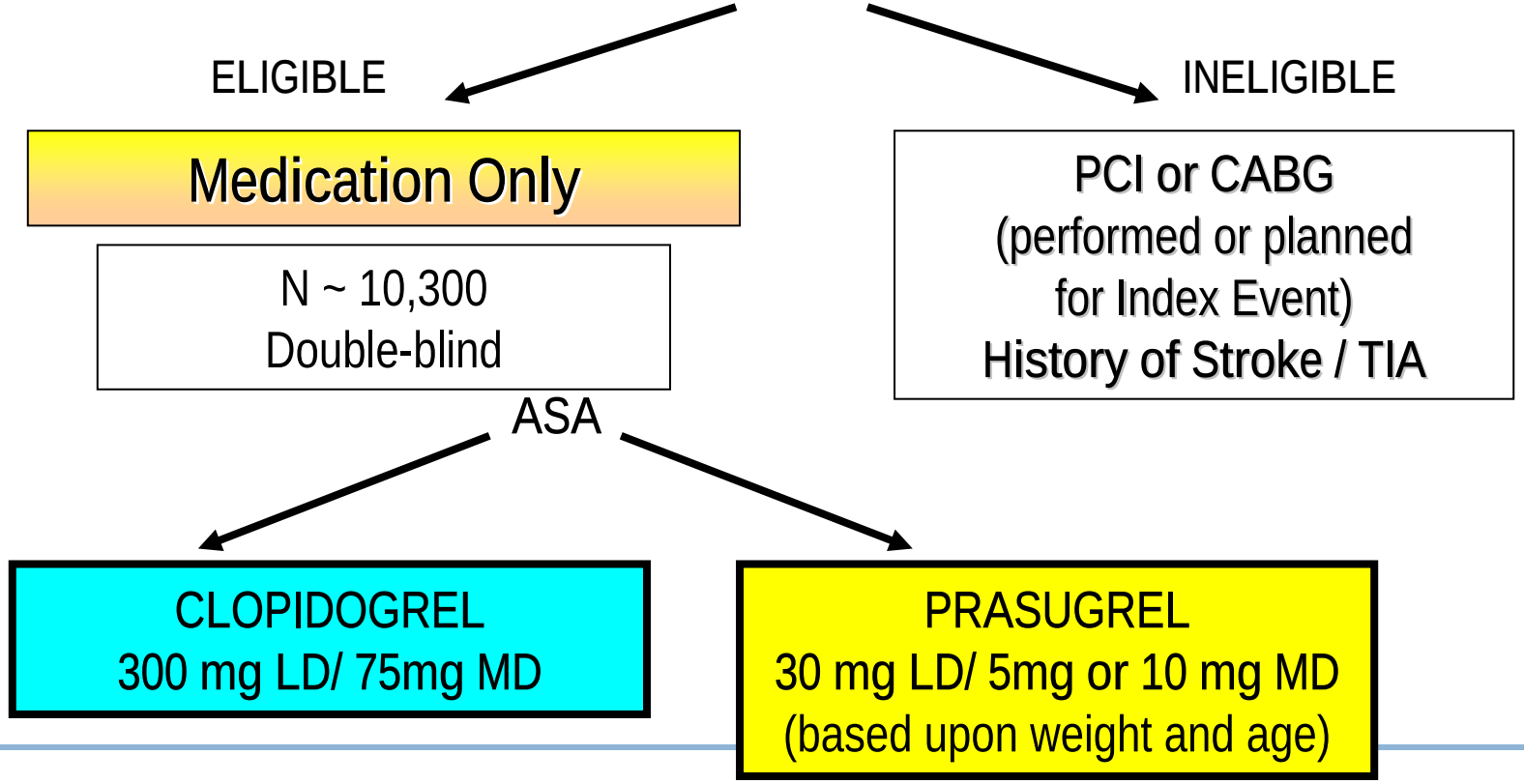
TaRgeted platelet Inhibition to cLarify the Optimal strateGy to medicallY managed Acute Coronary Syndromes

- Double-blind, parallel-arm, active control study
- To evaluate safety and efficacy of prasugrel against clopidogrel in reducing the risk of cardiovascular death, heart attack or stroke in UA/NSTEMI patients who are to be medically managed without planned revascularization
- About 10,300 patients, more than 800 hospitals, 35 countries
- Duke Clinical Research Institute (Dr. Magnus Ohman)

Study Population

Med-High Risk UA/NSTEMI ACS

Management decision ≤ 7 days after presentation



DU-176b - Best in Class Inhibitor of Blood Coagulation Factor Xa -

- Efficacy not inferior to warfarin
  - High oral absorbability, rapid onset of action
  - Scarcely metabolized, possible once daily-dosing
- Wide divergence of dosage in terms of antithrombotic effect and bleeding risk, indicating a wide therapeutic range and lower incidence of bleeding
  - Bleeding risk not inferior to warfarin
  - No hepatotoxicity signals in pre-clinical studies including toxicogenomics and clinical studies
  - No food effects, no monitoring necessary
- Target indications: Prevention and treatment of VTE / NVAF

VTE: venous thromboembolism
NVAF: nonvalvular atrial fibrillation

- Significant market opportunity but with competitors

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Multiple Chronic Indication Strategy

NVAF (nonvalvular atrial fibrillation)	
Phase 2b	Completed, results to be presented at scientific conference in 2008
Phase 3	Planned in 2nd half of 2008
VTE (venous thromboembolism)	
Phase 2b in THR (US/EU) THR: total hip replacement	Completed, results presented at ESC on September 2nd ESC: European Society of Cardiology
Phase 2b in TKR (Japan) TKR: total knee replacement	Completed, results presented at APSTH on September 19th APSTH: Asian Pacific Society on Thrombosis and Hemostasis
Phase 3	Planned

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Ph2b in THR (US/EU) & TKR (Japan)

- Study design and primary objective

Randomized, double-blind studies to assess the efficacy of DU-176b in the prevention of VTE		
vs.	dalteparin (THR)	placebo (TKR)
Treatment period	7 to 10 days	11 to 14 days
Number of patients	750	410
Dose	15 mg – 90 mg qd	5 mg – 60 mg qd

- Summary of results
  - Dose-dependent inhibition of VTE incidence
  - Low incidence of major bleeding, including at doses with very effective VTE inhibition
  - Favorable PK/PD profile
  - Possible QD (once daily) regimen

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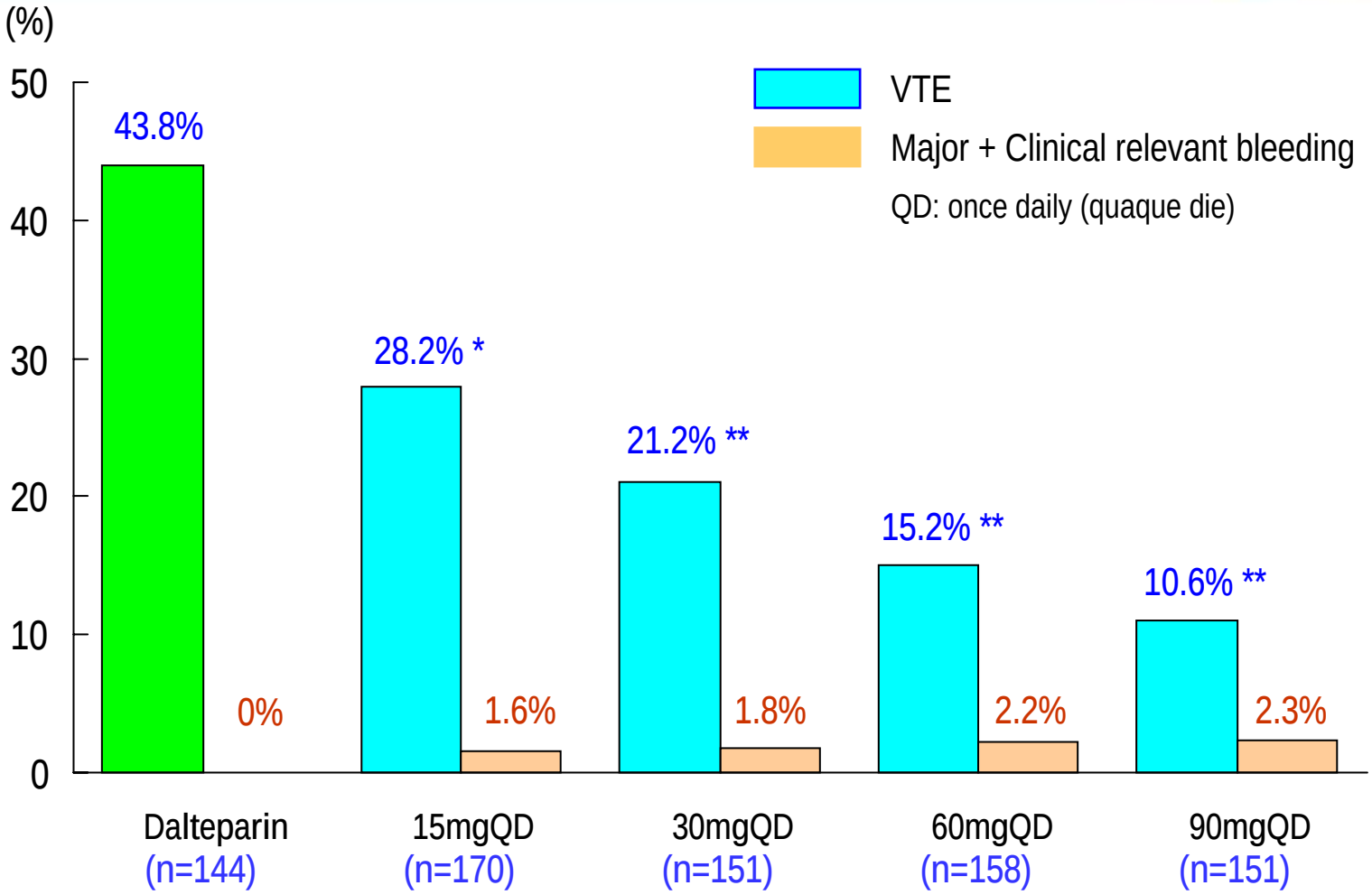
Efficacy and Safety in US/EU THR



* p=0.005 (vs Dalteparin) ** p<0.001(vs Dalteparin)

Dose-dependency in VTE incidence; P＜0.001 (Cochran-Armitage)

No increase in major or clinically relevant bleeding

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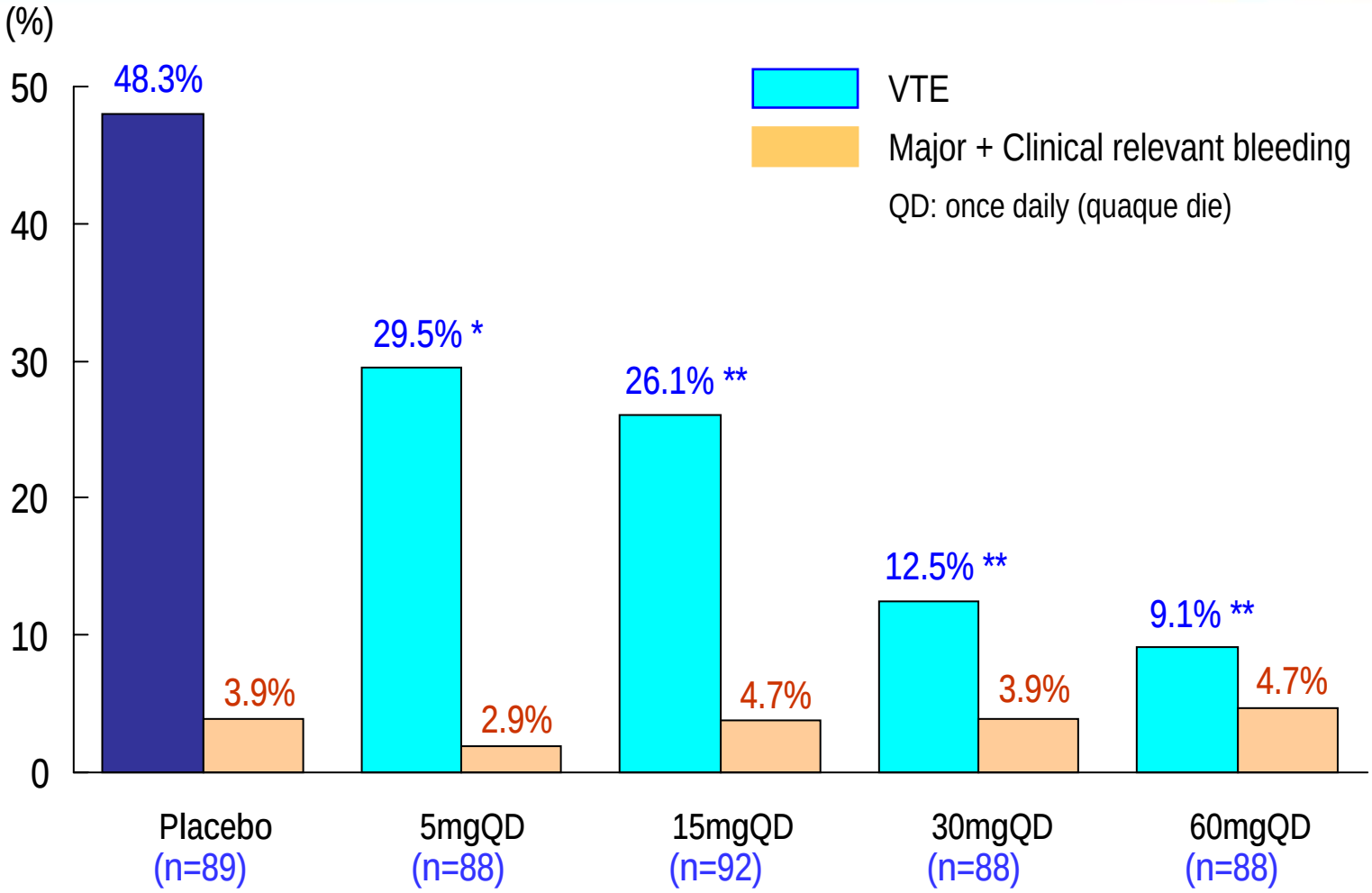
Efficacy and Safety in JPN TKR



* p=0.005 (vs Placebo) ** p<0.001(vs Placebo)

Dose-dependency in VTE incidence; P＜0.001 (Cochran-Armitage)

No increase in major or clinically relevant bleeding

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Status of CS-8635

- Development concept
  - Triple combination will maximize the sales of Olmesartan franchise and key opportunity for growth
  - Next step for patients who are on either an ARB / HCTZ or CCB / ARB and need additional blood pressure reduction
- Target Indication: Treatment of hypertension
- Region: US
- Development Stage: Phase 3
- NDA Submission: 2009

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Oncology Franchise

Denosumab, AMG 162 (Phase 3)

- Human monoclonal antibody that targets RANK Ligand (an essential mediator of cells that break down bone)
- Licensed from Amgen into Japan
- Phase 3 : bone metastasis of cancer, Phase 3 : osteoporosis

CS-1008 (Phase 2)

- A humanized version TRA-8, a murine agonistic monoclonal antibody raised against human death receptor 5 (DR5)
- CS-1008 induces apoptosis of tumor cells expressing DR5 on the cell surface
- Anti-cancer effect and good safety profile in pre-clinical studies

CS-7017 (Phase 1)

- Antitumor PPAR-gamma activator
- Inhibits growth of tumor cells *in vitro* without killing those cells

Nimotuzumab, DE-766 (Phase 1)

- Humanized monoclonal antibody to epidermal growth factor receptor (EGFR)
- Best-in-Class among EGFR antibodies

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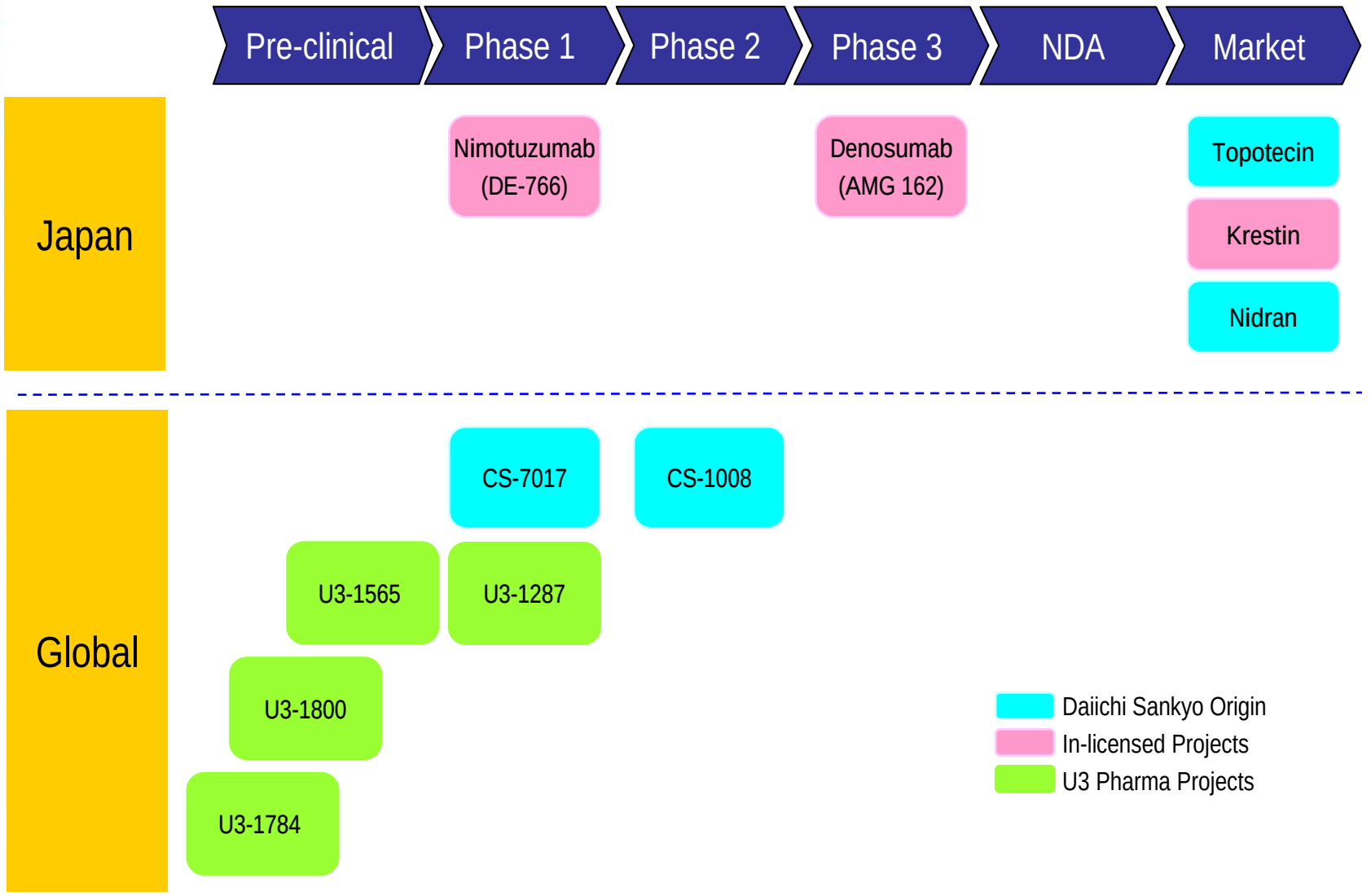
Oncology Pipeline with U3 Pharma Projects



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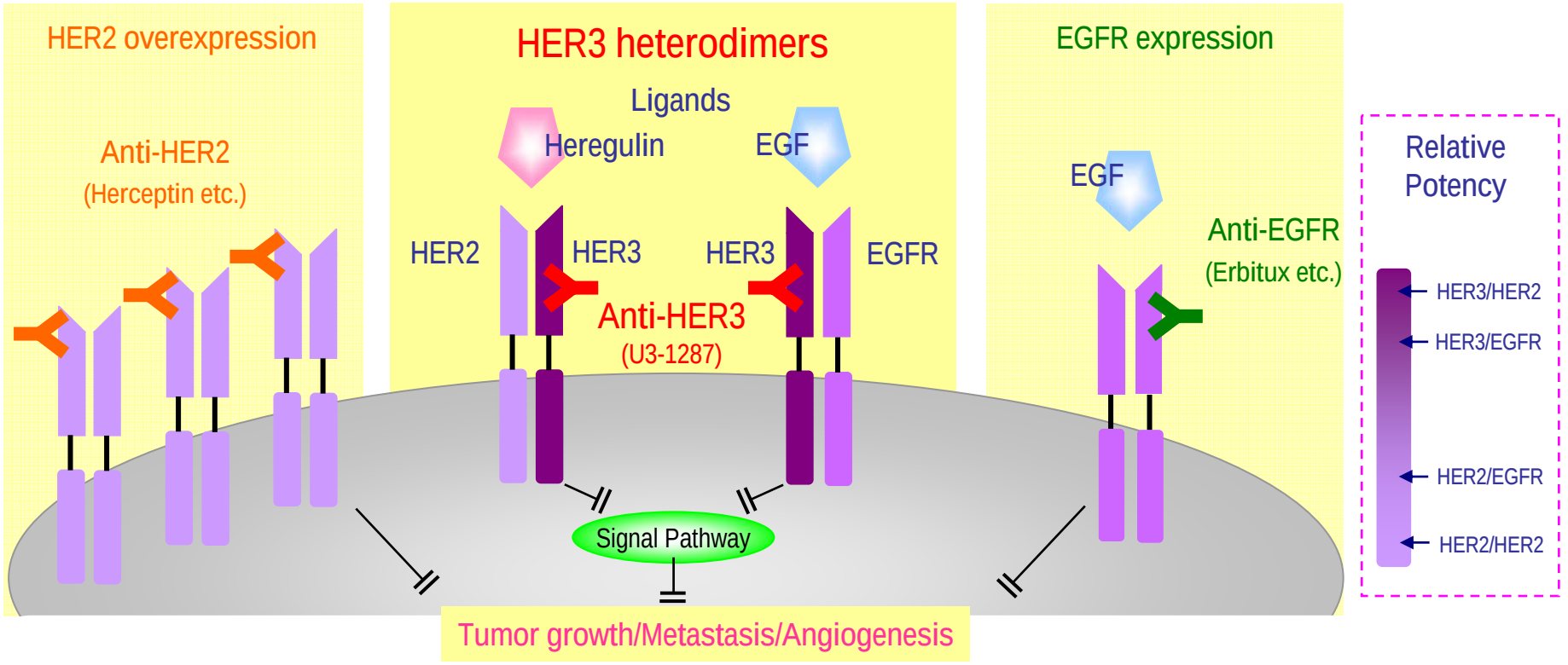
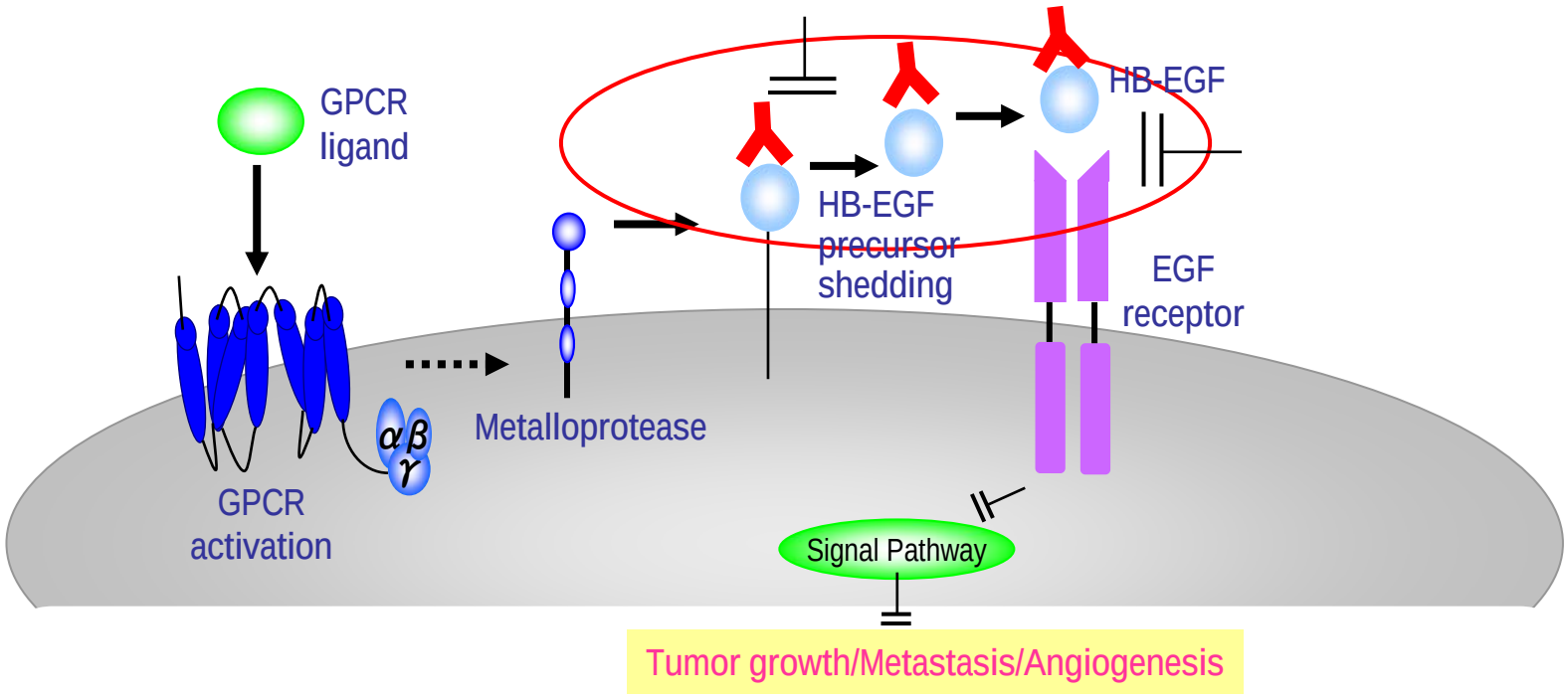
U3-1287 (Anti-HER-3 Antibody)



HER3 is the third member of EGFR family:

- Expression up-regulated in several cancer cell
  - breast, gastrointestinal, lung, pancreas, prostate, and skin tumors etc.
- Gatekeeper of HER2 activation (ligand binding)
- Crucial heterodimerization partner for EGFR
- Highest mitogenic potential among HER heterodimers

U3-1565 (Anti-HB-EGF Antibody)



HB-EGF is a membrane-bound receptor tyrosine kinase ligand

- Mediator of autocrine cancer proliferation
- Important function in angiogenesis
- Involved in multiple cancers & non-malignant diseases

Daiichi Sankyo R&D Strategy Vision Statement

As a **Global Pharma Innovator**,

Daiichi Sankyo R&D will discover and develop value added first-in-class and best-in-class therapies expanding on our legacy of quality and innovation to improve patient health and raise global standards for disease treatment and prevention

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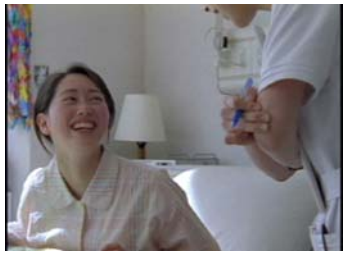
We make the impossible possible and make the incurable curable
~ Our Challenge ~



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