R&D Meeting 2008

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Key Milestones Achieved in FY2007

Achievement of milestones for major projects

- Prasugrel (CS-747, anti-platelet agent)
  - Nov-07 AHA, Proved superiority over current benchmark treatments
  - Dec-07 FDA filing for 1st indication (ACS-PCI) Brand Name : Effient™
  - Feb-08 NDA filing in Europe
  - 2Q-08 Trials to be started for 2nd indication (ACS-Medical Management)

- CS-8663 (anti-hypertensive Amlodipine/Olmesartan combination)
  - Sep-07 FDA approved, Brand Name : AZOR®
    ⇒ Launched in October
  - Sep-07 NDA filed in Europe (28 countries), Brand Name : Sevikar™
    ⇒ Approvals gradually expected from autumn 2008

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Key Milestones Achieved in FY2007

- Rivoglitazone (CS-011, anti-diabetes agent)
  - May-07 First Phase 3 trial launched
  - Aug-07 FDA removed clinical hold regarding of carcinogenicity
  - Dec-07 Second Phase 3 trial launched

Strategic investment for pipeline expansion

- Denosumab (AMG 162, anti-RANKL antibody)
  - Jul-07 In-licensed from Amgen
  - Phase 3 : bone metastases of cancer
  - Phase 3 in preparation: osteoporosis

Prioritized Projects (as of Feb-08)

The following post-Phase 2 projects are highly prioritized.

Project	Class
Prasugrel (CS-747)	Anti-platelet
DU-176b	Blood coagulation factor Xa inhibitor
CS-8635	AZOR & HCT Triple Combo, Olme LCM
Rivoglitazone (CS-011)	Anti-diabetes, PPAR-gamma agonist
Denosumab (AMG 162)	Anti-RANKL antibody

Prasugrel (CS-747)

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Current Status

- US submission was made on December 26, 2007
  - October 26, 2008 PDUFA goal date for standard review
  - If approved, trade name is Effient™ in the US
- EU submission was made on February 8, 2008
- Post-hoc analysis about TRITON study will be presented at ACC late March, 2008

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TRITON TIMI-38

Study Design

ACS (STEMI or UA/NSTEMI) & Planned PCI

ASA ↓ **N= 13,600**

Double-blind

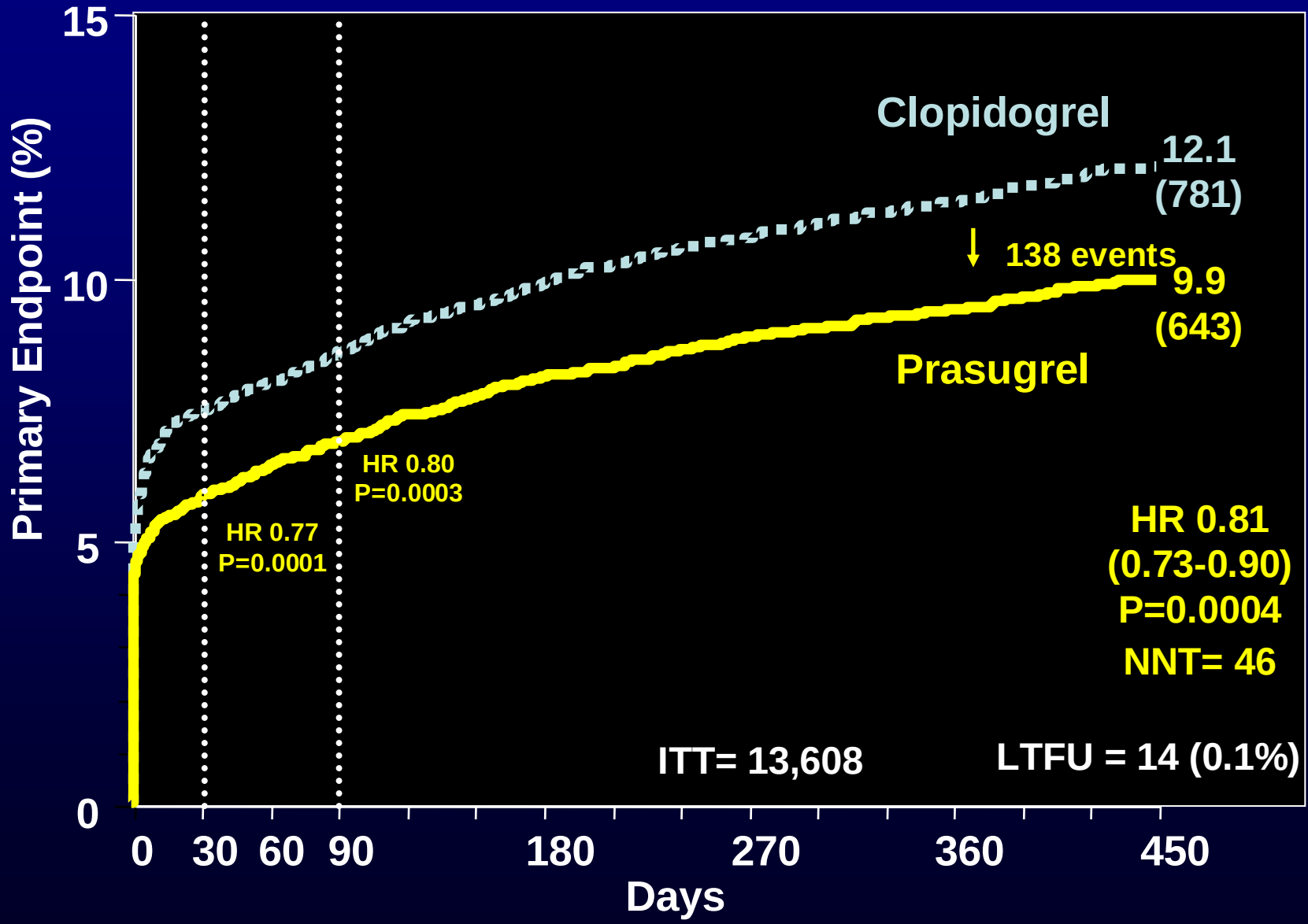
CLOPIDOGREL 300 mg LD/ 75 mg MD	**PRASUGREL** 60 mg LD/ 10 mg MD

Median duration of therapy - 12 months

1º endpoint:	CV death, MI, Stroke
2º endpoints:	CV death, MI, Stroke, Rehosp-Rec Isch
	CV death, MI, UTVR
	Stent Thrombosis
Key Substudies:	Pharmacokinetic, Genomic

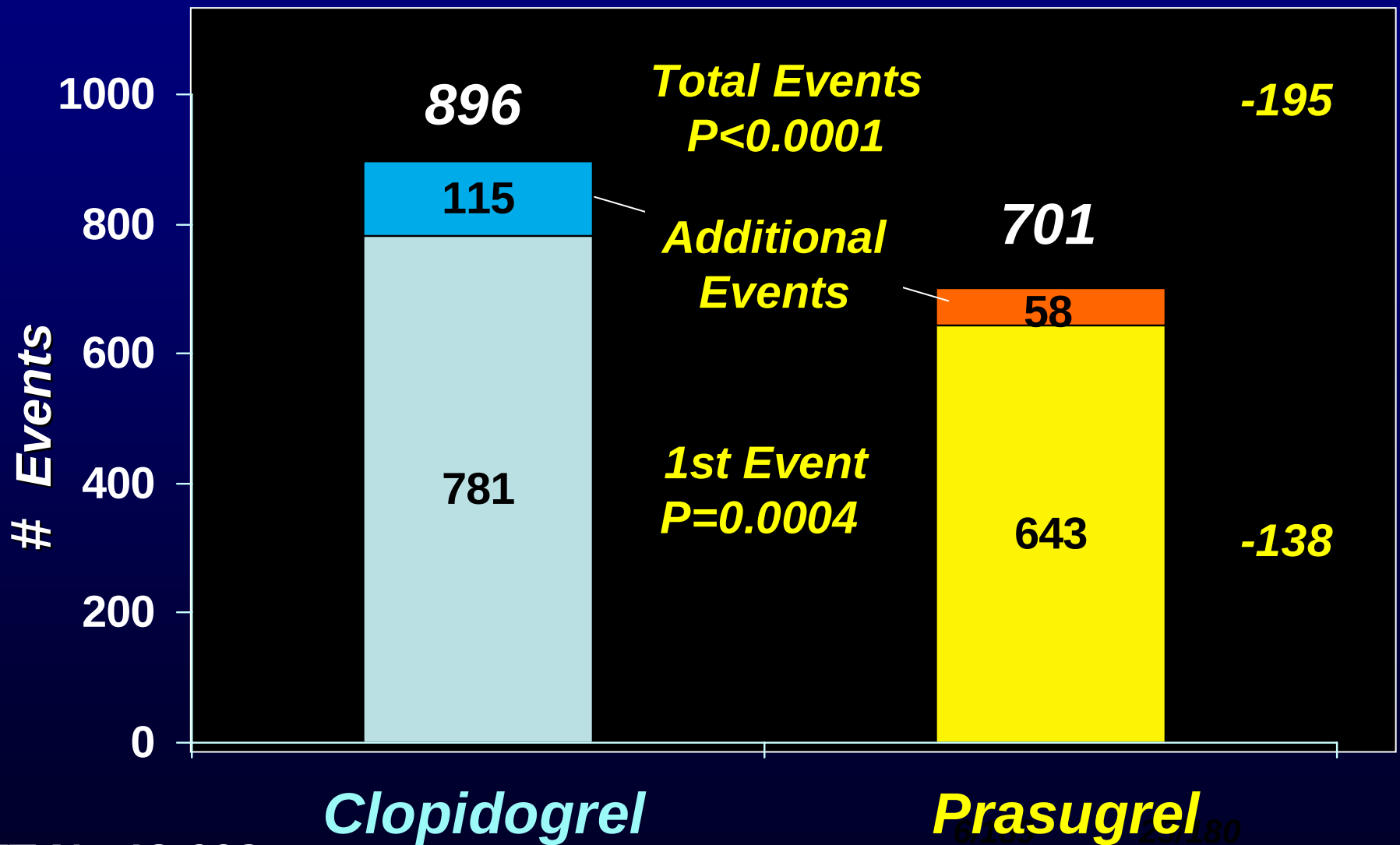
TRITON TIMI·38

Primary Endpoint
CV Death,MI,Stroke



TRÎTON TIMI·38

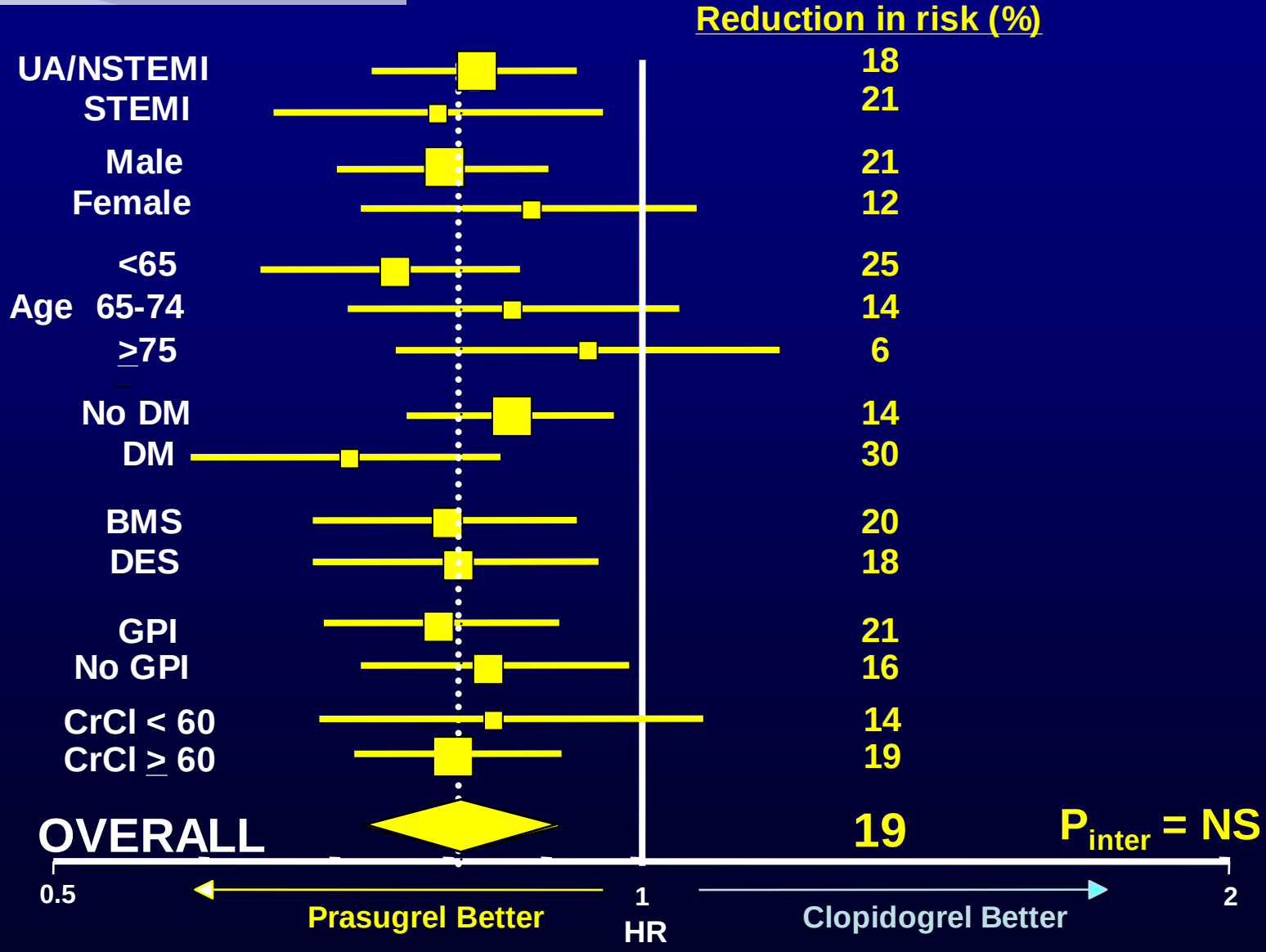
1^0 Endpoint Events Prevented
Post-hoc Analysis



ITT N= 13,608

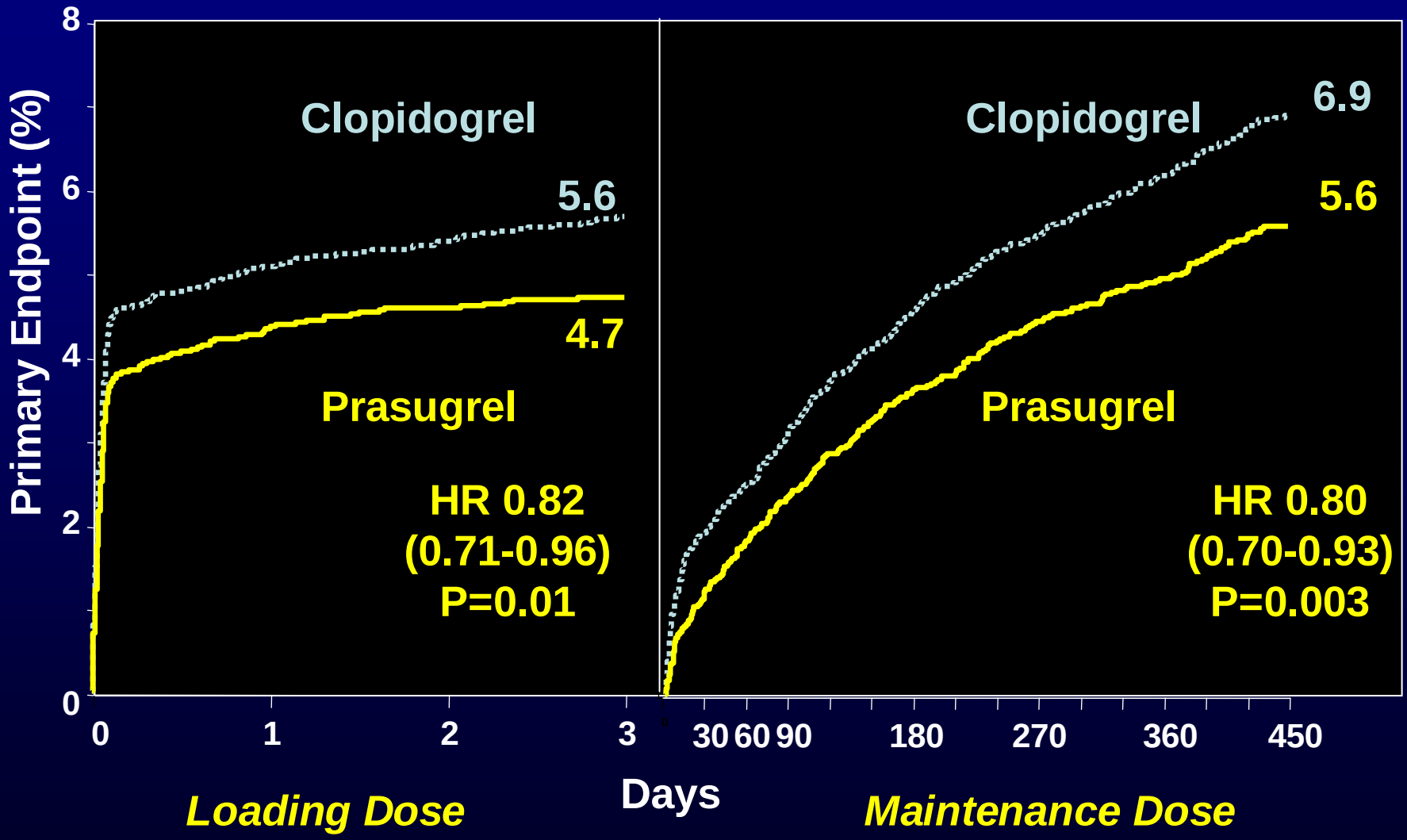
TRITON TIMI·38

CV Death, MI, Stroke
Major Subgroups



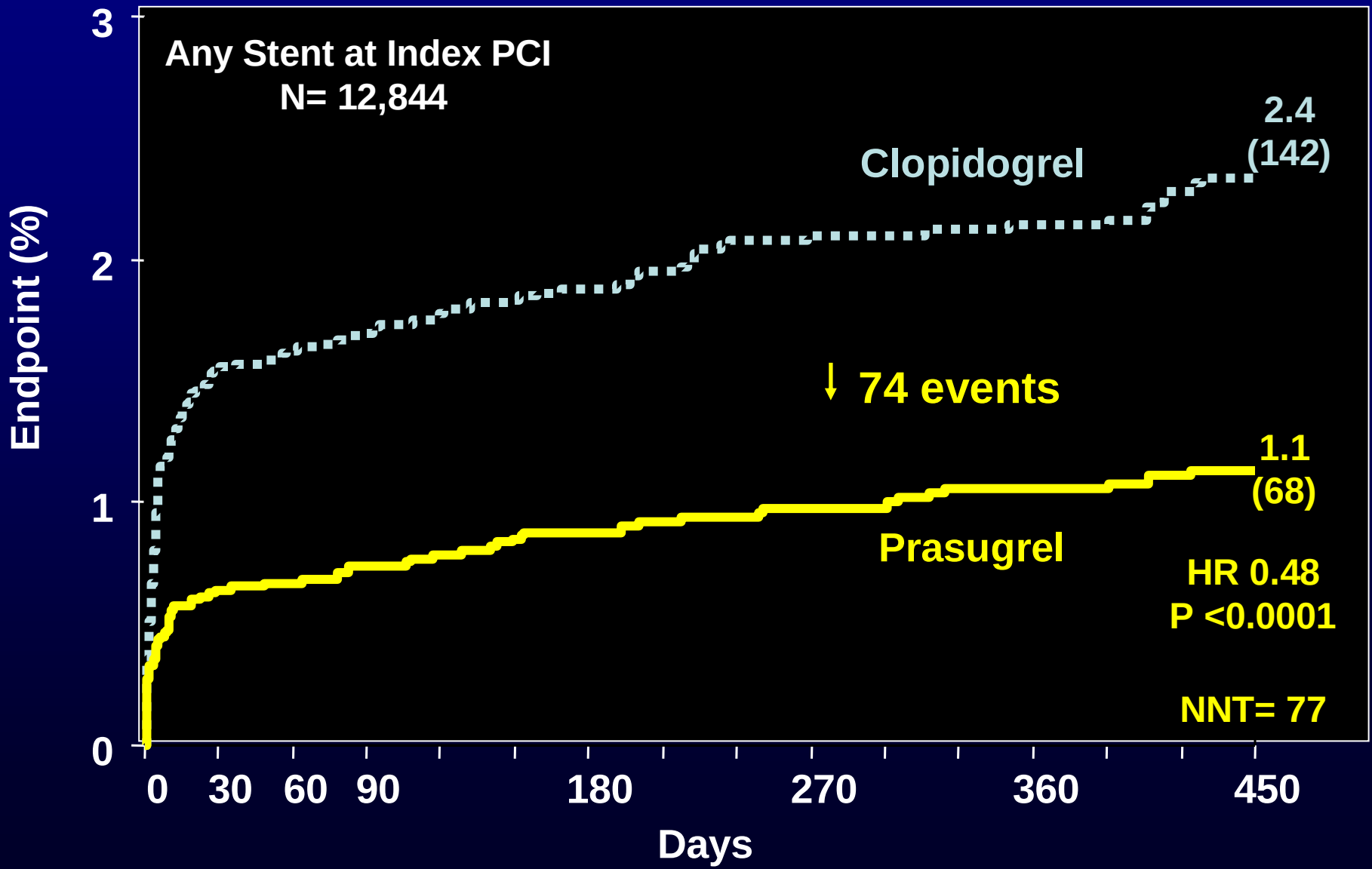
TRÎTON TIMI·38

Timing of Benefit (Landmark Analysis)



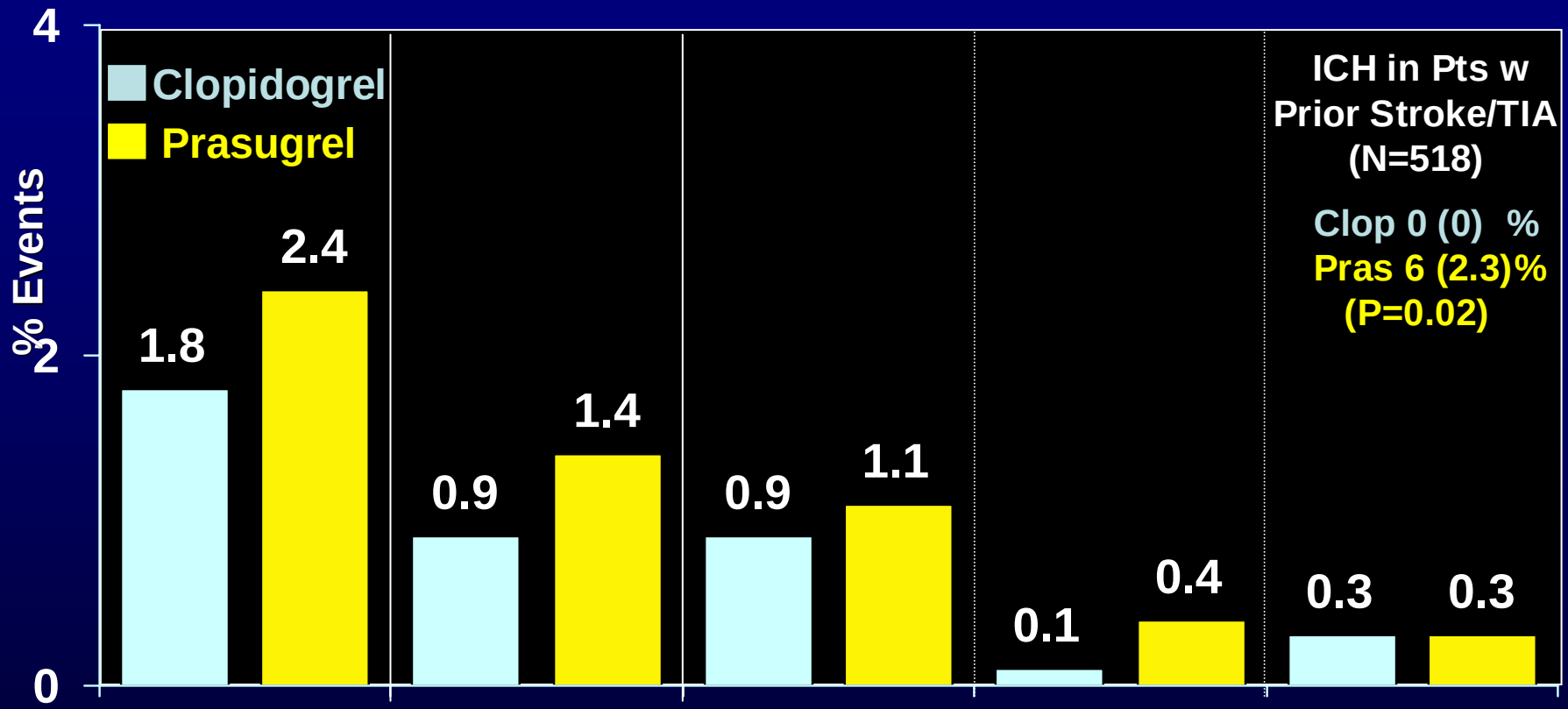
TRÎTON TIMI·38

Stent Thrombosis (ARC Definite + Probable)



TRITON TIMI·38

Bleeding Events (N=13,457)



ARD 0.6%
HR 1.32
P=0.03
NNH=167

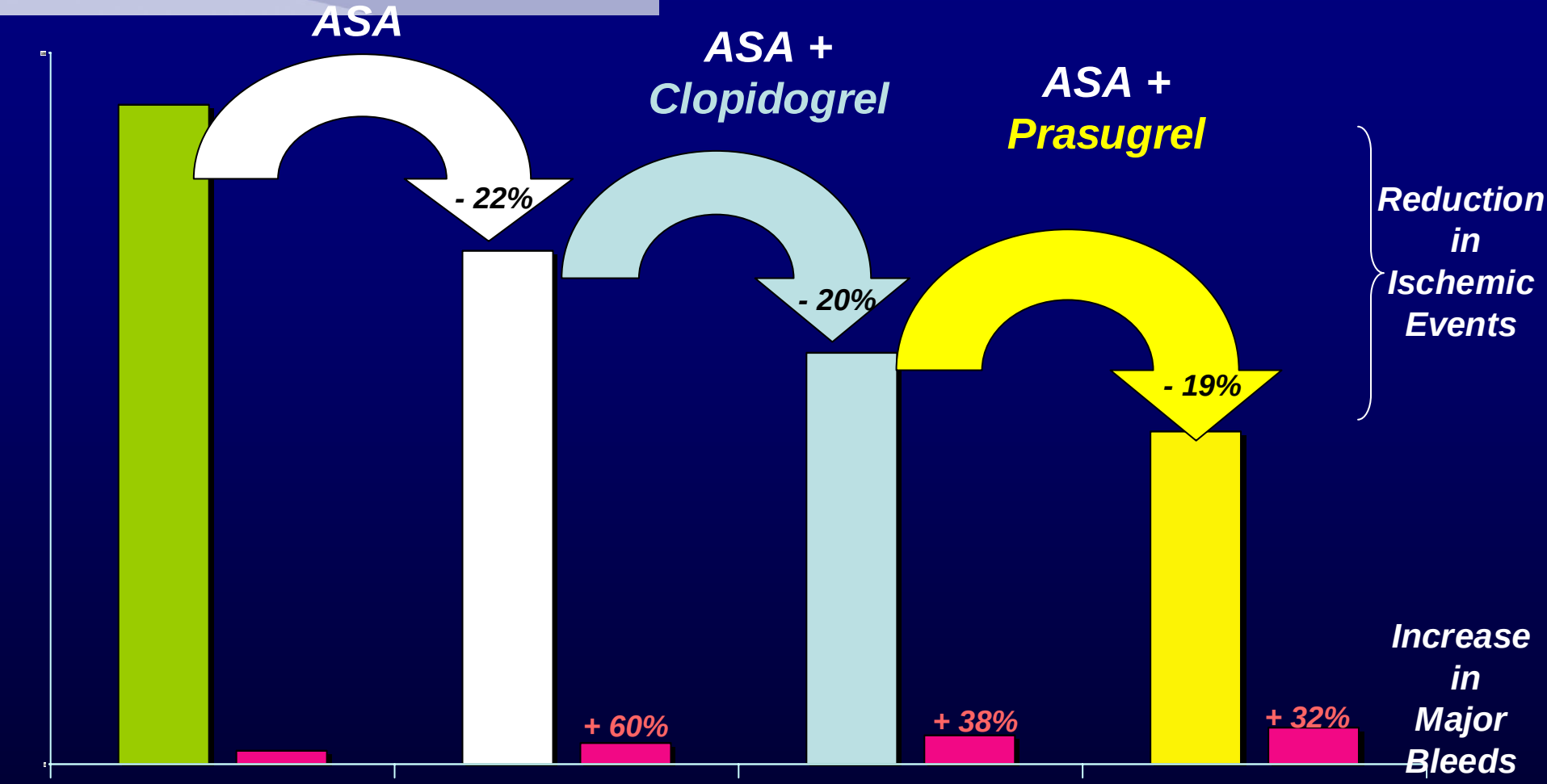
ARD 0.5%
HR 1.52
P=0.01

ARD 0.2%
P=0.23

ARD 0.3%
P=0.002

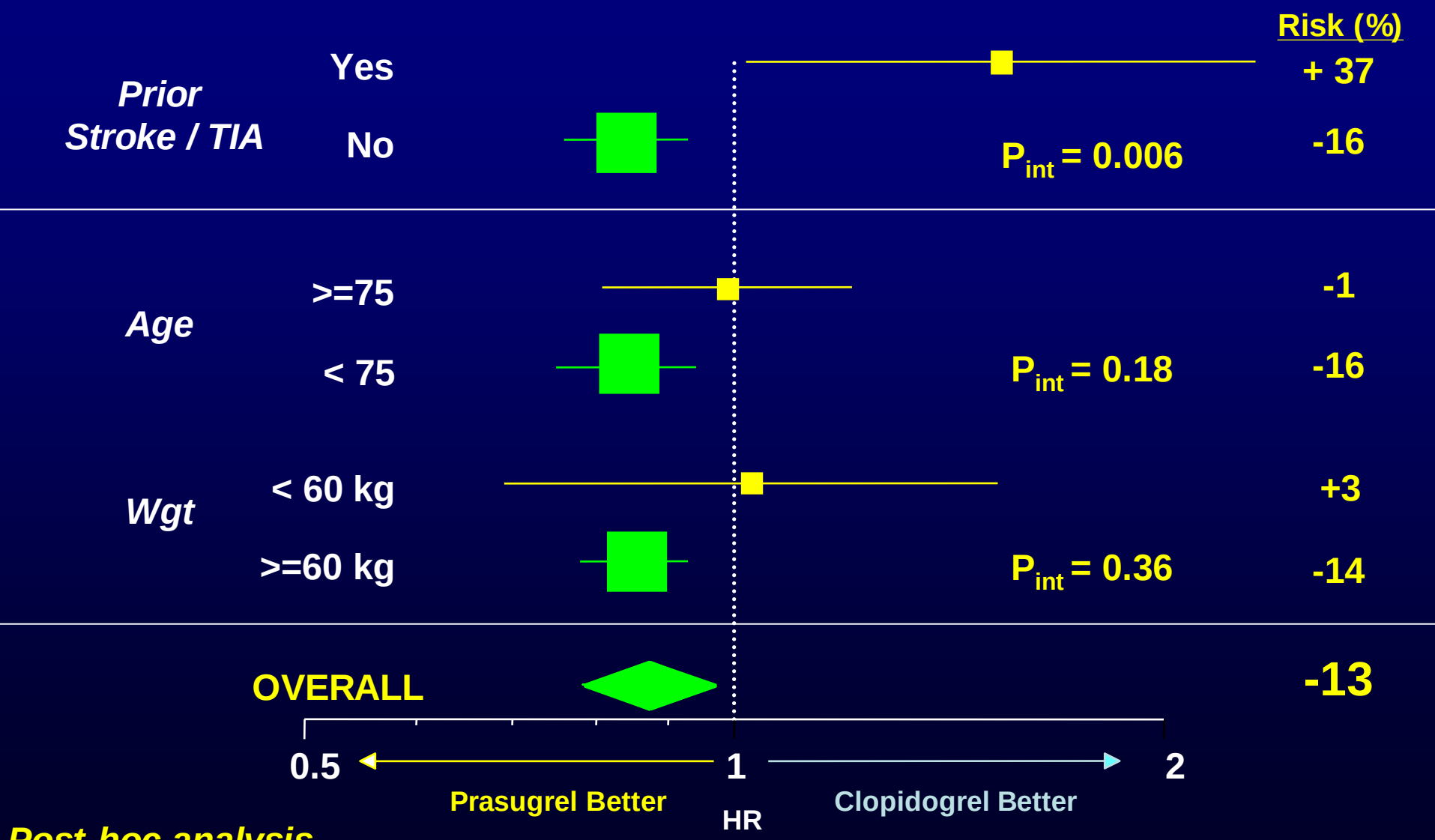
ARD 0%
P=0.74

Antiplatelet Therapy in ACS



TRÎTON TIMI·38

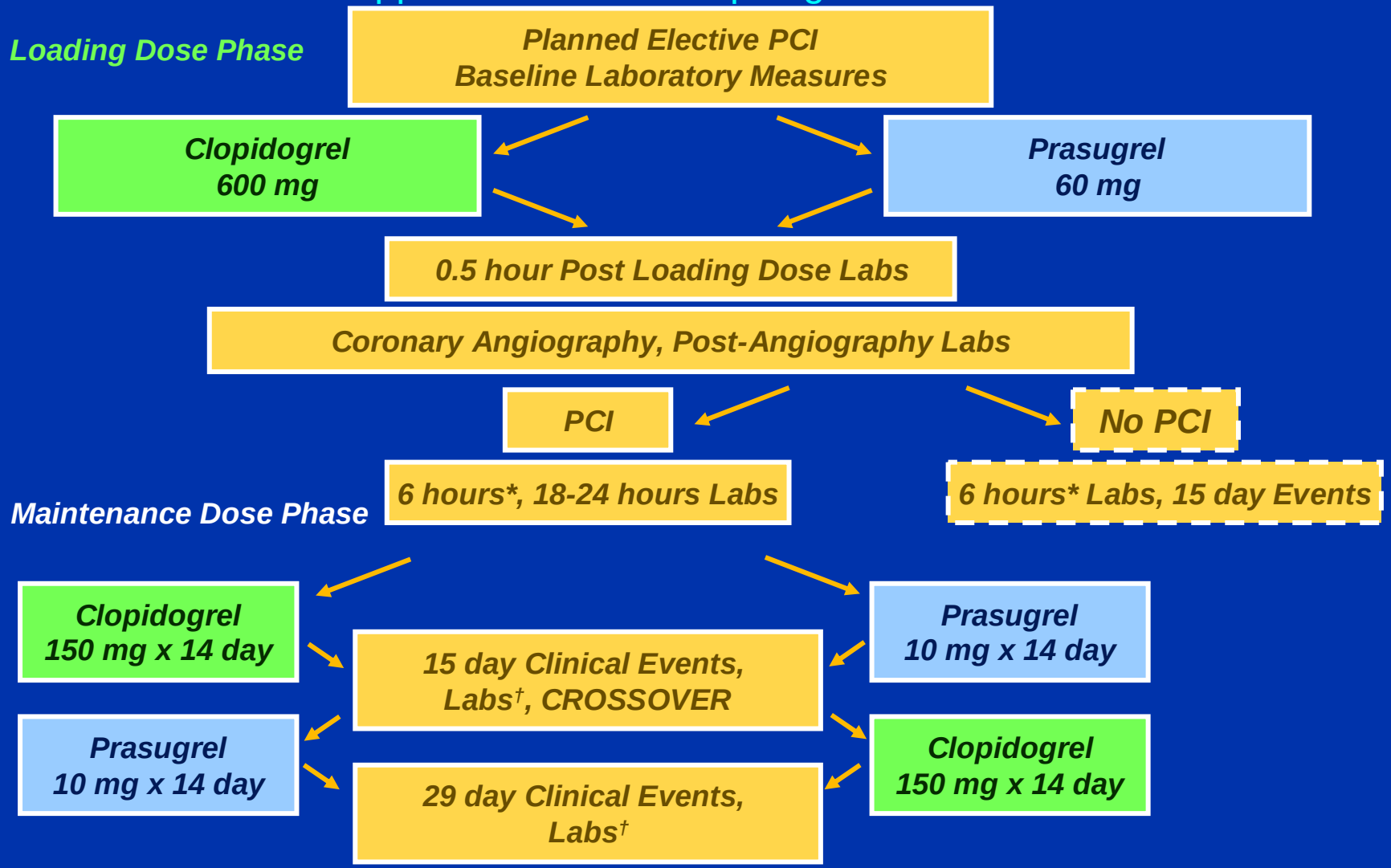
Net Clinical Benefit
Bleeding Risk Subgroups



Post-hoc analysis

PRINCIPLE TIMI-44: Study Design

Study Objective: compare the pharmacodynamic response of prasugrel to higher than approved doses of clopidogrel

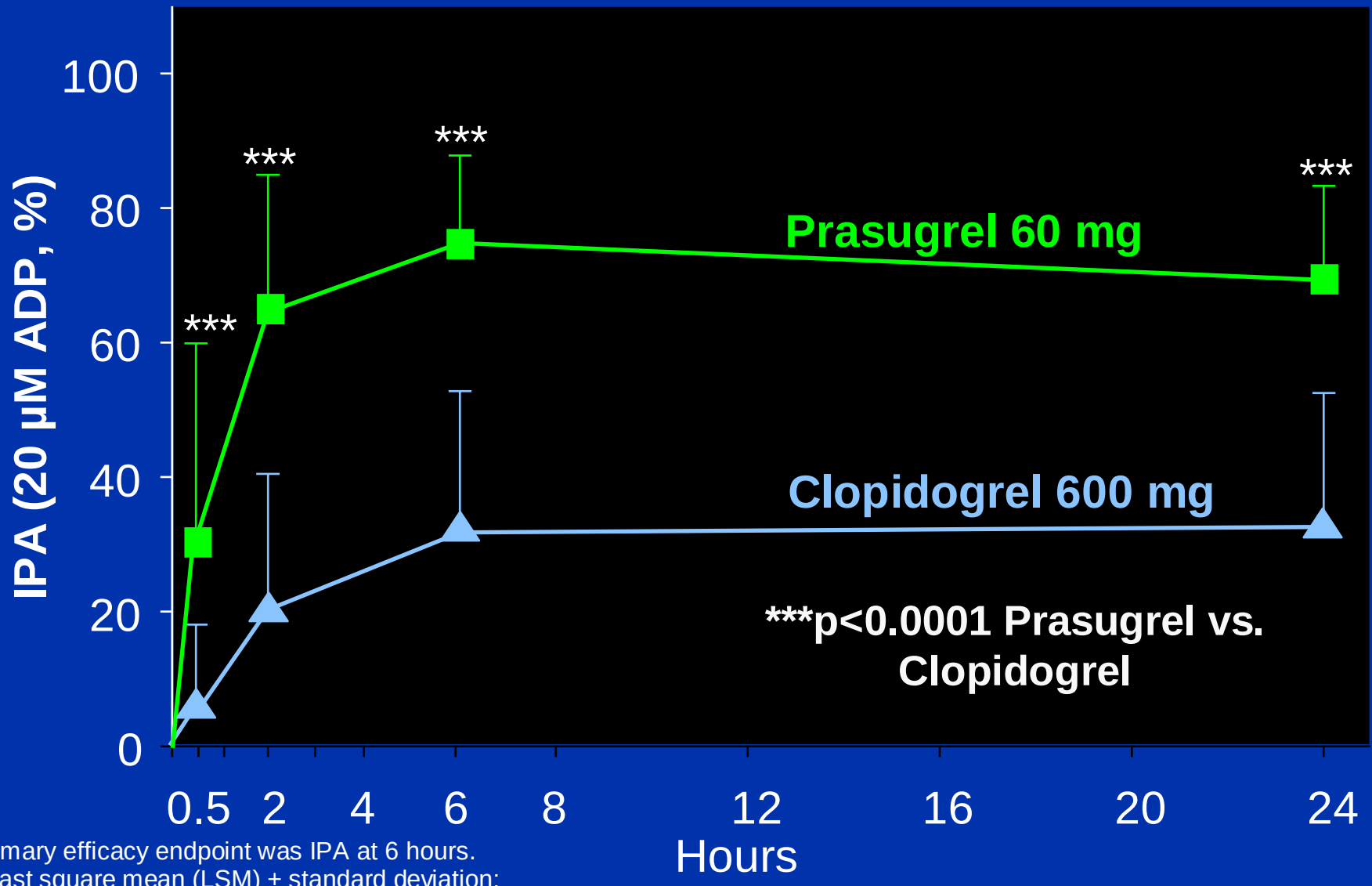


*1º EPs: *Loading = 6h IPA (20 µM ADP) ; †Maintenance = 15d or 29d IPA (20 µM ADP)*

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

Primary Endpoint: Loading Dose Phase IPA

Highly significant differences emerged throughout the LD phase

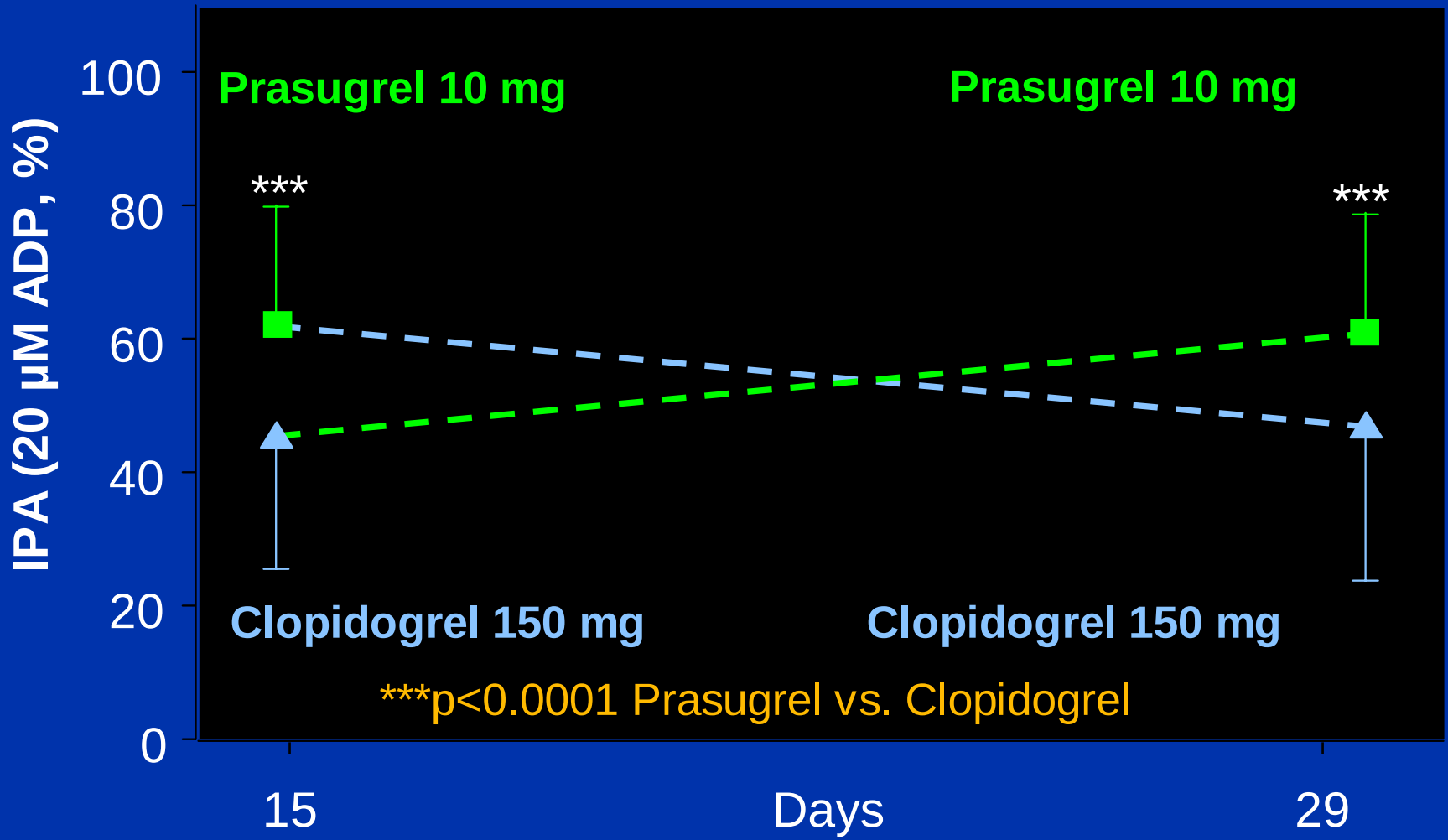


Primary efficacy endpoint was IPA at 6 hours.
Least square mean (LSM) + standard deviation;
IPA=inhibition of platelet aggregation

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

Purpose: to expand the prasugrel indication

- ACC/AHA and ESC guidelines[1] endorse an early invasive strategy with prompt coronary angiography and revascularization in UA/NSTEMI patients with intermediate to high-risk features
- Despite this recommendation, observational studies show that nearly 50% of subjects with UA/NSTEMI do not undergo catheterization and/or revascularization procedures during initial hospitalization[2]
- Furthermore, prognosis for medically managed patients, excluding those with insignificant CAD, is poor compared to those treated with early revascularization[3]

[1] Anderson 2007; Bassand 2007

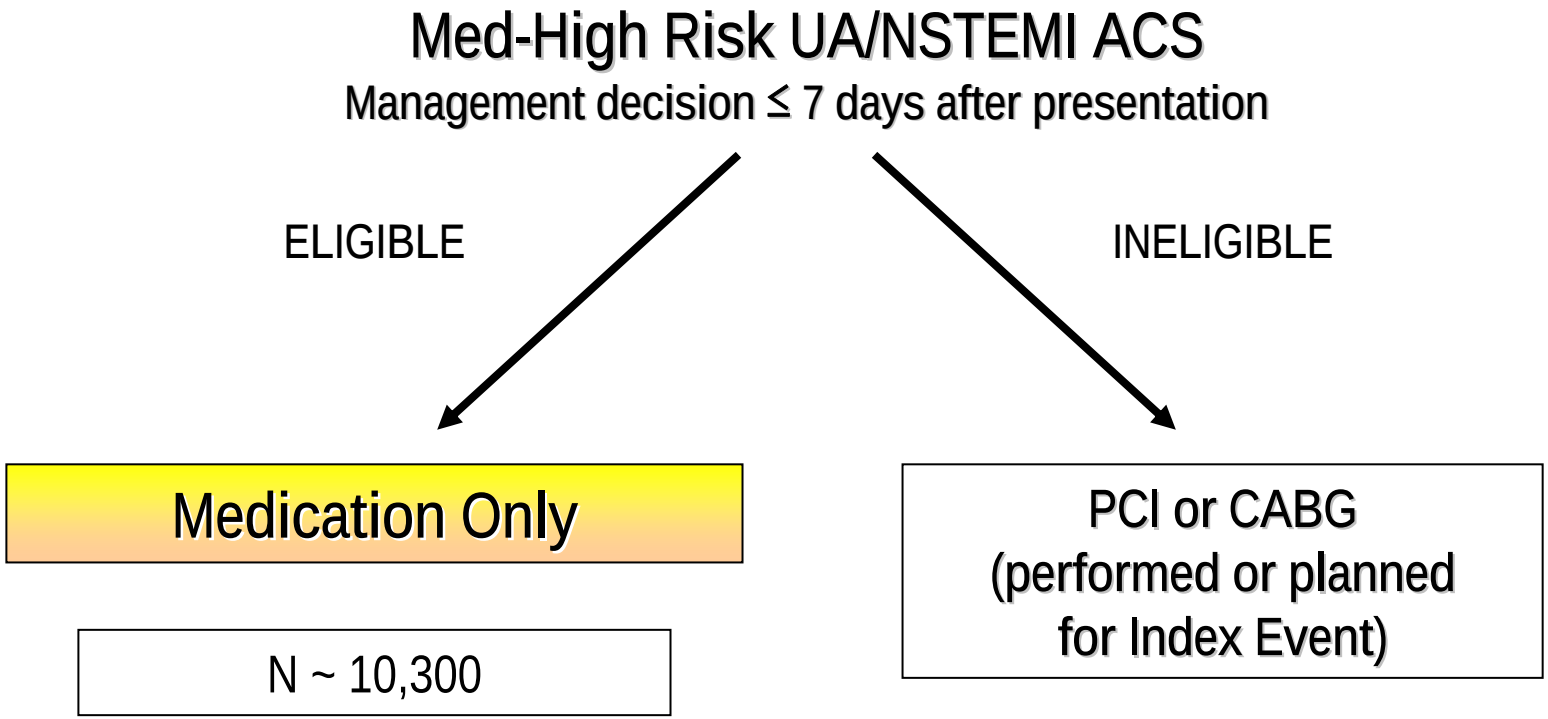
[2] Goldberg 2004, Carruthers 2005; Roe 2005; Mandelzweig 2006; Tricoci 2006

[3] Fox 2007

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, 800 hospital, 35 countries
- Duke Clinical Research Institute (Dr. Magnus Ohman)

Study Population



Rivoglitazone (CS-011)

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Product Profile of Rivoglitazone

- Potent selective PPAR-gamma agonist
- Superior efficacy to pioglitazone
- Early onset of therapeutic benefits
- Favorable lipid profile
  - TG reductions and HDL-C increases, similar to or better than pioglitazone
  - No significant increase in LDL-C
- Equivalent safety profiles to pioglitazone
  - Hemodilution, weight gain and edema
  - Adequate safety margins on animal carinogenecity studies
  - No indication of liver toxicity
- Over 12,000 patients to be studied with careful monitoring of safety and efficacy

Target Product Profile

- Indication for treatment of type 2 diabetes
  - Monotherapy
  - Combination use with other classes of agents
- Significantly superior efficacy to pioglitazone
  - At top dose, glycemic benefits 20 to 30% greater than with pio 45mg
- Safety profile generally similar to pioglitazone
  - Edema and fluid retention
  - CV outcomes
- Favorable lipid data included in the product label
  - TG reductions and HDL increases; no significant effect on LDL-C

Development Timeline

US / EU

- Ph3 2007 – 2010
- NDA / MPP 2011

JPN / Asian

- Ph2 2007 – 2008
- Ph3 2009 – 2011
- NDA 2011

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Summary of Rivoglitazone Ph2 Study

- HbA1c
  - Both 2 and 3 mg rivoglitazone showed significantly greater HbA1c placebo-corrected decreases from baseline than pioglitazone 45 mg
- TG and HDL-C
  - Rivoglitazone showed greater TG reductions and HDL-C increases than pioglitazone 45 mg

Results to be presented at scientific conference(s) in 2008

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Olmesartan Franchise

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Olmesartan Franchise

- CS-8663（Combination drug with Amlodipine）
  - Sep. 2007 Approved in the US, Brand name：AZOR®
  - Sep. 2007 NDA filed in Europe (28 countries), Brand name：Sevikar™

    ⇒ Approvals gradually expected from autumn 2008
- CS-8635（Combination drug with Amlodipine and Hydrochlorothiazide）
  - Phase 3 trials planned in the US
- CS-866AZ（Combination drug with Azelnidipine*）
  - Phase 3 trials ongoing in Japan

    ** Azelnidine is marketed in Japan as brand name of Calblock*
- CS-866DM（New indication for diabetic nephropathy）
  - Phase 3 trials ongoing in Japan
- CS-866CMB（Combination drug with Hydrochlorothiazide）

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 planned
- NDA Submission: 2009

Status of CS-866AZ

- Development concept
  - Maximize the sales of Olmesartan and Calblock as one of LCM strategies
  - Fixed dose combination of ARB and CCB which are most frequently co-administered in Japan for hypertension treatment
- Target Indication: 2nd line therapy for hypertensive patients who responded poorly to Olmetec or Calblock treatment
- Region: Japan
- Development Stage: Phase 3
- NDA Submission: 2009

Status of CS-866DM

- Development concept
  - Additional indication of Olmesartan as one of LCM strategies
  - Evaluate the composite renal endpoints* as primary endpoint in ORIENT study

  *:Doubling of serum creatinine (Scr), Onset of ESRD (Scr≥5 mg/dL, dialysis, kidney transplantation), Death
- Target Indication: Diabetic nephropathy with type 2 diabetes
- Region: Japan
- Development Stage: Phase 3
- NDA Submission: 2009

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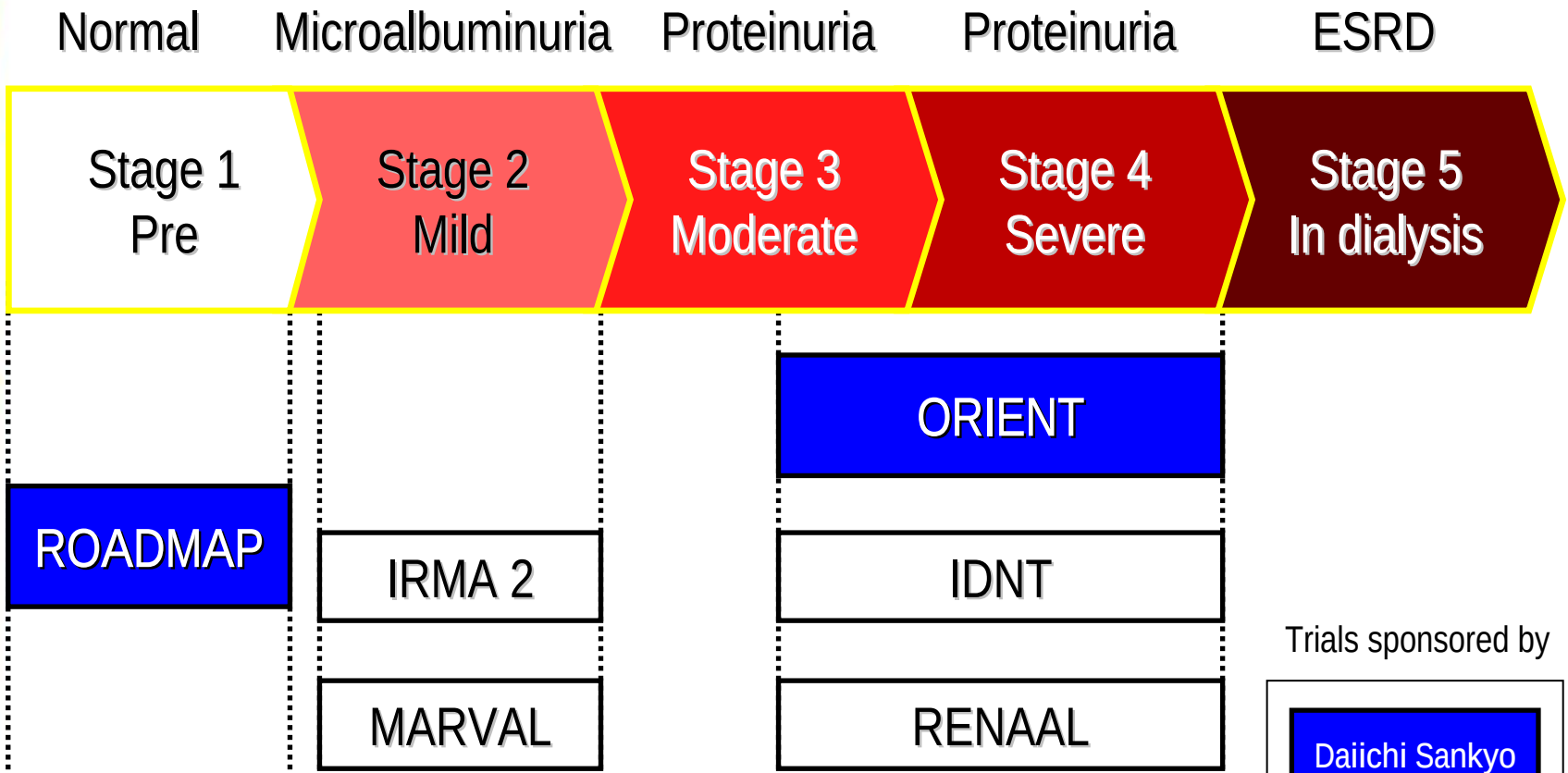
ROADMAP Study

Originality; Diabetic Nephropathy and Outcome Studies

The subject condition of ROADMAP is normal renal function



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ROADMAP Study

- The ROADMAP study will establish whether olmesartan can prevent microalbuminuria in patients with type 2 diabetes, and whether this signifies vascular protection
  - First study to examine whether an ARB can prevent or delay the onset of microalbuminuria
- Randomized, double-blind, placebo-controlled, multicentre, multinational, parallel-group trial of olmesartan 40 mg/day vs. placebo
- 4,400 patients with Type-2 diabetes mellitus and normoalbuminuria with at least 1 cardiovascular risk factor
- Study Schedule
  - Started Nov. 2004
  - Recruitment ended Jun. 2006
  - Clinical phase to end 2011
  - Study report 2012

Olmesartan Lifecycle Management

<Mono>	Phase 2	Phase 3	NDA filed	Marketing
US				Benicar
Europe				Olmetec
Japan		CS-866DM (diabetic nephropathy)		Olmetec

<Combo>	Phase 2	Phase 3	NDA filed	Marketing
US		CS-8635 (CS-8663 + HCTZ)		Benicar HCT AZOR
Europe		CS-866CMB (with HCTZ)	Sevikar (CS-8663) (with Amlodipine)	Olmetec Plus
Japan	CS-866CMB (with HCTZ)	CS-866AZ (with Calblock)		

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DU-176b

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Target Profile and Positioning of DU-176b

Attributes	DU-176b
Dosage Regimen	Once daily dosing
Efficacy	Not inferior to warfarin in VTE / NVAF
Safety and tolerability	
- Bleeding	Not inferior to warfarin Low incidence of bleeding
- Liver Toxicity	No hepatotoxicity
Indications	VTE NVAF
Food Effects	No
Monitoring	No

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Protocol of Ph2b Studies in THR & TKR

- Primary objective
  - Assess the efficacy of DU-176b in the prevention of VTE vs. dalteparin (THR) or placebo (TKR)

THR: total hip replacement
TKR: total knee replacement

- Patient population
  - Patient undergo elective THR / TKR
- Design
  - Randomized, double-blind
- First dosing
  - 6 to 8 hours after surgery (THR), 6 to 24 hours after surgery (TKR)
- Treatment period
  - 7 to 10 days (THR), 11-14 days (TKR)
- Number of patients
  - 750 (THR), 410 (TKR)

Summary of Ph2b Results in THR & TKR

- Dose-dependent inhibition of VTE incidence
  - THR 15 mg – 90 mg qd, superior to dalteparin (US/EU)
  - TKR 5 mg – 60 mg qd, superior to placebo (Japan)
- Low incidence of major bleeding, including at doses with very effective VTE inhibition
- Favorable PK/PD profile
- Possible QD (once daily) regimen

Results to be presented at scientific conference(s) in 2008

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Protocol of Ph2b Studies in AF

- Primary objective
  - Evaluation of safety of DU-176b vs. warfarin
- Patient population
  - Patients with non-valvular AF
- Design
  - Randomized, double-blind, active-controlled, DU-176b and open−label warfarin study
- Treatment period
  - 3 months treatment
- Number of patients
  - 1,000 (US/EU), 500 (Japan)

Multiple Chronic Indication Strategy

Indication	Current status
VTE prophylaxis	Phase 2b studies completed
VTE prophylaxis / treatment	Phase 3 planned
NVAF in US/EU	Phase 2b Patients enrolment completed
NVAF in Japan	Phase 2b Patients enrolment completed
NVAF	Phase 3 planned

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

- No hepatotoxicity signals in pre-clinical including toxicogenomics and clinical studies
- Phase 2b studies in patients with total hip replacement and total knee replacement completed and patients with atrial fibrillation are ongoing globally
  - Favorable balance of efficacy versus bleeding in studies to date
- Phase 3 NVAF study planned to be started in 3Q 2008
- Significant market opportunity but with competitors

Denosumab (AMG 162)

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What is Denosumab (AMG 162)

- Denosumab (Dmab) is a fully human monoclonal antibody that specifically targets the receptor activator of nuclear factor kappa B ligand (RANKL), a key mediator of the resorptive phase of bone remodeling.
- Dmab is being studied across a range of conditions, including osteoporosis, treatment-induced bone loss, rheumatoid arthritis, bone metastases, and multiple myeloma.
- On July 11, 2007, Amgen and Daiichi Sankyo announced a collaboration and license agreement for the development and commercialization of Dmab in Japan.

RANK: Receptor activator for nuclear factor kappa B

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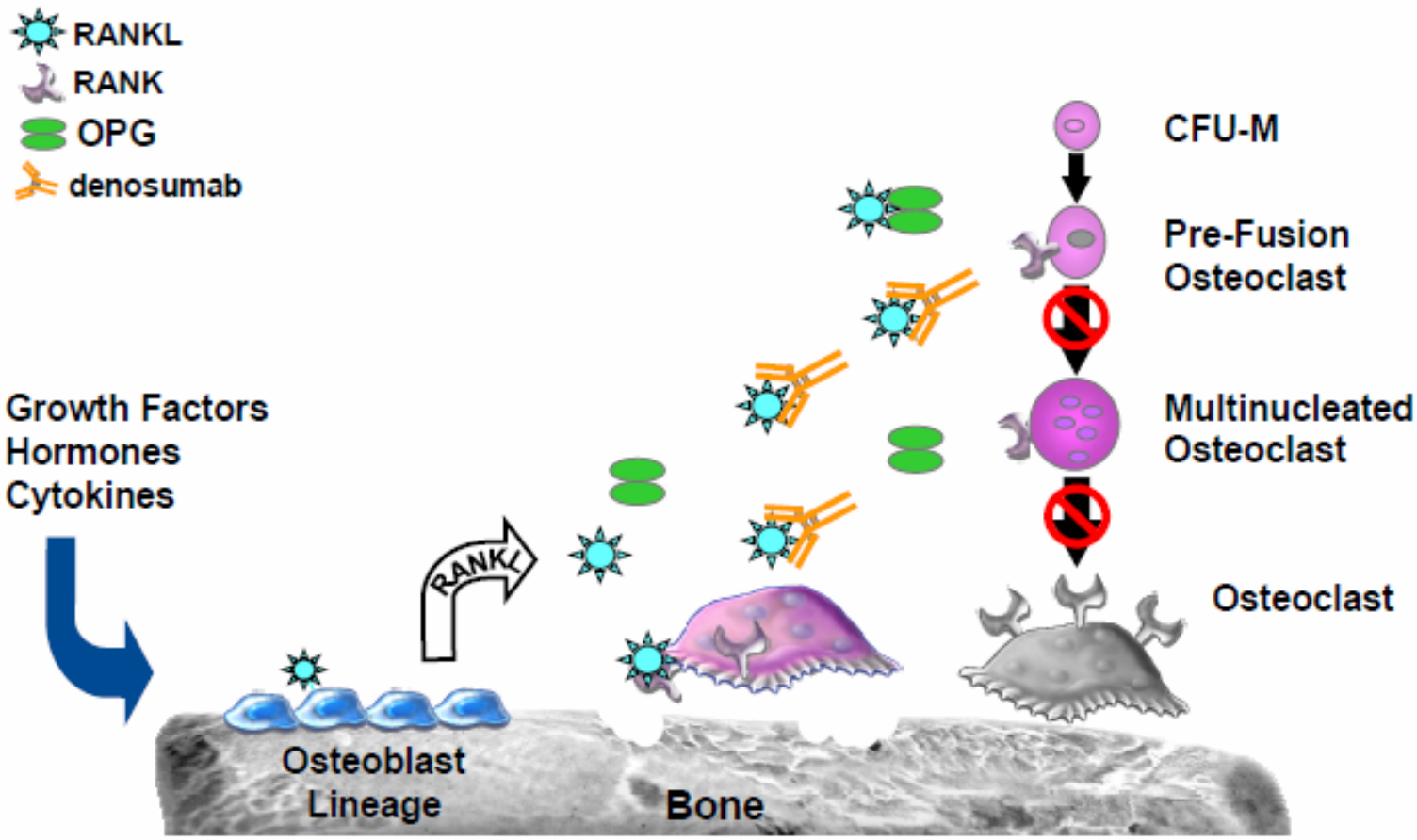
Proposed Mechanism of Action for Dmab



CFU-M = colony-forming unit-macrophage.

Provided September 27, 2007 as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.

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Development Overview

Indication	Dose	Development Stage	
		US/EU	Japan
Osteoporosis	60 mg every 6 months SC	Ph.3	Ph.3 preparing
Oncology (Bone Metastasis)	120 mg every month SC	Ph.3	Ph.3
Rheumatoid Arthritis	60-180 mg every 6 months SC (TBD)	Ph.2	-

- Generally well tolerated; adverse events were similar among Dmab, placebo, and alendronate groups
- No neutralizing antibodies observed

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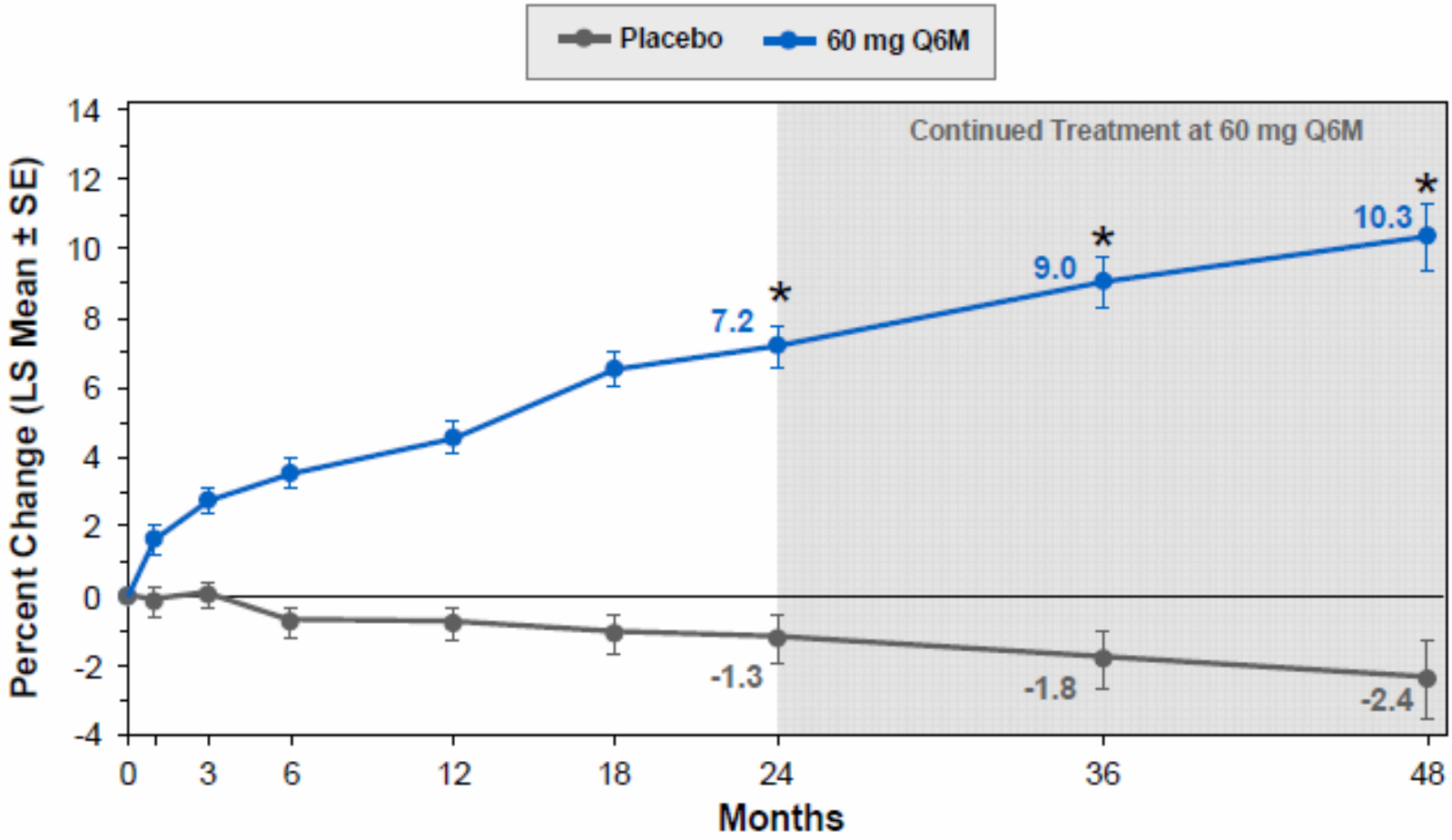
Effect of 4 Years of Dmab Treatment on Lumbar Spine BMD



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Recent Outcomes and Upcoming Events

- Phase 3 head-to-head study vs alendronate met primary and all secondary endpoints
  - Denosumab showed approximately 40% greater increases in bone mineral density as compared to alendronate
  - Denosumab and alendronate exhibited similar safety profiles
- Completed phase 3 breast SRE study enrollment

SRE: skeletal related events

- Continue to expect robust data set in 2008

Data	Timing
Phase 3 HALT prostate cancer	H2 ’08 - data in house
Phase 3 PMO fracture study	H2 ’08 - data in house

HALT: hormone-ablative therapy

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Development Plan (JPN) - Osteoporosis -

- Ph 1 study: Completed
  - Postmenopausal women
  - PK/PD study
- Ph 2 study: Completed
  - A randomized, double-blind, placebo-controlled, dose response study of Dmab in Japanese postmenopausal osteoporosis subjects
  - Dose: 14, 60 and 100mg SC once every 6 months
  - Primary endpoints
    - Percent change of lumbar spine BMD at month 12
    - Safety profile
  - Phase 2 PMO study met both primary and secondary endpoints
- Ph 3 study: In preparation

Development Plan (JPN) - Bone Metastasis -

- Ph 1 study: Completed
  - Breast cancer patients with bone metastasis
- Ph 3 multinational studies including Japan: Ongoing
  - A randomized, double-blind, multicenter study of Dmab compared with Zoledronic Acid (Zometa®) in the treatment of bone metastases in subjects with advanced breast cancer

Oncology Franchise

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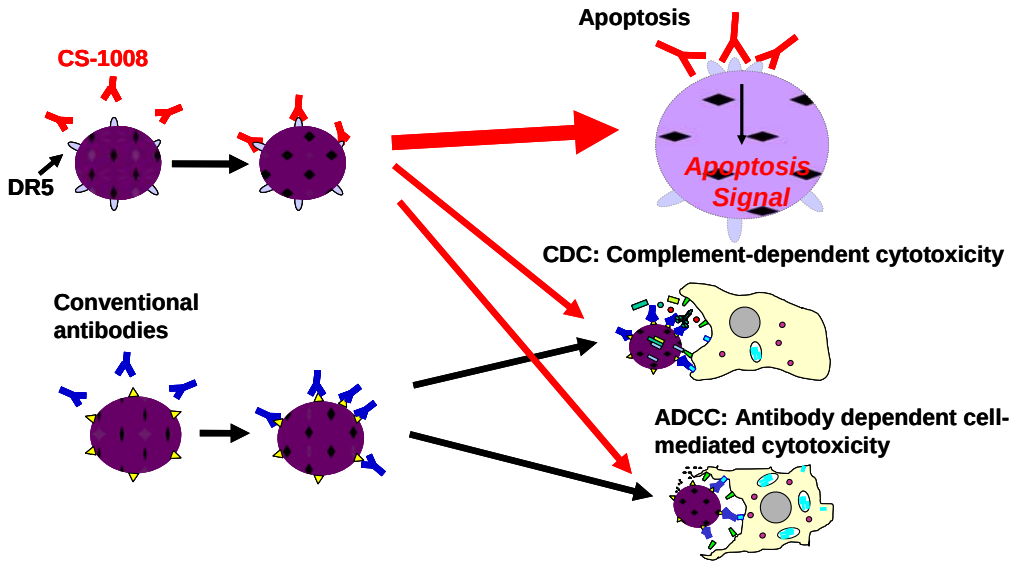
Oncology Franchise

- AMG 162 Denosumab (Phase 3)
  - Human monoclonal antibody that targets RANK Ligand (an essential mediator of cells that break down bone)
- CS-1008 (Phase 2)
  - A humanized version TRA-8, a murine agonistic monoclonal antibody raised against human death receptor 5 (DR5)
- CS-7017 (Phase 1)
  - Antitumor PPAR-gamma activator
- DE-766 Nimotuzumab (Phase 1)
  - Humanized monoclonal antibody against the epidermal growth factor receptor

CS-1008

- A humanized version TRA-8, a murine agonistic Mab raised against human death receptor 5 (DR5)
  - DR5 is rarely expressed in normal tissues, expected to show selective activity against tumor cells
- Induces apoptosis of tumor cells expressing DR5 on the cell surface
- Anti-cancer effect from pre-clinical studies
  - Human cancer cell lines *in vitro*
  - Tumor-bearing mice *in vivo*
- Good safety profile in pre-clinical studies
- Development timeline
  - IND: Dec 2005
  - Phase 2 start: 3Q 2007



CS-7017

- Antitumor PPAR-gamma activator
  - Positive correlation between PPAR-gamma activation and inhibition against colony formation of tumor cells *in vitro*
- Inhibits growth of tumor cells *in vitro* without killing those cells
  - Expected to be less toxic compared to standard chemotherapeutics
- Effective against human tumor-implanted *in vivo* models
- Could be used either alone or in combination with other chemotherapeutic agents
- Phase 1 study is ongoing in US

Nimotuzumab DE-766

- Humanized Mab to epidermal growth factor receptor (EGFR)
- Target indication; tumors expressing EGFR
  - Glioma, NSCLC, Esophagus, Gastric, Colorectal, etc
- Combination therapy (with radiotherapy and/or chemotherapy)
- Superior safety in terms of skin rash and comparable efficacy to other EGFR Mabs
  - Best-in-Class among EGFR antibodies
- Development timeline
  - Phase 1 study in Japan: ongoing
  - Phase 2 start: 2Q 2008
- Current Status in Other Countries
  - Head & Neck cancer: Approved in Cuba, India, South America countries etc.
  - Nasopharyngeal carcinomas: Approved in China, Cuba
  - Glioma: Approved in Cuba, Argentina and Ukraine
    Phase 3 study is ongoing in Germany

Closing Remarks

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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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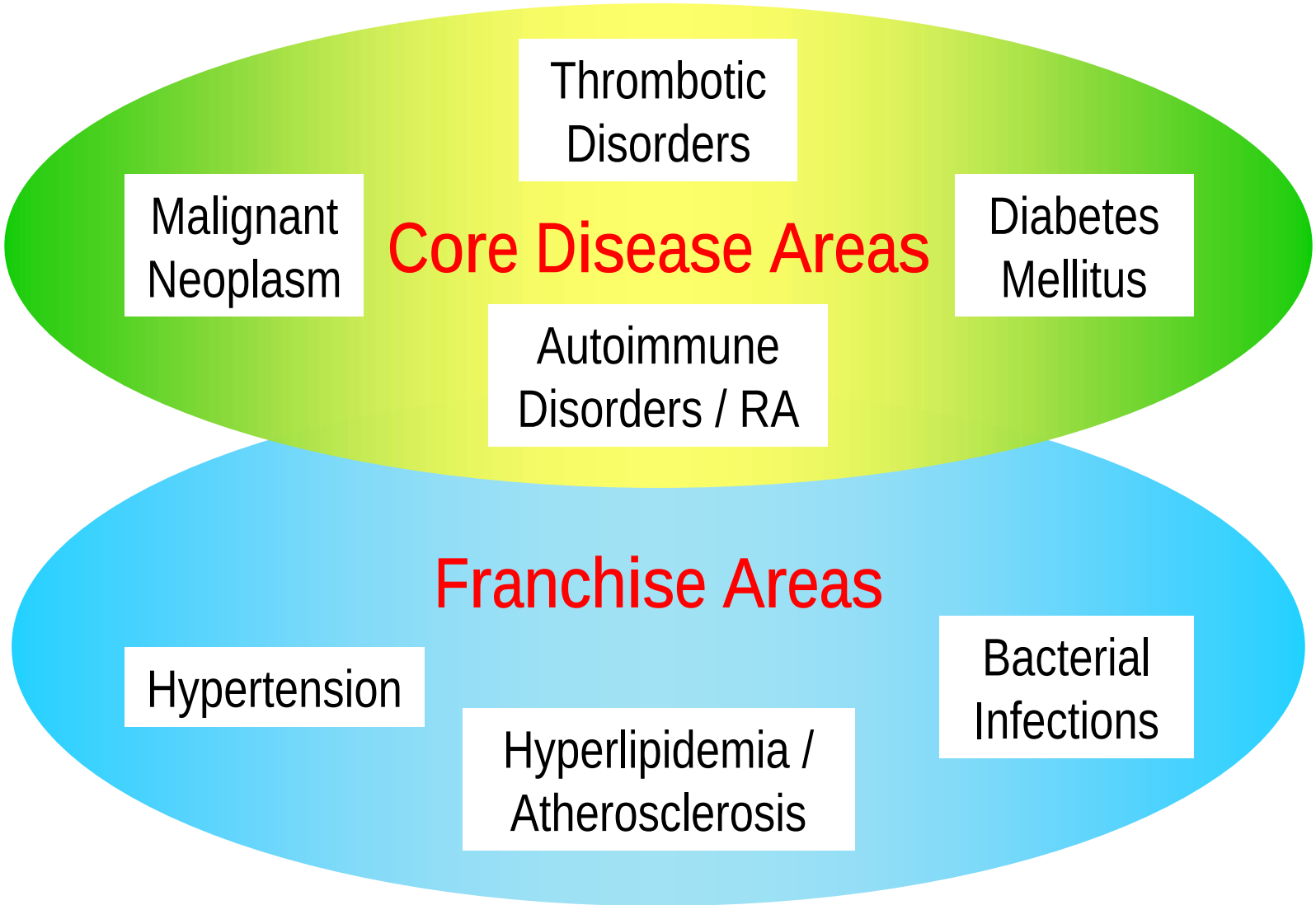
Therapeutic Area Prioritization



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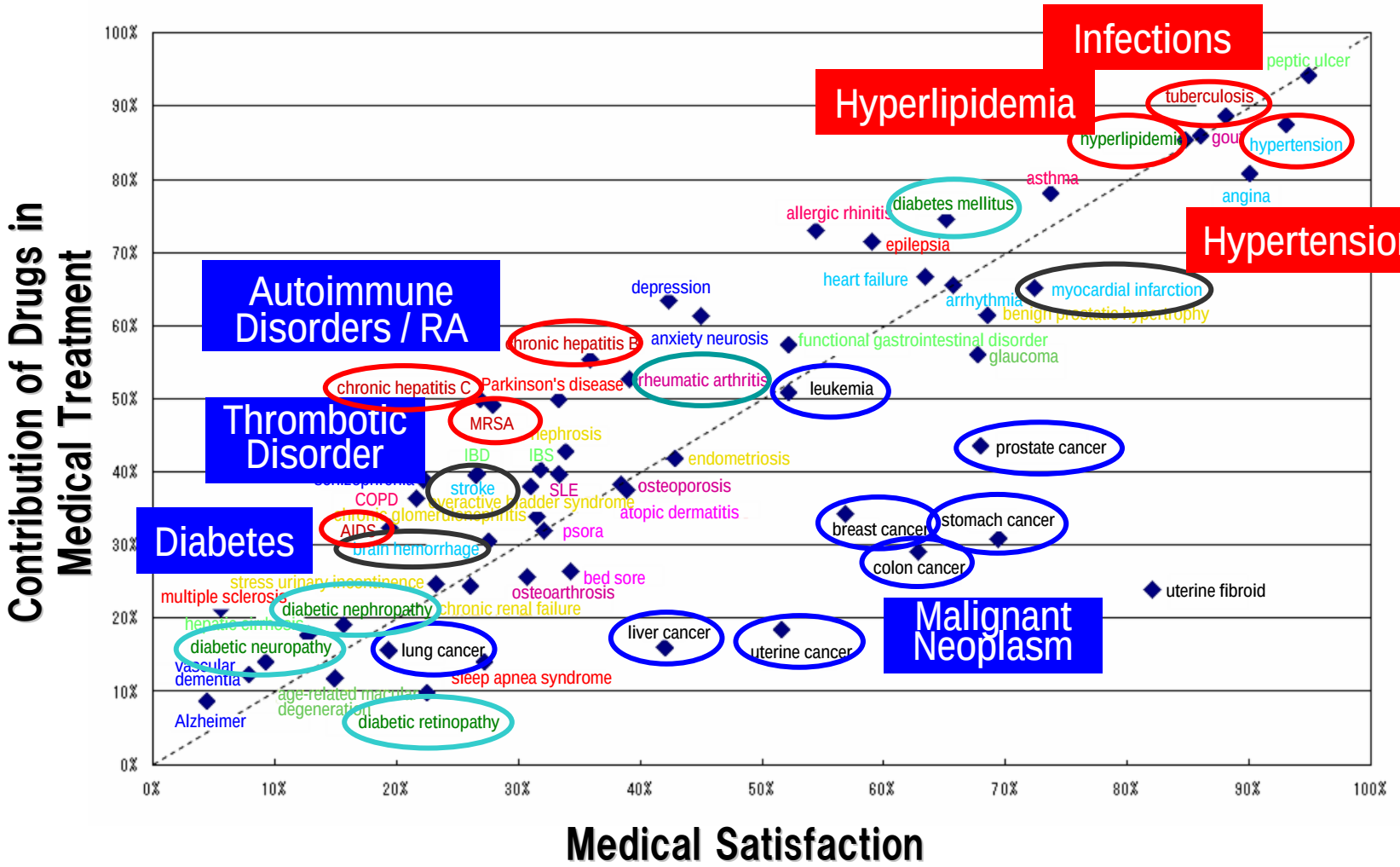
Correlation between Medical Satisfaction and Contribution of Drugs

Results of Questionnaire to Physicians



Japan Human Health Sciences Foundation;
Investigation of Japan fundamental technology report -View of medical treatment needs in 2015, (2005)

Therapeutic Area Prioritization

Core Disease Areas

Thrombotic Disorders	Malignant Neoplasm	Diabetes Mellitus	Autoimmune Disorders / RA

- High Unmet Medical Needs
- Novel products with high efficacy and good safety based on our excellent science and technologies

Franchise Areas

Hypertension	Bacterial Infections	Hyperlipidemia / Atherosclerosis

- Relatively Low Unmet Medical Needs because of good therapeutics including our products : Olmetec / Benicar, Cravit / Levaquin, Mevalotin / Pravachol, etc.
- Products with improved usefulness for patients by developing combination drugs, additional formulations, and others.





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

Daiichi-Sankyo



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