R&D Meeting 2009

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Memo

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R&D Highlights

- EFIENT® E.U. approval and first patients treated.
- Edoxaban Phase III multi-dose AF study initiated.
- Biotech partnerships with ArQule (ARQ197) and U3 Pharma.
- SEVIKAR® (olmesartan/amlodipine) EU approval.
- Start of Phase III for anti-influenza drug, CS-8958
- Denosumab (Amgen) positive Phase III studies in osteoporosis and cancer.

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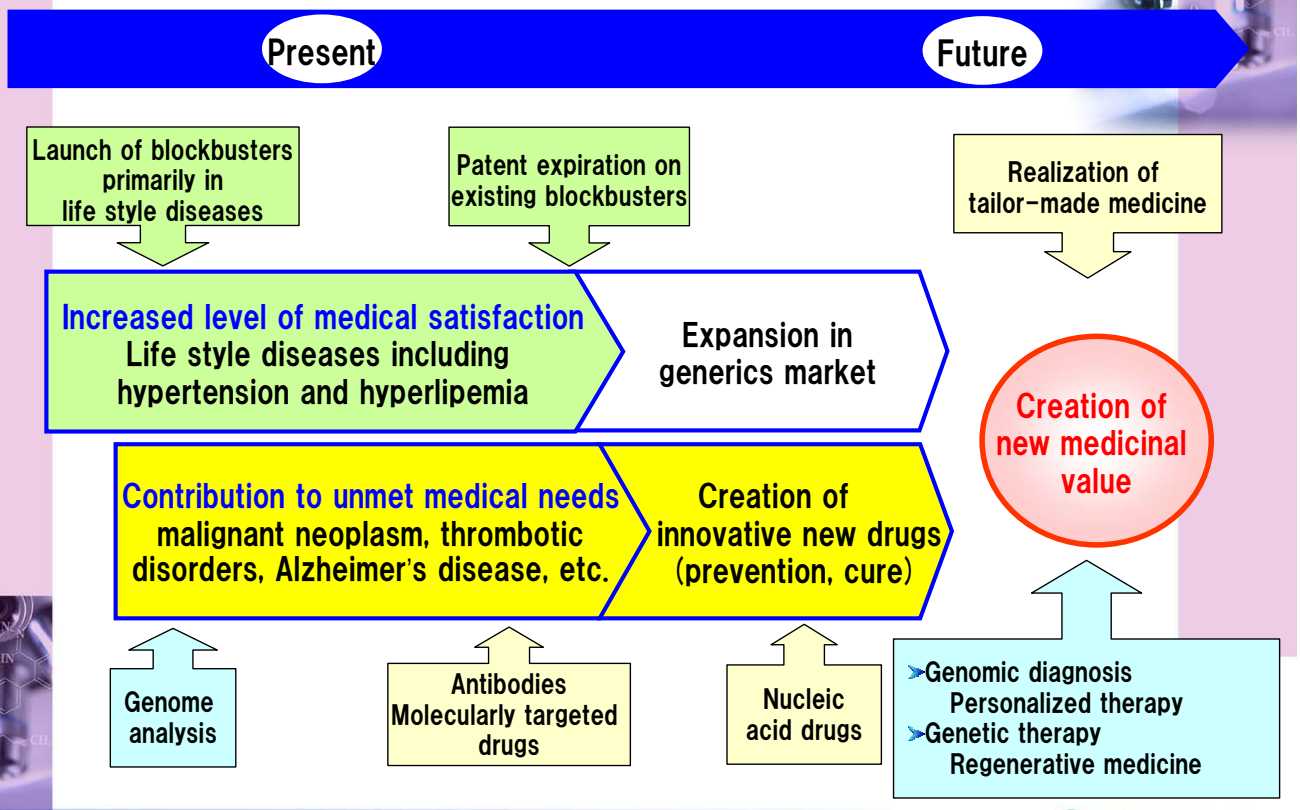
Trends in Medical Technology and Drugs



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R&D Challenges

- Increase innovation including new products from biotechs.
- Greater emphasis by regulatory agencies on drug safety.
- Continued increase in the cost of product development , greater need for clinical endpoint and safety experience.
- Development efficiency and outsourcing will be intensified.
- “Health technology assessments” of efficacy versus costs.
- Evolution to personalized medicine.

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Concept of Therapeutic Areas

R&D Core Disease Areas

Areas where R&D investment is focused on for development as our future growth drivers

- Thrombotic Disorders
- Malignant Neoplasm
- Diabetes Mellitus
- Autoimmune Disorders / RA

Franchise Areas

Areas on which current revenue is based and should be maintained and expanded

- Hypertension
- Hyperlipidemia / Atherosclerosis
- Bacterial Infections

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Prasugrel / Efient® / Effient™

Hospitalizations in the US Due to ACS

Acute Coronary Syndromes*

↓

1.57 Million Hospital Admissions – ACS

UA/NSTEMI**	STEMI
↓	↓
1.24 million	**0.33 million**
Admissions per year	Admissions per year

*Primary and secondary diagnoses.

**About 0.57 million NSTEMI and 0.67 million UA.

Heart Disease and Stroke Statistics – 2007 Update. *Circulation* 2007; 115:69–171

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Recent Trials Reporting Clinical Outcomes at 1 Yr for Patients with ACS Undergoing PCI

		Patients, n (%)			
	Total N	D/MI/TVR	Death	MI	TVR
ACUITY*	7789[a]	1465 (18.8)	247 (3.2)	682 (8.8)	928 (11.9)[b]
ISAR-REACT 2*	2022	515 (25.5)	94 (4.6)	202 (10.0)	301 (14.9)[c]

* Clopidogrel plus ASA

[a] Subset of patients in the ACUITY trial who underwent PCI

[b] Unplanned revascularization for ischemia.

[c] Target vessel revascularization = CABG or repeat PCI for symptoms or ischemia.

White HD et al. *JACC* 2008; 52: 807-814
Ndrepepa G et al. *EHJ* 2008; 29: 455-461

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Major Milestones in FY2008

- Jun 24, 2008 – FDA Extends Review Period for Prasugrel
- Sep 27, 2008 – FDA Continues to Review Prasugrel NDA
- Dec 18, 2008 – CHMP provided positive opinion to prasugrel approval
- Feb 3, 2009 – FDA Cardio-Renal Advisory Committee unanimously recommended approval for prasugrel.
- Feb 25, 2009 – EU approves EFIENT® for ACS PCI.

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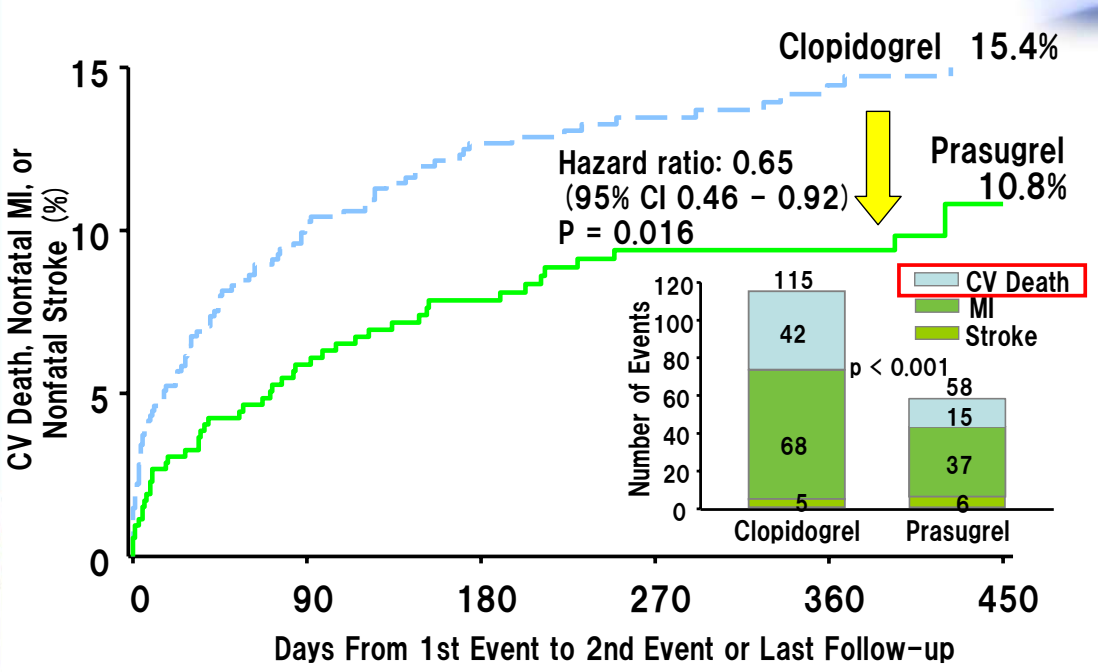
TRITON Sub-Analysis (Recurrence)

- *Prasugrel significantly prevented recurrence of primary composite endpoint, including CV death*



Murphy SA et al. *EHJ* 2008; 29: 2473-2479

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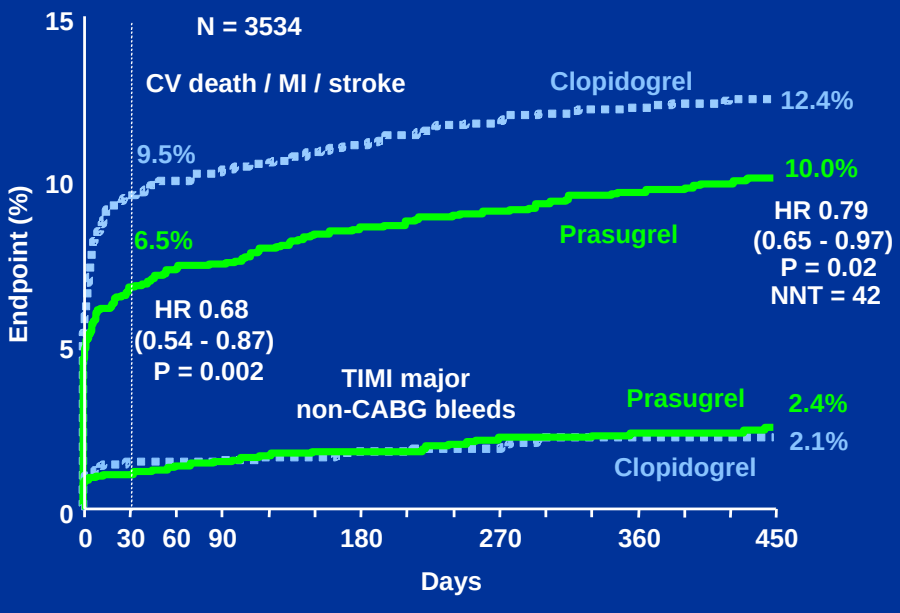
TRITON Sub-analysis (STEMI)



Montalescot G et al *Lancet* 2009, 373 723-731

- ST elevation MI (STEMI) refers to patients with a more severe form of heart attack – as detected by electrocardiogram
- 32% risk reduction at 30 days of treatment
- 21% risk reduction at 15 months of treatment
- No significant difference in TIMI Major non-CABG bleeding

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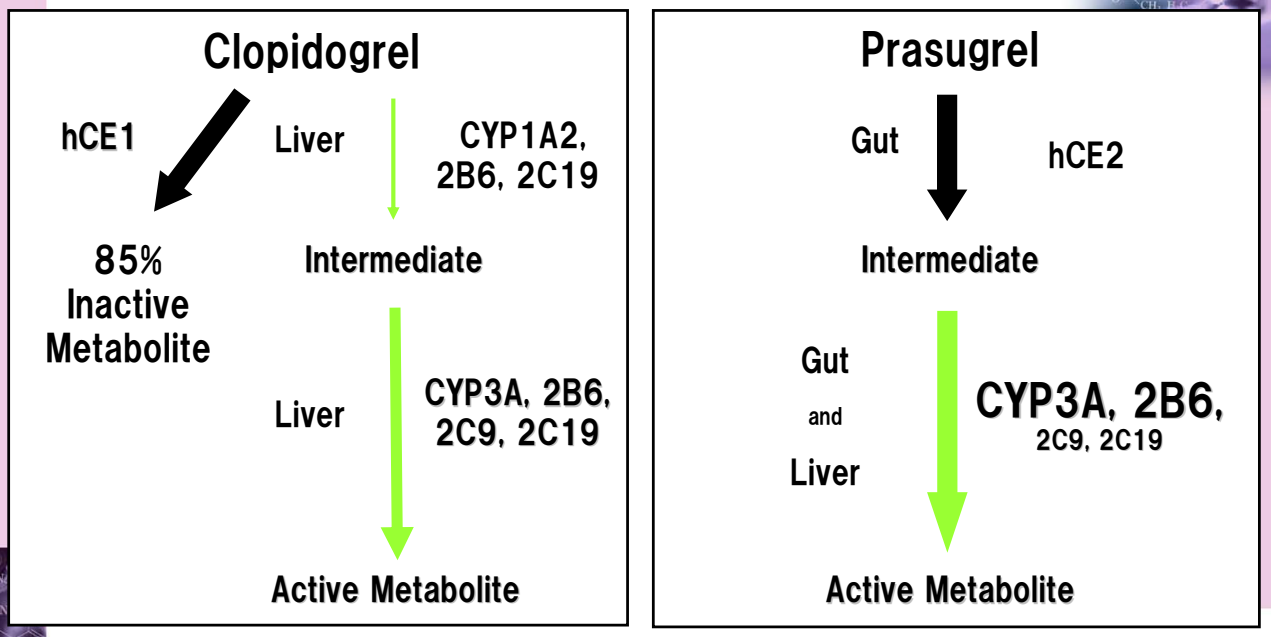
Prasugrel Is More Effective and Less Variable (Metabolic pathway)



CYP2C19 variants and inhibitors affect the PK and PD of clopidogrel

Prasugrel has no clinically relevant interactions with CYP2C19 variants or inhibitors

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EU Labeling Summary (1)

Indication Statement

- Efient®, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).

Posology

- 60 mg LD & 10 mg MD
- Very Elderly (≥75 years)
  - Use generally not recommended
  - Individual benefit/risk evaluation
  - 5 mg MD (after 60 mg LD)
- Patients weighing <60 kg
  - 5 mg MD (after 60 mg LD)

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EU Labeling Summary (2)

- Duration of Treatment
  - Treatment of up to 12 months
- Contraindications
  - Hypersensitivity to active substance or to any of excipients
  - Active pathological bleeding
  - History of stroke or TIA
  - Severe hepatic impairment

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Additional Indication (Medical Management)

- TRILOGY
  - ACS Medical Management indication
  - Study commenced in June 2008
  - 10,000 patients, 800 hospitals in 35 countries
  - ACS-PCI plus ACS-Medical Management represents approximately 60% of Plavix sales
  - Includes a 5 mg dose
  - Leverage key lessons from TRITON

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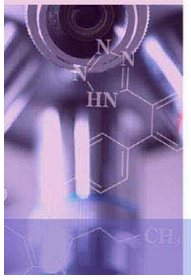
Edoxaban (DU-176b)



DU-176b is now

Edoxaban

the Journey begins

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 AF
Food Effects	No
Monitoring	No

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Oral FXa Inhibitor: Edoxaban

- A series of Phase IIb studies completed

Indication	Phase IIb		Phase III
AF Prevention of thromboembolic event in atrial fibrillation	US/EU	Presented at ASH (Dec 2008)	Started in Nov 2008
	Japan	Completed (Plan to present in 2009)	
	Asia	Completed (Plan to present in 2009)	
VTE Prevention of post-surgical thromboembolic event)	US/EU Japan	Presented at ESC (Sep 2009) Presented at APSTH (Sep 2008), at ASH (Dec 2008)	Started in Mar 2009
VTE Prevention of thromboembolic event in patient with DVT/PE			Plan to start in 4Q 2009

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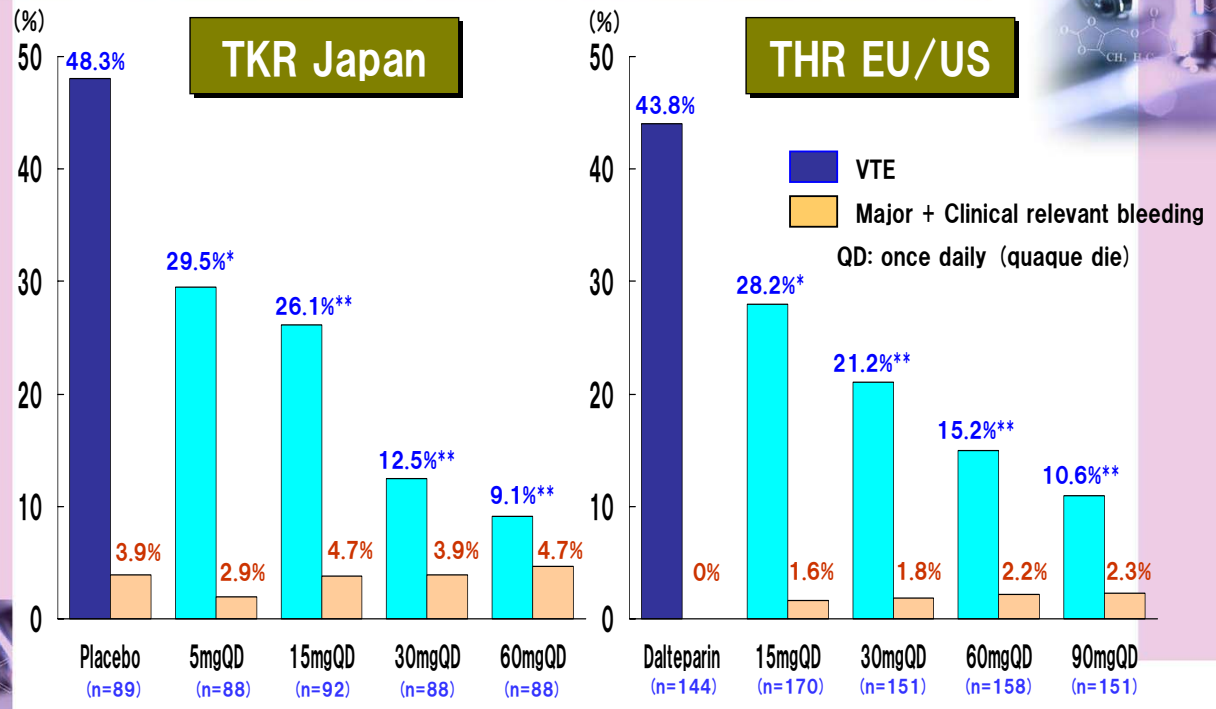
Ph IIb Results in THR & TKR



*p=0.005 (vs Control) **p<0.001 (vs control)
Dose-dependency in VTE incidence: p<0.001 (Cochran-Armitage)
No increase in major or clinically relevant bleeding

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Summary of Ph IIb 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**

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VTE Ph III Studies

<TKR, THR Phase III Studies, JAPAN>

- Primary Objective
  - Assess the efficacy of Edoxaban in the prevention of VTE vs. Enoxaparin in THR or TKR

THR: total hip replacement
TKR: total knee replacement

- Patient population
  - Patient undergo elective THR or TKR
- Design
  - Randomized, double-blind
- Dose, Treatment period and First dosing
  - 30mg once daily for 11-14 days , 6 to 24 hours after surgery
- Number of patients
  - 600 (THR), 520 (TKR)

<VTE Global Phase III Study: Plan to start in 4Q 2009>

- Prevention of thromboembolic event in DVT/PE

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Protocol of Ph IIa in Atrial Fibrillation : Japan

- Objective
  - Evaluation of safety and effect on biomarker of Edoxaban in comparison with Warfarin
- Patient population
  - Warfarin naïve non-valvular atrial fibrillation (NVAF)
- Study design
  - Open-label, dose-escalation
- Dose, duration of treatment and petient number
  - 5mg 2wk→15mg 2wk→30mg 2wk, once daily, 24 patients
  - 30mg 2wk→45mg 4wk→60mg 4wk, twice daily, 32 patients

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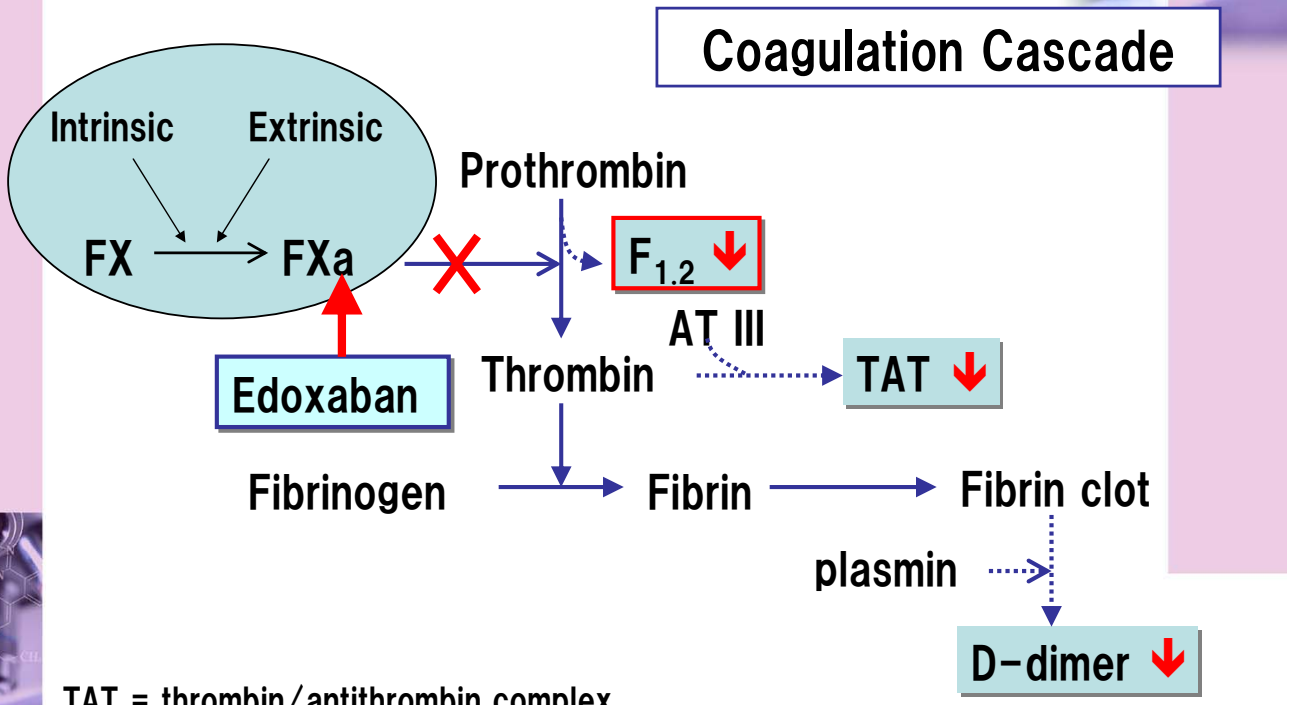
Edoxaban : Mechanism of Action



TAT = thrombin/antithrombin complex

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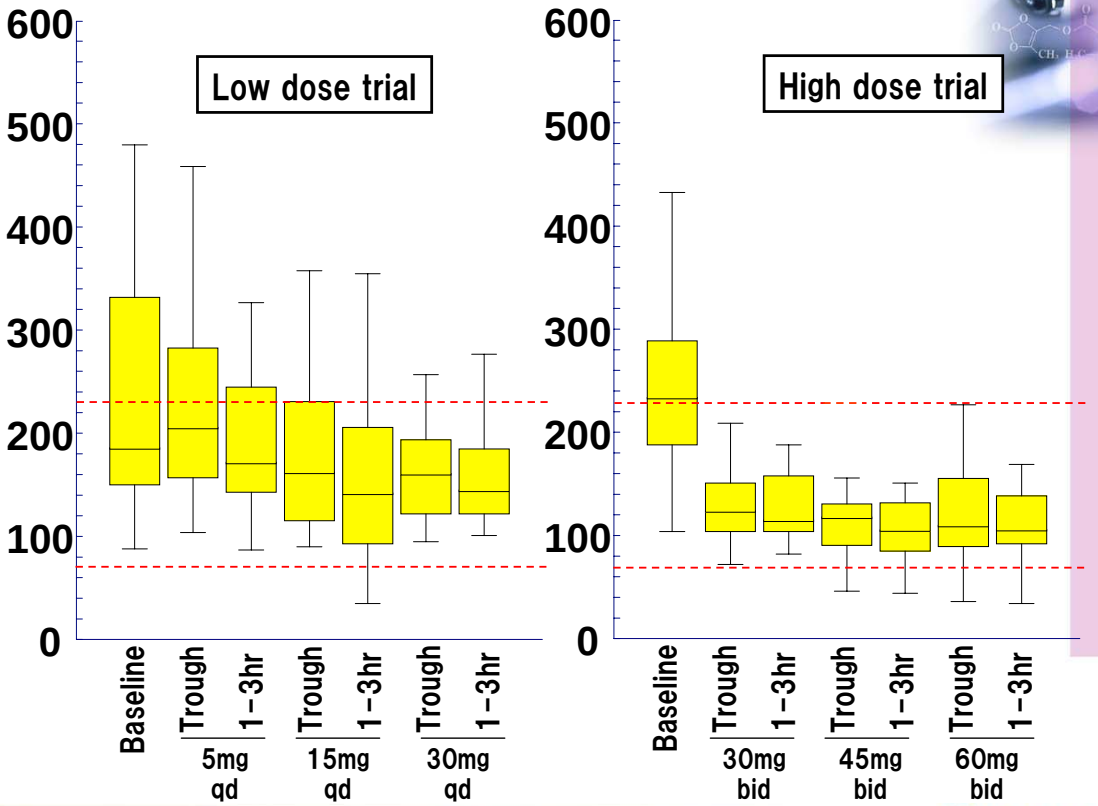
Effect of Edoxaban treatment on biomarker F_{1+2}



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Summary of Ph IIa Results in AF : Japan

- Relationship between plasma concentration of Edoxaban and PT prolongation, anti-Xa activity
- Decrease in biomarkers (D-dimer, TAT, F1+2) by Edoxaban administration
- No thromboembolic event, major bleeding, serious adverse drug reaction observed

ACC (Mar 29, 2009, Orlando)

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Protocols of Ph IIb in Atrial Fibrillation Studies

- Objective
  - Evaluation of safety of Edoxaban in comparison with warfarin
- Patient population
  - Non-valvular atrial fibrillation (NVAF)
- Study design
  - Randomized, double-blinded (open-label warfarin)
- Duration of treatment
  - 3 months
- Number of patients
  - 1,146 (US/EU)
  - 536 (Japan)
  - 235 (Asia)

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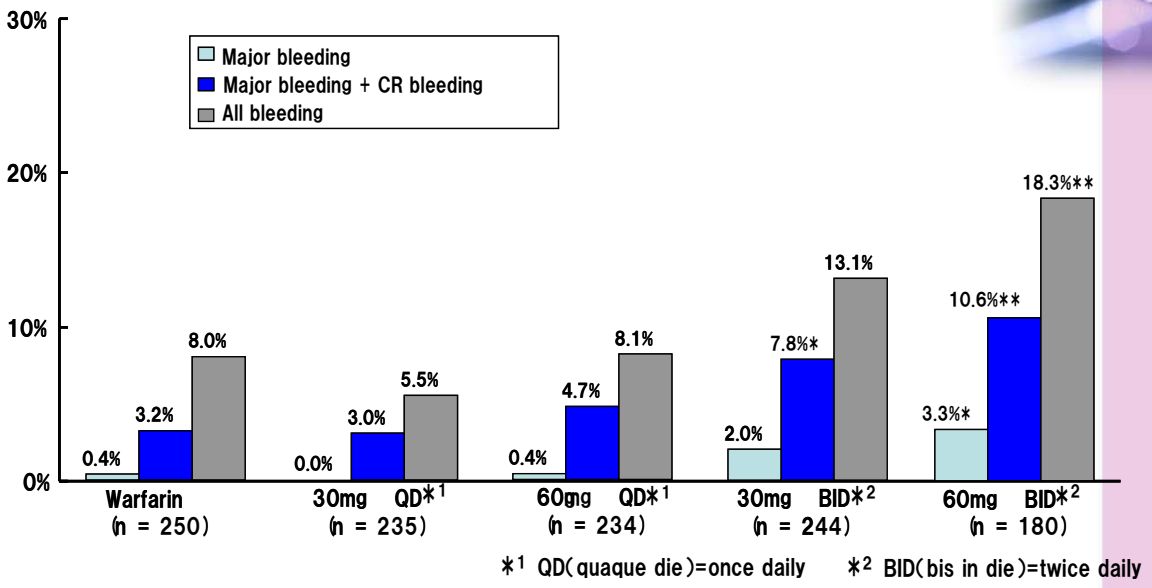
Safety of Edoxaban in NVAF : US/EU



* p<0.05 ** p<0.01 (vs Warfarin)
Bleeding events of 30mg QD and 60mg QD were comparable to those of Warfarin

Am Soc Hematology
(Dec 7, 2008, San Francisco)

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Summary of Ph IIb studies in AF

- In Edoxaban 30mg or 60mg once daily groups:
  - Comparable clinically relevant bleeding rate to Warfarin
  - No difference observed in cardiac event compared to Warfarin
  - Predictable PK/PD profile
  - Decrease in biomarkers at 24 hrs after dosing
- Select Edoxaban dosing regimen for global Phase III study; 30mg or 60mg once daily

Japan AF study and ENGAGE AF dosing regimen
-> ISTH 2009 (Boston)
Asian AF study -> Scientific Conference in 2009

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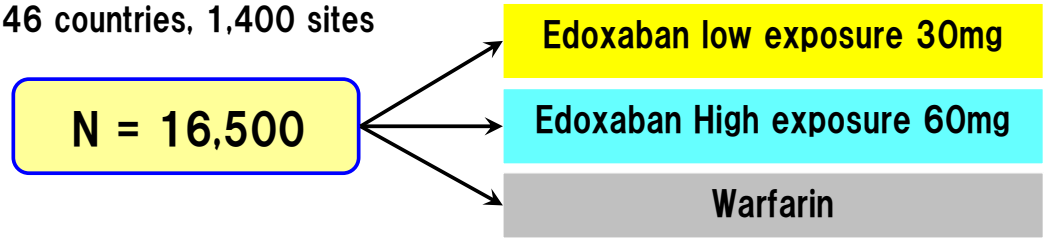
ENGAGE-AF (Edoxaban Ph III)

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
- 46 countries, 1,400 sites



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

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Edoxaban Best in Class Inhibitor of Blood Coagulation Factor Xa

- Multiple Chronic Indication Strategy
  - Phase III AF study started in Nov 2008
  - Phase III post-orthopedic surgery study started in March 2009 in Japan
  - Phase III DVT/PE study planned to be started in 4Q 2009
- No hepatotoxicity signals in pre-clinical including toxicogenomics and clinical studies
- Significant market opportunity but with competitors

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Denosumab (AMG 162)

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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, and bone metastases.

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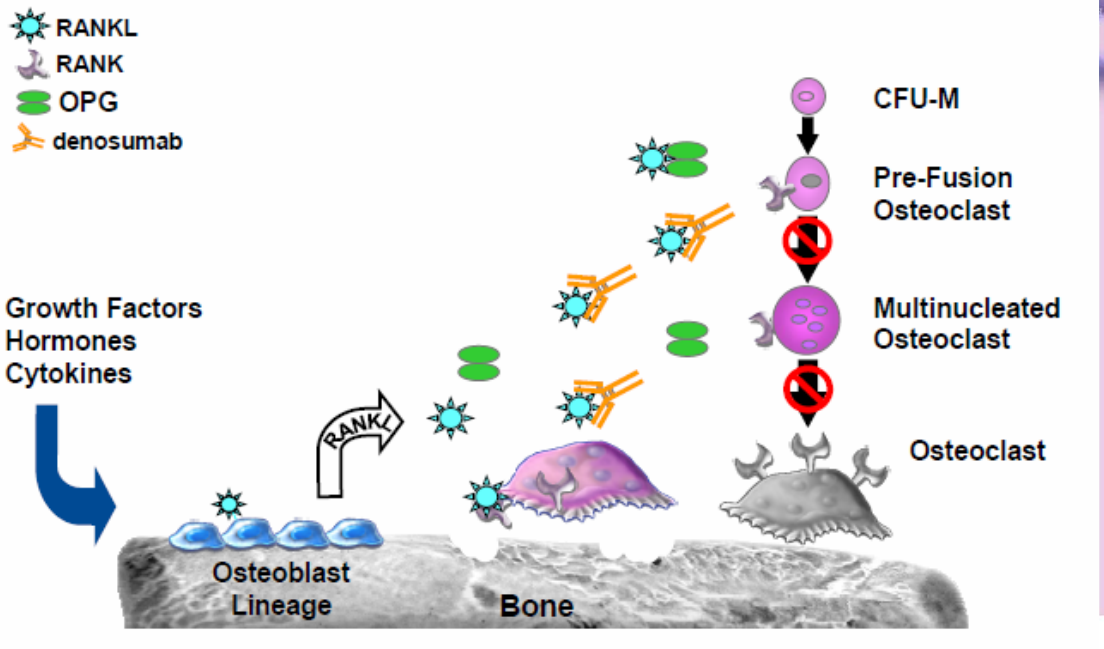
Proposed Mechanism of Action of Dmab



CFU-M: colony-forming unit-macrophage

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Development Overview

Indication	Dose	Development Stage	
		Japan	US/EU
PMO	60 mg every 6 months SC	Ph III	BLA submitted
HALT	60 mg every 6 months SC	-	BLA submitted
Oncology (Bone Metastasis)	120 mg every 4 weeks SC	Ph III	Ph III
Rheumatoid Arthritis	TBD	TBD	Ph II

PMO: postmenopausal osteoporosis, HALT: hormone ablation therapy

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Development Status in Japan

- Osteoporosis
  - Phase III study (DIRECT*) : Ongoing
    - A Randomized, double-Blind, placebo-controlled study evaluating efficacy and safety of Dmab in Japanese osteoporotic subjects
    - Primary endpoints
      - Reduction in the incidence rate of fragility vertebral fractures
      - Safety profile

*:DIRECT stands for Denosumab fracture Intervention Randomized Placebo Controlled Trial in Japanese patients with osteoporosis

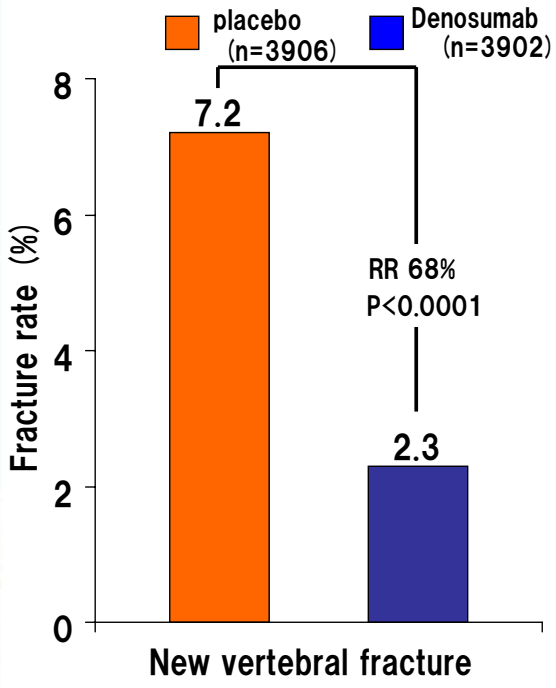
- Bone Metastasis
  - Phase III multinational studies : Ongoing
    - A randomized, double-blind, multicenter study of Dmab compared with Zoledronic Acid (Zometa®) in the treatment of bone metastases in subjects with advanced breast cancer

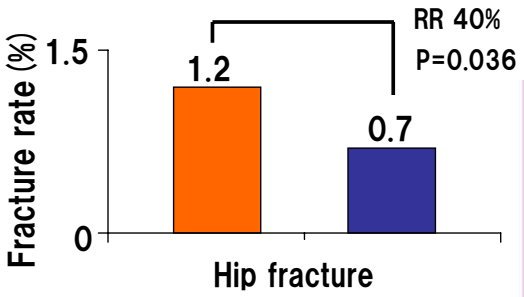
Development Status in Overseas

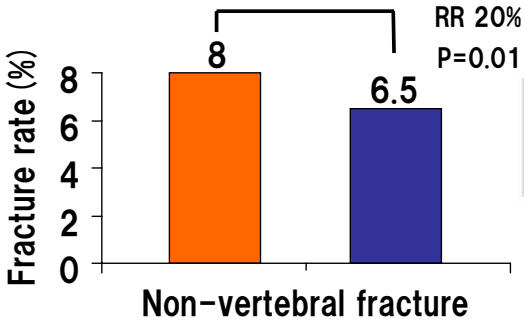
- PMO and HALT indication
  - Amgen submitted biologics license application (BLA) for FDA approval of Dmab in women with postmenopausal osteoporosis (PMO) and in patients undergoing hormone ablation therapy (HALT) for either prostate or breast cancer on December 19, 2008

- Amgen obtained the results of Phase III pivotal fracture study (FREEDOM)
  - The study met primary and all secondary endpoints
  - Incidence and types of adverse and serious adverse events, including serious infections and neoplasm, were similar between Dmab and placebo groups

FREEDOM:
Dmab 60 mg Q6M Reduced the Fracture Risk at 36 Months







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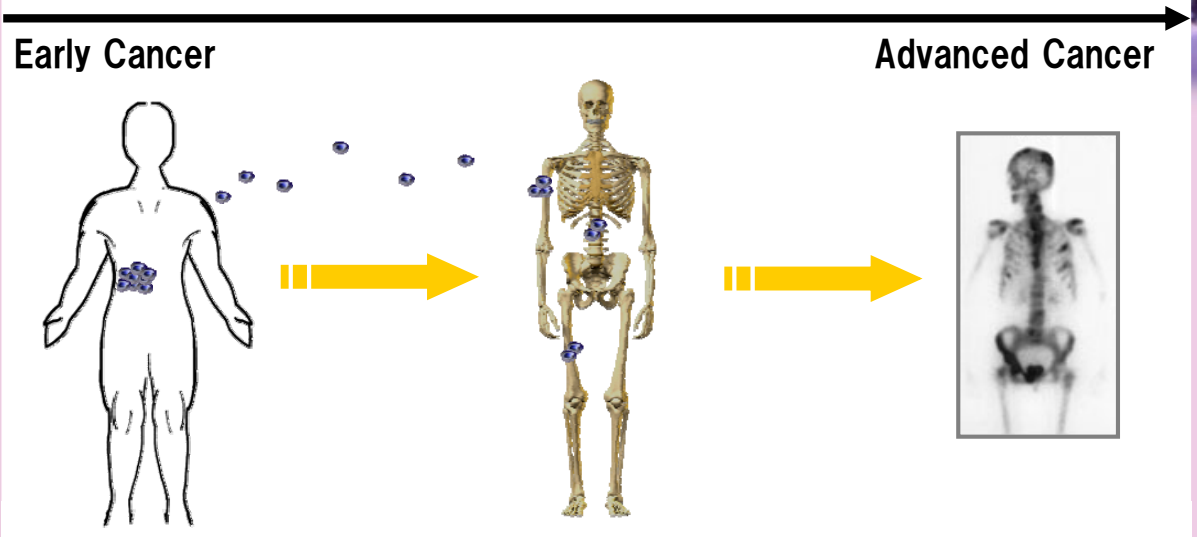
Dmab Is Being Studied in Multiple Stages of Cancer



Cancer Treatment–Induced Bone Loss	Prevention of Bone Metastases	Prevention of Skeletal Related Events (SREs)
HALT Study	Bone Mets Prevention Study	SRE Study

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HALT Indication: Recent Outcomes

- Amgen obtained the results of Phase III pivotal study in men with non-metastatic prostate cancer undergoing androgen deprivation therapy
  - Greater increases in BMD at the lumbar spine (primary endpoint) and non-vertebral sites compared with placebo
  - Less than half the incidence of new vertebral fractures compared with placebo
  - Similar incidence and types of adverse events between the Dmab and placebo groups

BMD: bone mineral density

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Oncology Franchise

- Collaboration
- ARQ 197
- Tigatuzumab, CS-1008
- CS-7017
- Nimotuzumab, DE-766
- U3-1287

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Collaboration : U3 Pharma & ArQule Inc.

U3 PHARMA

- Acquisition (21st May 2008)
- Initiation of Collaboration with U3 Pharma
  - 1st Integrated Project Team Meeting (24th July 2008)
- Initiation of Collaboration with Amgen
  - Joint Project Team Meeting (30th July 2008)
  - Joint Steering Committee (30th July 2008)

ARQULE

- Strategic R&D Partnership (AKIP) (11th Nov. 2008)
- License, co-development and co-commercialization agreement (ARQ 197) (18th Dec. 2008)
- Initiation of Collaboration
  - Work Shop (17th/18th Dec. 2008)
  - 1st Joint Working Team Meeting (9th Feb. 2009)

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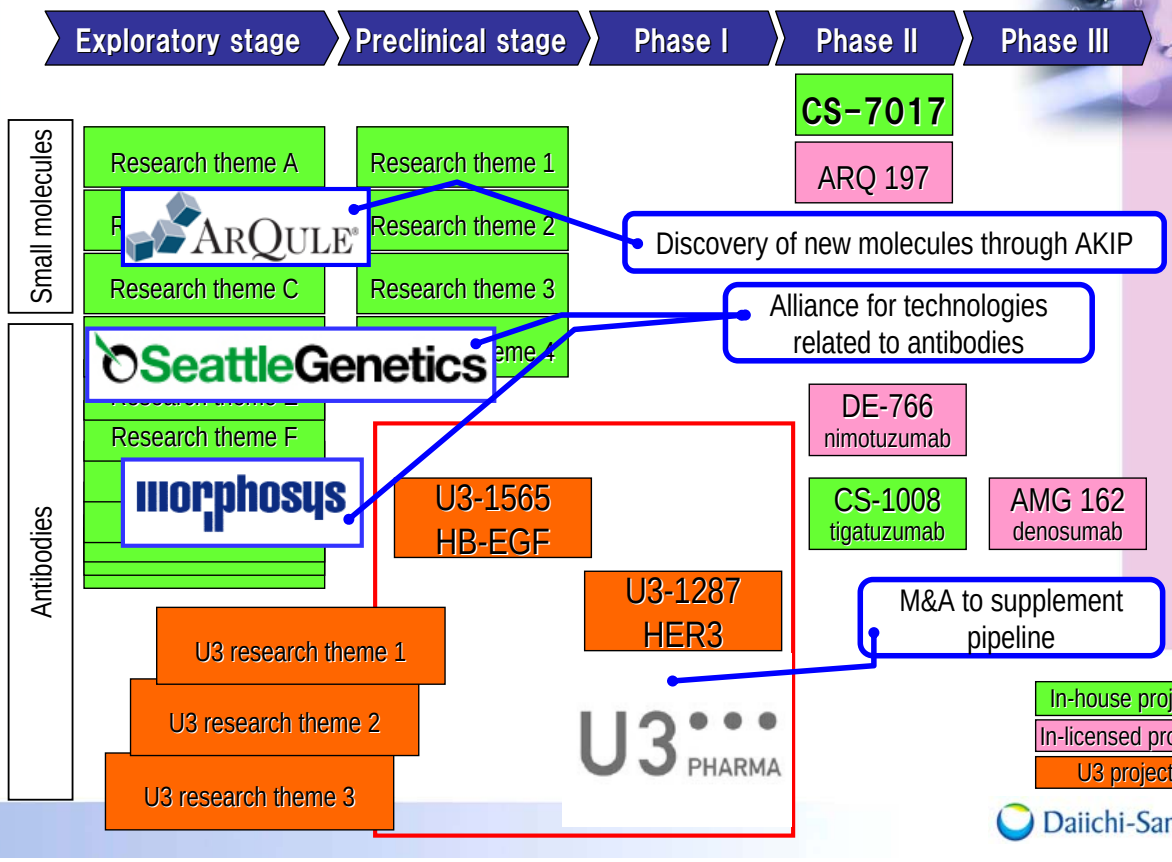
Malignant Neoplasm Pipeline



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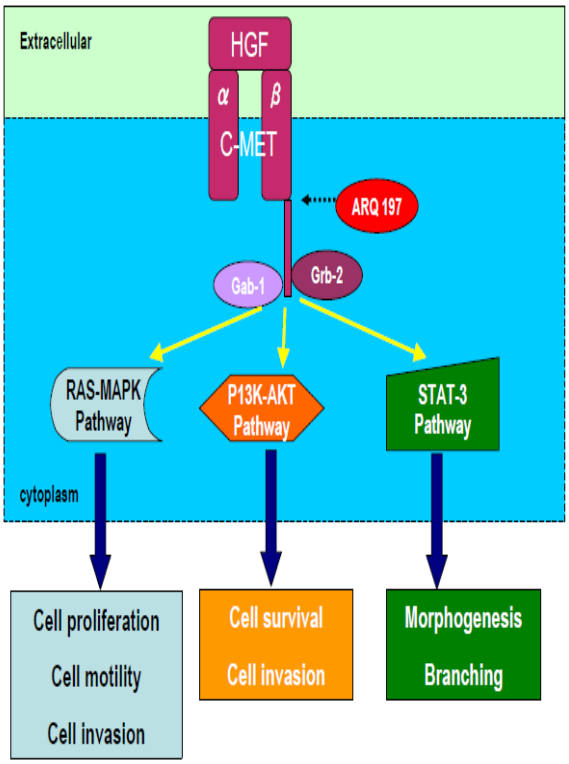
ARQ 197



- c-Met: receptor for tyrosine kinase of hepatocyte growth factor (HGF)
  - Multiple roles in intracellular signal transductions such as cancer cell motility, proliferation, angiogenesis, invasion, and apoptosis induction
- Variation of c-Met
  - Gastric, HCC, Head and Neck cancer
- High expression of c-Met
  - Colon, HCC, Pancreatic, Prostate, Breast cancer, etc
- Current Development Status
  - US/UK Phase I studies on-going
  - US/EU Phase II studies on-going
  - (MiT, NSCLC, Pancreatic)

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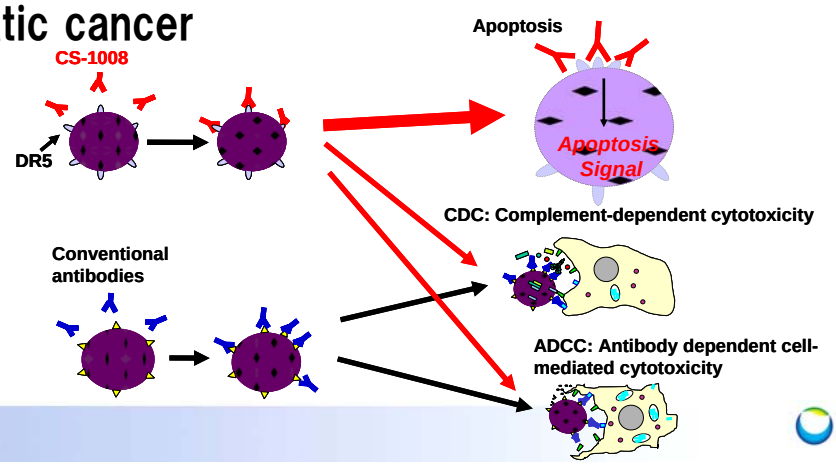
Tigatuzumab CS-1008 (1)

- Agonistic Mab raised against human death receptor 5 (DR5)
  - A humanized version TRA-8, a murine agonistic Mab
  - Rare DR5 expression in normal tissues, expected to show selective activity against tumor cells
  - Induces apoptosis as well as CDC and ADCC in tumor cells expressing DR5 on the cell surface
- Target Disease: Several solid tumors including pancreatic cancer



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Tigatuzumab CS-1008 (2)

Current Development Status

- US Phase I study completed
  - Good safety profile in human as well as in preclinical studies
  - Several patients experienced long term disease stabilization
- Japan Phase I study ongoing
- US Phase II study ongoing
  (Pancreatic cancer)
- Other Phase II studies to be initiated

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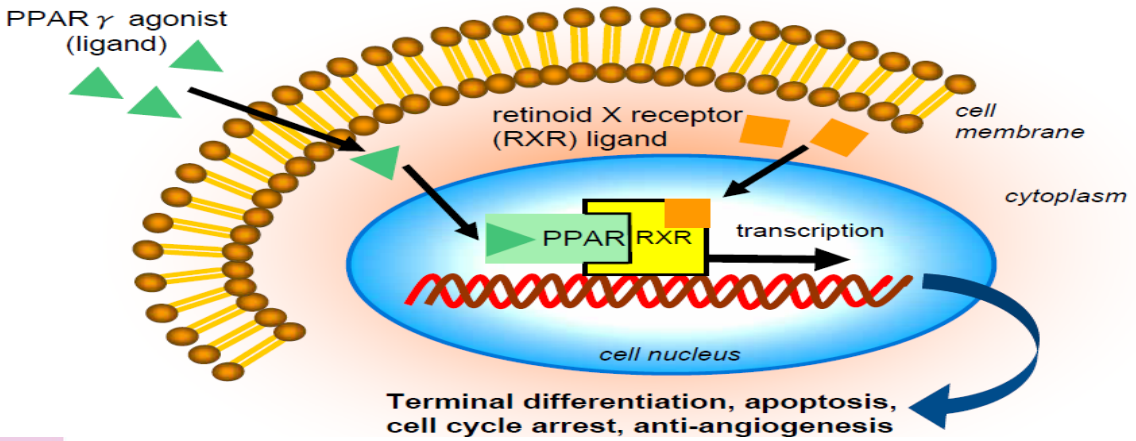
CS-7017



- Anti-tumor PPAR-gamma activator
- Inhibits growth of tumor cells in vitro without killing those cell
  - Expected to be less toxic compared to standard chemotherapeutics
- Effective against human tumor-implanted in vivo models
- Current Development Status
  - US Phase Ib/II study on-going (ATC)
  - US Phase II study on-going (NSCLC)

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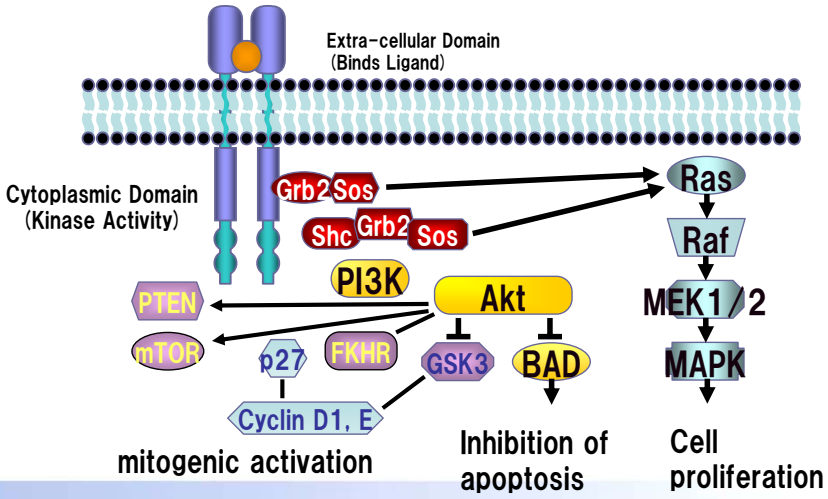
Nimotuzumab DE-766 (1)

- A humanized monoclonal antibody that binds to epidermal growth factor receptor (EGFR, member of the tyrosine kinase family of cell surface receptors)
  - Targeting the extracellular ligand-binding domain and block the intracellular tyrosine kinase (TK) domain.



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Nimotuzumab DE-766 (2)

- Target indication; tumors expressing EGFR
  - Glioma, NSCLC, Esophagus, Gastric etc
- Development Status (Japan)
  - Phase I study: completed
  - Phase II study (Gastric) in Japan and Korea: started in 3Q 2008
- Superior safety in terms of skin rash and comparable efficacy to other EGFR Mabs
- Current Status in Other Countries
  - Head & Neck cancer: Approved in Cuba, India etc.
  - Nasopharyngeal carcinomas: Approved in China and Cuba
  - Glioma: Approved in Cuba, Ukraine, Indonesia etc.
    Phase III study is ongoing in Germany

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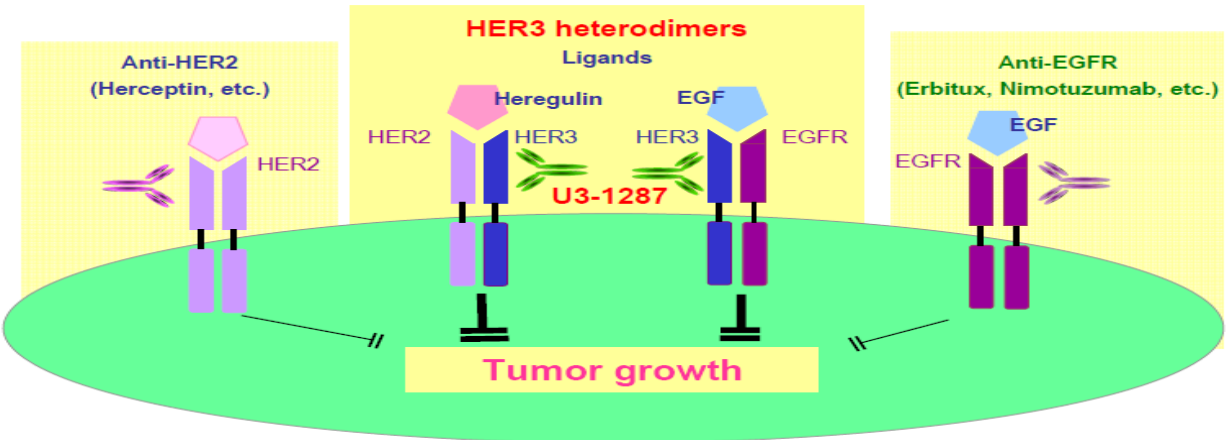
U3-1287: Anti-HER3



- HER3: Third member of the EGFR family
- HER3 heterodimers have relatively higher mitogenic potential than HER2 homodimers or EGFR homodimers
- Expression upregulated in several cancer cells
  - breast, gastrointestinal, lung, pancreas, prostate, skin tumors, etc.
- Current Development Status
  - US Phase I study on-going

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CS-8958

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Concept of Anti-influenza drug CS-8958

Long Acting Neuraminidase Inhibitor

LANI

Long Acting Anti-influenza Drug

Neuraminidase inhibitors in the market

Relenza (inhalation)
Tamiflu(oral agent)

- Twice daily for 5 days for treatment (10 times)
- Once daily for 7-10 days for prophylaxis

CS-8958 (inhalation)

- Single administration for treatment
- Once weekly for prophylaxis

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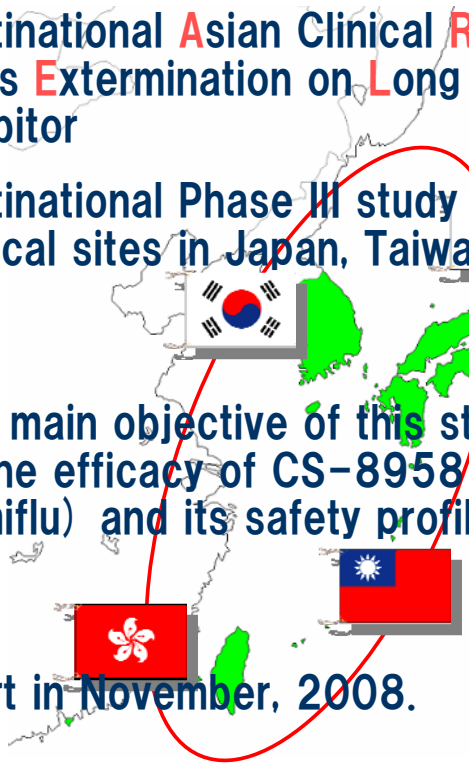
CS-8958 Phase III study -MARVEL Study-

- Multinational Asian Clinical Research for Influenza Virus Extermination on Long acting Neuraminidase-Inhibitor
- Multinational Phase III study conducted at 127 clinical sites in Japan, Taiwan, Korea and Hong Kong
- The main objective of this study is the confirmation of the efficacy of CS-8958 (non-inferiority to Tamiflu) and its safety profile.
- Start in November, 2008.



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Clinical Development Strategy (2008~2009 flu season)
– Wide-Range of Clinical Use, from Pediatrics to Elderly –

Below 9 years	10-19 years (restriction on use of Tamiflu)	Over 20 years
Phase II / III study CS-8958 *vs* Tamiflu (Assessments of Efficacy, Safety)	Phase III open labeled study (Assessments of Efficacy, Safety)	Multinational Phase III study (MARVEL Study)
PK study (below 15 years)		Phase II Multi Dose Study
		Phase III study for Device Switching

- The patient enrollments of all the clinical trials for CS-8958 in this flu season successfully were finished.
- The total numbers of the patients for these studies are more than 1500.

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Levofloxacin 500 mg PO & IV

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Levofloxacin oral 500 mg qd (sNDA)

- Change the dosing regimen to prevent acquisition of resistance
  - Avoid accumulation of one-point mutant of target enzymes, which easily acquire resistance after an additional mutation
  - Develop relationship among academia, authority, and industry
  - 500 mg qd regimen is global standard
  - Efficacy and safety profiles are confirmed in Japan and China
  - Tablets (250 mg and 500 mg) and fine granule (10%)
- The same application (32 bacterial species) and indication (43) as the application of existing regimen of 100 mg tid
- Symposium at 57th Annual meeting of Japanese Society for Chemotherapy (June 5th, 2009)

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Oral 500 mg qd development rationale

Efficacy and acquisition of resistance to quinolones is well correlated with AUC/MIC and Cmax/MIC values.

【Prevention of resistance in *S. pneumoniae* by PK-PD analysis】

100 mg tid (AUC 24.5 μg·h/mL, Cmax 1.8 μg/mL)

Wild-type strains → (1/10^7) → One-point mutants → (1/10^7) → Highly resistant strains

LVFX MIC≒0.5 | MIC≒2 | MIC≒16～32 μg/mL

- Cmax/MIC value which is required to avoid resistance is not achieved in some wild-type strains → Reservoirs of one-point mutation are accumulated
- Highly resistant strains will appear after an additional point mutation to reservoirs

500 mg qd (AUC 58.0 μg·h/mL, Cmax 7.4 μg/mL)

Wild-type strains → (no) → One-point mutants

LVFX MIC≒0.5 | MIC≒2 μg/mL

- Dosing regimen based on PK-PD (AUC/MIC≧30 and Cmax /MIC≧5)
  → No reservoirs appeared
- Effective against one-point mutants

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Levofloxacin injection

- Product profile
  - First injectable quinolone for respiratory infections in Japan
  - Efficacy against Gram-positive and Gram-negative bacteria (*S. pneumoniae* etc) and atypical pathogens (*Legionella* spp, *Mycoplasma pneumoniae* etc)
  - Ideal dosing regimen based on PK-PD analysis and sequential therapy from injection to oral levofloxacin is possible
  - Once a day regimen, which is convenient for not only inpatients but also outpatients
  - Approved in 123 other countries
- Target indication: Pneumonia, AECB
- Development stage: Phase III (Enrollment finished)
- NDA: Planned for 1Q 2010

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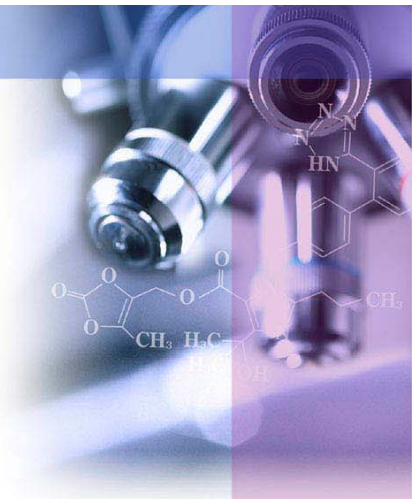
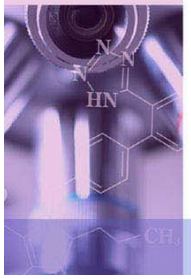


Olmesartan Franchise



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Olmesartan Combination Drug

US・EU

- CS-8663: Combination drug with Amlodipine
  - Oct 2007 Launch in US, Brand name: AZOR®
  - Aug 2008 Approved in Netherlands

  ⇒ Currently getting approval from 22 countries

  ⇒ Launch in the Netherlands and Germany, Brand name:Sevikar®

- CS-8635: Combination drug with Amlodipine and Hydrochlorothiazide
  - Phase III on-going in US
  - NDA expected in 4Q 2009

Japan

- CS-866AZ: Combination drug with Azelnidipine*
  - Dec 2008 NDA filed

** Azelnidipine is marketed in Japan as brand name of Calblock*

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Olmesartan Lifecycle Management

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

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

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Closing Remarks

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Concept of Therapeutic Areas

R&D Core Disease Areas

Areas where R&D investment is focused on for development as our future growth drivers

- Thrombotic Disorders
- Malignant Neoplasm
- Diabetes Mellitus
- Autoimmune Disorders / RA

Franchise Areas

Areas on which current revenue is based and should be maintained and expanded

- Hypertension
- Hyperlipidemia / Atherosclerosis
- Bacterial Infections

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Approach for Thrombotic Disorders

Prasugrel
Anti platelet agent
Arterial thrombosis

TRÎTON TIMI-38

TRILOGY ACS

Edoxaban
Anti-coagulant agent
Venous thrombosis

Engage AF TIMI 48

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Approach for Malignant Neoplasm

Promote our own R&D activity

ArQule

morphosys

U3 PHARMA

SeattleGenetics

Biologics Research Laboratories

Expand development pipeline

AMGEN

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Franchise Areas

Daiichi Sankyo has been contribute to the global medical needs in these franchise areas

Hypertension	Hyperlipidemia	Bacterial Infection
Olmesartan > 50 countries	Pravastatin > 100 countries	Levofloxacin > 120 countries
オルメテック錠	メバロチン	クラビット Cravit 錠／細粒
Benicar HCT (olmesartan medoxomil • hydrochlorothiazide)	PRAVACHOL (pravastatin sodium)	LEVAQUIN (levofloxacin) Tablets/Injection (levofloxacin in 5% dextrose) Injection
AZOR amlodipine besylate olmesartan medoxomil		

Contribution to further medical needs by additional value

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