




Today's explanation projects


	Candidates for development	Phase 1	Phase 2	Phase 3
Cardiovascular	DZ-697b (JP)	CS-747 (JP) DZ-697b (US/EU)	DU-176b (US/EU/JP) CS-9803 (US/EU)	CS-747 (US/EU) CS-8663 (US/EU)
Cancer	CS-1008 (US/EU)	DJ-927 (JP) CS-7017 (US/EU)	DJ-927 (US/EU)	
Infection	DC-159a (US/EU/JP) DX-619 (JP)	DX-619 (US/EU) CS-8958 (US/EU)	CS-023 (JP)	
Glucose metabolism	CS-011 (JP)		CS-011 (US/EU) CS-917 (US/EU)	WeiChol DM (US)
Immunity and allergies	CS-0777 (US/EU)			

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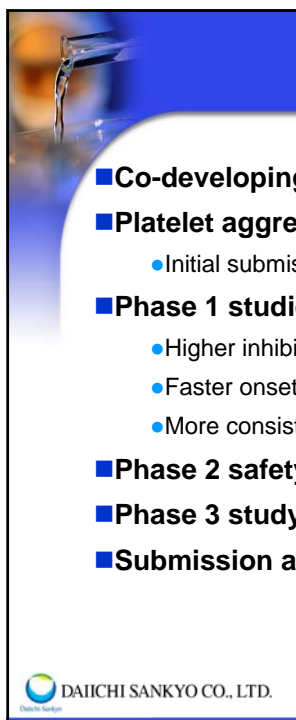


Cardiovascular Diseases

Prasugrel (CS-747)
CS-8663
DU-176b
DZ-697b
CS-9803




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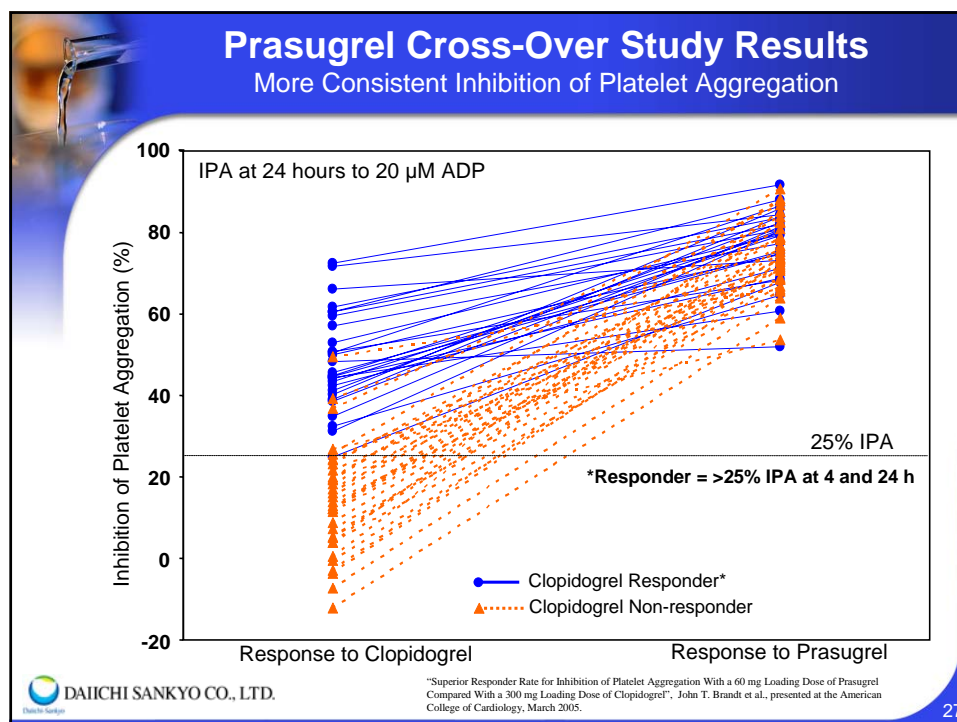
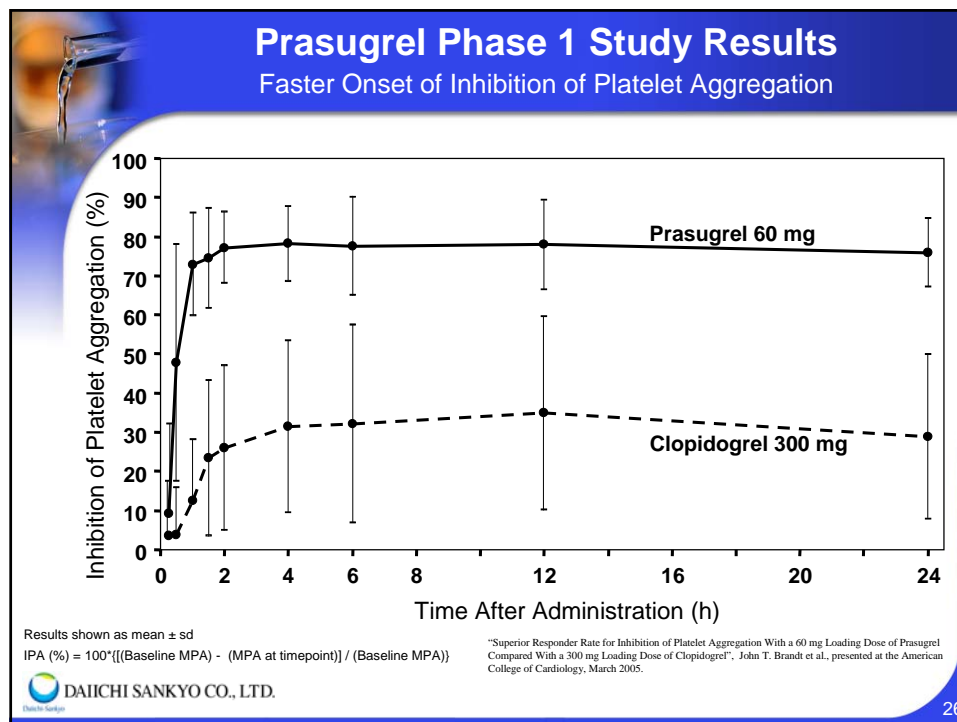
Prasugrel (CS-747)

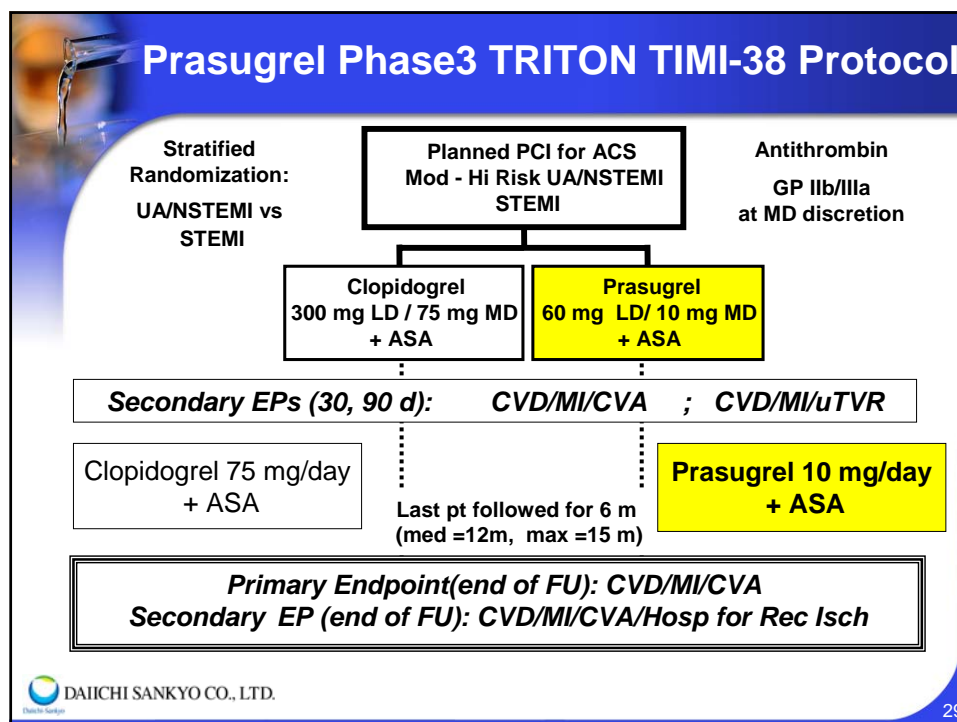
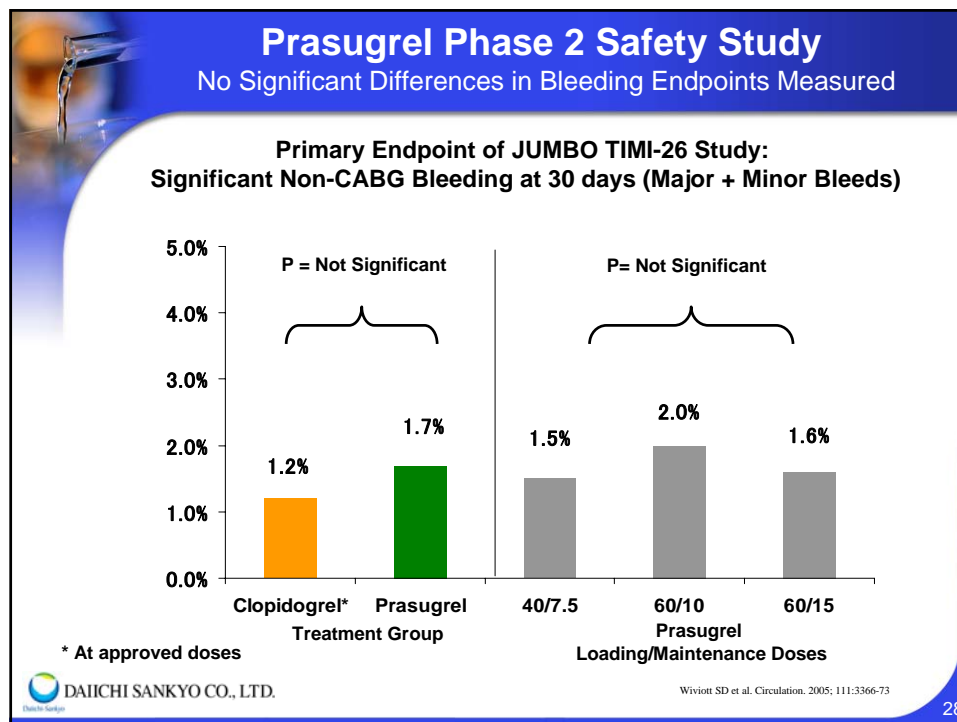
- **Co-developing & co-commercializing with Eli Lilly and Co.**
- **Platelet aggregation inhibitor**
 - Initial submission for acute coronary syndromes (ACS)
- **Phase 1 studies suggest prasugrel may have superior profile**
 - Higher inhibition of platelet aggregation (IPA)
 - Faster onset of IPA
 - More consistent IPA
- **Phase 2 safety study indicated acceptable bleeding profile**
- **Phase 3 study currently enrolling 13,000 patients**
- **Submission anticipated in second half of 2007**

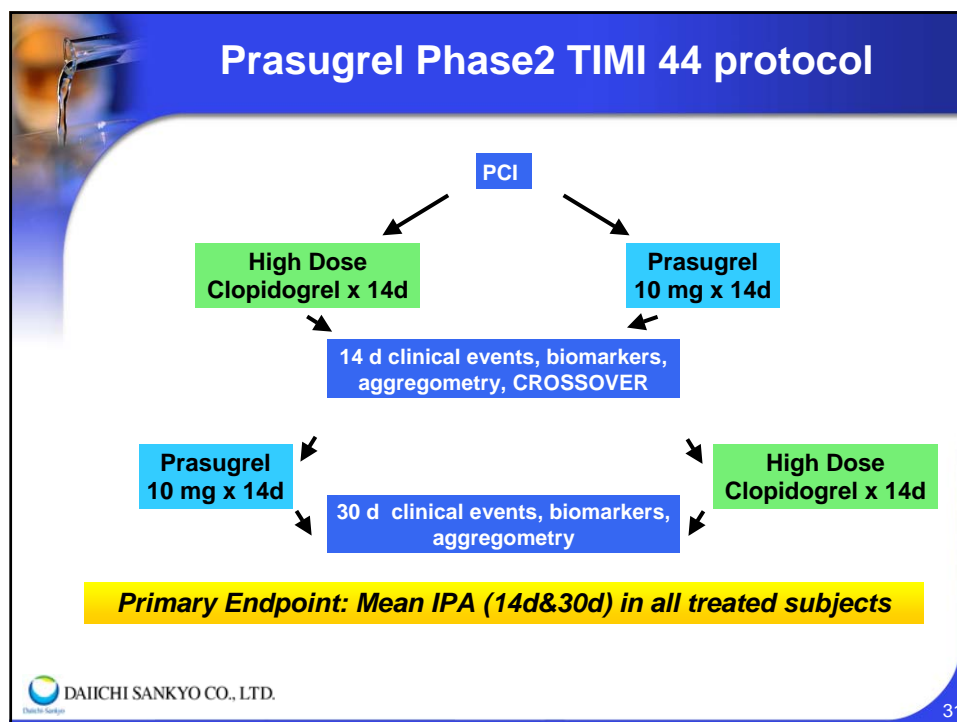
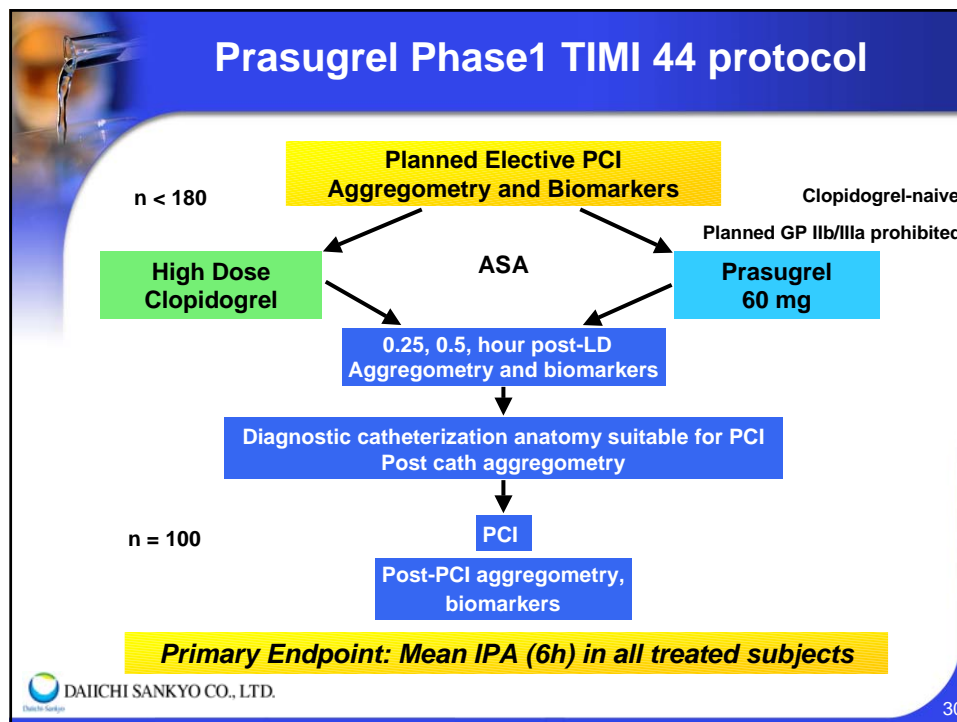


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Prasugrel Japan Clinical Development

■ Current Status

- Phase 1 study is on-going

■ Target Indications

- The following have been considered as target indication
 - Prevention of atherothrombotic events in patients who undergo percutaneous coronary intervention (PCI) while having acute coronary syndrome (ACS)
 - Secondary prevention of thrombotic vascular events in patients with cerebrovascular accident (CVA)

CS-8663

■ A fixed dose combination of two antihypertensives, amlodipine (most widely used CCB) and olmesartan medoxomil (fastest growing ARB)

- ARBs continue to be the fastest growing anti-hypertensive class
- Life cycle management strategy to grow Benicar®(US) /Olmetec®(Europe) franchise

■ Target indication : second line therapy for hypertensive patients who fail monotherapy

- Over 120 million hypertensive patients in the US/EU and still growing
- Only 40 - 50% of hypertensive patients are being treated, and only about half of them achieving target blood pressure goals
- Addresses unmet medical need, getting more patients to treatment goals recommended by the guidelines

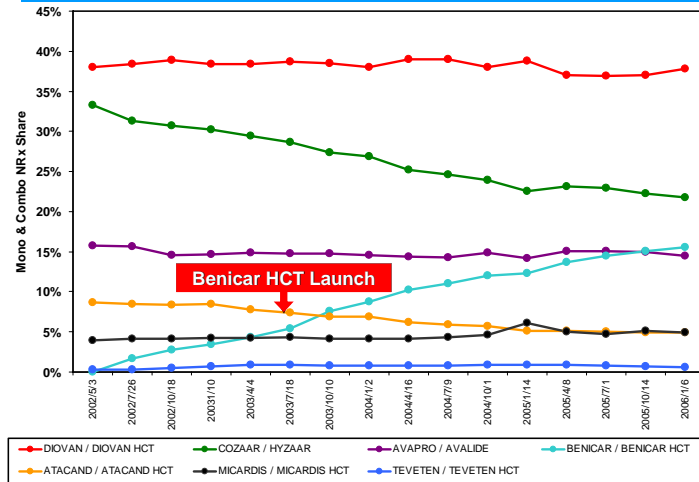
■ Phase 3 studies on-going

- Target market entry soon after amlodipine (Norvasc®) patent expiry (US)

Grows to third-largest seller in US ARB market – Benicar/Benicar HCT

Accounts for approx. 15% of new prescriptions to join the top 3; aiming for No. 2 spot

Trends in share of new prescriptions in US ARB market since Benicar went on the market



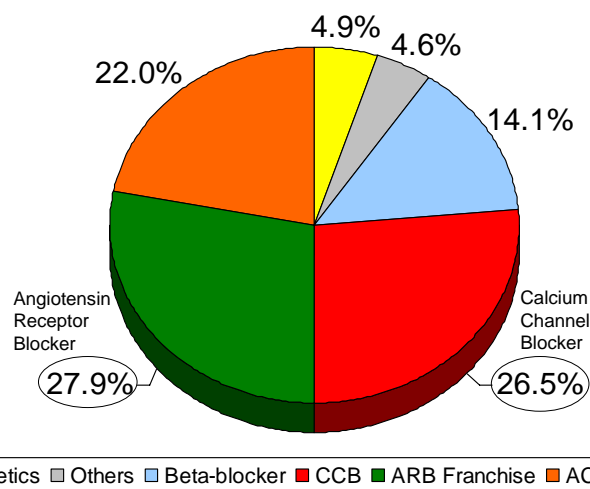
15.7%
2006/3

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2004 Sales Share of Anti-Hypertensive Class US, EU5 (DE, UK, FR, ES & IT) & JP



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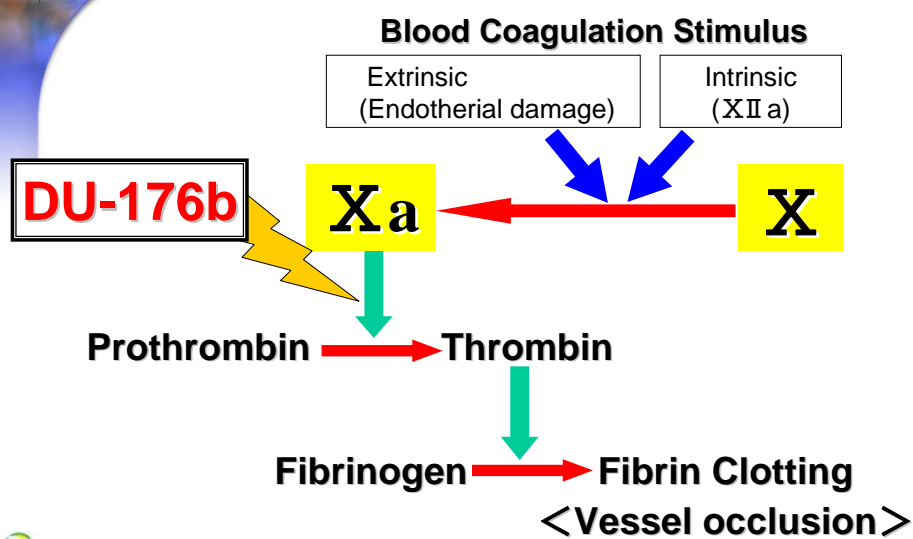
[Source: IMS]

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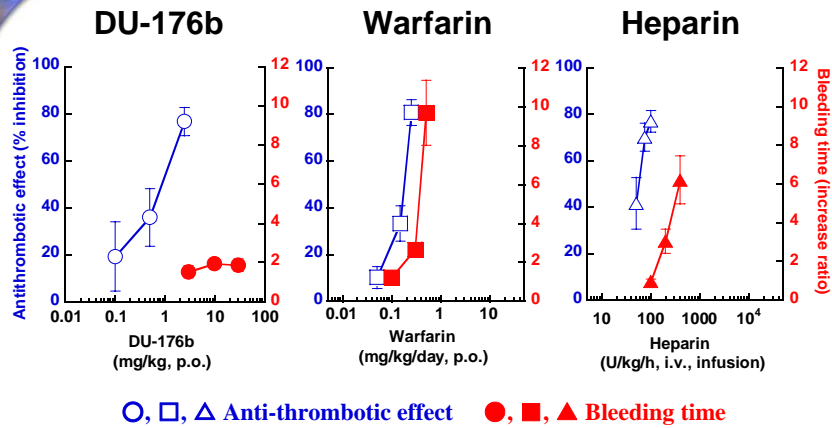
DU-176b

- Best in class inhibitor of blood coagulation factor Xa.
- Oral doses inhibit thrombin generation dose-dependently in human volunteers.
- VTE prevention was confirmed by QD and BID dosing in the patients with total hip replacement without causing increased bleeding (605pts).
- Phase2b studies are under preparation.
Targets : AF
VTE
- Clinical data is consistent with preclinical data including toxicogenomics that suggests a low risk of hepatotoxicity.
- Significant market opportunity but with many competitors.
\$11billion
9% increase every year

Mechanism of DU-176b



Greater separation of anti-thrombotic effect and bleeding risk with DU-176b



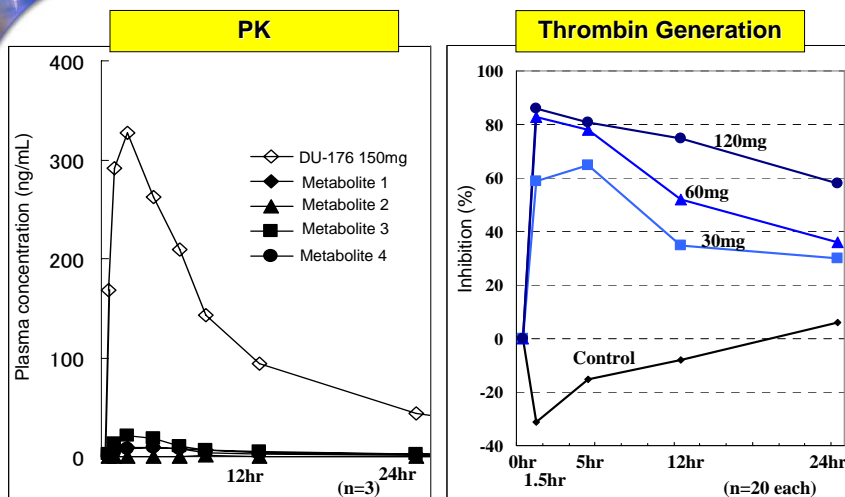
Platinum-wire induced venous thrombosis model
and tail cut bleeding time in rats

[DSK]

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DU-176b was scarcely metabolized and QD dosing was suggested in human volunteers



Thrombin generation was measured by F1+2 formation

[JPSY 2006]

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DZ-697b

■ First in class anti-platelet agent

- Inhibit platelet adhesion to the injured endothelium
- Inhibit high-shear stress induced platelet aggregation
- Little inhibition on aggregation at low-shear stress suggests lower bleeding risk

■ Phase 1 study

- Rapid onset and prolonged inhibition
- Inhibited platelet aggregation induced by shear stress (PFA-100), collagen and ristocetin
- Excellent PK profiles in oral absorption and AUC
- High tolerance without increase in bleeding time

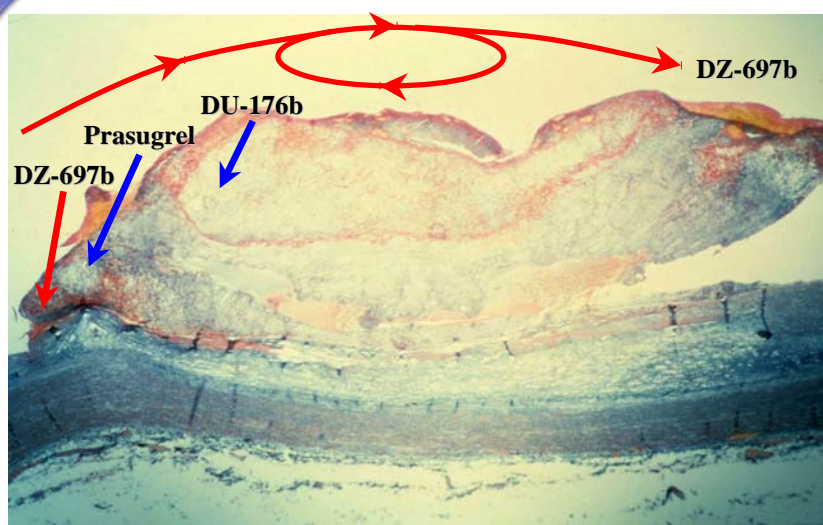
■ Phase 2a study

- The clinical plan was reviewed with FDA and obtained agreement to proceed with stroke and stable CVD (Pre IND meeting)

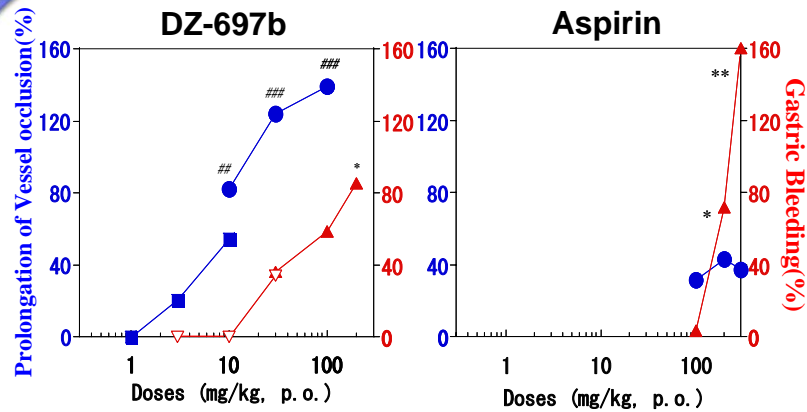
■ Potential Indications

Stroke, ACS, Microcirculation disorders

DZ-697b



DZ-697b Lower Bleeding Risk than Aspirin



●, ■ Anti-thrombotic effect ▲, ▼ Bleeding

Photo-Induced Thrombosis (PIT) model and gastric bleeding evoked by HCl in guinea pigs.

Bleeding was measured by Hb leakage into the stomach

[ASH 2005]

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CS-9803

- Co-developing with KAI pharmaceuticals, South San Francisco, CA
- Delta PKC* inhibitor, is expected to be a first in class agent for reduction of reperfusion injury in acute myocardial infarction patients undergoing revascularization procedures
- Currently a Phase1/2 study("DELTA-MI") is on-going in US/EU in acute heart attack patients undergoing balloon angioplasty
- Promising pre-clinical efficacy in models of ischemic stroke
- FDA fast track designation

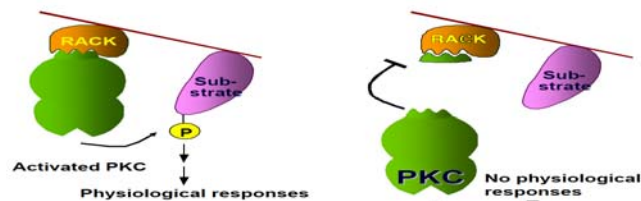
*PKC: protein kinase C

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Mechanism of CS-9803

- CS-9803 is a small peptide that works by inhibiting the translocation of delta PKC to its specific intracellular receptor.
- Delta PKC activation during reperfusion initiates the inflammatory molecular processes leading to cell death and damage to the heart.
- CS-9803 inhibits both apoptotic and necrotic pathways of myocardial cell death and heart muscle damage.

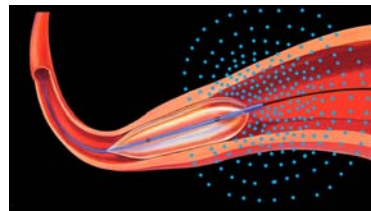
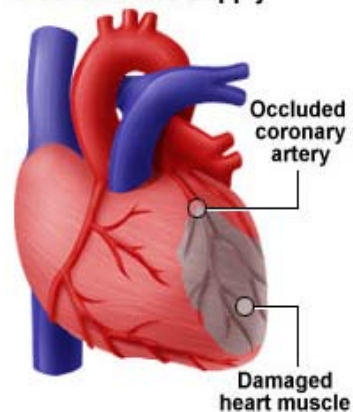


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CS-9803 AMI Model for Reperfusion Injury

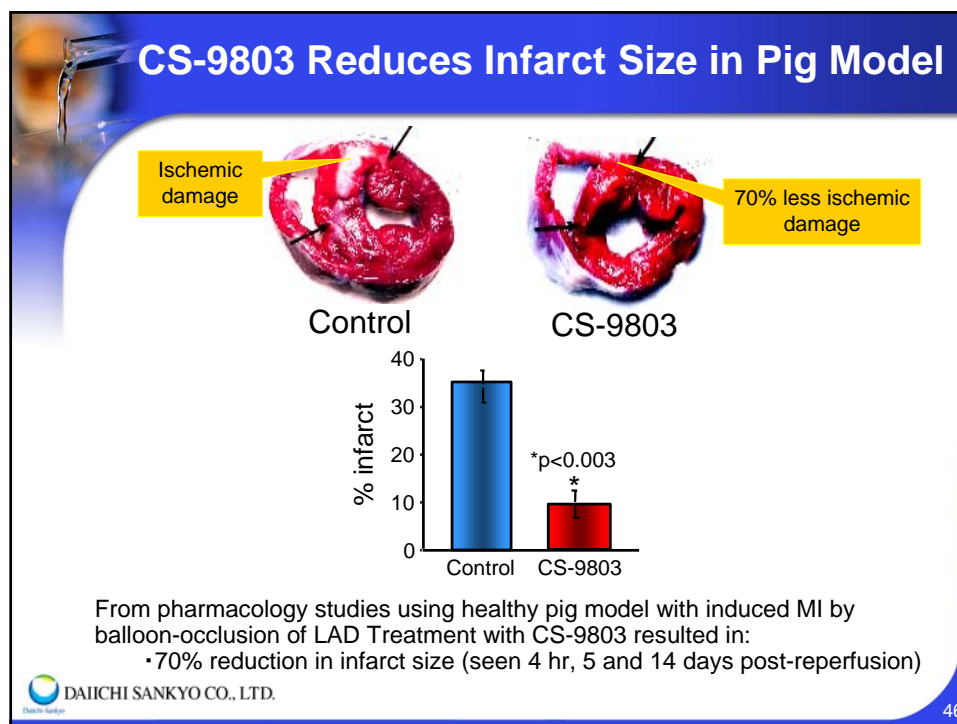
Blocked blood supply



Pig model of acute MI by occluding LAD coronary artery with a balloon

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Oncology

DJ-927

CS-7017

CS-1008



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DJ-927

New Oral Taxane anticancer

- Excellent antitumor activity in oral administration
- Less affected by P-gp, a drug excretion pump, and effective in multidrug resistant (MDR) cell lines such as colorectal cancer
- Reduced risk of peripheral neuropathy

DJ-927

1. Phase 1 study

- Oral absorption confirmed
- MTD: 27–35 mg/m²
- DLT : Neutropenia
- Potential anti-tumor activity
in breast cancer and bladder cancer

DJ-927

2. Phase 2a study

■ Colorectal cancer:

Response (CR and PR) observed after failure of Oxaliplatin- or Irinotecan-based chemotherapy
First Taxane effective for Colorectal cancer

■ Breast cancer:

Response (PR) observed after failure of anthracycline-based chemotherapy

■ Gastric cancer:

Response (PR) observed after failure of 5-FU based chemotherapy

■ Predominant ADR:

Neutropenia
Gastrointestinal toxicities (nausea and vomiting)

3. Phase 2b study

■ Under consultation with FDA

Colorectal cancer
Breast cancer

CS-7017

■ Antitumor PPAR γ activator

■ A positive correlation between PPAR γ activation and inhibition against colony formation of tumor cells have been demonstrated *in vivo*

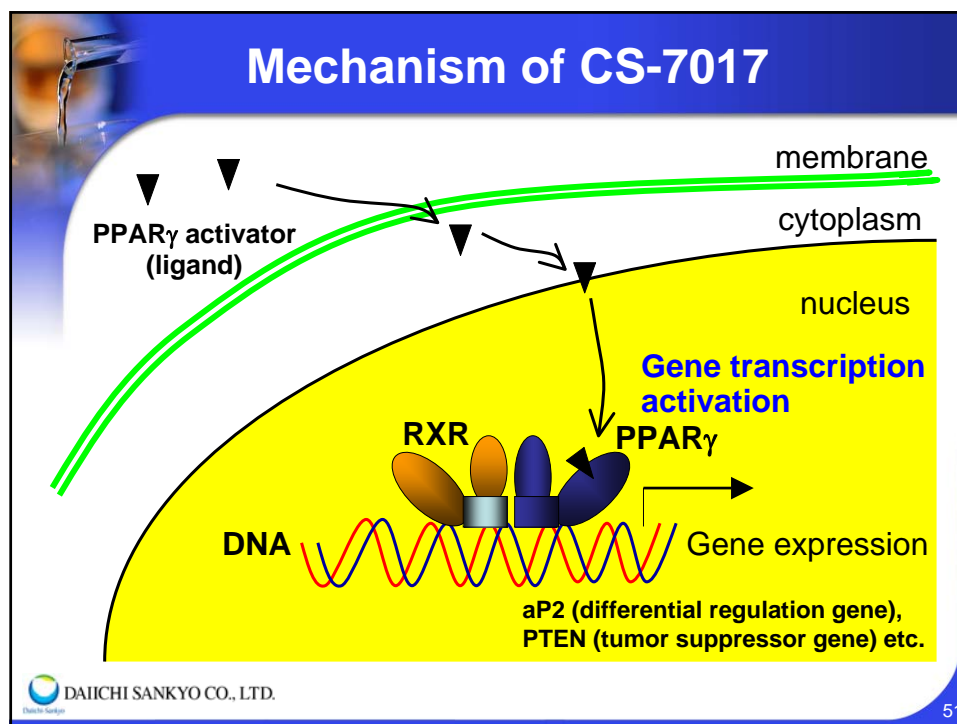
■ Effective against human tumor-implanted *in vivo* models

■ Inhibits growth of tumor cells *in vitro* without killing those cells

■ Expected to be less toxic compared to standard chemotherapeutics

■ Could be used either alone or in combination with other chemotherapeutic agents

■ Phase 1 study is on-going in US

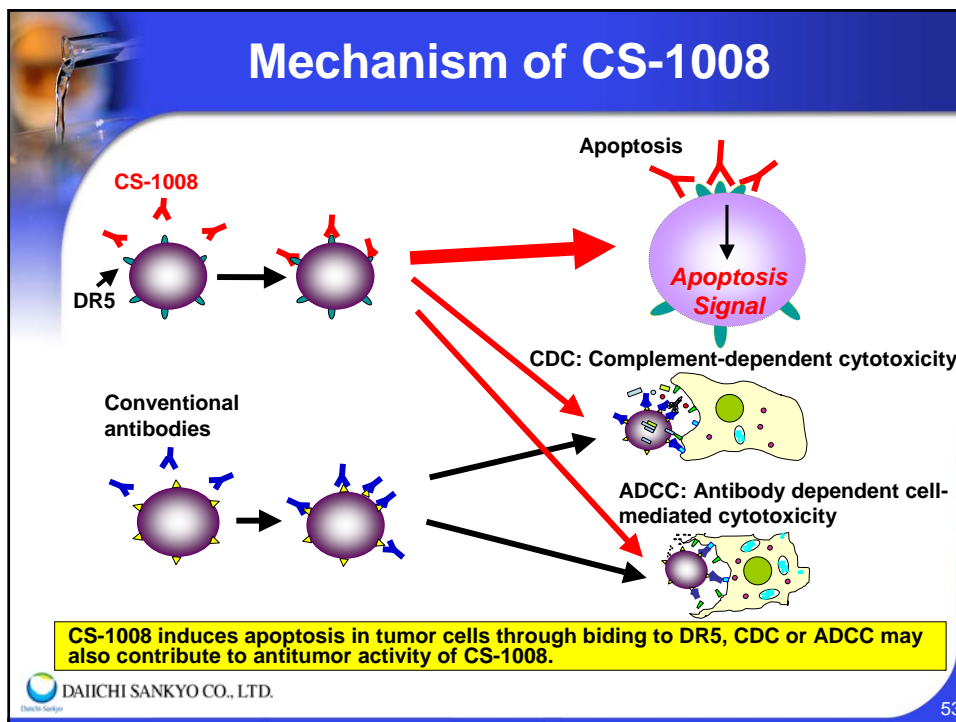


CS-1008

- A humanized version TRA-8, a murine agonistic moAb raised against human death receptor 5 (DR5)
- Discovered through collaboration with the University of Alabama at Birmingham in U.S.
- CS-1008 induces apoptosis of tumor cells expressing DR5 on the cell surface
- Pre-clinical studies showed an anti-cancer effect against human cancer cell lines *in vitro* and in tumor-bearing mice *in vivo*
- Good safety profile demonstrated in pre-clinical studies
- DR5 is rarely expressed in normal tissues, CS-1008 is expected to show selective activity against tumor cells
- IND was filed Dec 2005 and Phase 1 study will start this April

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Infection

DX-619
DC-159a
CS-023
CS-8958

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DX-619

- Best in class quinolone injection against multi-drug resistant Gram(+) bacteria.

MRSA
VRE
MRCNS
PRSP

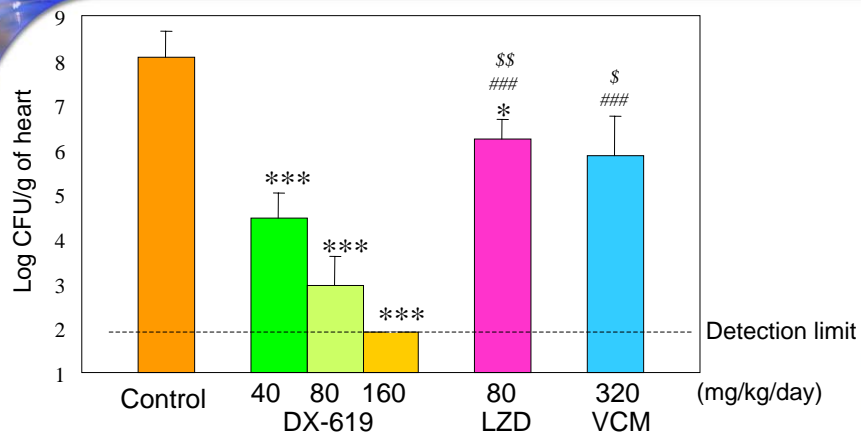
- Did not induce resistant mutants *in vitro*, possibly due to dual mechanisms: DNA gyrase & TopoIV
- Enhanced relative efficacy and rapid speed of onset of bactericidal activity
- Phase 1 program is on-going

DX-619, Most Potent against Resistant Gram(+)

Drug	MIC ₉₀ (μg/mL)
DX-619	0.25
Ciprofloxacin	>64
Levofloxacin	32
Gatifloxacin	8
Moxifloxacin	4
Vancomycin	32
Teicoplanin	4
Linezolid	1

Vancomycin-resistant MRSA (VRSA) USA 2002

DX-619 Cures Severe Infection Model



*: $P < 0.05$, ***: $P < 0.001$ vs Control, ##: $P < 0.01$ vs DX-619; 160 mg/kg/day, \$: $P < 0.05$, \$\$: $P < 0.01$ vs DX-619; 80 mg/kg/day

Endocarditis due to LVFX-R MRSA in rats

[ICAAC 2003]

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DC-159a

■ Best in class respiratory quinolone with broad spectrum enabling empiric therapy

QR *S.pneumoniae*
MDR *S.pneumoniae*
Mycoplasma pneumoniae
RFP-R *M.tuberculosis*

■ Covering Major Gram-(+) & (-) pathogens and atypical pathogens

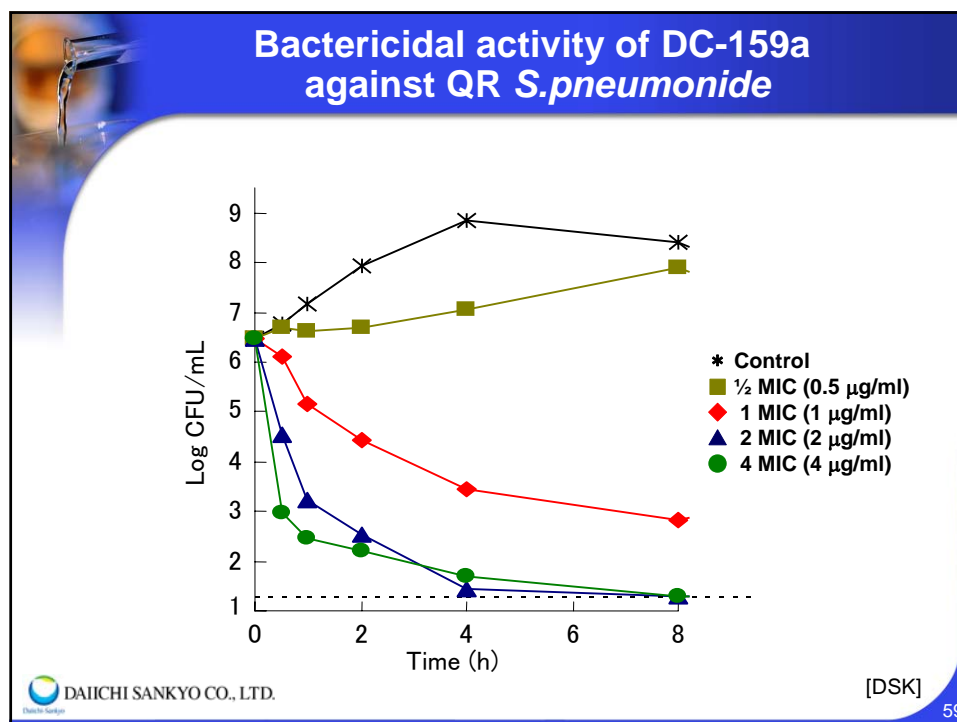
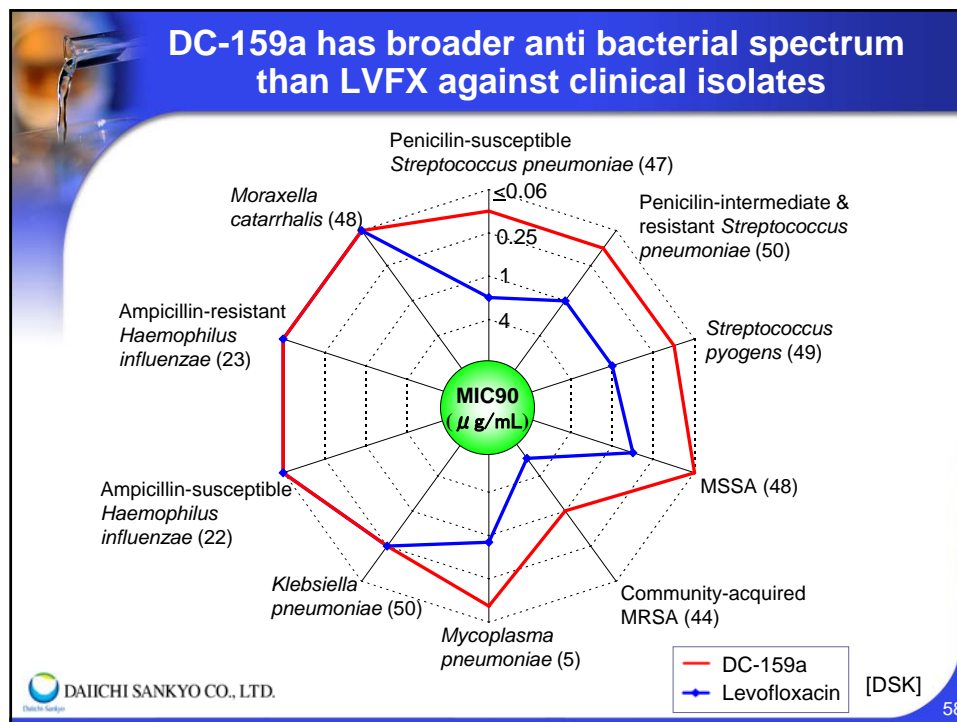
■ Faster cure is expected with its rapid bactericidal action

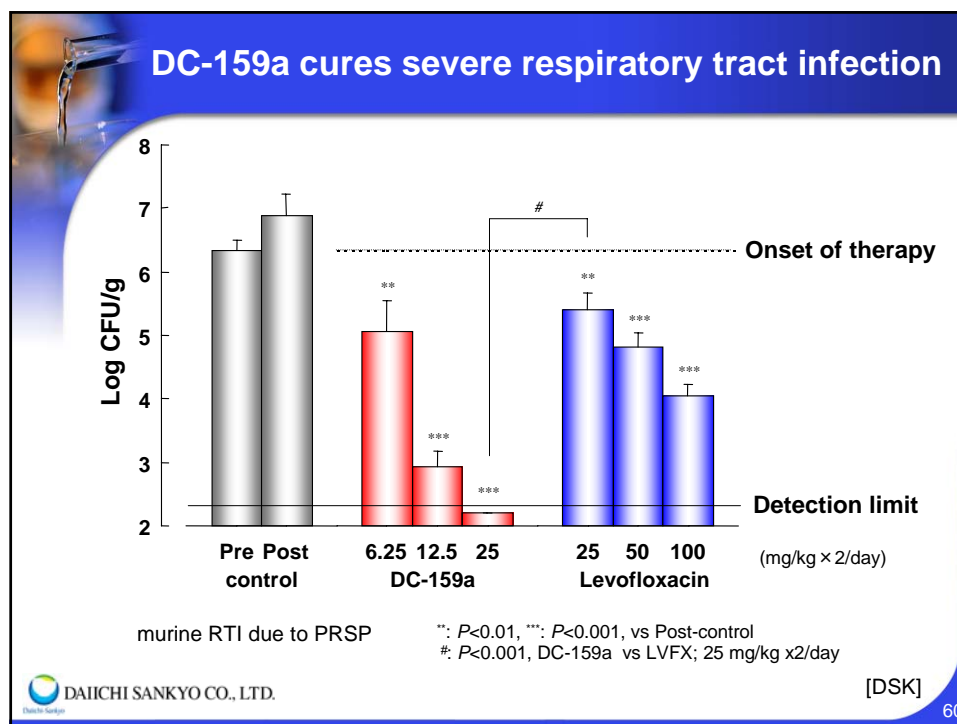
■ Preferable penetration into target organs

■ Phase 1 study under preparation

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DC-159a has potent inhibitory effects on RFP-Resistant Mycobacterium and MAC

	MIC ₉₀ (μg/mL)		
	<i>M.tuberculosis</i> Wild n=21	<i>M.tuberculosis</i> RFP-R n=12	<i>M.avium</i> AIDS associated n=33
DC-159a	0.06	0.5	2
MFLX	0.25	4	4
LVFX	0.5	16	32
RFP	0.13	>128	128

MFLX: Moxifloxacin
LVFX: Levofloxacin
RFP: Rifampicin

[Res.Inst.Tuberculosis]

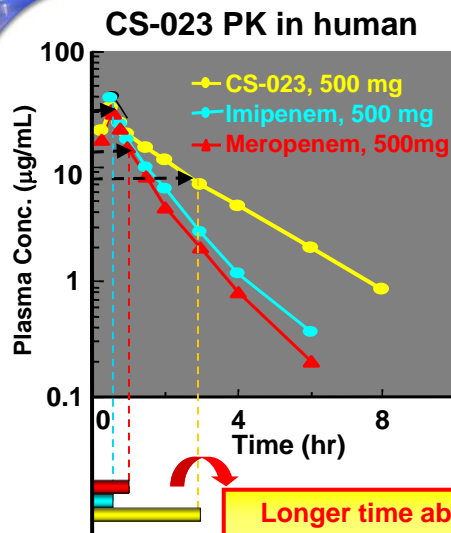
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CS-023

- A novel parenteral carbapenem for bacterial infections
- Best in class can be expected based on;
 - Broad spectrum and superior activity against pathogens
 - Longer half-life than competitors
 - High safety
- Target indications are moderate to severe infections such as;
 - Nosocomial pneumonia
 - Systemic infections
 - Surgical or soft tissue infections etc.
- Longer half life (2-fold) than other carbapenems and good safety profile were demonstrated in Phase 1 studies
- License-out to Roche in US/EU: Phase 2 studies on-going
- Phase 2 studies on-going in Japan

CS-023 efficacy depends on *in vitro* activity (=MIC) and length of half life



MIC₉₀ for IPM*-resistant *P. aeruginosa*

Drug	MIC ₉₀ (µg/mL)
CS-023	8
Imipenem	32
Meropenem	16

* Imipenem MIC: ≥ 16 µg/mL

Longer time above
MIC than competitors

“Stronger Efficacy”

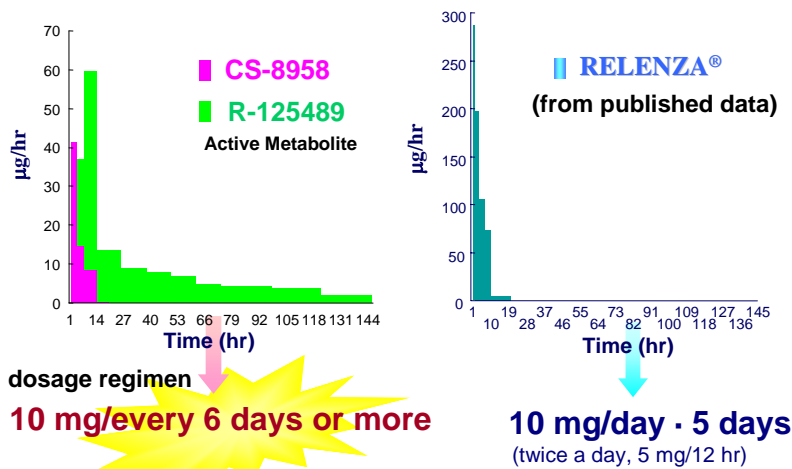
CS-8958


- Novel neuraminidase inhibitor as an anti-flu drug
- Inhaled formulation (dry powder inhaler & nebulizer)
- Longer-acting than existing drugs
- Could possibly use for influenza treatment and prophylaxis
- Single dosing for treatment and once a week dosing for prophylaxis are expected based on exploratory clinical study
- Collaborate with Biota to find appropriate partner in US/EU
- In-house development in Japan: Preparation for Phase 1 study is on-going

Human PK results in exploratory clinical study

- Efficacy of CS-8958 was expected to be longer-acting than Relenza -


Urinary excretion after administration of CS-8958 and Relenza to human at a dose of 10 mg (inhalation).



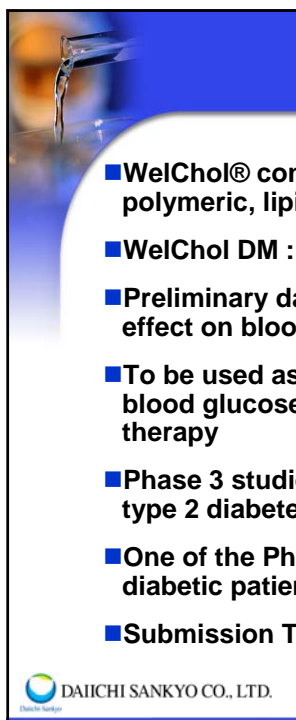


Glucose Metabolic Diseases

WelChol DM CS-011 CS-917




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WelChol DM

- WelChol® contains colestevlam hydrochloride, a non-absorbed, polymeric, lipid-lowering agent intended for oral administration
- WelChol DM : Expansion of indication for diabetes in the US
- Preliminary data suggest WelChol® may have a beneficial effect on blood glucose levels in patients with type2 diabetes
- To be used as an adjunct to diet and exercise to lower blood glucose for type 2 diabetes not responding to current therapy
- Phase 3 studies are on-going for inadequately controlled type 2 diabetes patients
- One of the Phase 3 studies suggests 0.5% in HbA1c decrease in diabetic patients on insulin
- Submission Target: 4Q 2006



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CS-011/ Rivoglitazone

Product Description

- Potent selective PPAR- γ agonist for treatment of diabetes
- Greater glycemic and non-glycemic effects than demonstrated by pioglitazone or rosiglitazone
- Goal is to achieve superior glycemic control and safety compared to pioglitazone (Best in Class)
- Dose-dependent efficacy on plasma glucose and lipid parameters superior to pioglitazone were demonstrated in Phase 2b study
- Carcinogenicity studies are on-going
- License agreement of development for the purpose of dry eye treatment was concluded with Santen

CS-917

Product Description

- First in class, the fructose 1-6 bisphosphatase (FBPase) inhibitor
- FBPase is a rate-limiting enzyme that regulates hepatic glucose production
- Potential to treat a majority of type 2 diabetic patients as monotherapy or in combination with other therapies
- Completed Phase 2a studies Dose-dependent reductions in levels of fasting plasma glucose(FPG) was demonstrated and proof of concept was established
- Phase 2b study with low dose range for the sake of safety is on-going after re-evaluation of lactic acidosis elicited in patients taking concomitant metformin

A slide titled 'CS-0777' with a blue header bar. The background features a close-up of a glass dropper with a single drop of liquid falling. The slide contains a bulleted list of key points about the drug. At the bottom left is the Daiichi-Sankyo logo, and at the bottom right is the text 'DAIICHI SANKYO CO., LTD.' and the page number '69'.

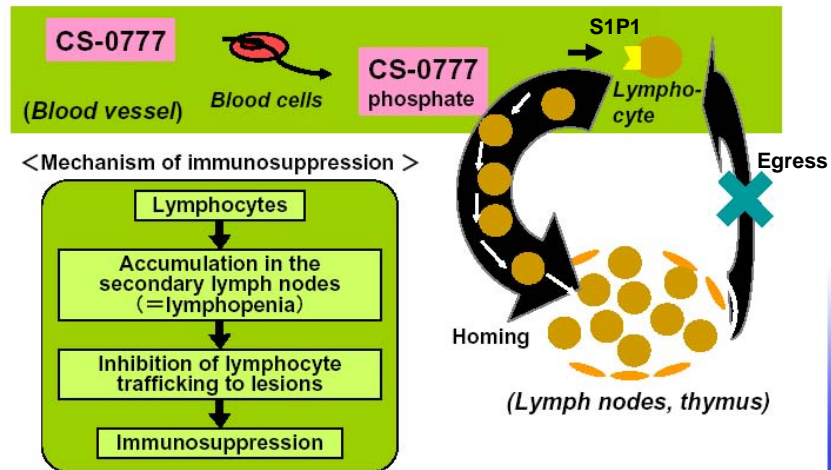
CS-0777

- **Novel immunomodulator**
- **Unique mechanism of action:**
 - CS-0777, converted to phosphorylated form *in vivo*, is an agonist of sphingosine 1-phosphate receptor 1 (S1P1).
 - CS-0777 causes peripheral lymphopenia through lymphocyte retention in secondary lymphoid organs.
- **Target indications are autoimmune diseases such as RA, Psoriasis and MS, as well as organ transplantation.**
- **First in class or Best in class**
- **IND submission in March 2006**

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Mechanism of CS-0777



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