





Safe Harbor Statement

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Agenda

- I. Eisai R&D: Overview
- II. Global Clinical Development
- III. Clinical Research in Japan
- IV. Oncology Research Strategy
- V. Introduction to Morphotek



Eisai R&D: Overview

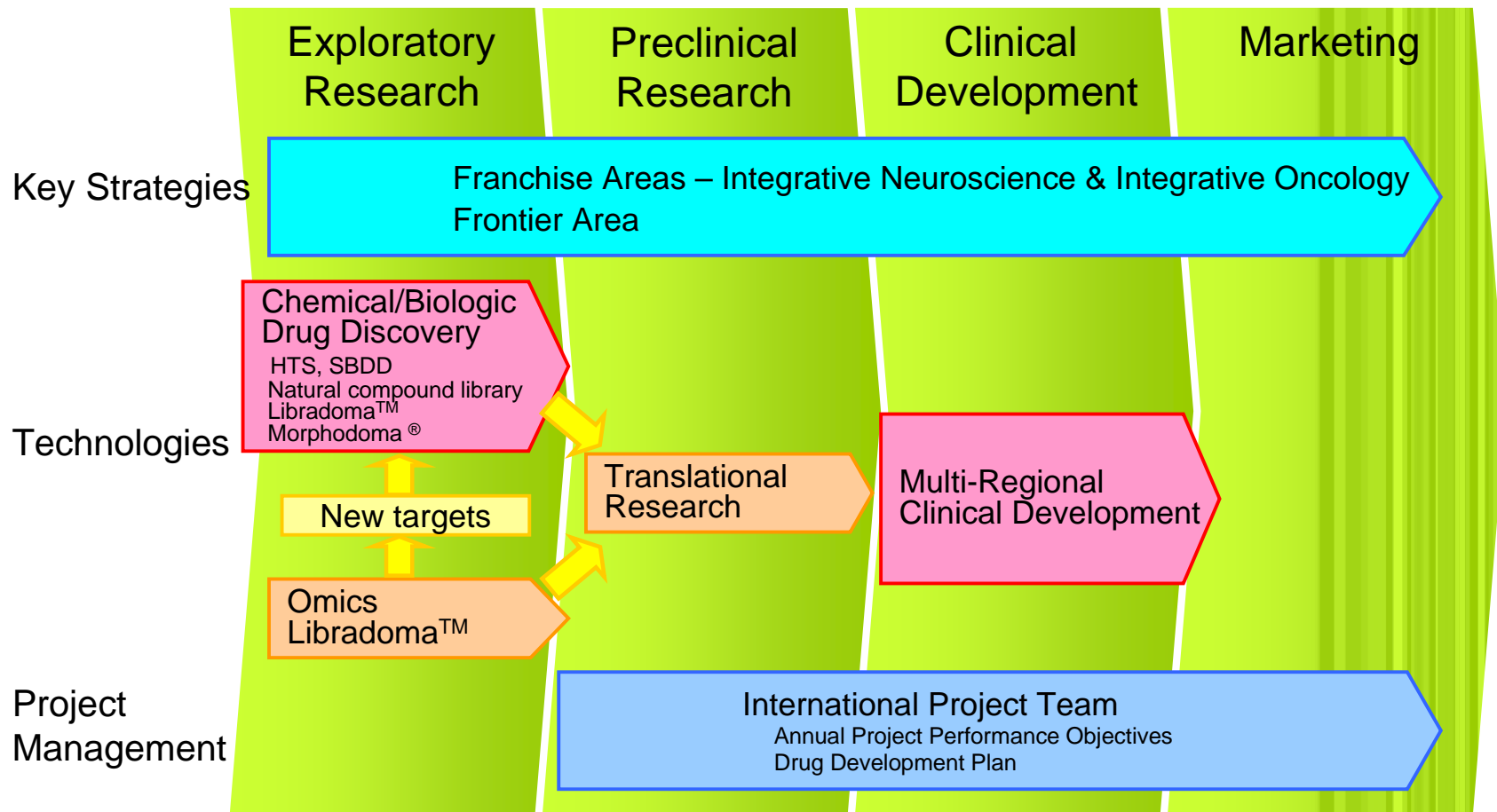
Kentaro Yoshimatsu

Senior Vice President, Research & Development, Eisai Co., Ltd.

President, Eisai R&D Management Co., Ltd.

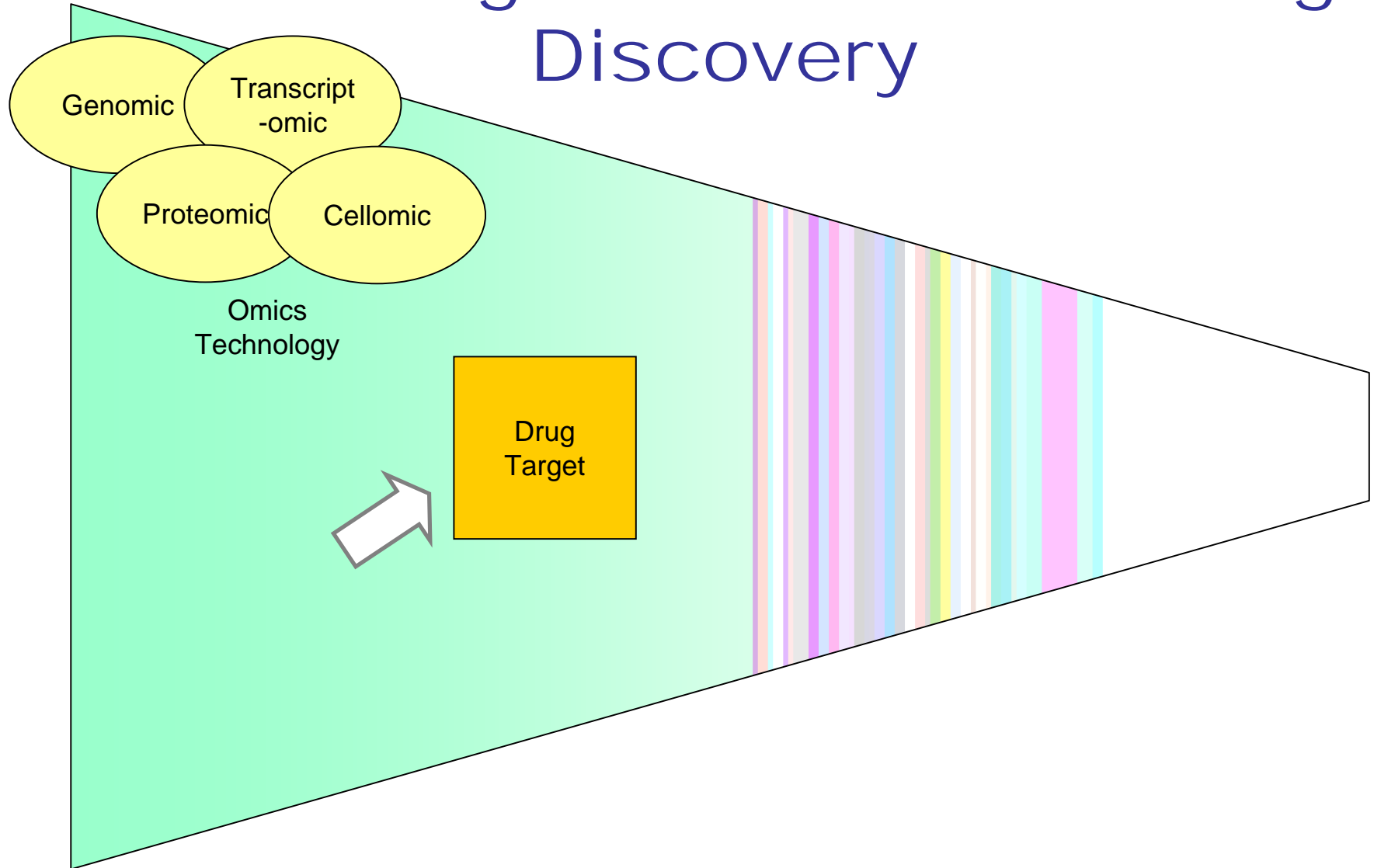
Eisai's R&D Strategy

- › Optimizing Multi-Regional and Multi-Functional R&D Activities under Eisai R&D management Co., Ltd.(ERDC) management system





Application of the New Technologies for Efficient Drug Discovery





Enhance Project Management Capability

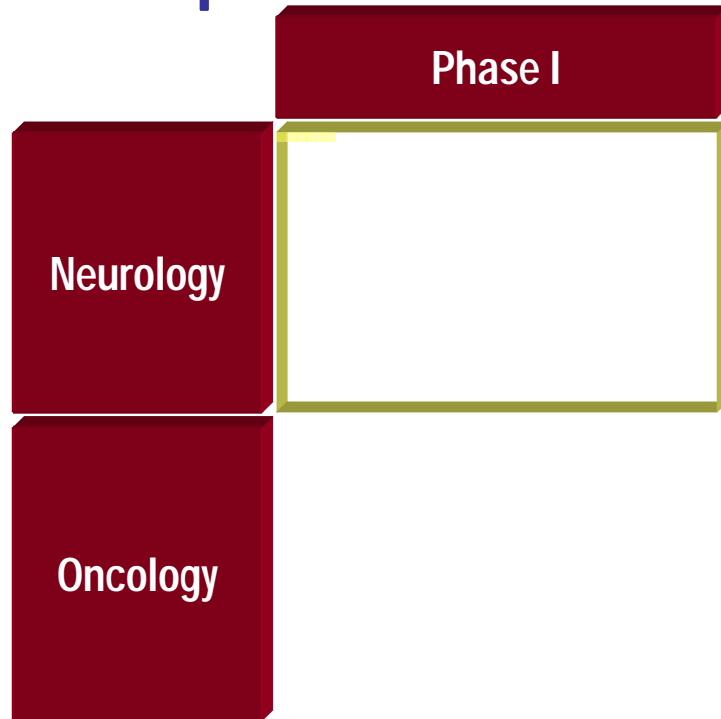
- **Project management by Eisai R&D Management Company**
 - Direct management of 50 projects
 - Sharing of goals, single management vision
 - Decision-making by all officers responsible for R&D functions with participation from marketing, regulatory and safety management
 - Setting Drug Development Plan (DDP) and Annual Project Performance Objectives (APPOs) for each IPT and checking on the progress
 - R&D resource allocation to maximize overall productivity







Pipeline: New Molecular Entities





Global Clinical Development

Masanori Tsuno

Vice President, Global Clinical Research, Eisai Co., Ltd.
President, Eisai Medical Research,
President, Eisai Global Clinical Development



E2007 (perampanel)

AMPA Receptor Antagonist



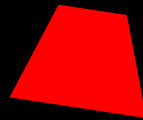
AMPA Receptor Antagonist

- Highly selective AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) -type glutamate receptor antagonist
- Potential for therapeutic utility in various neurological diseases
- Development Status
 - **Parkinson's disease**
 - 3 Phase III studies ongoing
 - NDA/MAA in FY2007
 - **Epilepsy**
 - POC achieved
 - Phase III study in preparation
 - **Migraine prophylaxis**
 - Phase II study with 2 mg completed
 - Higher doses to be evaluated
 -

Mechanism of Action

Imbalance of CNS circuit

**Parkinson's disease
Epilepsy
Pain**



Excitotoxicity

Multiple sclerosis

E2007

Parkinson's Disease

- **Placebo control Phase III studies (Study 301 and 302)**
 - Target: Add-on therapy in idiopathic PD patients with levodopa therapy with motor fluctuations of a “wearing off” type
 - Purpose: To compare the efficacy of 2mg and 4mg of E2007 and placebo on motor function
 - Treatment groups: 2mg, 4 mg or Placebo
 - Endpoints: OFF time change
 - Target number of patients: 702 patients
- **Placebo and Entacapone control Phase III study (309 study)**
 - Treatment groups: 4 mg E2007, placebo or 200mg Entacapone
 - Target number of patients: Total 702 patients
- **Target submission**
 - 4Q FY2007 in U.S. and Europe

Epilepsy

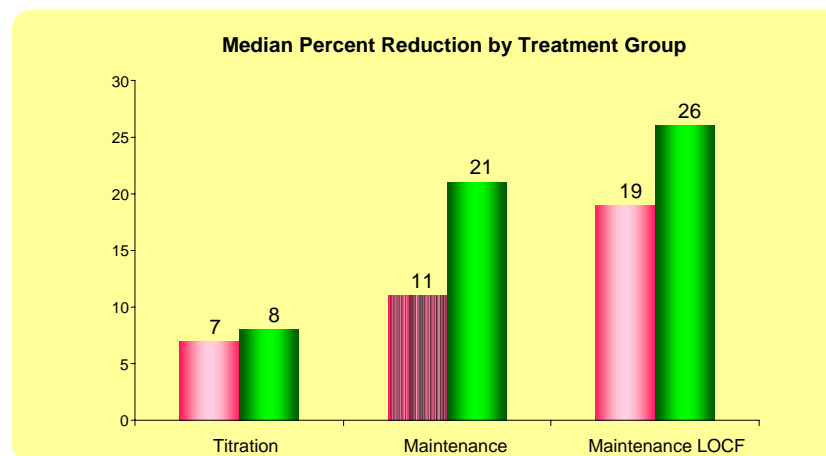
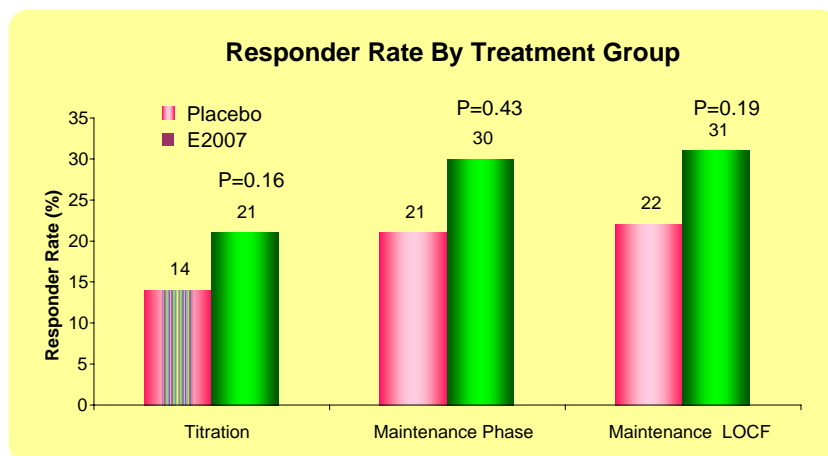
- **Phase II POC study (Study 206)**

- Target: Adjunctive therapy in patients with refractory partial seizure
- Dosing period: 4 weeks of baseline phase, 8 weeks of dose titration, 4 weeks of maintenance phase
- Treatment groups: E2007 (increase from 1mg to 4mg) or placebo

- **Results**

- 153 patients enrolled (E2007 group: 102 patients; placebo group: 51 patients)
- Responder rate (percentage of patients who reduced the frequency of seizure by 50% or more) and percent reduction in frequency of seizure were better than placebo group, and effect size was about same level as low doses of existing epilepsy drugs. Results supported the activity of E2007 in epileptic seizure (below)
- E2007 4mg was very well tolerated

- **Finalize Phase III study design based on the result of ongoing high-dose Epilepsy study**





Neuropathic Pain

-



Clinical Studies on E2007



E7389 (eribulin mesylate)

Microtubule Growth Suppressor

E7389

Breast Cancer Study 201

Presentation at ASCO 2007

- **Study 201: Advanced/metastatic breast cancer heavily pre-treated (median prior regimens = 4) with chemotherapy including anthracycline and taxane**
 - Dose: 1.4 mg/m² by 2-5 min IV administration
 - Schedule: Days 1, 8, and 15 of a 28-Day cycle (Group 1) or on Days 1 and 8 of a 21-Day cycle (Group 2)

∅ **Efficacy**

- ORR: 11.5% (all PR)
- Clinical benefit rate: 17.2%
- Median response duration: 162 days
- Median survival: 253 days

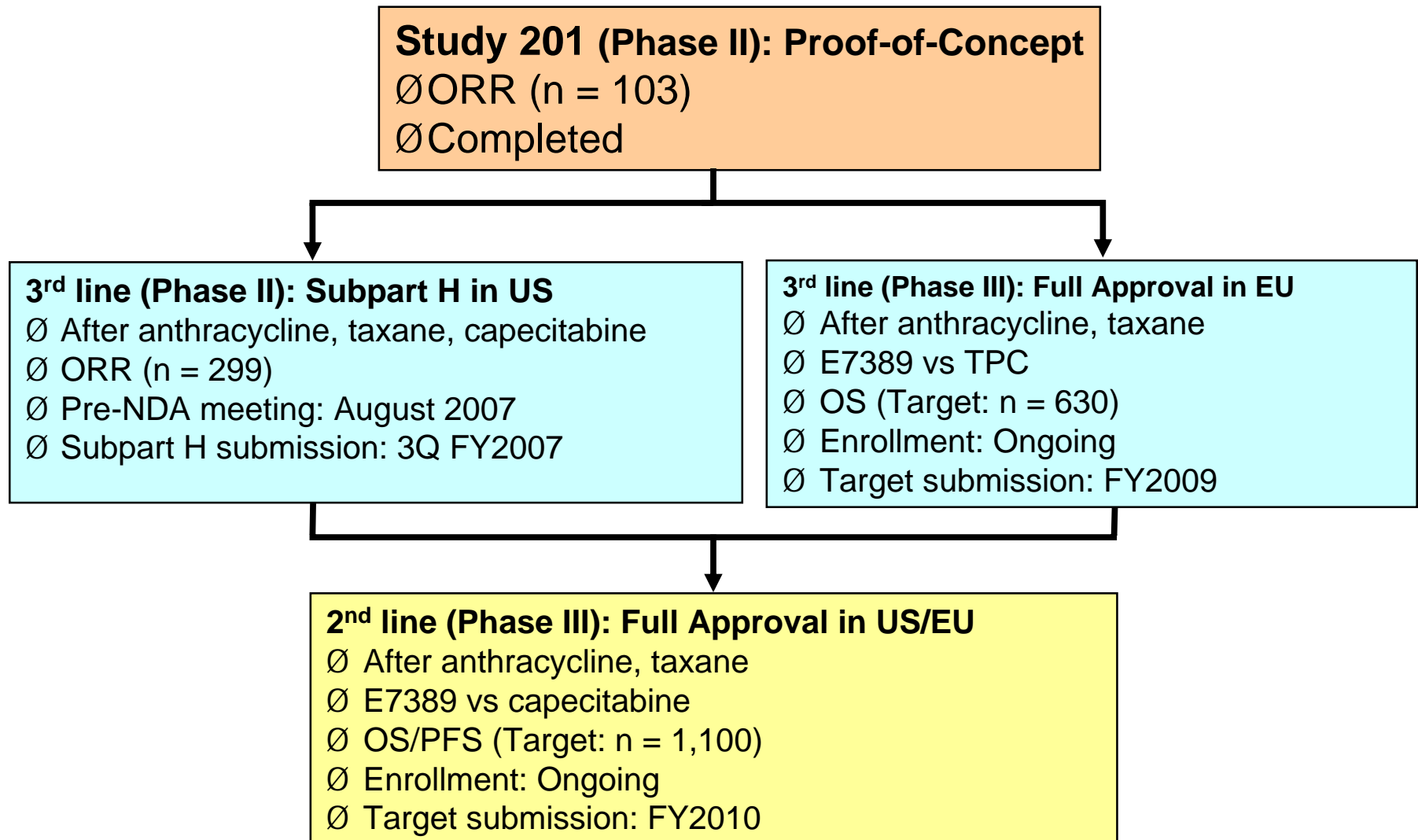
ORR: Objective Response Rate
PR: Partial Response
AE: Adverse Events

∅ **Safety**

- Group 2 showed an acceptable tolerability profile
 - Most common drug-related AE: neutropenia (61% grade 3/4; 4% febrile neutropenia)
 - Incidence of neuropathy: grade 3 (5%) and No grade 4

E7389

Breast cancer



ORR: Objective Response Rate, OS: Overall Survival, PFS: Progression Free Survival
TPC: Treatment of Physician's Choice



Non-Small Cell Lung Cancer : Study 202

Presentation at ASCO 2007

-

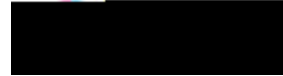
Other Studies

- **Prostate cancer (Phase II POC study)**
 - Target number of patients: 110
 - Endpoints: Objective prostate specific antigen (PSA) response rate, duration of PSA response, tumor-related symptom assessment, Progression Free Survival, overall tumor response rates, duration of tumor response
 - Enrollment completed (June 2007)
 - Accomplish POC: FY2007
- **Sarcoma (Phase II POC study)**
 - Target number of patients: 150
 - Endpoint: Progression free survival in 12 weeks
 - Enrollment ongoing in EU
- **NSCLC (Phase Ib study in combination with carboplatin)**
 - Enrollment ongoing in US
- **Cancer (Phase I study in Japan)**
 - Recommended dose for Japanese population determined



Current Status of E7389

- Proof of Concept (POC) achieved
 - Breast cancer
 - Non-small cell lung cancer (NSCLC)
- Submission studies ongoing
 - Breast 3rd line; Subpart H Phase II, Phase III
 - Breast 2nd line; Phase III
- Phase II POC studies ongoing
 - Prostate cancer
 - Sarcoma
- US National Cancer Institute (NCI) studies
 - Ovarian cancer, Head & Neck cancer, etc.
- Phase Ib study ongoing
 - NSCLC (combination with carboplatin)
- Japan
 - Phase I study completing
 - Phase II study under preparation



E5564 (eritoran tetrasodium) Endotoxin Antagonist



TLR4 Antagonist for Severe Sepsis

- Phase III (ACCESS study)
 - To demonstrate reduction of 28-day all cause mortality for severe sepsis patient
 - Randomized, double-blind, placebo-controlled study
 - Administration: intravenous infusion total dose 105mg, administered as one 28mg loading dose followed by a 14mg loading dose at 12 hours, and nine 7mg maintenance doses every 12 hours



E5555
Thrombin Receptor (PAR-1)
Antagonist

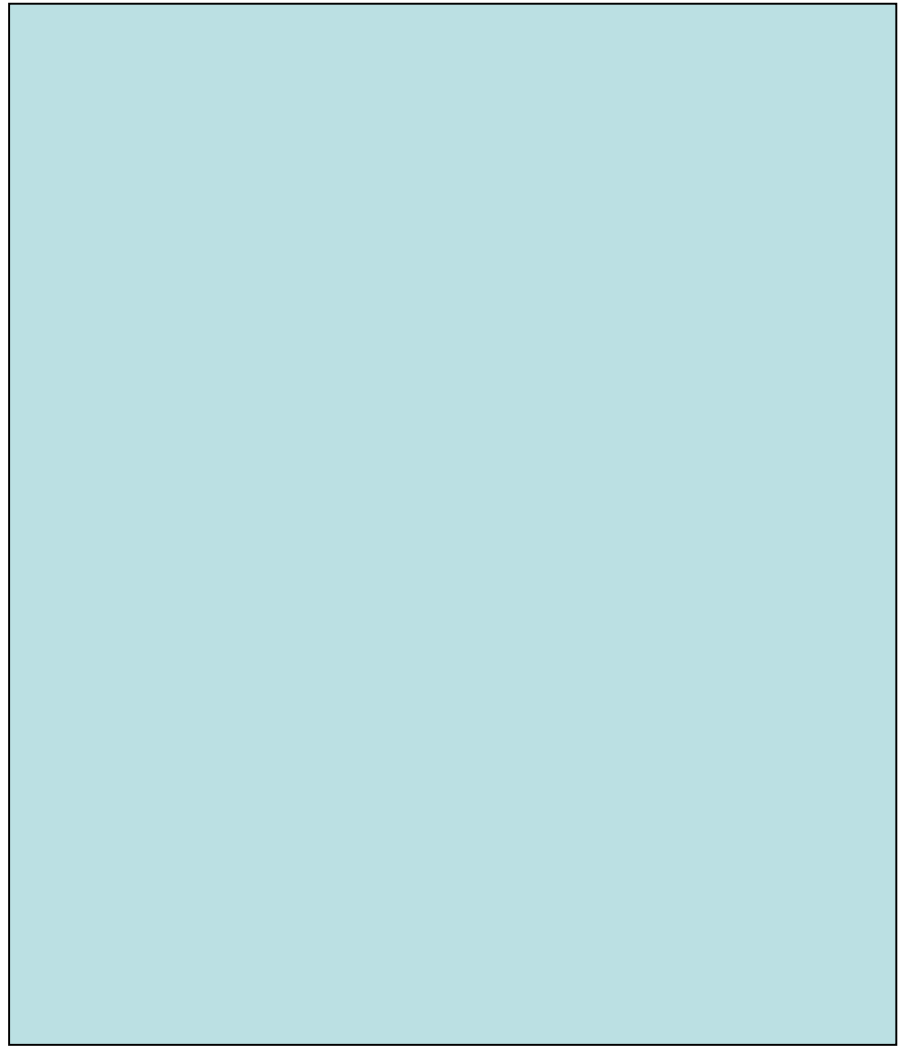




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- **Atherothrombotic Disease**

- Symptomatic CAD, with high risk of cardiovascular events
- Administration
 - No loading dose, Once a day
 - Placebo, 50mg, 100mg, 200mg/day, 600 patients
 - Treatment 24 weeks, Follow up 4 weeks
- Efficacy endpoints
 - Major Adverse Cardiovascular Events (MACE)
 - Plasma levels of possible biomarkers: hsCRP, MPO, soluble CD40 ligand, PIGF, IL-6, IL-18 and LpPLA2





Approaches to Alzheimer's Disease Treatment

Takehiko Miyagawa
Neuro Internal Medicine Group
Discovery Research Laboratories
Eisai Co., Ltd.

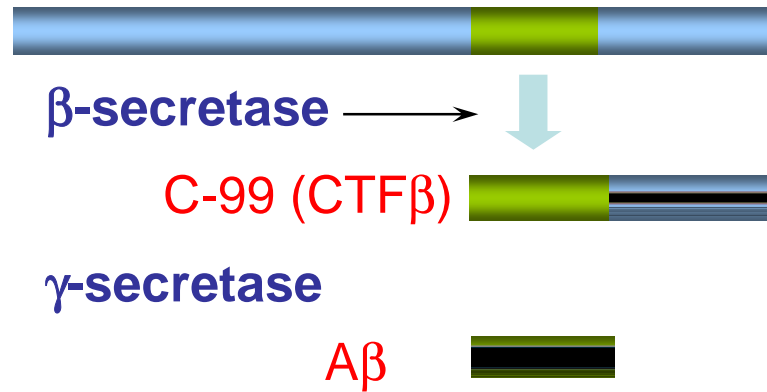


Alzheimer's Disease (AD) Therapies

- Present therapeutic agents improve the symptoms of AD
 - Such as the declining cognitive function, activities of daily living and behavior
 - Disease modification is not sufficient with current doses
- Recent findings implicate beta amyloid (A β) 42 as a potential causative agent in AD
 - Suggesting that reducing A β levels in the brain, in particular A β 42 levels, is a viable therapeutic strategy for the treatment of AD
 - A number of therapeutic strategies targeting various steps in the production, deposition, or clearance of A β 42 are presently being evaluated in pre-clinical studies and in clinical trials
 - New therapies designed to modify its progression could reduce the overall number of people suffering from AD

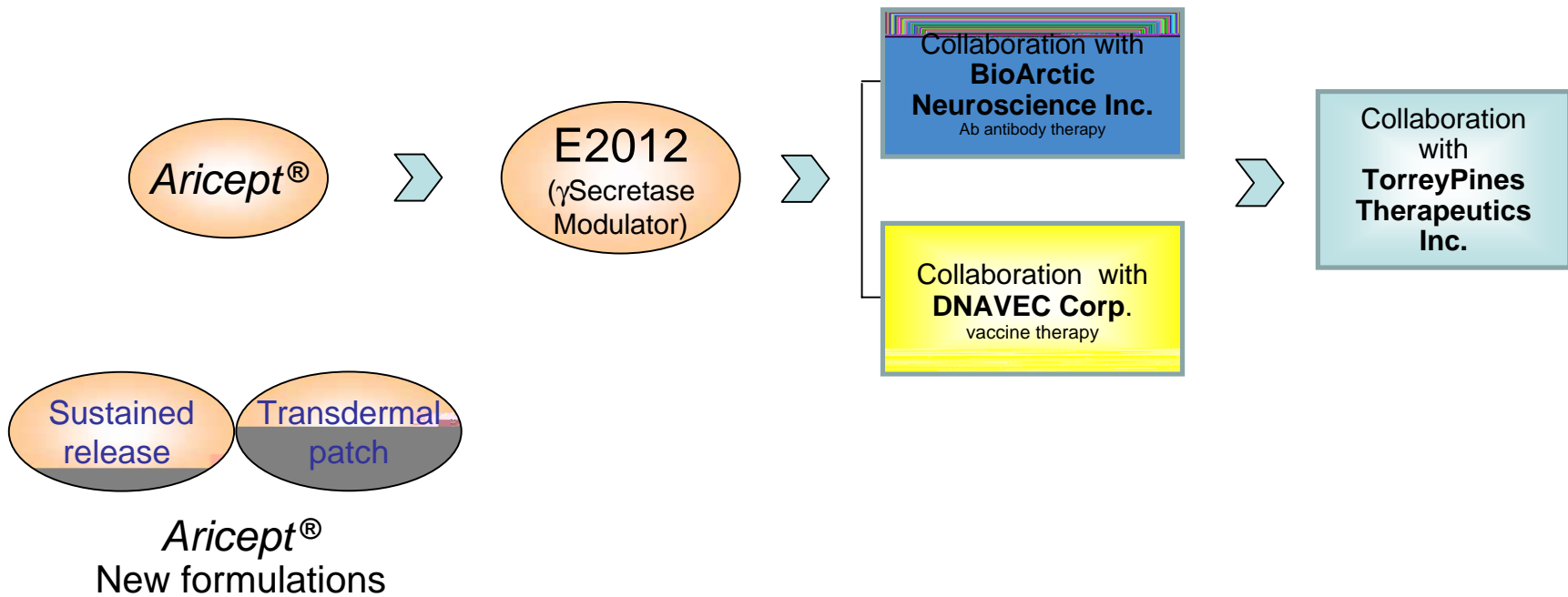
Therapeutic strategies targeting A β

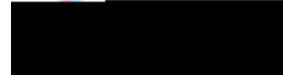
Amyloid Precursor Protein (APP)



Multidisciplinary Approach to Alzheimer's Disease


Small Molecule	Immunotherapy	Gene related therapy
Improving Cognitive Function	Disease Modifier Reduction of A β deposition	Possible Disease Cure





E2012

- Secretase Modulator

- 
- E2012 is a novel and potent γ -secretase modulator that has been shown to inhibit the production of both A β 42 and A β 40 in rat primary neuron culture
 - E2012 decreased A β



-Secretase Inhibitor/Modulator

Treatment of AD

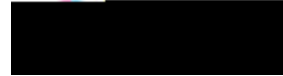


E2012

Suspension of Phase I

- Lenticular change in rats
 - In the 13-week oral toxicity study, lenticular opacity was observed in rats treated at high doses
 - In the rat (4-week) and monkey (4-week, 13-week) toxicological studies, lenticular change have not been observed
- Suspension of Phase I study
 - Eisai voluntarily suspended a single Phase I study and notified this finding to FDA on February 2007
 - FDA then imposed a Clinical Hold on April 2007

Development Plan



AS-3201

Aldose Reductase Inhibitor



Diabetic Neuropathy

- Japan Phase IIa study and good safety profile warrant subsequent clinical development
- Japan Phase IIa study by Dainippon Sumitomo
 - AS-3201 20mg/day showed significant improvement in summed SNCV in comparison with placebo
 - mTCNS sensory score showed the trend in the whole population and improved in mild to severe population
- 253 study (Phase II/III in US) by Dainippon Sumitomo
 - Statically significant effect for SNCV was not achieved, while some effect on MNCV was shown
 - Well tolerated, with more than 100 patients treated at doses of 20mg and 40mg for at least 1 year
 - Unexpected high placebo effect

SNCV: Sensory Nerve Conduction Velocities

MNCV: Motor Nerve Conduction Velocities

mTCNS: Modified Toronto Clinical Neuropathy Score



Diabetic Neuropathy

- Strategy
 - Study duration
 - Due to slow progression of disease, long-term treatment would be necessary
 - Patient population
 - Based on the MOA, AS-3201 is expected to prevent worsening rather than to show quick improvement
 - Prevention of disease progression is beneficial for the patients
 - Endpoint
 - Clinical meaningful scores reflecting electrophysiological measures



Aricept[®], AcipHex[®]/Pariet[®]
New Formulations



Aricept[®] Sustained Release Formulation

Central (cortical)%

10mg
current
tablet

77.3

19-39^{1, 2, 3)}

23mg
Sustained
Release



Aricept[®] Sustained Release Formulation: Phase III study

- Outline of Phase III (Study 326)
 - A double-blind, double-dummy, pa

Aricept[®] Patch Formulation

Equivalent Efficacy → **Higher Compliance / Convenience**

Pill burden and/or difficulty swallowing in Alzheimer's disease patients



Reduction of caregivers and patients' burden to administer
(no titration, easy to apply)

Target: Once a 3-days, or once a week patch



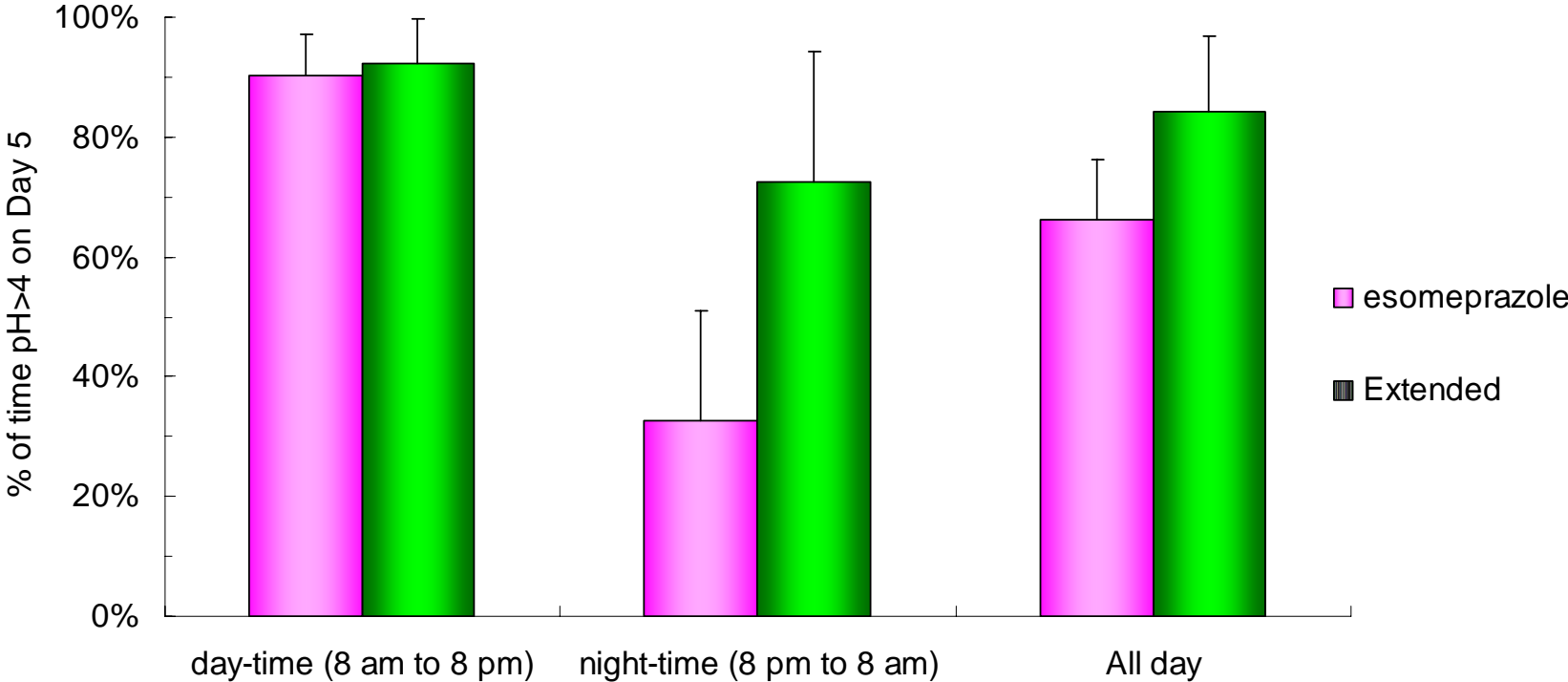
Improvement of compliance

Current status:

Pre-IND meeting with FDA (June 07)

Preparation of IND submission

Target submission: FY2009





Pariet[®] / AcipHex[®] Extended Release Formulation

- End-of-Phase II meeting with FDA has been requested
- Phase III Plan
 - **Erosive Gastroesophageal Reflux Disease (GERD)**, vs. esomeprazole
 - **Symptomatic GERD**, vs. placebo
 - **GERD maintenance**, vs. placebo
- Target submission: FY2009

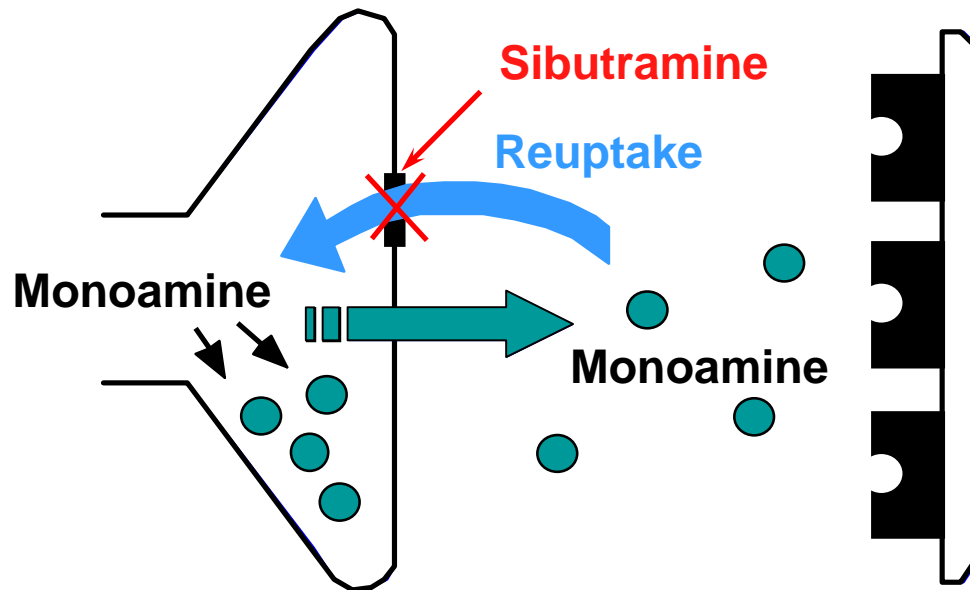


Clinical Research in Japan

Toshio Obayashi
Director,
New Product Development Department
Clinical Research Center
Eisai Co., Ltd.

KES524 (sibutramine)

- Noradrenalin and serotonin reuptake inhibitor



- Reducing energy intake through enhancing satiety
- Mild thermogenic effect
(Accelerate energy consumption)

Obesity Management

- **Phase III pivotal study (Study 161)**

- **Objective:** To investigate the efficacy and safety of KES524 in patients with obesity (visceral fat obesity with type 2 diabetes and dyslipidemia)
- **Study design:** A Multi-center, randomized, double-blind, placebo-controlled, parallel group study
- **Main inclusion criteria:** BMI ≥ 25 kg/m², VFA ≥ 100 cm², Diagnosed type 2 diabetes (HbA1c $\geq 6.1\%$), Dyslipidemia (TG ≥ 150 mg/dL and/or HDL-C ≤ 40 mg/dL)
- **Dosage:** KES524 10 mg/day (increased to 15 mg if inadequate weight loss at week 4) or Placebo
- **Study period:** Screening period 4 weeks, Treatment period 52 weeks, Follow-up 12 weeks
- **Primary endpoints:** Change and percent change in bodyweight
- **Secondary endpoints:** BMI, waist circumference, VFA, HbA1c, TG, HDL-C etc.
- **Number of patients completed:** 342

- **Target submission for J-NDA**

- **November 2007**

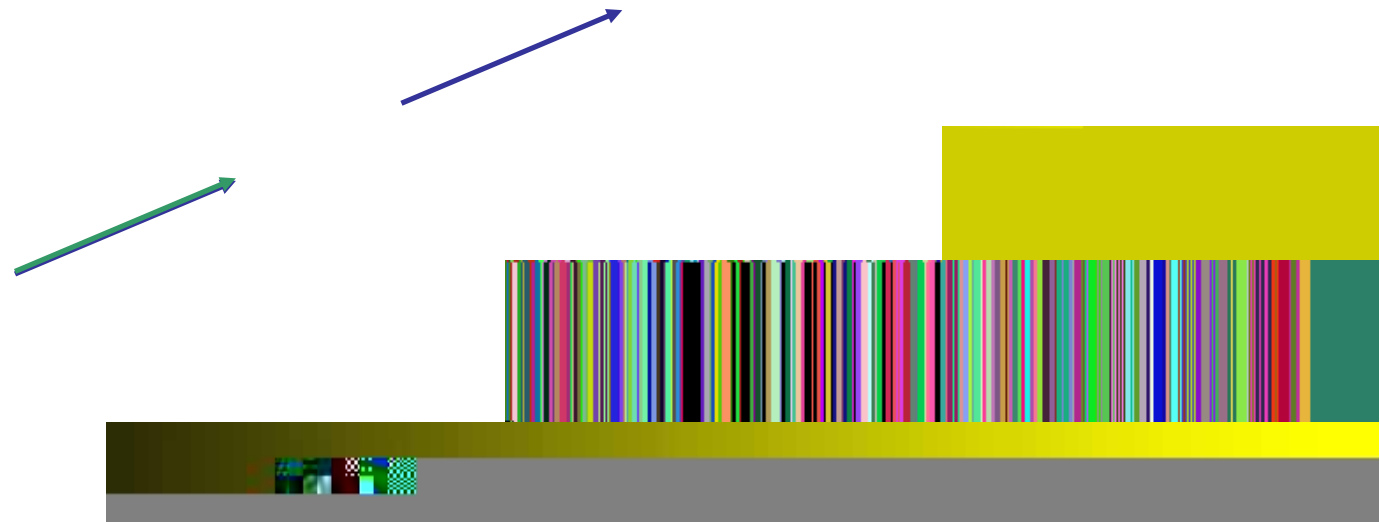
HbA1c: Hemoglobin A1c
TG: Triglyceride
HDL-C: High-density lipoprotein cholesterol
BMI: Body Mass Index
VFA: Visceral fat area



D2E7 (adalimumab)

Generations of TNF- α Antibodies

Fully Human



D2E7



Comparison with Competitors



Mouse



Rheumatoid Arthritis

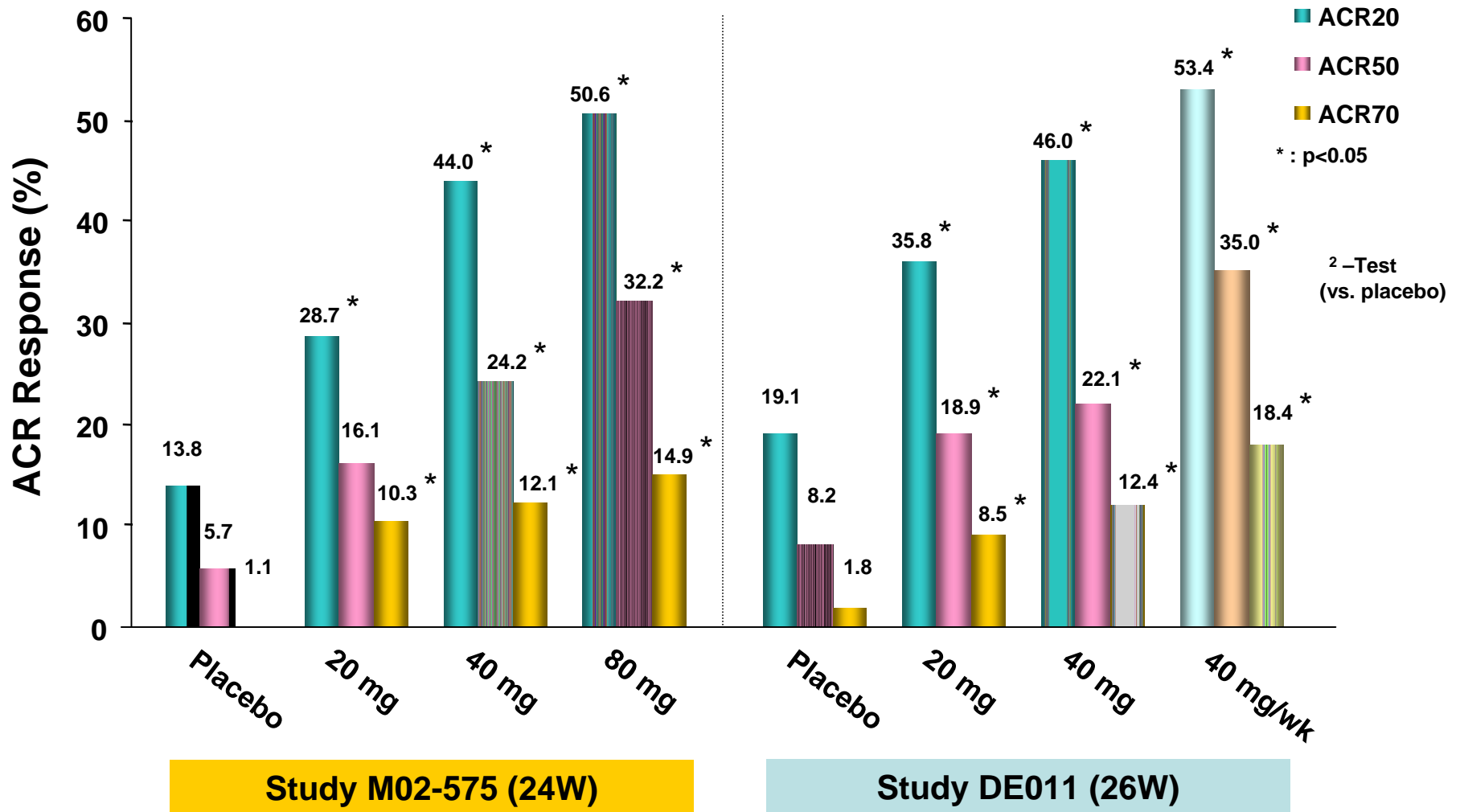
- Phase II / III study (Study M02-575)
 - **Objective:** To evaluate the efficacy, safety and pharmacokinetics of sc doses of 20 mg adalimumab eow, 40 mg adalimumab eow, and 80 mg adalimumab eow and placebo eow in adult Japanese subjects with Rheumatoid Arthritis.
 - **Study design:** A Multi-center, randomized, double-blind, placebo-controlled, parallel group study
 - **Main inclusion criteria:** Meet ACR criteria for diagnosis of active rheumatoid arthritis, TJC: 12, SJC: 10, CRP: 2 mg/dL
 - **Dosage:** Adalimumab 20 mg, 40 mg, 80 mg and Placebo, subcutaneous injection, eow
 - **Study period:** 24 weeks
 - **Primary endpoint:** ACR20 response rate at Week 24
 - **Secondary endpoints:** ACR 50/70 response rate, ACR Core Set, Morning Stiffness etc.
 - **Number of patients completed:** 352
- Submission for J-NDA
 - **December 2005**

eow: every other week
ACR: American College of Rheumatology
TJC: Tender joint count
SJC: Swollen joint count
CRP: C-reactive protein

D2E7



M02-575 / DE011: ACR Response



Source: Partially modified materials for the 51th Annual General Assembly and Scientific Meeting of Japan Colleague of Rheumatology



Psoriasis

- Phase II / III study (Study M04-688)
 - **Objective**: To assess the efficacy and safety of repeated administration of adalimumab in adult Japanese subjects with moderate to severe chronic



Crohn's Disease

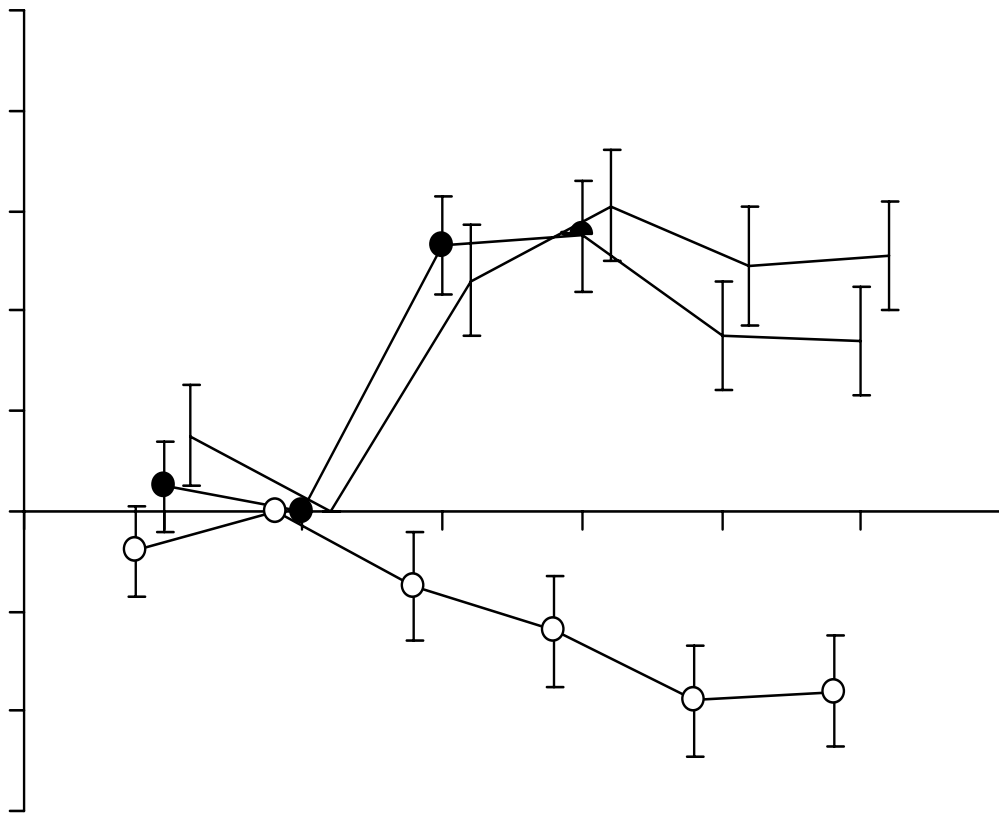
- Phase II / III study (Study M04-729)
 - **Objective**: To demonstrate the efficacy and safety of adalimumab for the



Aricept[®] (donepezil HCl)

Severe Alzheimer's Disease

- Phase II study (Study 231)
 - **Objective**: To determine donepezil's efficacy and tolerability in severe Alzheimer's disease (AD)
 - **Study design**: A Multi-center, randomized, double-blind, placebo controlled, parallel group study
 - **Main inclusion criteria**: Severe AD, FAST ≤ 6 , MMSE 1-12
 - **Dosage**: 5 mg, 10 mg, Placebo
 - **Study Period**: Treatment period : 24 weeks
 - **Primary endpoint**: CIBIC-plus, SIB
 - **Secondary endpoints**: Behave-AD, ADCS-ADL-sev
 - **Number of patients completed**: 325
- **Submission for J-NDA**
 - **December 2005**

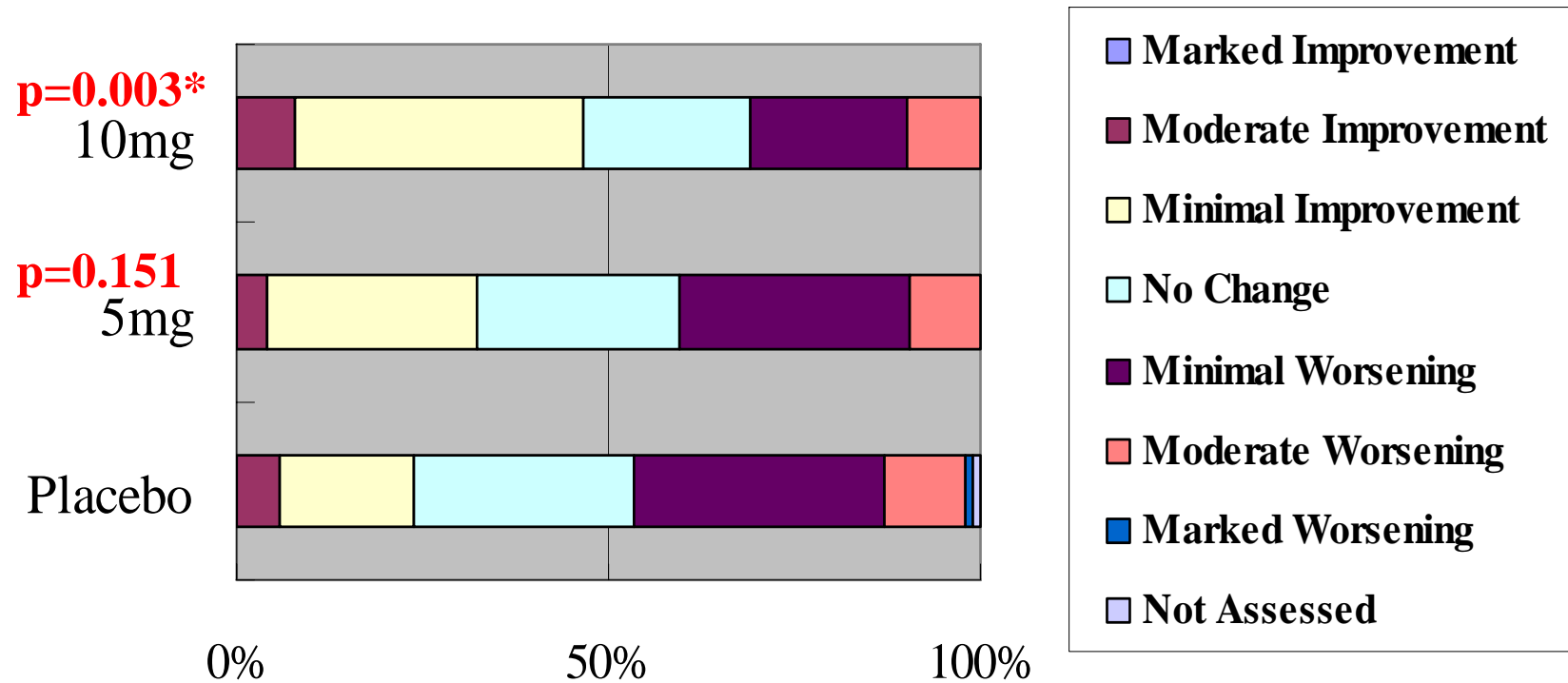




Primary Efficacy: CIBIC plus Global Function

FAS-LOCF

The dose-response of 3 groups was also observed.



* : $p < 0.025$ CMH Test

NME Pipeline in Japan

E2014	Botulinum toxin type B	Cervical dystonia	NDA submitted in December 2006	Submitted
T-614	Suppression of lymphocyte proliferation, immunoglobulin and inflammatory cytokines production	Rheumatoid arthritis	NDA submitted in September 2003	Submitted
		Rheumatoid arthritis	NDA submitted in December 2005	Submitted
D2E7	Fully human anti-TNF-alpha monoclonal antibody	Psoriasis	Phase II/III study ongoing	Sep2007
		Crohn's disease	Phase II/III study ongoing	FY2009
E5564	Endotoxin antagonist	Severe sepsis	J-IND for ACCESS study (Phase III) for severe sepsis completed in June 07. Phase I study completed using Japanese volunteers in the U.S., before conducting Phase III Plan to submit simultaneously in the U.S., Europe and Japan in FY2009	FY2009 (Japan, U.S. EU)
				Nov.2007



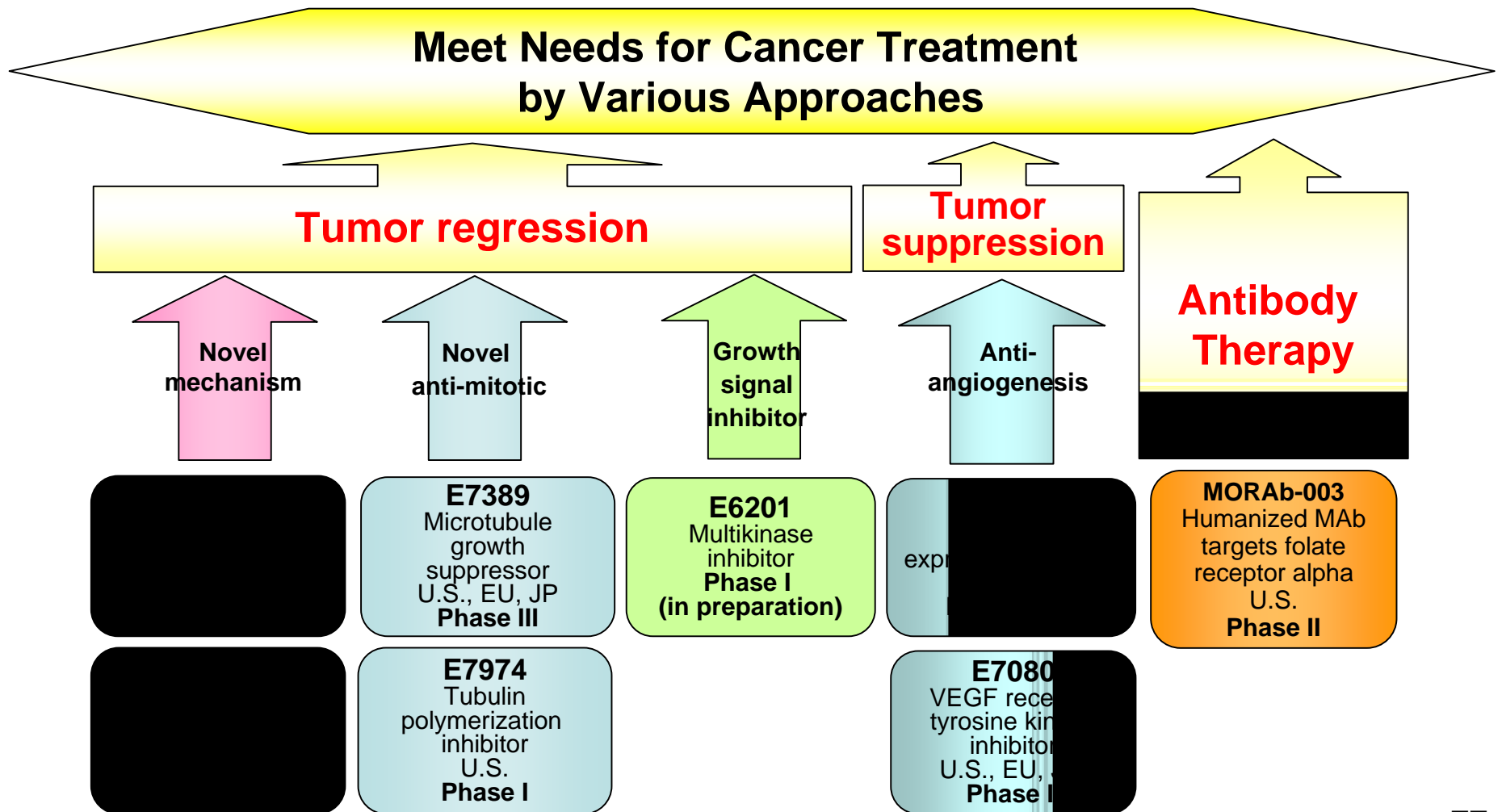
Oncology Research Strategy

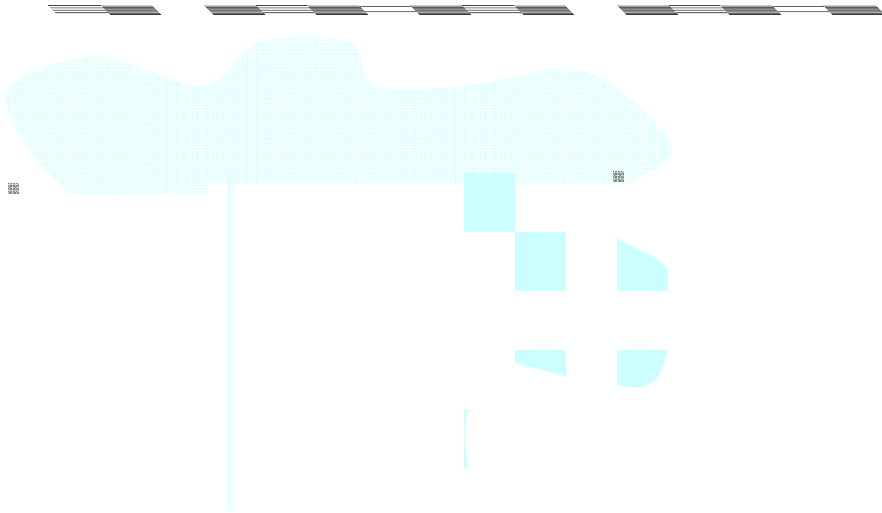
Kentaro Yoshimatsu

Senior Vice President, Research & Development, Eisai Co., Ltd.

President, Eisai R&D Management Co., Ltd.

Oncology projects under development







Significance of Having both Small Molecules and Biologics in drug discovery

- Drug discovery
 - Improve R&D profitability by combining research basis of small molecules, pharmacological evaluation and antibodies
 - Drug discovery utilizing both small molecules and biologics
 - One molecule may yield both antibodies and small molecules: develop antibodies first and then develop small molecules
- Discover new antigens and generate candidate antibodies by utilizing

Oncology Portfolio Overview

		Target Indication		
		Breast cancer		
		Prostate cancer	Phase II POC study enrollment completed	
		NSCLC	Phase Ib study in combination with carboplatin ongoing	
		Sarcoma	Phase II POC study ongoing	
		Cancer	Phase I study ongoing in Japan	
		Cancer	Phase Ib/II study for 3 rd line use in combination with	FY2011
E7070	Cell cycle G1 phase targeting agent	Small cell lung cancer, pancreatic cancer	Phase Ib in combination with irinotecan (U.S.)	
		Cancer		
		Cancer		
MORAb-003	Monoclonal antibody (anti-folate receptor alpha)	Ovarian cancer	Phase II ongoing (U.S.)	
MORAb-009	Monoclonal antibody (anti-mesothelin)	Pancreatic cancer	Phase I ongoing (U.S.)	
E7107	Novel mechanism	Cancer	Initiated Phase I (U.S., EU)	
E6201	Multi-kinase inhibitor	Cancer	Preparation for Phase I	

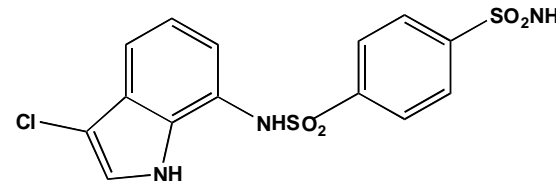
E7820

Phase I monotherapy study

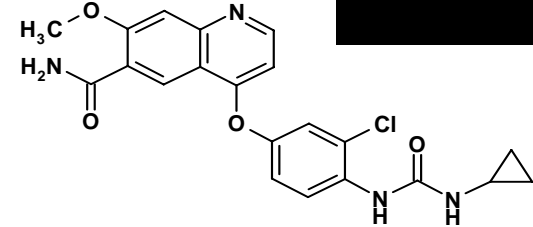
- Open label, non- randomized, chronic daily dosing, single center
- Study conclusion presented at ASCO 2006
 - Dose-limiting toxicity (DLT) and Maximum Tolerated Dose (MTD)
 - E7820 can be safely administered to patients with advanced cancer at all doses up to 100 mg
 - DLT at 200 mg were thrombocytopenia (2 patients) and neutropenia (1 patient)
 - MTD determined to be 100 mg
 - Suggested drug activity
 - Disease stabilization beyond Cycle 4 observed in 6 patients
 - Three patients have been on study for > 6 months
 - Two patients were on study for 11 and 14 months

E7070 (indisulam)

Cell cycle G1 phase targeting agent



- Different antitumor spectrum from existing anticancer drugs, due to new mechanism (cell cycle G1-targeting)
- Synergic antitumor effect in combination with irinotecan
 - Mechanism assumed inhibition of topoisomerase II expression which is increased by irinotecan (topoisomerase I inhibitor)
- Current Status:
 - Phase Ib for small cell lung cancer and pancreatic cancer is ongoing in the U.S. (combination with irinotecan)



E7080

Oral VEGF receptor tyrosine kinase inhibitor

- Inhibition of all VEGF receptor family (VEGFR1:Flt-1, VEGFR3:Flt-4), not only VEGFR2:KDR
- Inhibition of other angiogenesis-related molecules such as FGFR1 and PDGFRb, in addition to VEGFR family
- Inhibition of c-Kit, inhibition of proliferation of SCF-dependent small cell lung cancer
- Anti-proliferation activity against human colorectal, pancreatic, non-small cell lung, breast, ovarian, prostate and small cell lung cancers xenograft models; tumor regression in some models
- Current status:
 - Three Phase I studies are ongoing (U.S., EU and Japan)
 - Once a day, continuous dosing
 - Twice a day, continuous dosing
 - Twice a day, 2 weeks ON & 1 week OFF

- Synthesis
- Binding to tubulin
- Effect on microtubule dynamics





Ongoing Phase I studies

- Three Phase I studies for MTD determination ongoing with patients with solid malignancies:
 - 101 (Day 1, 8, 15 of a 28-day cycle)
 - 102 (Day 1, 15 of a 28-day cycle)
 - 103 (Day 1 of a 21-day cycle)

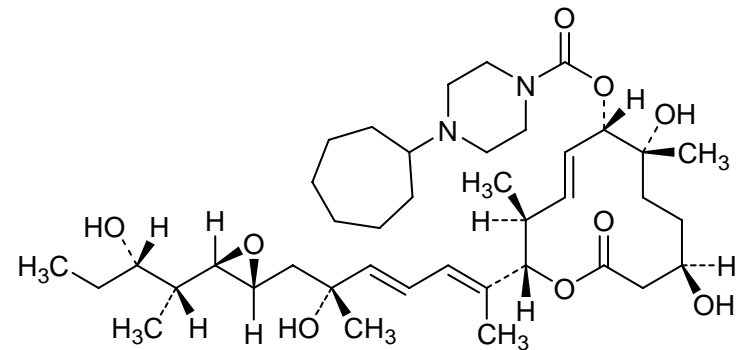
Results of 101 and 102 studies were presented at ASCO 2007

- Conclusion of 102 study at ASCO 2007:
 - The recommended Phase II dose of E7974 on Days 1 and 15 of a 28-day schedule is 0.31 mg/m²
 - Neutropenia was the dose-limiting toxicity, but all observed toxicities were manageable and reversible
 - One patient with esophageal cancer had a confirmed PR and remained on study treatment for 6 cycles. Patients with esophageal cancer, prostate cancer, liposarcoma, and bladder cancer had a best response of SD and all remained on the study for >6 cycles

E7107

(Pladienolide derivative)
Novel anti-tumor agent

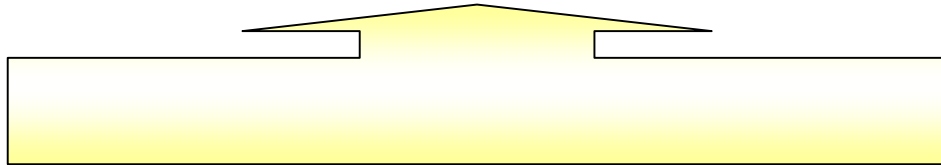
- Pladienolide was discovered from the fermentation broth of *streptomyces platensis* Mer-11107
- Different antitumor spectrum from existing anticancer drugs
- Most potent tumor regression activity in nude mouse xenograft models (human cancer cells)
- Inhibition of expression of multiple genes, causing splicing abnormality for mRNA of specific proteins
- Current Status:
 - Phase I ongoing



Streptomyces platensis
Mer-11107

Reference: T. Sakai et al, J Antibiot., 57, 173-179, 2004

Oncology projects under development





Morphotek Inc.

Eisai's biologics R&D center
developing monoclonal antibody products through use of a
proprietary human antibody technology

Nicholas Nicolaides
Morphotek Inc. CEO

Product Development Approach

leverage technology with collaborations for product development



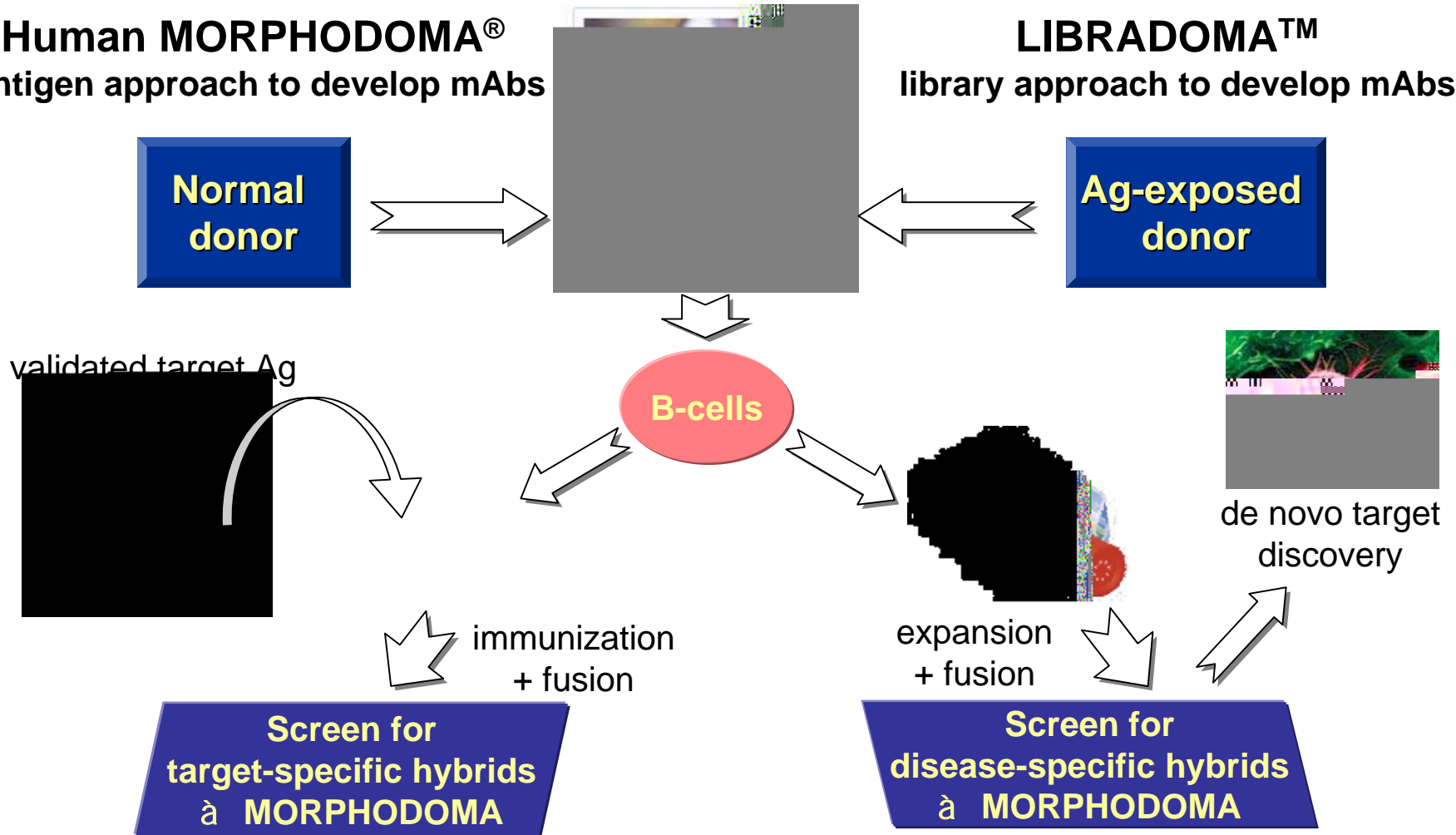
	rodent	chimeric	humanized	human
mAb structure				
% human	0	70	95	100
limits as human therapeutics	-immunogenic -lack of immune effector activity	-immunogenic	-low affinity -immunogenic	-high affinity, target specificity
benefits as human therapeutics	-target specificity	-target specificity low immunogenicity -mediate immune rx	-target specificity -low immunogenicity -mediate immune rx	-target specificity -low immunogenicity -mediate immune rx
commercial examples	OKT3, Zevalin, Bexxar	Rituxan, Erbitux, Remicade	Avastin, Synagis, AtTw(-lack /Cs6 cx,)Tj643.56 138256 is,	



Morphotek Human Antibody Platforms

Human MORPHODOMA[®]
antigen approach to develop mAbs

LIBRADOMA[™]
library approach to develop mAbs



Competitive Antibody Platform Technologies



	MORPHODOMA	Humanization Technology	Phage Technology	Xenomouse Technology
Company	Morphotek-Eisai	Protein Design Labs	CAT- AstraZeneca Dyax,	



Antibody	1 st Indication	Other indications	Description	Collaborator	Stage
MORAb-003	Ovarian cancer	Breast, CRC, NSCLC, Renal	antigen on >90% ovarian tumors		

MORAb-003

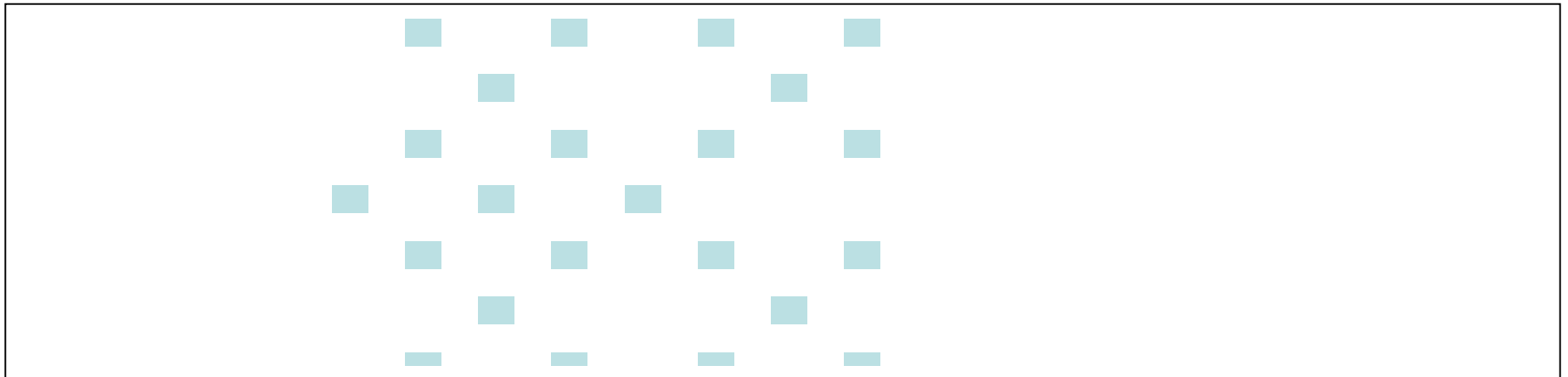


- Humanized IgG1 mAb to Folate Receptor Alpha
- FRA over-expressed in ovarian, breast, colon, NSCLC and renal tumors
- FRA biology associated with transformation
- Suppresses growth of ovarian cancers in vivo
- No toxicity observed in cynomolgus GLP studies
- Phase I clinical trials in ovarian cancer at Memorial Sloan Kettering
 - No DLT or SAEs observed
 - 15 of 19 showed stable disease
- Multi-institutional Phase II open for 1st line relapse ovarian cancer patients
- Granted orphan status by FDA June 2006
- IP to antibody and antigen

Phase II Study



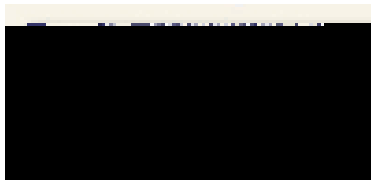
Natural course of disease





MORAb-009

- mAb to mesothelin (MT)
- MT confirmed to be over-expressed in pancreatic, lung, mesothelioma, ovarian, and colon cancers
- MT biology associated with invasion
- Suppresses growth of pancreatic cancers in vivo
- No toxicity observed in cynomolgus GLP studies
- Phase I clinical trials in mesothelin+ cancers ongoing at JHU, FCCC, NCI
- Granted orphan status by FDA November 2006
- IP to antibody and antigen





Phase I Study Update

- **Mesothelin-expressing tumors at JHU, FCCC, NCI**
 - Single agent in pancreatic, mesothelioma, NSCLC, and ovarian cancers
 - Standard dose escalation design
 - Dose cohorts (12.5, 25, 50, 100, 200 & 400 mg/m²)
 - 3 patients per cohort until DLT/MTD reached
 - Target to initiate Phase II in 1st line therapy for pancreatic cancer FY3Q-07
- **Status:**
 - Completing 6th cohort
 - Three patients were recommended by their physician for extended therapy
 - Pancreatic cancer gemcitabine failure, stabilized disease for 7 months