

Progress and Status of 5th Mid-term Strategic Plan *'Dramatic Leap Plan'*

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New Globalization Era

1. Good Balance of Global Sales

(Unit: %)

	Japan	North America	Europe	Asia
Market Growth CAGR FY05-11	2	8	7	9
Eisai FY2005	47	42	8	3
Eisai FY2011	35	45	15	5

2. Clear View for Regional Headquarters as well as Global Functional Initiative in the Best Location

- Eisai R&D Management Company (Japan)
Integrative R&D Management, Project Management**
- Eisai Global Clinical Development (U.S.)**
- Global Medical & Marketing Services (U.S.)**
- Asia, Oceania and Middle East Business Headquarters
(Japan)**

3. Capability of Global Policy/ Strategy Building

- Start up Global Policy & Strategy Committee**
- Regional and Functional Representation, Chair: CEO
US, Japan, Europe, Asia, Discovery, Clinical,
Marketing, Manufacturing, Regulatory,
Compliance, Safety etc.**

4. Discovery Research

Enlargement of the capacity in the U.S. and Europe



Eisai Research Institute of Boston

Number of Scientists: 140 → 200



European Knowledge Center (Image)

Number of Scientists: 50 → 100

Integrative Oncology Approach

1. Areas

Cancer Therapies

Cytotoxics
Anti-angiogenesis
Antibodies
Vaccines

Supportive Therapies

Anemia
Thrombosis
Pain
Nausea/vomiting
Oral mucositis
Neuropathy

2. Our Pipeline & Acquisition

Our Pipeline

Status	Research Code	Mechanism of Action	Therapeutic Strategy		Filing Schedule	Development Area
Subpart H application /Phase III	E7389	Microtubule Growth Suppressor	Tumor Regression	Novel Anti-mitotic	FY2006	US, Europe, Japan
Phase III	E0167	Prevention of Hepatocellular Carcinoma Recurrence by Vitamin K2	Life-span Prolongation	Prevention of Recurrence	FY2008	Japan
Phase II	E7070	Cell Cycle G1 Phase Targeting Agent	Tumor Regression	Novel Mechanism	FY2010	US, Europe, Japan
Phase I	E7820	Integrin Alpha-2 Expression Inhibitor	Tumor Suppression	Anti-Angiogenesis	FY2011	US
Phase I	E7080	VEGF Receptor Tyrosine Kinase Inhibitor	Tumor Suppression	Anti-Angiogenesis	FY2012	US, Europe, Japan
Phase I	E7974	Hemiasterlin Type Tubulin Polymerization Inhibitor	Tumor Regression	Novel Anti-mitotic	FY2012	US
Pre-Clinical	E7107	Novel Anti-tumor Agent Derived from Fermentation	Tumor Regression	Novel Mechanism	FY2013	-

Product Acquisition

Product	Indication	Patent	Sales '05
Fragmin <i>dalteparin sodium</i>	Prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) Prophylaxis of ischemic complications resulting from unstable angina and non-Q-wave myocardial infarction (heart attack), when used with aspirin.	—	\$35 (6mo)
Prialt <i>ziconotide acetate</i>	Treatment of severe, chronic pain in patients who require intrathecal analgesia	Feb 2015*	—
ONTAK <i>denileukin diftitox</i>	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma, whose malignant cells express the CD25 component of the Interleukin-2 receptor	Dec 2014	\$31 mil
Targretin capsule <i>bexarotene</i>	Treatment of cutaneous manifestations of cutaneous t-cell lymphoma in patients who are refractory to at least one prior systemic therapy	Oct 2016	\$19mil
Targretin gel 1% <i>bexarotene</i>			\$3 mil
Panretin gel <i>alitretinoin</i>		Treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma	Oct 2016

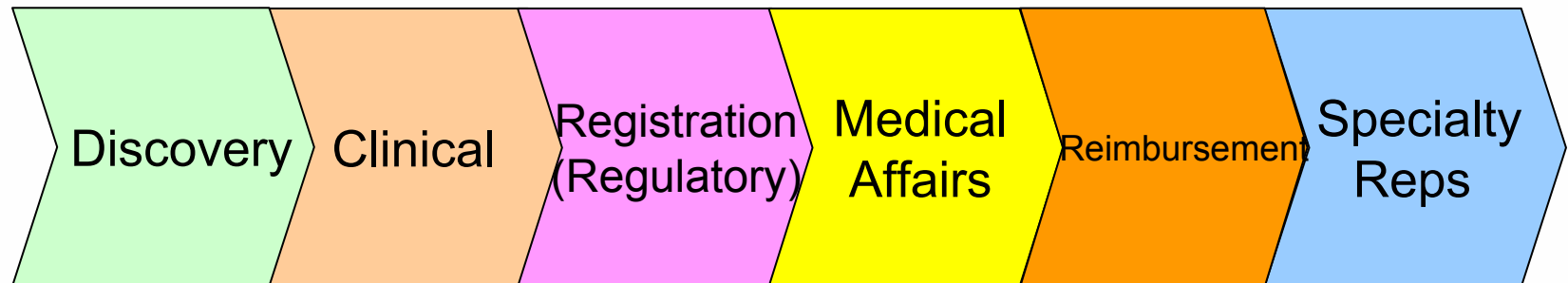
*data protection period

- Acquisition from Ligand Pharmaceuticals (subject to closing of the transaction):
ONTAK, Targretin capsule & gel, Panretin gel at \$205 million
- Fragmin got positive recommendation for extended use in patients with cancer to reduce the recurrence of venous thromboembolism at Oncology Drug Advisory Committee on 2006/9/6

3. Discovery Capability

- **Molecular/Cellular Biology** to find new target molecules for: novel cytostatics, novel cytotoxics, novel diagnostics, novel agents for prevention
- **Antibodies**
- **Vaccines**
- **Gene/RNA targeting technologies**
- **Biomarkers**

4. Cohesive Alignment of Oncology Functions as One Business Unit



Pipeline

- **Large Unmet Medical Needs Coverage:**
 - Four Key Global Projects' Phase III studies are fully ongoing**
 - Japanese Projects are progressing as well as starting to join in the global developments**
- **Extensive new indications/formulations programs are ongoing**

Current Status of Global NME Development (1)

- **E7389: Microtubule Growth Suppressor (target Subpart-H NDA submission in FY2006)**
 - Studies for 3rd line breast cancer Subpart H NDA submission ongoing
 - Initiated Phase III study for 2nd line breast cancer
 - Phase II POC study for prostate cancer ongoing
 - Initiated Phase I study in Japan
- **E2007: AMPA Receptor Antagonist (target submission for PD in FY2007)**
 - PD: Phase III study in Europe ongoing
Completed End-of-Phase II meeting with US FDA, initiate Phase III study in the US
 - Migraine Prophylaxis: Phase II POC study in progress
 - Epilepsy: Phase II POC study in progress
- **E5564: Endotoxin Antagonist (target submission in FY2009)**
 - Phase III study for severe sepsis started
 - Plan to sequentially initiate study at approx. 250 sites in Americas, Europe, Japan, Asia, Oceania, etc.
 - Preparing Phase I study with Japanese participants
 - Target simultaneous submission in the US, Europe and Japan in FY2009

Current Status of Global NME Development (2)

- **AS-3201: Aldose Reductase Inhibitor (target submission in FY2009)**
 - Diabetic Neuropathy
 - Phase II/III in progress by Dainippon Sumitomo Pharma
 - Eisai will conduct its Phase III study upon outcomes of End-of-Phase II meeting to be held in FY2006
- **E5555: Thrombin Receptor Antagonist (target submission in FY2010)**
 - Prevention of major adverse cardiac events in acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction)
 - Confirmed safety, PK and pharmacological action in Phase I
 - Phase II in progress in US and Europe
 - Phase I in progress in Japan
- **E2012: Gamma-secretase Modulator (target submission in FY2010)**
 - Alzheimer's disease
 - IND submitted in March 2006 to US FDA
 - Phase I study started
 - To establish Proof of Principle in Phase I by measuring beta amyloid in blood and spinal fluids

Global NME Projects

Project Code		Target Indication	Progress	Submission Target
E2080	Na ⁺ channel modulator	Epilepsy (rufinamide)	Filed (US & EU)	Filed
E7389	Microtubule growth suppressor	Breast cancer	Subpart H study Phase III (US)	FY2006 (Subpart H submission)
		Non-small cell lung cancer	Phase II (US)	FY2010
		Prostate cancer	Phase II (US)	-
		Sarcoma, ovarian cancer	Phase II in preparation	-
E2007	AMPA receptor antagonist	Parkinson's disease	Phase III (US & EU)	FY2007
		Migraine prophylaxis	Phase II (US)	FY2008
		Epilepsy	Phase II (US & EU)	FY2009
		Multiple sclerosis	Phase II (US & EU)	-
E5564	Endotoxin antagonist	Severe sepsis	Phase III (US)	FY2009 (JP, US, EU)
clevudine	Antiviral agent	Chronic hepatitis B	Phase III (Asia)	Start from FY2006
AS-3201	Aldose reductase inhibitor	Diabetic neuropathy	Phase II/III (US)	FY2009
E5555	Thrombin receptor antagonist	Prevention of major adverse cardiac events in acute coronary syndrome	Phase II (US)	FY2010
E7070	Cell cycle G1 phase targeting	Gastric cancer (Japan) Small cell lung cancer (combination with irinotecan)	Phase II (JP) Phase I	FY2010
E2012	Gamma-secretase modulator	Alzheimer's disease	Phase I (US)	FY2010
E1224	Anti-fungal agent	Fungal infection	Phase I (US)	FY2011
E7820	Alpha 2 integrin expression inhibitor	cancers	Phase I (US)	FY2011
E7974	Tubulin polymerization inhibitor	cancers	Phase I (US)	FY2012
E7080	VEGF receptor tyrosine kinase inhibitor	cancers	Phase I (US, EU & JP)	FY2012

Development Projects in Japan

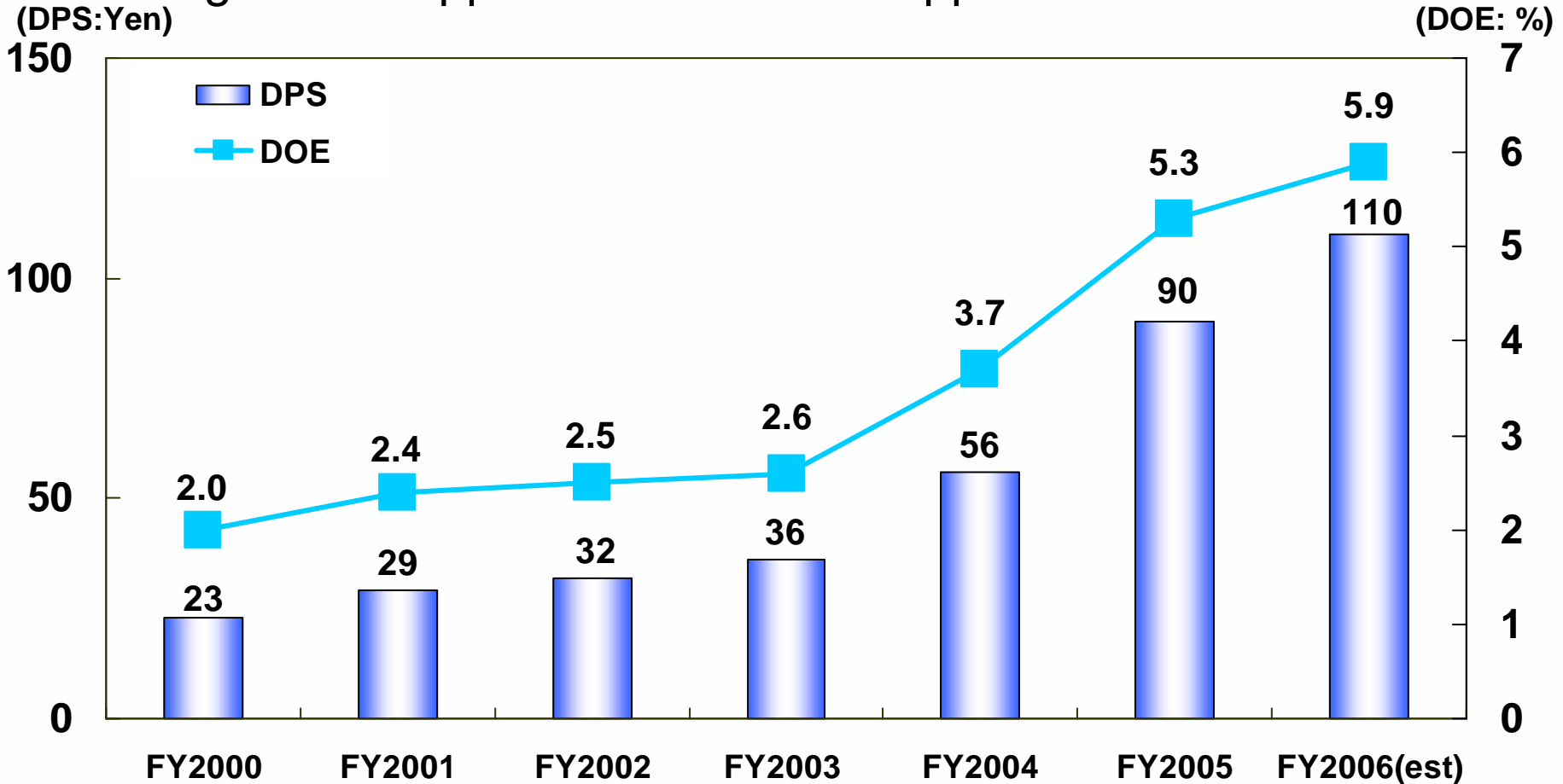
Project Code	Progress	Submission Target
T-614	Rheumatoid arthritis (RA) Filed for the treatment of RA	Filed
D2E7	Rheumatoid arthritis (RA) Filed for the treatment of RA	Filed
E2014	Cervical dystonia Phase II/III ongoing	FY2006
KES524	Obesity management Phase III ongoing	FY2007
E0167	Vitamin K ₂ preparation Recurrence of hepatocellular carcinoma Phase II/III ongoing	FY2008
E7389	Cancers Enrolled the first patient in Phase I study	FY2009
E5564	Endotoxin antagonist Phase I in preparation	FY2009
E7070	Cancers Gastric cancer, Phase II ongoing	FY2010
E2007	AMPA receptor antagonist Phase II for Parkinson's disease in preparation	FY2010
E5555	Thrombin receptor antagonist Single-dose Phase I completed	FY2011
E7080	Cancers Phase I ongoing	FY2012

New Indication/Formulation Programs

Product	Target Indication	Submission Target
Aricept[®] Acetylcholin-esterase Inhibitor	Severe Alzheimer's disease	Filed (JP, US & EU)
	Sustained release formulation	FY2009
	Transdermal patch formulation	FY2009
Pariet[®] Anti-ulcer agent (PPI)	<i>H. pylori</i> eradication	Filed (JP)
	Symptomatic GERD	Filed (JP)
	Extended release formulation	FY2009
Zonegran[®] Anti-epileptic Agent	Pediatric use	FY2009
	Monotherapy	FY2010

Enriching Return to Shareholders

Target DOE approx. 8% and DPR approx. 50% in FY2011



Share buyback	vol.	4 mil.	1.97 mil.		4 mil.
	Yen	11.4 bil.	6.1 bil.		22.0 bil.

DOE = Dividends On Equity (= ROE x Dividend Payout) DPS = Dividends Per Share

DPR = Dividend Payout Ratio