FY2004
Financial Results
Presentation

May 16, 2005
Eisai Co., Ltd.

FY2004 Financial Results

FY2004 Consolidated Results

			FY2004			
Cost of Sa82 scn/09910	97.2	19.4	**98.5**	18.5	101	1.3
Gross Profit	402.9	80.6	**434.5**	81.5	108	31.6
R&D Expenses	69.0	13.8	**78.3**	14.7	113	9.3
SG&A Expenses	250.9	50.2	**269.4**	50.5	107	18.5
Operating Income	83.1	16.6	**86.8**	16.3	105	3.7
Ordinary Income	83.4	16.7	**89.1**	16.7	107	5.7
Net Income	50.1	10.0	**55.5**	10.4	111	5.4
EPS (yen)	172.1		**193.4**		112	21.3

Sales of Major Products

Sales to Customers by Geographic Area

(billions of yen, %)

	FY2003		FY2004			
	Results	%	Results	%	YOY (%)	Inc./Dec.
Japan	260.9	52.2	**268.3**	50.3	103	7.3
North America	194.5	38.9	**214.5**	40.3	110	20.0
Europe	34.8	7.0	**38.3**	7.2	110	3.5
Asia & others	9.9	2.0	**11.9**	2.2	121	2.0
Overseas	239.2	47.8	**264.7**	49.7	111	25.5
Total	500.2	100.0	**533.0**	100.0	107	32.8

Operating Income by Geographic Area

(Pre-royalty deduction)

(billions of yen, %)

	FY2003		FY2004			
	Results	%	Results	%	YOY (%)	Inc./Dec.
Japan	46.7	53.0	**40.1**	43.9	86	(6.6)
North America	35.0	39.8	**44.3**	48.5	126	9.3
Europe	4.6	5.2	**4.9**	5.3	107	0.3
Asia & others	1.8	2.1	**2.1**	2.3	113	0.2
Overseas	41.4	47.0	**51.3**	56.1	124	9.8
Sub Total	88.1	100.0	**91.3**	100.0	104	3.3
Elimination/ Corporate	(5.0)		**(4.5)**		90	0.5
Total	83.1		**86.8**		105	3.7

Performance of Eisai Inc.

(millions of dollars, %)

Aciphex®	933	53.8	**968**	48.4	104	35
Zonegran®	-	-	**104**	5.2	-	104
Operating Income	88	5.1	**96**	4.8	109	8
Net Income	53	3.1	**62**	3.1	115	8
Operating Income (Pre-royalty deduction)	301	17.4	**402**	20.1	133	101

Consolidated Free Cash Flow

(billions of yen)

	Cash Flow from Operating Activities		Capital Expenditures		Free Cash Flow	
	Results	Inc./Dec.	Results	Inc./Dec.	Results	Inc./Dec.
FY2002	57.6	0.7	26.5	1.8	31.1	(1.0)
FY2003	72.7	15.1	23.8	(2.7)	48.9	17.8
FY2004	**49.2**	**(23.5)**	**38.7**	**14.9**	**10.5**	**(38.4)**

4 Proof of Concepts Projects

Status of 4 Proof Of Concept (POC) Studies

E2007

Accomplished the world's first POC for Parkinson's disease
in oral AMPA receptor antagonists

E7389

Accomplished the world's first POC for anti-cancer agent based on microtubule growth suppression
Good response rate in breast cancer and
non-small cell lung cancer (NSCLC)

E5564

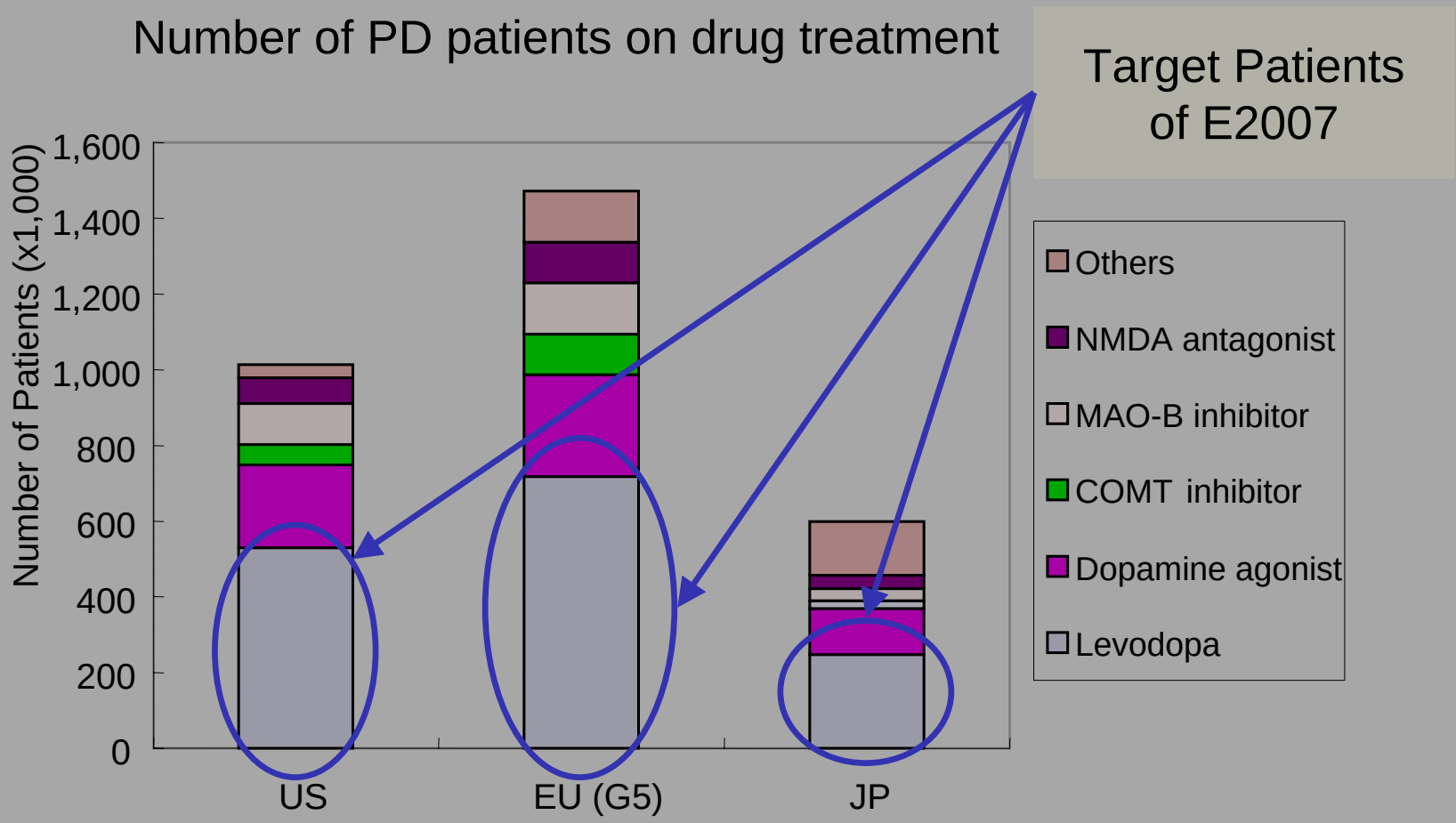
E2007 Accomplished World's First POC for Parkinson's Disease in Oral AMPA Receptor Antagonists

- In the placebo-controlled Phase IIb study for Parkinson's disease, demonstrated statistically significant dose dependency in OFF time reduction while showing clinically meaningful reduction in high-dose group (per protocol)
- Excellent safety profile and no worsening of dyskinesia
- Pursue Phase III studies after end-of-Phase II meeting with US and EU regulatory authorities in June – September 2005 (studies expected to start in 3Q FY2005)
- Target NDA/MAA submission in US and EU in FY2006

E2007: Target Product Profile (PD)

Drug Interactions	No major drug-drug interactions
Adminis-tration	Once a day, oral administration
Formulation	Small tablets

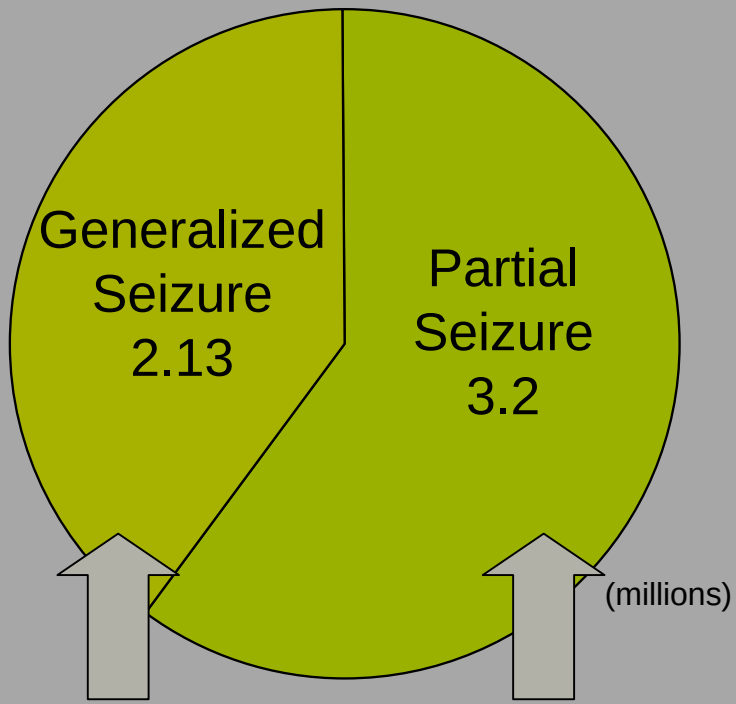
E2007, as a Novel PD Treatment, Has Potential to Reach 1.5 Million Patients



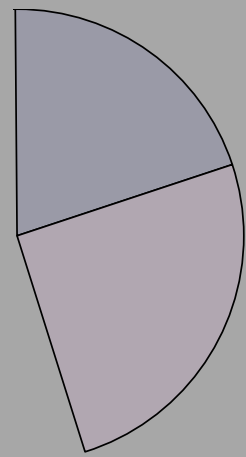
Source: Data Monitor (Total number of patients, 2005)

POC for Epilepsy Initiated and Planned for Multiple Sclerosis

Epilepsy Patients (JP, US, EU)



MS Patients (JP, US, EU)



E7389 Accomplished World's First POC for Microtubule Growth Suppressor

- Partial response (PR) as monotherapy in breast cancer and NSCLC has been demonstrated in Phase II studies
  - PR for breast cancer (3rd line):
    6 patients out of 22 in interim analysis
  - PR for NSCLC (2nd line):
    3 patients out of 10 in interim analysis

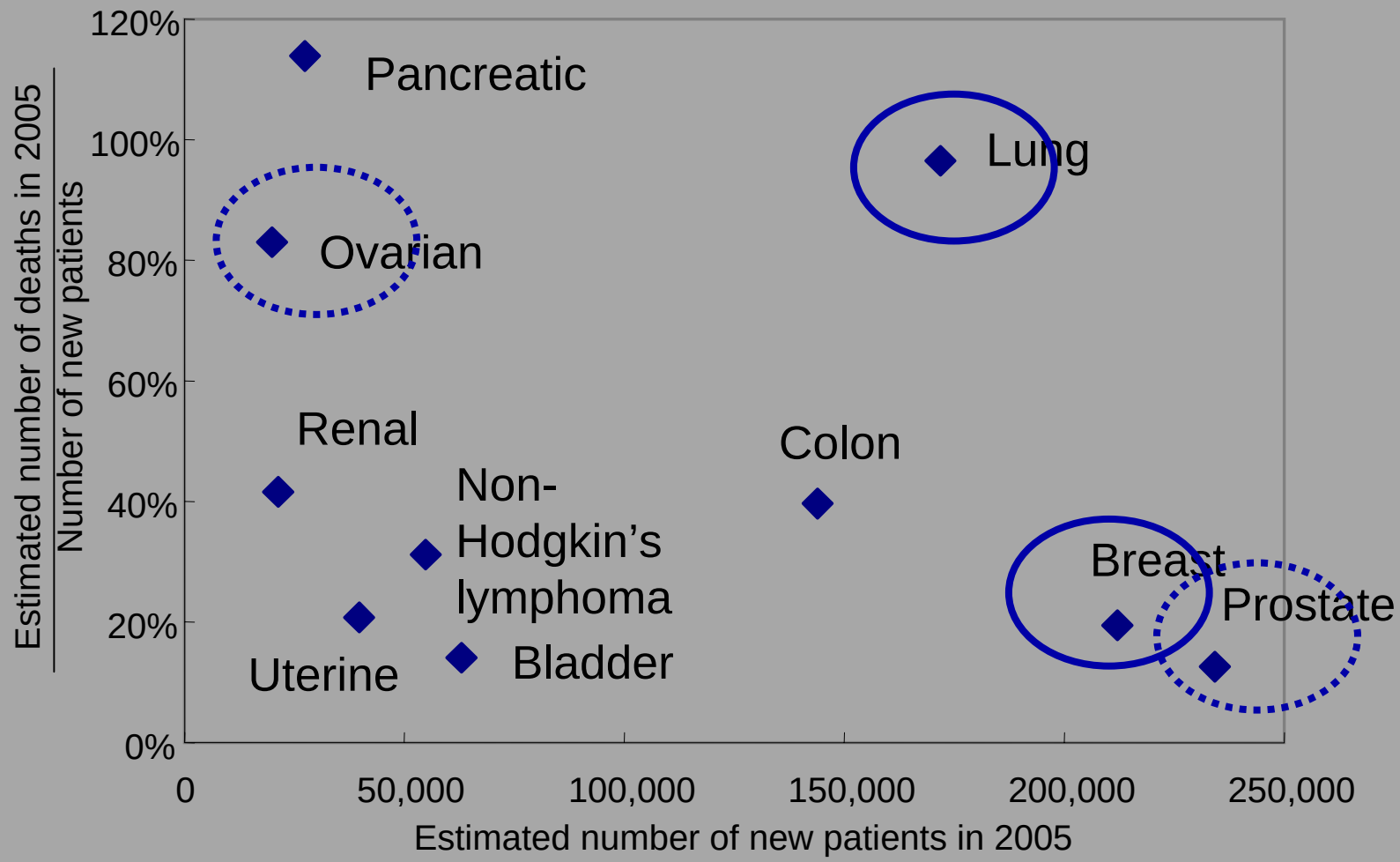
  Note: PR cases include unconfirmed cases
- Showed good safety profile
  - Neurotoxicity was infrequent and not severe
- Pursue NDA submission under Subpart H in FY2006 after consultation with FDA for both cancer types in August-September 2005
- Initiate clinical studies for soft tissue sarcoma, prostate cancer and ovarian cancer

E7389: Target Product Profile

Indications	Breast cancer: 3rd line + 2nd line + 1st line NSCLC: 2nd line + 1st line Soft tissue sarcoma: 2nd line + 1st line Prostate cancer (hormone resistant): 2nd line Ovarian cancer: 2nd line + 1st line
Efficacy	Also effective for taxane refractory tumors Effective for wide variety of cancers
Safety	No severe peripheral neurotoxicity Fewer hypersensitivity reactions (no need for premedication with steroid or anti-histamine)
Administration	Bolus (5-minute IV) Day 1, 8, 15, every 4 weeks
Formulation	Vials (solution)

E7389 is to be Studied with Additional Indications

Number of new patients by cancer type and death rate (US)



Source: American Cancer Society, 2005

E5564 - Endotoxin Antagonist - Progress and Future Plan

- Coronary artery bypass graft surgery complication (CABG)
  - Statistically significant efficacy not achieved in analysis of all-pooled active group but lower incidence of new organ dysfunction and lower mortality were demonstrated at high dose group and the effect was most apparent in high-risk subgroup of patients
- Sepsis
  - Clinical phase was completed for targeted 300 patients
  - Data analysis to be completed in early August 2005
- Future plan
  - Complete data analysis of Phase IIb sepsis study by August 2005
  - Plan to hold meetings with FDA in 3Q FY2005 for both sepsis and CABG studies

E7070 - G1 Phase Targeting Agent - Progress and Future Plan

- Breast cancer: Monotherapy (4th line)
  - Discontinue monotherapy study – i

POC Studies in FY2005 and FY2006

- FY2005
  - E7070: Cell cycle G1 phase targeting agent
    - Colorectal cancer in combination with irinotecan and gastric cancer
    - Potential further development for SCLC will be evaluated based on positive Phase I study results in combination with irinotecan
  - E5564: Endotoxin antagonist
    - Sepsis
- FY2006
  - E2007: AMPA receptor antagonist
    - Epilepsy
  - E7389: Microtubule growth suppressor
    - Soft tissue sarcoma, prostate cancer and ovarian cancer
  - E5555: Orally active PAR-1 antagonist

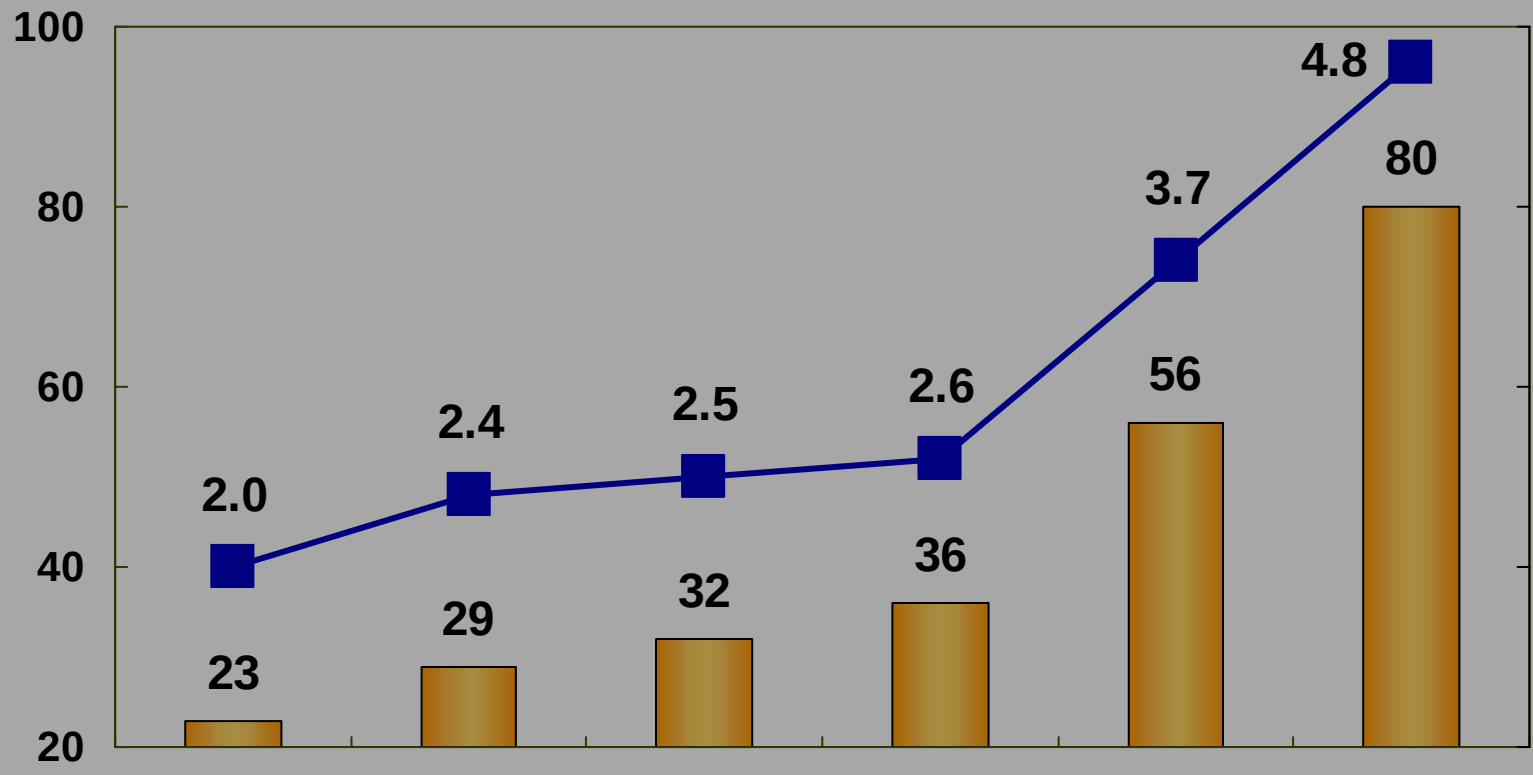
    Anti-thrombolitic, Small Muscle Cell (SMC) proliferation inhibitor:

    Expect effective prevention of angio-stenosis, low risk of bleeding (First-in-class)
    - Acute coronary syndrome

4 POC Projects in Summary

- Achievement of POCs for E2007 and E7389 substantially increased the possibility of development for 2 first-in-class products in focused areas where significant unmet medical needs exist
- Continue to pursue rapid completion of POC studies for E5564 and E7070

Return to Shareholders


100
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80

Corporate Alliances/Partnerships

Pursue corporate alliances/partnerships opportunities to expand product pipeline, new technologies and reinforce marketing, production in franchise (neurology, GI) and target areas (oncology/critical care)

Performance Forecast

(billions of yen, %)

	FY2004			FY2005						
	Results	%	YOY	Forecast	%	YOY				
	533.0	100.0	107	575.0	100.0	108	Net Sales			
	98.5	18.5	101	103.0	17.9	105	R&D Expenses	100.0	16.7	112
Gross Profit	434.5	81.5	108	472.0	82.1	109	Operating Income	100.0	16.7	110
	78.3	14.7	113	89.0	15.5	114	(R&D + OI)			
SG&A Expenses	269.4	50.5	107	292.0	50.8	108	Net Income	60.0	10.0	103
	86.8	16.3	[illegible]	[illegible]	15.8	[illegible]				
	165.1	31.0	109	180.0	31.3	109				
	55.5	10.4	111	58.0	10.1	104				
	193.4		112	203.0		105				
		56.0			80.0					
DOE (%)		3.7			4.8					
Dividend Payout Ratio (%)		29.0			39.4					

Overview of 4 POC Projects

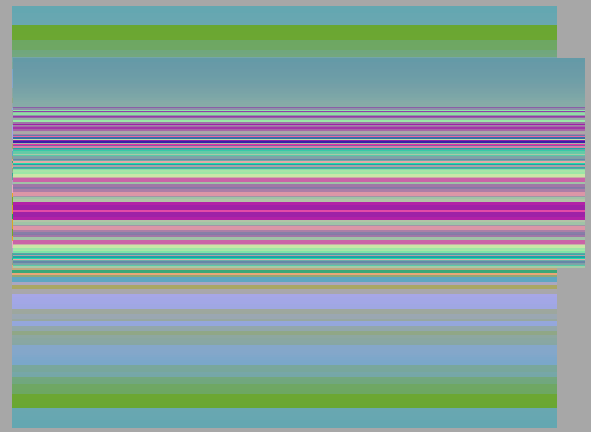
May 16, 2005

Eisai Co., Ltd.

1. **E2007 (Parkinson's disease)**
2. **E7389 (Breast cancer, NSCLC)**
3. **E5564 (CABG, Sepsis)**
4. **E7070 (Breast cancer, Colorectal cancer)**

E2007 (AMPA-Receptor Antagonist)

- C



E2007: Future Plans

- Phase III studies in PD to be initiated after the end-of-Phase II meeting with regulatory authorities in June-September 2005
  - Two placebo-controlled Phase III studies
  - One Phase III study with active control

  (Expected 3Q FY2005)
- Pursue NDA/MAA submission in US and EU in FY2006
- Complete POC for epilepsy in FY2006
- Continue Phase I studies in Japan

E7389 – Microtubule Growth Suppressor –

- Concept
  - New chemical entity featuring unique mechanism of action based on microtubule growth suppression and different from current tubulin polymerization inhibitors (taxanes, vinca alkaloids); effective against taxane-resistant cancers
  - Effective against wide spectrum of cancers
  - Better tolerability than current chemotherapy
- Proof of concept
  - Basic research indicates suppression of microtubule growth and no influence on microtubules in stable condition unlike taxanes or vinca alkaloids (paper submitted)
  - Pre-clinical studies showed superior anti-cancer effects in taxane sensitive and resistant cancers than that of taxanes
  - Phase I studies revealed PRs in multiple cancer types, including non-small cell lung cancer (NSCLC), resistant to taxane therapy and has no other treatment options
  - Phase II studies in 2 major cancer types, breast and NSCLS, showed many PRs in patients resistant to combination chemotherapies including standard therapy with taxanes
  - Neurotoxicity was infrequent and not severe
  - No hypersensitivities observed and no pretreatment with steroid or anti-histamine required as in cases of taxane therapy

E7389: Study Synopsis for Phase II – Study 201–

(Breast cancer, Monotherapy)

- Subjects
  - Breast cancer previously treated with chemotherapy, which must have included anthracycline and taxane
- Study design
  - IV bolus on Days 1, 8, and 15 of a 28-day cycle
  - Dose = 1.4mg/m^2
  - Target enrollment: 61 patients (interim analyses: 19 patients)
- Endpoints
  - Response rate
  - Safety and tolerability, duration of response, TTP, survival
- Study location
  - US

E7389: Interim Analysis for Phase II – Study 201–

(Breast cancer, Monotherapy)

- Enrollment
  - 22 patients (all taxane resistant)
- Efficacy
  - 6 patients with PR
    - 3 confirmed PRs
    - 3 unconfirmed PRs (before cycle 4)
    - All responses reviewed by independent assessors
- Safety
  - Neurotoxicity was infrequent and not severe

E7389: Study Synopsis for Phase II – Study 202–

(NSCLC, Monotherapy)

- Subjects
  - Advanced NSCLC, progressed during or after platinum-based doublet chemotherapy
- Study design
  - IV bolus on Days 1, 8, and 15 of a 28-day cycle
  - Dose = 1.4mg/m^2
  - Target enrollment: 48 patients
- Endpoints
  - Response rate
  - Safety and tolerability, duration of response, TTP, survival, and QOL (Lung Cancer Symptom Scale)
- Study location
  - US

E7389: Target Indications

- Breast cancer
  - 3rd line therapy
  - 2nd line therapy
  - 1st line combination therapy
- NSCLC
  - 2nd line therapy
  - 1st line combination therapy
- Soft tissue sarcoma
  - 2nd line therapy
  - 1st line therapy
- Hormone resistant prostate cancer
  - 2nd line therapy
- Ovarian cancer
  - 2nd line therapy
  - 1st line combination therapy

E7389: Future Plans

- Initiate registration study based on discussions with FDA (end of Phase II meeting; breast cancer and NSCLC) in August-September 2005
- Potential Subpart H NDA filing in FY2006
- Initiate clinical studies for other indications within FY2005

E5564 (Endotoxin Antagonist)

- Concept
  - World's first endotoxin antagonist as lipid-A analog that reduces mortality in sepsis
  - Reduce organ dysfunction incidences and mortality after CABG surgery
  - Good safety profile
- Proof of concept
  - All patients in Phase IIb of sepsis study, targeting 300 patients, completed clinical phase; data analysis due by August 2005
  - In CABG study, statistically significant efficacy was not achieved between all-pooled active group and placebo group in reduction in incidence of new organ dysfunction, nor in apparent dose dependency
  - In CABG study, lower incidence of new organ dysfunction and lower mortality were demonstrated in high dose group and the effect was most apparent in high-risk subgroup of patients
  - Well tolerated at doses tested in more than 800 patients with CABG
  - Independent data safety management board (DSMB) assessment requested by FDA concluded no safety concerns in interim analysis of sepsis study

E5564: Study Synopsis for Phase II – Study 204 – (CABG)

- Subjects
  - Patients undergoing cardiopulmonary bypass for coronary artery bypass graft and/or valve surgery
- Study design
  - Intravenous infusion for 4 hrs starting 1 hr prior to operation
  - Placebo, low-dose (2 mg), mid-dose (12 mg) and high-dose (28 mg)
  - Target enrollment: 1,000 patients (250 patients/dose)
- Endpoints
  - Reduction in incidence of new organ dysfunction within 14 days of surgery
  - Duration of organ dysfunction, organ dysfunction scores, length of total and organ dysfunction-associated ICU and hospital stays, ventilation assistance and renal dialysis days, volume of blood and blood products infused within 24 hrs of surgery, incidence of hospital readmission, 28-day all-cause mortality, etc.
- Study location
  - Europe and Canada

E5564: Summary for Phase II – Study 204 – (CABG)

- Enrollment
  - 1,018 patients (evaluable: 982 patients)
- Efficacy
  - Statistically significant efficacy was not achieved between all-pooled active group and placebo group in reduction in incidence of new organ dysfunction, nor apparent dose dependency
  - A numerically lower incidence of new organ dysfunction was demonstrated in high dose (28 mg) group compared to placebo group

    At 28 days and overall, the lower mortality occurred in high dose (28 mg) group. The effect was most apparent in high-risk subgroup of patients
  - No significant difference in time on artificial respirator adapter or kidney dialysis, volume of blood transfusion within 24 hrs of surgery or in length of ICU stay; no correlation with incidence of new organ failure
- Safety and tolerability
  - Confirmed good safety profile

E5564: Study Synopsis for Phase II – Study 201– (Sepsis)

- Subjects
  - Septic patients with acute organ malfunction
- Study design
  - Intravenous infusion of up to 6 days
  - Placebo, low-dose (total 45 mg), high-dose (total 105 mg)
  - Target enrollment: 300 patients (100 patients/dose)
- Efficacy endpoints
  - 28-day all-cause mortality
  - Number of organ-failure free days, organ failure scores, length of ICU and hospital stays, etc.
- Study location
  - US and Canada

E5564: Status for Phase II – Study 201– (Sepsis)

- Independent data safety management board (DSMB) requested by the FDA did not identify any safety concerns based on the interim analysis

- Enrollment (300 patients) was completed in March 2005 as well as clinical phase of all patients in April Data analysis is ongoing

- Data analysis will be completed by early August 2005

E5564: Future Plan

- Complete data analysis of Phase IIb sepsis study by August 2005
- Plan to hold a meeting with FDA for both sepsis and CABG study in 3Q FY2005

E7070 – Cell Cycle G1 Phase Targeting Agent –

- Concept
  - Exhibit unique anti-tumor spectrum compared to conventional anti-cancer drugs based on a new mechanism of action at cell cycle G1 phase where the control mechanism is most different between normal cells and cancer cells
  - Synergistic effects in combination with other anti-cancer agents
  - Synergistic effects are especially obvious with down regulation of topoisomerase II when combined with irinotecan that triggers up-regulation of topoisomerase II
- Proof of concept
  - Breast cancer 4th line monotherapy had no PR case
  - Continue Phase II studies for colorectal cancer (CRC) in combination with irinotecan and for breast cancer in combination with capecitabine
  - Continue Phase I/II study for gastric cancer in Japan
  - Plan to start efficacy confirmation study for SCLC as 3PRs and 4SDs out of 9 patients reported in Phase I study for SCLC in combination with irinotecan

E7070: Study Synopsis for Phase II – Study 211–

(Breast cancer, Monotherapy)

- Subjects
  - Advanced or metastatic breast cancer - patients previously treated with anthracycline, taxane, and fluoropyrimidine including capecitabine
- Study design
  - Target: 232 patients
    - 1st stage: 30 patients, 2nd stage: 89 patients
  - 800mg/m^2, administered once every 3 weeks
- Efficacy endpoints
  - Response rate (1st interim analysis is intended for 30 evaluable patients)
  - Duration of response, TTP, 6-month survival, safety, tolerability, and QOL
- Study location
  - US

E7070: Interim Analysis for Phase II – Study 211–
(Breast cancer, Monotherapy)

- Enrollment
  - 51 patients
- Efficacy
  - PR was not demonstrated
  - Average number of administration cycle comes out to 2 (3 weeks per cycle)

E7070: Study Synopsis for Phase II – Study 214–

(CRC, Phase II in combination with irinotecan)

- Subjects
  - Metastatic colorectal cancer
  - Received prior therapy with 5-fluorourasil/leucovorin and oxaliplatin; no more than three previous chemotherapy regimens
- Study design
  - Target enrollment: 40 evaluable patients
  - Administered on Days 1 and 8 of a 21-day cycle
  - Treatments (administered consecutively):
    - Irinotecan 125 mg/m^2 IV infusion over 90 minutes
    - E7070 400 mg/m^2 IV infusion for more than 40 minutes
- Efficacy endpoints
  - Response rate
  - Duration of response, TTP, 6-month survival, safety and tolerability
- Study location
  - Europe

E7070: Interim Analysis for Phase II – Study 214–

(CRC, Phase II in combination with irinotecan)

- Enrollment
  - 29 patients
- Best response
  - Stable disease (SD)
- Results of 40 evaluable patients due by September 2005

E7070: Future Plans

- Discontinue development as monotherapy (4th line) for breast cancer
- Continue development for CRC in combination with irinotecan and for breast cancer in combination with capecitabine
- Continue Phase I/II study for gastric cancer
- Plan to start study for SCLC (some responses recognized in the Phase I study for SCLC in combination with irinotecan)