Eisai

hhc

human health care

FY2004
Financial Results
&
POC Results

Safe Harbor Statement

- Materials and information provided during this presentation may contain "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors, challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; obtaining regulatory approvals; domestic and foreign healthcare reforms; trends toward managed care and healthcare cost containment, and governmental laws and regulations affecting domestic and foreign operations.
- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

FY2004 Consolidated Results

(billions of yen, %)

	FY2003		FY2004			
	Results	%	Results	%	YOY (%)	Inc./Dec.
Net Sales	500.2	100.0	**533.0**	100.0	107	32.8
Cost of Sales	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

(billions of yen, %)

Product Name	Area	FY2003	FY2004		
		Results	Results	YOY (%)	Inc./Dec.
Aricept® Alzheimer's Disease Treatment	Total	141.6	**162.9**	115	21.3
	Japan	28.4	**35.1**	123	6.7
	US	87.9	**97.6**	111	9.7
	$ million	777	**907**	117	130
	Europe	22.8	**27.2**	120	4.5
	Asia	2.5	**2.9**	118	0.4
Aciphex®/ *Pariet*® Proton Pump Inhibitor	Total	129.0	**132.3**	103	3.3
	Japan	14.6	**19.4**	133	4.8
	US	105.5	**104.1**	99	(1.4)
	$ million	933	**968**	104	35
	Europe	7.3	**6.8**	92	(0.6)
	Asia	1.6	**2.1**	133	0.5

Performance of Eisai Inc.

(millions of dollars, %)

	FY2003		FY2004			
	Results	%	Results	%	YOY (%)	Inc./Dec.
Net Sales	1,734	100.0	**2,001**	100.0	115	267
Aricept®	777	44.8	**907**	45.3	117	130
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)**

Active Investment to Enhance Corporate Value

- To Improve Capital Efficiency -

Operating cash flow

– Earlier disposition of liability for retirement benefit allowance

- Contribution to employee retirement benefit trust: ¥20.0 billion

Investing cash flow

– Strategic acquisition of products

- Cash-out for acquisition of *Zonegran*®: ¥13.9 billion

– Active investment in CAPEX worldwide

- Fixed asset procurement: ¥21.7 billion

Japan: PF Building (Kashima), Formulation Facility (Misato), Tsukuba Research Laboratories (Tsukuba), etc.

Overseas: RTP Plant (North Carolina), Eisai Research Institute (Boston), Suzhou Plant (China), etc.

Status of 4 Proof Of Concept (POC) Studies

E2007

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

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

Phase IIb study for sepsis is in data analysis and plan a meeting with FDA
Statistically significant efficacy not achieved in all-patient analysis of CABG

E7070

Usefulness not confirmed in 4th line monotherapy study in breast cancer
Explore POCs globally as combination therapy for colorectal cancer (CRC) and breast cancer and as therapy for small cell lung cancer (SCLC), and gastric cancer in Japan

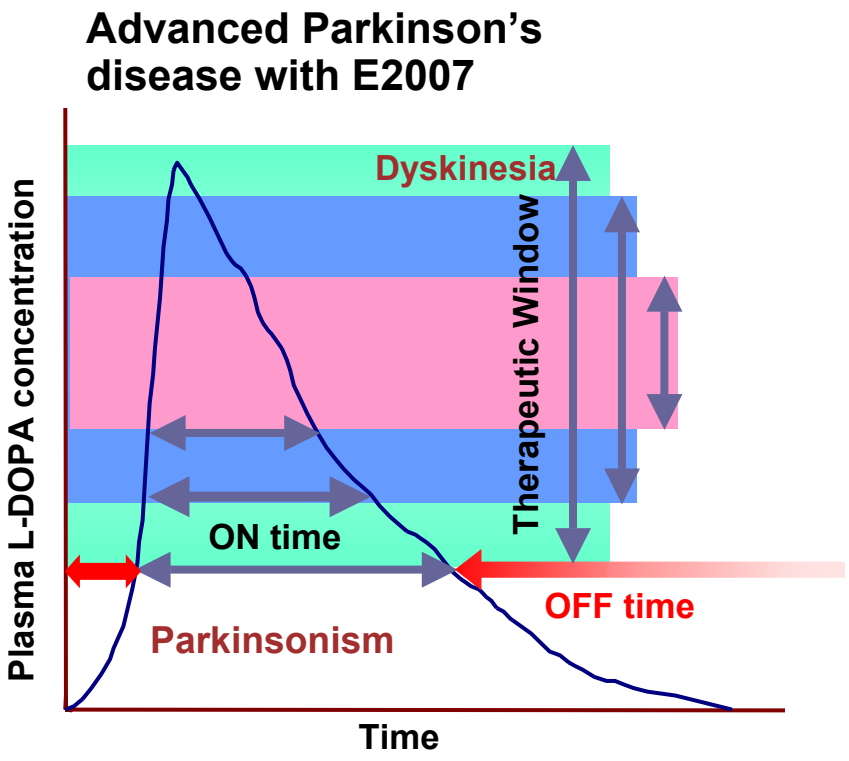
E2007 Accomplished World's First POC for Parkinson's Disease in an Oral AMPA Receptor Antagonist

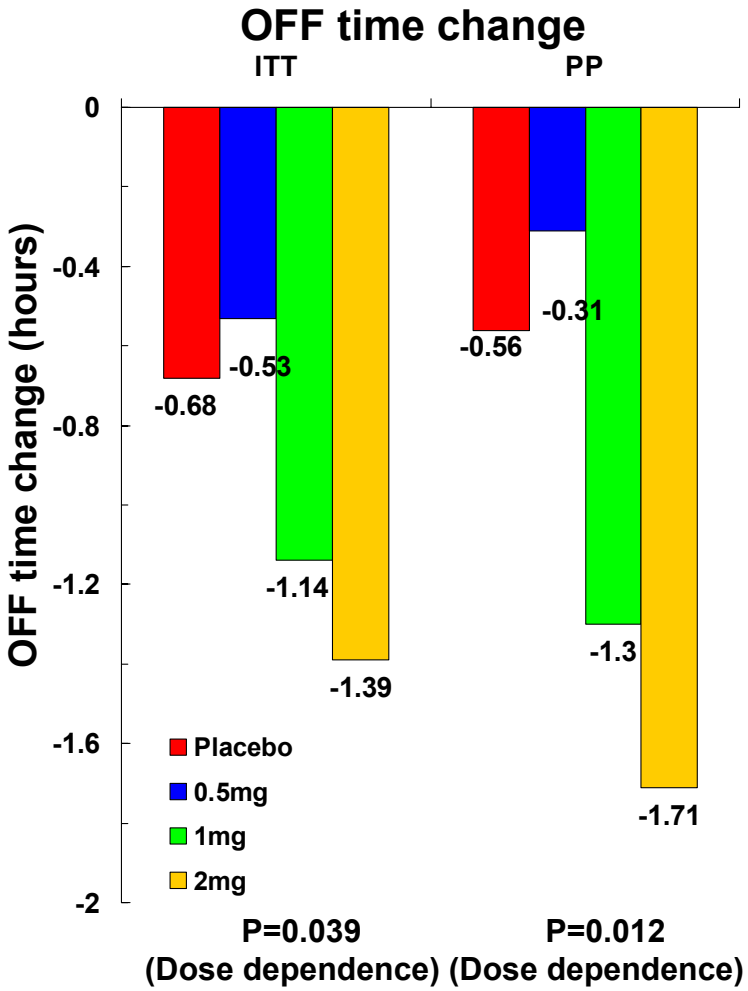
- In the placebo-controlled Phase IIb study for Parkinson's disease, demonstrated statistically significant dose dependency in OFF time reduction while showing clinically meaningful reduction in high-dose group (per protocol)
- Well tolerated and no worsening of dyskinesia
- Pursue Phase III studies 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)

Indication	Adjunctive therapy with levodopa for Parkinson's disease (First-in-class as AMPA receptor antagonist)
Efficacy	Similar to or better than MAO-B inhibitor and COMT inhibitor in shortening OFF time
Safety	Excellent safety profile No worsening of dyskinesia
Drug Interactions	No major drug-drug interactions
Adminis-tration	Once a day, oral administration
Formulation	Small tablets

E2007: Primary Endpoint and Results





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 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

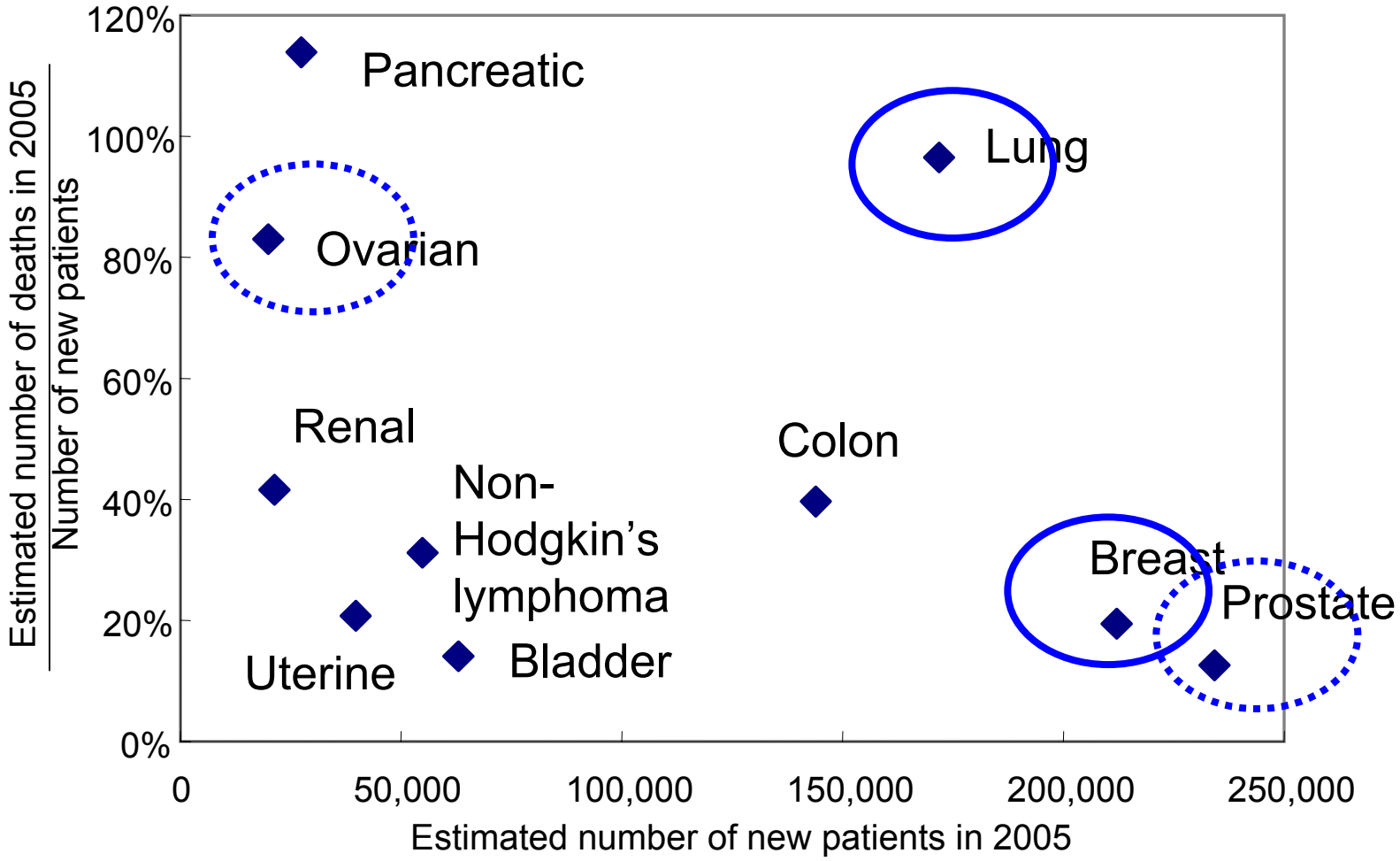
  Note: PR cases include unconfirmed cases
- Showed good tolerability
  - Neurotoxicity was infrequent and not severe
- Pursue NDA submission under Subpart H in FY2006 after consultation with FDA for both cancer types in August-September 2005
- Initiate clinical studies for soft tissue sarcoma, prostate 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 all-patient analysis but lower incidence of new organ dysfunction and mortality was demonstrated at high dose group and the effect was most apparent in the 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 – interim analysis of 51 breast cancer patients did not demonstrate PR
- Future plan
  - Continue clinical studies for colorectal cancer in combination with irinotecan and breast cancer with capecitabine
  - Continue Phase I/II study for gastric cancer in Japan
  - Potential further development in combination with irinotecan for SCLC will be evaluated based on positive Phase I study results

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:

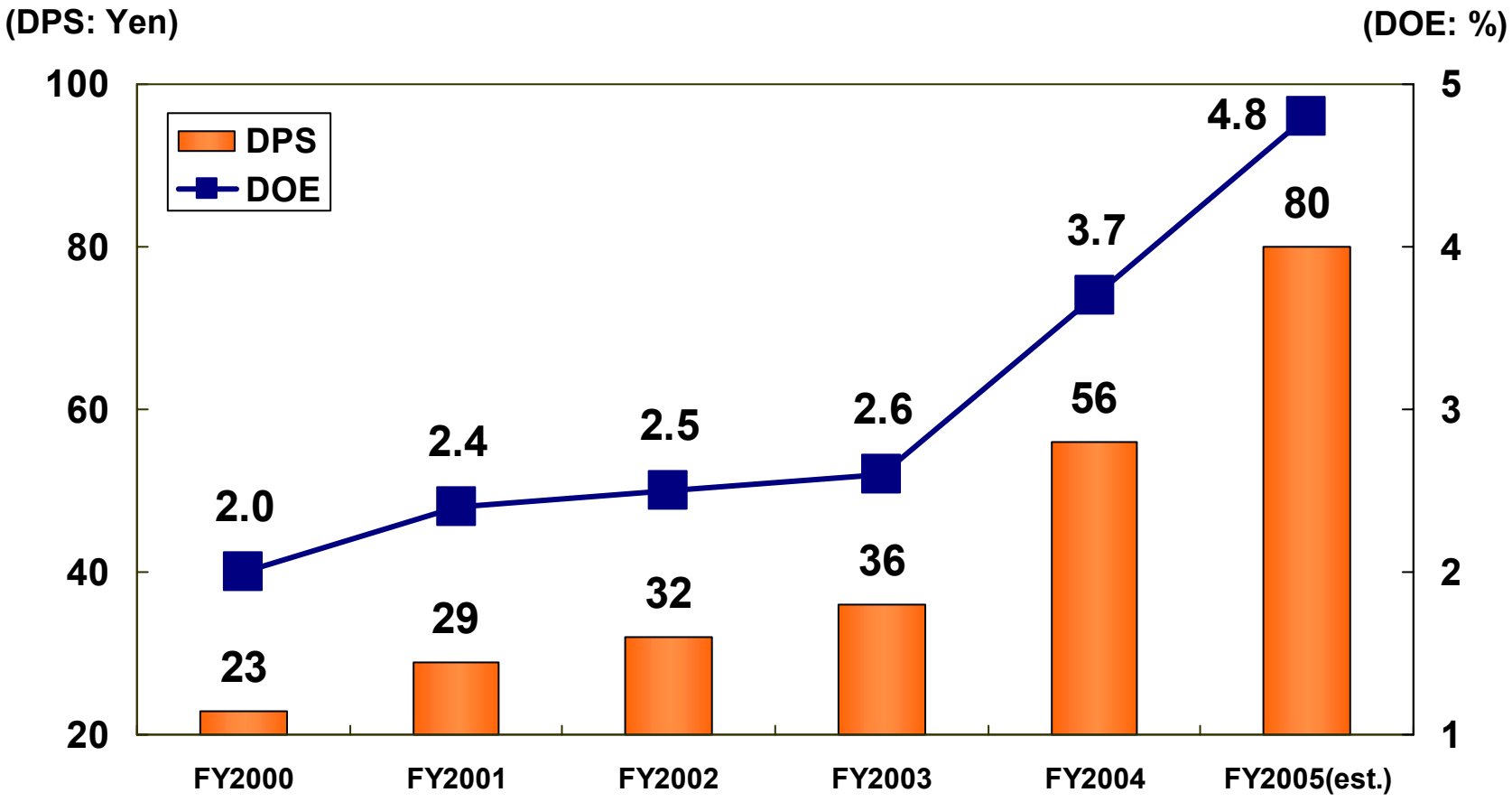
    Expect effective prevention of angio-stenosis, low risk of bleeding (First-in-class)
    - Acute coronary syndrome
      (including secondary prevention of Myocardinal dysfunction)

4 POC Projects in Summary

- Achievement of POCs for E2007 and E7389 substantially increased the possibility of development for two 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

Strive for Early Achievement of DOE 5% in FY2007



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

Dividend Yield
Top 20 Ranking in Japan

	Company	Yield (%)
1	Showa Shell Sekiyu	3.42
2	Mitsui O.S.K. Line	2.86
3	Kawasaki Kisen Kaisha	2.84
4	Nippon Yusen Kaisha	2.79
5	Sumitomo Metal Industries	2.74
6	Nissan*	2.68
7	Konami	2.50
8	Kansai Electric Power	2.39
9	NTT DoCoMo	2.38
10	Chubu Electric Power	2.38
11	Tokyo Electric Power	2.37
12	Nippon Steel*	2.35
13	Shiseido	2.30
14	**Eisai**	**2.23**
15	Heiwa Real Estate	2.16
16	Kobe Steel*	2.15
17	Sumitomo Corp.*	2.15
18	Osaka Gas	2.12
19	NSK (Nippon Seiko)	2.11
20	Oji Paper	2.09

Reference Rates

	Rate (%)
10-year Japanese Government Bond	1.284
20-year Japanese Government Bond	1.932

Planned Dividends	Share Price as of 5/24
80 Yen	**3,570 Yen**

Source: Nikkei
Notes: Ranking is based on companies listed for Nikkei Average

Performance Forecast

(billions of yen, %)

	FY2004			FY2005		
	Results	%	YOY	Forecast	%	YOY
Net Sales	533.0	100.0	107	575.0	100.0	108
Cost of Sales	98.5	18.5	101	103.0	17.9	105
Gross Profit	434.5	81.5	108	472.0	82.1	109
R&D Expenses	78.3	14.7	113	89.0	15.5	114
SG&A Expenses	269.4	50.5	107	292.0	50.8	108
Operating Income	86.8	16.3	105	91.0	15.8	105
(R&D Expenses + Operating Income)	165.1	31.0	109	180.0	31.3	109
Net Income	55.5	10.4	111	58.0	10.1	104
EPS (yen)	193.4		112	203.0		105

Dividend (yen)	56.0	80.0
DOE (%)	3.7	4.8
Dividend Payout Ratio (%)	29.0	39.4

Currency exchange rate: FY2004: ¥107.54/$, FY2005 (est.) ¥103/$

Resolution for Shareholder Approval (1)

THE 93RD ORDINARY GENERAL MEETING OF SHAREHOLDERS

Partial Amendments to the Articles of Incorporation

1. **It is proposed that a new provision be added to state the Company's corporate concept and corporate vision to be realized.**
2. The "Partial Revision to the Commercial Code for the Introduction of Electronic Advertisements" (2004, Law No. 87), which became effective on February 1, 2005, allows companies to change the distribution of public notices from conventional public notices to electronic ones. Accordingly, it is proposed that the related article concerning this matter be amended.
3. **It is proposed that the number of shares the Company is authorized to issue be increased for flexible capital strategies. (700→1,100million)**
4. In accordance with the change of position for convening the Board of Directors meeting, it is proposed that the contents of the related articles be amended.
5. In accordance with the preceding revisions, corresponding changes shall be made to the number of articles.

Corporate Concept

1. The Company's corporate concept is to give first thought to patients and their families, and to increase the benefits that health care provides. Under this concept, the Company endeavors to become a human health care (hhc) company.
2. The Company's mission is the enhancement of patient satisfaction. The Company believes that revenues and earnings will be generated as a consequence of the fulfillment of the mission. The Company places importance on this positive sequence of the mission and the ensuing results.
3. Positioning compliance, the observance of legal and ethical standards as a core in all business activities, the Company strives to fulfill corporate social responsibilities.
4. The Company's principal stakeholders are patients, customers, shareholders and employees. The Company seeks to foster a good relationship with stakeholders and to enhance their value through making the following efforts:
   - Satisfying unmet medical needs, ensuring stable supply of high quality products, and providing useful information of safety and efficacy.
   - Timely disclosure of corporate managerial information, enhancement of corporate value, and proactive return to shareholders.
   - Ensuring stable employment, offering challenging and fulfilling duties, and providing full opportunities for the development and enhancement of employees' capabilities.

Resolution for Shareholder Approval (2)

THE 93RD ORDINARY GENERAL MEETING OF SHAREHOLDERS

Election of twelve (12) Directors

The candidates for the position of Director are as follows ;

1. Haruo Naito: President and CEO
2. Yuji Naito: Senior Advisor
3. Hiromasa Nakai: Chairman
4. Tadashi Tenmyo: Director
5. Shintaro Kataoka: Senior Vice President (New candidate)
6. Stuart Meiklejohn: Partner, Sullivan & Cromwell
7. Mitsuo Minami: Pprofessor, Graduate School of Business Administration, Bunkyo Gakuin University
8. Tadashi Kurachi: Chairman, Kanematsu Corporation
9. Naoto Nakamura: Partner, Nakamura, Tsunoda and Matsumoto
10. Ikujiro Nonaka: Professor, Graduate School of Hitotsubashi University
11. Tadahiro Yoshida: Chairman and President, YKK Corporation
12. Yoshiyuki Kishimoto: Director of Strategy, Booz Allen Hamilton (Japan) Inc.

Appendices

Financial Data

POC Studies Detail

- E2007
- E7389
- E5564
- E7070

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)

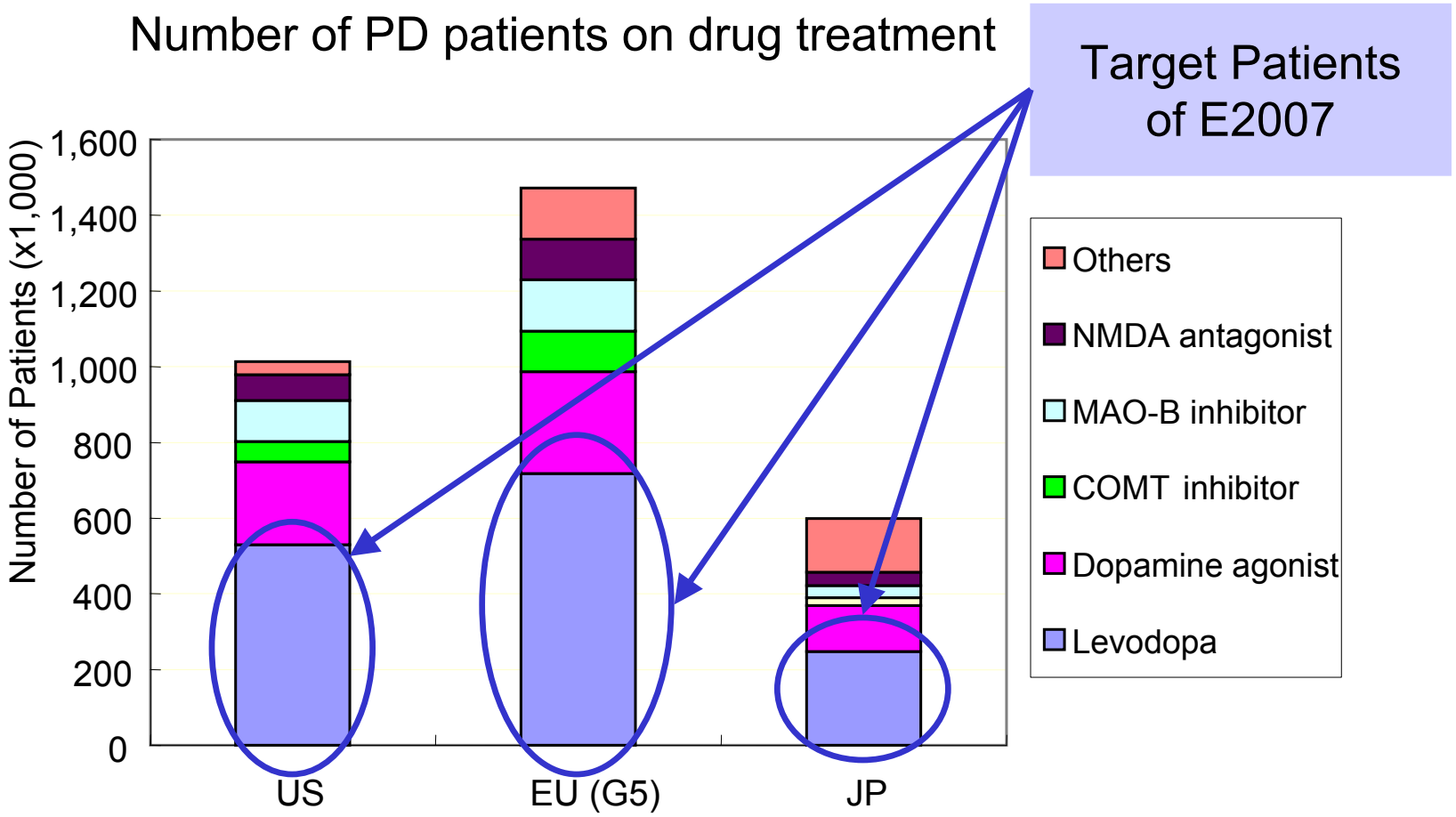
(billions of yen, %)

	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

E2007 (AMPA-Receptor Antagonist)

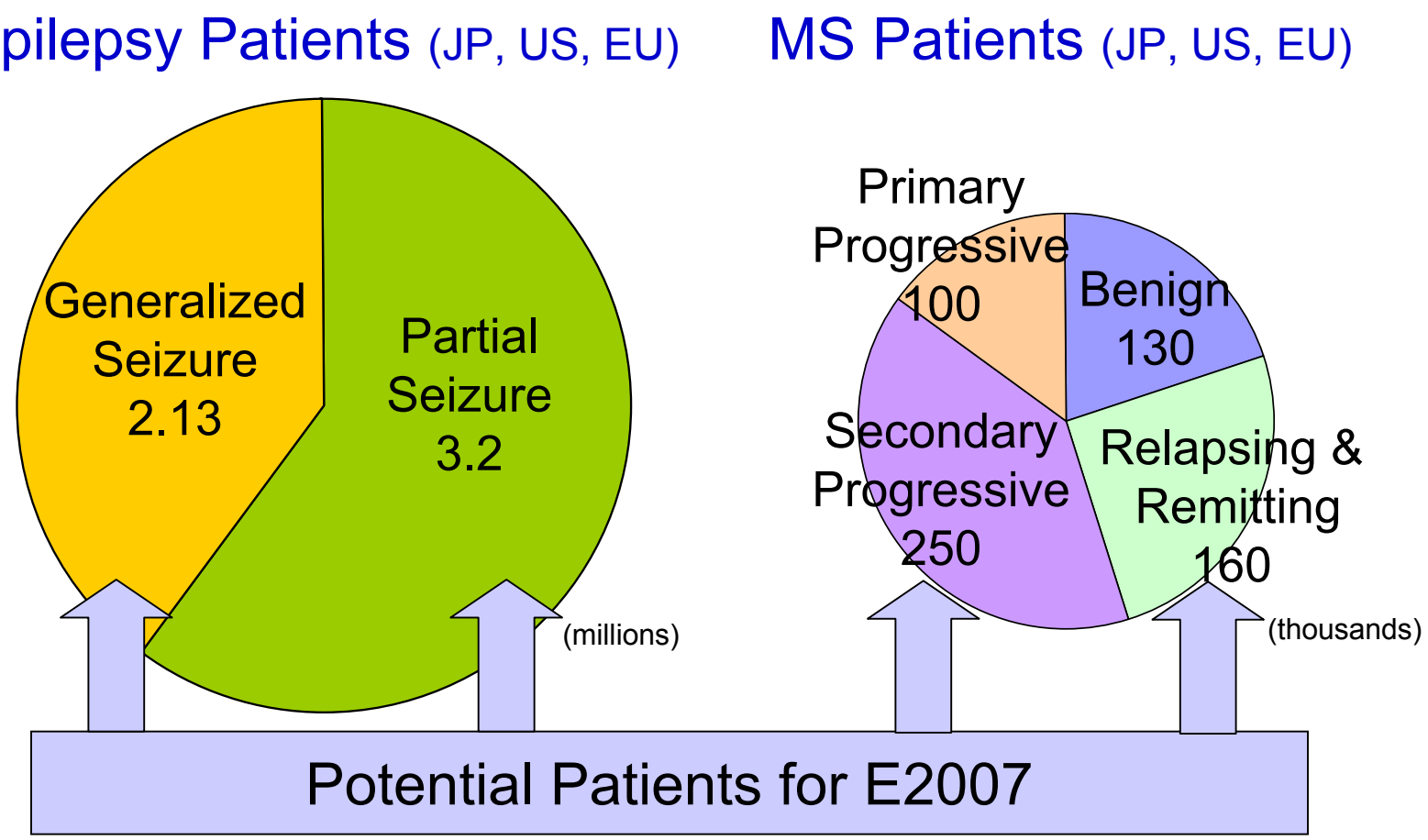
- Concept
  - Suppress neuronal damage caused by stimulation with excessive amount of glutamate based on AMPA-receptor antagonism. Expect good efficacy and safety profile for neurodegenerative diseases: Parkinson's disease, epilepsy and multiple sclerosis
  - Aim for first-in-class oral AMPA-receptor antagonist with excellent ADME profile (once a day, fewer drug-drug interaction)
  - Equal or better OFF time reduction than current therapy as well as dose dependency in combination with levodopa in Phase IIb studies of Parkinson's disease
  - No worsening of dyskinesias in Parkinson's disease
  - Excellent safety profile
- Proof of concept
  - Long half-life and possible once-a-day administration
  - Clinically meaningful OFF time reduction and statistically significant dose dependency in Phase IIb in Parkinson's disease
  - Excellent safety profile and no worsening of dyskinesias

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



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

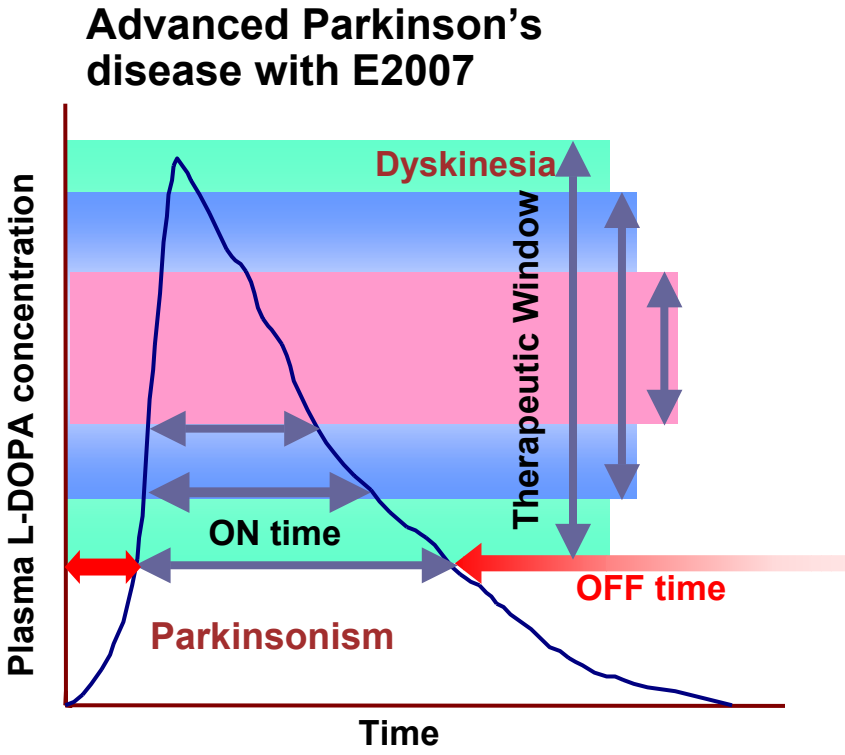
POC for Epilepsy Initiated and Planned for Multiple Sclerosis



Source: Data Monitor, Decision Resources, Eisai

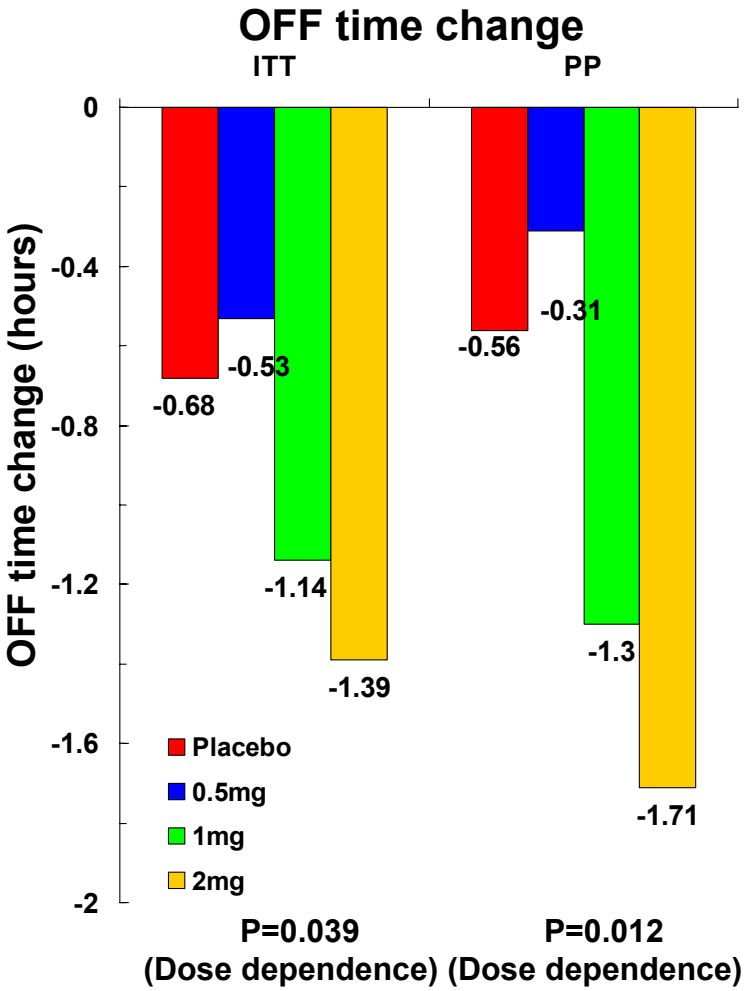
E2007: Study Synopsis for Phase II – Study 204 –

- Subjects
  - Parkinson's disease with motor fluctuations and dyskinesias on levodopa (maintenance dose)
- Study design
  - 12-week dosing
  - Placebo, 0.5 mg, 1 mg, 2 mg (once-a-day treatment)
  - Target enrollment: 180 patients (45 patients/dose)
- Endpoints
  - Reduction of OFF time
  - Extension of ON time
  - Severity of dyskinesias
- Study location
  - Europe



E2007: Phase II Results – Study 204 –

- Enrollment
  - ITT: 258 (62-67/group)
  - Per Protocol: 166 (36-44/group)
- Efficacy
  - Statistically significant dose response ($p<0.025$) in OFF time reduction observed in cases conforming with the protocol
  - Active group did not show statistical significance in OFF time reduction over placebo group, but showed clinically meaningful reduction at high dose (2 mg) in protocol population
  - Equal or greater efficacy than current therapy in OFF time reduction is expected
- Safety and tolerability
  - Excellent safety profile
  - No worsening of dyskinesias



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 anti-cancer spectrum
  - 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 required pretreatment with steroid or anti-histamine not 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
  - I.V. 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 PR
    - 3 unconfirmed PR (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
  - I.V. 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: Interim Analysis for Phase II – Study 202–

(NSCLC, Monotherapy)

- Enrollment
  - 55 patients (all taxane resistant)
  - 10 currently evaluable patients
- Efficacy
  - 3 PRs, 1 confirmed PR (after cycle 3) and 2 unconfirmed PRs (after cycle 2)
  - PRs were evaluated by independent assessors

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 reduce mortality in sepsis
  - Reduce organ dysfunction rate 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 in August 2005
  - In CABG study, statistically significant efficacy was not achieved between all-pooled active group and placebo group in new organ dysfunction, nor in apparent dose dependency
  - In CABG study, lower incidence of new organ dysfunction and mortality was demonstrated in high dose group and the effect was most apparent in the 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, 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 new organ dysfunction, nor apparent dose dependency
  - A numerically lower incidence of new organ dysfunction was demonstrated in the E5564 high dose (28 mg) group compared to placebo

    At 28 days and overall, the lower mortality occurred in the E5564 high dose (28 mg) group. The effect was most apparent in the high-risk subgroup of patients
  - No 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 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 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 patient 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) 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 meetings with FDA for both sepsis and CABG studies 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 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 metastatic breast cancer - patients previously treated with anthracycline, taxane, and fluoropyrimidine
- 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 over 40 minutes
- Efficacy endpoints
  - Response rate
  - Duration of response, TTP, 6-month survival, tolerability and safety
- 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)