エーザイ株式会社



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This English presentation was translated from the original Japanese was included the award of

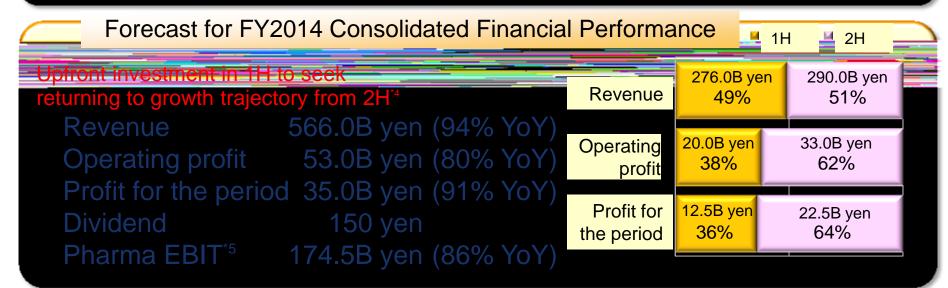


# Strategic Plan of FY2014 Strategic investment for return to growth trajectory



#### Transformation in FY2014

- 1. Expansion and development of new growth drivers (4 global brands<sup>1</sup>, 8 pipeline assets<sup>2</sup>, Asia and strategic markets<sup>3</sup>)
- 2. Business expansion responding to the needs of global market Launch of Global Business Matrix Improve access to medicine
- 3. Adoption of IFRS to increase capability in global comparison of financial status



<sup>\*1:</sup> Halaven, Fycompa, BELVIQ® and investigational lenvatinib \*2: Halaven, Fycompa and BELVIQ® (Investigational): lenvatinib, E2006, BAN2401, E2609 and Avatrombopag

<sup>\*3:</sup> Canada, Mexico, Brazil, Russia, Middle East and Australia \*4: An increase in operating profit is forecast for the 2<sup>nd</sup> half of FY2014 excluding the impact of the divesture of development and marketing lights of Dacogen to Otsuka Pharmaceutical Co., Ltd. (as of March 31, 2014), an increase in revenue is forecast for the 2<sup>nd</sup> half of FY2014

<sup>\*5:</sup> Pharma EBIT: Operating profit + R&D Expenses

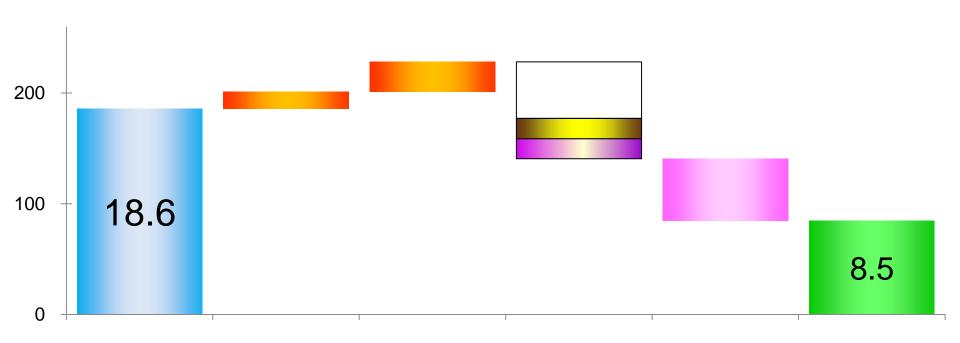


April – June 2013		Ар	April – June 2014		

<sup>\*</sup> Pharma EBIT: Operating profit + R&D Expenses FY2014 1Q average exchange rates: U.S. \$ = 102.16 yen (+3.5% YoY), Euro = 140.06 yen (+8.6% YoY), GBP = 171.91 yen (+13.4% YoY)







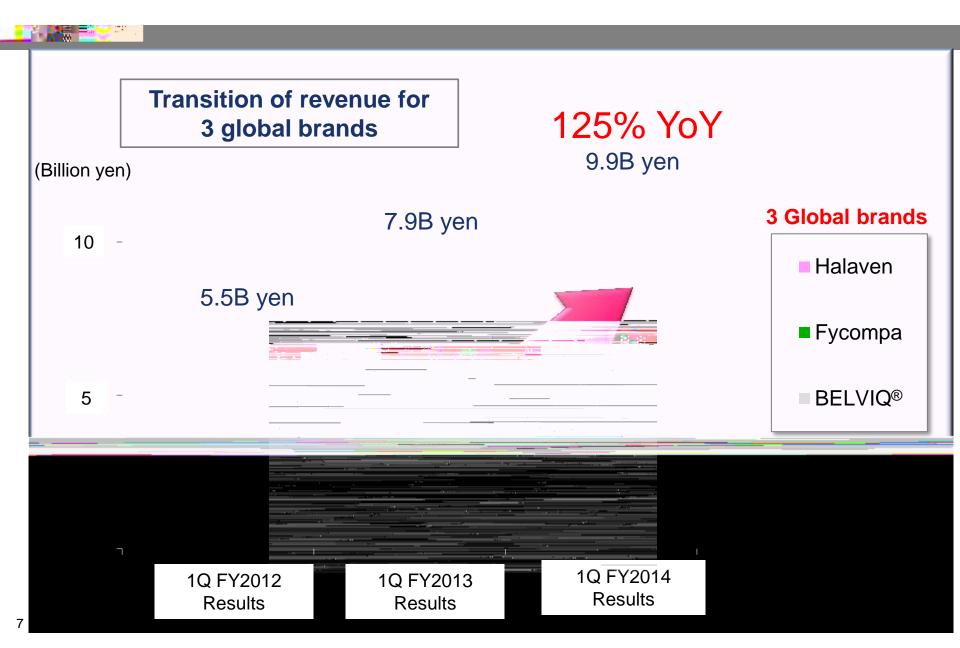






#### Growth of 3 Global Brands





# Eisai Global Oncology Business Unit







Americas: Achieved 117% YoY<sup>2</sup> growth in 1Q FY2014
Increased market share of 3<sup>rd</sup> line+ treatment by focusing on patients with HER2 negative type
EMEA\*3: Achieved 129% YoY<sup>2</sup> growth in 1Q FY2014
Obtained approval for earlier line treatment in EU on June 30<sup>th</sup>
Japan:

#### **Aloxi**

U.S.: Obtained approval for pediatric use on May 27<sup>th</sup>
Received additional six months US market exclusivity until October 13<sup>th</sup>, 2015

Investigational Lenvatinib\*5

Achieved submission in Japan on June 26<sup>th</sup>
Plan to submit in August in U.S. and EU



### Eisai Global Neurology Business Unit Seeking global ramp-up in FY2015 and beyond



# Fycompa

Obtained approval in 39 countries for adjunctive therapy for partial-onset seizures (as of the end of July 2014)

Expansion of approved and launched countries in EMEA

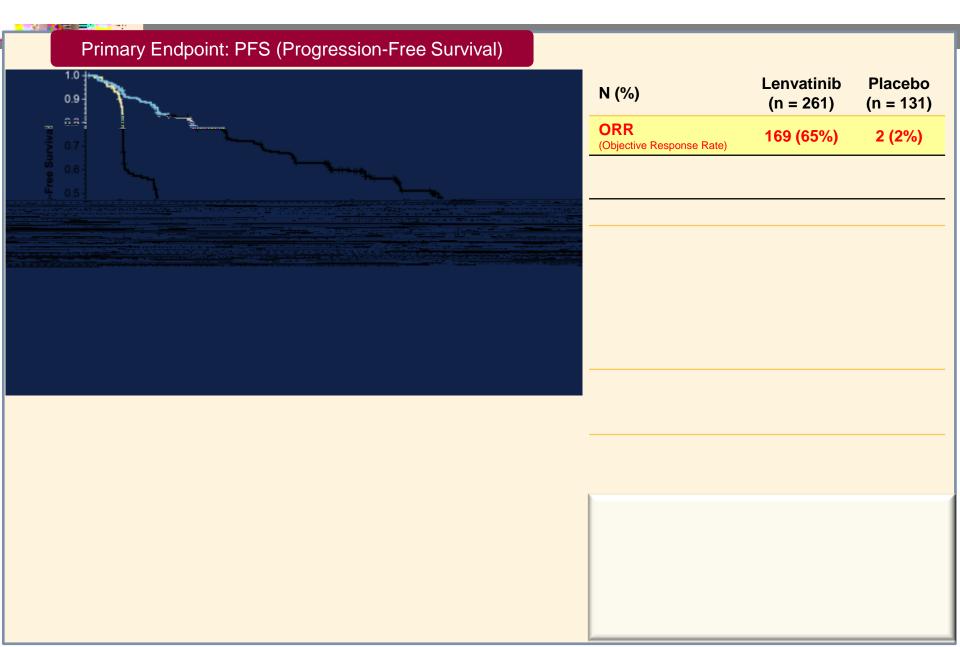
Launched in France, the Netherlands and Russia

Obtained approval in Australia (May 2014), seeking to launch in FY2014

# **BELVIQ®**

Seeking growth through continued strategic investment

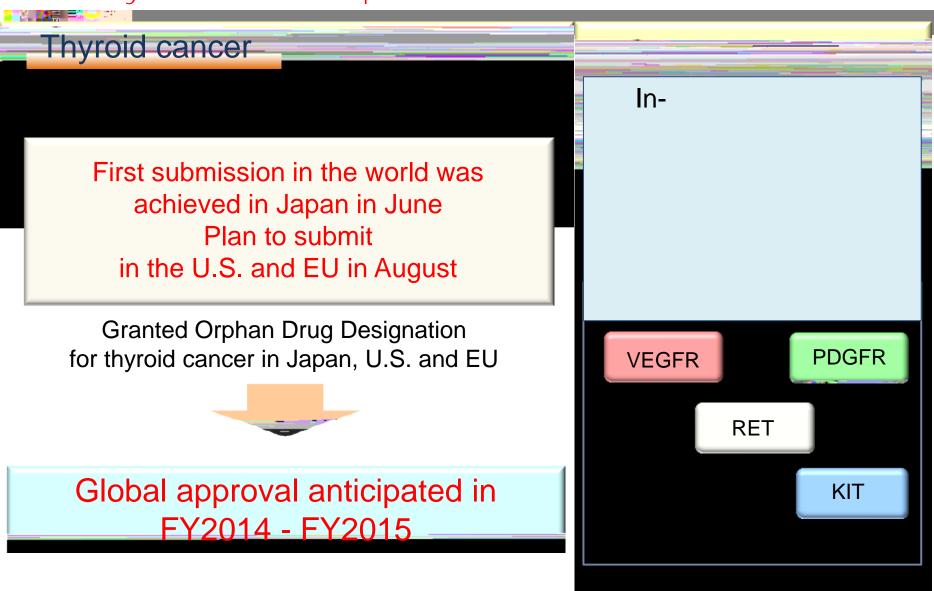




# Investigational Lenvatinib



Thyroid cancer: Japan submission achieved in June





#### Halaven



#### Received approval for earlier line treatment for MBC in EU

Metastatic Breast Cancer(MBC) Important efficacy data from a pooled analysis of over 1,800 subjects with all subtypes of MBC was presented at ASCO\*1

nooled analysis of Studios 205 and 201

_	Data from a pooled analysis of Studies 305 and 301											
		Overall		Overall HER2 positive		HER2 negative		Triple negative				
		eribulin	control*2	eribulin	control*2	eribulin	control*2	eribulin	control*2			
	N	1062	802	160	123	7/10	572	2/13	185			
		15.2	12.8			15.2	12.3	12.9	8.2			
		0.0	0.003				002	0.0	006			

#### Earlier line treatment (EU): Received approval in June 2014

HER2 negative breast cancer 1st /2nd lines (U.S.): phase III study with ACCRU\*5 network is ongoing Neoadjuvant therapy for triple-negative breast cancer: preparing for phase III study

Non-small cell lung cancer and soft tissue sarcoma<sup>\*6</sup>

Phase III study ongoing

<sup>\*1:</sup> ASCO: Annual Meeting of the American Society of Clinical Oncology in 2014 \*2:

capecitabine \*3: Based on survival curve adjusted by study

<sup>15 \*4:</sup> Stratified by geographic region, prior capecitabine use and study (plus HER2 status for overall group only; plus triple negative for HER2 negative group only) \*5: ACCRU The Academic and Community Cancer Research United \*6: Investigational use

#### Product Pipeline To Support Sustainable Growth Strategic investments along with investigational Lenvatinib, Halaven and Fycompa





#### FY2014 Goals

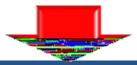




Simultaneous multi-brand expansion 4 global brands\*1 + Regional brands

Proactive investments and steady progress in major R&D projects

Rapid expansion and strengthening business in Asia and strategic markets<sup>2</sup>



Return to growth trajectory in terms of revenue and profit in FY2015 beyond





# Reference Data







	April – June 2013		April – June 2014			
	Results	%	Results	%	YoY	
Japan*¹	81.1	53.0	73.7	55.5	91	
Americas*2	41.3	27.0	25.4	19.1	62 [60]	
Asia*³	13.4	8.7	16.3	12.3	122 [119]	
EMEA*4	7.7	5.0	8.8	6.7	115 [106]	
Consumer Healthcare (Japan)						



# Profit by Reporting Segment





	Apri	l – June 20	)13				
	Results	%	% of revenue	Results	%	% of revenue	YoY
Japan*1	42.9	73.3	52.9	33.7	83.5	45.7	78
Americas*2	8.7	14.9	21.1	0.1	0.2	0.3	1 [1]
Asia <sup>*3</sup>	3.0	5.2	22.7	4.3	10.7	26.4	142 [138]
EMEA*4	0.7	1.3	9.7	1.1	2.7	12.2	144 [125]
Consumer Healthcare (Japan)*5	0.5	0.9	12.0	(0.2)			
Reporting segment Total	55.9	95.5	37.9	39.0	96.7	30.5	70
Others	2.6	4.5	50.3	1.3	3.3	27.4	50
R&D expenses & Group 504,62[8E8T2BT1 0 612,62[89							

# Performance of Japan Pharmaceuticals Business



(Billion yen, %)

	April – J	une 2013	A	pril – June 201	14
	Results	%	Results	%	YoY
Revenue	81.1	100.0	73.7	100.0	91
Prescription medicines	73.9	91.1	66.0	89.5	89
Aricept	18.3	22.6	13.4	18.2	73
Pariet	12.8	15.8	10.8	14.6	84
HUMIRA	6.9	8.5	7.8	10.5	112
Methycobal	6.7	8.2	6.3	8.6	94
Lyrica <sup>·</sup>	4.1	5.1	4.3	5.8	104
Warfarin	2.6	3.2			

## Performance of Americas Pharmaceuticals Business





(Billion yen, %)

	April – J	une 2013		April – June 2014			
	Results	%	Results	%	Yo	Υ	
Revenue	41.3	100.0	25.4	100.0	62	[60]	
Aloxi	10.3	25.0	12.6	49.5	122	[118]	
AcipHex	15.5	37.5	3.9	15.2	25	[24]	
Halaven	3.3	7.9	3.8	15.0	117	[113]	
Banzel	1.5	3.7	2.2	8.8	145	[141]	
<b>BELVIQ</b> ®	0.4	1.0	1.0	4.0	250	[241]	
Fycompa	0	0.0	0.2	0.6	1548	[1511]	
Segment Profit	8.7	21.1	0.1	0.3	1	[1]	

[] based on local currency







	April – J	une 2013	April – June 2014			
	Results	%	Results	%	Yo	Υ
Revenue	13.4	100.0	16.3	100.0	122	[119]
Methycobal	3.6	26.8	4.6	28.3	129	[127]
Aricept	2.9	22.0	3.2	19.8	110	[104]
HUMIRA	1.6	12.1	2.0	12.1	122	[114]
Pariet	1.4	10.7	1.5	9.5	108	[107]







(Billion yen, %)



## FY2013 1Q Consolidated Financial Results Impact of IFRS Introduction





(Billion yen)

	(Dillion yen)									
	Revenue	Cost of sales	R&D expenses	SG&A expenses	Other income / expenses	Operating profit	Non- operating income / expenses, Special gain / loss	Financial income / costs	Income taxes	Profit for the period
Japan GAAP	154.2	46.3	39.6	54.2	-	14.2	-0.7	-	4.0	9.4
Adjustment of sales incentives from SG&A to deduction of revenue	-0.5			-0.5		-				-
Amortization of intangibles (In-licensing products) capitalized under IFRS		0.2				-0.2			-0.1	-0.1
Capitalization upfront/milestone payments for in-licensing products			-2.2			2.2			0.8	1.4
Non-amortization of goodwill				-2.3		2.3				2.3
Reclassification of foreign exchange losses					-0.3	-0.3	0.3			-
Reclassification of gain on sales of non- current assets					0.2	0.2	-0.2			-
Interest and dividend income / Interest expenses						-	1.0	-1.0		-
Reclassification of gain on investment securities (special gain)						-	-0.4	0.1	-0.1	-0.2
Other	-0.9	-0.3	-0.2	-0.8	-0.0	0.3	0.0	-0.1	0.7	-0.5
Total adjustments	-1.4	-0.1	-2.4	-3.6	-0.2	4.4	0.7	-0.9	1.3	2.9
IFRS	152.8	46.2	37.3	50.6	-0.2	18.6	-	-0.9	5.3	12.3

