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# Mid-term Strategic Plan "HAYABUSA" (FY2011-2015)

- Era of Transformation -



Hayabusa:

Hayabusa, an asteroid explorer, has traveled over 6 billion kilometers overcoming two major crises yet returned having achieved its original objectives.

### More Stringent Environment and Stagnant Growth in Matured Markets

1. General Environment:
  - Governments to introduce further cost-containment measures due to economic downturn and augmented medical costs
  - HTA(Health Technology Assessment) as de facto hurdle for drug reimbursement
2. Drug Discovery/Development:
  - Innovative Ideas
  - Cutting-edge Technologies
  - Stratified Patients Trial
3. Taxation System:
  - R&D expense benefit
  - Patent Income benefit  
(Innovation Box, Patent Box)

### Significant Growth Opportunity in Emerging Markets

1. General Environment:
  - Rapid expansion of middle-income class
  - China, South Korea, India, Brazil, Russia, Indonesia, and Turkey:
    - Exceeding 20% of the global pharmaceutical market by FY2015
    - CAGR 15% (40% of global pharmaceutical market growth)
2. Drug Discovery/Development:
  - Conventional Technologies
  - Large-Scale Screening
  - Large-Scale Trials
3. Taxation System:
  - Tax Holiday (SEZ: Special Economic Zone)
  - Tariff reduction  
(TPP: Trans-Pacific Partnership, EPA: Economic Partnership Agreement)



# Aspiration

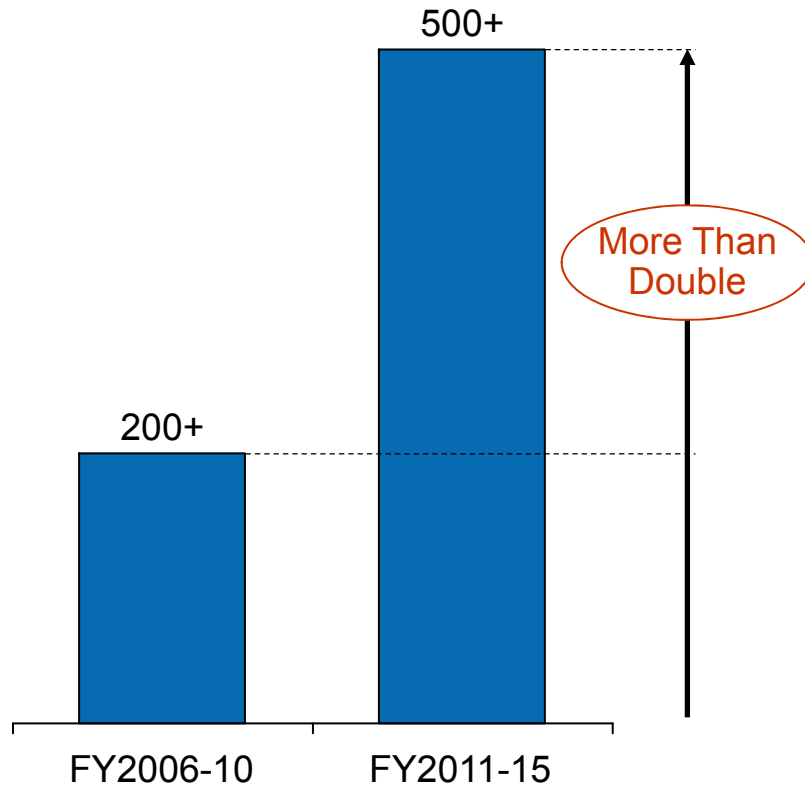
We Will Benefit Millions More Patients  
in the Great Globalization Era,  
Wind Down Japan/US/Europe-Centric  
Relationship with Global Partners,  
and Transform Ourselves into  
a Global Top-Tier  
High-Performing Company



# Enhancing Contributions to Patients in the Era of Great Globalization

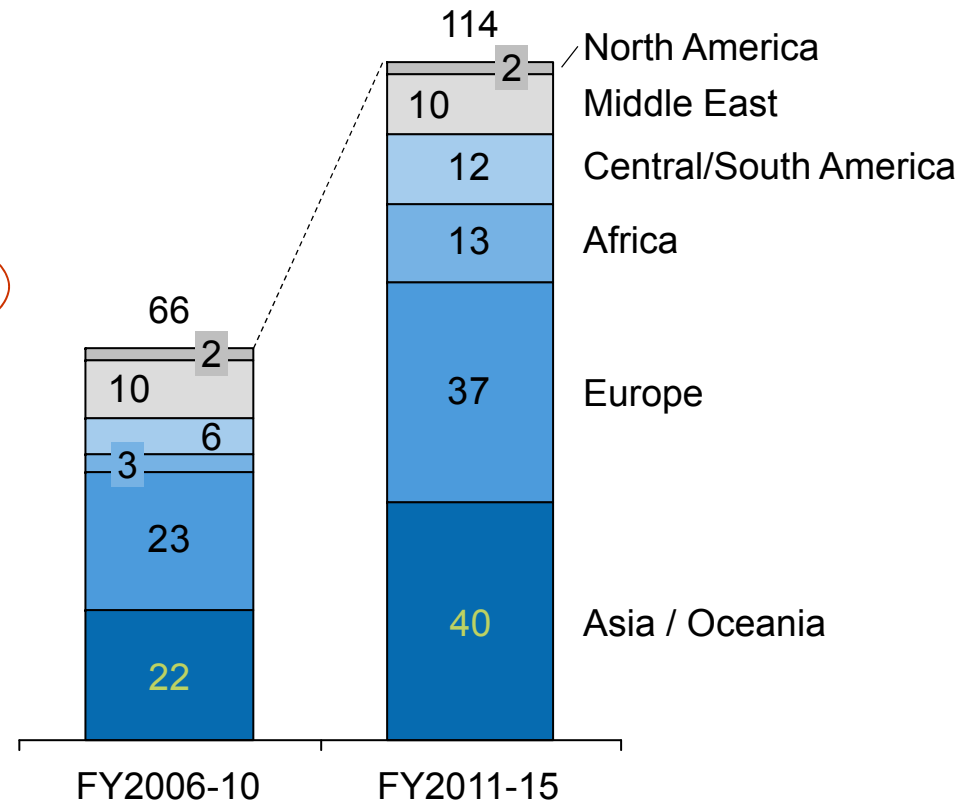


5-year cumulative number of patients served by Eisai Products (Million)



(internal estimates)

Number of countries served by Eisai products



**Note:** including all types of market entry (affiliates, branches, distributors, and rep offices) and countries to provide DEC for lymphatic filariasis



# Dawn of Great Globalization

## Entries to All Top 20 Countries in Next 5 years



Outlook of global pharmaceutical market (\$ million)

		2010	2014	Global share(%)	CAGR
1	United States	308,436	368,262	33.5%	4.5%
2	Japan	85,672	102,812	9.3%	4.7%
3	Germany	44,886	49,720	4.5%	2.6%
4	France	43,719	46,469	4.2%	1.5%
5	China	32,076	71,889	6.5%	22.4%
6	Italy	28,946	32,168	2.9%	2.7%
7	Spain	25,270	30,747	2.8%	5.0%
8	United Kingdom	21,640	24,574	2.2%	3.2%
9	Canada	21,582	25,356	2.3%	4.1%
10	Brazil	17,097	25,487	2.3%	10.5%
11	Russia	12,099	18,977	1.7%	11.9%
12	South Korea	11,161	16,322	1.5%	10.0%
13	Australia	10,961	13,132	1.2%	4.6%
14	Turkey	10,531	15,071	1.4%	9.4%
15	India	9,761	16,932	1.5%	14.8%
16	Poland	7,373	9,674	0.9%	7.0%
17	Mexico	7,344	7,661	0.7%	1.1%
18	Netherlands	6,633	6,657	0.6%	0.1%
19	Greece	6,500	6,443	0.6%	-0.2%
20	Venezuela	6,004	18,952	1.7%	33.3%

*Significant expansion of contributions to patients through our corporate mission “human health care” concept\*1*

Global number of patients Eisai serves to significantly expands from 200 million+ during FY2006-2010 to 500 million+ during FY2011-2015

Contribution to over 250 million populations at risk of lymphatic filariasis in 37 countries, providing 2.2 billion tablets of DEC (Diethylcarbamazine) at price zero in collaboration with WHO

Entries to all top 20 countries during FY2011-2015 to achieve further patient contribution

Providing disease solutions, enhancing access by PPP\*2, and providing products at affordable pricing

\*1 hhc: The Eisai Group’s corporate philosophy: To give first thought to patients and their families and to increasing the benefits healthcare provides.

\*2PPP: Public-Private Partnership

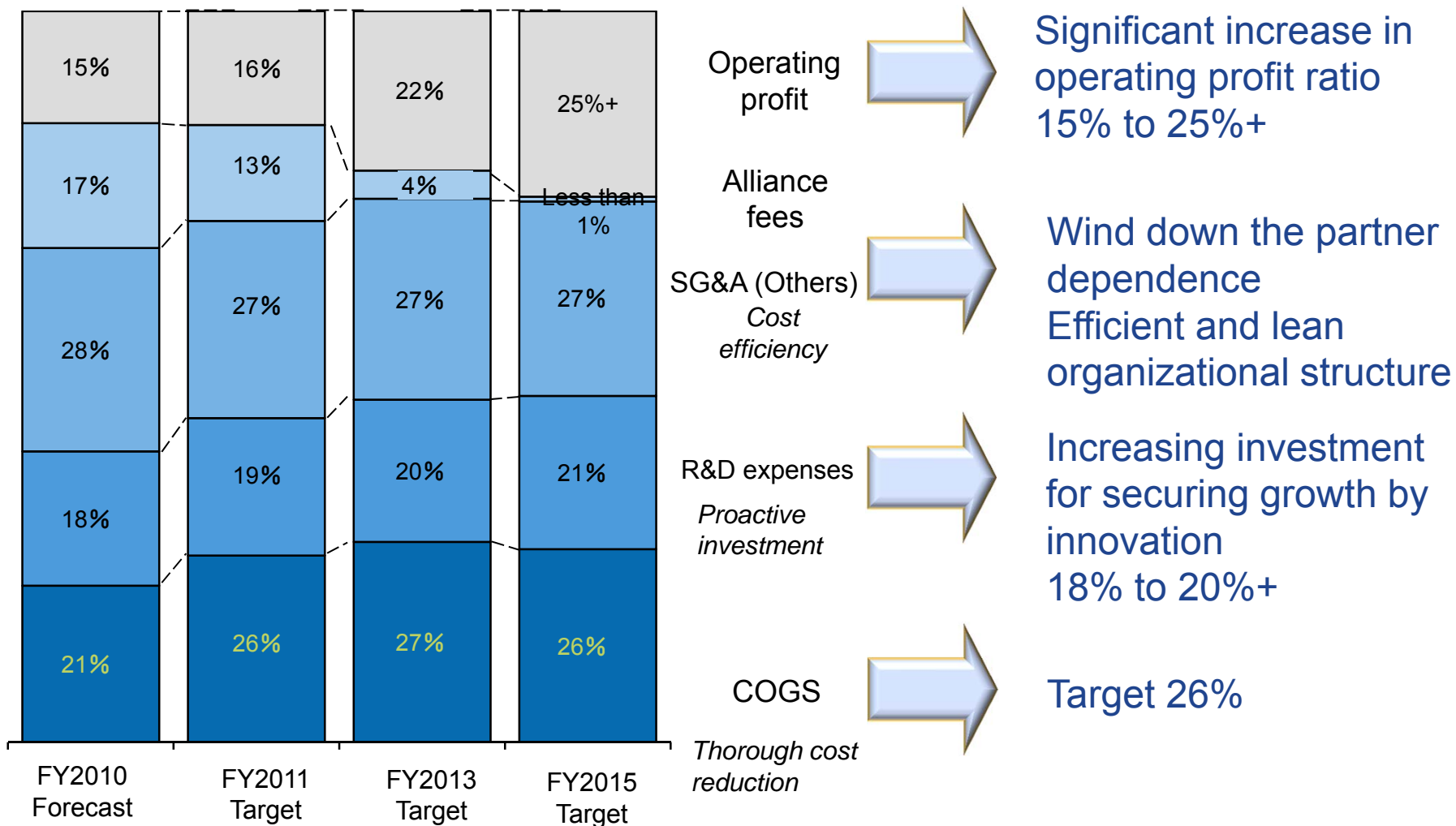
Current presence

Markets to enter

\*1CAGR: Compound Annual Growth Rate; \*2PPP: Public Private Partnership

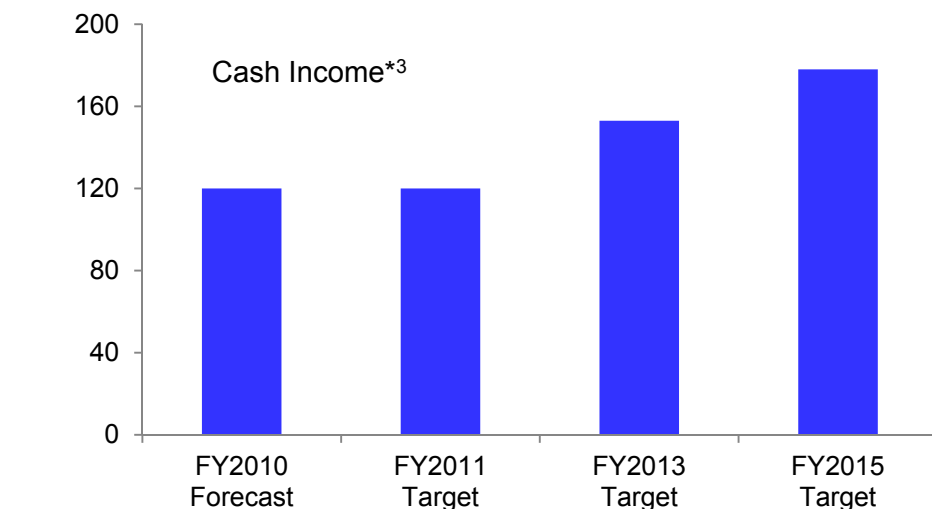
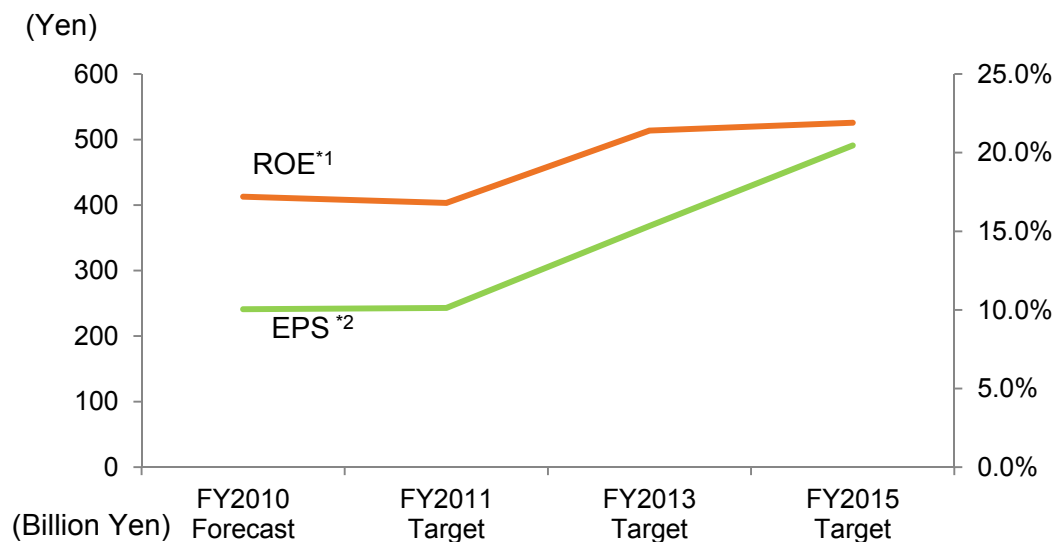
# Toward Global Top Tier (1)

## Transformation of P/L structure





## Streams of ROE, EPS, and Cash Income



- EPS will increase to nearly 500 yen by FY2015 (CAGR 15%)
- ROE enhancing from 17% in FY2010 to 20%+ in FY2015
- Cumulative cash income during FY2006 – 2010 is approx. 570B yen



Cash income to increase to approx. 750B yen level during FY2011 - 2015

\*1ROE: Return On Equity

\*2EPS: Earnings Per Share

\*3Cash income is the total amount of cash available for investments for growth, business development, dividend payment, and repayment of borrowings, etc.  
 Cash income = Net income + Depreciation of PP&E and Amortization of intangible assets + In-process R&D + Amortization of goodwill + Loss on impairment (including loss on devaluation of investment securities)



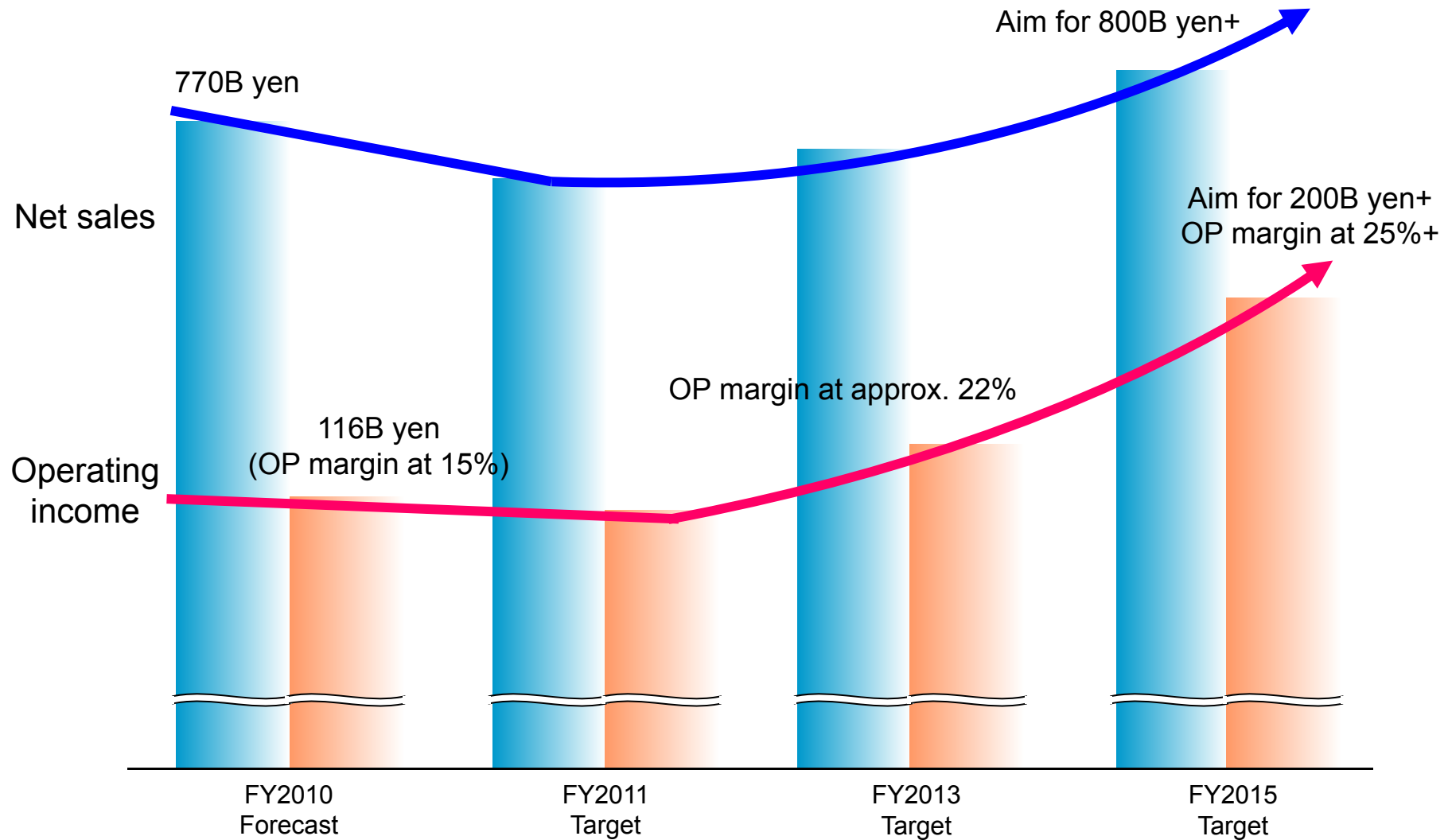
# Overview of Plan “HAYABUSA”



1. Rise of East Asia Region to drive growth of global Eisai
2. Dawn of the great globalization era: benefiting millions more patients with our product line-up including zero-price product and entering all of global top 20 markets
3. Efficient and lean commercial structure to create value for patients
4. Thrusting into global top 10 in oncology by reaching US\$2 billion sales through women’s oncology strategy
5. Evolving towards “focused” medicines to maximize patient benefits

# Roadmap for the Plan "HAYABUSA"

Resuming growth trajectory from FY2013; record-high level in FY2015



Assumed average exchange rates:

FY2010: \$1 = 85.6 yen; 1 Euro = 112.0 yen; and 1 GBP = 131.9 yen

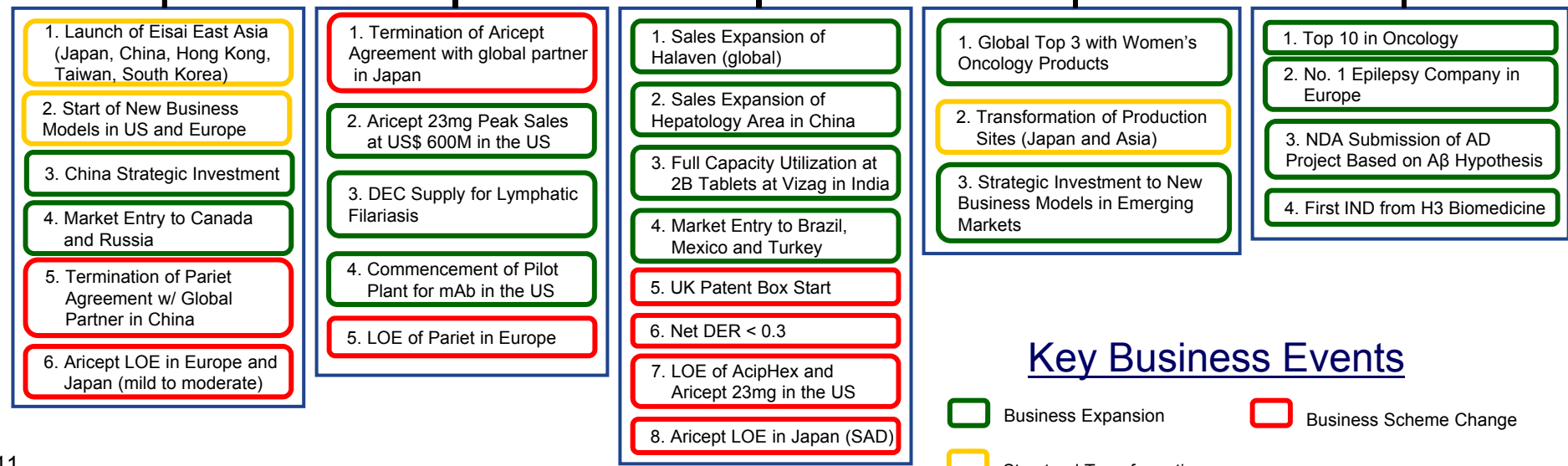
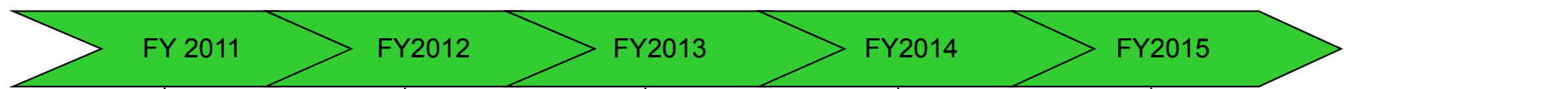
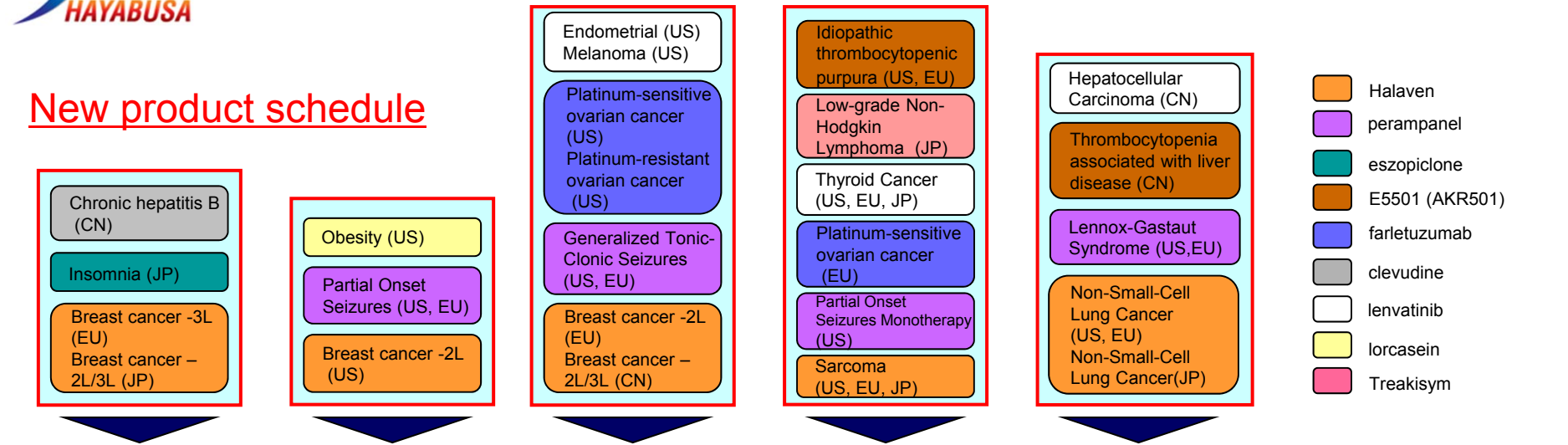
FY2010-2015: \$1 = 85 yen; 1 Euro = 110 yen; and 1 GBP = 135 yen



# Roadmap Supported by Key Events



## New product schedule



## Key Business Events

- Business Expansion
- Business Scheme Change
- Structural Transformation

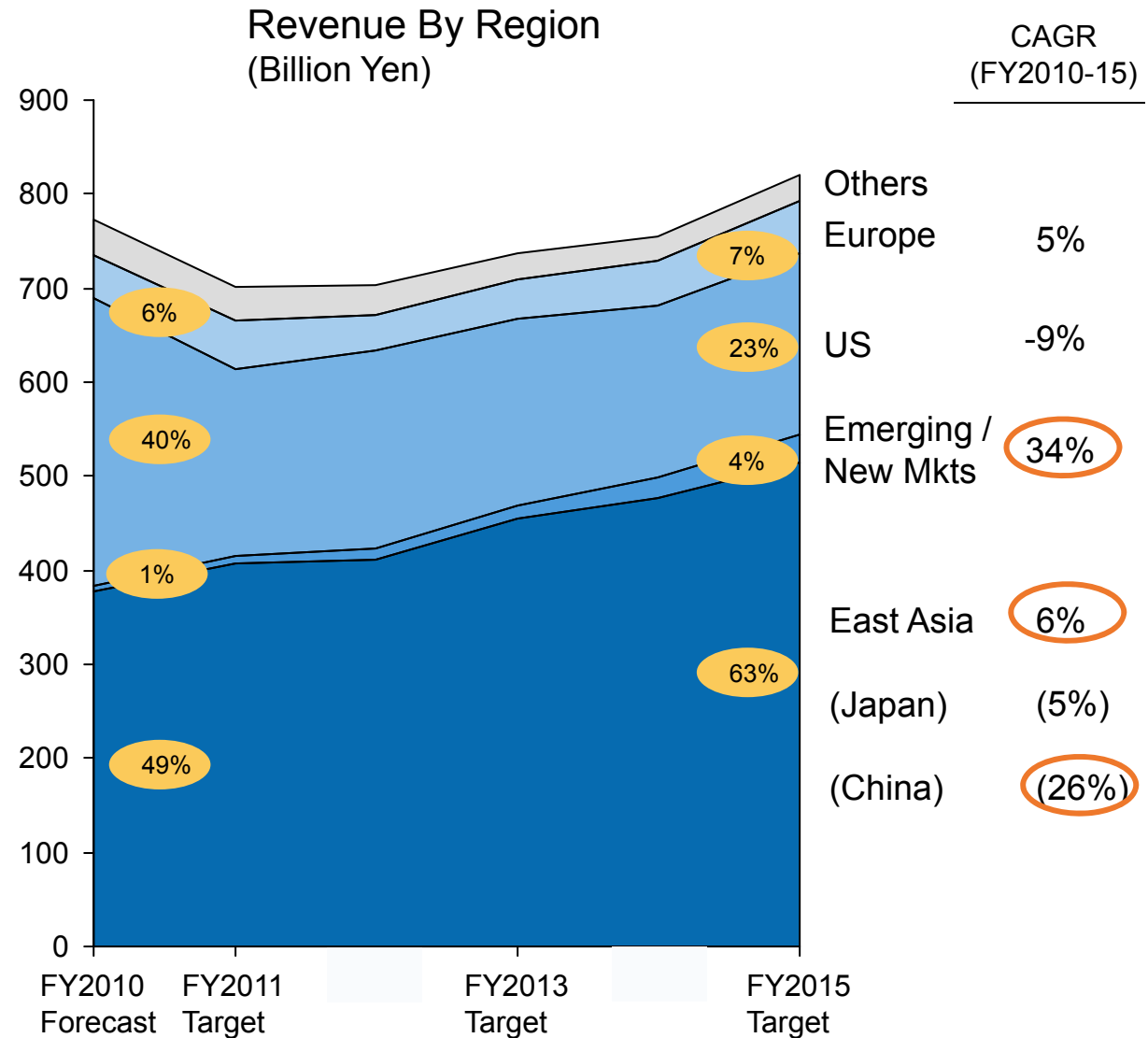


# Transformation of Regional Balance

## From U.S. to East Asia and New Markets



- East Asia to lead overall growth, especially in Japan and China, expanding from 49% in FY2010 to 63% in FY2015 with 6% CAGR (26% CAGR in China, 5% CAGR in Japan)
- Emerging / New Markets in investment period, increasing from 1% to 4% and focusing on India, Brazil, Russia, Canada and ASEAN with CAGR of 34%
- Streamlined and refocused US and Europe operations, shifting to specialty businesses such as oncology and epilepsy

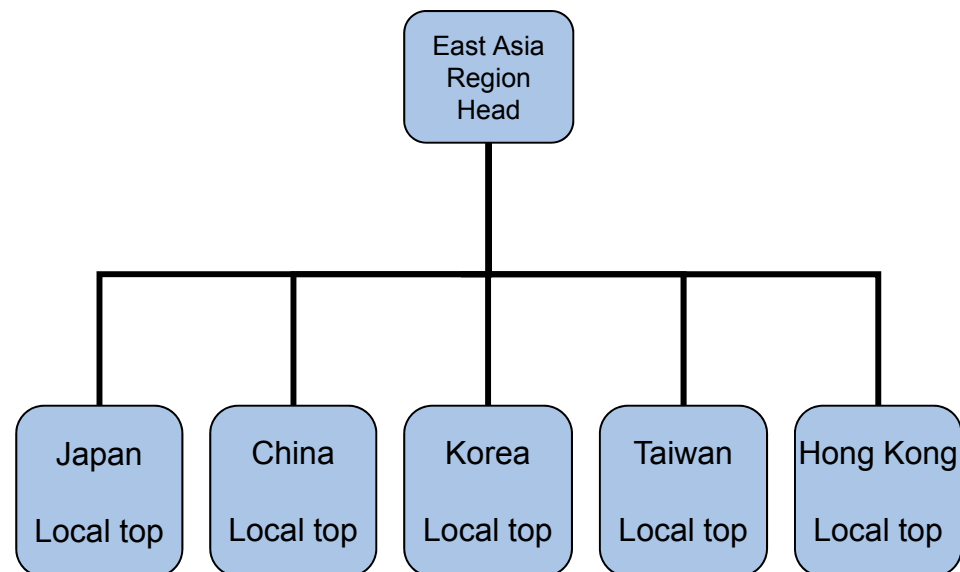


## Concept of East Asia

**Ahead of the competition,  
synergy of knowledge sharing,  
local talents across East Asia Region**

- **Sharing and expanding *hhc* knowledge**
  - Local talents across East Asia to experience *hhc* with Eisai Japan and bring back knowledge to East Asia
  - Globalization of Eisai Japan
- **Sharing business practices (CNS, Oncology, RA, GI/Liver) such as KOL (Key Opinion Leader) exchange**
  - Aricept: Japan/ China/ South Korea/ Taiwan/ HK
  - Pariet: Japan/ China/ South Korea/ Taiwan/ HK
  - Halaven: Japan/ China/ South Korea / Taiwan /HK
  - Humira: Japan/ South Korea/ Taiwan
  - Stronger Neo Minophagen C: Japan/ China/ Taiwan
- **To be led by strong local leadership**
  - Advancement of the management by local head
  - Acceleration of clinical development in East Asia with JAC (Japan/Asia Clinical Research PCU)

## Framework of East Asia



	Prescription	OTC	Diagnostics	Generics
Japan	✓	✓	✓	✓
China	✓	TBD	TBD	TBD
Korea	✓			
Taiwan	✓	✓		
Hong Kong	✓	✓		



# Transformation to Efficient and Lean Commercial Structure



## Japan

Transform from Solo Eisai Japan to the Core of East Asia

- From “building supportive communities for patients” to “Patient Journey” business model”; Expanding further to East Asia
- “Patient journey” business model: provide value-added services and information through advantage of four integrated segments (prescription drug, OTC, diagnostics, and generics) from prevention, diagnosis, treatment to prognosis
- Leverage strong network with KOLs in common therapeutic areas
- Headcounts from 2,400 to 2,300+

## China

Massive Fieldforce Model to Focus Approach Adaptive to Areas and Product Characteristics

- Improve employee turnover rate and productivity through dissemination of hhc, personnel exchanges, and enhanced career programs in East Asia
- Cancer, liver disease, CNS: marketing-driven business model by establishing business units for covering major cities
- Sales-led business model through alliance with local partners to efficiently expand coverage to rural areas
- Headcounts in principle flat at approximately 1,300



# Transformation to Efficient and Lean Commercial Structure



## US

Transform from Mass Market/Co-Promotion Model to Independent Neuroscience/Oncology Franchise Model

- Optimize smaller cross-functional field teams, including clinical nurse educator team and Managed Markets, to reach customers
- Accelerate shift to oncology franchise model by focusing in women's oncology
- Further enrich neuroscience franchise with addition of epilepsy product line
- Headcounts from under 1,600 to 1,000+

## EU

Transform from Country-Based Business Model to "One Europe" Business Model

- One Europe with three pan-European business units (Epilepsy, Institutional Care, Mature Brands) and three sub-European regions (North, Central, South) to create value for patients with more optimized resources
- Pan-European Market Access Team: purpose is to acquire price and reimbursement based on Health Technology Assessment in a timely manner
- Headcounts from under 900 to under 700



# New Business Models in Emerging Markets

## Provide Disease Solution Model leveraging Eisai's strengths

- Focus Diseases: CNS (elderly), Oncology (breast cancer), Liver Diseases, and Epilepsy
- Wide Range of Product Lineup: Brand Products + Branded Generic Products

## Approach to rapidly growing Middle-Income Class population

- PPP(Public Private Partnership)  
Establish medical network and enhance awareness by collaborating with public sectors
- Local Partnership  
Provide products to wider area by leveraging local partners' strength
- Affordable Pricing  
Realize pricing policy that matches with patients' out-of-pocket costs

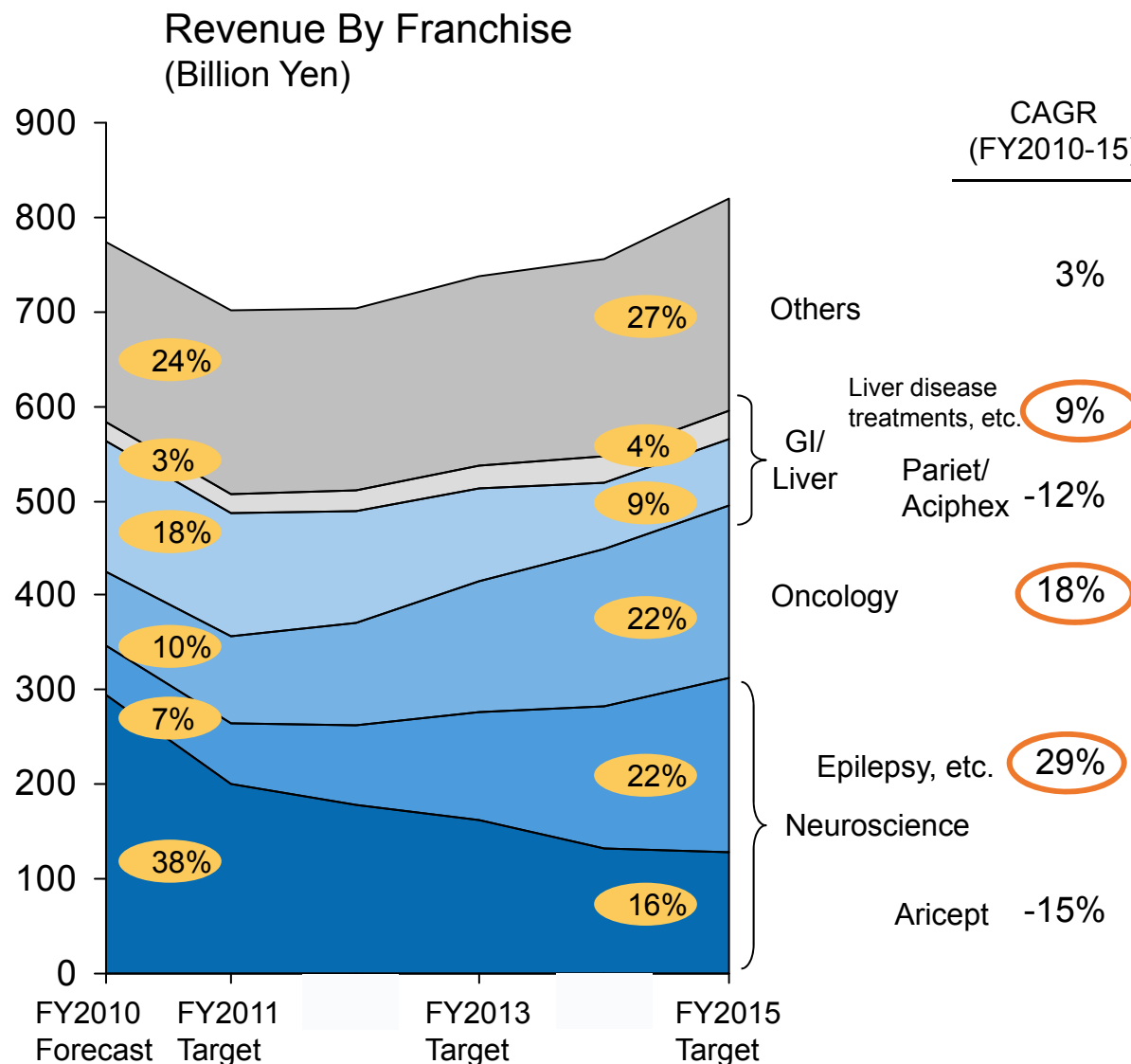


# Transformation of Franchise Portfolio



From Aricept/Pariet to Oncology, Epilepsy, and Liver Diseases

- Oncology represents significant unmet medical needs in both matured and emerging markets – rapid expansion surpassing 180B+yen in FY2015 to place Eisai in top 10 globally (150B yen in women oncology alone)
- Aim for global leadership position within neuroscience
  - Further enhancement of patient values with Aricept (23mg etc.) in the \$5B+ AD market
  - Growth in East Asia and emerging markets
  - Franchise expansion (perampanel, Zebinix, Banzel/Inovelon, etc.) towards global top3 in \$4B+ market of epilepsy
- Build-up of liver business in emerging markets (clevudine, Stronger Neo-Minophagen C, Livact, etc.)



Note: assuming no acquisitions



## 7 Major NMEs Expected to be Launched During the Plan "HAYABUSA"



Halaven	Microtubule dynamics inhibitor	Cancer	Approved
clevidine	DNA polymerase inhibitor	Hepatitis B	Filed
perampanel	AMPA receptor antagonist	Epilepsy	Preparation for Filing
lorcaserin	5HT <sub>2C</sub> receptor agonist	Obesity	Filed (Preparation for Reply to FDA)
lenvatinib	VEGF receptor multi target tyrosine kinase inhibitor	Cancer	Ph III in preparation
farletuzumab	Humanized IgG1 Molecular antibody that targets folate receptor alpha (FRA)	Cancer	Ph III
E5501	Thrombopoietin receptor agonist	Thrombocytopenia	Ph III in preparation



# Prioritize Projects with High Probability of Success



- Focus on the in-house projects with POC completed to deliver meaningful result by 2015

Project	Indication	Development Stage	Submission Schedule
Halaven LCM	Breast cancer 2nd line	Ph III	FY2012
	Non-small cell lung cancer	Ph III in preparation	Beyond FY2014
	Sarcoma	Ph III in preparation	FY2013
perampanel LCM	Generalized seizures		FY2013
	Partial onset seizures (monotherapy)		FY2013
	Lennox-Gastaut syndrome		Beyond FY2014
farletuzumab	Platinum-sensitive ovarian cancer	Ph III	FY2012
	Platinum-resistant ovarian cancer	Ph II	FY2012
lenvatinib	Thyroid cancer	Ph III in preparation	FY2013
	Melanoma	Ph II	FY2012
	Endometrial cancer	Ph II	FY2012
	Hepatocellular carcinoma	Ph I/II	Beyond FY2014
E5501	Idiopathic thrombocytopenic purpura (ITP)	Ph III in preparation	FY2013

# "(Approval of Halaven was) a Triumph of Chemistry and Tenacious Research" -Wall Street Journal-

- An article on Wall Street Journal titled "New Breast Cancer Drug Found Deep in the Sea" by Peter Landers on January 3, 2011

Amid a dry spell for breakthrough cancer drugs, recent U.S. approval of Eisai Co.'s Halaven represents some vindication for a small group of researchers who believe, contrary to recent pharmaceutical fashion, that molecules from nature hold promise against hard-to-treat diseases.



Halaven is derived from a substance in a Japanese black sponge Okadai

The Food and Drug Administration's approval of Halaven in November for treating late-stage breast cancer was a triumph of chemistry and tenacious research. Its path, extending nearly three decades from the first studies, demonstrates not only potential benefits but also some of the hurdles in the hunt within nature's bounty for drugs of the future. (excerpts)

# Halaven and Perampanel 2 Blockbuster Candidates

## Halaven

Liposomal Formulation

Combination therapy strategy with in-house anti-cancer agent

Breast Cancer Adjuvant

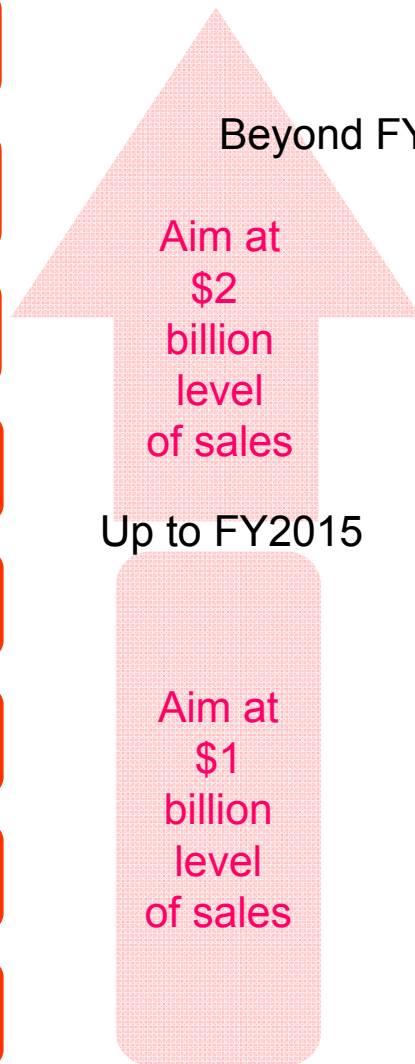
Breast Cancer 1<sup>st</sup> Line

Non-small-cell lung Cancer

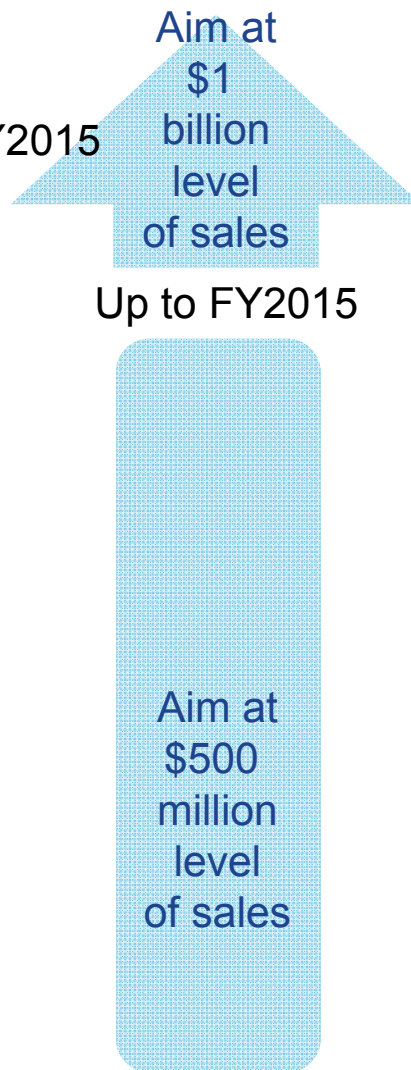
Sarcoma, prostate, etc.

Breast Cancer 2<sup>nd</sup> Line

Breast Cancer 3<sup>rd</sup> Line



## perampanel



Partial Onset Seizure (Pediatric Adjunctive)

Lennox-Gastaut Syndrome

Partial Onset Seizures Monotherapy

Primary Generalized Tonic-Clonic Seizures Adjunctive

Partial Onset Seizures Adjunctive





# Contribution to Alzheimer's Disease Treatment

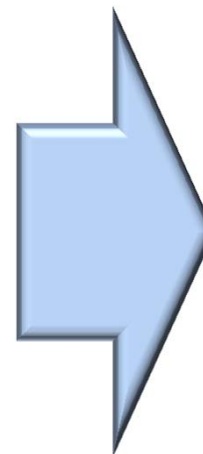
## Next generation AD treatment in addition to Aricept franchise



### Aricept franchise strategy

Growth Ratio of  
Dementia Population  
over next 20 years  
(internal estimates)

<b>US</b>	<b>+63%</b>	<ul style="list-style-type: none"> <li>Position Aricept 23mg as essential drug for moderate-to-severe AD</li> <li>Rapid uptake of 23mg to achieve \$600 million sales in FY2012</li> </ul>
<b>Japan</b>	<b>+57%</b>	<ul style="list-style-type: none"> <li>Realize "AD life-time care" for AD patients and caregivers by providing product, services, information, and network for disease prevention, diagnosis, and treatment</li> <li>Maintain approx. 100 billion yen sales annually</li> </ul>
<b>China</b>	<b>+117%</b>	<ul style="list-style-type: none"> <li>Establish Aricept business unit</li> <li>Expand market access with business unit focused on AD</li> <li>Pursue five-fold sales increase from FY2010 to FY2015</li> </ul>
<b>South Asia Latin America</b>	<b>+107%</b> <b>+77%</b>	<ul style="list-style-type: none"> <li>Expand market access through disease awareness programs and affordable pricing</li> <li>Increase 10mg contribution for upcoming 23mg launches</li> </ul>



### Next generation AD treatment

#### **BAN2401**

Novel fully humanized monoclonal antibody that removes neurotoxic beta-amyloid protofibrils, which is considered as one of the causes of AD

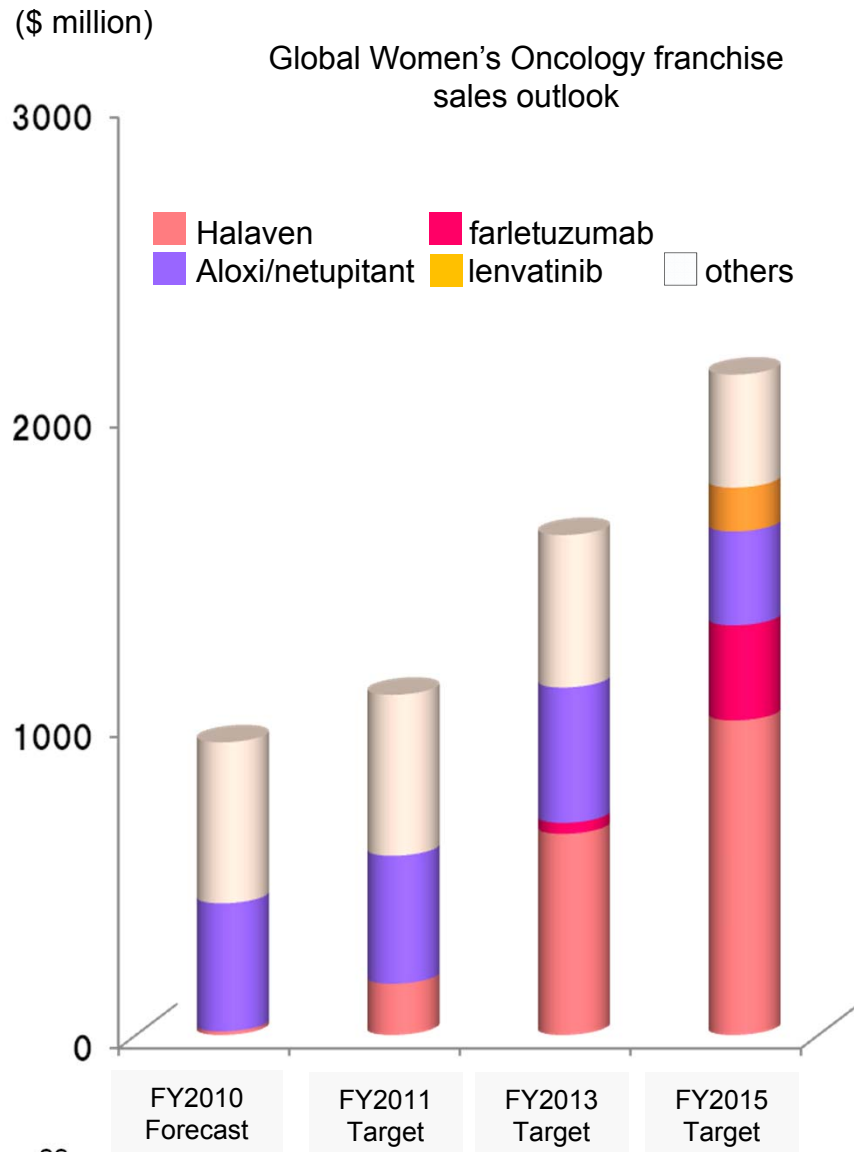
#### **E2609**

Next-generation AD treatment that reduces total beta-amyloid, aiming not only symptomatic improvement but also disease modification

#### **E2212**

Next-generation AD treatment that expects symptomatic improvement as well as disease modification

# Focus in women's oncology Vying for a Top 10 Oncology Spot



- Top 10 Global Oncology Player
  - 2009 top 10 ranking entry point of at least \$1.5B with market growth at 8% per year
  - FY2015 revenue target of \$2B+ vying for a top 10 spot
  
- Top 3 Position in Women's Oncology
  - Halaven in breast cancer + Farletuzumab in ovarian cancer + lenvatinib in endometrial cancer and thyroid cancer + Aloxi/netupitant for supportive care totaling \$1.5B+ in FY2015 and 10%+ market share
  - Aiming a top 3 spot in women's oncology by 2015





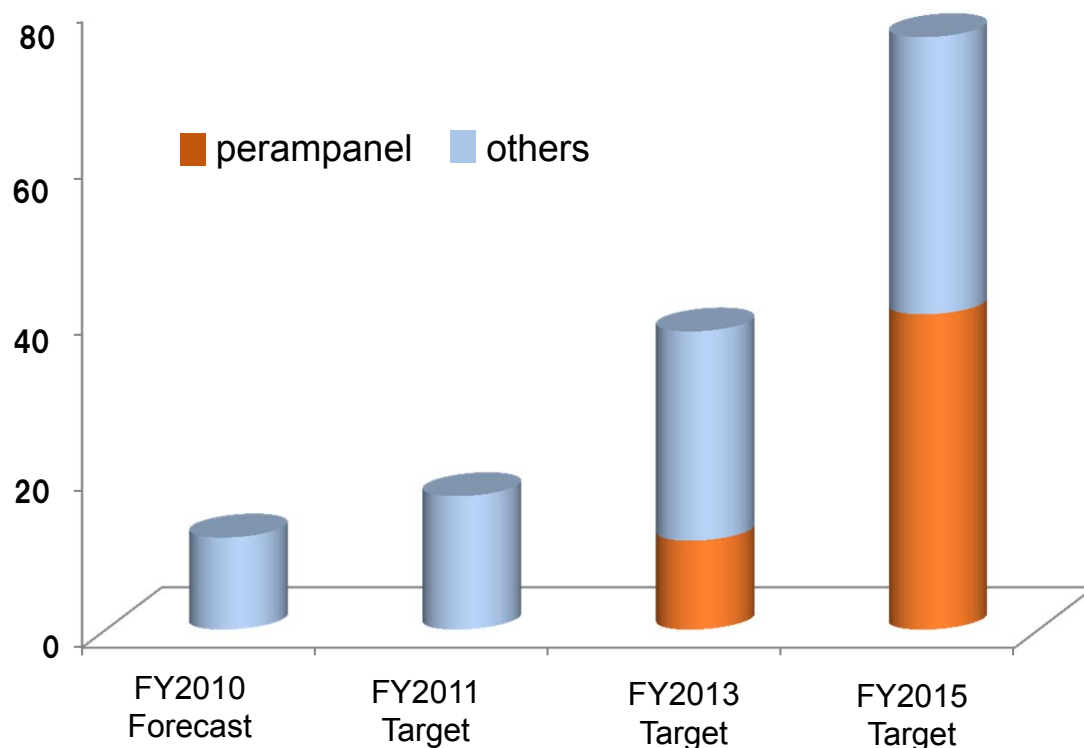
# Aim for Global Top Three Epilepsy Player



## Perampanel to Drive Growth

### Global Epilepsy Franchise Sales Outlook

(billion yen)



- Extensive epilepsy treatment lineup with different mechanism of action, including perampanel, Banzel/Inovelon, Zebinix, and Zonegran
- Perampanel as first-in-class AMPA receptor antagonist to provide a new treatment option to epilepsy patients
- Further enhancement of patient value by perampanel: adjunctive therapy of primary generalized tonic-clonic seizures, monotherapy of partial seizures, and Lennox-Gastaut Syndrome
- Provide value-added information utilizing rich clinical data and patient data
- Evaluate for potential combination therapy within Eisai products

Accumulate knowledge about epilepsy while providing physicians and patients with value-added services as well as information



# Growth of Liver Disease Franchise



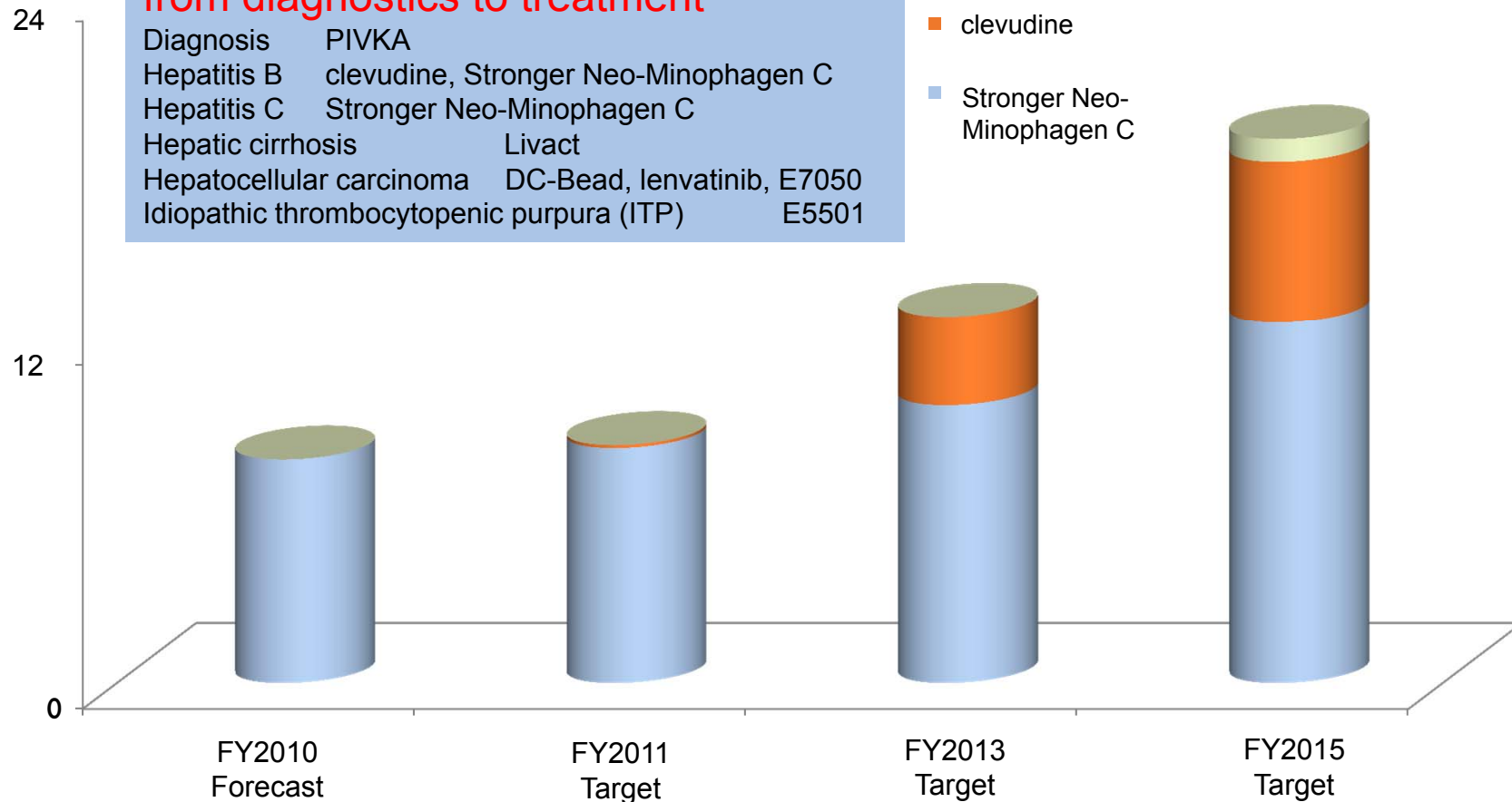
Expansion in East Asia and New Markets  
with clevudine, Livact, Stronger Neo-Minophagen C, and E5501

(billion yen)

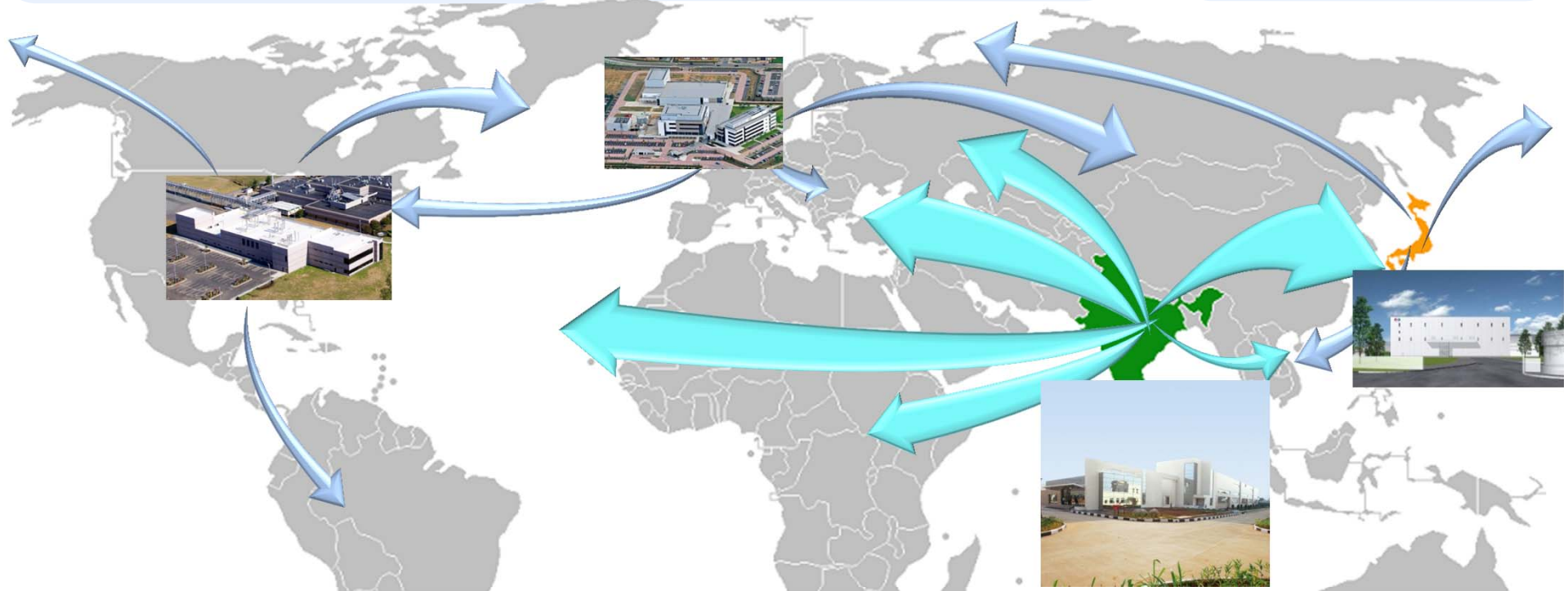
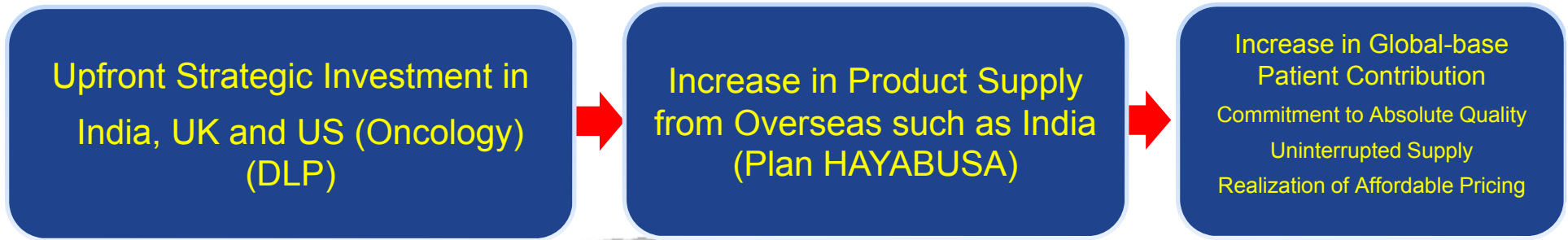
## Product lineup to cover liver diseases from diagnostics to treatment

Diagnosis	PIVKA
Hepatitis B	clevudine, Stronger Neo-Minophagen C
Hepatitis C	Stronger Neo-Minophagen C
Hepatic cirrhosis	Livact
Hepatocellular carcinoma	DC-Bead, lenvatinib, E7050
Idiopathic thrombocytopenic purpura (ITP)	E5501

- Livact
- clevudine
- Stronger Neo-Minophagen C

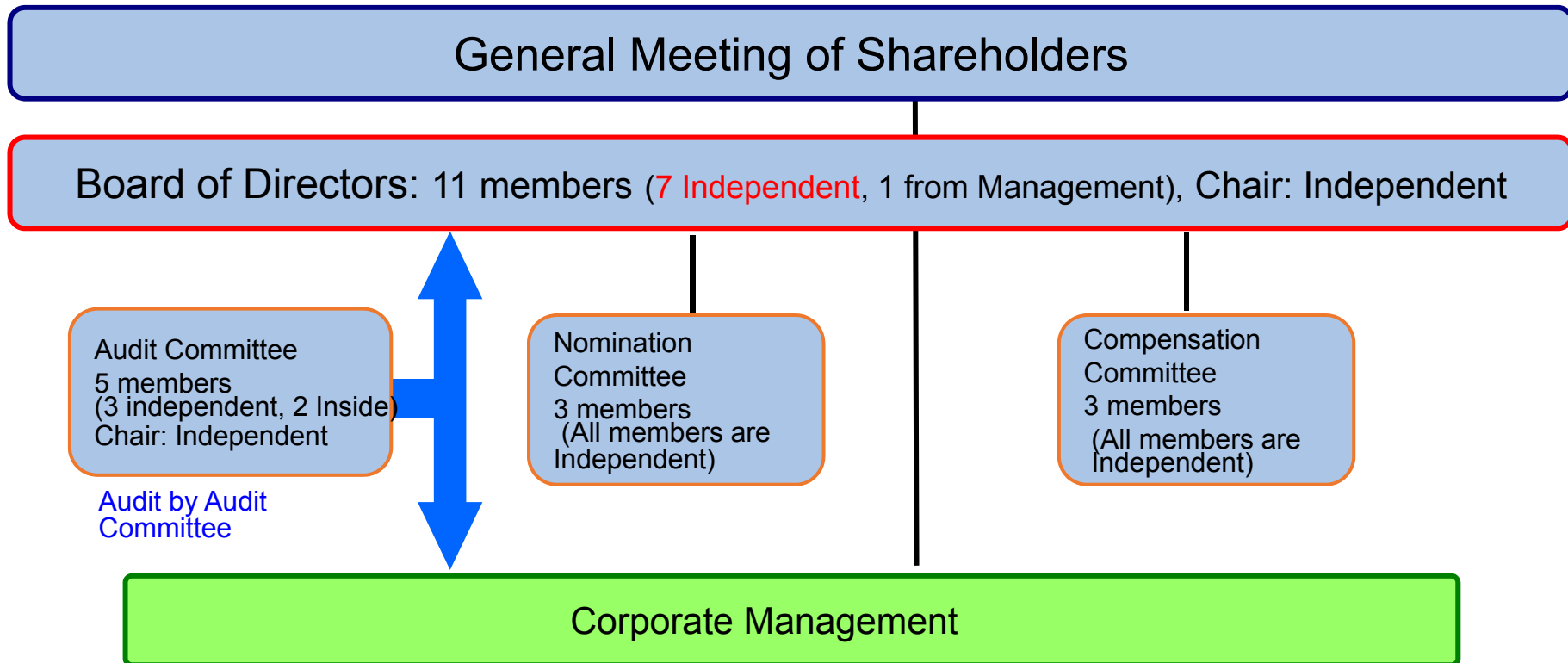


Fulfill Asian-specific unmet medical needs with multiple treatment options in different stages of liver diseases



**Toward Implementation Phase of Global Logistics**

(since June 2004)



- CEO and Chairperson of the Board are segregated with the Chair being an independent outside director
- Three Committees (Audit, Nomination, Compensation) with each Chair thereof being an independent outside director

(Yen) Image of Dividend Trajectory

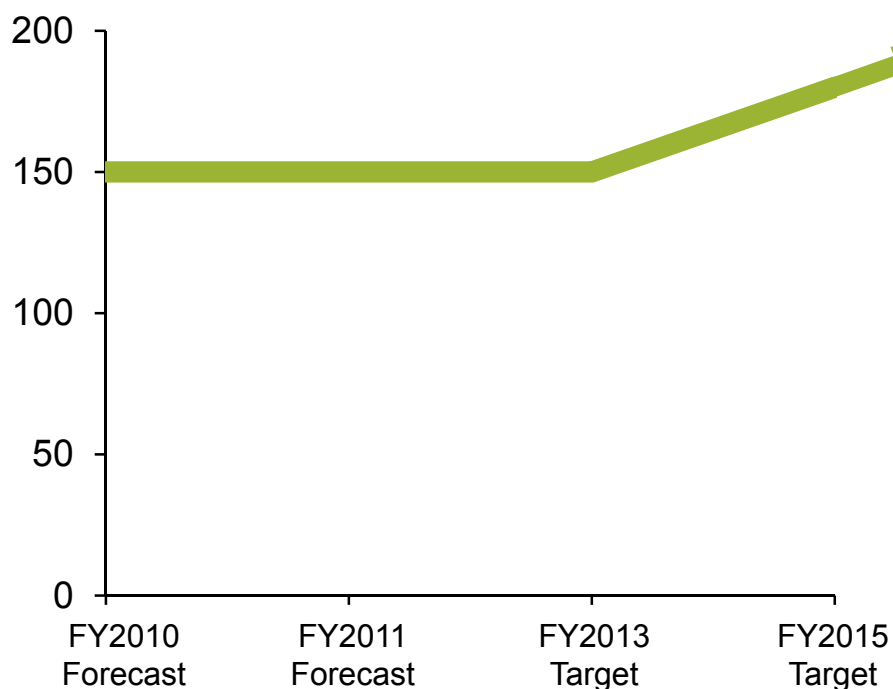
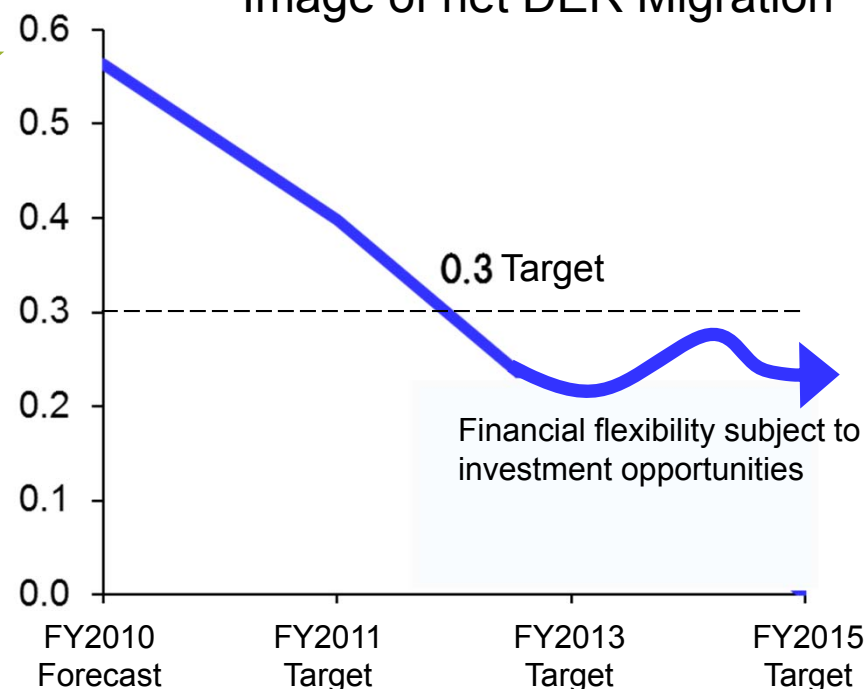


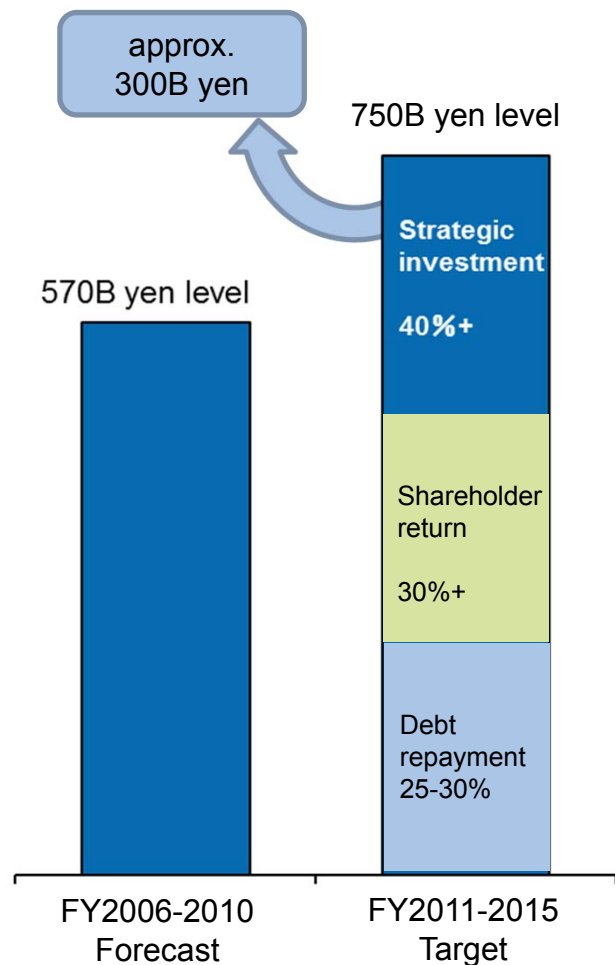
Image of net DER Migration



- DPS (dividend per share) 150 yen+
- DOE (dividend on equity) 8%+
- FY2011-15 cumulative dividends = approx. 1/3 level of cumulative cash income

- Cash generating capability to enable debt repayment in line with maturity ladder
- Strive to achieve the targeted net DER of 0.3 by FY2013

## Cash income



## Case

### 1. Objectives of M&A and business development (BD):

- Accelerating growth in East Asia
- Establish new business model in new markets
- Enhance CNS product portfolio
- Enrich the product line-up in the area of women's oncology

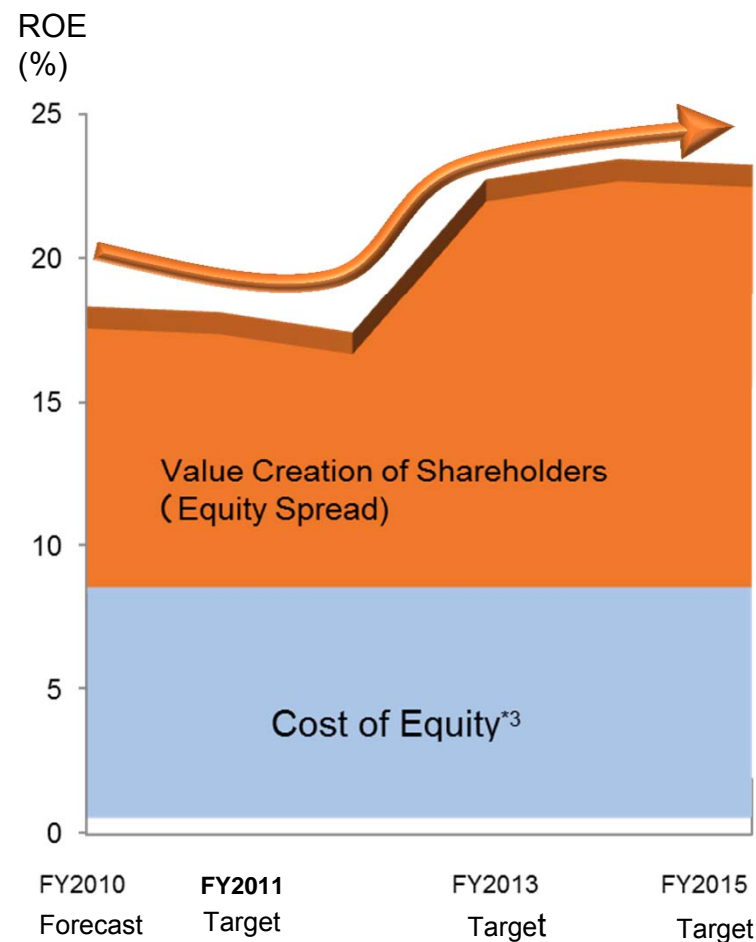
### 2. Technology platform:

- Investment for transforming to "focused" medicine

### 3. Strategic CAPEX:

- Production of monoclonal antibody
- Expansion of manufacturing facility in India

- **ROE: 20% or more**
  - Positioned as top priority indicator for shareholder value creation
  - Far exceeding Cost of Equity
  - Aim at world-class 15% of Equity-Spread\*<sup>1</sup>
  - Enhance capital efficiency by reducing cross-shareholdings and other means
  
- **DOE: 8% or more**
  - Intend to reimburse Cost of Equity with actual cash dividend
  - Allotting 1/3 of Cash Income as dividend
  - Stability policy for sustainable dividend payout
  
- **Net DER\*<sup>1</sup>: 0.3 or less**
  - Decreasing WACC\*<sup>2</sup> and maintaining credit rating
  - Secure the financial leeway in balance sheet management



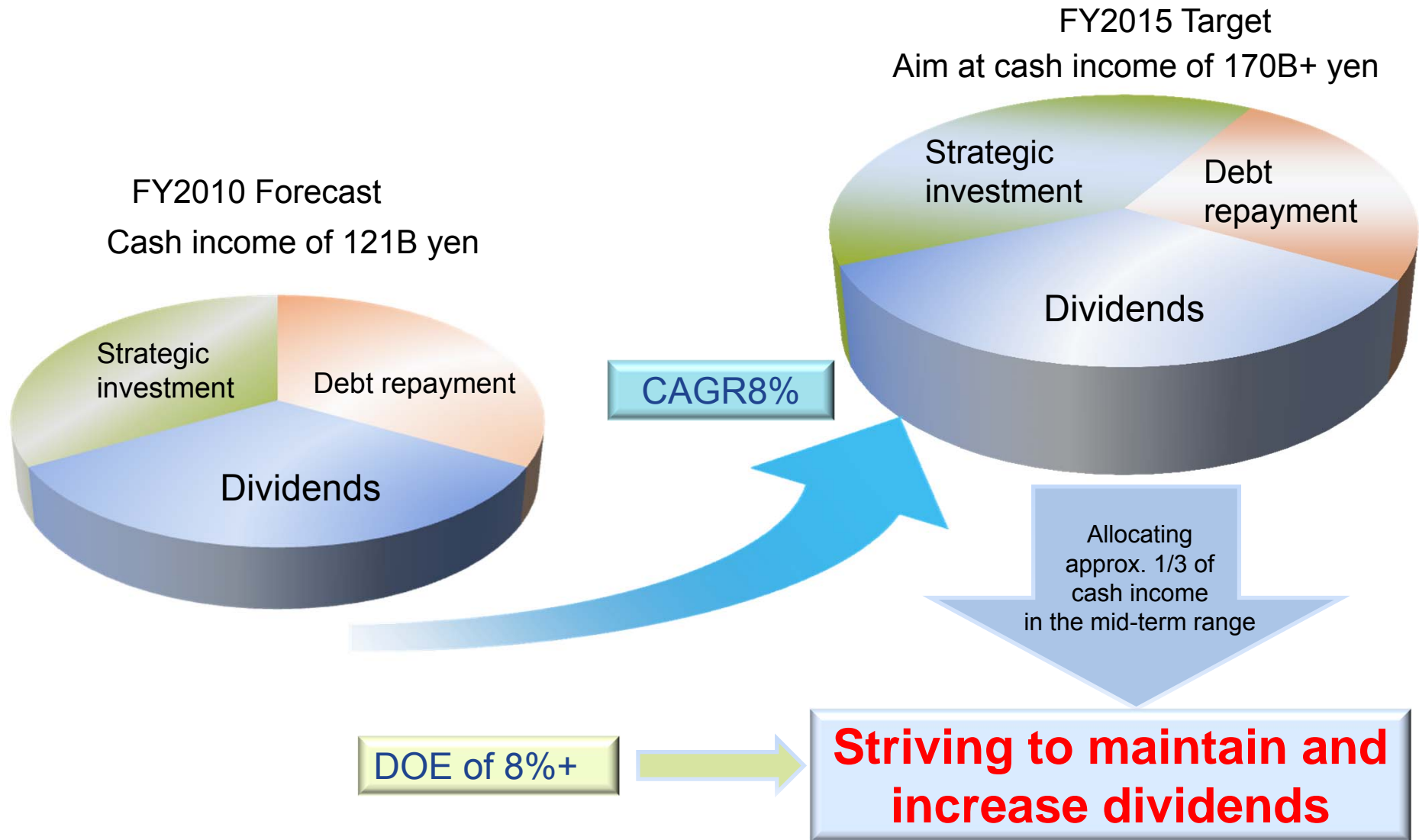
\*<sup>1</sup>Equity spread: ROE – cost of equity (%)

\*<sup>2</sup>WACC: Weighted Average Cost of Capital

\*<sup>3</sup>Assuming 8% level of cost of equity



# Robust Increase of Cash Income







# Reference Information



# Overview of the Dramatic Leap Plan (DLP\*)

\*DLP: Mid-term Strategic Plan  
during FY2006 and FY2011  
replaced by plan "HAYABUSA"



# Global success of Aricept and Pariet/AcipHex



- Aricept
  - Peak sales: approx. 323B yen (FY2009)
  - Established its market position as a gold standard treatment for mild, moderate, and severe Alzheimer's disease
- Pariet/AcipHex
  - Peak sales: approx. 176B yen (FY2007)
  - Contributed to significant number of patients as one of the few patent-protected branded PPIs in the U.S. and Europe
  - Gained No.1 share among branded PPI products in the Japanese market

Established global capabilities in all functions including manufacturing and commercial by these two products

- Equipped with drug discovery capabilities for both small molecules and antibodies
- Aim for full-fledged product line from chemotherapy agents, molecular-targeting agents, antibodies, to supportive care agents
- Established franchise with 3 acquisitions: Ligand products, Morphotek, and MGI
- Success of drug discovery for Halaven
- Oncology franchise accounts for 10% of global sales

Successfully entered oncology therapeutic area  
where largest unmet medical needs exist globally

- 2006 Acquisition of Ligand products (US\$205M) = cash deal
- 2007 Acquisition of Morphotek (US\$325M) = cash deal
- 2008 Acquisition of MGI (US\$3.9B) = debt financing

Funding with pecking order of shareholder value creation,  
thereby avoiding dilution and improving capital efficiency



- Significant enhancement of EPS, cash EPS, and ROE
- Net DER to maintain credit rating of A or above by B/S management

- EPS will be reaching 246 yen (FY2010) from 222 yen (FY2005)
- Cash EPS will be increased to 425 yen (FY2010) from 311 yen (FY2005)
- ROE will be improved to 17% (FY2010) from 13% (FY2005)
- Net DER at 0.5 level in FY2010

\*FY2010 figures are forecasts

Realized strategic vision to enter into oncology therapeutic area by M&A

- Consequences of challenging unmet medical needs
  - Terminated projects
    - Parkinson's disease: perampanel (AMPA receptor antagonist)
    - Pediatric indications in the U.S. and Europe: Aricept
  - Projects lagged behind the schedule
    - Halaven (previously assumed filing under subpart H: microtubule dynamics inhibitor)
    - eritoran (endotoxin antagonist)
    - E5555 (PAR-1 antagonist)
    - AcipHex-ER (long-acting PPI)
- Major development projects in Japan progressed as scheduled
- Achieved approvals of Aricept 23mg and Halaven, and successful phase III study for perampanel in FY2010

Deviated from the original plan to launch new products

- Global partnership greatly contributed to global expansion of Aricept and Pariet/AcipHex (R&D, regulatory, manufacturing, and commercial), thereby leading to accumulation of knowledge obtained from such partners
- Established own commercial structure and full value chain in the U.S. and Europe

Increase of alliance fees in accordance with sales expansion

# Pros and Cons of Financials

- FY2010 net sales will underperform the DLP target due to delays of new products (perampanel, Halaven, and eritoran), project termination for Aricept pediatric indication in the U.S., foreign exchange impact, and other factors. Operating profit will also fall short of the DLP target due to non-achievement of targeted sales of new products and the Aricept in the U.S., attributed to the amortization of marketing rights, and the increase of COGS
- Enhanced cash generation capability as a result of success of Aricept and Pariet/AcipHex, strategic investment in MGI, and cost efficiency (the cumulative cash income, excluding foreign exchange impact from FY2006 through FY2010, outperformed the DLP target)

Allocating 1/3 of cash income to investment for growth,  
1/3 to shareholder return, and 1/3 to debt repayment  
in the mid-term range





Transformation  
from “mass” medicine  
to “focused” medicine

# Alzheimer's disease: Development of disease modifiers

Development of disease modifiers for AD: Two high-priority projects plus biomarker research moving in parallel; confirm POC for both symptomatic and disease modification (DM) claims within one study

## ***BAN2401 (anti-A $\beta$ protofibril humanized monoclonal antibody)***

### Milestone

**POM\*1/POP\*2**  
in patients



**POC\*3**  
Interim to confirm  
symptomatic  
then continue to confirm DM



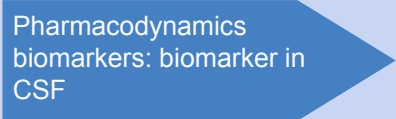
**BLA\*4 submission  
(symptomatic)  
FY2015-FY2016**  
Symptomatic data of  
pivotal study



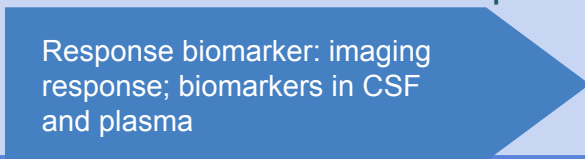
**Submission  
(DM)  
FY2017**  
Full data of pivotal study

### Biomarker research

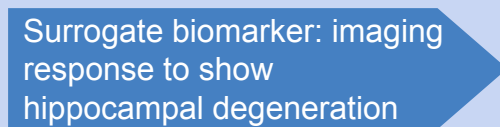
Pharmacodynamics  
biomarkers: biomarker in  
CSF



Response biomarker: imaging  
response; biomarkers in CSF  
and plasma



Surrogate biomarker: imaging  
response to show  
hippocampal degeneration



## ***E2609 (beta secretase inhibitor)***

### Milestone

**Ph I**  
In healthy  
volunteers



**POM/POP**  
in patients



**POC**  
Interim to confirm  
symptomatic  
then continue to confirm DM



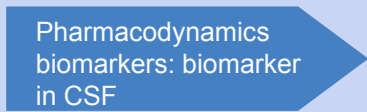
**NDA/MAA  
submission  
(symptomatic)  
FY2016**  
Symptomatic data of  
pivotal study



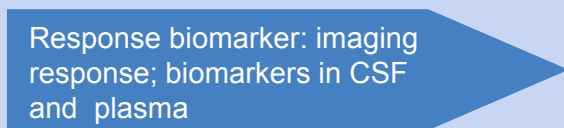
**Submission  
(DM)  
FY2017**  
Full data of  
pivotal study

### Biomarker research

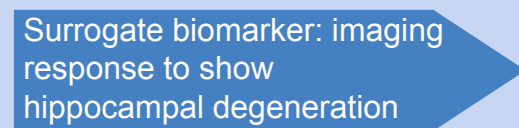
Pharmacodynamics  
biomarkers: biomarker  
in CSF



Response biomarker: imaging  
response; biomarkers in CSF  
and plasma



Surrogate biomarker: imaging  
response to show  
hippocampal degeneration



## *Focused Drug Discovery*

- Identification of target-pathologically relevant/root cause of disease:
  - Genetic / physiological / pathological information from patients; application of advanced bioinformatics
- Assays-relevant to function of target:
  - Phenotypic screens reflecting pathology of diseases using ES/iPS technology
  - Unique cell-based screening system, e.g. protein-protein-interaction
- Compound Libraries:
  - Therapeutic area specific compound libraries
  - DOS libraries
- *In-vivo* Models:
  - Disease models: well characterized disease-target relationship
  - Non-human disease models

## *Biomarker-driven Product Creation*

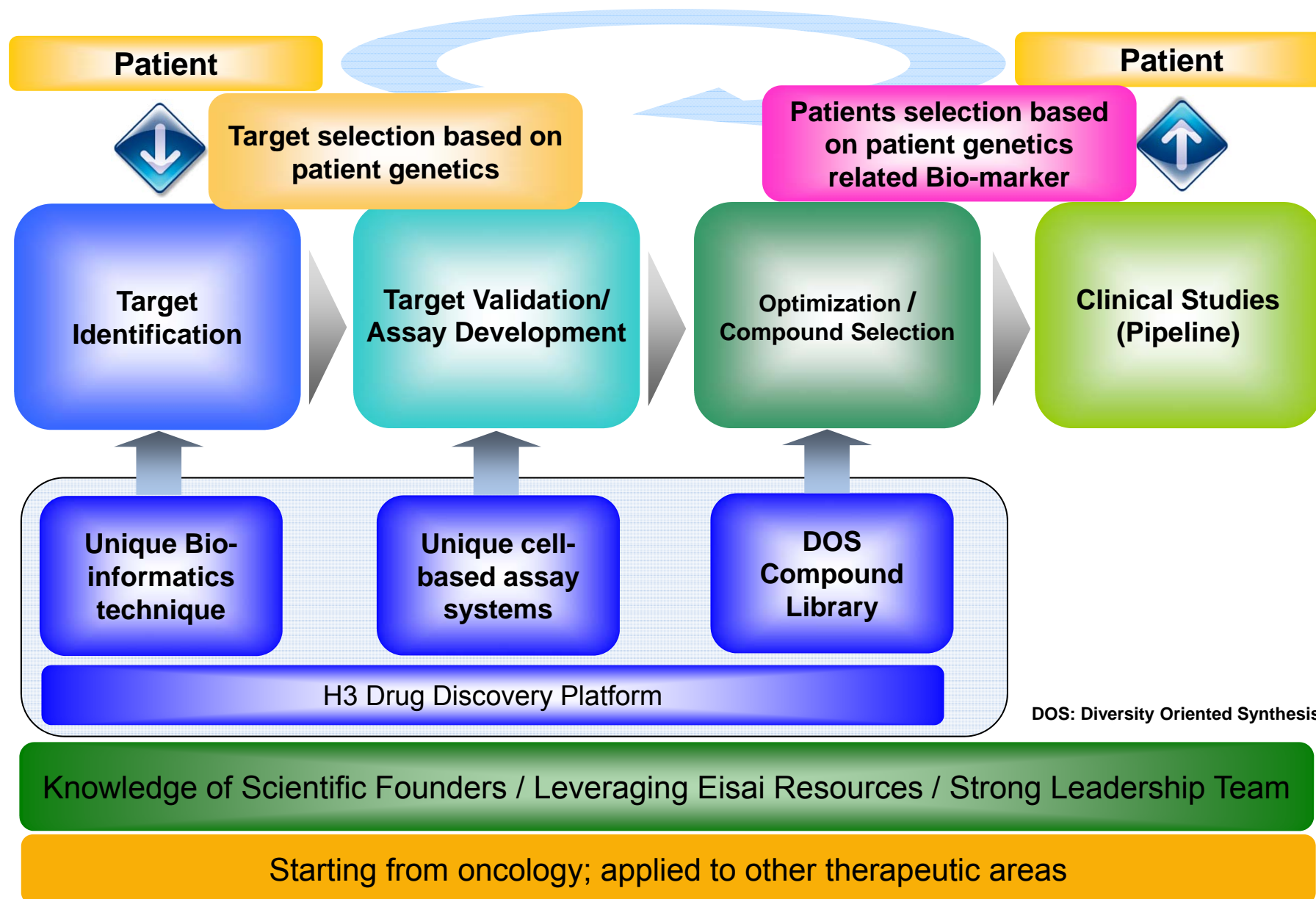
- Pharmacodynamics and Response Biomarkers:
  - Establish POM and POP in Phase I/II
  - Increase of probability of success and evidence of efficacy in Phase II
- Stratification Biomarkers :
  - Phase III study focusing on appropriate patient populations
- Integrative Biomarker Technologies:
  - Tissue bank, immunohistochemistry (IHC), bioinformatics, imaging (SPECT, PET, MRI), integrative omics, diagnostics

*At least 50% of new projects during the Plan “HAYABUSA” are specific to single target;  
→ Enabling “Focused” medicines*

*New projects should have biomarker strategy*

# H3 Biomedicine: Realization of personalized medicine

Higher efficacy and better safety profile for selected patient population





# Enriching Pipeline



# Pipeline Engine: Over 40 NME and LCM Submissions



FY2011

FY2012

FY2013

Beyond FY2014

perampanel  
- Partial Onset Seizures (US, EU)

Aricept  
-Lewy Body Dementia (JP)

perampanel  
-Primary Generalized Tonic-Clonic Seizures (US, EU)  
-Partial Onset Seizures Monotherapy (US)

perampanel  
-Lennox-Gastaut Syndrome (US, EU)  
-Partial Onset Seizures (JP, CN)

BAN2401  
-AD (US, EU, JP)

Aricept  
- Dry Syrup (JP)  
- New ODT (JP)

lorcaserin  
-Obesity (US)

Aricept  
-Patch (JP)  
-23mg (JP)

LUSEDRA  
-Sedation (CN)

Zonegran  
- Monotherapy (EU)  
- Pediatric (EU)

Lyrica  
-Central Neuropathic Pain (JP)

Halaven  
-Sarcoma (US, EU)

Halaven  
-Non-Small-Cell Lung Cancer (US,EU,JP)

Halaven  
-Breast Cancer 1L (US,EU)

Lyrica  
- Fibro-myalgia (JP)

Halaven  
-Breast cancer 2L (US, EU)  
-Breast Cancer 2L/3L (CN)

lenvatinib (E7080)  
-Thyroid Cancer (US,EU,JP)

lenvatinib (E7080)  
-Hepatocellular Carcinoma (JP, CN)

E5501 (AKR501)  
-Acute TLD (US, EU)

Humira  
- Ulcerative Cholititis (JP)

farletuzumab  
-Ovarian Cancer (US, EU)

netupitant  
-Chemotherapy Induced Nausea and Vomiting (US)

Treakisym  
-Multiple Myeloma (JP)  
-Low-grade Non-Hodgkin Lymphoma (JP)

Livact  
- Liver Cirrhosis (CN)

lenvatinib (E7080)  
-Melanoma (US)  
-Endometrial Carcinoma (US)

E5501 (AKR501)  
-Idiopathic thrombocytopenic purpura (ITP)(US, EU)

E5501 (AKR501)  
-Thrombocytopenia associated with liver disease (TLD) (CN)

cinitapride  
- Functional Dyspepsia (CN)

Treakisym  
-Low-grade Non-Hodgkin Lymphoma (JP)

Uritos  
- Overactive bladder (CN)

Humira  
New indication (JP)

Humira  
- Inhibition of Joint Damage in RA (JP)

Neuroscience  
Oncology  
GI/Liver  
Immunology/Inflammation

Own Pipeline Product  
In-licensed Products