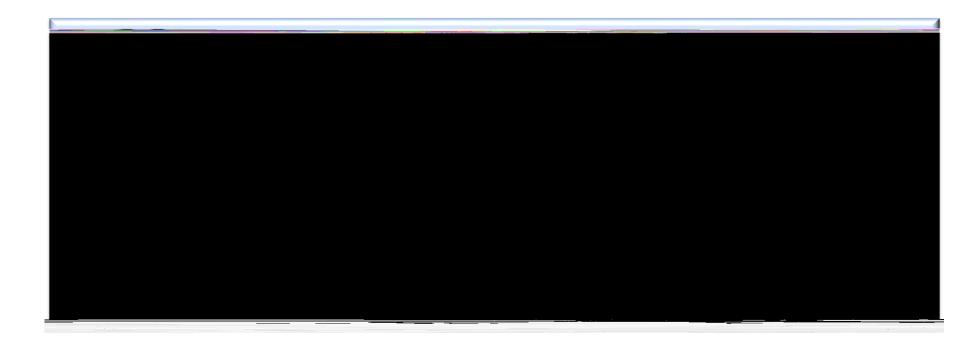


# Press Conference

March 3, 2016 Eisai Co., Ltd.

## Safe Harbor Statement







# Plan 'E-WAY 2025'

Converting

KnoE



Overview of Plan '

# Plan "HAYABUSA" Overall Summary



- 1. Qualitative aspect of 5 Aspirations (Rise of Asia Region, New Market Entry, Establishment of Global Business Organization, Foundation for Oncology Business, Improvement of Product Creation Capability) were attained to some extent.
- 2. While target in connection with Profit and Loss Statement was not attained, on the contrary, we managed to achieve sound Balance Sheet and shareholder value creation.
- 3. The factors behind the underachievement of the revenue target were lack of relevant measures against business environmental changes due to loss of exclusivities of main products, and



### Pharmaceutical Industry Environment Seven Keys



Expansion of middle-income class, progress of aging society and

Patient-centricity Prevention, Cure and Care Regional Care / Home Care Outcome Payer Access Digital Technology



# Strategic Intent 1







# Strategy 1 Therapeutic Area Focus

Find out "Ricchi" and focus on innovation



# 1. Dementia related diseases



# Establishment of End to End Organization



# Design of Therapeutic Area Focused End to End Organization



- The key to pipeline productivity improvement is making Early Decision in a competitive landscape. This is only possible at an organization where Discovery, Clinical and Commercial functions are integrated.
- Important decisions for prioritizing pipeline, lifecycle management, and changes in commercial mix should be made promptly through collaboration between Discovery, Clinical and Commercial.
- Scientific Acumen, an important organizational culture, is developed through integrated business structure including Discovery.

### Neurology, Oncology Business Group Structure











# Strategy 2 "Ricchi" and Innovation

Aim to form our business with Innovation as a pillar at "Ricchi", the place where landscape is clear without crowd as if we would choose the place to build our house ("Center Line").



# Neurology Discovery Engine 4 sites (63)





### Tsukuba Research Laboratories (Ibaraki, Japan)

**Platform Technology** 

- Integration of bio-pharmacology and medicinal chemistry with sound knowledge of CNS drug discovery
- Outstanding medicinal chemistry method for small molecule medicine creation platforms established through in-house discovery projects
- Super Resolution Fluorescence Microscopy (partner's technology), Blood-based Biomarker
- Human translation technologies (EEG, CSF measurement) in genome-editing cell/animal
- Analysis method by integrating behavior, electrophysiology, neurochemistry and PET tracer imaging in various animal models

Early and minimallyinvasive diagnostics

Proteinopathy

Synapse micro-environment

Novel neuro-transmission pathways



#### **Andover Product Creation Innovation Systems (Andover, U.S.) Platform Technology**

- Immunogenetic and immunoepigenetic driven target discovery
- Analysis of large genome sequence data followed by functional genomics focusing on neuroinflammation to identify drug targets strongly supported by human biology
- Human translation technologies using imaging method (fMRI, PET)
- Creation of small compounds with brain penetration based on excellent synthesis technology cultivated through natural product synthesis

Neuro-inflammation and immuno-genetics

#### KAN Research Institute, Inc. (Kobe, Japan) Platform Technology

- Integrated cell biology: Synapse biology, developmental biology and inflammation biology
- New perspective in pathophysiology by sharing knowledge/technology among neural, immune and tumor cell biology
- Identification of novel cells and molecules causing disease
- Modulation of protein-protein interaction by functional biologics
- Handling stem cell and iPS cell aiming at next-generation therapy including glia cells (astrocyte) implantation

Synapse micro-environment

Neuro-inflammation and immuno-genetics

Neuronal regeneration

### **European Knowledge Centre (Hatfield, UK) Platform Technology**

- Innovative Product Creation for neurodegenerative diseases through organic collaboration with UCL (University College London)
  - UCL: Target identification through latest genome association analysis including tauopathy and synucleinopathy, establishment and analysis of gene-modified animals, and biomarker research

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**Proteinopathy** 

Neuro-inflammation and immuno-genetics



### E2609\*1

Co-development with Biogen
BACE inhibitor
(Beta-secretase)

Preliminary Phase II study's safety and PK/PD data anticipated, and request for End of Phase II meeting with FDA planned in March 2016 Planning development scenarios for Phase III studies

### BAN2401\*1

Co-development with Biogen Anti-a-beta protofibrils antibody

### Aducanumab\*1

(BIIB037)

Biogen

Anti-a-beta antibody

### Lemborexant\*1

Co-development with Purdue Pharma L.P.

Orexin receptor antagonist

E2027\*1

PDE9 inhibitor



## Global Brand Fycompa and BELVIQ®

Value maximization projects\*1 (Lifecycle management)

Eisai

Partial onset seizure/ Primary generalized tonic-clonic seizures	Submitted in July 2015 in Japan	Launch target FY2016
Oral suspension formulation	Submitted in June 2015 in U.S. and EU	Launch target FY2016
Monotherapy	Under discussion with agencies in U.S. and EU	Launch target FY2016 (U.S.) FY2017 (EU)
Pediatric for partial-onset seizure	Phase II study ongoing in U.S. and EU	Launch target FY2018 (U.S., EU, Japan)
Partial onset seizure	Accelerate development for launch in China	Launch target FY2019
Lennox-Gastaut syndrome	Currently planning strategy for expanding indication in U.S., EU and Japan	Launch target FY2020
Once-daily formulation	Submitted in September 2015 in U.S.	Launch target FY2016
Cardiovascular outcomes trial (CVOT)	<ul> <li>Evaluation on MACE<sup>*2</sup>, conversion to type 2 diabetes and MACE+<sup>*3</sup></li> <li>Completed patient enrollment (approx. 12,000) in November, 2015</li> </ul>	

## Oncology "Ricchi" and Innovation



#### Ricchi 1: Cancer Microenvironment

Ricchi 1-1: Mesenchymal Cells and Tumor Stroma (Cell Differentiation and Cancer Stemness)

Ricchi 2: Driver Gene Mutation and Aberrant Splicing

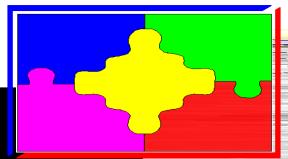
#### **Platform technology**

- Cancer genomics platform:
   State-of-the-art bioinformatics and genetic tools to identify and validate new cancer driver gene and splicing targets
- Splicing platform:

#### **Projects**

• Halaven+anti-PD-1 antibody pembrolizumab\*1, Halaven+PEGPH20\*1\*2, Halichondrin derivatives and other new projects

Ricchi 1-2: Myeloid Cells (Immunosuppressive Myeloid Lineage)



Ricchi 1-3: Endothelial Cells (Abnormal Tumor Vessels)

#### Platform technology

 lenvatinib/Kinase inhibitor platform (including combination with PD-1 inhibitors):

Tsukuba original diverse small molecule libraries targeting kinases. Biomarker/profiling data sets from lenvatinib clinical samples to identify new targets on abnormal tumor vessels and tumor microenvironment associated with drug resistant mechanisms.

**Projects** 

E7046<sup>\*1</sup> (Cancer immunotherapy agent based on inhibitory effect of

EP43) and other new projects



### **Lenvatinib/Kinase Inhibitor Platform**

- Diverse small molecule library targeting kinases
- Biomarker/profiling data sets for Lenvatinib clinical samples allowing us to further identify new targets on abnormal tumor vessels and tumor microenvironment associated with drug resistant mechanisms.

### **Cancer Stemness Platform**

•

# Strategy for Drug Discovery based on Human Cancer Genome for Personalized Medicine

Aim to launch H3 Biomedicine products within 10 years of establishment

Advancing innovative drug discovery based on human cancer genome since its inception in 2010

Diverse scientific talents in Boston, innovative collaboration with outside partners, and swift and robust decisions based on human biology data

Developed 2 compounds for clinical trials

within 5 years of establishment

Identification and validation of driver gene mutations based on cancer patients' genomic data

Capabilities of cancer genome analysis and validation which have been established at H3B

Inhibitor of FGFR4\*
Driver to occurrence and progression of Hepatocellular understanding

Discovery of drugs targeting modulation of aberrant splicing in cancer cells

Deep understanding of splicing biology at H3B

Discovery of next-generation compounds targeting drug resistant mutations which inhibits cure of cancer

Eisai

Drug discovery and diagnosis for drug resistant mutation in cancer cells

progression of Hepatocellular understanding og d1 0 /P <</MCID 37>> 0 1 83 0 0 1 52.2

Initiation of first clinical trials: targeted in 1H FY2016

## World-class Small Molecular Science Aiming for Cure of Cancers



### Halaven Halichondrins

World-Class excellence in natural product synthetic organic chemistry nurtured through the creation of Halaven to pursue further pharmaceutical potential of Halichondrins

Unique MOAs beyond simple anti-angiogenesis (actions on immuno-

Investigational E7046

Morphotek technologies



hhe human health care

### Global brand LENVIMA and Halaven



Launch target U.S., EU: FY2016 Japan: FY2019

### Value maximization projects (Lifecycle management)

Submitted in November 2015 in U.S.  PDUFA*2 action date: May 16th, 2016  Submitted in January 2016 in EU	
Phase I study ongoing in Japan	
	PDUFA <sup>*2</sup> action date: May 16 <sup>th</sup> , 2016

♠ Halarra



<sup>\*1:</sup> Investigational \*2: Prescription Drug User Fee Act \*3: Anti-PD-1 antibody, pembrolizumab \*4: Approved for advanced liposarcoma

<sup>\*5:</sup> Investigational PEGylated recombinant human hyaluronidase under development by Halozyme Therapeutics, Inc.



# Strategy 3 ICT Driven Innovation

## ICT Driven Innovation



Launch of the Data Creation Center as the Global Hub

### 1. Build state-of-the-art ICT Infrastructure

Build state-of-the-art cloud-based ICT infrastructure which enables one-stop access and smart search functions through integrated internal data and company-wide uniform management of access to Big Data such as genome data, compound data, electric medical record, care data and medical bill data.

### 2. Innovation based on analysis of Big Data

Analyze Big Data including real world data utilizing advanced analytical technology with artificial intelligence. Such analysis enables us to identify potential new drug targets, biomarkers. Furthermore, possibly provide customized solution to patients' individual needs and create evidence for outcome evaluation and others.







### Solution

# Strategic Intent 2



- Establish patient-friendly community network through partnership with local government in home care oriented environment
- Provide integrated product package aiming for





# Strategy 1 Dementia Solutions Business

### Eisai's Accumulated Dementia Assets



### **Provide information**

Provide social resource map in connection with dementia including specialized medical institutions and

### Disease awareness

Provide information on dementia through e-65.net\*1

Enhance awareness through TV ads
Operate forums for citizens in
collaboration with local government
Collaboration with dementia support
organizations

approx. 130,000 inquiries have been received)

Pioneer in Dementia Field Eisai's dominant advantages

21 reports on Aricept double blind trials (6804 cases)
Aricept post marketing clinical data of approx. 30,000 cases
Abundant experience in development

of disease modifier

Treatment/Care options

Provide information on dementia through e-65.net

Aricept's various formulations to fulfill patients' needs; OD tablet, jelly, dry syrup, film coated tablet, granule and film Obtained world's first indication for dementia with Lewy bodies in Japan Development of adherence support

Eisai original diagnostic scale/treatment effect measure such as ADCOMS\*2 VSRAD\*3, diagnosis support software for early AD

Collaboration with key opinion leaders in the field of dementia through academic meeting, education for physicians how to diagnose dementia and others

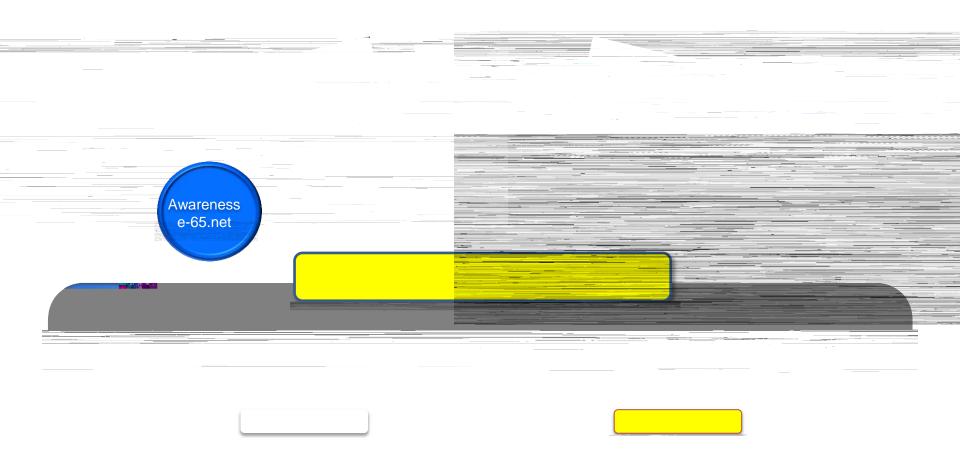
Long term activities to support patients with dementia and community networking with 527 communities in Japan Collaboration with local government (Agreement with 53 communities as of February 2016)

Development of multidisciplinary model cloud system



# Strategy for "Eisai Dementia Solutions" (Eisai)







# Strategy 2

Regional Medicine Focused Business Mix

We aim to demonstrate Outcomes more than treatment efficacy, toward Prevention,





### <Home care market>

### <Corporation of Regional Medical Collaboration>







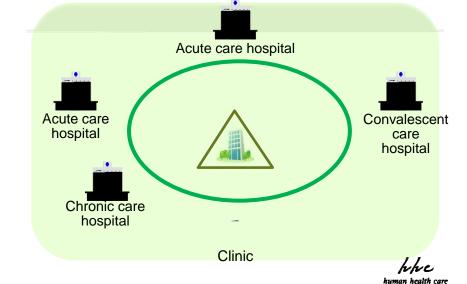
Local comprehensive care support center



Healthcare supporting pharmacy







# Establish Project Mix with Medical, Outcome and Access as the Core



### Medical

Explain the data with certain qualification

### Outcome

 Information on treatment outcome of pharmacotherapy and integrated product package more than treatment efficacy;

Prevention of tumble
Prevention of fracture
Shortening of length of
stay at nursing home
Improvement of labor
productivity
Prolongation of healthy
life expectancy
Prolongation of working
years
Improvement in the level
of care requirement
assessment
Improvement of QoL

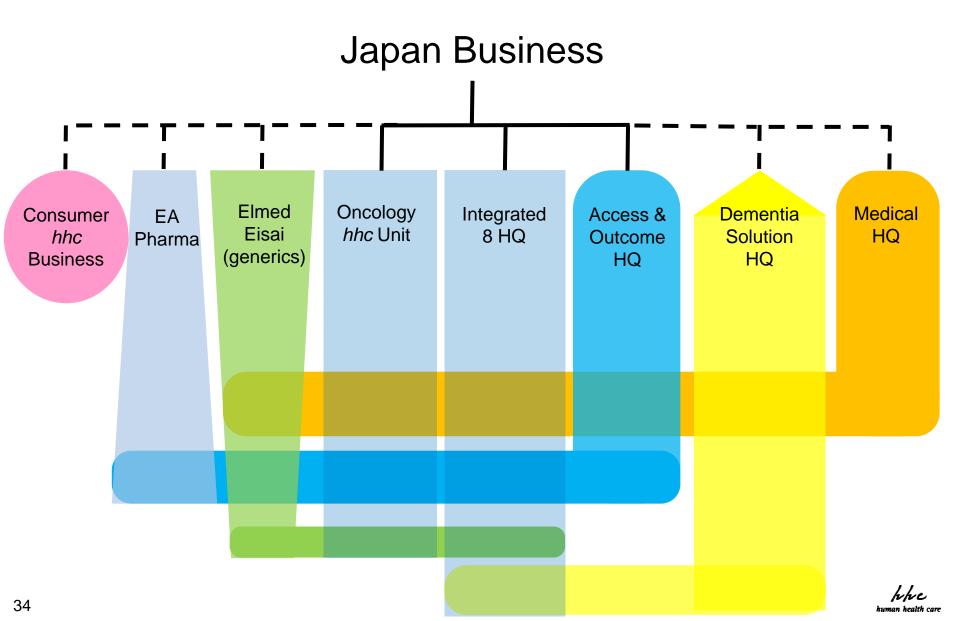
at home care and others

### Access



# Renewal of Japan Business







# Strategy 3 Integrated Product Package

Provide integrated product package aiming for maximization of Outcomes



#### Overview of Integrated Product Package



- "Ricchi" will be formed with the emergence of unconventional stakeholders in growing home care market and Corporation of Regional Medical Collaboration (establishment planned in FY2017 by MHLW), a major player for regional healthcare in the future.
- 2. We will provide integrated product package consist of Eisai, EA Pharma and Elmed Eisai products to "Ricchi". And will aim to increase access by creating information of Outcomes.

### Strategy for Creating Integrated Product Package of Eisai, EA Pharma and Elmed Eisai products





Evaluate the Outcomes including treatment efficacy and economical efficiency from integrated product package



#### Strategic Intent 3



Focus on a business domain where Eisai can find out "Ricchi" based on heeds and fulfill them with Eisai innovation





### Strategy 1

Transformation of Business Portfolio

We will find "Ricchi" and focus on business



# Milestone of Business Portfolio Transformation

- 2012 Pharmaceutical machinery business Eisai Machinery Co., Ltd. (Transferred to Bosch Group)
- 2013 Soil amelioration business Eisai Seikaken Co., Ltd. (Transferred to Lawson, Inc.)
- 2015 Diagnostic business
  EIDIA Co., Ltd.
  (Transferred to Sekisui Chemical Co., Ltd.)
- 2016 Food and chemical business
  Eisai Food & Chemical Co., Ltd.
  (Transferred to Mitsubishi-Kagaku Foods Corporation)

### EA Pharma Co., Ltd.







Objectives:

As the gastrointestinal disease area gains a more important position in home care market and community medicine, we will continuously operate pharmaceutical full-value chain of Discovery to Commercial

"Ricchi":

Lower digestive tract area, liver/bile/pancreas areas, constipation and nutrition area

Innovation:

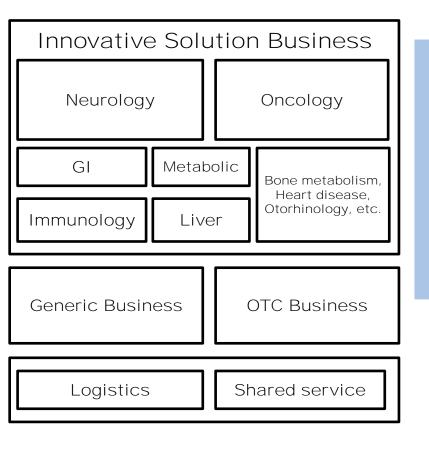
- Product creation based on proprietary AminoScience technologies
- New product pipeline
- Established opinion leader networks
- Eisai group's integrated product package

hhe human health care

#### Transformation of Business Portfolio (Eisa)



Plan "HAYABUSA"



Plan 'E-WAY 2025'

**Neurology Business Group** 

**Oncology Business Group** 

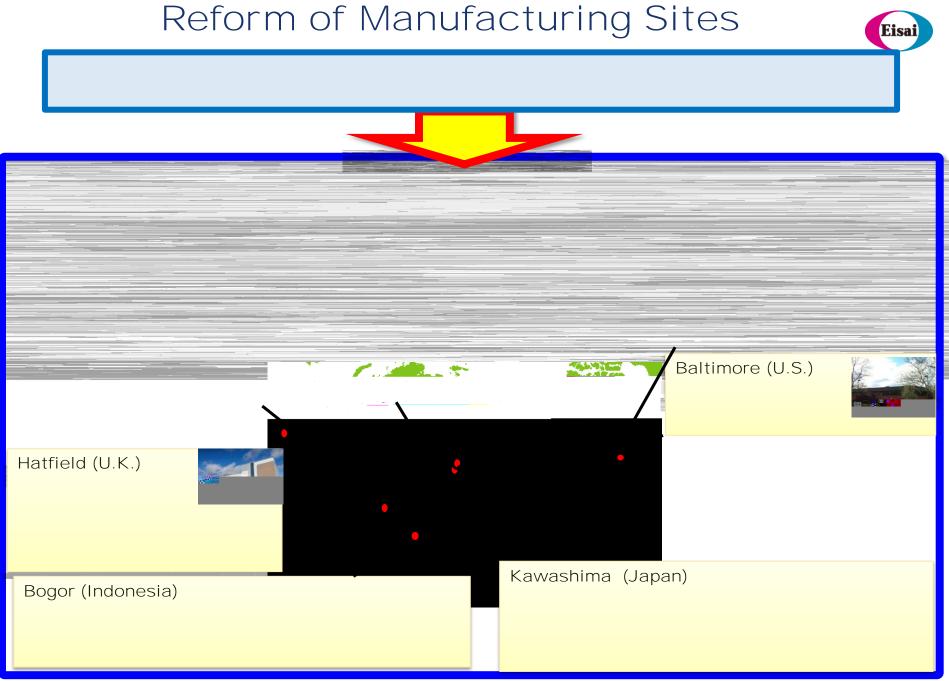
EA Pharma Co., Ltd.

Integrated Generic Business

Consumer *hhc* Business

hhc Solutions Group





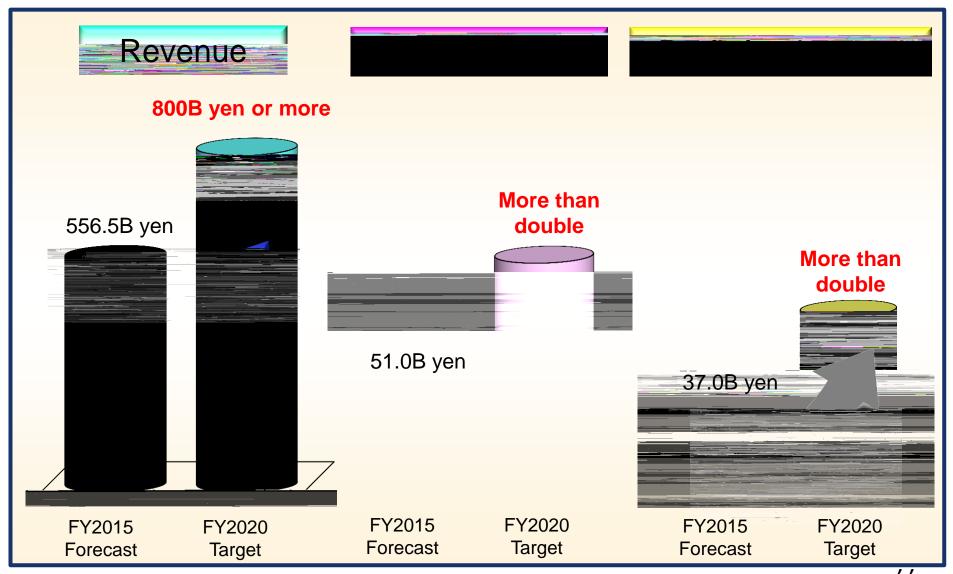
<sup>&</sup>quot;Demand Innovation Plus" is the symbol of aspiration aiming for maximizing value on products and solutions for patients.



## Financials

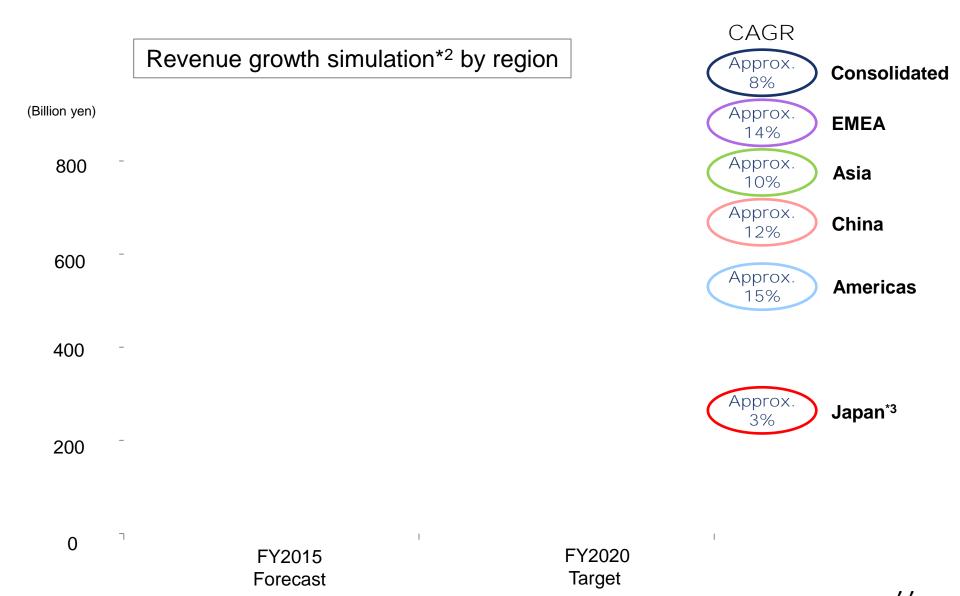
### Target toward FY2020 in Plan 'E-WAY 2025'





### Aim for Double-digit Growth of CAGR\*1 in Americas, China, Asia and EMEA





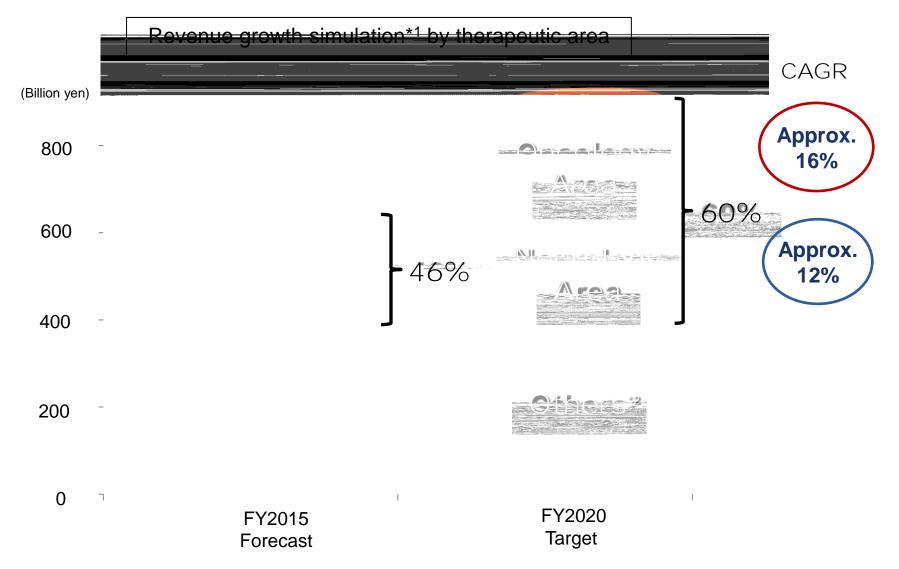
# Growth Simulation of Global Brands including Planned Value Expansion Projects

Revenue growth simulation\* of global brands

hhe

#### Progress of Therapeutic Area Focus

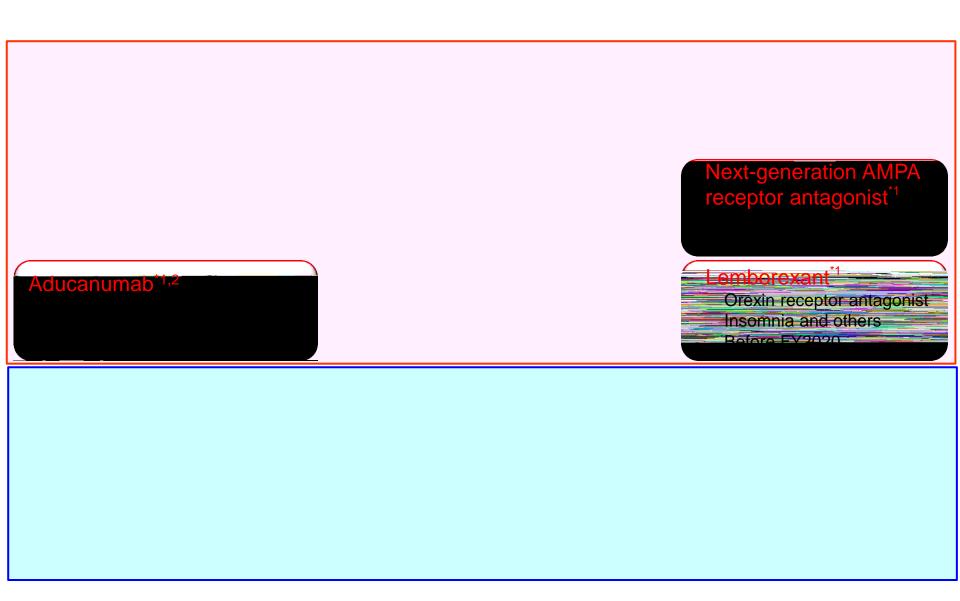






## Towards 2025









KPIs	Target for FY2020	
ROE	10% or more	
Equity Spread*1	2% or more	
DOE*2	8% leN27 1 035 0 0 1	2802 leo0