

Passion for Innovation.  
Compassion for Patients.™



# 5-Year Business Plan (FY2016 - FY2020)

DAIICHI SANKYO CO., LTD

Joji Nakayama  
President and CEO

March 31, 2016

# Forward-Looking Statements

- ◆ Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.
- ◆ Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.
- ◆ The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain.
- ◆ This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.
- ◆ This material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion.
- ◆ Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information.

- ◆ Review of the past
- ◆ External Environment
- ◆ 2025 Vision
- ◆ 5-Year Business Plan (5YBP)
  - Challenge 1: Grow beyond FY2017 LOE
  - Challenge 2: Establish Foundation of Sustainable Growth
  - Conclusion

# Review of the Past

**Our Mission** To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs

**Vision** To become a Global Pharma Innovator

## 1<sup>st</sup> MTP\* (2007-09)

**Maximization of synergy and expansion of growth foundation**

- Focus on thrombosis, cancer, diabetes, and other fields
- Maximize sales of Olmesartan franchise
- Acquired Ranbaxy into Group in 2008

## 2<sup>nd</sup> MTP (2010-12)

**Advancement of Global Hybrid Business Model**

- Focus on thrombosis, CV-M, and cancer fields
- Expand operating foundations in Japan
- Conduct frontline and backyard collaboration with Ranbaxy

## 3<sup>rd</sup> MTP (2013-15)

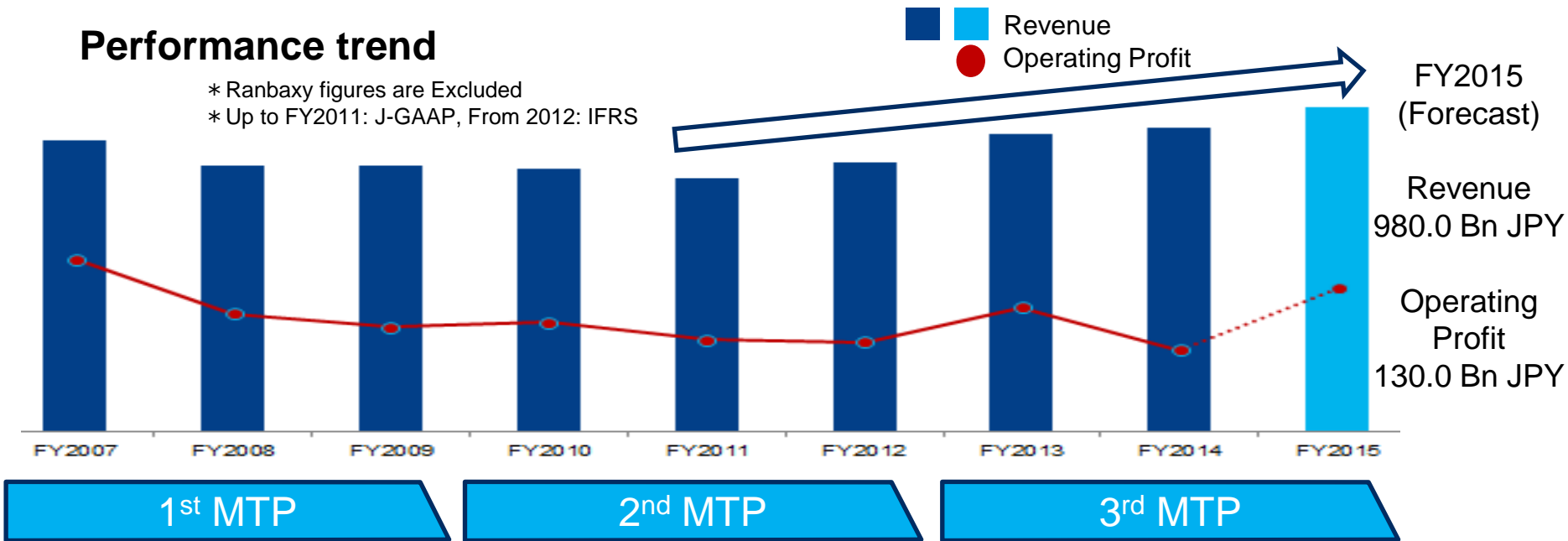
**Promotion of measures toward Sustainable Growth beyond LOE**

- Focus on thrombosis, CV-M, and cancer fields
- Divest and liquidate Ranbaxy over period from April 2014–April 2015
- Return to innovative business

# Review of the Past

## Performance trend

\* Ranbaxy figures are Excluded  
 \* Up to FY2011: J-GAAP, From 2012: IFRS



- ◆ Maximize OLM franchise
- ◆ Establish Thrombosis franchise
- ◆ Launch Oncology business
- ◆ Expand JP business
- ◆ Create global top class pipeline
- ◆ Establish industry best operational efficiency
- ◆ Realize global hybrid business

☆☆☆

☆☆

☆

☆☆☆

☆

☆☆

Change of Strategy

- ◆ Rising pressure for healthcare cost containment, emphasis on cost effectiveness, and influence of Payer
- ◆ Growing market for drugs prescribed at hospitals and by specialists (specialty area drugs such as those for cancer and other serious illnesses)
- ◆ Significant opportunities for innovative medicine changing standard of care (SOC)
- ◆ Intensified competition for acquiring promising products and pipeline
- ◆ Differences in market share of drugs by country and region due to differences in regulatory and insurance systems
  - **Japan**  
Stagnant market growth expected due to worsening national finances (80% target for generics, recalculation of market growth projections, etc.) while advancement of policy to encourage innovation (promotion of regenerative medicine and cell therapy advancement, new drug discovery incentives, etc.)
  - **US**  
Stable growth expected for world's No. 1 market, home to cutting-edge science born out of intense competition
  - **EU**  
Low-growth market presenting opportunities for pharmaceuticals that have been highly evaluated for cost effectiveness
  - **China**  
Continual growth as world's No. 2 market, but sense of uncertainty rising recently

## **Global Pharma Innovator with Competitive Advantage in Oncology**

- ◆ To have Specialty area\* business centered on Oncology business as the core business
- ◆ To have enriched regional value products\*\* aligned with regional market
- ◆ To have innovative products and pipeline changing SOC\*\*\*
- ◆ To realize shareholders' value through highly efficient management

\*Specialty area: Drugs mainly prescribed at Hospital and/or by Specialty practitioners

\*\*regional value products: Products aligned with regional market

\*\*\*SOC: Standard of Care

## 2025 Vision

### 2016-2020 5-Year Business Plan

Transformation  
toward 2025 Vision

Until 2015

- CVM area
- PCP focus
- Global products
- In-house
- Sales volume

- Oncology area
- Specialty area
- Regional value
- Alliance
- Sustainable profit growth



A decorative graphic consisting of numerous thin, parallel yellow lines that curve and flow across the page, creating a sense of movement and energy. The lines are more densely packed in some areas, creating a gradient of yellow intensity.

**5-Year Business Plan**

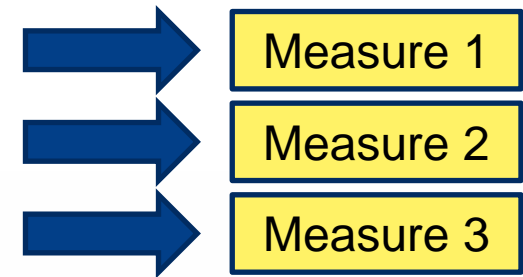
(FY2016 - FY2020)

# **DS Transformation** **— A Bridge to Tomorrow**

- ◆ Challenge 1: Grow beyond FY2017 LOE
  - Measures of Revenue Recovery
  - Measures of Profit Generation
- ◆ Challenge 2: Establish Foundation of Sustainable Growth
  - FY2020 Targets and Business Strategy
  - Investment for Future Growth and Shareholder Returns
  - CSR and Corporate Governance
- ◆ Conclusion

## ◆ Challenge 1: Grow beyond FY2017 LOE

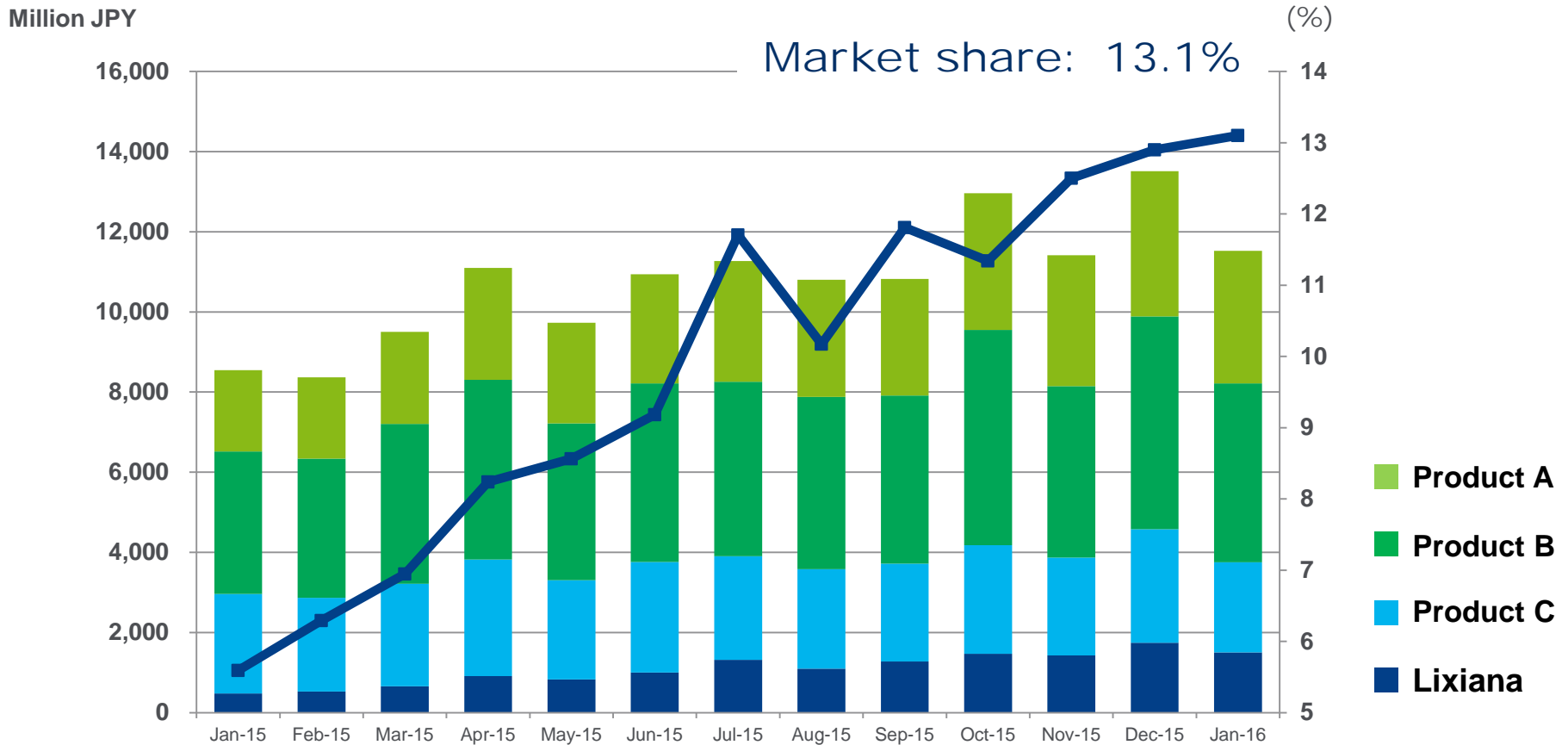
- Measures of revenue recovery
  - ✓ Growth of Edoxaban
  - ✓ Growth of Japan Business
  - ✓ Growth of Luitpold Business
- Measures of profit generation



# Measure 1: Growth of Edoxaban

# Steady Growth of Market Share in Japan

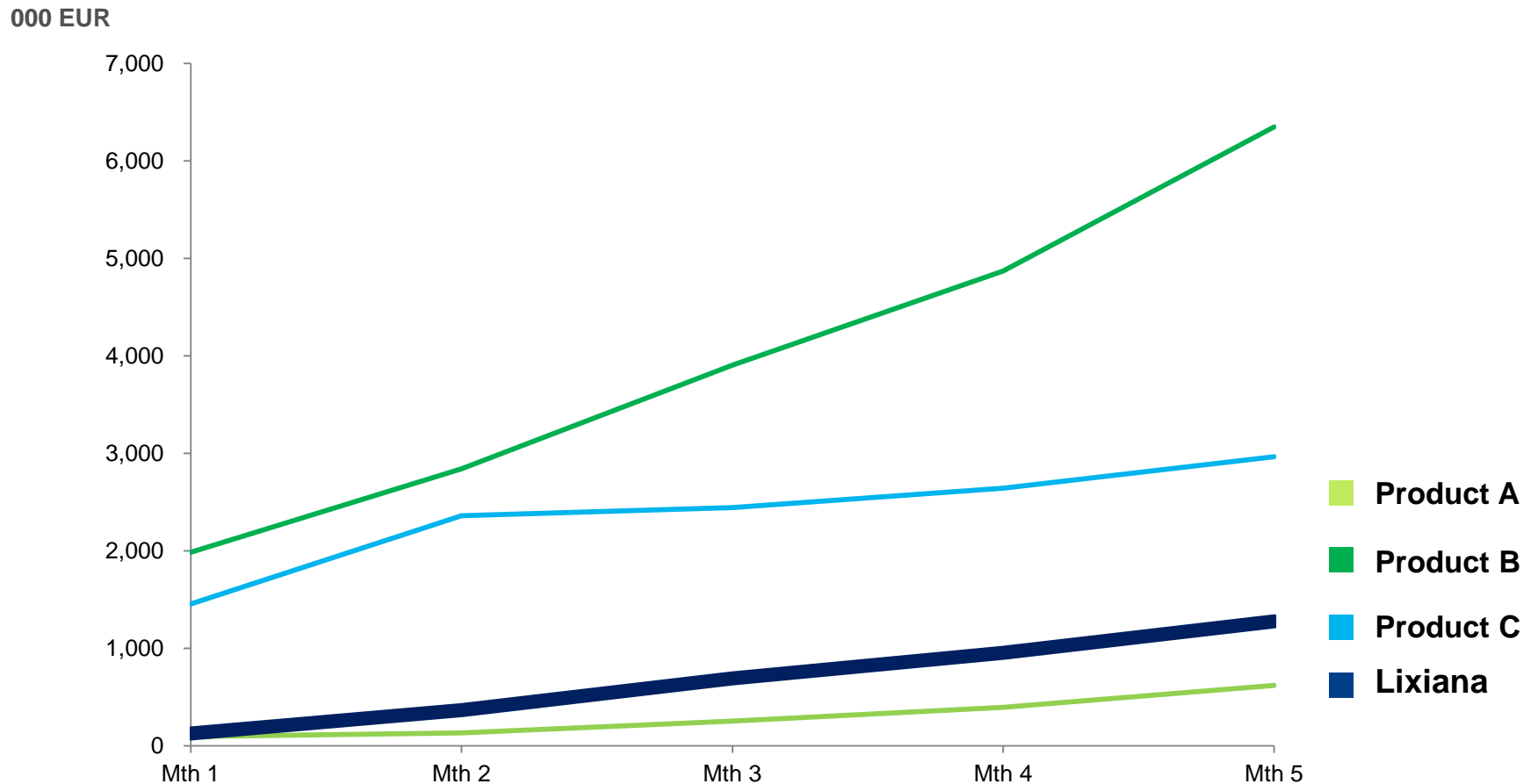
Market share grew by 7.5 points in one year and reached 13.1%



Japan: Monthly IMS sales of DOAC\* products and monthly share of Lixiana

# Smooth Launch in Germany

Start is better than that of Product A which is now at the No.2 position in Germany



Germany: Monthly IMS sales for 5 months from launch in SPAF

# Accelerate Growth in Japan and Europe



## Appeal unique product profile

### ◆ Product profile

- The only once-daily DOAC that offers superiority to warfarin with less major bleeding in non-valvular atrial fibrillation and with less clinically relevant bleeding in DVT/PE
- Dosing optimization per patients' condition
- Evidence backed by the largest single comparative studies in NVAf and VTE with very high quality

## Strategies in Japan and Europe

### ◆ Japan

- The only domestically manufactured DOAC with 3 indications
- Sales capabilities with high quality

### ◆ Europe

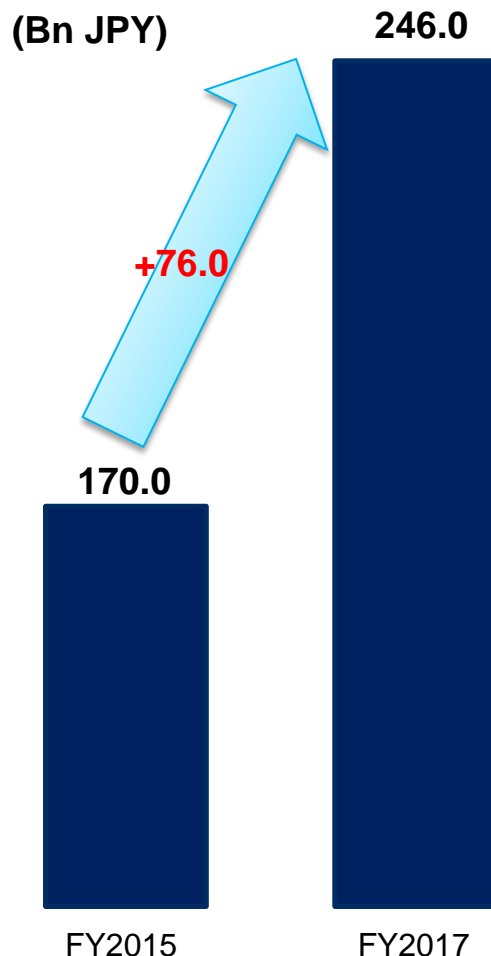
- Steady launch in major countries
- Further promote access models in line with market needs in each country

## **Measure 2: Growth of Japan Business**



# Grow Major Products in Japan

Quickly maximize major product sales by leveraging high quality sales capabilities



## Product strategies

- ◆ **Nexium (anti-ulcer :Proton Pump Inhibitor)**  
Maintain No. 1 share by establishing position as “first choice” drug for GERD\* treatment
- ◆ **Memary (treatment for Alzheimer’s Disease)**  
Standardize combination therapy with ChE\*\* inhibitor for the treatment of moderate-to-severe AD\*\*\* by provision of clinical evidence
- ◆ **Pralia (treatment for osteoporosis)**  
Accelerate market penetration by promoting high evaluation received by guidelines
- ◆ **Ranmark (treatment for bone metastasis )**  
Maintain position as standard of care for treating bone metastasis of cancer
- ◆ **Efient (antiplatelet)**  
Acquire dominating No. 1 share in heart area by promoting dosage ideal for Japanese
- ◆ **Teneria (treatment for type 2 diabetes)**  
Appeal efficacy and ease of use for elderly people and patients with renal impairment to aim for first-line treatment for diabetes

\*GERD: Gastrosophageal Reflux Disease

\*\*ChE: Cholinesterase

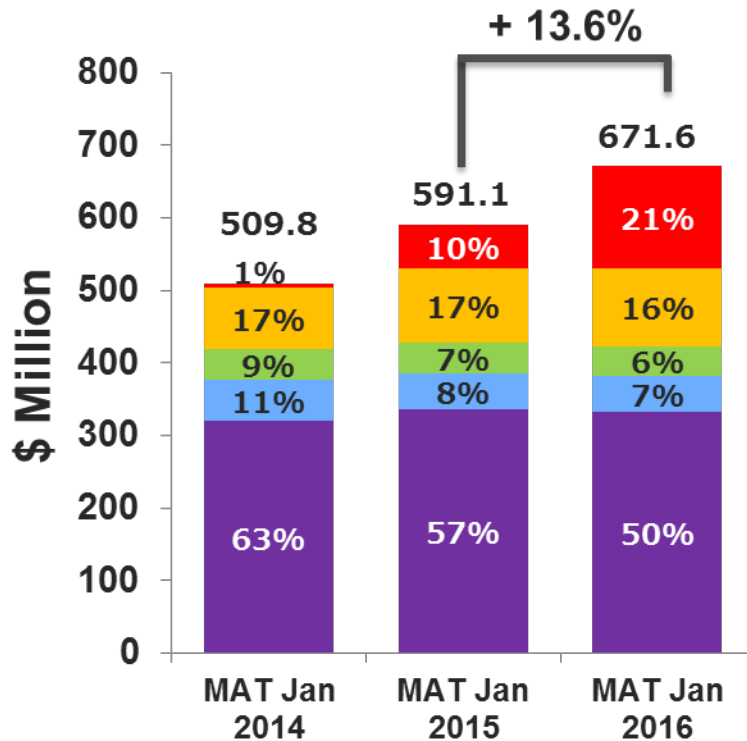
\*\*\*AD: Alzheimer’s disease

## **Measure 3: Growth of Luitpold Business**

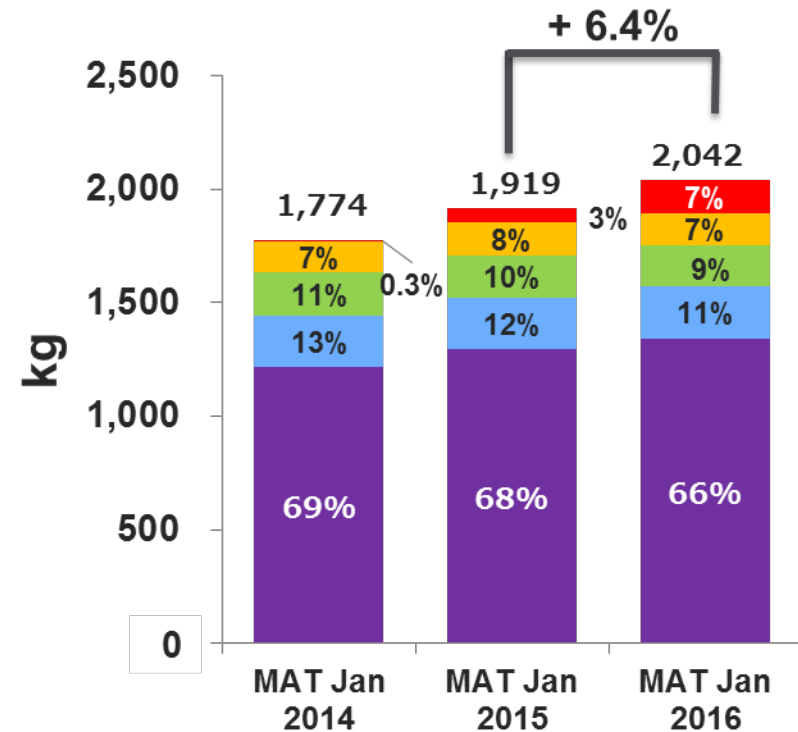
# Growing US IV Iron Market

**Injectafer drives the IV Iron Market growth of 13.6% in \$ and 6.4% in gram volume**

**IV Iron \$ sales (includes dialysis)**



**IV Iron kg sales (includes dialysis)**

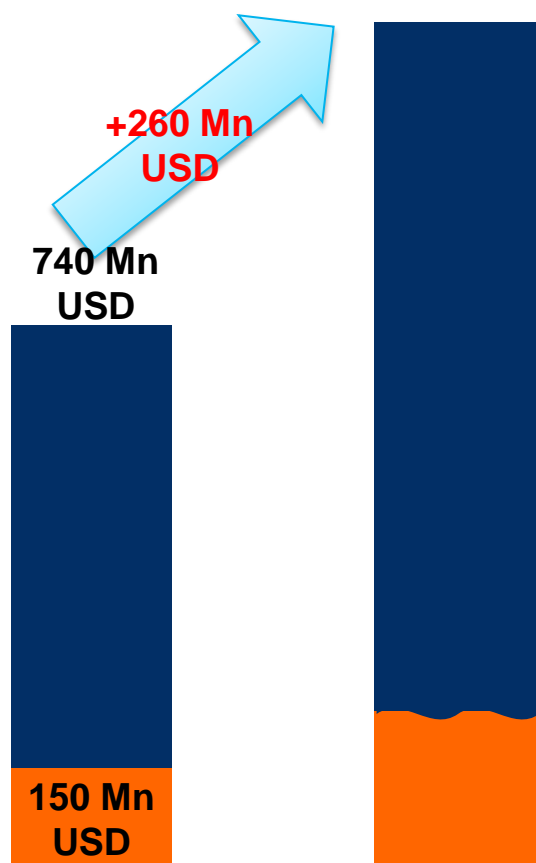


■ Venofer ■ SFG ■ Iron Dextran ■ Feraheme ■ Injectafer

Source: IMS National Sales Perspectives Jan 2016 (includes all US IV Iron sales in all channels including dialysis chains).

# Accelerated Growth of Injectafer and Generic Injectable

Become **1 Bn USD** company  
in FY2017



FY2015

FY2017

 Injectafer

## IRON FRANCHISE

- ◆ **Market: 665 Mn USD in sales (2015) with consistent growth trends (>10%)**
- ◆ **Accelerate Injectafer Growth (CAGR 20-30%)**
  - Differentiate from other i.v. irons
  - Expand Sales team coverage to Gastro, Oncologist, Nephrologist
  - Become Market share leader in non-dialysis segment
  - Raise awareness of IDA among physicians & patients
  - Roll out new patient centric campaign

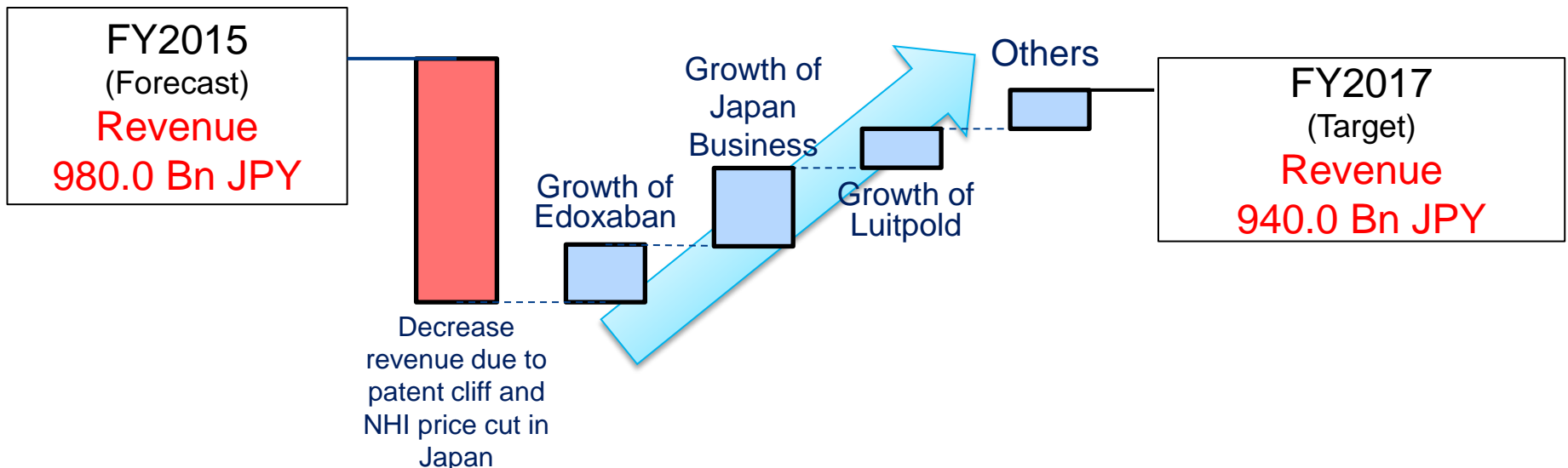
## GENERIC INJECTABLE FRANCHISE

- ◆ **Market: 22.8 Bn USD in sales (2015) with consistent growth trends**
- ◆ **Maximize / expand existing portfolio**
  - Reintroduce historical products\*
  - Expedite Commercial Launches
  - Respond to rapid market change

\*Historical products: Luitpold manufactured and sold in the past

## ◆ Accelerate growth of main products

- Growth of Edoxaban
- Growth of Japan Business
- Growth of Luitpold Business



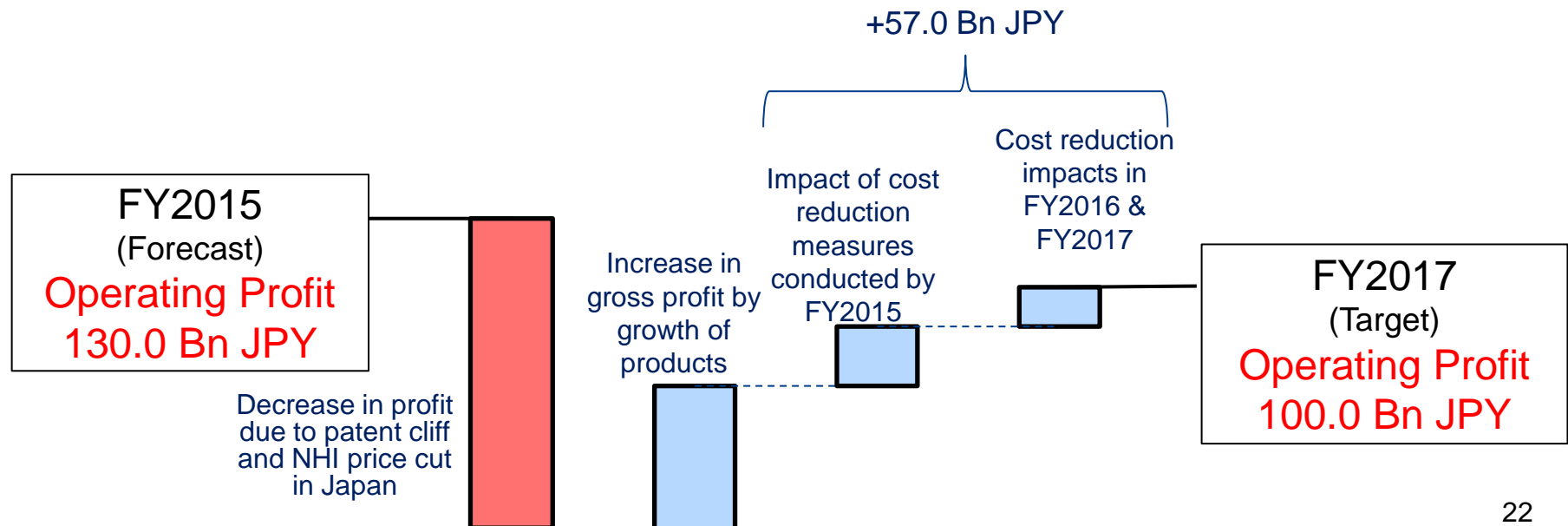
## Major measures conducted by FY2015

- ◆ Restructuring in Europe (FY2014)
- ◆ Restructuring in Japan (FY2014)
- ◆ Sale of Akita plant (FY2014)
- ◆ Restructuring in US (FY2015)
- ◆ Restructuring in R&D (FY2015)



**The impact of above measures will be realized as cost reduction effect during 5YBP**

- ◆ **Impact of cost reduction measures conducted by FY2015**
- ◆ **Cost reduction impacts in FY2016 & FY2017**
  - Realization of Process Excellence
    - ✓ Further cost reductions and streamlining
    - ✓ Optimization of manufacturing systems globally
    - ✓ Further enhancement of procurement



- ◆ Challenge 1: Grow beyond FY2017 LOE
  - Measures of Revenue Recovery
  - Measures of Profit Generation
- ◆ **Challenge 2: Establish Foundation of Sustainable Growth**
  - **FY2020 Targets and Business Strategy**
  - Investment for Future Growth and Shareholder Returns
  - CSR and Corporate Governance
- ◆ Conclusion



# FY2020 Targets

	<b>FY2015 (Forecast)</b>	<b>FY2017 (Target)</b>	<b>FY2020 (Target)</b>
<b>Revenue (Bn JPY)</b>	<b>980.0</b>	<b>940.0</b>	<b>1,100.0</b>
<b>Operating Profit (Bn JPY)</b>	<b>130.0</b>	<b>100.0</b>	<b>165.0</b>

## ◆ Increase value of late-stage pipeline

3 - 5 products launched within the next 5 years with peak-sales of more than 100.0 Bn JPY each

## <Global Products>

- ◆ **Strategy 1** : Grow Edoxaban
- ◆ **Strategy 2** : Establish Oncology Business

## <Regional Value Products>

- ◆ **Strategy 3** : <JP> Grow as No.1 company in Japan
- ◆ **Strategy 4** : <US> Expand US Businesses

## <Value for Pipeline>

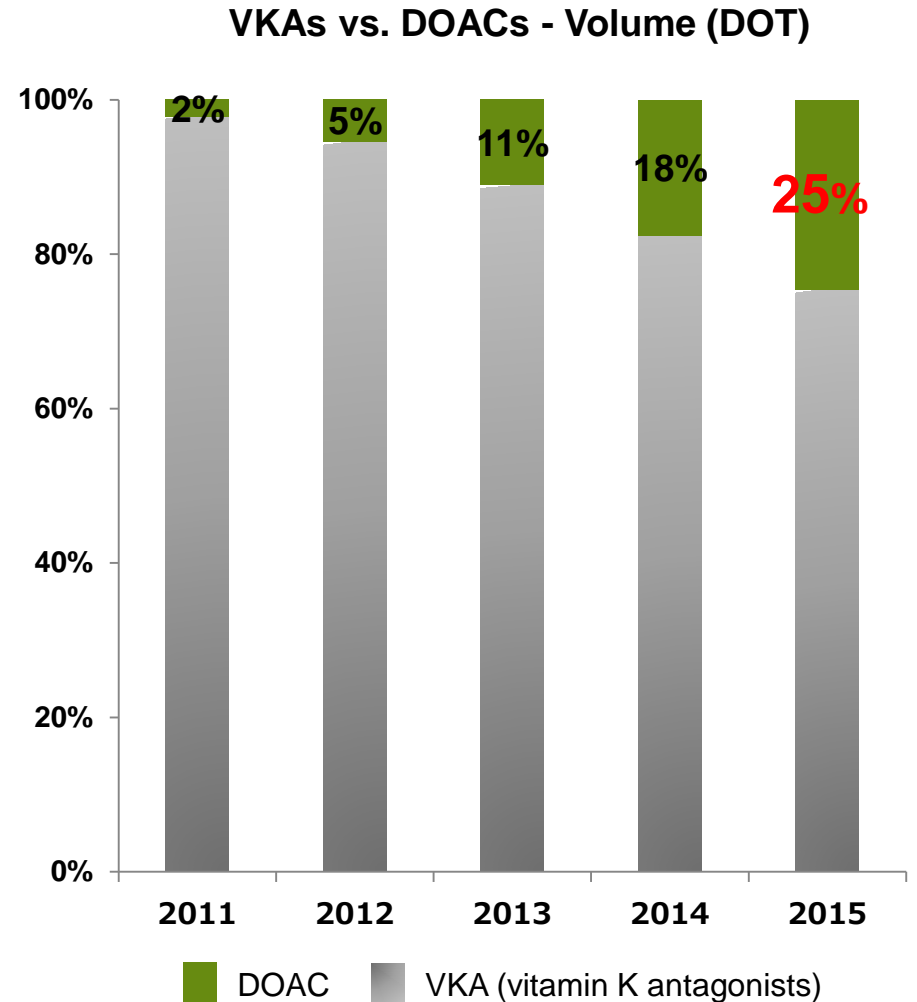
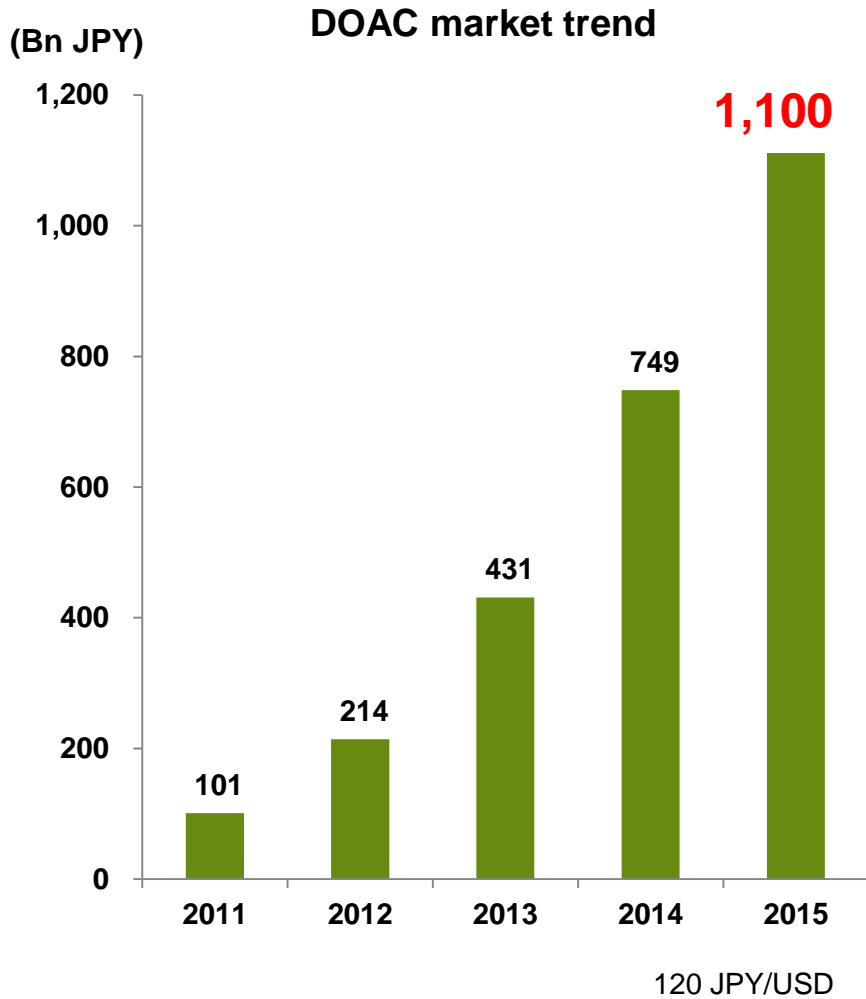
- ◆ **Strategy 5** : Continuously Generate Innovative Medicine  
Changing SOC

## <Highly Efficient Management>

- ◆ **Strategy 6** : Enhance Profit Generation

Global Products  
**Strategy 1**  
**Grow Edoxaban**

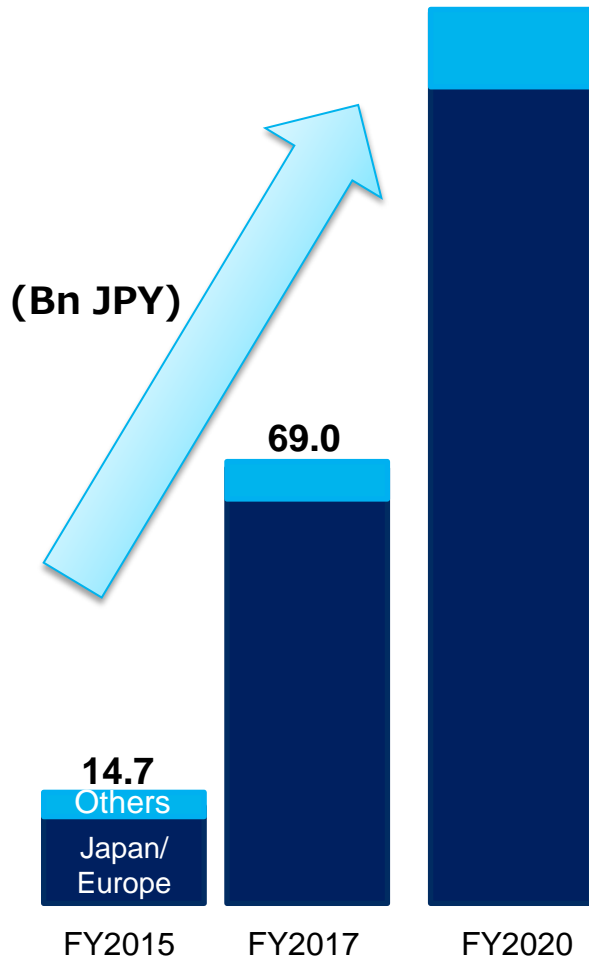
# Growth of Global DOAC\* Market



\*DOAC : Direct Oral Anticoagulant Same meaning as NOAC (novel oral anticoagulant)

# Expand as Growth Driver for Mid to Long Term

**Over 120.0 Bn JPY**  
**(1 Bn USD)** in FY2020



## Global strategies

- ◆ Execute launch strategy
- ◆ Appeal product profile continuously
- ◆ Generate new evidence to strengthen product
  - Ensure-AF, Hokusai-VTE Cancer etc.
  - ENTA Registries

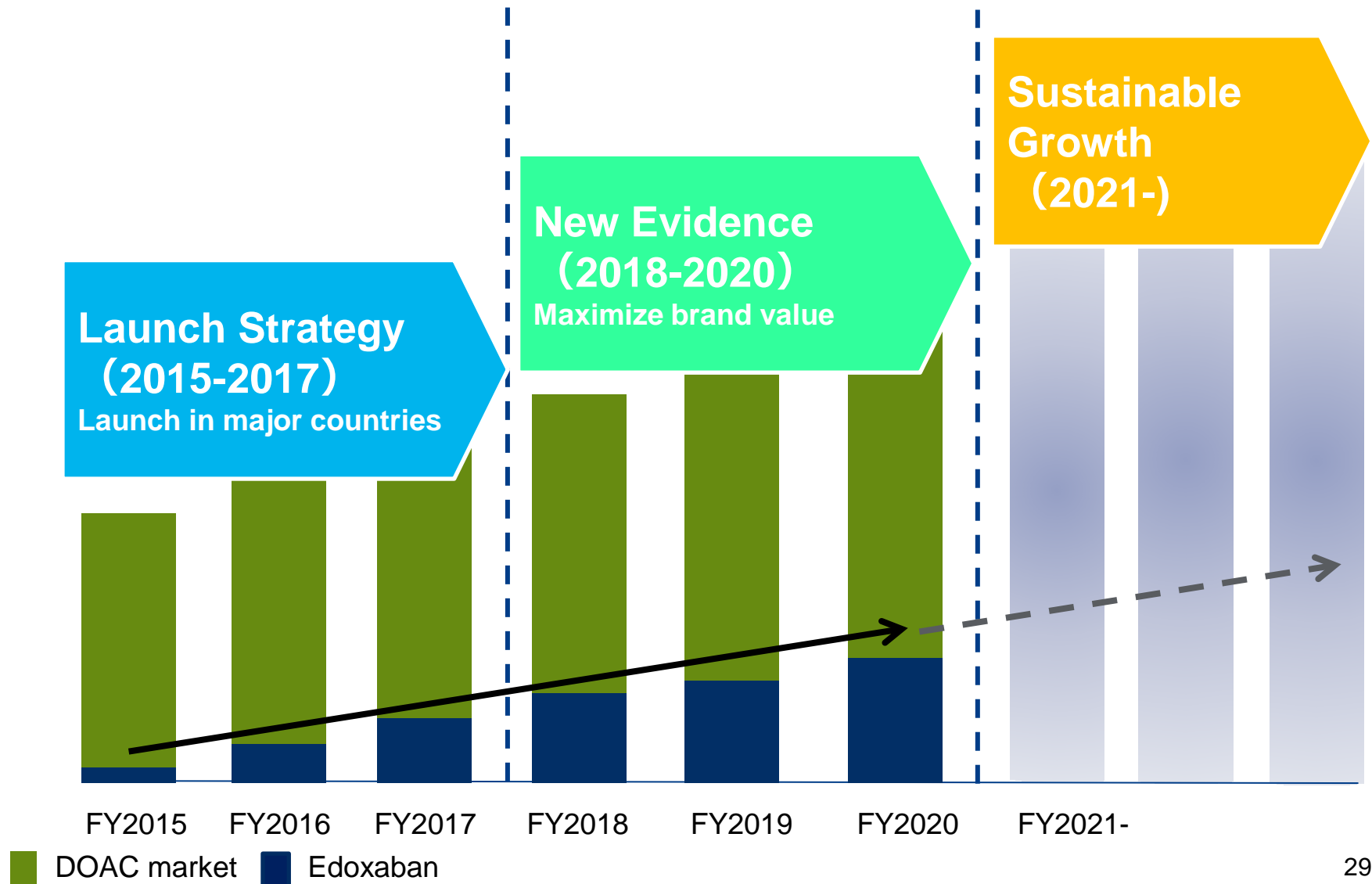
## Regional strategies

- ◆ **Japan**
  - Utilize product profile and fine-tuned sales capabilities with high quality
  - Nurture into Japan's No. 1 DOAC
- ◆ **Europe**
  - Conduct promotion across Europe through collaboration with MSD\*
- ◆ **US**
  - Acquire prescriptions through specifically targeted promotions
  - Improve market access
- ◆ **ASCA and other regions**
  - Realize early approval and launch in all countries of operation
  - Conduct promotion through collaboration with best partners

\*MSD: Merck Sharp and Dohme Europe Subsidiary of Merck & Co., Inc.

# Brand Strategy for \$1 Billion Product

Grow sales with the expanding DOAC market (image)



Global Products

**Strategy 2**

**Establish Oncology Business**

# Establish Oncology Business

Revenue

FY2020: over **40.0 Bn JPY**

FY2025: approx. **300.0 Bn JPY**

- ◆ Establish oncology business by launching current late-stage pipeline
- ◆ Steadily drive development of early-stage pipeline
- ◆ Enrich pipeline by acquisition of external assets
- ◆ Accelerate oncology R&D by new R&D organization



# Oncology Business Expansion

Contribution to Revenue

Approx. 300.0 Bn JPY

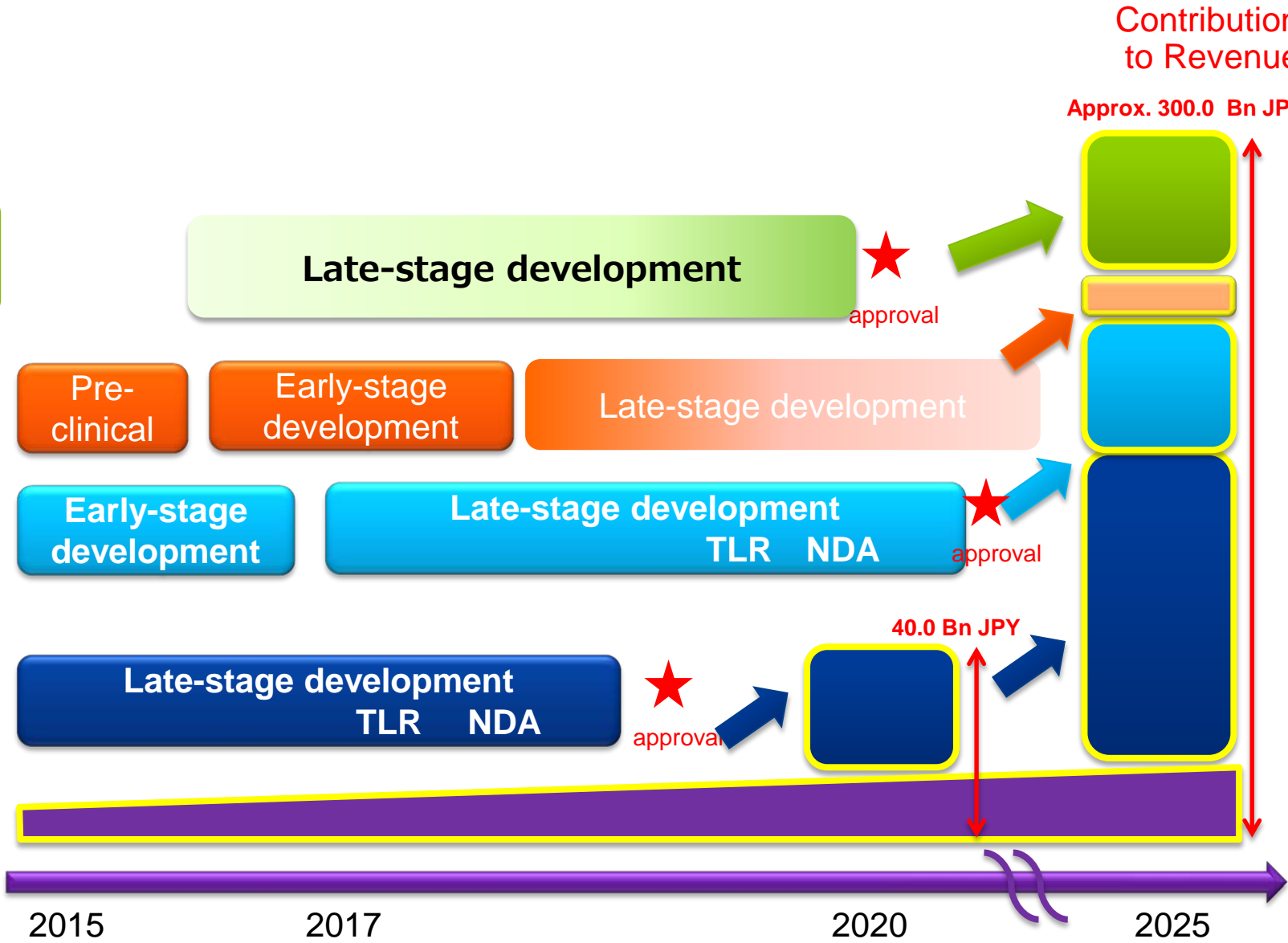
New in-license

Innovative technology etc.

- DS-8201
- DS-3201
- DS-3032
- DS-6051

- quizartinib
- tivantinib
- pexidartinib
- patritumab

- vemurafenib
- denosumab



(Image)

# Establish Oncology Business by Launching Current Late-stage Pipeline

## ◆ Contribute to 40.0 Bn JPY in Revenue with 4 products in FY2020

TLR : anticipated Top Line Result

**Quizartinib**  
~100.0 Bn JPY  
expectation

Acute myeloid  
leukemia (AML)  
2<sup>nd</sup> line (P3)  
(TLR:1H CY2017)

- Orphan Drug Designation by the FDA and EMA
- Fast Track Status by the FDA
- Anticipating effectiveness to patients with FLT3-ITD patients to whom midostaurin doesn't show efficacy
- First-line study in preparation

**Tivantinib**  
~30.0 Bn JPY  
expectation

Hepatocellular  
carcinoma  
(HCC)(P3)  
(TLR:1H CY2017)

- Orphan Drug Designation by the FDA and EMA
- Refractory HCC
- Anticipating high effectiveness by stratification of patients

**Pexidartinib**  
~100.0 Bn JPY  
expectation  
including LCM

Tenosynovial giant  
cell tumor  
(TGCT)(P3)  
(TLR:1H CY2018)  
-----  
Solid tumor(P1/2a)  
(TLR:2H CY2019)

- Orphan Drug Designation by the FDA and EMA
- Breakthrough Therapy designation by FDA
- -----  
• Combination therapy with Merck's anti-PD-1 antibody

**Patritumab**  
~50.0 Bn JPY  
expectation

Non-small cell lung  
cancer  
(NSCLC)(P2/3)  
(TLR:2H CY2018)  
-----  
Head and Neck  
cancer (P2)

- Anticipating high effectiveness in specific group of patients selected by biomarker
- -----
- Have obtained good results in P1b study
- Data to be published at ECHNO in April 2016

# Steadily Drive Development of Early-stage Pipeline

## ◆ Contribute to 300.0 Bn JPY in Revenue in FY2025

<p><b>DS-8201 (HER2-ADC)</b></p>	<p><b>Solid tumor (P1)</b></p>	<ul style="list-style-type: none"> <li>• Anticipating effectiveness to patients resistant to treatment by Herceptin or Kadcyla</li> <li>• Applied DS proprietary ADC* technology</li> <li>• Target: obtaining of phase 1 results in <b>FY2017</b> *:Antibody Drug Conjugate</li> </ul>
<p><b>DS-3201 (EZH1/2 )</b></p>	<p><b>Non-Hodgkin's lymphoma (incl. adult T-cell leukemia) (P1)</b></p>	<ul style="list-style-type: none"> <li>• Targeted epigenetics**</li> <li>• Expecting permanent cure of hematological cancer by eradication of “cancer stem cell”</li> <li>• FIC as an EZH 1 /2 dual inhibitor</li> <li>• Anticipating More potent as compared to EZH2 inhibitor</li> <li>• Target: completion of phase 1 study in <b>FY2018</b> **:chemical modification of DNA or histone leading to acquired change in gene expression without modification of DNA sequence</li> </ul>
<p><b>DS-3032 (MDM2)</b></p>	<p><b>Solid tumor Hematologic tumor(P1)</b></p>	<ul style="list-style-type: none"> <li>• Anticipating high effectiveness to cancer with MDM2 gene amplification/Wt p53</li> <li>• FIC</li> <li>• Based on the phase 1 study in the US suggesting effectiveness in patients with liposarcoma (LPS), LPS is selected as a potential indication for further development, which is under consideration.</li> </ul>
<p><b>DS-6051 (NTRK/ROS1)</b></p>	<p><b>Solid Tumor (Lung cancer)</b></p>	<ul style="list-style-type: none"> <li>• ROS1 fusion is one of the major diver mutations observed in lung cancer etc.</li> <li>• Phase 1 study is planned to complete in <b>FY2017</b> (US/JP)</li> <li>• Partial response is observed in a patient in US P1 study. Interim analysis of efficacy and safety to be presented at AACR in <b>April 2016</b>.</li> <li>• Utilizing SCRUM-Japan*** for patient selection in Japan</li> </ul>

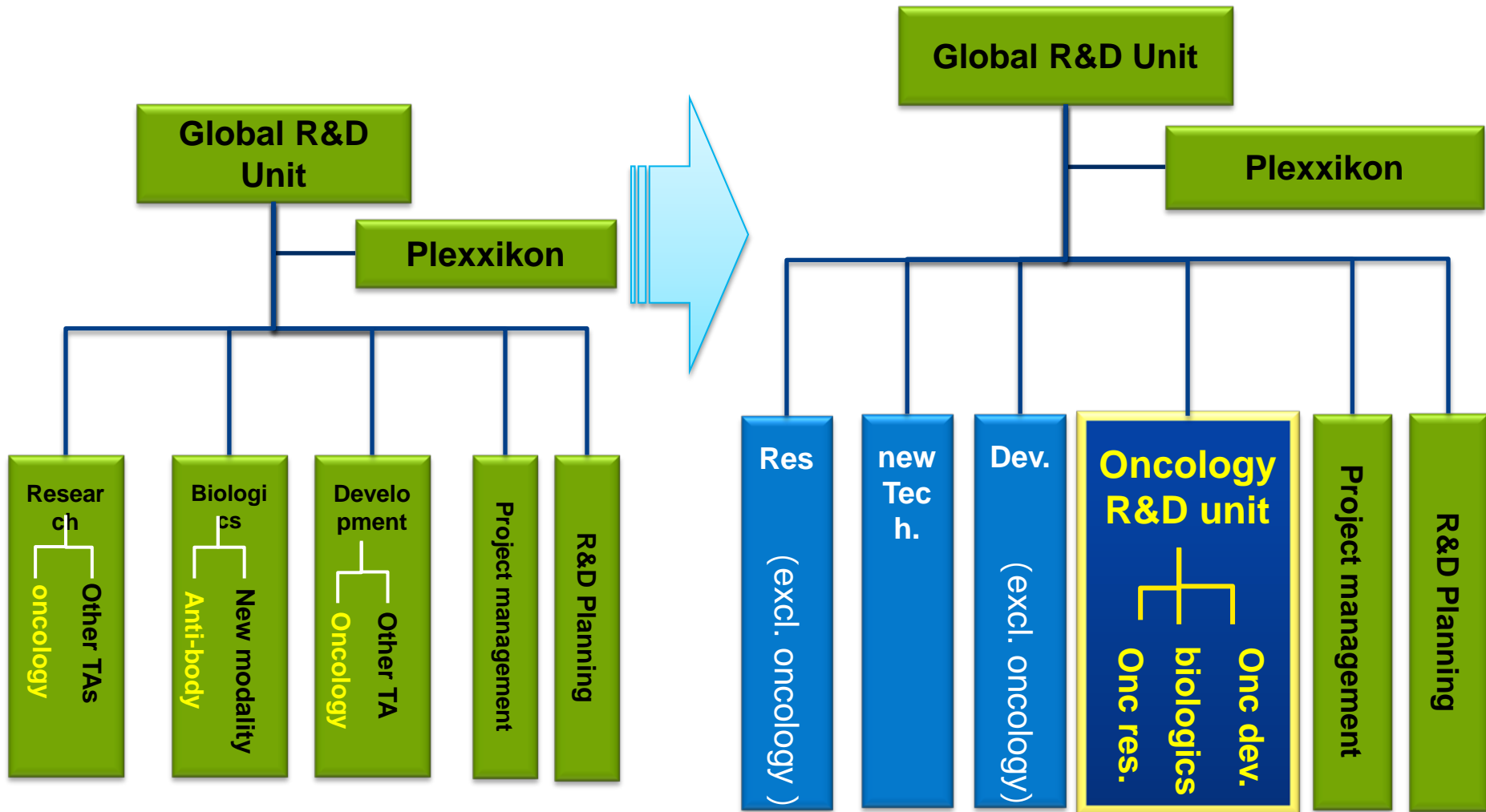
\*\*\*SCRUM-Japan: National project led by National Cancer Center Japan to screen oncogenic abnormality of cancer patients in order to provide the best-fit medicines to them

- ◆ **Enhanced portfolio through M&A**  
U3 pharma (patritumab, U3-1784 etc.)  
Plexxikon (Zelboraf, pexidartinib etc.)  
Ambit (quizartinib etc.)
- ◆ **Alliance: collaboration in R&D or sales**  
ArQule (tivantinib)



- ◆ **Accelerate alliance opportunities or product acquisition**
- ◆ **Prioritize oncology as an investment target for business development**

## <Global Structure>



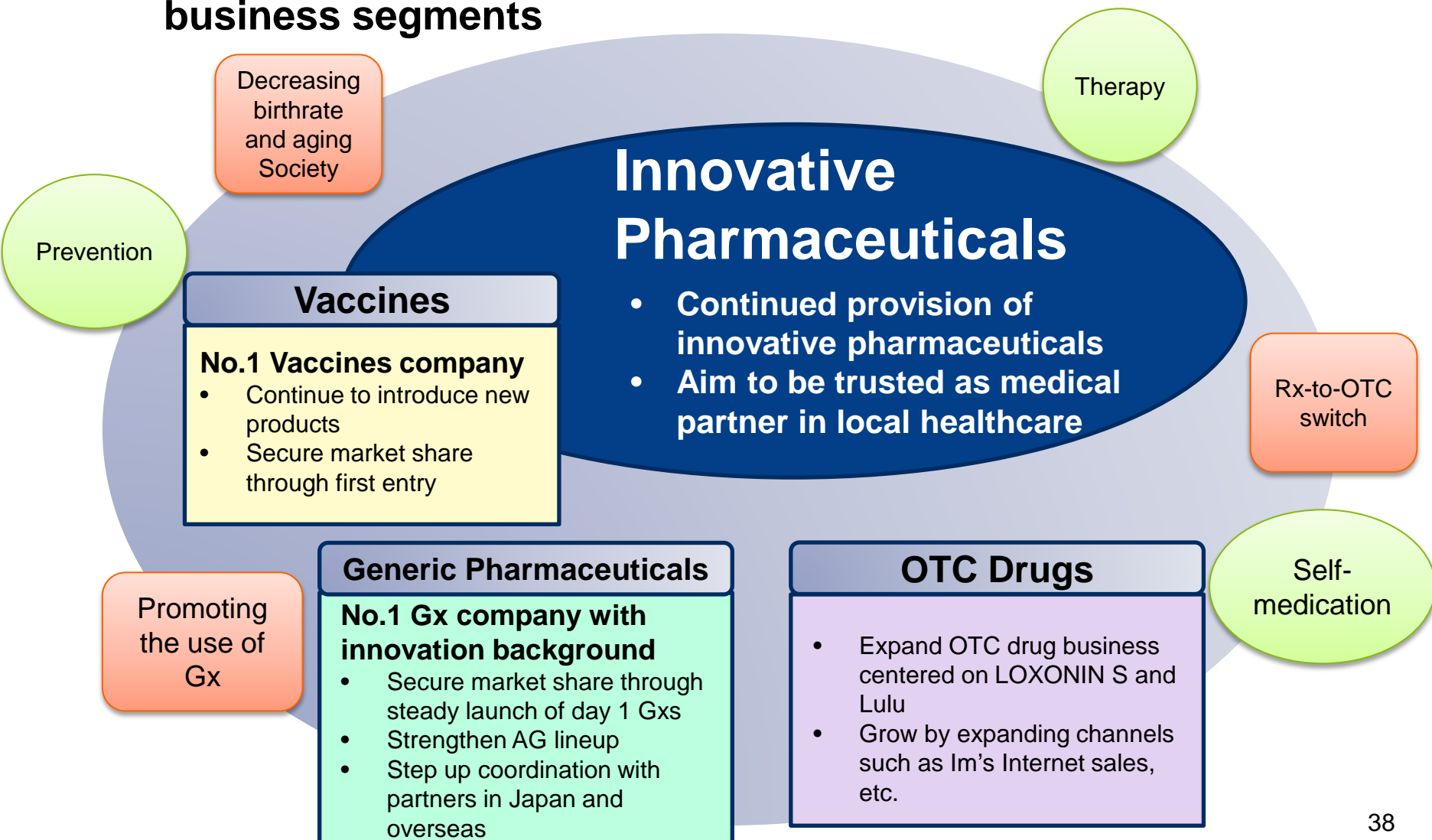
Regional Value Products

**Strategy 3**

**Grow as No.1 company in Japan**

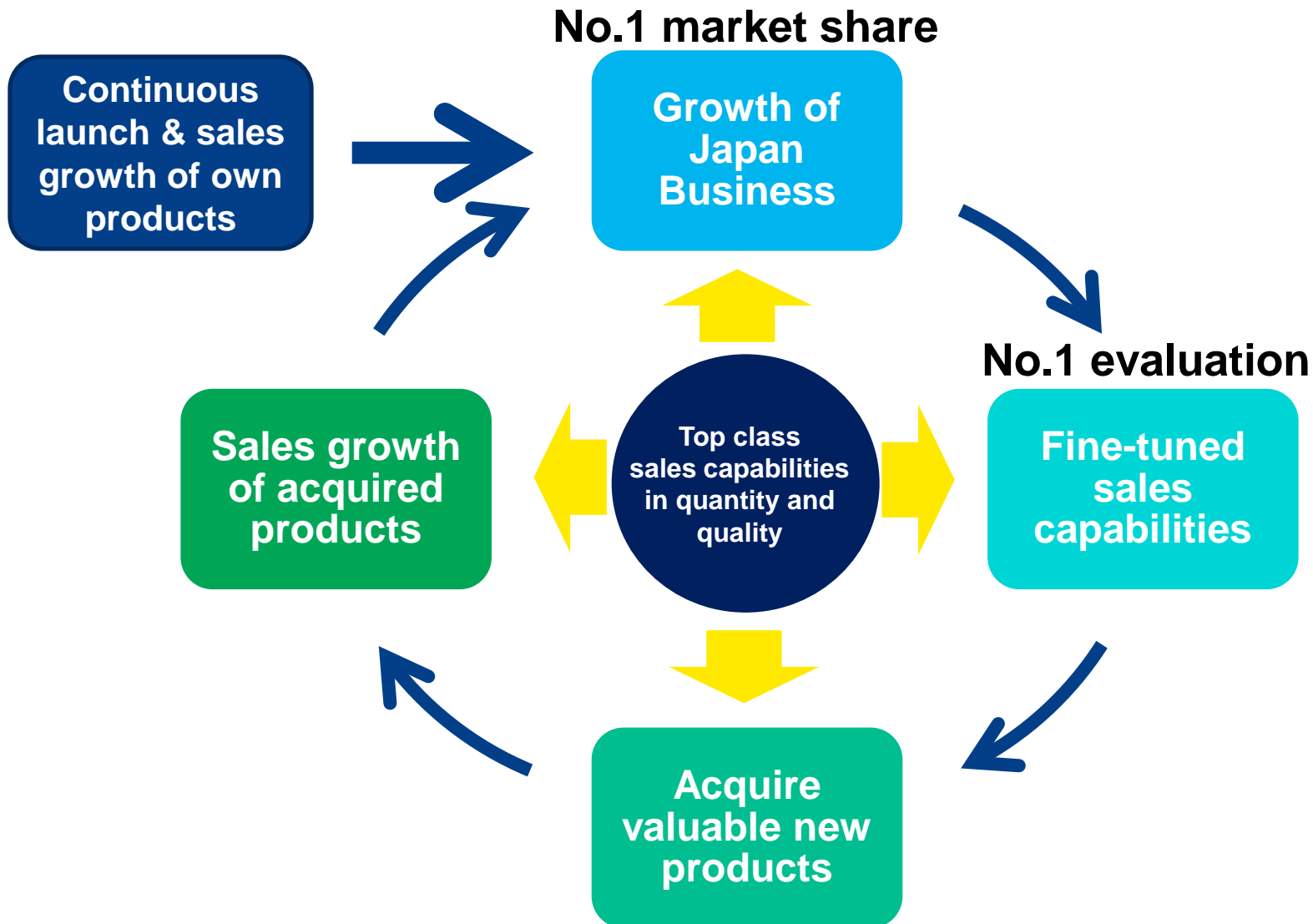
# Comprehensive Contribution to Medical Needs in Japan with 4 Business Segments

## Tailoring various medical/health needs in Japan with 4 business segments



# Process for Sustainable Growth

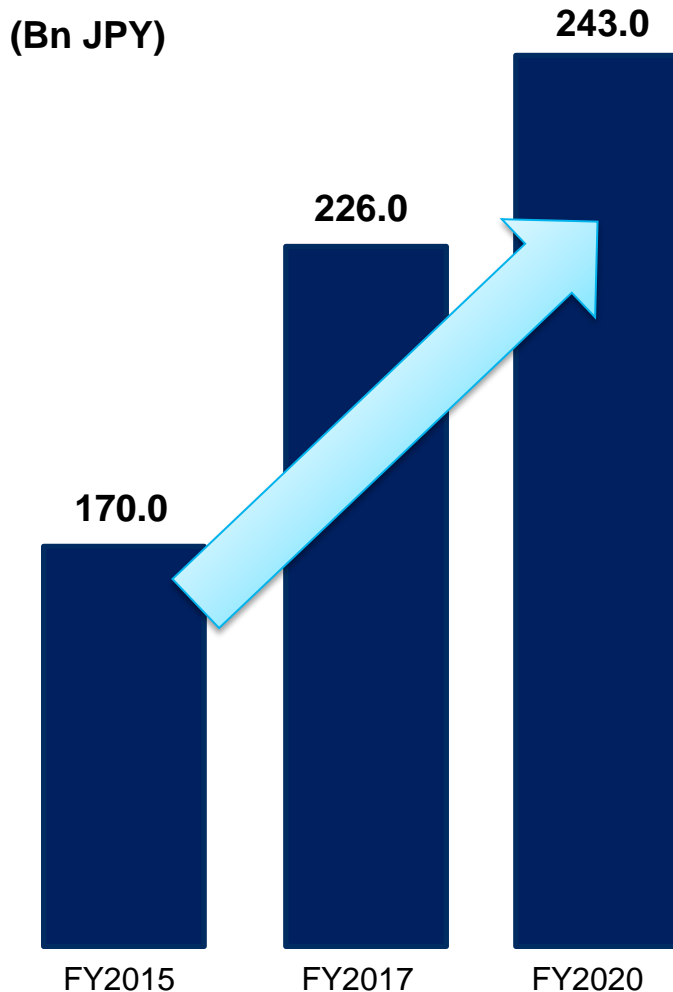
Realize sustainable growth by leveraging No.1 sales capabilities of leading company in Japan





# Grow Major Products in Japan

## Maintain growth by existing products and additional indications



### Product strategies

- ◆ **Nexium (anti-ulcer :Proton Pump Inhibitor)**  
Maintain No. 1 share by establishing position as “first choice” drug for GERD\* treatment
- ◆ **Memary (treatment for Alzheimer’s Disease)**  
Standardize combination therapy with ChE\*\* inhibitor for the treatment of moderate-to-severe AD\*\*\* by provision of clinical evidence
- ◆ **Pralia (treatment for osteoporosis)**  
Expand market penetration by promoting high evaluation received by guideline  
**Further growth by additional indication of rheumatoid arthritis**
- ◆ **Ranmark (treatment for bone metastasis )**  
Maintain position as standard of care for treating bone metastasis of cancer  
**Further growth by additional indication of breast cancer**
- ◆ **Efient (antiplatelet)**  
Maintain dominating No. 1 share in heart area by promoting dosage ideal for Japanese  
**Lead next generation of antiplatelet treatment in Japan by additional indication of brain area**
- ◆ **Teneria (treatment for type 2 diabetes)**  
Appeal efficacy and ease of use for elderly people and patients with renal impairment to aim for first-line treatment for diabetes and expand market share  
**Red : additional indication (Planned)**

\*GERD: Gastroesophageal Reflux Disease

\*\*ChE: Cholinesterase

\*\*\*AD: Alzheimer’s disease

## Seamless launch of new products and additional indications

### New product

- Lacosamide (Epilepsy)
- VN-100 (Seasonal flu vaccine)

### New product

- Mirogabalin (DPNP, PHN)\*

### New product

- VN-0102 (Measles-Mumps-Rubella vaccine)

### Additional indication

- Denosumab (Breast cancer adjuvant)

FY2016

FY2017

FY2018

FY2019

FY2020

### New product

- Hydromorphone (Cancer pain)
- Etanercept BS (Rheumatoid arthritis)
- VN-0107/MEDI3250 (Seasonal flu vaccine as a nasal spray)

### Additional indication

- Prasugrel (Ischemic stroke)
- Denosumab (Rheumatoid arthritis)

### New product

- CS-3150 (Hypertension)
- Quizartinib (Acute myeloid leukemia)
- VN-0105 (DPT-IPV/Hib vaccine)

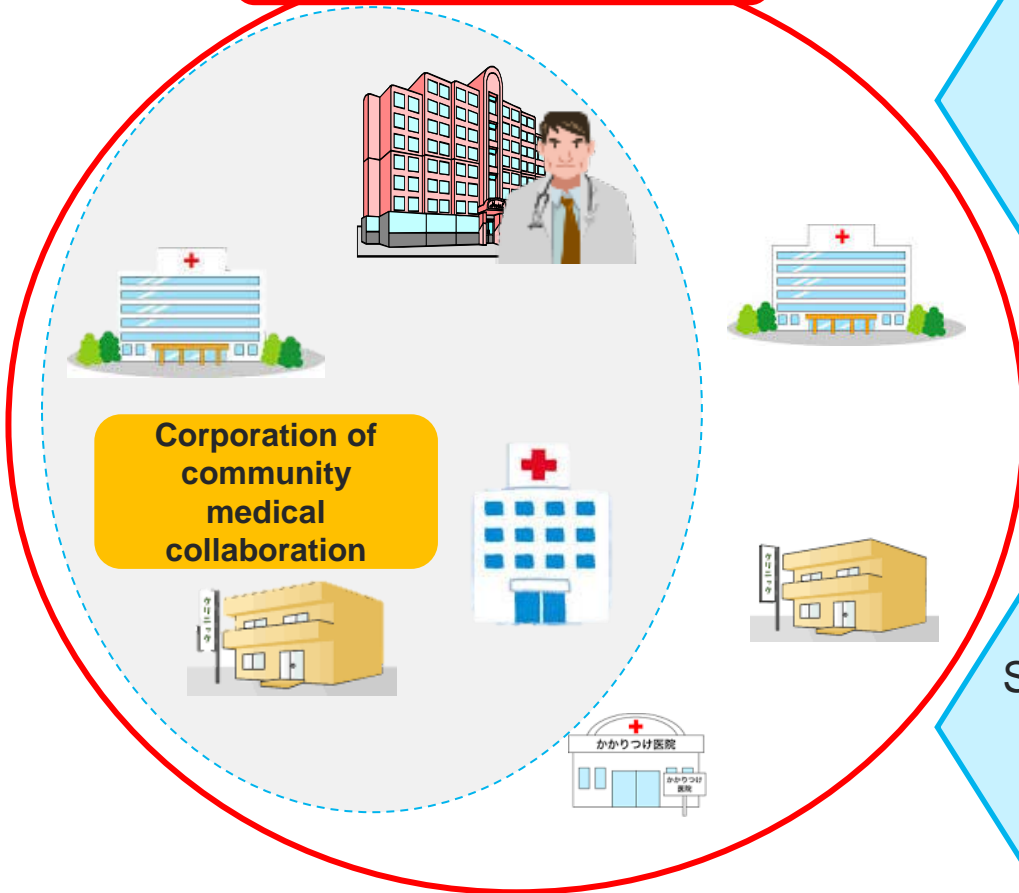
\*DPNP: Diabetic peripheral neuropathic pain  
PHN : Postherpetic neuralgia

# Establish Area Marketing Structure for Integrated Community Care System

Aim to be trusted as medical partner in medical community

**Enhance the necessary role and system in accordance with integrated community medical system on the basis of medical community vision**

**Medical community area**



Enhance area marketing structure

- Align with segmentation of medical function
- Engage with home doctor
- Engage with medical association and local government
- Engage with corporation of community medical collaboration

Set up staff supporting community medical collaboration

**Daiichi Sankyo**

**Reorganization to strengthen the structure (April 2016)**

Regional Value Products  
**Strategy 4**  
**Expand US Businesses**

## ◆ Business expansion in Pain Franchise (DSI\*)

- Movantik
- CL-108
- Mirogabalin

\* DSI: Daiichi Sankyo Inc.

## ◆ Growth of Luitpold Business

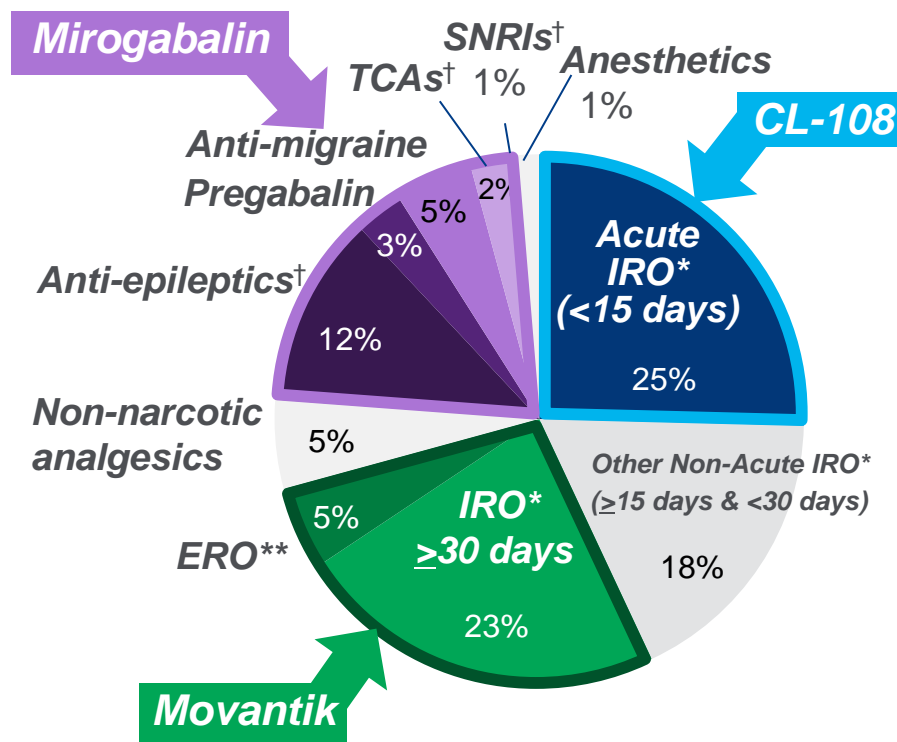
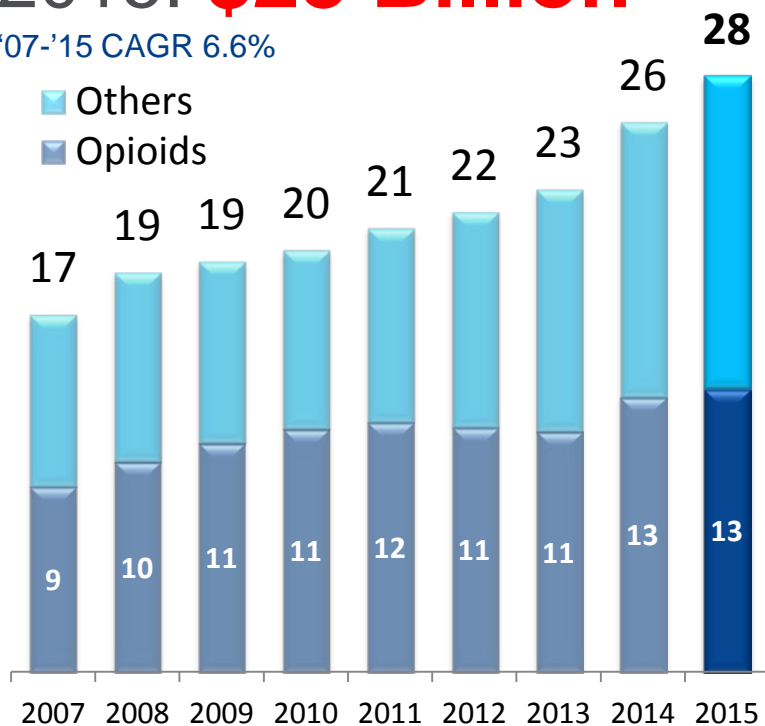
- Iron Franchise
- Generic Injectable

## Large, Growing Market with Diverse Segments

U.S. Pain Market Gross Sales  
(US\$ Billion)

**2015: \$28 Billion**

'07-'15 CAGR 6.6%



**330~ Million TRx**

\* Immediate-Release Opioid, \*\* Extended-Release Opioid  
† Pain management use only

- ◆ First once-daily oral product FDA approved for the treatment of opioid-induced constipation (OIC) for adults with chronic non-cancer pain
- ◆ Co-promotion with AstraZeneca from FY15 and 1.3 billion yen revenue up to December 2015
- ◆ While the reported occurrence of OIC varies, it affected roughly **40%** of patients in clinical trials who were taking opioids for chronic pain<sup>1</sup>

**Early Success Strengthens  
Our Belief**

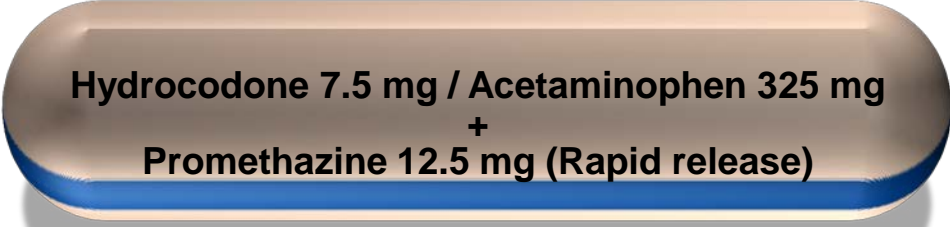


- ◆ Novel, bi-layered tablet containing hydrocodone, acetaminophen and promethazine to treat moderate to severe pain and prevent or reduce opioid-induced nausea and vomiting (OINV)
- ◆ Hydrocodone/Acetaminophen (HC/APAP) is the standard of care for acute pain after injury & surgery and prescribed for 53.2 Mn patients in the U.S.<sup>1</sup>
- ◆ Reports in the literature suggest approximately **40%** of patients experience OINV, and the incidence may be higher in clinical practice<sup>2-6</sup>
- ◆ Met primary endpoints in two pivotal Ph3 studies
  - ◆ Similar efficacy and lower incidence of OINV vs HC/APAP alone in first pivotal Ph3 study\*
  - ◆ Significant pain relief vs placebo and prevention of OINV vs HC/APAP (both p<0.001)\*\*

\* (N=466 Molar Extraction Patients in the U.S.)

\*\* (N=550 Bunionectomy Patients in the U.S.)

1. *Symphony*, Aug 2014 to July 2015
2. Kalso, et al. *Pain*. 2004; 112(3):372-380.
3. Chang, et al. *Curr Med Res Opin*. 2004;20(6):939-949.
4. Daniels, et al. *Curr Med Res Opin*. 2009; 25(5):1551-1561.
5. Park et al. *Curr Med Res Opin*. 2015; 31(1):75-84.
6. Musclow, et al. *Pain Res Manage*. 2012; 17(2):83-88.

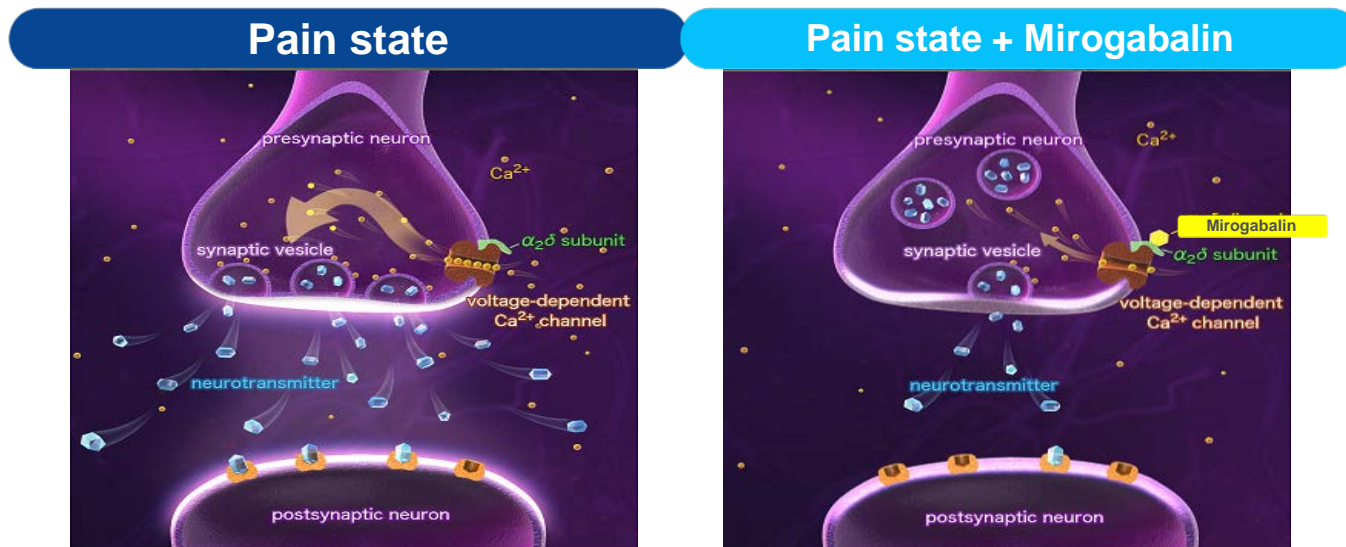


**Hydrocodone 7.5 mg / Acetaminophen 325 mg**  
+  
**Promethazine 12.5 mg (Rapid release)**



# Mirogabalin

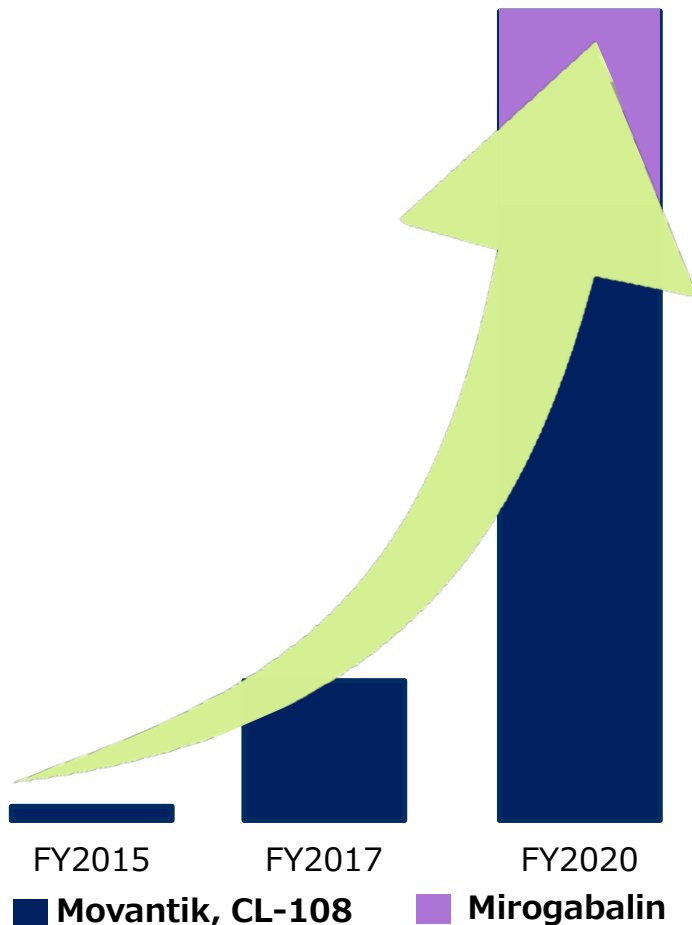
- ◆ If approved, mirogabalin could provide a superior, more convenient and safe therapeutic option for patients with pain associated with fibromyalgia
- ◆ The  $\alpha 2\delta$ -ligand Market as large as 64MM Prescriptions in 2015 <sup>1</sup>
- ◆ Ph3 control drug: pregabalin - U.S. Net sales reached \$2.7 Billion in 2015 <sup>2</sup>
- ◆ ~57% drop treatment of  $\alpha 2\delta$ -ligand at 12 months (unsatisfied with its efficacy) <sup>3</sup>
- ◆ Top line results anticipated **1H CY2017**



1. Symphony Health Solutions, PHAST Prescription Monthly, 2015  
2. Pfizer Quarterly Corporate Performance – Fourth Quarter 2015  
3. Robinson RL et al. Pain Med. 2013;14:1400-1415

# Rapid Growth in Pain Franchise

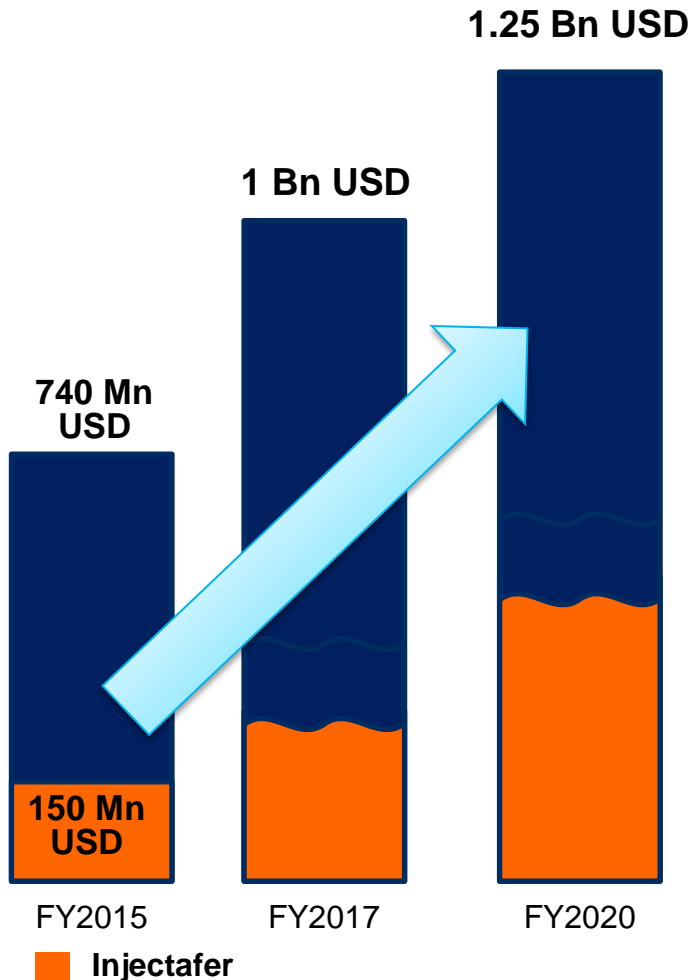
> **100 Bn JPY** business  
in FY2020



## KSF & main tactics

- ◆ **Movantik**
  - Raise awareness of burden of OIC
  - Inspire a conversation about OIC
  - Deliver affordable access
- ◆ **CL-108: Targeted launch in FY 2017**
  - Raise HCPs' OINV awareness
  - Engage the medical community
- ◆ **Mirogabalin :Targeted launch in FY 2019**
  - Differentiate from pregabalin based on Ph3 results

## Realize rapid and sustainable growth with Iron Franchise and Generic injectable franchise



### IRON FRANCHISE

- ◆ **Build Injectafer into our flagship product & market leader (CAGR 20-30%)**
  - Execute LCMs
  - Expand Sales Team coverage to other specialties that treat IDA such as Cardiology, OBGYN, etc.
  - Gain Market share >40% in Hem/Onc segment

### GENERIC INJECTABLE FRANCHISE

- ◆ **Maximize / expand existing portfolio**
  - Focus on high market value products, e.g. anti-cancer drugs
- ◆ **Expand Manufacturing capabilities as a top 4 supplier in US Generic Injectable Market**
  - Shirley plant: Upgrade existing manufacturing infrastructure
  - New Albany plant: Consolidate operation & capacity expansion
  - Hilliard plant: Maximize space use & capacity expansion

Value for Pipeline

## **Strategy 5**

**Continuously Generate Innovative Medicine  
Changing SOC**

- ◆ **Create new drugs in Oncology/New Horizon area**
  - Target therapeutic area
  - Transform research organization to bioventure model
  
- ◆ **Realize clinical application of innovative technology**
  - Advancement of technologies
  - Nucleic acid drug : develop drugs for Duchenne muscular dystrophy
  - Cell therapy : explore seeds utilizing alliance and move them forward to commercialization quickly

Primary  
Focused Area

## Oncology (incl. Immune Oncology)

Generate molecular target drugs with potential  
to cure or prolong life significantly by mono therapy or combination

New horizon  
Area

### Pain

- Generate drugs for pain complementing MOA of current development pipeline

### CNS\* disease

- Generate drugs for neurodegenerative disease through collaborative research with UCSF

### Heart·Kidney disease

- Utilize accumulated knowledge
- Utilize collaborative research with Sanford Burnham

### Rare diseases

- Optimize modality, such as nucleic acid, antibody and small molecule

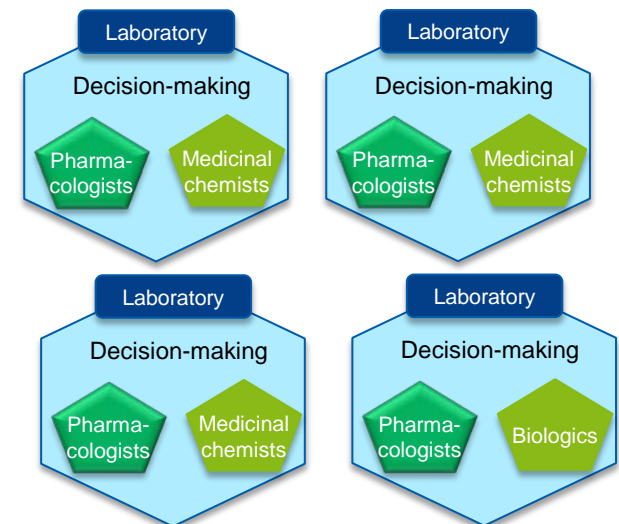
Partnering, Open innovation  
Translational Research

Continuously generate innovative medicine  
changing SOC

## Bioventure model

- Small unit with both functions of pharmacologists and medicinal chemists (biologics)
- **Empowered decision making** for research theme
- **Resource allocation in accordance with outputs (results)**

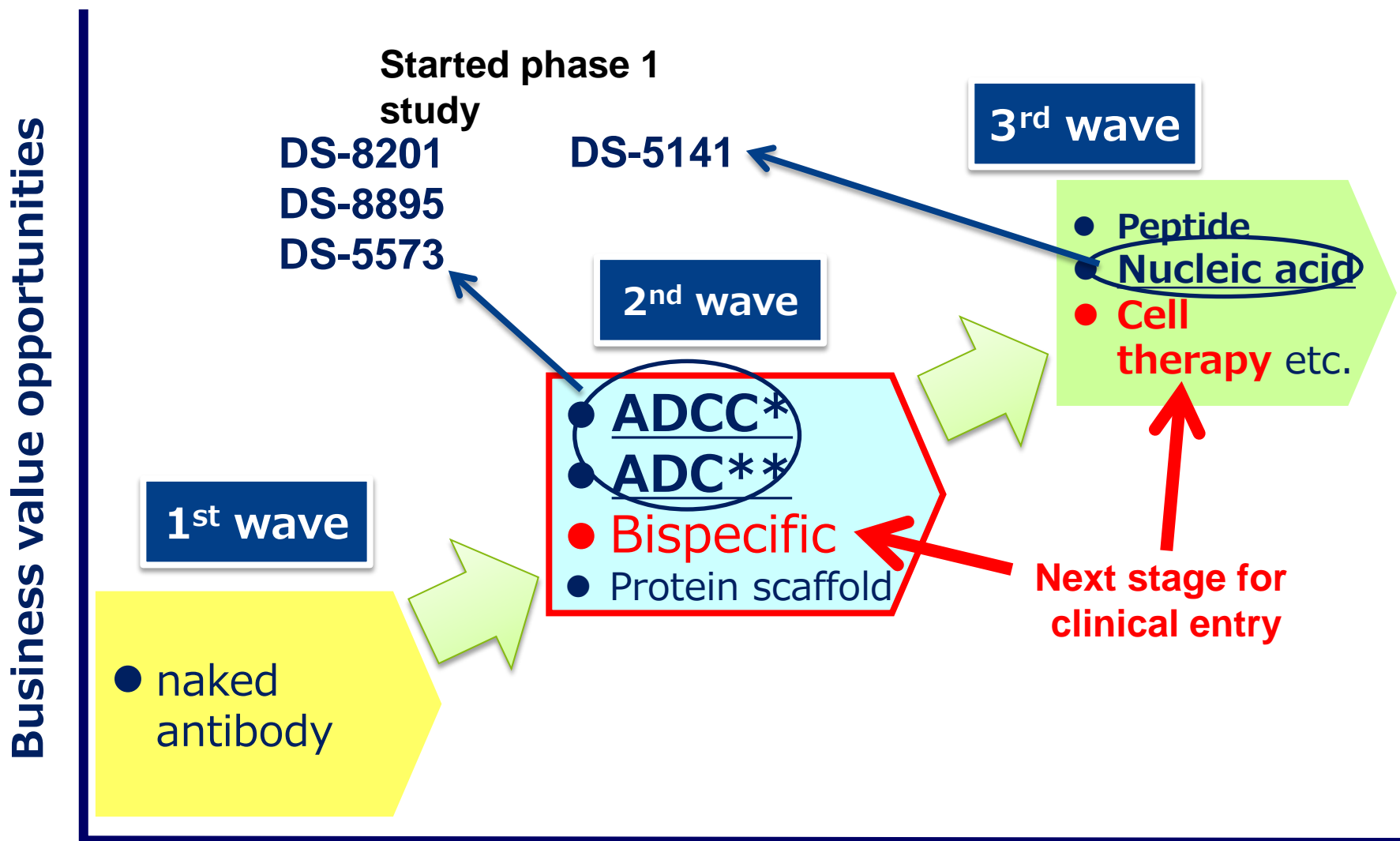
Small unit in therapeutic area



- ◆ Activation of innovative mind
- ◆ Quick decision making

Acceleration of research & improvement of productivity

# Realize Clinical Application of Innovative Technology: Advancement of Technologies



\* ADCC: Antibody Dependent Cellular Cytotoxicity

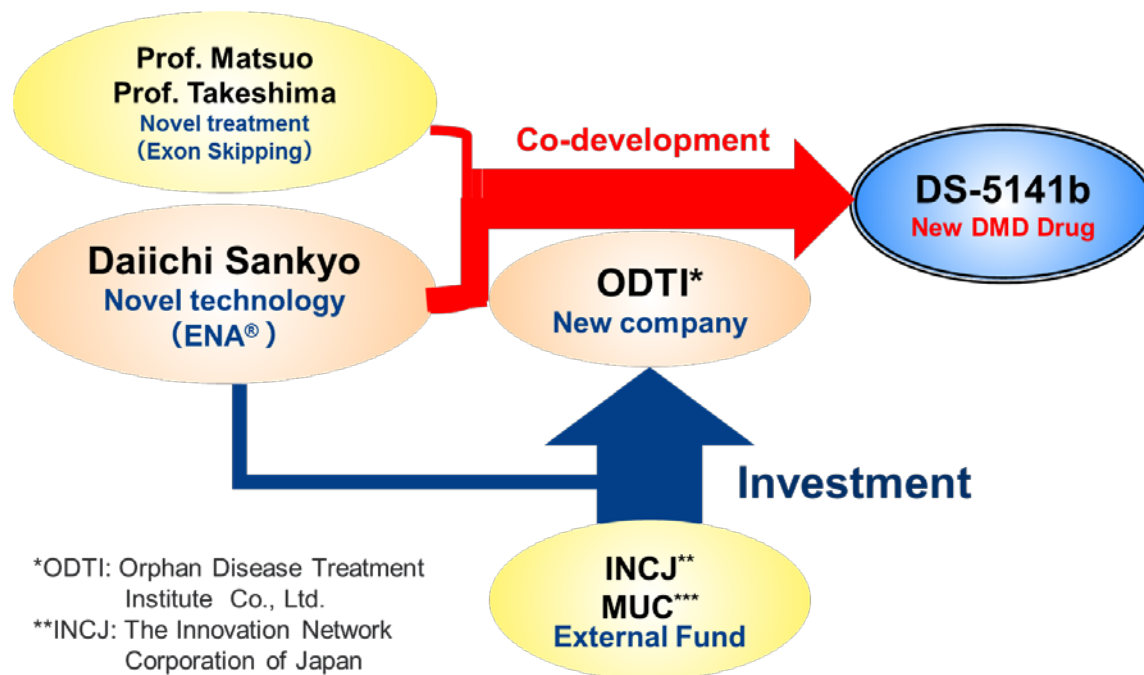
\*\*ADC: Antibody Drug Conjugate



## ◆ **DS-5141: Duchenne muscular dystrophy**

- Achieved the first dosing in the First-in-human phase 1/2 study (Feb. 2016)
- Targeted manufacture and sales approval by 2020 in Japan

[application of DS proprietary technology and risk-hedge mechanism]



## ◆ Establish Cell Therapy Laboratories

- Expand initiatives for cell therapy across the DS Group
- Pursue synergy between DS and Asubio through integration of each organization's advantages, such as biologic technologies, iPS, and stem cell research

## ◆ Explore seeds utilizing alliances and move them forward to commercialization quickly

- Enter cell therapy business quickly by expansion of alliance and in-licensing activities
- Establish pipelines by open innovation from mid-term or long-term viewpoints
  - ✓ Find seeds from academia using TaNeDS or OiDE fund
- Target therapeutic areas with high unmet medical needs, such as heart disease or neurological disease, and plan to clinical entry during 5-Year Business Plan

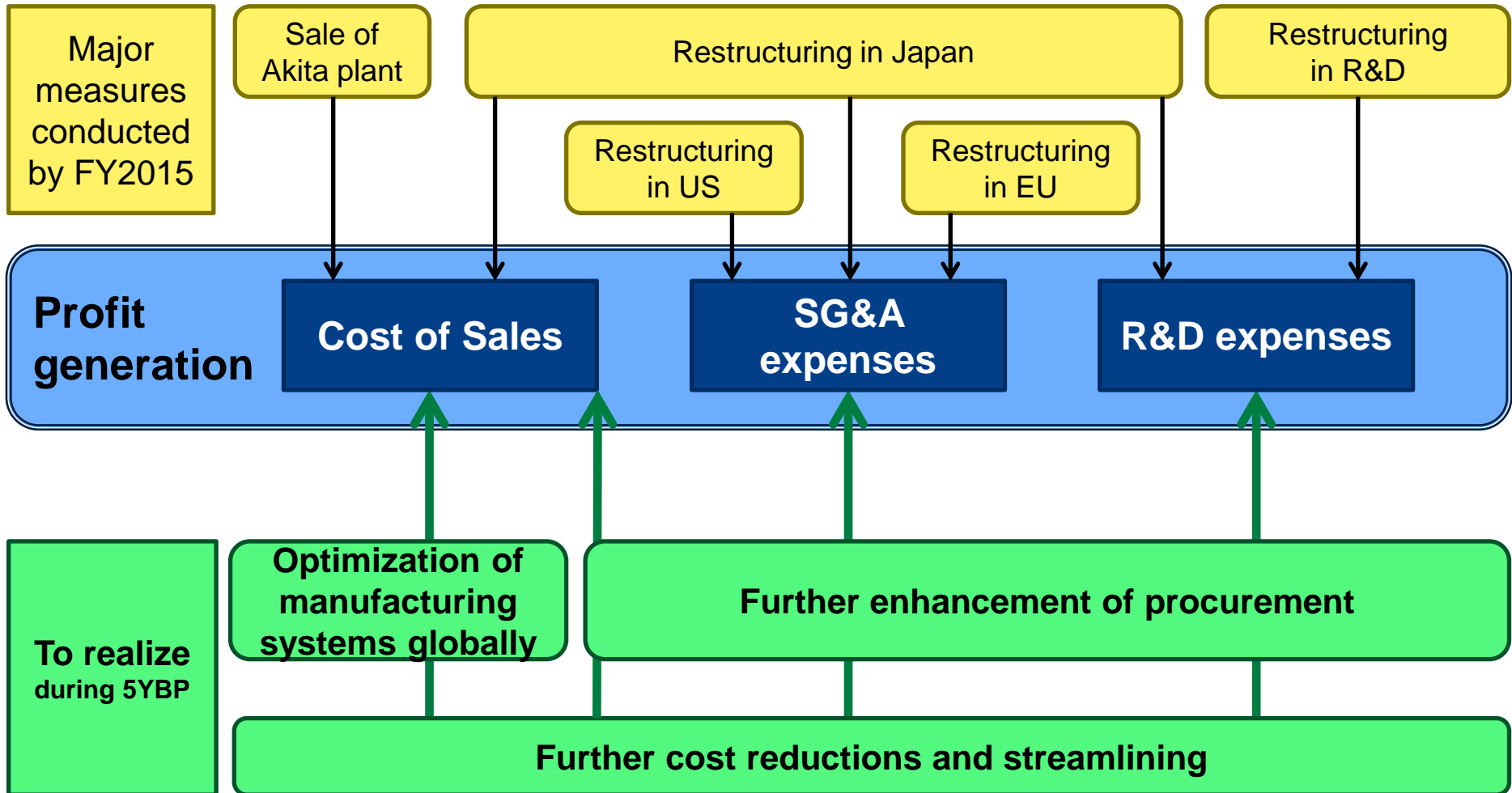
→ Collaborative research on-going with several academia

# Highly Efficient Management **Strategy 6** **Enhance Profit Generation**

A decorative graphic consisting of numerous thin, parallel lines that form a wavy, ribbon-like shape. The color transitions from a light yellow on the left to a pale green on the right, with a slight dip in the middle.

# Enhance Profit Generation

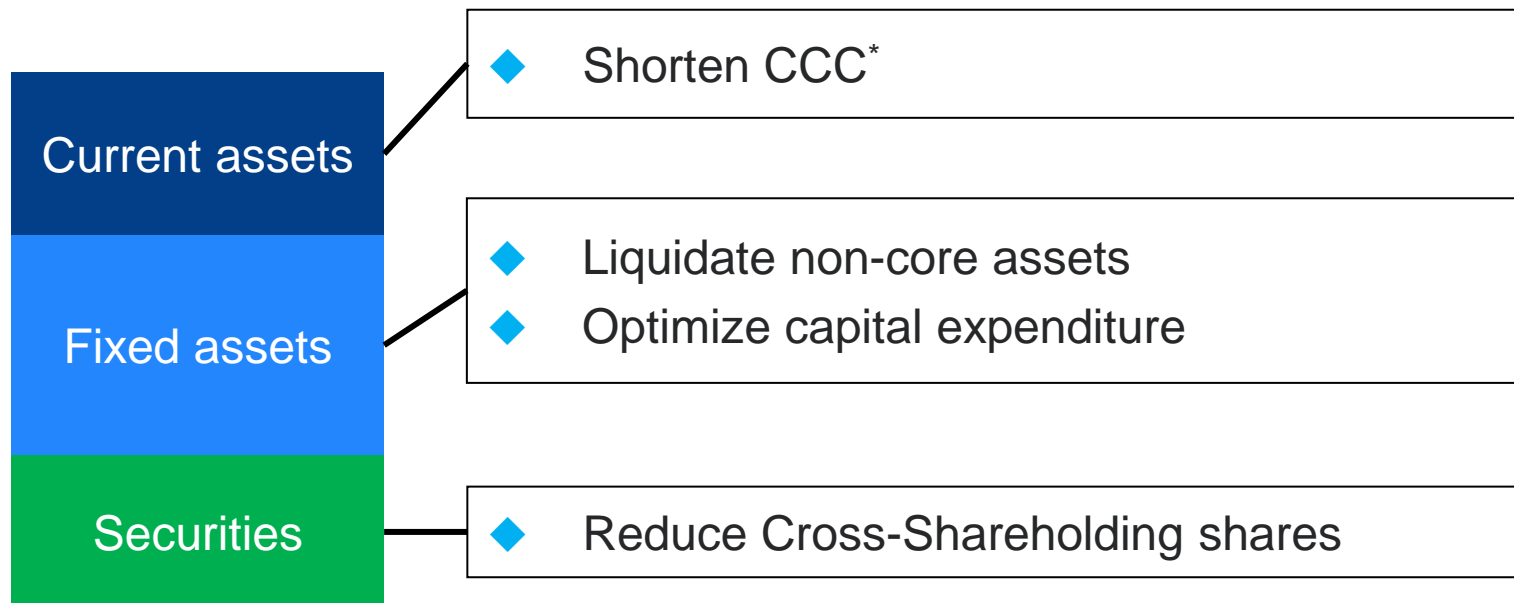
## Realize Process Excellence



- ◆ Challenge 1: Grow beyond FY2017 LOE
  - Measures of Revenue Recovery
  - Measures of Profit Generation
- ◆ Challenge 2: Establish Foundation of Sustainable Growth
  - FY2020 Targets and Business Strategy
  - **Investment for Future Growth and Shareholder Returns**
  - CSR and Corporate Governance
- ◆ Conclusion

## Increase in free cash flow before R&D expenses

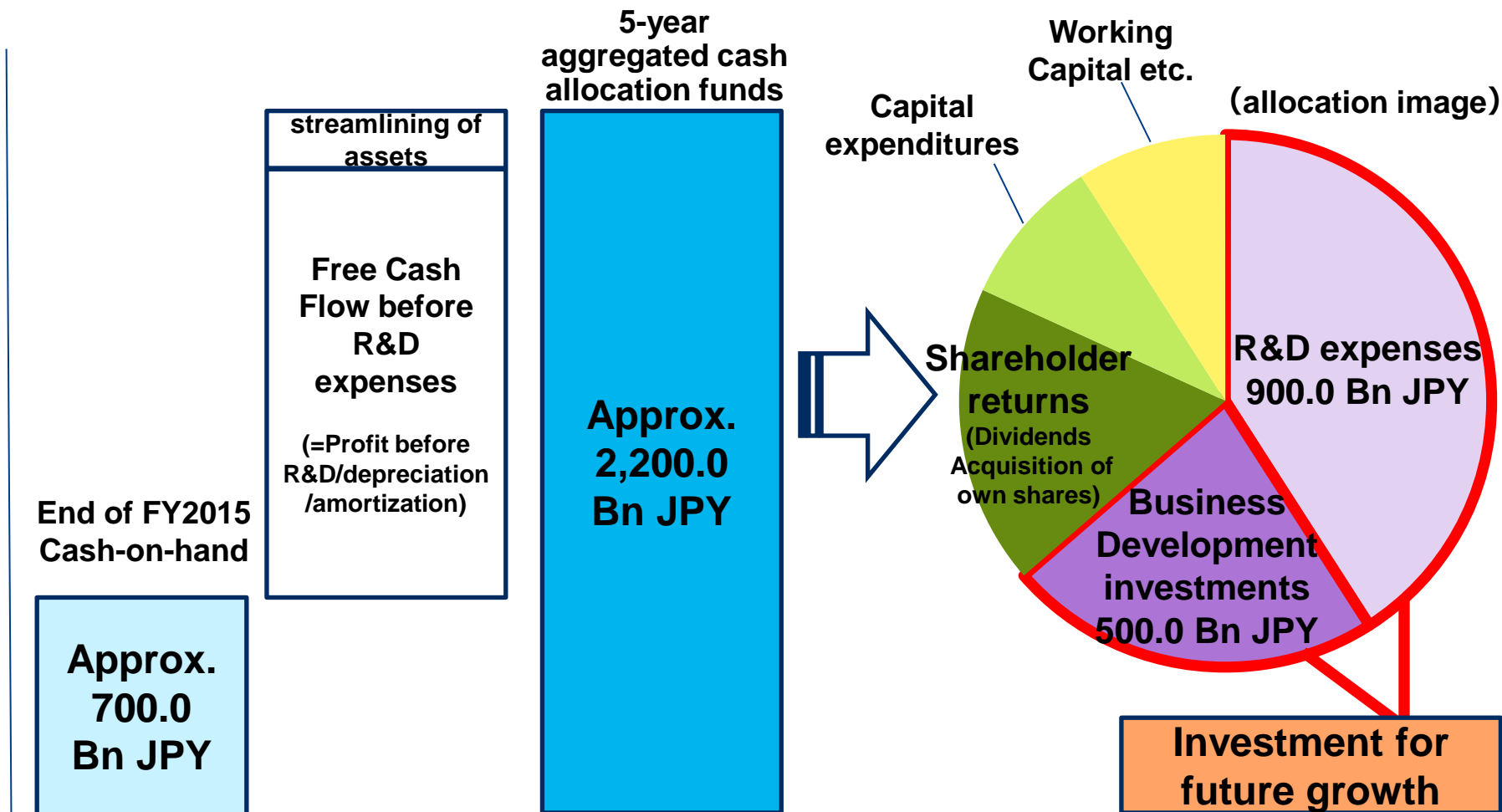
### Streamlining of assets



\*CCC: Cash conversion cycle

# Investment for Future Growth and Shareholder Returns

## Prioritize growth investments while enhancing shareholder returns



## Investment for future growth

R&D expenses  
Approx. 900.0 Bn JPY

Business development  
investments  
Approx. 500.0 Bn JPY

**Most prioritized investment: Oncology** <Strategy 2>

Invest others according to our below strategies

<Strategy 1>

Grow Edoxaban

<Strategy 3>

Grow as No.1 company in Japan

<Strategy 4>

Expand US businesses

<Strategy 5>

Continuously generate innovative medicine changing SOC



## ◆ Total return ratio\* : 100% or more

Total return ratio = ( Dividends + Total acquisition costs of own shares) / Profit attributable to owners of the company

## ◆ Annual ordinary dividends : more than 70 JPY

## ◆ Flexible acquisition of own shares

\*Statement on total return ratio

The total shareholder return ratio may be different from the numbers Daiichi Sankyo forecasts due to factors involving strategic investments, including R&D costs and business development investments, material changes of the business environment surrounding Daiichi Sankyo or business performance of Daiichi Sankyo, legal or compliance issues such as insider trading regulations, or other facts or circumstances. The increase of cash flow related to the total shareholder return ratio may not be realized as expected in this material due to a variety of circumstances, such as the market penetration of generic drugs, delay or cancelation of approvals for new drugs, payment of damages or compensation in connection with litigation or other legal proceedings.

- ◆ Challenge 1: Grow beyond FY2017 LOE
  - Measures of Revenue Recovery
  - Measures of Profit Generation
- ◆ Challenge 2: Establish Foundation of Sustainable Growth
  - FY2020 Targets and Business Strategy
  - Investment for Future Growth and Shareholder Returns
  - **CSR and Corporate Governance**
- ◆ Conclusion

## ◆ Promote compliance management

- Dissemination of global compliance policy, such as Daiichi Sankyo Group Individual Conduct Principles

## ◆ Facilitate mutual growth of employees and Company

- Human resources development to realize value creation and secure competitive advantage through our corporate values of Innovation, Integrity, Accountability and respect for diversity

## ◆ Enhance communication

- Effective disclosure and performance improvement of CSR & ESG

## ◆ Promote environmental management

- Reducing environment impacts and risks, and addressing climate change (FY2020 CO2 emissions target: 5.6% reduction from FY2015)

## ◆ Access to healthcare

- Promoting R&D for Intractable disease, Orphan disease and Global Health
- Mobile healthcare field clinics, Healthcare professionals development, Health and hygiene training to the local in the regions face a lack of medical infrastructure

## Current Status

- ◆ Four out of ten members of the Board are independent outside directors
- ◆ A Nomination Committee and a Compensation Committee, each of which is chaired by a outside director, are established voluntarily
- ◆ An Audit & Supervisory Board system is adopted. The Audit & Supervisory Board consists of four members, including two outside members
- ◆ Specific criteria for the judgment of independence of outside members of the Board and the Audit & Supervisory Board are disclosed
- ◆ The Corporate Governance Code is fully complied

**Continuous improvement of Corporate Governance structure**

**Enhance Shareholders' Value**

- ◆ Challenge 1: Grow beyond FY2017 LOE
  - Measures of Revenue Recovery
  - Measures of Profit Generation
- ◆ Challenge 2: Establish Foundation of Sustainable Growth
  - FY2020 Targets and Business Strategy
  - Investment for Future Growth and Shareholder Returns
  - CSR and Corporate Governance
- ◆ **Conclusion**

# FY2020 Targets

	FY2015 (Forecast)	FY2017 (Target)	FY2020 (Target)
Revenue (Bn JPY)	980.0	940.0	1,100.0
Operating Profit (Bn JPY)	130.0	100.0	165.0

- ◆ Increase value of late-stage pipeline  
3 - 5 products launched within the next 5 years with peak-sales of more than 100.0 Bn JPY each
- ◆ ROE: 8% or more (FY2020)
- ◆ Total return ratio: 100% or more (during 5YBP)
- ◆ Annual ordinary dividends: more than 70 JPY (during 5YBP)

# Global Pharma Innovator with Competitive Advantage in Oncology

## 2025 Vision

### 2016-2020 5-Year Business Plan

Transformation  
toward 2025 Vision

Until 2015

- CVM area
- PCP focus
- Global products
- In-house
- Sales volume

- ◆ To have Specialty area business centered on Oncology business as the core business
- ◆ To have enriched regional value products aligned with regional market
- ◆ To have innovative products and pipeline changing SOC
- ◆ To realize shareholders' value through highly efficient management

A decorative graphic consisting of numerous thin, parallel yellow lines that curve and flow across the page, creating a sense of movement and energy. The lines are more densely packed in some areas, creating a gradient of yellow intensity.

**5-Year Business Plan**

(FY2016 - FY2020)

# **DS Transformation** **— A Bridge to Tomorrow**



# Reference

# Major R&D Pipeline

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
<b>Oncology</b>	<ul style="list-style-type: none"> <li>■ DS-3032 (US/JP) (MDM2 inhibitor)</li> <li>■ PLX7486 (US) (FMS / TRK inhibitor)</li> <li>■ PLX8394 (US) (BRAF inhibitor)</li> <li>■ DS-6051 (US) (NTRK/ROS1 inhibitor)</li> <li>■ PLX9486 (US) (KIT inhibitor)</li> <li>■ DS-3201 (JP) (EZH1/2 inhibitor)</li> <li>■ DS-8895 (JP) (Anti-EPHA2 antibody)</li> <li>■ DS-8273 (US) (Anti-DR5 antibody)</li> <li>■ DS-5573 (JP) (Anti-B7-H3 antibody)</li> <li>■ DS-8201 (JP) (Anti-HER2 ADC)</li> <li>■ U3-1784 (EU) (Anti-FGFR4 antibody)</li> <li>■ DS-1123 (JP) (Anti-FGFR2 antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ Patritumab (US/EU) (U3-1287 / Anti-HER3 antibody)</li> <li>■ Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor)</li> </ul>	<ul style="list-style-type: none"> <li>■ Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor)</li> <li>■ Denosumab (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody)</li> <li>■ Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody)</li> <li>■ Vemurafenib (US/EU) (PLX4032 / Melanoma Adjuvant / BRAF inhibitor)</li> <li>■ Quizartinib (US/EU/Asia) (AC220 / AML / FLT3-ITD inhibitor)</li> <li>■ Pexidartinib (US/EU) (PLX3397/TGCT / CSF-1R/KIT/FLT3-ITD inhibitor)</li> </ul>	
<b>Cardiovascular-Metabolics</b>	<ul style="list-style-type: none"> <li>■ DS-1040 (Acute ischemic stroke / TAF1a inhibitor)</li> <li>■ DS-2330 (Hyperphosphatemia)</li> <li>■ DS-9231/TS23 (Thrombosis / <math>\alpha 2</math>-PI inactivating antibody)</li> <li>■ DS-9001 (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod)</li> </ul>	<ul style="list-style-type: none"> <li>■ CS-3150 (JP) (Hypertension · DM nephropathy / MR antagonist)</li> <li>■ DS-8500 (JP/US) (Diabetes / GPR119 agonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ Prasugrel (JP) (CS-747 / Ischemic stroke / Anti-platelet agent)</li> </ul>	<ul style="list-style-type: none"> <li>■ Edoxaban (ASCA etc.) (DU-176b / AF / oral factor Xa inhibitor)</li> <li>■ Edoxaban (ASCA etc.) (DU-176b / VTE / oral factor Xa inhibitor)</li> </ul>
<b>Others</b>	<ul style="list-style-type: none"> <li>■ DS-1971 (Chronic pain)</li> <li>■ DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)</li> <li>■ DS-7080 (US) (AMD / Angiogenesis inhibitor)</li> <li>■ DS-2969 (<i>Clostridium difficile</i> infection / GyrB inhibitor)</li> <li>■ DS-5141 (JP) (DMD / ENA oligonucleotide)</li> <li>■ VN-0102/JVC-001 (JP) (MMR vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ Laninamivir (US/EU) (CS-8958 / Anti-influenza / out-licensing with Biota)</li> </ul>	<ul style="list-style-type: none"> <li>■ Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / <math>\alpha 2\delta</math> ligand)</li> <li>■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ <math>\alpha 2\delta</math> ligand)</li> <li>■ Mirogabalin (JP/Asia) (DS-5565 / PHN / <math>\alpha 2\delta</math> ligand)</li> <li>■ Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL anti-body)</li> <li>■ Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid <math>\mu</math>-receptor regulator)</li> <li>■ CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNF<math>\alpha</math> inhibitor)</li> <li>■ CL-108 (US) (Acute pain / Opioid <math>\mu</math>-receptor regulator)</li> <li>■ VN-0105 (JP) (DPT-IPV/Hib vaccine)</li> <li>■ VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ Intradermal Seasonal Influenza Vaccine (JP) (VN-100 / prefilled i.d. vaccine for seasonal flu)</li> <li>■ VN-101 (JP) (Cell-culture H5N1 Influenza vaccine)</li> </ul>

# Targeted Launch during 5YBP

	FY2016	FY2017	FY2018	FY2019	FY2020	
<b>Japan</b>		Prasugrel CVA		CS-3150 Hypertension		
		Hydromorphone Cancer pain		Quizartinib AML 2nd	Denosumab BC-adjvant	
	Lacosamide Epilepsy	Denosumab RA	Mirogabalin DPNP&PHN			
		Etanercept BS RA				
	VN-100 Seasonal flu	VN-0107 Nasal spray flu vaccine		VN-0105 DTP-IPV/Hib	VN-0102 MMR	
<b>US</b>			Tivantinib HCC	Pexidartinib TGCT	Patritumab NSCLC	
			Quizartinib AML 2nd			
		CL-108 Acute pain		Mirogabalin FM		
<b>EU</b>			Tivantinib HCC	Pexidartinib TGCT	Patritumab NSCLC	Specialty
			Quizartinib AML 2nd			
<b>China</b>				Edoxaban AF		PCP area
		Sitafloxacin Infection		Edoxaban VTE		Vaccine

Contact address regarding this material

Daiichi Sankyo Co., Ltd.  
Corporate Communications Department

TEL: +81-3-6225-1126