

Passion for Innovation.  
Compassion for Patients.™



# Focus on Innovation

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Financial forecasts, future projections and R&D information that Daiichi Sankyo discloses may include information that might be classified as “*Forward-Looking Statement*”.

These forward-looking statements represent our current assumptions based on information currently available.

Please note that such are subject to a number of known and unknown risks and uncertainties and our future performance may differ from the expectations as expressed in such statements.

- ◆ Major Management Topics
  - Background
  - Edoxaban
  - Japan Business
  - US Business
  
- ◆ R&D Topics (Oncology Strategy)
  
- ◆ Conclusion

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# Major Global Products

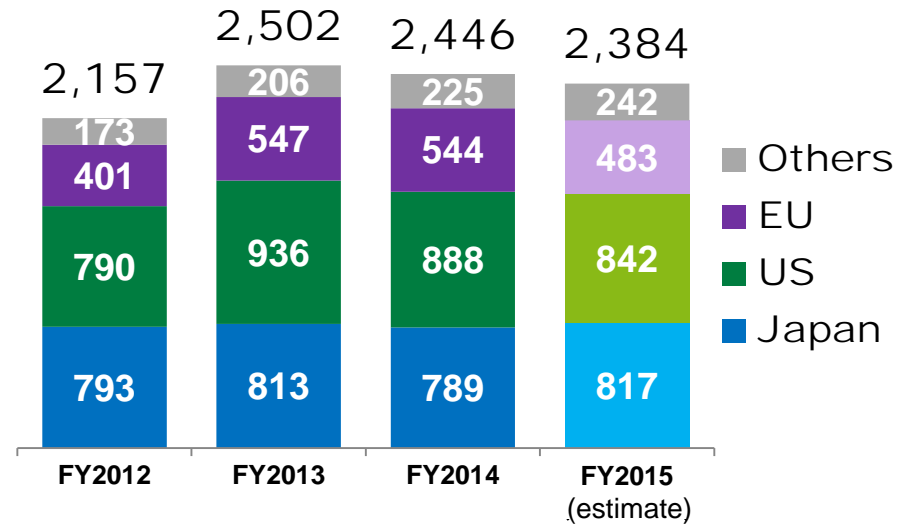
(USD M)

\*Currency rate : JPY/USD=120.0



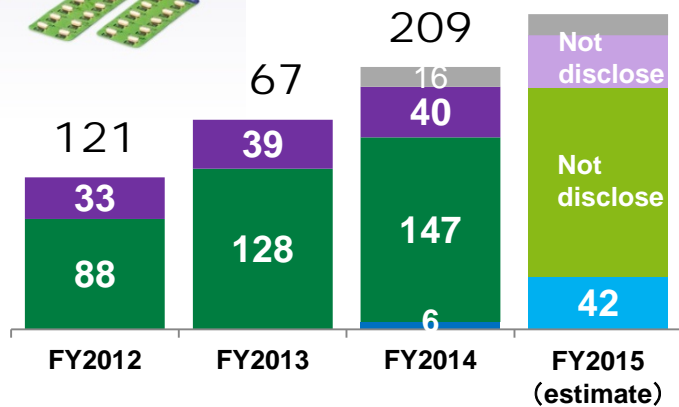
## anti-hypertension Olmesartan

(Benicar: US Olmetec: JP, EU)



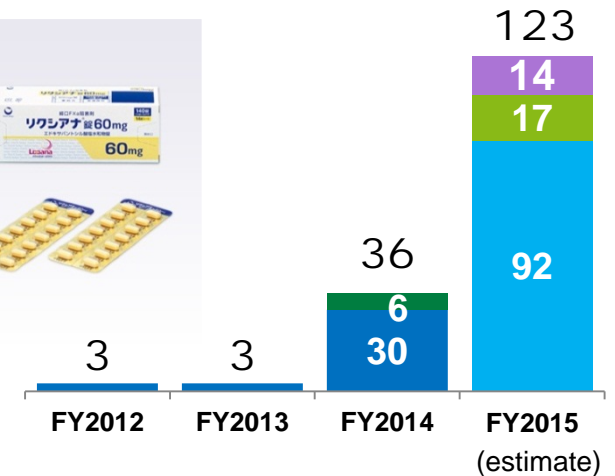
## antiplatelet Prasugrel

(Effient: US Efiect: JP, EU)



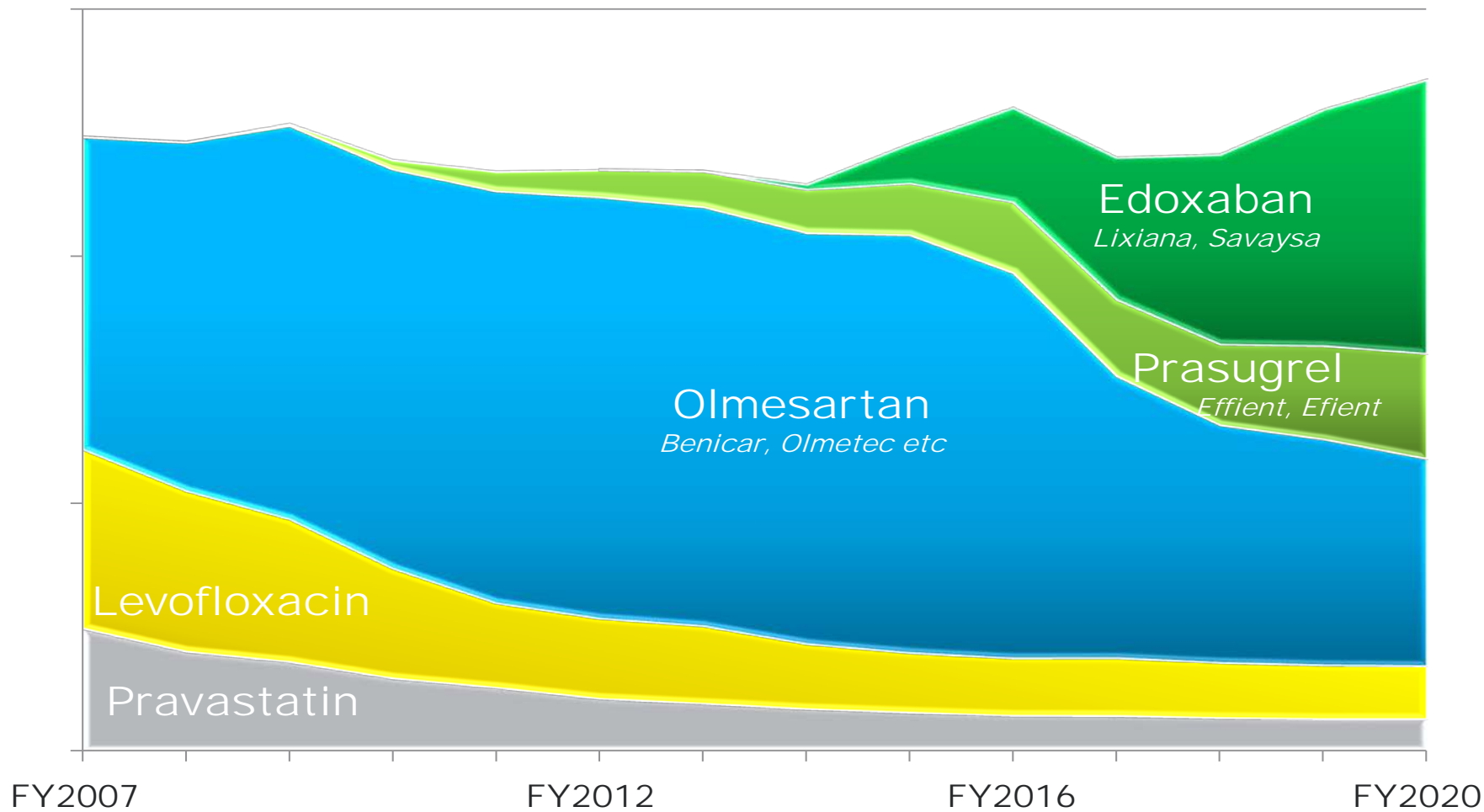
## anticoagulant Edoxaban

(Savaysa: US Lixiana: JP, EU)



# Management Focus

Sustainable growth with smooth transition of key drivers



\*The above figures do not include partner sales

## Strategies for growth beyond Olmesartan LOE

Global

**Launch Edoxaban (Lixiana/Savaysa) & maximize its potential as a flag-ship product**

Japan

**Achieve No. 1 market share by maximizing new drugs**

- Efiend (Effient), Memary (Namenda), Nexium, Pralia (Prolia), Ranmark (Xgeva) etc.
- Lacosamide (Vimpat)

US

**Achieve rapid growth of new drugs & establish core franchises**

- DSI: Movantik, CL-108, Mirogabalin → Pain  
Tivantinib, Pexidartinib, Quizartinib → Oncology
- LPI: Venofer, Injectafer → IV Iron franchise

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## ◆ Conclusion



# Edoxaban: Competitive Advantage



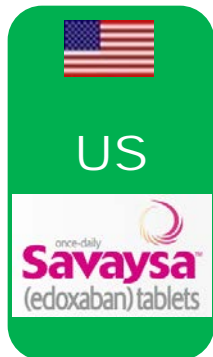
- ◆ Oral, highly selective, direct, and reversible Factor Xa inhibitor
- ◆ The only once-daily NOAC that offers superiority compared to warfarin with less major bleeding in non-valvular atrial fibrillation and with less clinically relevant bleeding in DVT/PE
- ◆ The only NOAC in Japan with three approved major indications : AF, VTE and DVT-OS

AF: Atrial Fibrillation; VTE: Venous Thromboembolism; DVT-OS: Deep Vein Thrombosis - Orthopedic Surgery

# Edoxaban: Major Regions



- ◆ Launched for DVT-OS in 2011
- ◆ Launched for AF and VTE in 2014
- ◆ Sales growing steadily
- ◆ Revenue target: ~USD 100mn in FY2015



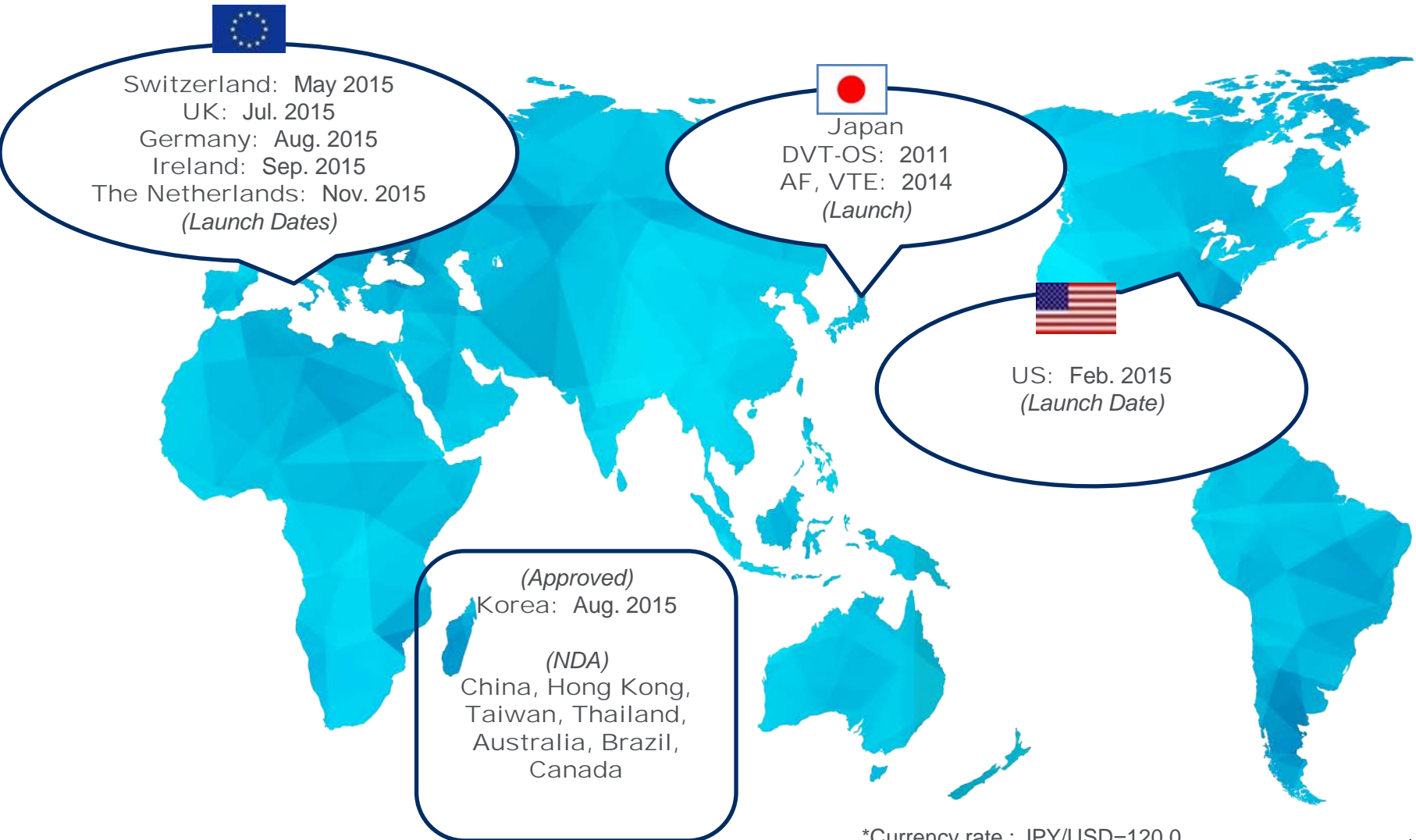
- ◆ Launched for AF and VTE in 2015
- ◆ AF: indicated only for patients with CrCL  $\leq 95$  mL/min
- ◆ VTE: without limitation of use
- ◆ Ongoing negotiations with payers



- ◆ Approved for AF and VTE by EC without limitation of use in 2015
- ◆ Recommended for VTE and AF by NICE
- ◆ Good start in each country

# Edoxaban: Global Development

Global revenue: USD 36M (FY2014)→USD 123M (FY2015 Plan)



\*Currency rate : JPY/USD=120.0

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## ◆ R&D Topics (Oncology Strategy)

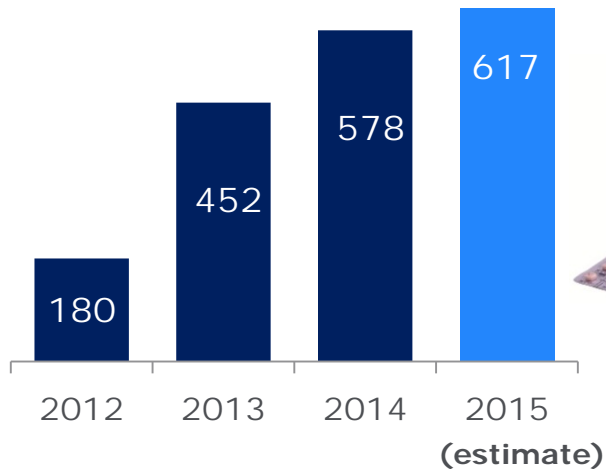
## ◆ Conclusion

# Japan: Major Products

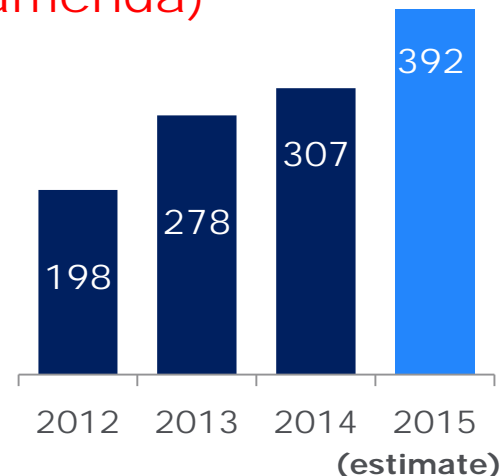
\*Currency rate : JPY/USD=120.0

For No.1 market share company in Japan

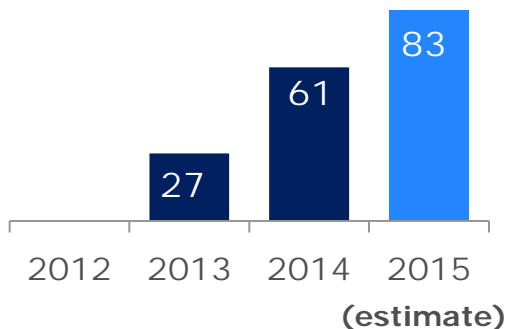
anti-ulcer(PPI)  
**Nexium**



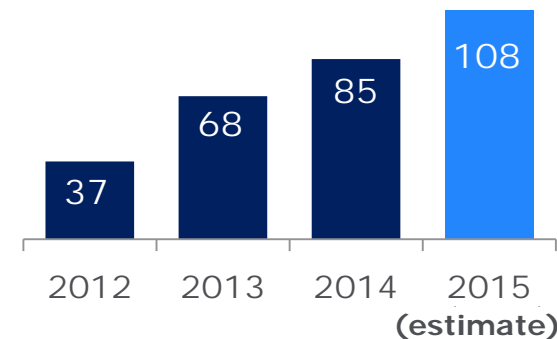
treatment for alzheimer  
**Memary (Namenda)**



treatment for osteoporosis  
**Pralia (Prolia)**



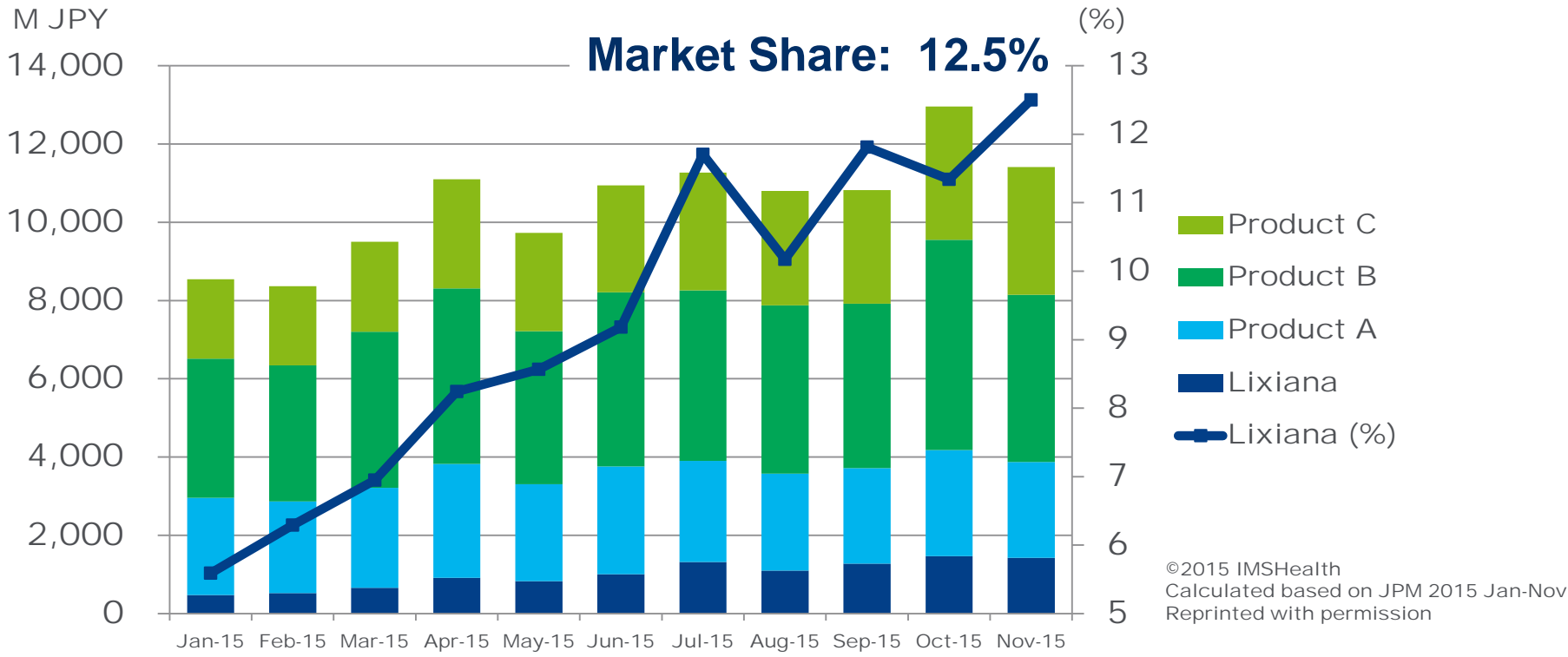
treatment for bone metastasis  
**Ranmark (Xgeva)**





## Steady sales growth

- Launched for DVT-OS in 2011
- Launched for AF and VTE in 2014
- Revenue target: ~USD 100mn in FY2015



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Two Subsidiaries in US with marketing functions

## DSI: Daiichi Sankyo, Inc.

- HQ Location: Parsippany, New Jersey
- Other function: Research, development and packaging

## LPI: Luitpold Pharmaceuticals, Inc.

- HQ Location: Shirley, New York
- Other function: Research, development and manufacturing



## DSI: Daiichi Sankyo, Inc.

- HQ Location: Parsippany, New Jersey
- Other function: Research, development and packaging





# United States: DSI Portfolio

To specialty products in CV, Pain and Oncology



## New Product Launches



**CL-108**

## FY18~

**Mirogabalin**  
**Quizartinib**  
**Tivantinib**

**Pexidartinib**  
**Patritumab**



## Pain franchise: Near-term opportunities

Three products targeting important, but unmet needs



Opioid-induced Constipation (OIC) for patients taking opioids for chronic, non-cancer related pain

Launched in U.S. May 2015

\*Co-Commercialized by AstraZeneca & Daiichi Sankyo, Inc.



Pain and Opioid-Induced Nausea & Vomiting (OINV)

Phase 3 completed



Pain Associated with Fibromyalgia

Phase 3 ongoing, TLR\* anticipated in 1H 2017

\*Top line results

Competitive among high value specialty-branded & generic injectable market segments

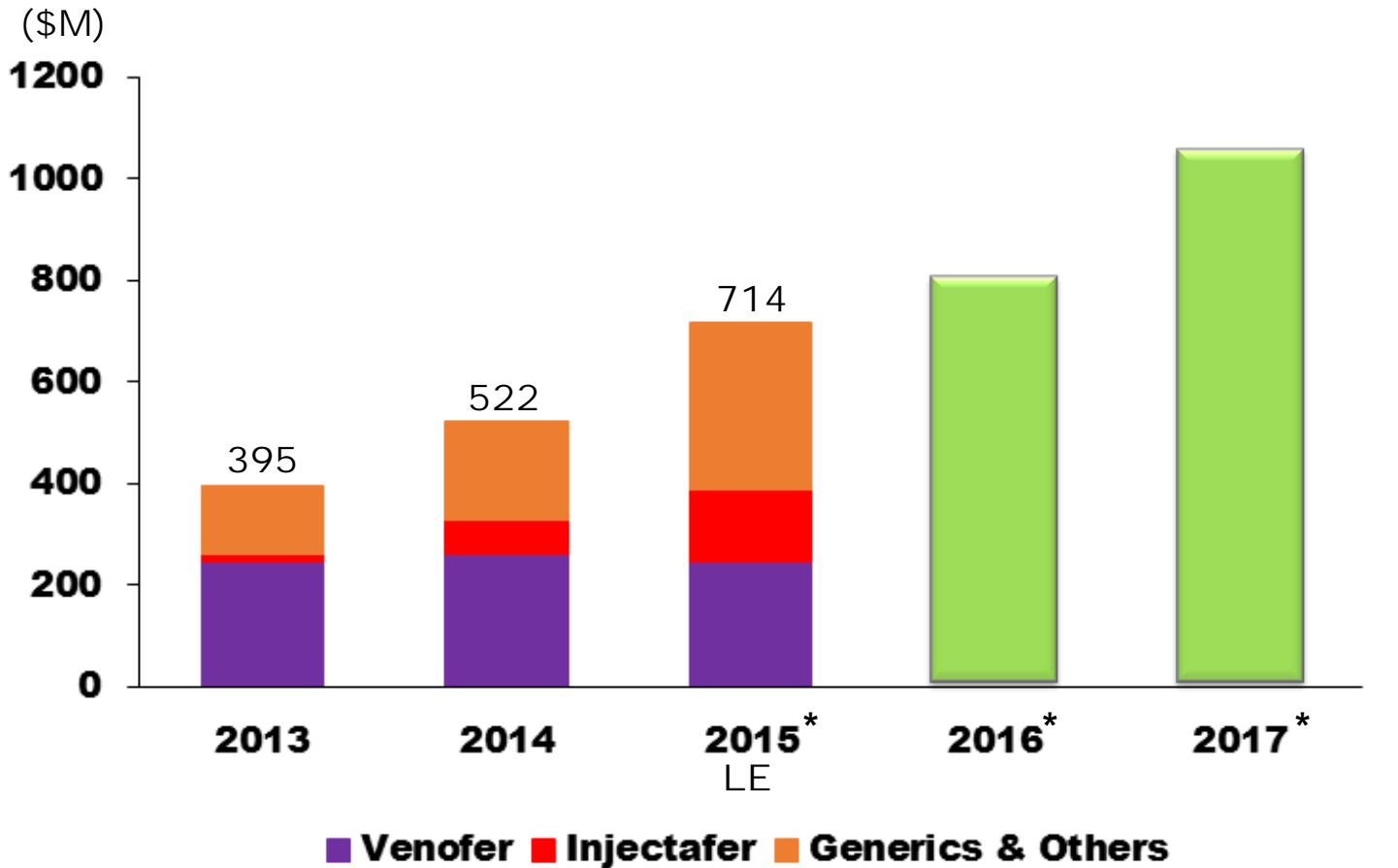
**IRON FRANCHISE**  
( > 50% share of non HD segment)



**GENERIC  
INJECTABLE  
FRANCHISE**



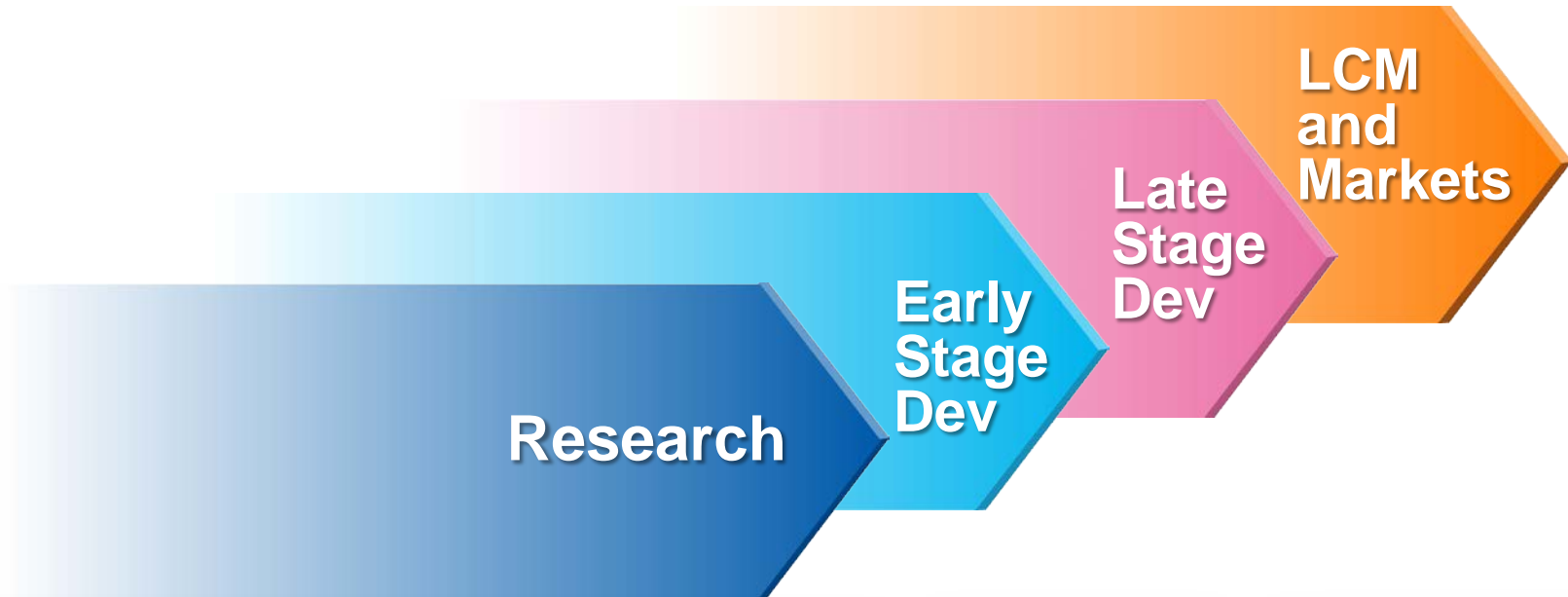
## Double-digit revenue and profit growth



\*Based on forecast

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## Priority Areas for Discovery\*

- **Oncology**
- **Cardiovascular-Metabolics**
- **Pain**

**Oncology**

**CV-M**

**Pain**

**Thrombosis**

**Hypertension**

**Pain**

\*Discovery: Research and Early Development up to Proof of Concept

# Major R&D Pipeline

As of October 2015

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
<p>Cardiovascular-Metabolics</p>	<ul style="list-style-type: none"> <li>■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor)</li> <li>■ DS-8312 (Hypertriglyceridemia)</li> <li>■ DS-2330 (Hyperphosphatemia)</li> <li>■ DS-9231/TS23 (Thrombosis / <math>\alpha 2</math>-PI inactivating antibody)</li> </ul>	<ul style="list-style-type: none"> <li>■ CS-3150 (JP) (Hypertension • DM nephropathy / MR antagonist)</li> <li>■ DS-8500 (JP) (Diabetes / GPR119 agonist)</li> </ul>	<ul style="list-style-type: none"> <li>■ Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent)</li> <li>■ Prasugrel (US) (CS-747 / sickle cell disease / 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>
<p>Oncology</p>	<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>■ U3-1565 (US/JP) (Anti-HB-EGF antibody)</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> </ul>	<ul style="list-style-type: none"> <li>■ Patritumab (US/EU) (U3-1287 / anti-HER3 antibody)</li> <li>■ Pexidartinib (US) (PLX3397 / FMS/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) (AC220 / AML / FLT3-ITD inhibitor)</li> <li>■ Pexidartinib (US/EU) (PLX3397/TGCT / FMS/KIT/FLT3-ITD inhibitor)</li> </ul>	
<p>Others</p>	<ul style="list-style-type: none"> <li>■ DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor)</li> <li>■ DS-3801 (Chronic constipation / GPR38 agonist)</li> <li>■ DS-1971 (Chronic pain)</li> <li>■ DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)</li> <li>■ DS-7080 (AMD / Angiogenesis inhibitor)</li> <li>■ VN-0102/JVC-001 (JP) (MMR vaccine)</li> </ul>	<ul style="list-style-type: none"> <li>■ SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system)</li> <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>

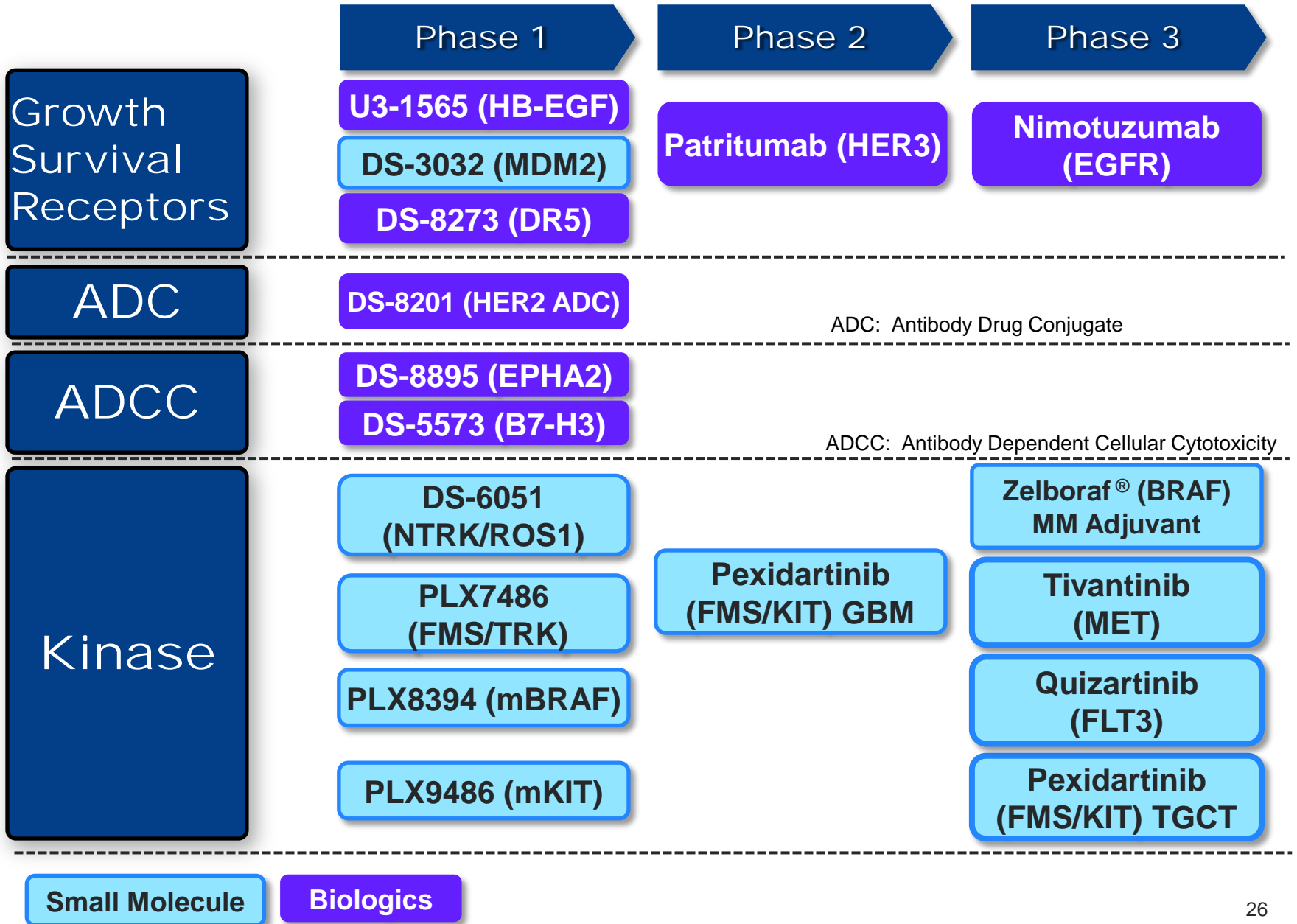


# R&D: Targets for Approval and Launch

	FY2015	FY2016	FY2017	FY2018	≥ FY2019
<b>Japan</b>	<ul style="list-style-type: none"> <li>Cravit® Injection</li> <li>Cravit® Tuberculosis</li> <li>Artist® Chronic AF</li> </ul>	<ul style="list-style-type: none"> <li>Hydromorphone Cancer Pain</li> <li>Lacosamide Epilepsy</li> </ul>	<ul style="list-style-type: none"> <li>Pralia® RA</li> <li>Effient® CVA</li> </ul>	<ul style="list-style-type: none"> <li>Mirogabalin DPNP &amp; PHN</li> </ul>	<ul style="list-style-type: none"> <li><b>Oncology</b> <ul style="list-style-type: none"> <li>Nimotuzumab</li> <li>Patritumab</li> <li>Pexidartinib</li> <li>Quizartinib (JPN)</li> <li>Zelboraf® (LCM)</li> <li>Ranmark® (BC adj)</li> </ul> </li> </ul>
<b>US</b>		<ul style="list-style-type: none"> <li>CL108 Acute Pain &amp; OINV</li> <li>Effient® Pediatric Exclusivity</li> </ul>		<ul style="list-style-type: none"> <li>Tivantinib HCC</li> <li>Quizartinib AML</li> </ul>	<ul style="list-style-type: none"> <li><b>CV-M</b> <ul style="list-style-type: none"> <li>CS-3150 (MRA)</li> <li>DS-8500 (GPR119)</li> <li>Effient® (LCM)</li> <li>Lixiana® (LCM)</li> </ul> </li> </ul>
<b>Western Europe</b>	<ul style="list-style-type: none"> <li>Lixiana® AF</li> <li>Lixiana® VTE</li> </ul>			<ul style="list-style-type: none"> <li>Tivantinib HCC</li> <li>Quizartinib AML</li> </ul>	<ul style="list-style-type: none"> <li><b>Pain</b> <ul style="list-style-type: none"> <li>Mirogabalin</li> </ul> </li> </ul>
<b>Other Regions</b>	<ul style="list-style-type: none"> <li>Lixiana® AF&amp;VTE (China•LTAM etc.)</li> </ul>				<ul style="list-style-type: none"> <li><b>Other</b></li> </ul>

- ◆ **Focus on first-in-class opportunities**
- ◆ **Develop personalized medicine based therapies**
- ◆ **Maintain strong academic partnerships**
  - **National Cancer Center of Japan**
  - **UCSF**
  - **Max Planck**
- ◆ **Partner with innovative biotech companies**
  - **ArQule**
- ◆ **Strategic acquisitions**
  - **Plexxikon**
  - **Ambit**

# R&D: Oncology Clinical Pipeline





## Four novel compounds targeting unique pathways in Phase 2/3 registration trials

### Quizartinib (Ph3)

- Acute myeloid leukemia (AML)
  - TLR\*: 1H 2017
- Orphan Drug Designation by the FDA and EMA  
Fast Track Status by the FDA

### Pexidartinib (Ph3)

- Tenosynovial giant cell tumor (TGCT)
  - TLR: 1H 2018
- Orphan Drug Designation by the FDA and EMA  
Breakthrough Therapy Designation by the FDA

### Tivantinib (Ph3)

- Hepatocellular carcinoma (HCC) in partnership with ArQule
  - TLR: 1H 2017
- Orphan Drug Designation by the FDA and EMA

### Patritumab (Ph2/3)

- Non-small cell lung cancer (NSCLC)
- TLR: 2H 2018

## Immuno-oncology

- Immune checkpoint inhibitors
- Cell therapy

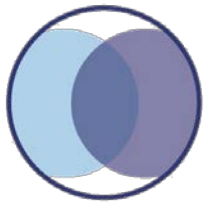
## Epigenetics

- IDH1 mutant inhibitor
- EZH 1/2 inhibitor

## Investigational CSF-1R (FMS) Inhibitor

- Tenosynovial Giant Cell Tumor (TGCT)
- Granted Orphan Drug Designation by the FDA and EMA
- Granted Breakthrough Therapy Designation by FDA

## Further Investigations



### Collaboration with Merck:

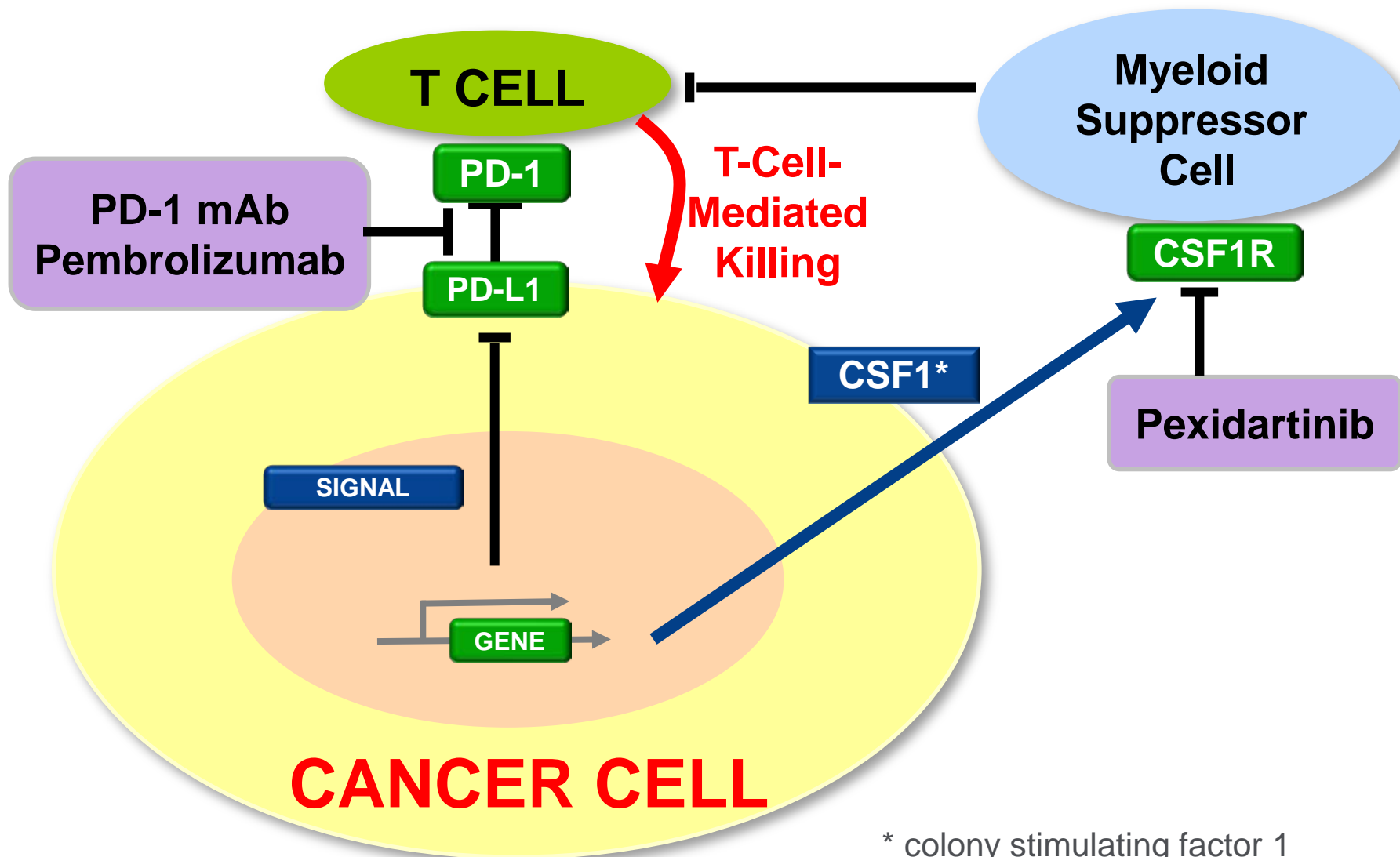
- **Pexidartinib in combination with anti-PD-1 therapy for advanced melanoma and multiple other solid tumors**



### Other potential indications:

- **Glioblastoma**
- **Ovarian cancer**
- **Breast cancer**
- **Sarcomas**

# Pexidartinib in Combination with anti-PD-1 Therapy for Advanced Solid Tumors



## Immuno-oncology

- Immune checkpoint inhibitors
- Cell therapy

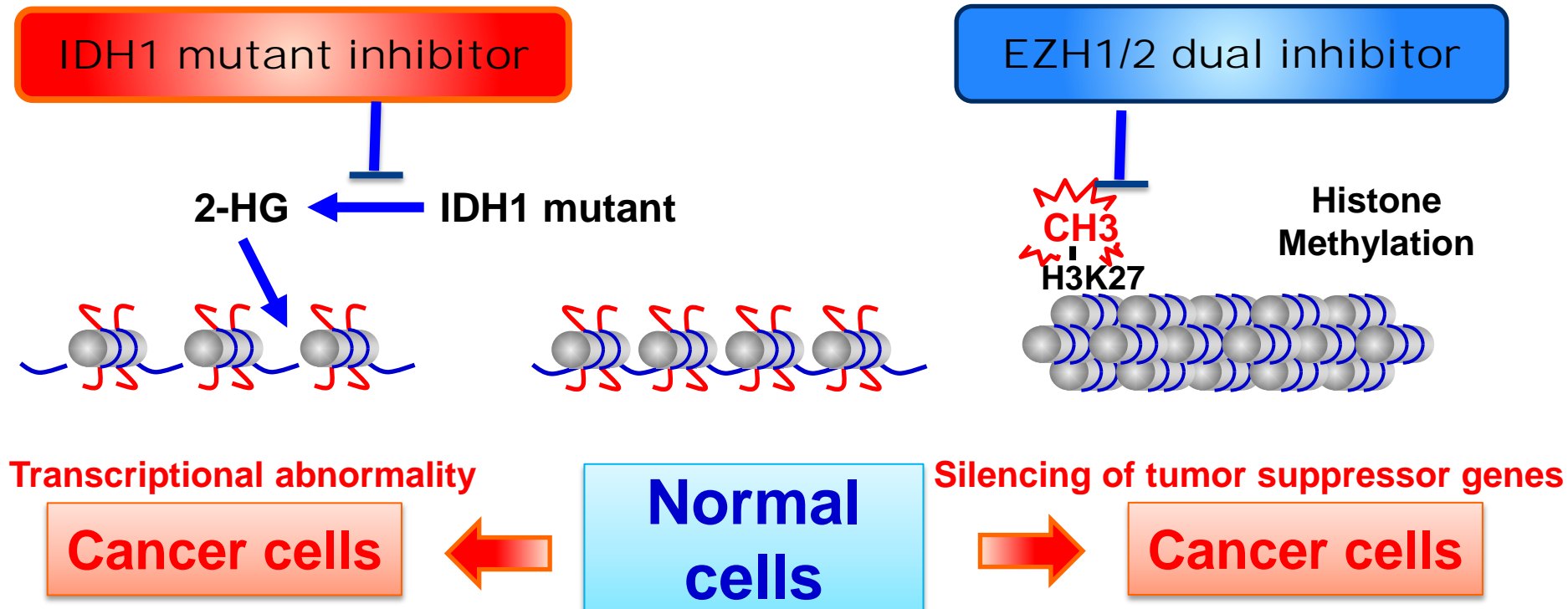
## Epigenetics

- IDH1 mutant inhibitor
- EZH 1/2 inhibitor



# Epigenetic Targeting of Cancer Cells

- IDH1 mutant inhibitor decreases 2-hydroxyglutarate (2-HG) and improve transcriptional abnormality
- EZH 1/2 inhibitor decreases histone methylation and increases transcription of tumor suppressor genes
- Clinical studies of both inhibitors planned for 2016

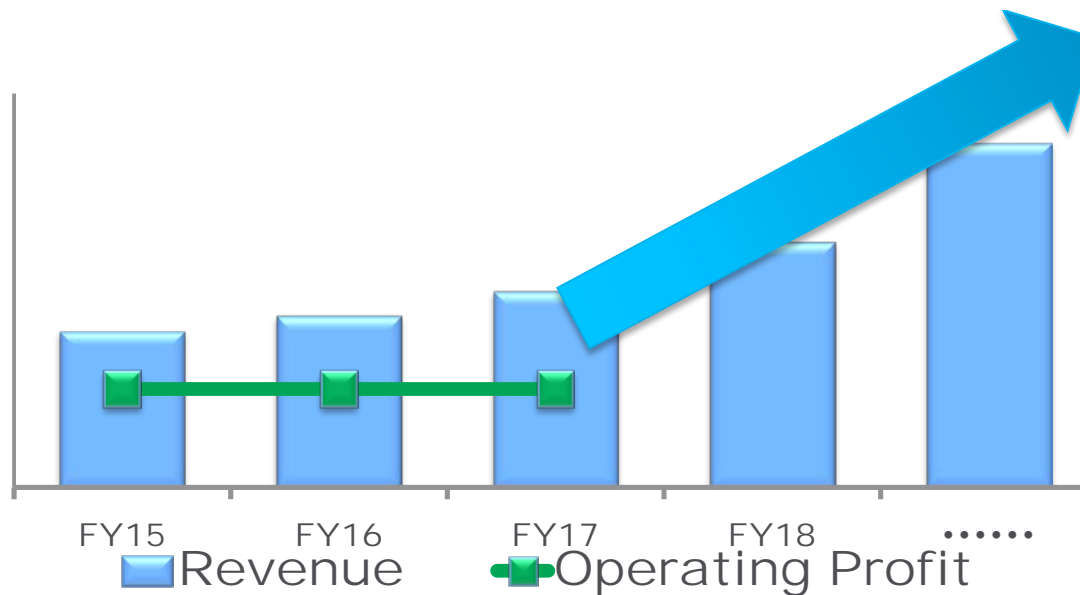


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# Next 5-year Business Plan

- ◆ Period: FY2016 – FY2020
- ◆ Contents:
  - Strategies for solid growth from FY2018
  - Improve profit-generating capability
  - Enhance R&D capabilities
  - Improve shareholder value (ROE) etc.
- ◆ Announcement : March 2016



# Business Priorities

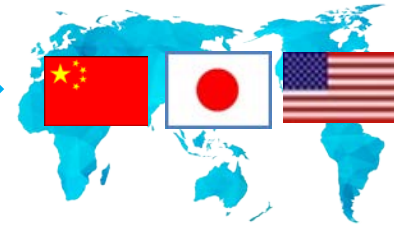
## Core Business

Concentrate on  
Innovative Business



## Core Regions

Invest in Priority Regions:  
Japan/US/China



## Core Capabilities

Enhance R&D Capabilities



# Passion for Innovation. Compassion for Patients.™

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