



The Growth Strategy of Shionogi

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President and CEO**



The Medium-Term Business Plan of SHIONOGI

Shionogi Growth Strategy 2020 (SGS2020)

**Grow as a drug discovery-based
pharmaceutical company**

◆ **Top-line Growth**

- Clear priorities and focused resourcing
 - Sales areas: Japan and US
 - Therapeutic areas: infectious disease and pain/CNS
- Approve and launch compounds in infectious diseases and pain/CNS areas

◆ **Bottom-line Growth**

- Continued improvement of business operations

Growth by Leveraging the Strengths of Shionogi



Strengths for the needs of society

- Small-molecule drug discovery
- Infectious disease, pain/CNS

Sales areas for driving growth

- Japan
- US



Wide variety of business partners



Global Health Innovative Technology Fund



Medium-term Business Plans since FY2000



1st stage: Laying the foundation (FY2000 - 2004)

- ◆ Focused specifically on the prescription drug business
- ◆ Established infrastructure for global development

2nd stage: Accelerating toward significant strides (FY2005 - 2009)

- ◆ Focused R&D efforts on priority therapeutic areas (infectious diseases, pain, and metabolic syndrome)
- ◆ Acquired US-based Sciele Pharma, Inc.

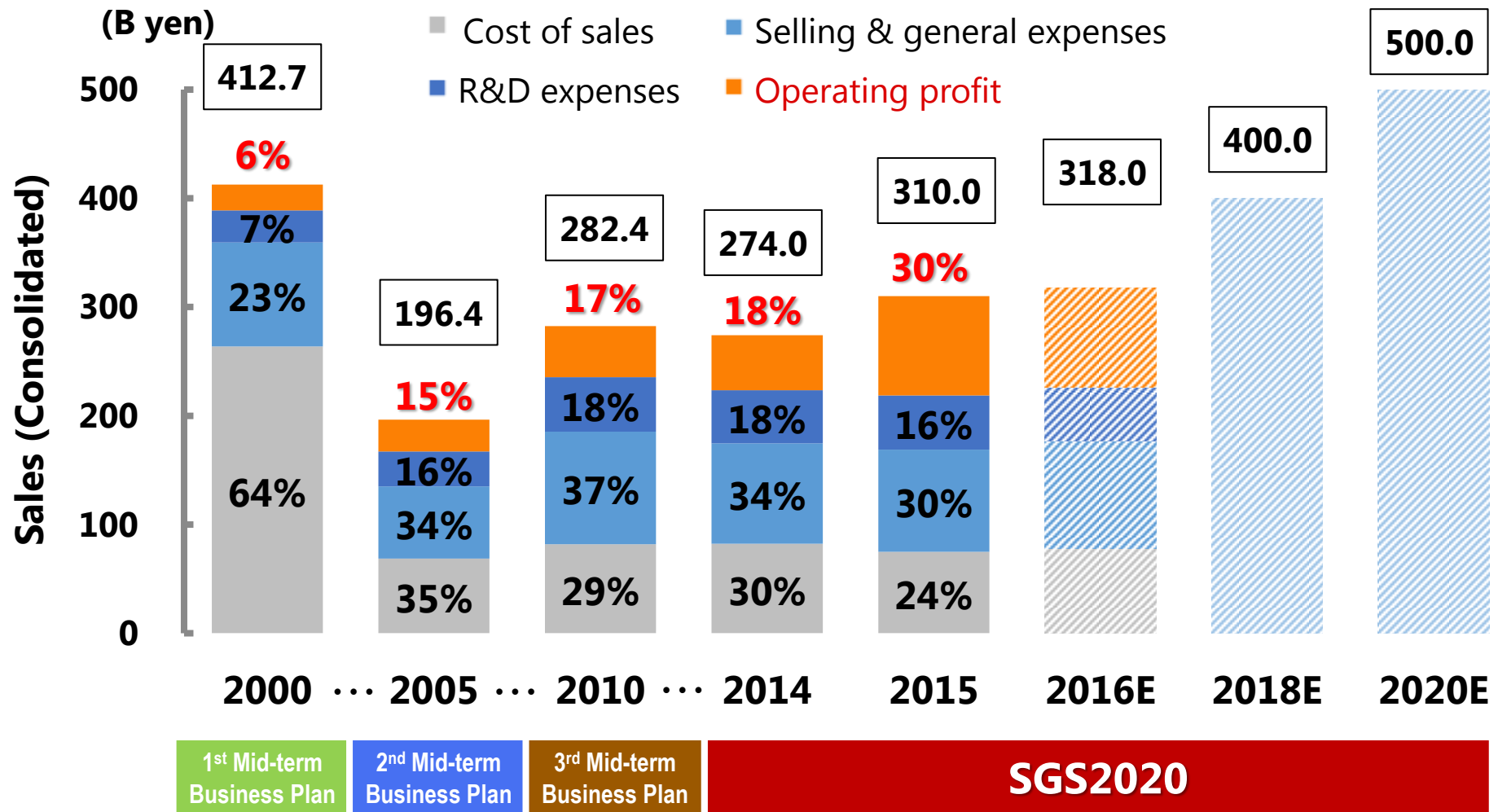
3rd stage: SONG for the Real Growth (FY2010 - 2013)

- ◆ Established a new scheme for anti-HIV drugs
- ◆ Modified Crestor® royalty structure
- ◆ Launched Tivicay® and Osphena®

4th stage: Shionogi Growth Strategy “SGS2020” (FY2014 - 2020)

- ◆ Sales and therapeutic areas based on our strengths and the need of society (Sales area: Japan and the US, therapeutic area: infectious disease and pain/CNS)
- ◆ Three-year rolling plan to respond to rapid environmental changes

Continued Improvement of Business Operations



Worldwide Changes in the External Environment



**Aging societies
worldwide**

**Economic pressure
on healthcare
systems**

**Increasing impact of
drug-resistant
bacteria and viruses**

**Rising social needs
for longer healthy
life expectancy**

Response to Rapid Environmental Changes



FY2015

FY2016

FY2017

FY2018

FY2019

FY2020

Growth led by FIC and LIC compounds

Shift Gears for Growth

Clear priorities and
focused resourcing

*Evolution of
Core Business*

Ordinary income and ROE
targets are projected to be
reached two years ahead of
schedule

[FY2015 results]

Net sales **310.0** B yen

Ordinary income **100.9** B yen

ROE **13.6%**

[FY2018 targets]

Net sales **400.0** B yen

Ordinary income **125.0** B yen

ROE **15%**

[FY2020 targets]

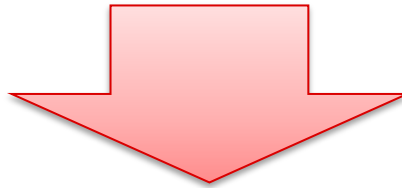
Net sales **500.0** B yen

Ordinary income **125.0** B yen

ROE **15%**

**Three-year rolling plan: Reflect current
results and business environment**

**Experience in overcoming
the Crestor[®] Cliff**



**Management skills with
strong revenue base**

Revenue base

- **Royalty income (Crestor[®] and HIV franchise)**

Japanese business

- **Scale**  **Efficiency**

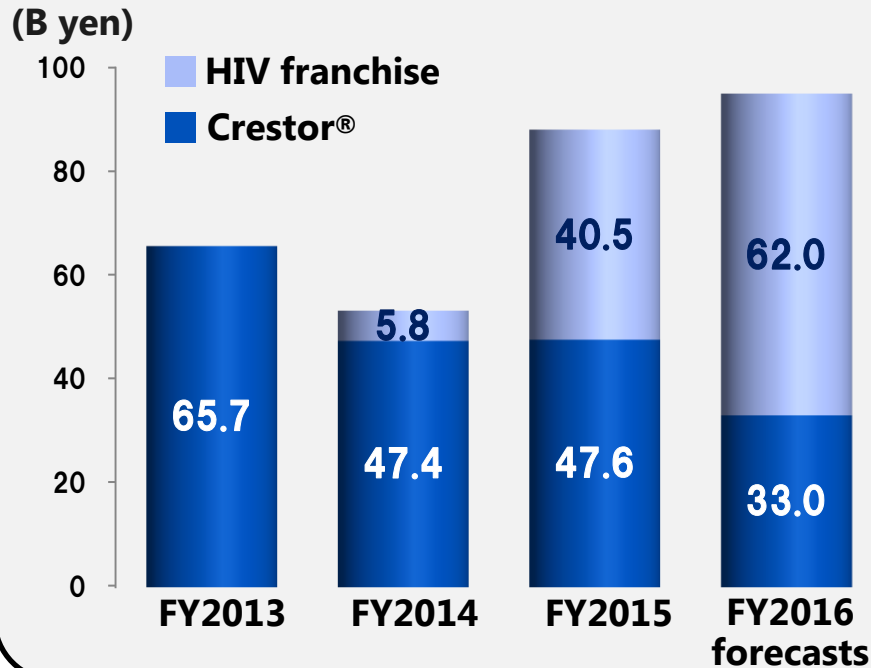
More compact (efficient)

- **R&D activities**
- **Productivity**

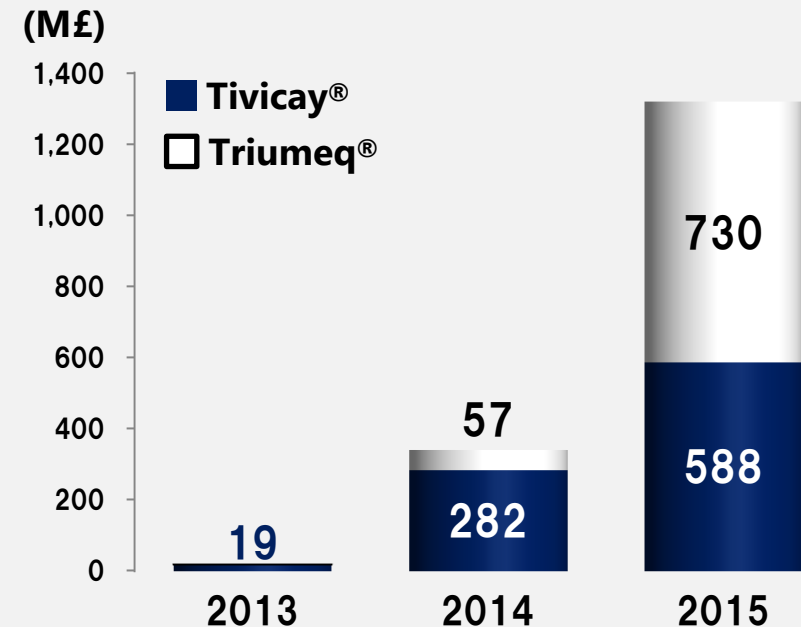
Revenue Base: Expanding Royalty Income



[Royalty from ViiV and AstraZeneca]



[Global sales of HIV franchise]



- ◆ Growth of the HIV franchise covers the royalty income decrease in Crestor®
- ◆ Sales of the HIV franchise continue to increase strongly worldwide

History and Future Strategy of HIV Therapy



1996: Established ART using three HIV medicines from at least two different drug classes

- Converted HIV to a chronic disease, with patients surviving long-term with HIV

Development strategy of anti-HIV drugs: improvement in the precision of ART

- Development of new drugs with better safety, efficacy and resistance profile
- Combination drugs to improve the convenience for patients living with HIV

2013: Developed and launched dolutegravir (DTG)

- Good efficacy and safety
- Key drug with the potential to become LIC
- Expected good resistance profile demonstrated in post-launch experience

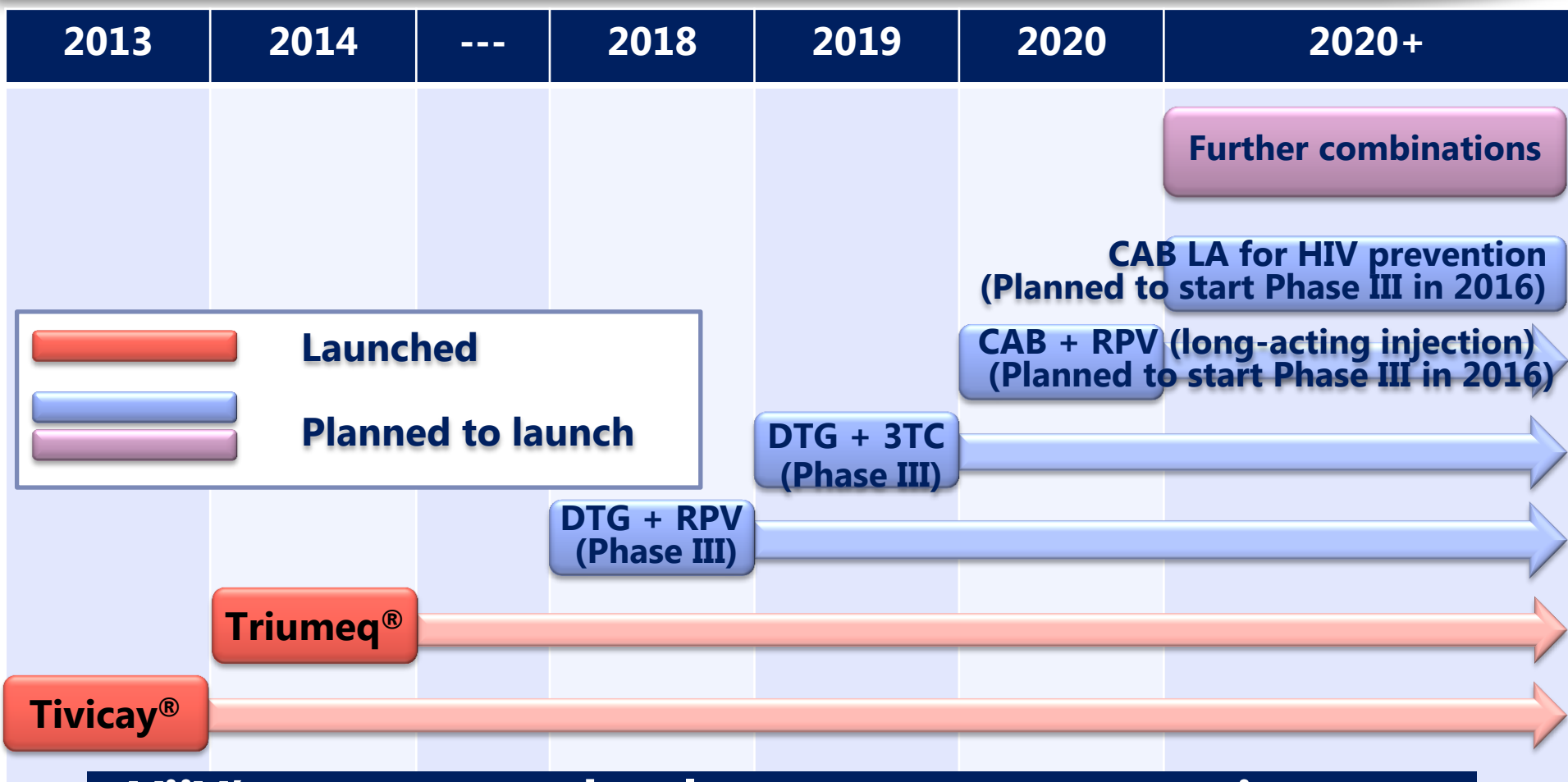
**ViiV's strategy:
New treatment regimens**

- Two-drug single tablet regimens with DTG at the core therapy
- Development of cabotegravir LA

**Competitors' strategy:
Improve current regimens or
withdraw from development**

- Improvement of adverse effects
- Seeking new agents that could compete with DTG
- Withdrawal from HIV research, transfer HIV assets

HIV Integrase Inhibitor Franchise



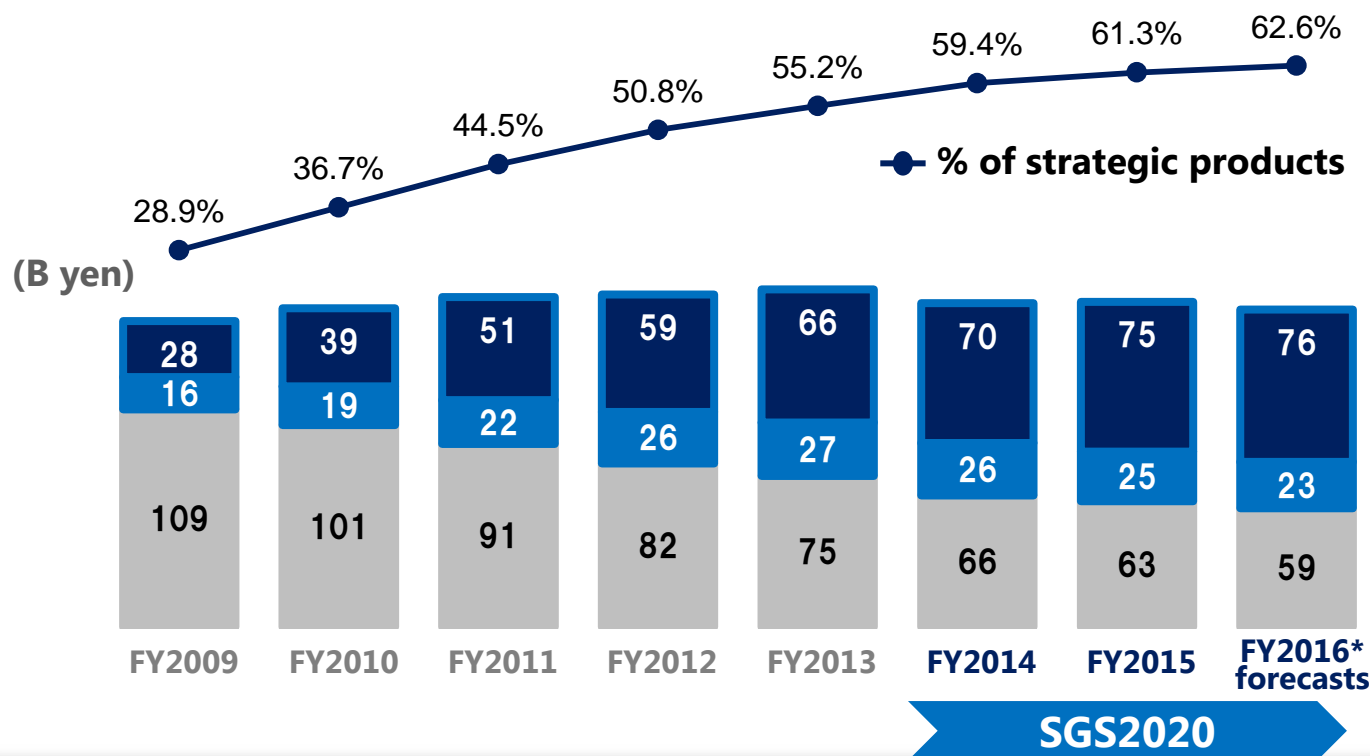
ViiV's strategy to develop new treatment regimens to address the needs of people living with HIV places our HIV integrase inhibitors at the core of therapy

Sales Growth of Strategic Products in Japanese Market



- ◆ Increase sales of strategic products by improving sales force impact
- ◆ Transfer of marketing and manufacturing rights for twenty-four long-listed drugs

- 3 products (oncology) ⇒ Nichiiko (July 2016)
- 21 products (CNS etc.) ⇒ Kyowa Pharmaceutical (December 2016)



Strategic products

Key strategic products

Crestor®

Irbetan® franchise

Cymbalta®

OxyContin® franchise

Finibax®

*Differin®

Pirespa®

Rapiacta

Other products

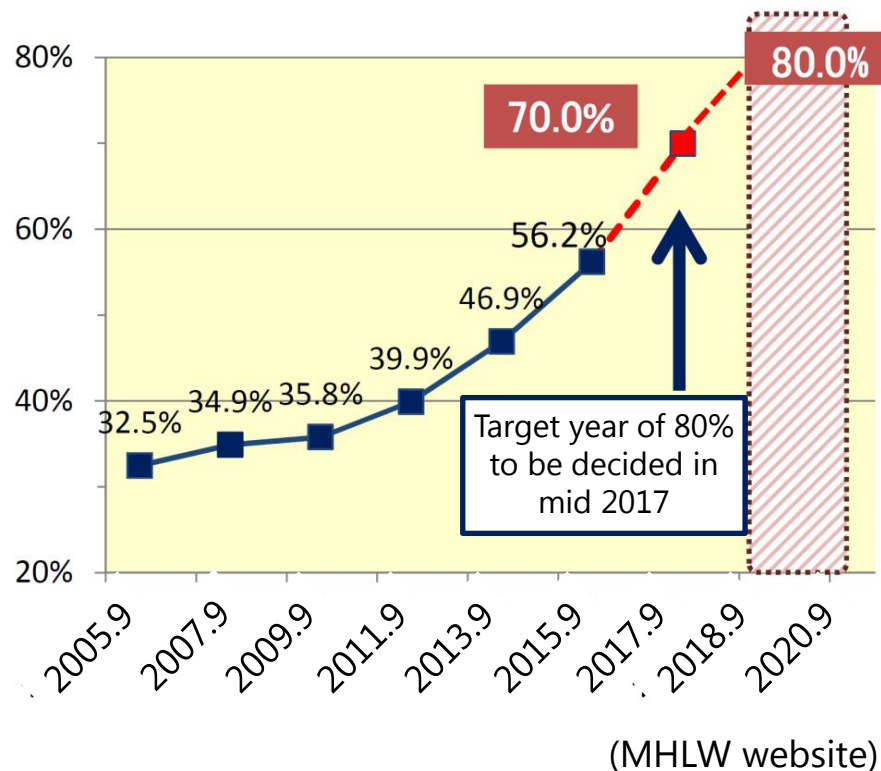


Rationale for the Transfer of 24 Long-listed Drugs



Business models depending on long-listed drugs is becoming more challenging due to the increasingly rapid penetration of generic drugs

Change in the generic drug ratio



Acceleration of generic drug use by the government

<NHI price revision in 2016>

- **Additional price cut** for long-listed drugs
- Lowering prices for the first generics (**50% of the price of branded drugs**)



Shionogi's Strategy: Continue to contribute to the advancement of healthcare and treatment by creating new drugs in infectious disease and pain/CNS areas

New Products to Drive Future Growth



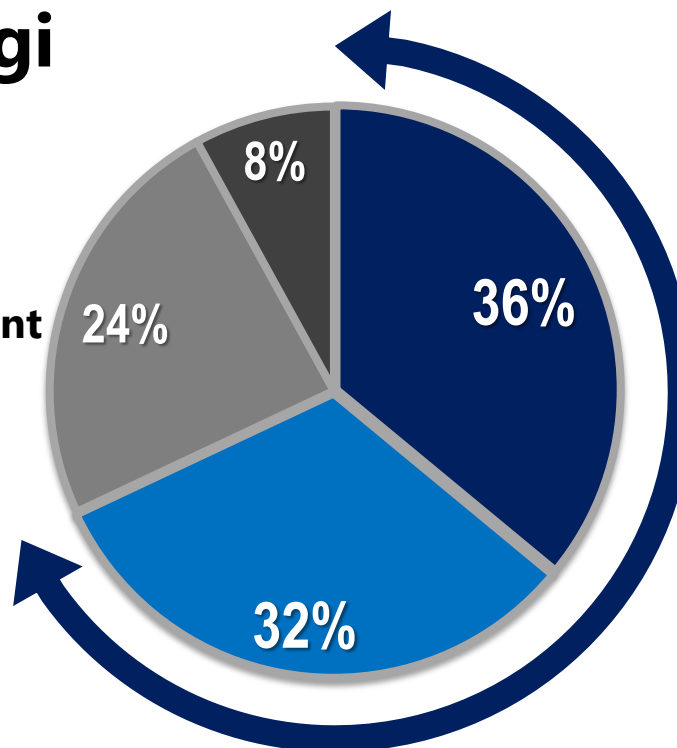
Target milestone for launch of new product

FY2016		FY2017		FY2018	
Japanese business					
Crestor® OD tablet Cymbalta® Pain associated with chronic low back pain Pain associated with osteoarthritis ISODINE® brand ethical products		Naldemedine Guanfacine hydrochloride Oxycodone Tamper resistant formulation Moderate to severe chronic pain		S-033188 Lisdexamfetamine Actair® Pediatric patients with perennial allergic rhinitis	
US business					
		Naldemedine S-649266 Lusutrombopag		Osphena® Further indication: vaginal dryness associated with postmenopausal VVA	
Global out-licensed products					
				Dolutegravir + rilpivirine	

◆ More than half of our pipeline* was discovered within Shionogi

(Origin/Development)

- In-house/In-house
- Collaboration/Co-development
- In-license/In-house
- In-license/Co-development



Percent of pipeline products discovered in Shionogi research laboratories

68%

[As of Mar. 2016]

- Leveraging our capabilities in small molecule drug discovery
- Open innovation: Identify novel drug seeds and develop them

S-033188 (Drug Candidate for Influenza Virus Infection)



S-033188

Indication

Influenza virus infection

Mechanism of action

Cap-dependent endonuclease inhibition
(Novel mechanism of action)

Special characteristics

Broad and potent antiviral activity against seasonal influenza A and B viruses as well as highly pathogenic avian influenza virus
Single oral dose treatment

Stage

Japan: Phase II Completion, US: Phase I

Plan

Japan: Phase III, Global: Phase III: FY2016
Planned NDA submission in Japan: FY2017

Notes

Designated for "Priority review system" by the MHLW
Out-licensed to Roche except for Japan and Taiwan

HIV-franchise, Crestor[®], Cymbalta[®], Anti-bacteria

- Modified contracts with alliance partners to produce win-win outcomes

Naldemedine

- Exploring partnering options to maximize the value of naldemedine

BACE inhibitor

- Research collaboration with Janssen

Global perspective

- Experience and expertise from Tamiflu®
(Development, Supply, Commercialization)

Development rights by Shionogi

- Shionogi retains the rights to develop S-033188 under the “priority review system” in Japan

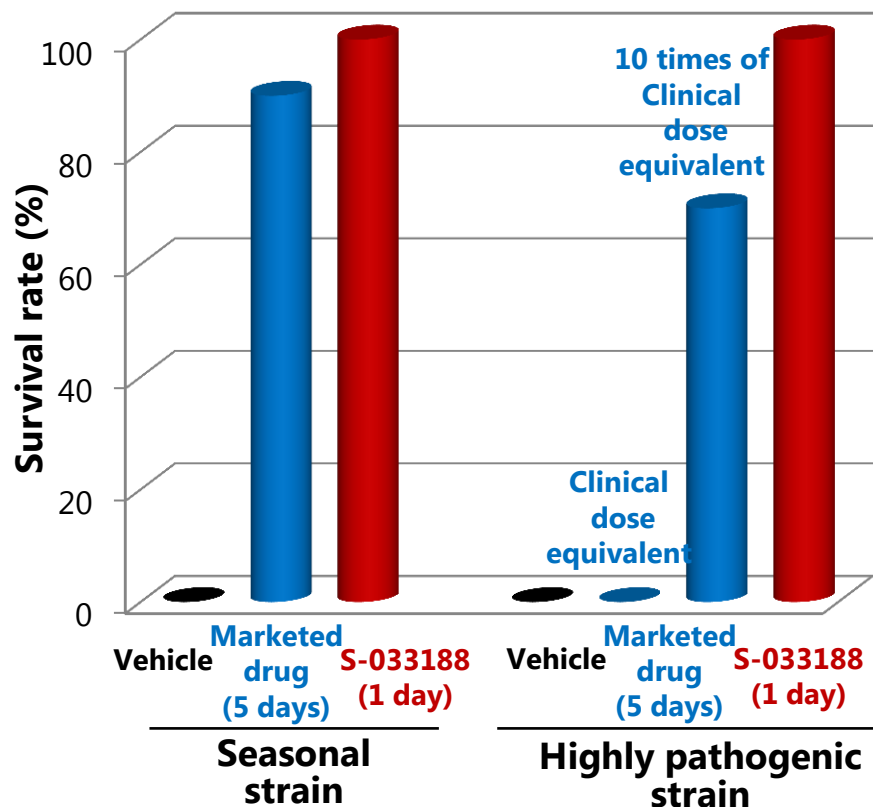


- Strengthening capability and experience in development in our prioritized therapeutic areas

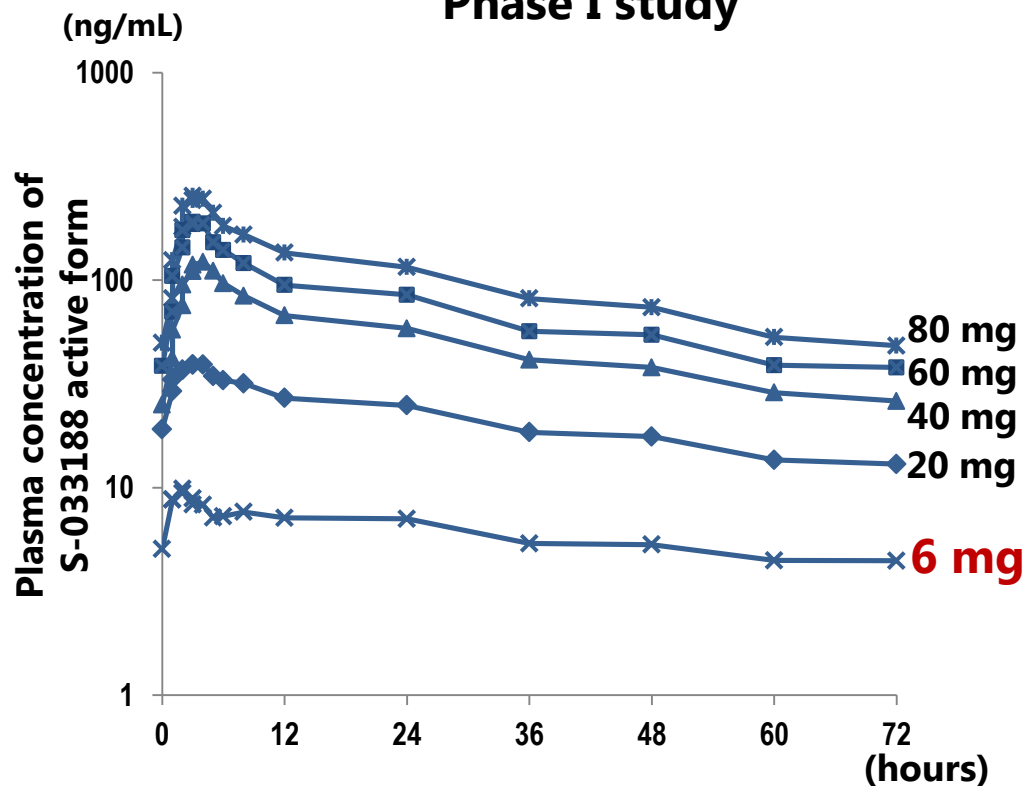
S-033188: Non-Clinical & Phase I (Single Dose) Study



Survival rate in mice infection model (14 days after dosing)



Plasma concentration in Phase I study

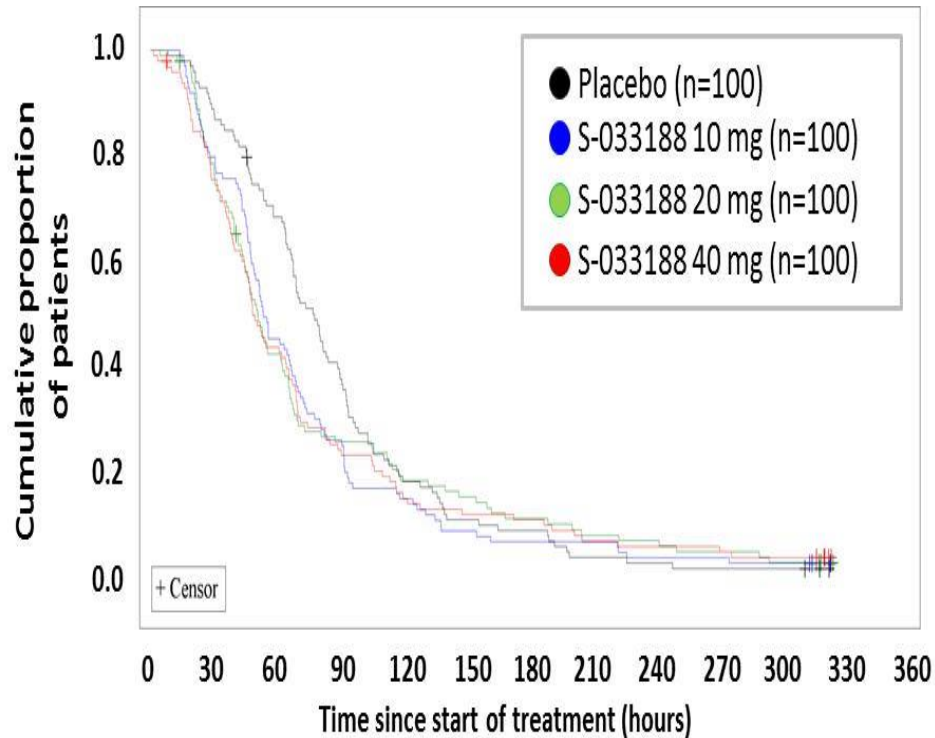


Single dose (6 mg) administration achieved plasma exposures that are expected result in efficacy surpassing currently marketed drugs

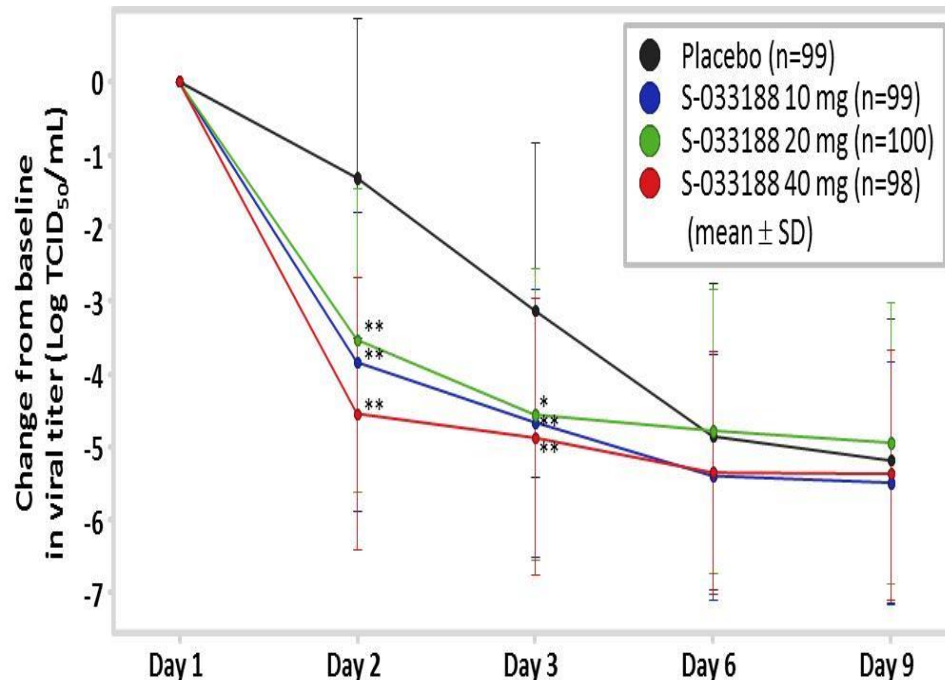
S-033188: Phase II Results



Time to alleviation of influenza symptoms



Change in the virus titer



**p<0.0001, *p<0.001 vs placebo
(van Elteren test, two-sided, covariates: smoking habit, composite symptom scores at baseline)

Pipeline (as of Aug. 2016)



Phase I		Phase II		Phase III		NDA submission
						【Global】
S-033188 Influenza virus Infection	S-120083 Inflammatory pain	S-649266 Multidrug-resistant Gram-negative bacterial infections	S-707106 Type2 diabetes	S-488210 Head and neck squamous cell carcinoma	S-649266 Multidrug-resistant Gram-negative bacterial infections	
S-237648 Obesity	S-117957 Insomnia	S-222611 Malignant tumor	S-588410 Bladder cancer	Osphena® Vaginal dryness associated with postmenopausal VVA	Lusutrombopag Thrombocytopenia	Naldemedine Opioid-induced constipation
Non-clinical						【In Japan】
	Oxycodone Tamper resistant formulation			S-649266 Multidrug-resistant Gram-negative bacterial infections		
	S-120083 Inflammatory pain	S-649266 Multidrug-resistant Gram-negative bacterial infections		Lisdexamfetamine ADHD (pediatric)	Guanfacine hydrochloride ADHD (adult)	Naldemedine Opioid-induced constipation
Antibody drug candidate against Pseudomonas	S-010887 Neuropathic pain	S-033188 Influenza virus Infection	S-237648 Obesity	Actair® Pediatric patients with perennial allergic rhinitis	Oxycodone Moderate to severe chronic pain	Cymbalta® Pain associated with osteoarthritis
NTE Inhalation	S-600918 Neuropathic pain	S-525606 Allergic rhinitis caused by Japanese cedar allergen	S-588410 Bladder cancer	S-555739 Allergic rhinitis	S-588410 Esophageal cancer	Guanfacine hydrochloride ADHD (pediatric)
		Infectious diseases	Metabolic disorder			
		Pain/CNS	Frontier			

Pipeline (as of Aug. 2016)

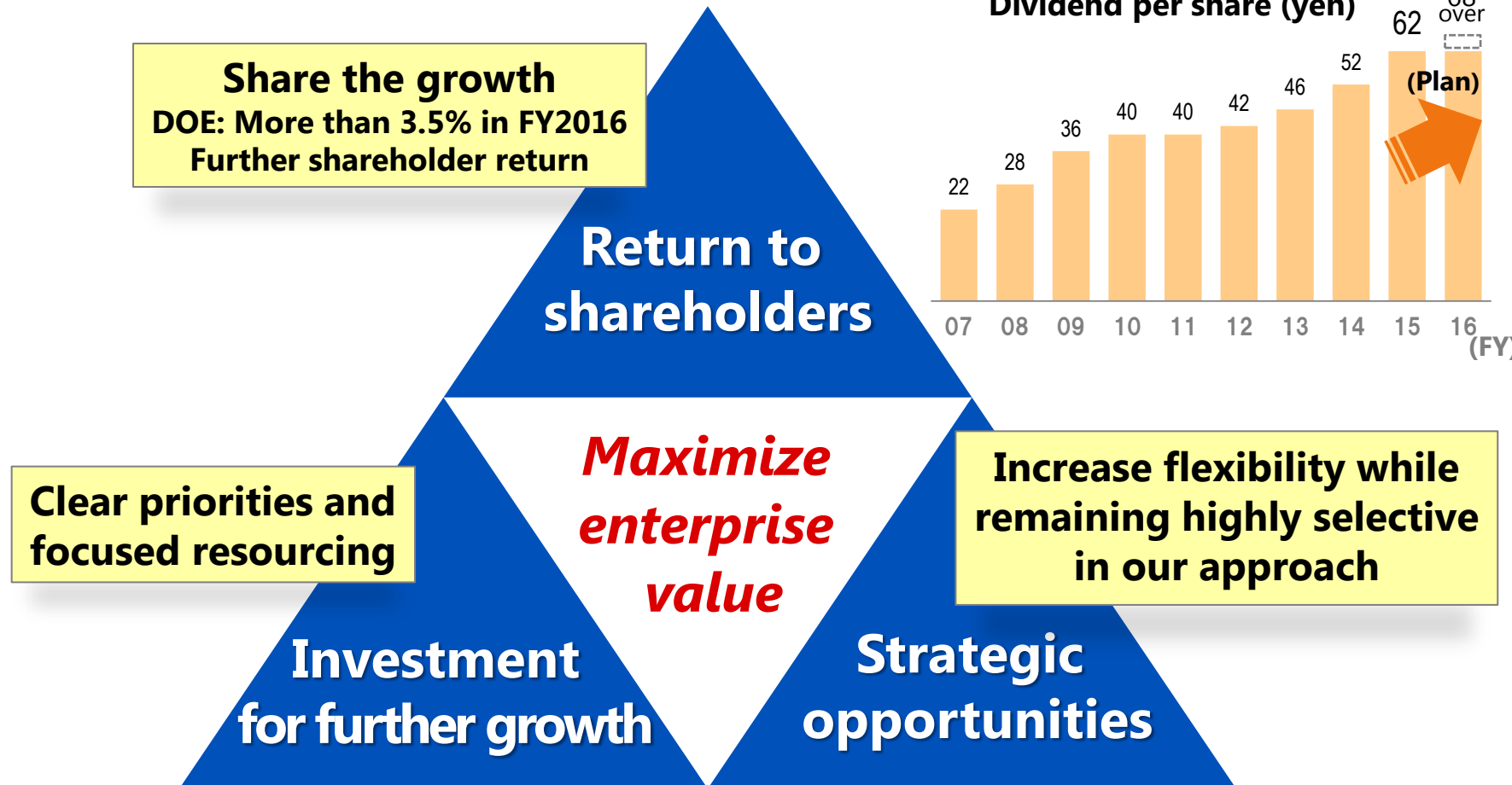


Non-clinical	Phase I	Phase II	Phase III	NDA submission
<p>【Out-licensed】</p> <div> GSK3342830 Multidrug-resistant Gram-negative bacterial infections </div> <div> Janssen/Shionogi Project compound Alzheimer's disease </div>		<div> Cabotegravir + rilpivirine LAP Treatment for HIV infection </div> <div> Cabotegravir LAP Prevention for HIV infection </div>	<div> Dolutegravir + rilpivirine Treatment for HIV infection </div> <div> Janssen/Shionogi BACE inhibitor Alzheimer's disease </div>	

Balancing Shareholder Return and Investment for Our Future



Maximize enterprise value by balancing three key factors



Forward-Looking Statements

- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
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