



1st Half of Fiscal 2016 Financial Results

November 1, 2016

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President and CEO



Agenda



- **1st Half FY2016 Financial Results**
- **FY2016 Financial Forecasts**
- **Dividend Forecasts**

Agenda

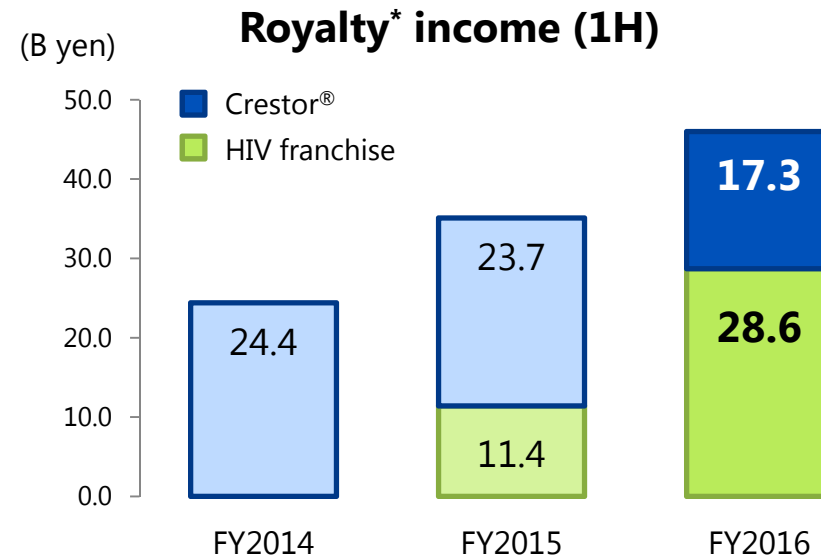
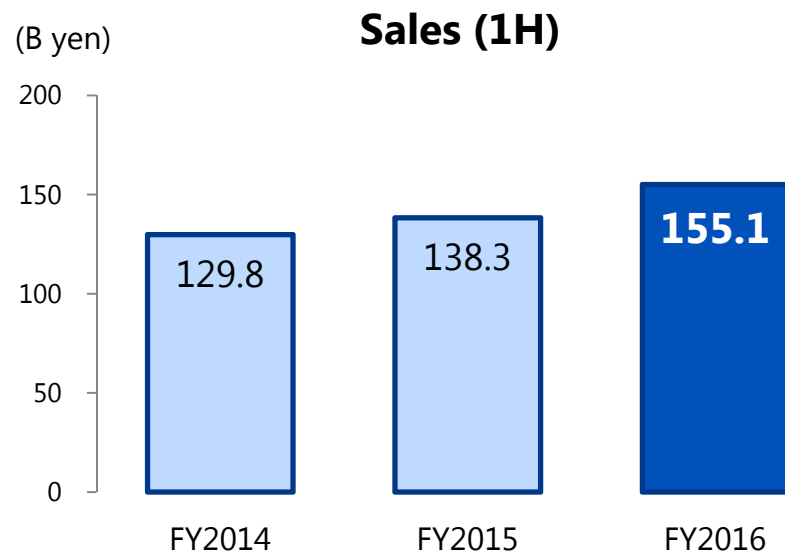


- **1st Half FY2016 Financial Results**
- FY2016 Financial Forecasts
- Dividend Forecasts

Summary of 1H FY2016: Strong Top-line Growth



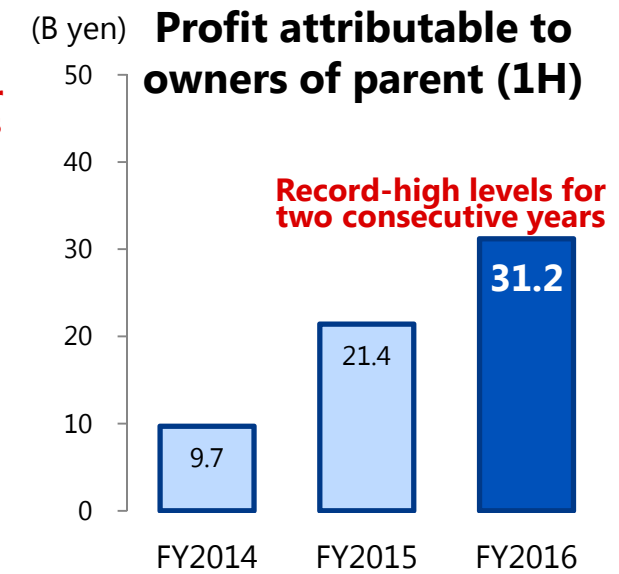
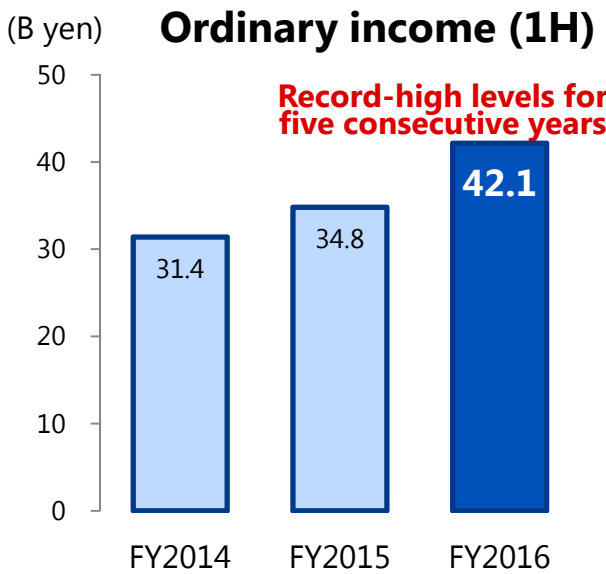
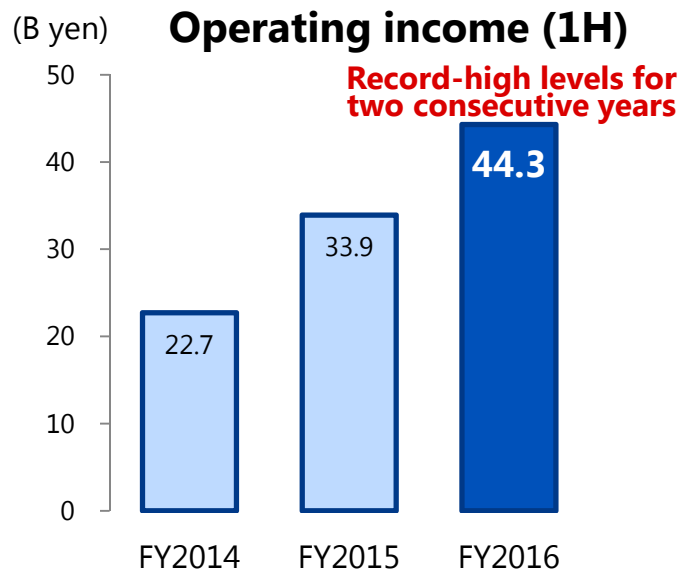
- Net sales: **155.1 B yen** vs 1H forecasts (107.0%)
- Royalty* income: **46.0 B yen** vs 1H forecasts (108.2%)



Summary of 1H FY2016: Profits Higher Than the Levels Achieved in 1H of Prior Fiscal Year



- Operating income: **44.3 B yen** (134.2%) vs 1H forecasts
- Ordinary income: **42.1 B yen** (127.7%) vs 1H forecasts
- Profit attributable to owners of parent: **31.2 B yen** (148.6%) vs 1H forecasts



Financial Results (Consolidated)



(Unit B yen)

	FY2016			FY2015 results	YoY change (%)
	1H Forecasts*	1H results	Progress vs forecasts		
Sales	145.0	155.1	107.0%	138.3	12.2%
Operating income	33.0	44.3	134.2%	33.9	30.5%
Ordinary income	33.0	42.1	127.7%	34.8	21.1%
Profit attributable to owners of parent	21.0	31.2	148.6%	21.4	45.9%

Exchange rate (average)	FY2016 forecasts	FY2016 1H results
USD (\$) – JPY (¥)	110	105.26
GBP (£) – JPY (¥)	155	144.81
EUR (€) – JPY (¥)	130	118.13

Net Sales Increased by 12.2% to 16.8 B Yen



(Unit B yen)

Prescription drugs YoY changes
+0.8 B yen, +0.9%

- Growth of strategic products

Royalty income YoY changes
+13.1 B yen, +35.2%

- **Crestor® (6.4) B yen:** Generic entries in the US
- **HIV franchise +17.2 B yen:** Continued growth
- Others
 - Licensed out early research program to Sanofi
 - Received milestone payment from GSK

Overseas subsidiaries/export YoY changes
+0.6 B yen, +3.7%

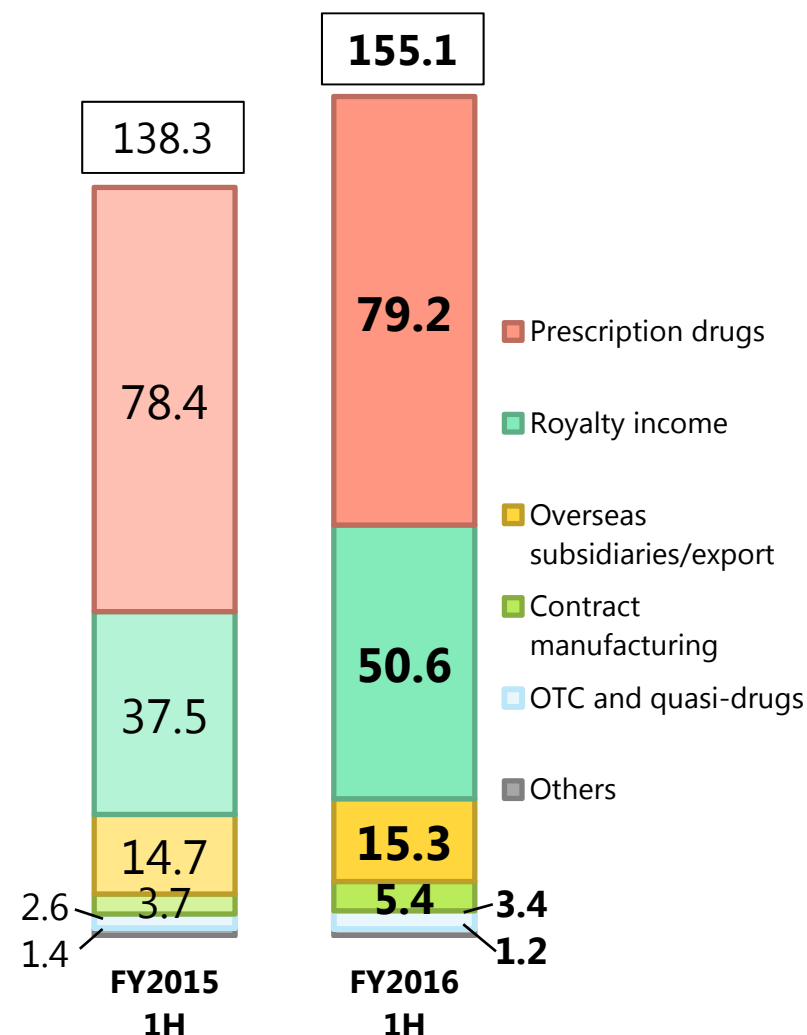
- **SI:** Royalty from authorized generic was higher than expectation

Contract manufacturing YoY changes
+1.7 B yen, +46.4%

- Growth of API for dolutegravir

OTC and quasi-drugs YoY changes
+0.8 B yen, +33.3%

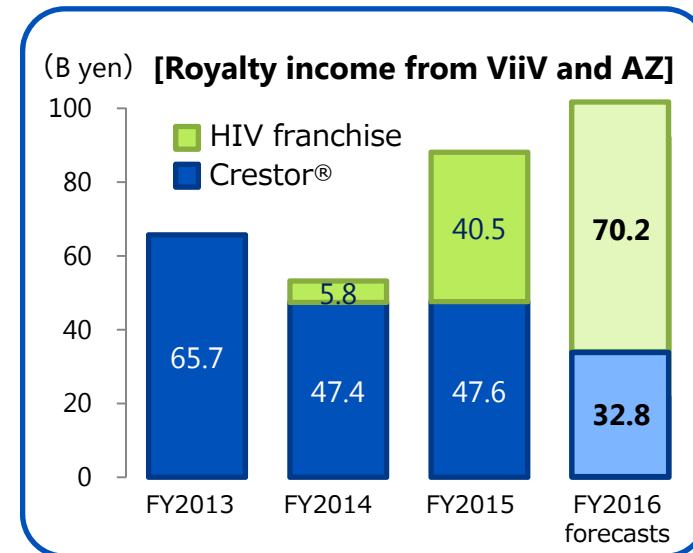
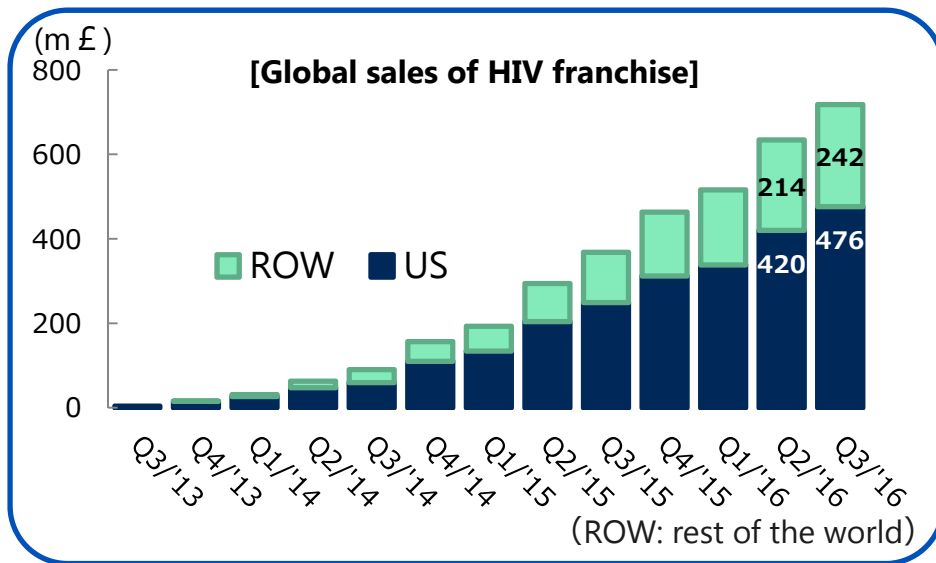
- **ISODINE®**, new products were launched in Sep.



Strong Growth in HIV Franchise Covers the Royalty Income Decrease in Crestor®



- Royalty income from ViiV increased due to HIV franchise sales expansion, and covered the royalty income decrease in Crestor®
- Development of two-drug single tablet regimens with DTG, and cabotegravir LAP for treatment and prevention



Developed into strong revenue base contributing for a mid- to long-term growth

Prescription Drugs Increased by 0.9% to 0.8 B Yen



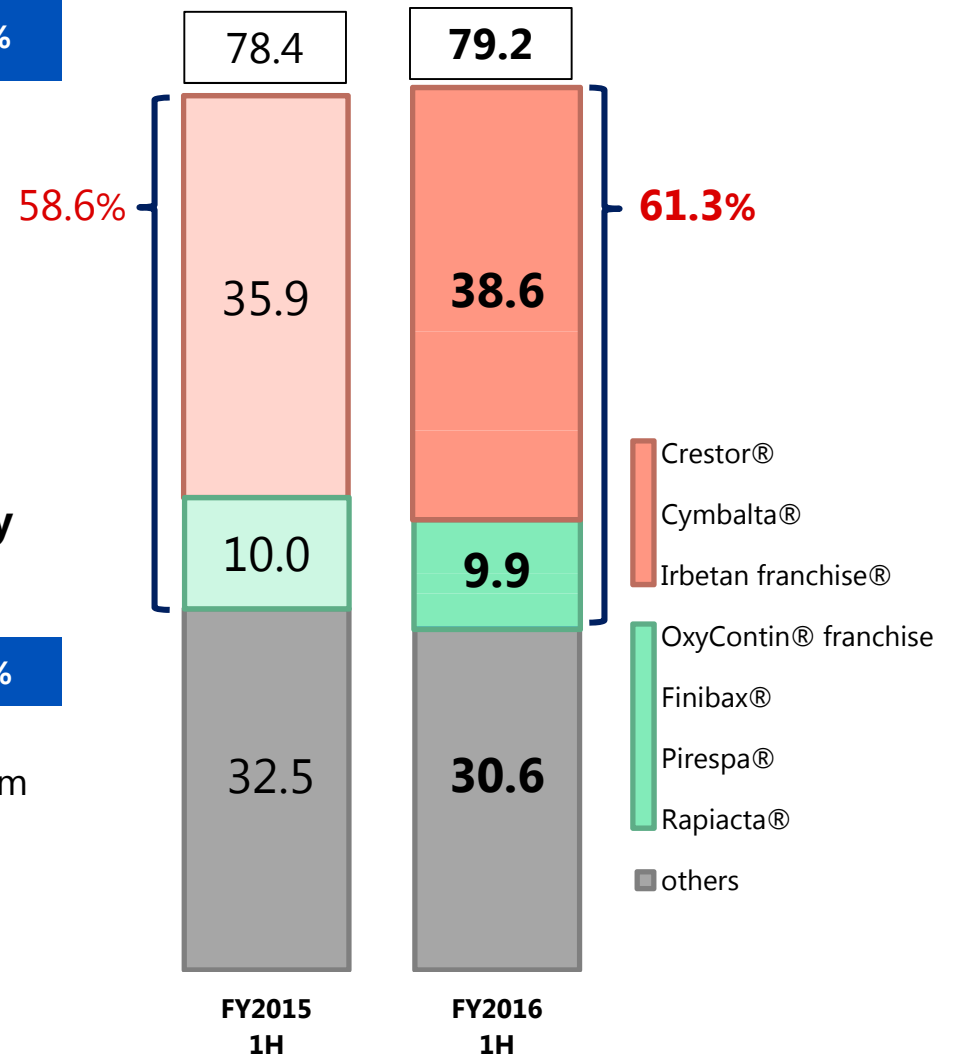
(Unit B yen)

Strategic products YoY changes +2.6 B yen, +5.7%

- **Crestor® increased to 1.5 B yen**
 - Launched OD Tablets
 - Activation of marketing activities
- **Cymbalta® increased to 1.7 B yen**
 - Focused resources on maximizing the product value
 - Expanded sales in depression and depressive symptoms
 - Increased awareness in pain area
- **Percent of strategic products increased by 61.3%**

Other drugs YoY changes (1.9) B yen, (5.7)%

- **Increased in Mulpleta® adoption**
 - Mulpleta® alleviate burden by avoiding risks from blood transfusion
- **Government stockpiling of Rapiacta®**
(Recorded 1.3 B yen as sales of other drugs)



Operating Income increased by 30.5% to 10.4 B Yen, Higher Than the Levels Achieved in 1H of Prior Fiscal Year



(Unit B yen)

Cost of sales Cost of sales ratio: (1.4)%

- Increase of royalty income improved cost of sales ratio
- Cost of sales ratio excluding royalty income increased 0.2% due to product mix, NHI price revisions and expansion of contract manufacturing of API for dolutegravir

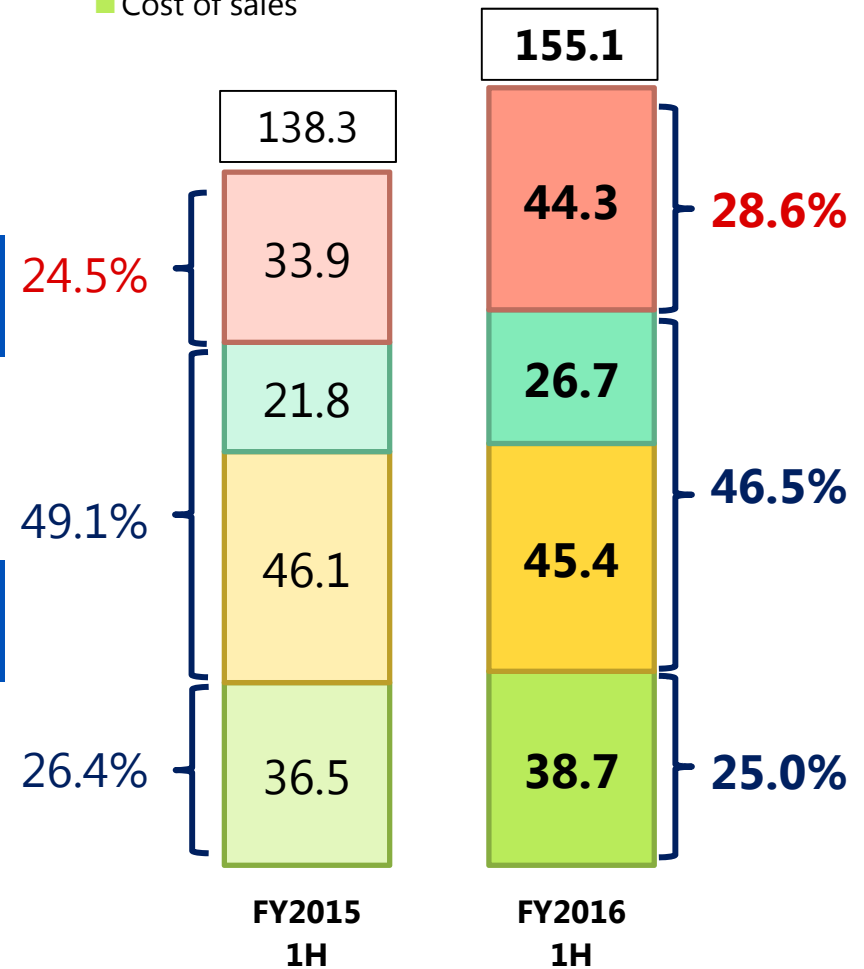
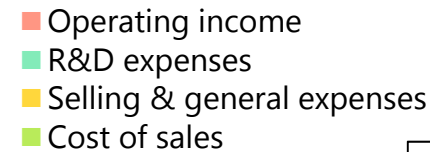
SG&A expenses SG&A expense ratio: (2.6)%

- Strategic investment by focusing on efficiency and prioritization and total cost management
 - Selling & general expenses ratio: (4.0)%
 - R&D expenses ratio: +1.4%

Operating income Operating income ratio: +4.1%

- Operating income was **44.3 B yen**: Higher than the levels achieved in 1H of prior fiscal year

Non-operating income and expenses: (2.1) B yen
 Ordinary income was **42.1 B yen**: Higher than the levels achieved in 1H of prior fiscal year



Target Milestones for FY2016



Areas	Product	As of Apr. 1, 2016	Target for FY2016
Infectious disease	Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections	Global: Phase II, III	US: NDA submission → US: NDA submission in preparation
	S-033188 Influenza virus infection	Japan: Phase II US: Phase I	Japan: Phase II completed US: Phase I completed Global: Phase III initiated, Japan: Phase III (pediatric) initiated
Pain/CNS	Guanfacine hydrochloride ADHD (pediatric)	Japan: NDA submission	Japan: Approval
	Cymbalta® Pain associated with osteoarthritis	Japan: NDA submission	Japan: Approval
	Naldemedine Opioid-induced constipation	Japan/US: NDA submission	Japan/US: Approval EU: NDA submission
	Oxycodone Treatment of moderate to severe chronic pain	Japan: Phase III	Japan: NDA submission
	Oxycodone Tamper resistant formulation	Japan: Phase I completed	Japan: NDA submission
	Lisdexamfetamine ADHD (pediatric)	Japan: Phase III	Japan: Phase III completed
Metabolic disorder	S-237648 Obesity	Japan: Phase II	Japan: Phase II completed US: Phase I initiated
Frontier	Lusutrombopag Thrombocytopenia associated with chronic liver disease	Global: Phase III	Global: NDA submission → Global: Phase III
	S-222611 Malignant tumor	EU: Phase I/II	EU: Phase I/II completed

New Products to Lead 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			<u>Cefiderocol (S-649266)</u> Osphena® Vaginal dryness associated with postmenopausal VVA <u>Lusutrombopag</u>		
Global out-licensed products								
						Dolutegravir + rilpivirine		

New Products to Lead Future Growth



Prepare for the launch of new products

Establish marketing platforms to maximize the value of new products

- **Cymbalta®**
 - Expanded indications: Pain associated with osteoarthritis
- **Naldemedine**
 - Prepare for launch and explore partner in the US
- **Guanfacine hydrochloride**
 - Initiate a project to establish presence in ADHD franchise (guanfacine hydrochloride and lisdexamfetamine)

Accelerating new drug development

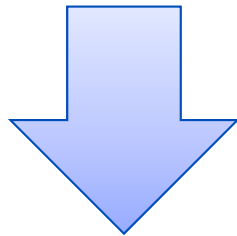
- **S-033188**
 - Initiate Global Phase III trials in 2016-2017 flu season
 - Designated for “priority review system” by MHLW
 - NDA submission in Japan in FY2017, as early as possible
- **Cefiderocol (S-649266)**
 - Pivotal cUTI and CR studies are ongoing

Maximize the Value of S-033188



Collaboration with Roche worldwide

- Roche brings experience and expertise from Tamiflu® (development, supply, commercialization)
- Shionogi brings its capability and experience in development in our prioritized therapeutic areas



Modified the global development plan to utilize the “priority review system” (SAKIGAKE designation) in Japan

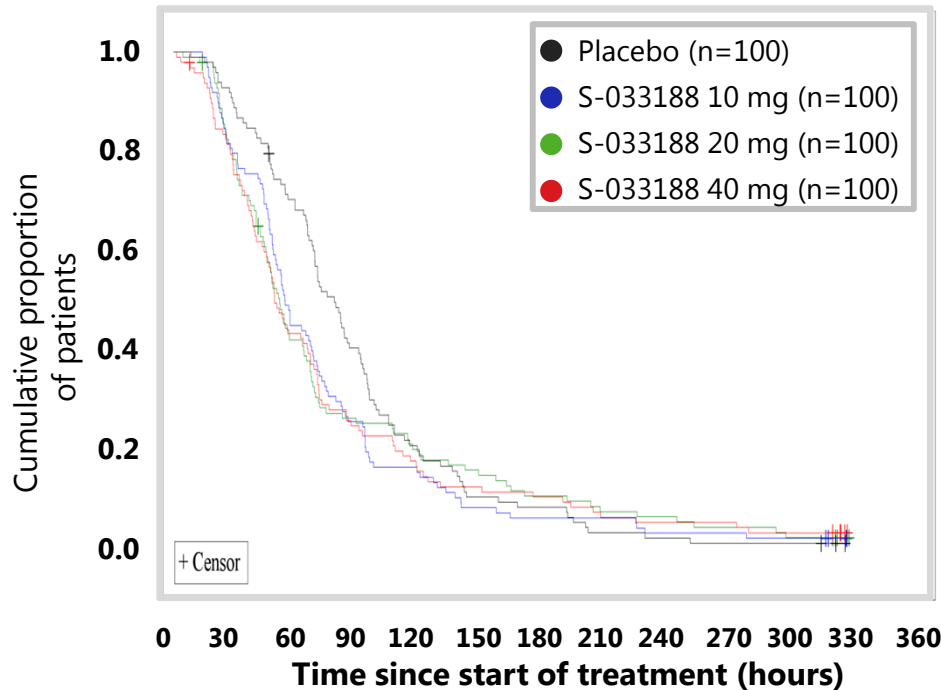
Progressing global phase III studies led by Shionogi

- Scientific advice with MHRA, BfArM and end of Phase II meeting with FDA have been completed
- Shionogi will pay development costs and will be eligible to receive milestone payments from Roche depending on the outcome of the studies

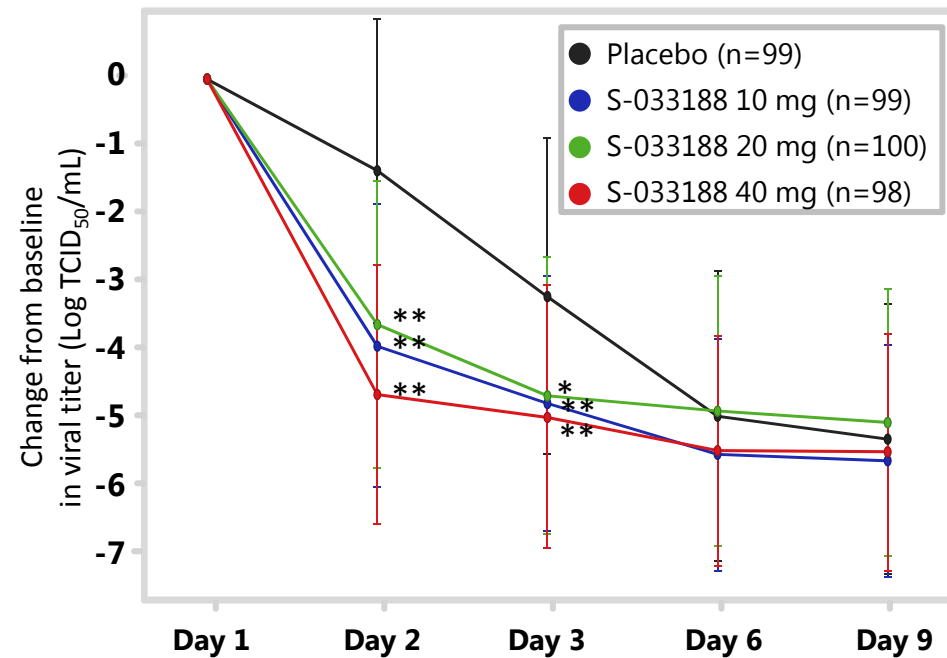
S-033188: Phase II Results



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)

**Conduct Global Phase III trials in 2016-2017 flu season
NDA submission in Japan in FY2017, as early as possible**

Protocol of S-033188 Phase III Trials



	Otherwise healthy study	High risk study
Study Patient	Uncomplicated otherwise healthy influenza patients aged 12-64years 0 – 48 hr from onset	Uncomplicated high risk influenza patients aged >12years 0 – 48 hr from onset
Season	2016/2017 flu season	From 2016/2017 to 2017/2018 flu season
Countries	Japan, US and Asia	All region including Japan, US and EU
Enrollment	About 1,500	About 2,200
Compound	① S-033188 : Receive two or four 20-mg S-033188 tablets single dosing on Day 1 ② Placebo ③ Oseltamivir : Receive 75-mg oseltamivir twice a day on Days 1 to 5	
Primary Outcomes	<ul style="list-style-type: none"> Time to improvement of 7 major flu symptoms : compared to placebo 	
Secondary Outcomes	<ul style="list-style-type: none"> Time to improvement of 7 major flu symptoms : compared to oseltamivir Virological parameters : compared to placebo and oseltamivir 	
Note	Participants aged 12 to 19 years will be divided into ① or ② groups	Considered to be high risk of flu complications as below <ul style="list-style-type: none"> Adults aged >65 years Residents of long-term care facilities(eg, nursing homes) Having designated underlying diseases Morbid obesity (BMI≥ 40), etc.

Focusing resources on the fastest development plan in order to deliver the novel flu drug to patients

Shionogi's Strength in Forming Alliances Maximizes Portfolio Value



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

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

Naldemedine

- Explore partnering options to maximize the value of naldemedine

BACE inhibitor

- Research collaboration with Janssen

Early stage frontier research program

- Licensed out to Sanofi
→ Focusing resources on our core research therapeutic areas

Basic Strategy in FY2016 and 1H Achievements



- **Basic Strategy in FY2016**

Continue growth based on increasing royalty income and improved cost management and

Strengthen and enhance Japanese/overseas business

- **1H Achievements**

Strengthen and enhance Japanese business

- Cymbalta® led the sales expansion of strategic products
- Transfer of long-listed drugs
- Progress in S-033188 development

Strengthen and enhance overseas business

- Naldemedine: Acceptance of NDA in the US
- PDUFA date: Mar. 23, 2017
- Osphena®: Focusing resources on high-potential areas

Royalty

- Crestor® royalty contributes until 2020
- Sales of HIV franchise expands very smoothly
- Reduced the negative impact of exchange rate by foreign exchange reservations

Cost management

- Total cost management
- Profits higher than the levels achieved in 1H of prior fiscal year

Agenda



- 1st Half FY2016 Financial Results
- **FY2016 Financial Forecasts**
- Dividend Forecasts

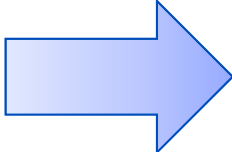
Response to Rapid Environmental Changes



Revenue base

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

Japanese business

- **Scale**  **Productivity**

More compact

Evolve the “clear priorities and focused resourcing”

- **R&D activities**
- **Business operations**

Actions to Achieve FY2016 Business Plan



Strengthen and enhance Japanese business

- **Cymbalta®**
 - Plan to expand indications: Pain associated with osteoarthritis
- **ADHD**
 - Plan to receive NDA approval for guanfacine hydrochloride
 - Establish platform for the launch

Strengthen and enhance overseas business

- **Naldemedine**
 - Continue to explore partnering options
 - Establish platform for the launch
- **Osphena®**
 - Expand market share
 - Continue Phase III clinical study for vaginal dryness

Global development

- **S-033188**
 - Initiate global Phase III trials
- **Cefiderocol**
 - Strong commitment to AMR issue

Cost management

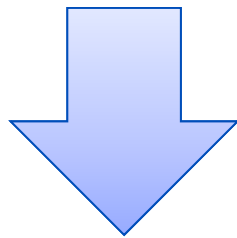
- Focus resources on high priority business activities
- Implement the new cost management scheme which combines general expenses and R&D expenses into one unified expense budget

Key Points of Revision of FY2016 Financial Forecasts



Increased from original forecasts

- **Royalty income from HIV franchise**
- **Investments for growth drivers: S-033188 and cefiderocol**



- **Strengthen and enhance Japanese/overseas business**
- **Total cost management**

Exceed original FY2016 profit targets while expanding investment in growth drivers

Revision of FY2016 Financial Forecasts (Consolidated)



(Unit B yen)

	FY2016			FY2015 results	YoY change (%)
	original	revised	change		
Sales	318.0	334.0	16.0	310.0	7.8%
Operating income	91.5	97.5	6.0	91.4	6.7%
Ordinary income	101.5	105.5	4.0	100.9	4.6%
Profit attributable to owners of parent	71.0	76.0	5.0	66.7	14.0%

Exchange rate (average)	FY2016 forecasts (original)	FY2016 forecasts (revised)	change
USD (\$) – JPY (¥)	110	105	5
GBP (£) – JPY (¥)	155	140	15
EUR (€) – JPY (¥)	130	120	10

Revision of Sales of Main Merchandise and Finished Goods (Consolidated)



(Unit B yen)

	FY2016			FY2015 results	YonY change (%)
	original	revised	change		
Prescription drugs	158.2	160.2	2.0	162.1	(1.2)
Crestor®	41.5	42.9	1.4	43.7	(1.9)
Cymbalta®	19.3	19.3	-	15.2	26.8
Irbetan® franchise	15.1	15.8	0.7	15.7	0.5
Total of 3 key products	75.9	77.9	2.0	74.6	4.5
OxyContin® franchise	10.5	9.9	(0.6)	10.0	(1.4)
Finibax®	3.9	3.6	(0.3)	3.8	(4.1)
Pirespa®	6.3	6.0	(0.3)	6.0	0.1
Rapiacta®	2.3	2.3	-	2.0	14.2
Total of 7 strategic products	99.0	99.8	0.8	96.5	3.5
[percent of sales]	[62.5%]	[62.3%]		[59.5%]	
Overseas subsidiaries/export	24.7	24.8	0.1	29.7	(16.5)
Shionogi Inc.	12.4	13.6	1.2	16.6	(18.1)
Osphena®	5.3	4.8	(0.5)	4.8	(1.0)
Contract manufacturing	10.9	12.4	1.5	8.4	46.6
OTC and quasi-drugs	7.0	7.0	-	4.9	44.3
Royalty income	114.9	112.3	(2.6)	101.8	10.3
Royalty income for the sales of Crestor® and HIV franchise	95.0	103.0	8.0	88.1	16.9
Crestor®	33.0	32.8	(0.2)	47.6	(31.2)
HIV franchise	62.0	70.2	8.2	40.5	73.5
Others	2.4	17.2	14.8	3.0	474.9
Total	318.0	334.0	16.0	310.0	7.8

Revision of Statement of Income (Consolidated)



(Unit B yen)

	FY2016			FY2015 results	YoY change (%)
	original	revised	change		
Sales	318.0	334.0	16.0	310.0	7.8
[Royalty* income]	95.0	103.0	8.0	88.1	16.9
	24.5	23.4		24.1	
	[35.0]	[33.8]		[33.7]	
Cost of sales	78.0	78.0	-	74.8	4.3
	46.7	47.5		46.4	
SG&A expenses	148.5	158.5	10.0	143.8	10.2
	31.0	29.3		30.3	
Selling & general expenses	98.5	98.0	(0.5)	94.0	4.2
	15.7	18.1		16.1	
R&D expenses	50.0	60.5	10.5	49.8	21.5
	28.8	29.2		29.5	
Operating income	91.5	97.5	6.0	91.4	6.7
[Excluding royalty* income]	(3.5)	(5.5)	(2.0)	3.3	-
Non-operating income and expenses	P10.0	P8.0	(2.0)	P9.5	(15.5)
	31.9	31.6		32.5	
Ordinary income	101.5	105.5	4.0	100.9	4.6

Agenda

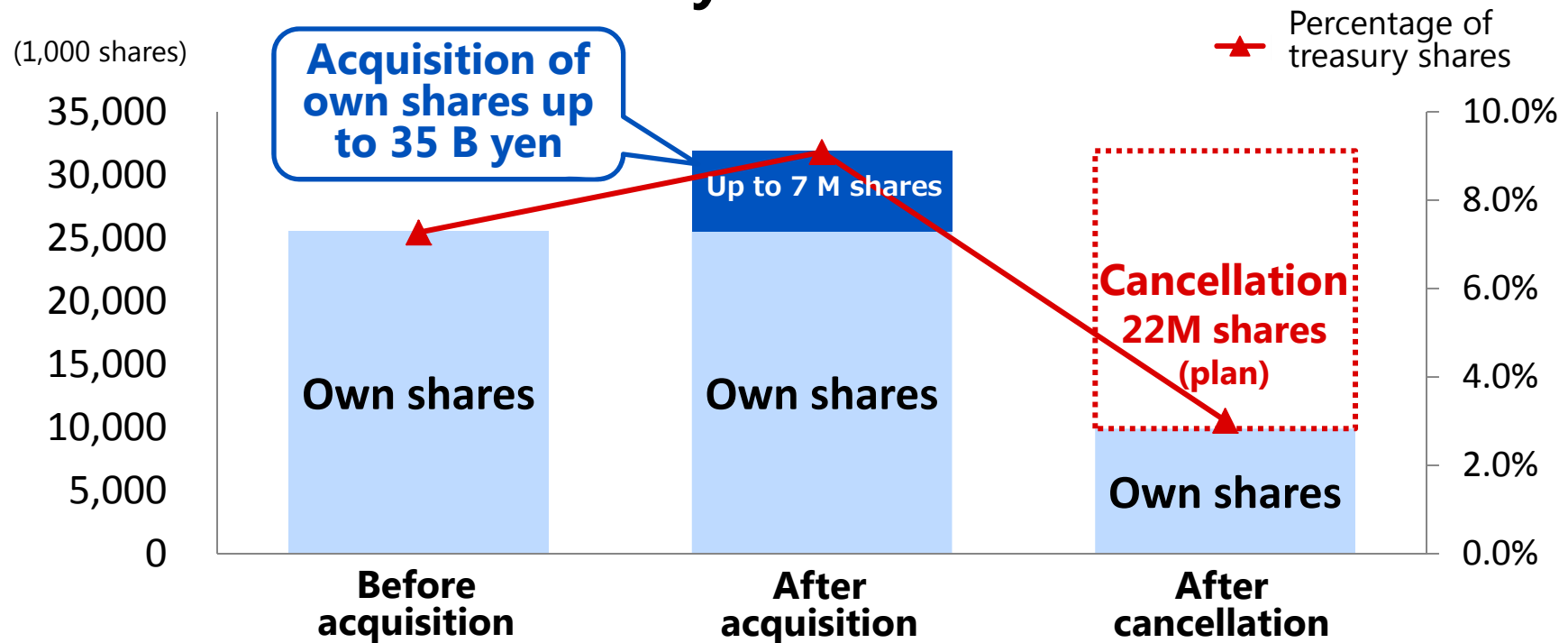


- 1st Half FY2016 Financial Results
- FY2016 Financial Forecasts
- **Dividend Forecasts**

Acquisition of Own Shares and Cancellation of Treasury Shares



- Acquisition of own shares (up to 35 B yen) and cancellation of treasury shares



Increase shareholder return and capital efficiency by following a flexible capital policy, aligning with strong business progress in accordance with SGS2020 to maximize Shionogi's enterprise value

Dividend Forecasts



- Maximize enterprise value by balancing three key factors: return to shareholders, investment for further growth and strategic opportunities
- Sharing our mid- to long-term profit growth with our shareholders by increasing returns as appropriate
- Dividend forecast for FY2016: **68 yen**

	Dividend per share			DOE	Payout ratio
	half-year	year-end	annual		
FY2015	28.00	34.00	62.00	4.1%	30.3%
FY2016	34.00	34.00 <small>(forecast)</small>	68.00 <small>(forecast)</small>	4.3%	28.9%

EOF



Appendix - Financial Results -

Japan: Sales of Strategic Products



(Unit B yen)

	FY2016				FY2015	YoY	
	full year forecasts (original)	1H forecasts	1H results	Progress vs forecasts (%)	1H results	change (%)	change
Crestor[®]	41.5	20.9	21.9	105.1	20.4	7.5	1.5
Cymbalta[®]	19.3	8.9	8.9	100.2	7.2	23.7	1.7
Irbetan[®] franchise	15.1	7.4	7.8	104.7	8.3	(6.3)	(0.5)
Total of 3 key products	75.9	37.2	38.6	103.9	35.9	7.6	2.7
OxyContin[®] franchise	10.5	5.5	5.0	91.1	5.2	(2.6)	(0.2)
Finibax[®]	3.9	2.0	1.8	87.7	2.1	(16.8)	(0.3)
Pirespa[®]	6.3	3.3	3.0	91.8	2.8	9.0	0.2
Rapiacta[®]	2.3	0.1	0.1	118.2	(0.0)	-	0.1
Total of 7 strategic products	99.0	48.1	48.5	100.9	45.9	5.7	2.6
[percent of sales]	[62.5%]	[63.0%]	[61.3%]		[58.6%]		
Prescription drugs	158.2	76.3	79.2	103.8	78.4	0.9	0.8

Sales of Main Merchandise and Finished Goods (Consolidated)



(Unit B yen)

	FY2016				FY2015	YoY	
	full year forecasts (original)	1H forecasts *	1H results	Progress vs forecasts (%)	1H results	change (%)	change
Prescription drugs	158.2	76.3	79.2	103.8	78.4	0.9	0.8
Overseas subsidiaries/export	24.7	12.4	15.3	123.4	14.7	3.7	0.6
Shionogi Inc.	12.4	6.0	9.1	152.1	8.4	8.0	0.7
Osphena®	5.3	2.6	2.0	77.7	2.6	(22.4)	(0.6)
Contract manufacturing	10.9	5.3	5.4	101.5	3.7	46.4	1.7
OTC and quasi-drugs	7.0	3.5	3.4	97.5	2.6	33.3	0.8
Royalty income	114.9	46.3	50.6	109.3	37.5	35.2	13.1
Royalty income for the sales of Crestor® and HIV franchise	95.0	42.5	46.0	108.1	35.0	31.2	11.0
Crestor®	33.0	16.5	17.3	105.0	23.7	(26.8)	(6.4)
HIV franchise	62.0	26.0	28.6	110.1	11.4	152.0	17.2
Others	2.4	1.2	1.2	103.3	1.4	(14.4)	(0.2)
Total	318.0	145.0	155.1	107.0	138.3	12.2	16.8

Statements of Income (Consolidated)



(Unit B yen)

	FY2016				FY2015	YoY	
	full year forecasts (original)	1H forecasts *	1H results	Progress vs forecasts (%)	1H results	change (%)	change
Sales	318.0	145.0	155.1	107.0	138.3	12.2	16.8
[Royalty** income]	95.0	42.5	46.0	108.2	35.0	31.2	11.0
	24.5 [35.0]	26.6 [37.6]	25.0 [35.5]		26.4 [35.3]		
Cost of sales	78.0	38.5	38.7	100.5	36.5	6.2	2.2
Gross profit	240.0	106.5	116.4	109.3	101.8	14.3	14.6
	46.7	50.7	46.5		49.1		
SG&A expenses	148.5	73.5	72.1	98.1	67.9	6.2	4.2
	31.0	33.8	29.3		33.3		
Selling & general expenses	98.5	49.0	45.4	92.7	46.1	(1.3)	(0.7)
	15.7	16.9	17.2		15.8		
R&D expenses	50.0	24.5	26.7	108.8	21.8	22.1	4.9
	28.8	22.8	28.6		24.5		
Operating income	91.5	33.0	44.3	134.2	33.9	30.5	10.4
[Excluding royalty** income]	(3.5)	(9.5)	(1.7)	-	(1.1)	-	-
Non-operating income and expenses	P10.0	-	L2.1	-	P0.9	-	(3.0)
	31.9	22.8	27.2		25.2		
Ordinary income	101.5	33.0	42.1	127.7	34.8	21.1	7.3

Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties

* The consolidated earnings forecasts announced on May 11, 2016 were written here, and the revisions to the forecasts were announced on Oct. 24, 2016

** Royalty income from AstraZeneca (Crestor®) and ViiV (HIV franchise)



Appendix - Pipeline -

Pipeline (as of Nov. 2016)



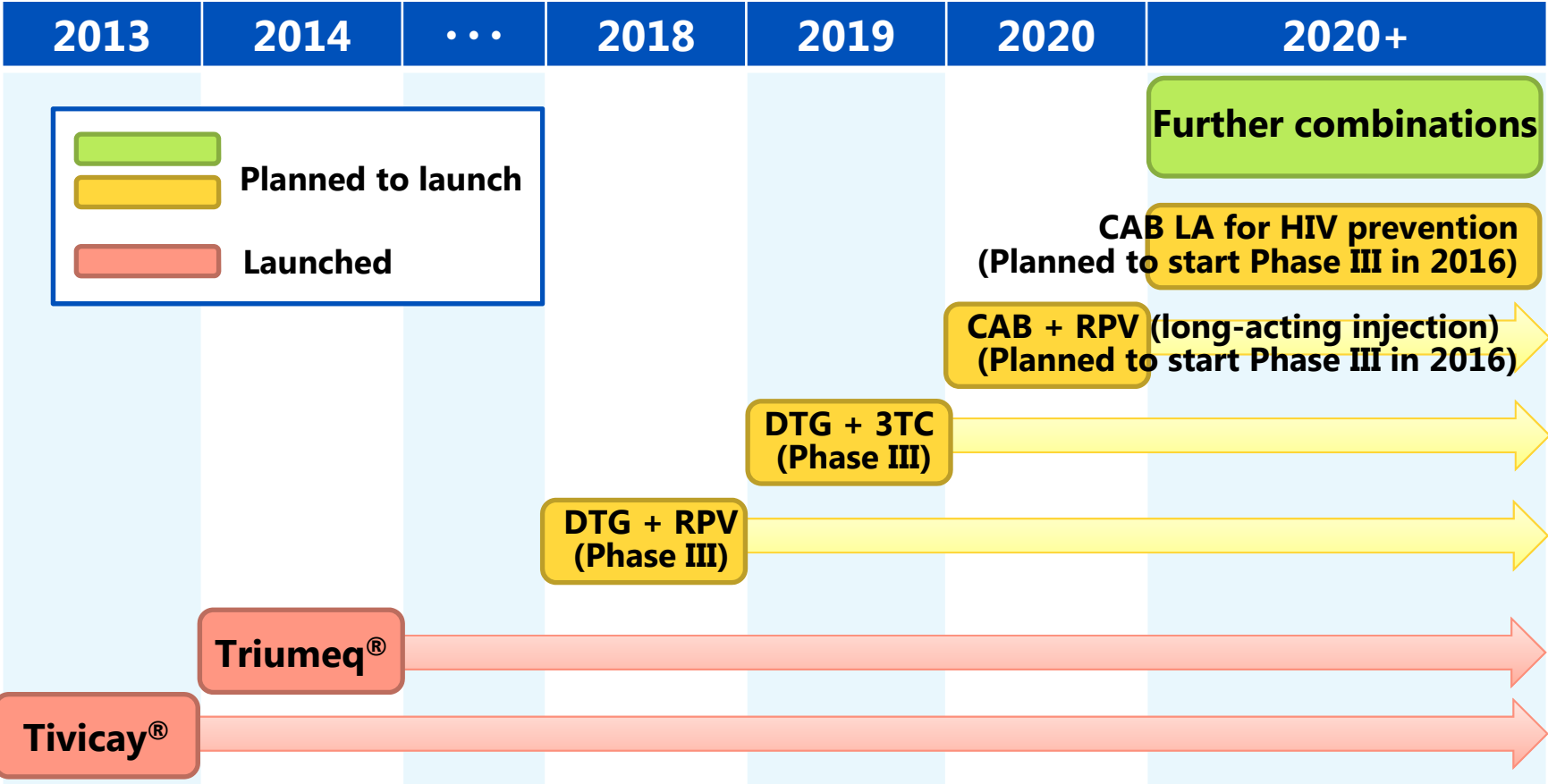
Non-clinical	Phase I	Phase II	Phase III	NDA submission
Antibody drug candidate against Pseudomonas NTE inhalation	【Global】 S-033188 Influenza virus infection S-120083 Inflammatory pain S-117957 Insomnia S-237648 Obesity	Cefiderocol (S-649266) Multidrug-resistant Gram-negative bacterial infections S-707106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

Pipeline (as of Nov. 2016)



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

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

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