



**1st Quarter of Fiscal 2017
Financial Results
*Conference Call***

July 31, 2017



Financial Results (Consolidated)



(billion yen)

	FY2017			Progress vs. 1H forecasts (%)	FY2016	YonY	
	Full year forecasts	1H forecasts	Apr.-Jun. results		Apr.-Jun. results	change (%)	change
Sales	340.0	162.5	75.0	46.2	73.2	2.5	1.9
Operating income	112.5	46.0	16.0	34.8	18.0	(11.4)	(2.0)
Ordinary income	123.5	51.5	21.1	40.9	16.7	26.3	4.4
Profit attributable to owners of parent	92.0	38.5	16.0	41.6	12.5	27.7	3.5

- **Ordinary income**

- Higher than the levels achieved in prior Fiscal Years for seven consecutive years

- **Profit attributable to owners of parent**

- Higher than the levels achieved in prior Fiscal Years for two consecutive years

Exchange rate (average)	FY2017 forecasts	FY2017 Apr.-Jun. results
USD (\$) – JPY (¥)	110.0	111.11
GBP (£) – JPY (¥)	140.0	142.03
EUR (€) – JPY (¥)	120.0	122.31

Statements of Income (Consolidated)



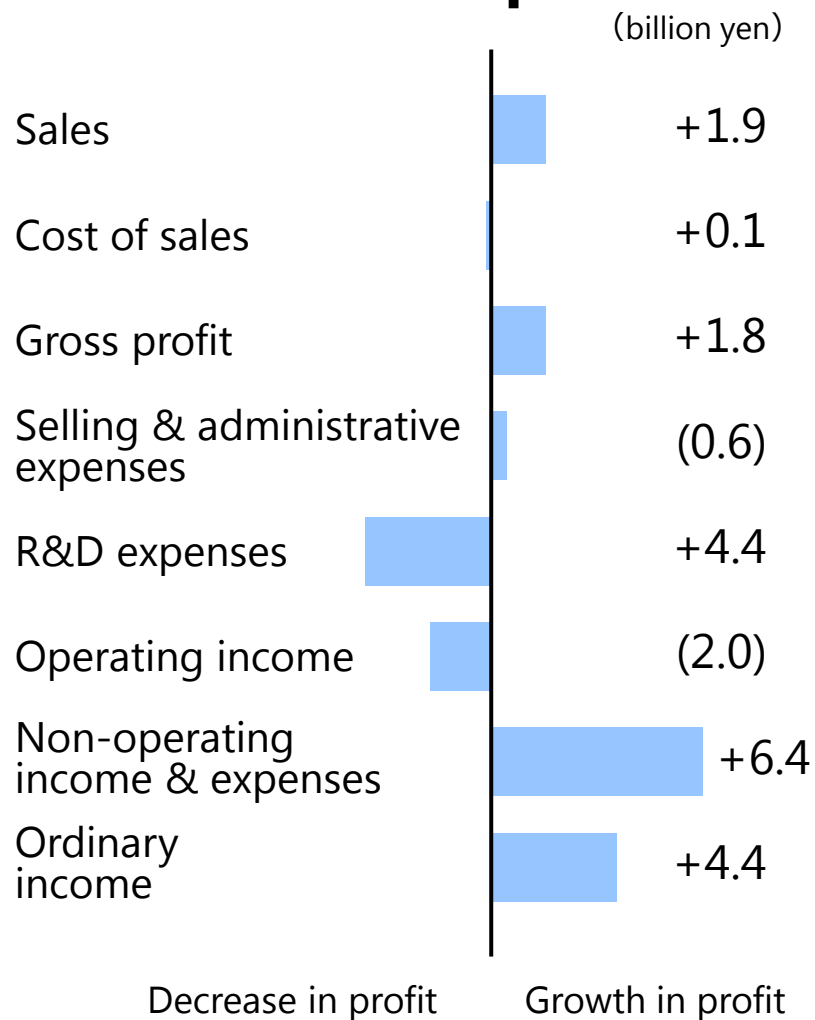
(billion yen)

	FY2017			Progress vs. 1H forecasts (%)	FY2016	YonY	
	Full year forecasts	1H forecasts	Apr.-Jun. results		Apr.-Jun. results	change (%)	change
Sales	340.0	162.5	75.0	46.2	73.2	2.5	1.9
[Royalty* income]	125.0	56.4	24.4	43.2	20.8	17.3	3.6
	22.5 [35.6]	24.9 [38.2]	26.5 [39.3]		27.1 [37.8]		
Cost of sales	76.5	40.5	19.9	49.2	19.8	0.5	0.1
Gross profit	263.5	122.0	55.1	45.2	53.3	3.3	1.8
	44.4	46.8	52.1		48.3		
SG&A expenses	151.0	76.0	39.1	51.5	35.3	10.8	3.8
Selling & administrative expenses	29.1 99.0	29.8 48.5	29.5 22.1	45.6	31.0 22.7	(2.6)	(0.6)
R&D expenses	15.3 52.0	16.9 27.5	22.7 17.0	61.9	17.3 12.6	34.8	4.4
Operating income	112.5	46.0	16.0	34.8	18.0	(11.4)	(2.0)
[Excluding royalty* income]	(12.5)	(10.4)	(8.4)	-	(2.7)	-	(5.7)
Non-operating income & expenses	P11.0	P5.5	P5.1	92.4	L1.4	-	6.4
Ordinary income	123.5	51.5	21.1	40.9	16.7	26.3	4.4
	36.3	31.7	28.1		22.8		

Y on Y comparison and Main Variation Factors (Statements of Income)



• Y on Y comparison



Main Variation Factors

- Cost of sales
 - Cost of sales ratio: Improved by 0.6%
 - > Increase in royalty income
 - Cost of sales ratio excluding royalty income: Increased by 1.5%
 - > Effect of product mix
 - > Increase in manufacturing of API for dolutegravir
- SG&A expenses: Total cost management
 - Selling & administrative expenses: (0.6) billion yen
 - > Reduced the impact of increased R&D expenses by tightly controlling selling & administrative expenses
 - R&D expenses: +4.4 billion yen
 - > Good progress in the global development of the highest priority compound S-033188
- Non-operating income & expenses
 - Received dividends: Global sales growth of HIV franchise and dividend payment in accordance with the revised contract with ViiV
 - Foreign exchange profits or losses: +1.4 billion yen
 - > Losses: 0.3 billion yen in Apr.-Jun. of FY2017
 - > Losses: 1.7 billion yen in Apr.-Jun. of FY2016

Sales by Segments (Consolidated)



(billion yen)

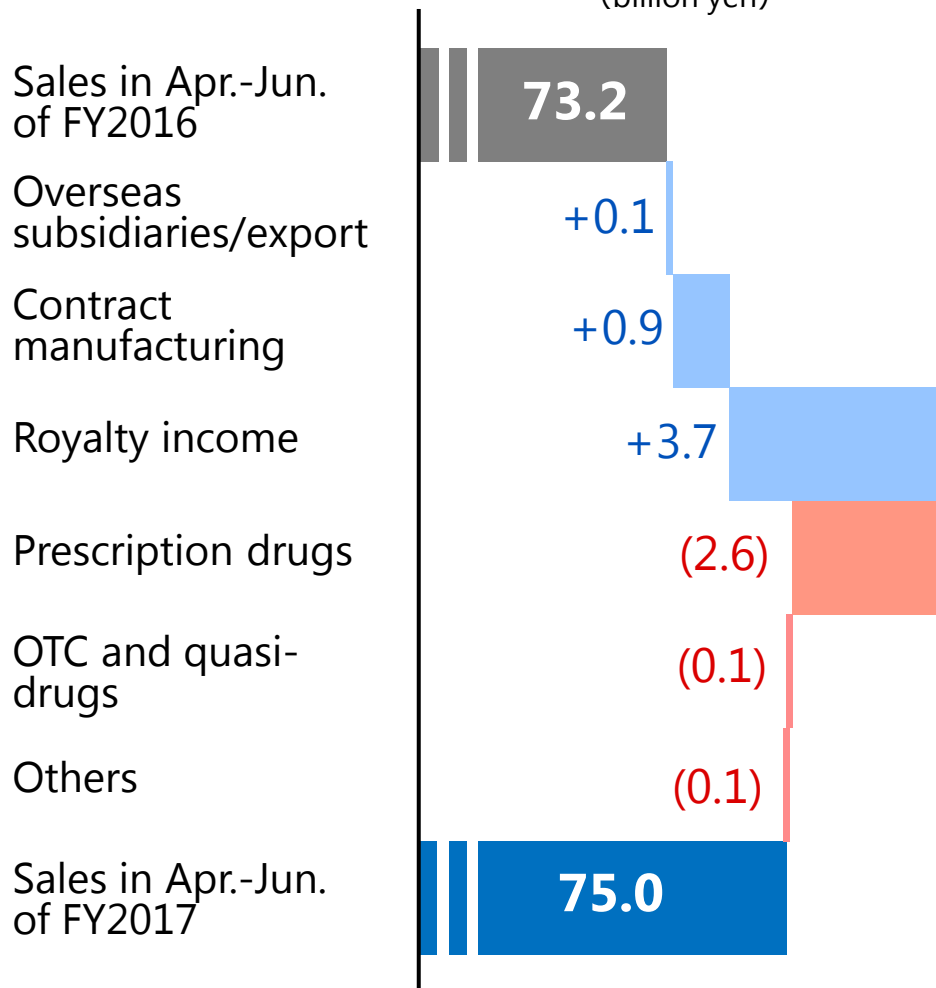
	FY2017				FY2016	YoY	
	Full year forecasts	1H forecasts	Apr.-Jun. results	Progress vs. 1H forecasts (%)	Apr.-Jun. results	change (%)	change
Prescription drugs	143.9	75.2	37.3	49.6	39.9	(6.6)	(2.6)
Overseas subsidiaries/export	25.4	12.3	6.6	53.7	6.5	1.2	0.1
Shionogi Inc.	12.0	6.0	3.5	58.1	3.6	(3.9)	(0.1)
Osphena®	4.6	2.2	1.1	50.7	1.2	(5.6)	(0.1)
Contract manufacturing	15.3	7.9	3.5	44.5	2.6	35.4	0.9
OTC and quasi-drugs	7.5	3.4	1.6	45.8	1.7	(7.8)	(0.1)
Royalty income	145.0	62.3	25.5	40.9	21.8	16.9	3.7
Royalty income for the sales of HIV franchise and Crestor®	125.0	56.4	24.4	43.2	20.8	17.3	3.6
HIV franchise	103.0	45.4	18.6	41.0	10.2	82.3	8.4
Crestor®	22.0	11.0	5.7	52.2	10.5	(45.6)	(4.8)
Others	2.9	1.4	0.6	40.0	0.6	(8.4)	(0.1)
Total	340.0	162.5	75.0	46.2	73.2	2.5	1.9

Y on Y comparison and Main Variation Factors (Sales by Segments)



• Y on Y comparison

(billion yen)



Main Variation Factors (YonY change: +1.9 billion yen, +2.5%)

- Contract manufacturing
 - Increase in API for dolutegravir
- Royalty income
 - Global sales growth of HIV franchise
 - Decrease in royalty income for Crestor®
- Prescription drugs
 - Sales growth of strategic products
 - Decreased sales due to transfer of marketing rights of long-listed drugs, etc.

Sales of Prescription Drugs in Japan



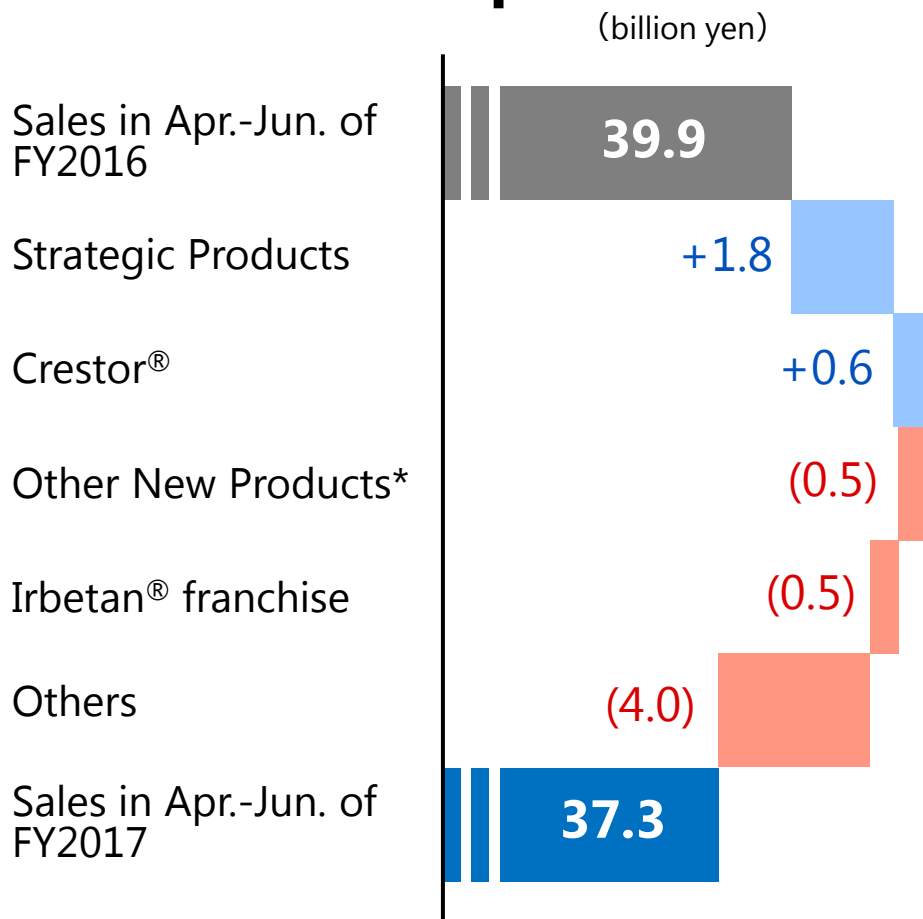
(billion yen)

	FY2017			Progress vs. 1H forecasts (%)	FY2016	YonY	
	Full year forecasts	1H forecasts	Apr.-Jun. results		Apr.-Jun. results	change (%)	change
Cymbalta[®]	25.3	11.1	5.8	51.7	4.4	30.6	1.3
Intuniv[®]	0.62	0.29	0.36	123.8	-	-	0.36
Symproic[®]	0.38	0.08	0.05	61.6	-	-	0.05
Total of Strategic Products	26.3	11.5	6.2	53.6	4.4	39.9	1.8
Actair[®]	0.13	0.05	0.03	55.5	0.01	131.4	0.02
Mulpleta[®]	0.17	0.08	0.05	58.1	0.03	41.4	0.01
Pirespa[®]	6.0	3.1	1.4	47.0	1.6	(11.6)	(0.19)
OxyContin[®] franchise	8.9	4.6	2.4	51.0	2.6	(8.2)	(0.21)
Rapiacta[®]	2.8	0.14	0.05	38.5	0.13	(57.5)	(0.07)
Brightpoc[®] Flu	0.93	0.09	0.05	53.5	0.05	3.9	0.00
Glashvista[®]	0.69	0.34	0.09	25.6	0.15	(40.3)	(0.06)
Total of New Products	45.8	19.9	10.2	51.4	9.0	14.0	1.3
Crestor[®]	36.4	24.7	12.1	48.9	11.4	5.6	0.64
Irbetan[®] franchise	14.8	7.6	3.7	49.0	4.2	(11.8)	(0.50)
Others	46.9	23.0	11.3	49.1	15.3	(26.3)	(4.0)
Prescription drugs	143.9	75.2	37.3	49.6	39.9	(6.6)	(2.6)

Y on Y comparison and Main Variation Factors (Prescription Drugs in Japan)



• Y on Y comparison



Main Variation Factors (YonY change: (2.6) billion yen, (6.6)%)

- Strategic Products
 - Cymbalta®: Sales expansion mainly in the pain area (+30.6% vs prior FY)
 - Smooth launch of new products such as Intuniv® and Symproic®
 - › Intuniv®: Already achieved the sales forecast for 1H
- Others
 - Decreased sales due to transfer of marketing rights of long-listed drugs, etc.

Responding to changes in our business environment

	Challenges	Actions
Sales	<p>Japan</p> <ul style="list-style-type: none"> • Launch of generic drugs • Reduced sales due to transfer of marketing rights 	<ul style="list-style-type: none"> • Japan: Growth led by Cymbalta[®]'s additional indications in the pain area, Intuniv[®], Symproic[®], and oxycodone tamper resistant formulation • US: Maximizing the value of Symproic[®] and Osphena[®] through smooth transition into strategic alliances
Royalty income	<ul style="list-style-type: none"> • Decreasing royalty income of Crestor[®] 	<ul style="list-style-type: none"> • Increasing royalty income due to expanding global sales of HIV franchise
Total cost	<ul style="list-style-type: none"> • Increasing costs due to launch of new products 	<ul style="list-style-type: none"> • Improving productivity based on total cost management including R&D expenses, cost of sales, etc.

Continued revenue and profit growth in FY2017

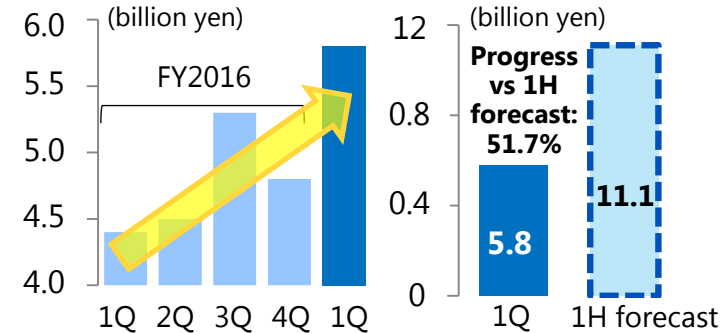
Growth led by Strategic Products (Pain/CNS)



Creating a more vigorous society

Sales expansion of Cymbalta® in the pain area

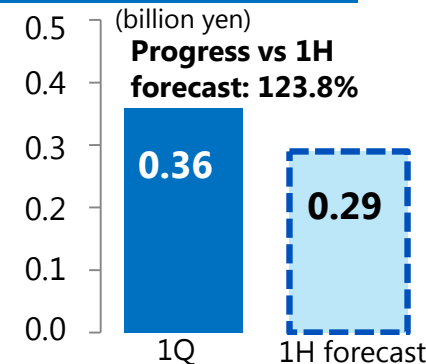
- Sales growth in the pain area from the orthopedics and internal medicine departments
 - Sales growth in CLBP and OA from orthopedic departments via Eli Lilly's expertise and from internal medicine departments via Shionogi's expertise
 - Increased awareness as a key pain management drug with its long-term safety profile



Smooth launch and sales growth of Intuniv® (launched on May 26, 2017)

→ Already achieved the sales forecast for 1H

- Strong sales growth as a new treatment option for ADHD
 - Intuniv® product information provided to healthcare practitioners by all sales forces of Shionogi
 - Allocation of sales forces with high level of expertise in each region
 - Co-promotion with our partner Shire Japan
 - Positive perception of Intuniv® by psychiatrists and pediatricians
- Maximize overall beneficial impact with complementary social support



Sales growth of opioids, and Smooth launch and sales growth of new product for the treatment of OIC

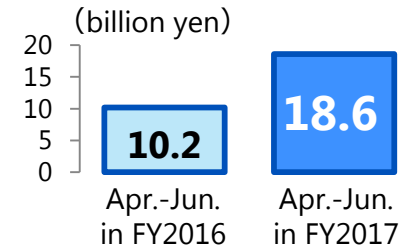
- Launched Methapain® (Apr. 11, 2017) and Symproic® (Jun. 7, 2017) on schedule

Expansion and progress of HIV franchise



Trend in royalty income from ViiV

- Increased royalty income due to sales growth of the HIV franchise
 - YonY change: +8.4 billion yen



Progress of next growth driver, two-drug regimen

- DTG+RPV: NDA submission in US and EU in Jun. 2017
 - First two-drug regimen for HIV maintenance therapy
 - Priority review voucher was submitted in US, and the anticipated target action date is six months after receipt of the application by the FDA

Launch schedule for new additions to integrase inhibitor franchise

2018	2019	2020	2020 +
			Future combinations
DTG + RPV NDA submission in US and EP	DTG + 3TC Phase III	CAB + RPV (long-acting injection) Phase III	CAB for HIV prevention (long-acting injection) Phase III

Flexible cost allocation amongst SG&A expenses

- Appropriate prioritization of investments in the Corporate Strategy Meeting
- Total cost management scheme which combines selling & administrative expenses and R&D expenses into one unified expense budget coupled with precise management thereof



- Proactive investment in R&D because of the rapid progress in the global Phase III study of the highest priority compound S-033188 (+4.4 billion yen vs prior FY)
 - Good progress in OwH* study and HR** study
 - In particular, patient enrollment rate is exceeding the original plan in the HR** study
- Reduced the cost impact of the increase in R&D expenses by carefully controlling selling & administrative expenses ((0.6) billion yen vs prior FY)
 - Progress vs 1H forecast in SG&A expenses: 51.5%



**Achieve revenue and profit growth in FY2017
based on total cost management**

S-033188: Profile of S-033188

Indication	Influenza virus infection
Mechanism of action	Cap-dependent endonuclease inhibition (novel mechanism of action)
Special characteristics	Influenza type A/B viruses Highly pathogenic avian influenza viruses Single oral dose
Stage	Japan/Global: Phase III study
Future plan	Japan: NDA submission in FY2017
Note	Designated for "priority review system" by Ministry of Health, Labour and Welfare (MHLW)

Global Phase III Study Design (OwH* Study)



OwH* study

(CAPSTONE-1)

- Uncomplicated otherwise healthy patients aged 12-64 years
- 0-48 hours from onset
- Japan/North America /Asia
- **N=approximately 1,500**

20-64
years

Randomization

S-033188 40 mg or 80 mg, single dose
(80 mg, body weight \geq 80 kg)

Placebo

Oseltamivir, 75 mg twice daily for 5 days

12-19
years

Randomization

S-033188 40 mg or 80 mg, single dose
(80 mg, body weight \geq 80 kg)

Placebo

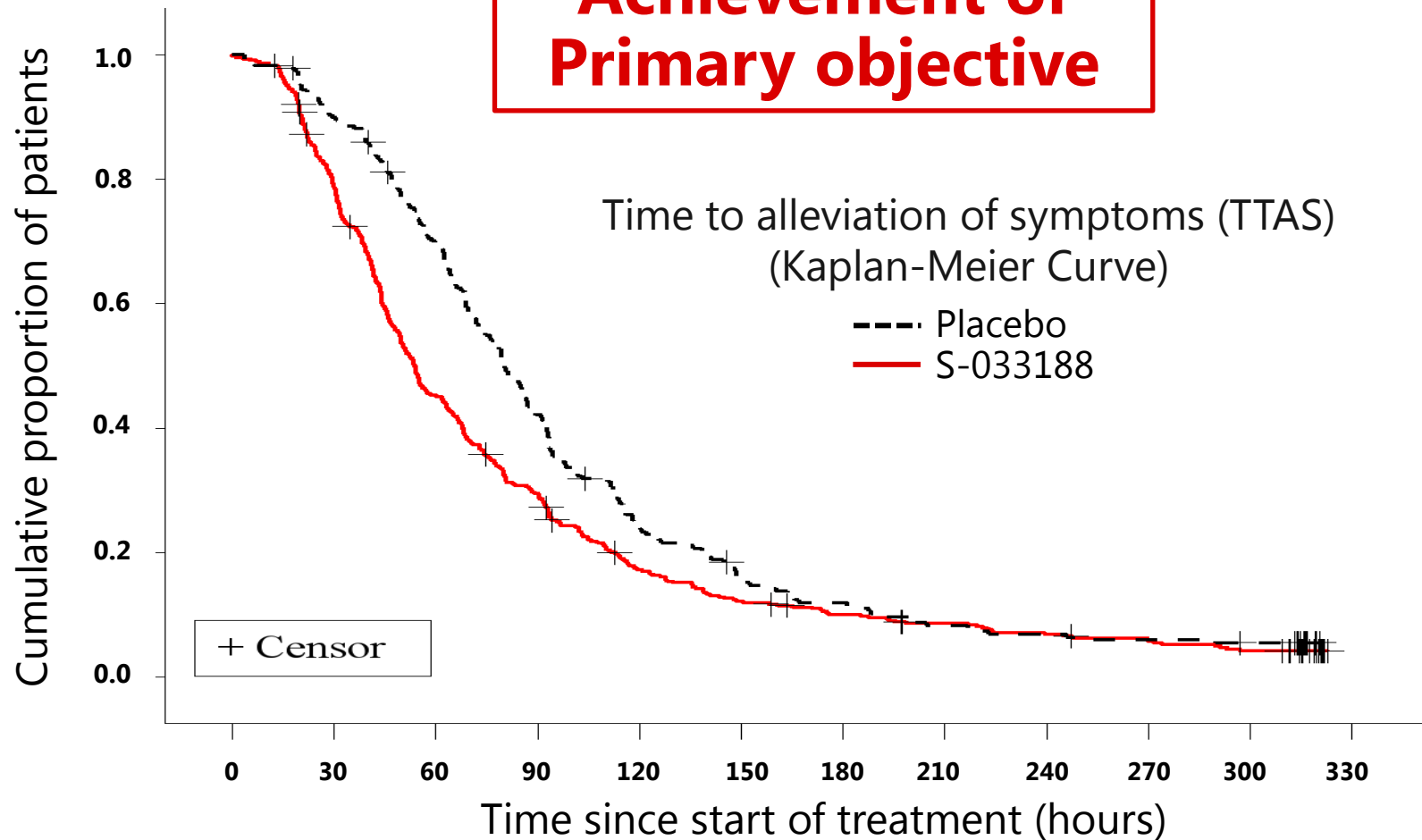
- Primary objective: Time to improvement of 7 major flu symptoms compared to placebo
- Major secondary objective: Time to improvement of 7 major flu symptoms compared to oseltamivir
(Using stratified generalized Wilcoxon test)

Top-Line Results for OwH study

- Primary objective -



Achievement of Primary objective



Top-Line Results for OwH study



- **Time to alleviation of symptoms (TTAS)**
 - S-033188 demonstrated a statistically significant reduction in TTAS compared to placebo and achieved the primary objective.
- **Viral titer**
 - S-033188 demonstrated statistically significant differences, in the early post-treatment period, both in the reduction of virus titer, and in the duration of viral shedding, compared to either placebo or oseltamivir.
- **Safety**
 - S-033188 was well tolerated. The incidence of treatment-related adverse events in the S-033188 treatment arm was comparable to that in the placebo arm.
 - The S-033188 treatment arm had statistically significantly fewer treatment-related adverse events compared to the oseltamivir arm.

Japan

- OwH study: Completed
- Preparing for NDA submission under the “priority review system” (SAKIGAKE designation) in Japan
 - The target premarket review period will be 6 months.



Submit NDA promptly

Global

- HR* Study: Ongoing
 - Patient enrollment rate is exceeding the original plan



**Accelerate
Global Phase III Studies**

Target Milestones for FY2017



Areas	Product	As of Apr. 1, 2017	Target for FY2017
Infectious disease	Cefiderocol Multidrug-resistant Gram-negative bacterial infections	Global: Preparation for NDA submission	US: NDA submission
	S-033188 Influenza virus infection	Global: Phase III Japan: Phase III (pediatric)	Japan: NDA submission
Pain/CNS	Intuniv® ADHD (pediatric)	Japan: NDA submission	Japan: Launch
	Symproic® Opioid-induced constipation	Japan: Approval	Japan: Launch
	Symproic® Opioid-induced constipation	US: Approval	US: Launch
	Oxycodone Treatment of moderate to severe chronic pain	Japan: NDA submission	Japan: Approval
	Oxycodone Tamper resistant formulation	Japan: NDA submission	Japan: Approval
	Lisdexamfetamine ADHD (pediatric)	Japan: Preparation for NDA submission	Japan: NDA submission
	S-600918 Neuropathic pain	Japan: Phase I	Phase II (regions to be determined)
Frontier	Lusutrombopag Thrombocytopenia associated with chronic liver disease	Global: Phase III	US and EU: NDA submission
	Actair® (Pediatric allergic rhinitis caused by house-dust mite allergen)	Japan: NDA submission	Japan: Approval

Appendix

- **Main Variation Factors in Sales of Prescription Drugs in Japan -**
- **Explanation of New Products -**
- **Definition of New Products -**

Main Variation Factors in Sales of Prescription Drugs in Japan



(billion yen)

New drugs	Full year forecast	1H forecast	Apr.-Jun. results
Growth of new drugs including Cymbalta®	+6.7	+2.2	+1.3
Launch of generics for Crestor® and Irbetan®	(7.2)	+2.5	+0.1
Long-listed drugs, etc.	Full year forecast	1H forecast	Apr.-Jun. results
Decreased sales of long-listed drugs including Flomox® Decreased stockpiling of Rapiacta®	(8.7)	(5.0)	(1.7)
Transferring the marketing rights for long-listed 24 drugs	(4.9)	(3.8)	(2.3)
Prescription drugs	(14.1)	(4.0)	(2.6)

Explanation of New Products



Pirespa®

Launched in December 2008

- The world's first drug for treatment of IPF*



Rapiacta®

Launched in January 2010

- Anti-viral Drug for Influenza
- The world's first intravenous injection for treatment of influenza infection



Brightpoc® Flu

Launched in September 2012

- Flu diagnosis kit which can provide results in only 1 minute



Glashvista®

Launched in September 2014

- Make eyelashes long, thick, and dark
- First and only drug for treatment of eyelash hypotrichosis in Japan



Actair®

Launched in November 2015

- The world's first sublingual immunotherapy tablet for the treatment of house dust mite induced allergic rhinitis in the world



Mulpleta®

Launched in December 2015

- Alternative treatment to the currently standard approach of platelet transfusion by oral administration



Methapain®

Launched in April 2017

- New choice of opioid for patients with poor pain control using existing opioids

Definition of New Products

(cited from Updated SGS2020)



Pain/ CNS

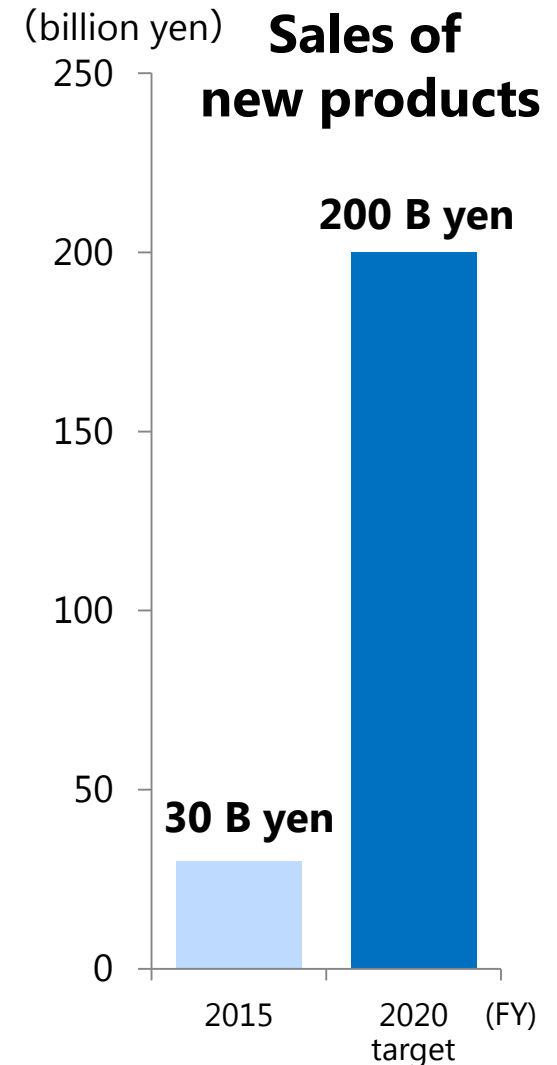
- Cymbalta[®]
- Oxycodone tamper resistant formulation, OxiNorm[®], OxiFast[®]
- Symproic[®]
- Intuniv[®], lisdexamfetamine

Infectious diseases

- S-033188
- Cefiderocol
- Rapiacta[®], flu diagnosis kit

Others

- Pirespa[®]
- Mulpleta[®]
- Actair[®]
- Glashvista[®]
- Osphena[®] (Senshio[®])



Appendix

- **Global Phase III Study Design (HR* Study)-**
- **Progress in Our Pipeline -**

Global Phase III Study Design (HR* Study)



HR* study

(CAPSTONE-2)

- Uncomplicated high risk patients aged ≥ 12 years
- 0-48 hours from onset
- Japan/US/Asia/
Southern Hemisphere
- **N=approximately 2,200**

Randomization

S-033188 40 mg or 80 mg, single dose
(80 mg, body weight ≥ 80 kg)

Placebo

Oseltamivir 75 mg, twice daily for 5 days

- Primary objective: Time to improvement of 7 major flu symptoms compared to placebo
- Major secondary objective: Time to improvement of 7 major flu symptoms compared to oseltamivir
(Using stratified generalized Wilcoxon test)

Pipeline (as of July 2017)



Preclinical	Phase I	Phase II	Phase III	Filed
	Global	Cefiderocol Multidrug-resistant Gram-negative bacterial infections S-120083 Inflammatory pain S-707106 Type2 diabetes S-488210 Head and neck squamous cell carcinoma epertinib Malignant tumor S-588410 Bladder cancer	S-033188 Influenza virus infection Cefiderocol Multidrug-resistant Gram-negative bacterial infections Lusutrombopag Thrombocytopenia	Naldemedine (EU) Opioid-induced constipation
Antibody drug candidate against pseudomonas Central neuropathic pain Obesity LCM inhalation	S-117957 Insomnia S-237648 Obesity			
	In Japan	Cefiderocol 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 Multidrug-resistant Gram-negative bacterial infections Guanfacine ADHD (adult) S-588410 Esophageal cancer	Oxycodone Moderate to severe chronic pain Oxycodone Tamper resistant formulation Lisdexamfetamine ADHD (pediatric) Actair® Pediatric patients with perennial allergic rhinitis
	S-010887 Neuropathic pain S-600918 Neuropathic pain			
Out-licensed	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		DTG+3TC Treatment for HIV infection CAB LAP Prevention for HIV infection CAB + RPV LAP Treatment for HIV infection Janssen/Shionogi BACE inhibitor Alzheimer's disease Osphena® Vaginal dryness associated with postmenopausal VVA	DTG+RPV Treatment for HIV infection Infectious diseases Pain/CNS Metabolic disorder Frontier
Janssen/Shionogi Project compound Alzheimer's disease				

Target Milestones for Launch of New Products



FY2017	FY2018	FY2019
Japanese business		
<p>Symproic® Intuniv® ADHD (pediatric)</p> <p>Oxycodone Tamper resistant formulation Moderate to severe chronic pain</p> <p>Actair® Pediatric patients with perennial allergic rhinitis</p>	<p>S-033188 Lisdexamfetamine</p>	<p>Intuniv® ADHD (adult)</p>
Overseas business		
<p>Symproic®(US)</p>	<p>Cefiderocol Osphena® Vaginal dryness associated with postmenopausal VVA</p> <p>Lusutrombopag Naldemedine (EU)</p>	
Global out-licensed products		
	<p>DTG + RPV</p>	<p>DTG + 3TC</p>

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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