



1st Half of Fiscal 2019 Financial Results

October 30, 2019

Isao Teshirogi, Ph.D.
President and CEO



Agenda



- 1. Overview of 1st Half FY2019 Financial Results (P.3-12)**
- 2. FY2019 Financial Forecasts (P.13-17)**
- 3. Shareholder Return (P.18-20)**

1. Overview of 1st Half FY2019 Financial Results

Highlight(1) Top Line Smoothly Progressed Toward 1H Forecasts



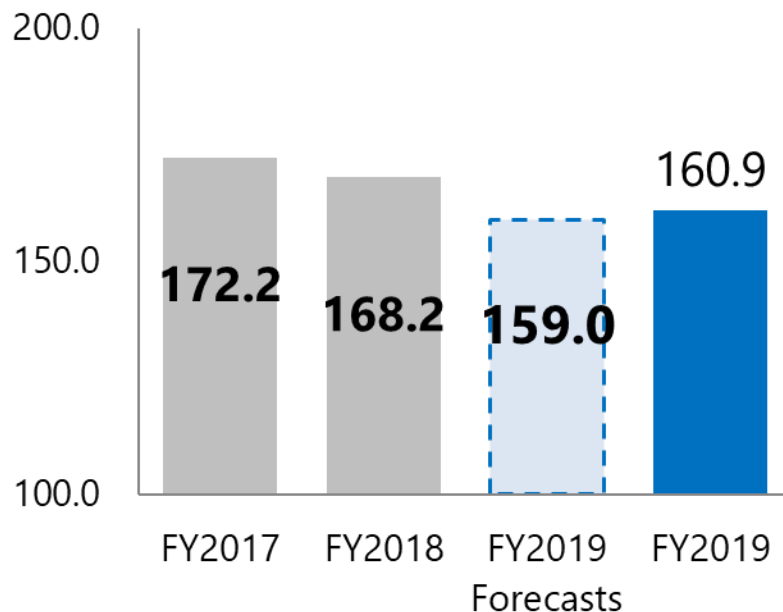
◆ Sales: **160.9 B yen** (YoY -4.4%, vs 1H forecast +1.2%)

For HIV franchise

◆ Royalty income: **61.1 B yen** (YoY +7.1%)

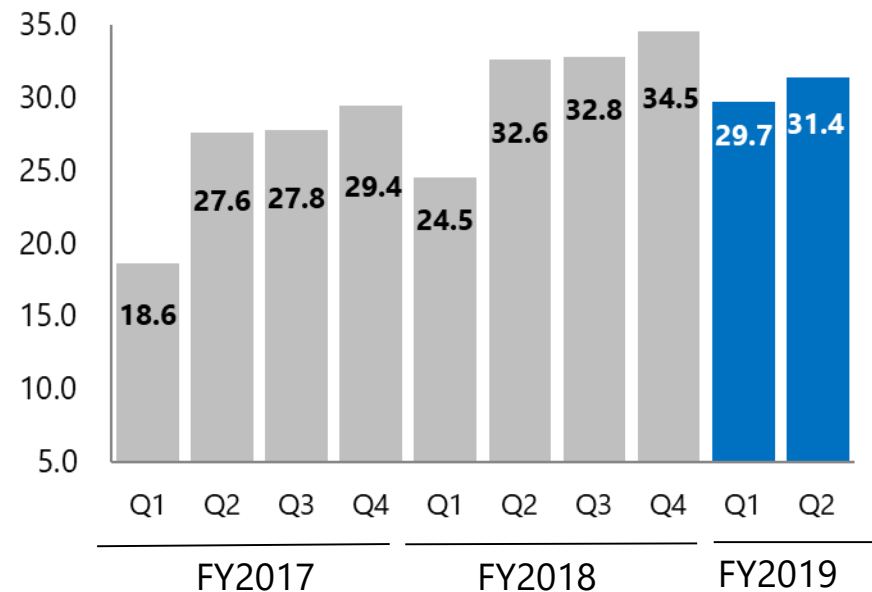
(Billions of yen)

Net Sales (1H)



(Billions of yen)

Quarterly Royalty Income from HIV Franchise



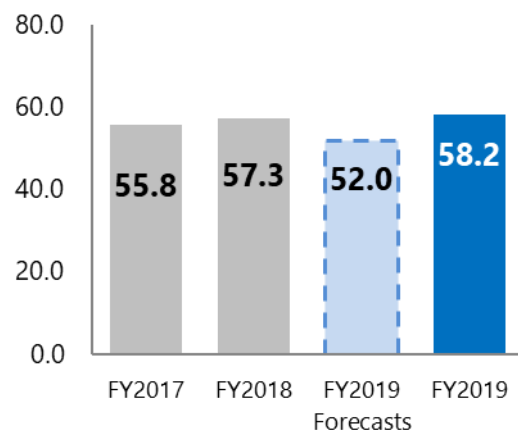
Highlight(2) Each Profit Measure Has Smoothly Progressed vs 1H Forecasts



- ◆ Operating income: **58.2 B yen** vs. 1H FY2018 vs. 1H Forecasts (+1.5%, +11.8%)
Record-high levels for 5 consecutive years
- ◆ Ordinary income: **65.3 B yen** vs. 1H FY2018 vs. 1H Forecasts (-6.8%, +3.7%)
- ◆ Profit attributable to owners of parent: **51.6 B yen** vs. 1H FY2018 vs. 1H Forecasts (-10.8%, +5.3%)

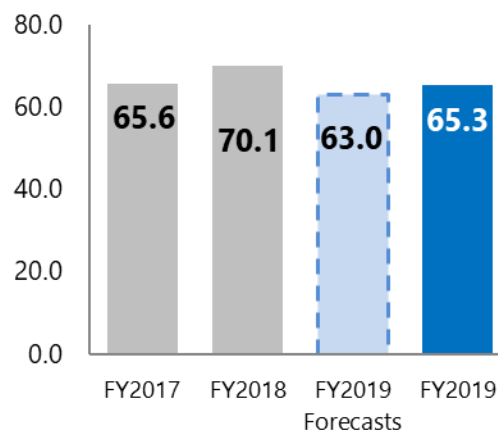
**Operating Income
(1H)**

(Billions of yen)



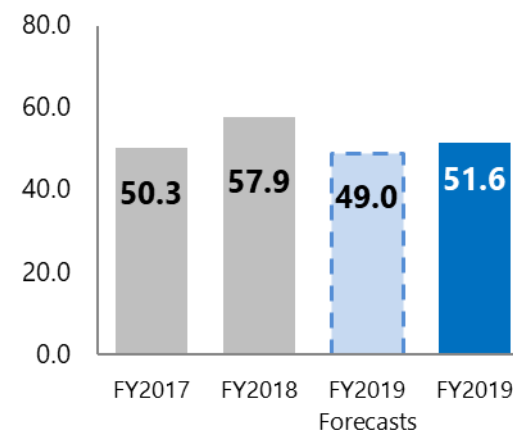
**Ordinary Income
(1H)**

(Billions of yen)



**Profit attributable to
owners of parent (1H)**

(Billions of yen)



Financial Results (Consolidated)



(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts*		1H results	Progress vs. forecasts	1H results	Change (%)	Change (B yen)
	Full year	1H					
Sales	365.5	159.0	160.9	101.2%	168.2	(4.4%)	(7.3)
Operating income	147.0	52.0	58.2	111.8%	57.3	1.5%	9.0
Ordinary income	170.5	63.0	65.3	103.7%	70.1	(6.8%)	(4.8)
Profit attributable to owners of parent	133.0	49.0	51.6	105.3%	57.9	(10.8%)	(6.3)

- Sales and each profit measure exceeded the 1H forecasts
- Operating income was higher than the levels achieved in prior fiscal years for 5 consecutive years

Exchange Rate (average)	FY2019 forecasts	FY2019 1H results
USD (\$) – JPY (¥)	110.0	108.61
GBP (£) – JPY (¥)	145.0	136.65
EUR (€) – JPY (¥)	130.0	121.41

Statement of Income



(Unit: B yen)

	FY2019			Achievement (%)	FY2018	Y on Y	
	Forecasts*		1H results		1H results	Change (%)	Change (B yen)
	Full year	1H					
Sales	365.5	159.0	160.9	101.2	168.2	(4.4)	(7.3)
	14.6	16.0	17.3		14.7		
Cost of sales	53.5	25.5	27.9	109.4	24.7	12.8	3.2
Gross profit	312.0	133.5	133.0	99.6	143.5	(7.3)	(10.5)
	45.1	51.3	46.5		51.2		
SG&A expenses	165.0	81.5	74.8	91.8	86.2	(13.2)	(11.4)
Selling & administrative expenses	31.6	35.5	32.2		28.3		
	115.5	56.4	51.8	91.9	47.5	9.1	4.3
	13.5	15.8	14.3		23.0		
R&D expenses	49.5	25.1	23.0	91.5	38.6	(40.6)	(15.7)
Ordinary R&D expenses**	49.5	25.1	23.0	91.5	25.6	(10.2)	(2.6)
Strategic investment	-	-	-	-	13.1	-	(13.1)
	40.2	32.7	36.2		34.1		
Operating income	147.0	52.0	58.2	111.8	57.3	1.5	0.9
Non-operating income & expenses	23.5	11.0	7.1	64.9	12.8	(44.1)	(5.6)
	46.6	39.6	40.6		41.7		
Ordinary income	170.5	63.0	65.3	103.7	70.1	(6.8)	(4.8)
Profit attributable to owners of parent	133.0	49.0	51.6	105.3	57.9	(10.8)	(6.3)

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



Y on Y comparison

(Unit: B yen)

Sales	(7.3)
Cost of sales	+3.2
Gross profit	(10.5)
Selling & administrative expenses	+4.3
R&D expenses	(15.7)
Operating income	+0.9
Non-operating income & expenses	(5.6)
Ordinary income	(4.8)
Profit attributable to owners of parent	(6.3)

Decrease in profit Increase in profit

Progress vs 1H Forecasts

(Unit: B yen)

Cost of sales	+2.4
Selling & administrative expenses	(4.6)
R&D expenses	(2.1)
Non-operating income & expenses	(3.9)
Decrease in profit Increase in profit	

Main Variation Factors (Y on Y)

- **Sales**
 - FY2018: Income from Roche for Xofluza® *
- **Cost of sales**
 - Increase in export of dolutegravir and Xofluza®, Sales increase of Flumarin®
- **SG & A expenses**
 - **Selling & administrative expenses**
 - › Increased in alignment with sales growth
 - **R&D expenses**
 - › FY2018: Strategic investment (13.1 B yen)
- **Non-operating income & expenses**
 - FY2018: One-time dividend from ViiV
 - Exchange-rate fluctuations

Main Variation Factors (vs 1H Forecasts)

- **Cost of sales**
 - Product mix
 - Increase in exports of dolutegravir and Xofluza®
- **SG & A expenses**
 - **Selling & administrative expenses**
 - › Controlled in preparation for 2H FY2019 activities
 - **R&D expenses**
 - › Change of development plan of S-812217
- **Non-operating income & expenses**
 - Exchange-rate fluctuations

Sales by Segment



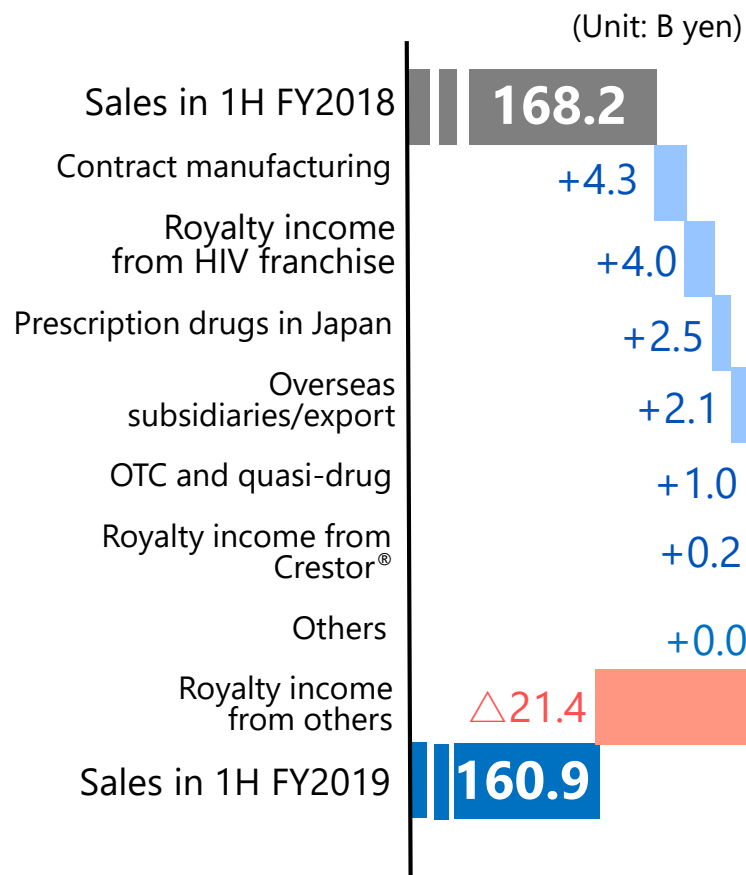
(Unit: B yen)

	FY2019			Achievement (%)	FY2018	Y on Y	
	Forecasts*		1H results		1H results	Change (%)	Change (B yen)
	Full year	1H					
Prescription drugs	144.1	53.7	52.4	97.6	50.0	4.9	2.5
Overseas subsidiaries/export	31.4	16.0	17.5	109.2	15.4	13.9	2.1
Shionogi Inc.	9.9	6.3	6.8	108.0	7.4	(8.0)	(0.6)
Mulpleta [®]	1.0	0.25	0.34	134.8	-**	-	0.3
C&O	14.6	6.8	7.2	104.9	5.0	42.7	2.1
Contract manufacturing	14.3	9.1	10.1	111.0	5.7	75.7	4.3
OTC and quasi-drug	9.7	4.6	4.7	102.3	3.8	25.1	1.0
Royalty income	163.6	74.3	75.0	100.9	92.2	(18.7)	(17.2)
HIV franchise	126.5	61.3	61.1	99.7	57.1	7.1	4.0
Crestor [®]	22.0	11.0	11.1	100.5	10.9	1.5	0.2
Others	15.1	2.1	2.8	135.6	24.2	(88.4)	(21.4)
Others	2.4	1.2	1.1	94.7	1.1	0.3	(0.0)
Total	365.5	159.0	160.9	101.2	168.2	(4.4)	(7.3)

Y on Y Comparison and Main Variation Factors (Sales by Segment)



• Y on Y comparison



Main Variation Factors (Y on Y)

• Royalty income

(Increase factor)

- Sales growth and termination of the threshold period of HIV franchise

(Decrease factor)

- FY2018: Income from Roche for Xofluza® *

• Contract manufacturing

- Increase in export of dolutegravir and Xofluza®

• Prescription drugs

- Sales Increase of Cymbalta® and Intuniv®

• Overseas subsidiaries/export

- C&O: Sales increase of rabeprazole
- Shionogi Inc.
 - > FY2018: One-time payment from Purdue
 - > FY2019: One-time payment from BDSI**

Sales of Prescription Drugs in Japan



(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts*		1H results	Achievement (%)	1H results	Change (%)	Change (B yen)
	Full year	1H					
Cymbalta®	29.3	13.0	12.9	98.8	11.9	7.8	0.9
Intuniv®	13.6	4.6	4.5	96.6	2.4	86.7	2.1
Xofluza®	28.0	0.28	0.00	0.5	0.46	(99.7)	(0.5)
Rapiacta®	2.6	0.05	0.01	21.8	0.01	77.8	0.0
Brightpoc® Flu	1.8	0.18	0.31	169.0	0.23	32.3	0.1
Total of strategic products	75.7	18.2	17.7	96.9	15.0	17.4	2.6
OxyContin® franchise	6.7	3.6	3.2	87.9	3.8	(16.6)	(0.6)
Symproic®	2.3	1.1	1.1	99.9	0.72	51.6	0.4
Actair®	0.27	0.12	0.12	95.6	0.09	39.8	0.0
Mulpleta®	0.33	0.17	0.07	40.1	0.08	(19.1)	(0.0)
Pirespa®	6.9	3.5	3.4	99.5	2.9	20.2	0.6
Total of new products	92.2	26.7	25.6	95.8	22.6	13.1	3.0
Crestor®	10.0	5.2	4.6	88.0	5.2	(11.5)	(0.6)
Irbetan® franchise	4.9	2.6	2.2	85.5	3.1	(26.6)	(0.8)
Others	36.9	19.2	20.1	104.4	19.1	4.8	0.9
Prescription drugs	144.1	53.7	52.4	97.6	50.0	4.9	2.5

Year-On-Year Comparisons (One-time Factors)



Sales (Unit: B yen)

168.2

(Sales of Prescription Drugs in Japan: 50.0)

160.9

(Sales of Prescription Drugs in Japan: 50.0)

Operating income
(Excluding one-time
factors)

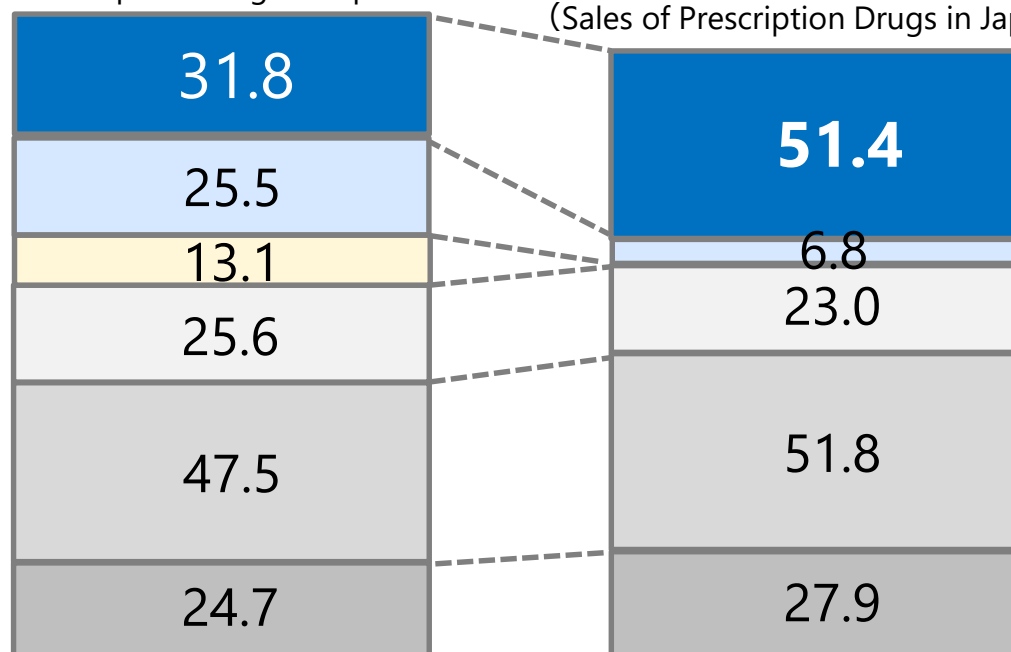
Operating income
(One-time factors)

Strategic investment

Ordinary R&D
expenses

Selling &
administrative
expenses

Cost of sales



1H FY2018

1H FY2019

<Main One-time Factors>

FY2018 :

- Income from Roche
- One-time payment from Purdue
- Strategic investment

FY2019 :

- Termination of the threshold period for the calculation of royalty payment of HIV franchise by ViiV
- One-time payment from BDSI*

**Our business is progressing steadily
including the sales of new products**

2. FY2019 Financial Forecasts

Revision of Forecasts (Announced on Oct 30, 2019)



(Unit: B yen)

	FY2019 Forecasts			FY2018	Y on Y	
	Original (May 9)	Revised (Oct 30)	Change (B yen)	Results	Change (%)	Change (B yen)
Sales	365.5	367.0	1.5	363.7	0.9	3.3
Operating income	147.0	150.0	3.0	138.5	8.3	11.5
Ordinary income	170.5	171.5	1.0	166.6	3.0	4.9
Profit attributable to owners of parent	133.0	135.0	2.0	132.8	1.7	2.2

Exchange rate (average)	FY2019 forecasts (May 9)	FY2019 forecasts (Revised on Oct 30)	1H FY2019 Results
USD (\$) – JPY (¥)	110.0	107.0	108.61
GBP (£) – JPY (¥)	145.0	133.0	136.65
EUR (€) – JPY(¥)	130.0	120.0	121.41

Revision of Statement of Income



(Unit: B yen)

	FY2019 Forecasts			FY2019 2H Forecasts			FY2018	Y on Y	
	Original (May 9)	Revised (Oct 30)	Change	Original (May 9)	Revised (Oct 30)	Change	Results	Change (%)	Change (B yen)
Sales	365.5 14.6	367.0 15.3	1.5	206.5 13.6	206.1 13.6	(0.4)	363.7 15.1	0.9	3.2
Cost of sales	53.5	56.0	2.5	28.0	28.1	0.1	54.9	2.0	1.1
Gross profit	312.0 45.1	311.0 43.9	(1.0)	178.5 40.4	178.0 41.8	(0.5)	308.8 46.8	0.7	2.2
SG&A expenses	165.0	161.0	(4.0)	83.5	86.2	2.7	170.3	(5.5)	(9.3)
Selling & administrative expenses	115.5 31.6 13.5	112.0 30.5 13.4	(3.5)	59.1 28.6 11.8	60.2 29.2 12.6	1.1	102.0 28.0 18.8	9.8	10.0
R&D expenses	49.5	49.0	(0.5)	24.4	26.0	1.6	68.3	(28.3)	(19.3)
Ordinary R&D expenses*	49.5	49.0	(0.5)	24.4	26.0	1.6	51.4	(4.7)	(2.4)
Strategic investment	-	-	-	-	-	-	16.9	-	(16.9)
Operating income	147.0 40.2	150.0 40.9	3.0	95.0 46.0	91.8 44.6	(3.2)	138.5 38.1	8.3	11.5
Non-operating income & expenses	23.5	21.5	(2.0)	12.5	14.4	1.9	28.0	(23.3)	(6.5)
Ordinary income	170.5 46.6	171.5 46.7	1.0	107.5 52.1	106.2 51.5	(1.3)	166.6 45.8	3.0	4.9
Profit attributable to owners of parent	133.0	135.0	2.0	84.0	83.4	(0.6)	132.8	1.7	2.2

Revision of Sales by Segment



(Unit: B yen)

	FY2019 Forecasts			FY2019 2H Forecasts			FY2018	Y on Y	
	Original (May 9)	Revised (Oct 30)	Change	Original (May 9)	Revised (Oct 30)	Change	Results	Change (%)	Change (B yen)
Prescription drugs	144.1	144.1	-	90.4	91.6	1.3	128.7	12.0	15.4
Overseas subsidiaries/export	31.4	31.3	(0.0)	15.3	13.8	(1.5)	29.4	6.5	1.9
Shionogi Inc.	9.9	10.2	0.3	3.6	3.4	(0.2)	11.8	(13.8)	(1.6)
Mulpleta [®]	1.0	1.0	-	0.75	0.66	(0.1)	0.08	N/A*	0.9
C&O	14.6	14.5	(0.0)	7.8	7.4	(0.4)	11.5	26.7	3.1
Contracting manufacturing	14.3	15.4	1.0	5.3	5.3	0.1	14.8	4.1	0.6
OTC and quasi-drug	9.7	9.7	-	5.1	5.0	(0.1)	8.1	19.7	1.6
Royalty income	163.6	164.2	0.6	89.3	89.3	(0.0)	180.3	(8.9)	(16.0)
HIV franchise	126.5	126.3	(0.2)	65.2	65.2	-	124.4	1.5	1.9
Crestor [®]	22.0	21.8	(0.2)	11.0	10.8	(0.3)	22.0	(0.7)	(0.1)
Others	15.1	16.1	1.0	13.0	13.3	0.2	33.9	(52.5)	(17.8)
Others	2.4	2.2	(0.1)	1.2	1.1	(0.1)	2.5	(8.7)	(0.2)
Total	365.5	367.0	1.5	206.5	206.1	(0.4)	363.7	0.9	3.3

Revision of Sales Forecasts for Prescription Drugs in Japan



(Unit: B yen)

	FY2019 Forecasts			FY2019 2H Forecasts			FY2018	Y on Y	
	Original (May 9)	Revised (Oct 30)	Change	Original (May 9)	Revised (Oct 30)	Change	Results	Change (%)	Change (B yen)
Cymbalta[®]	29.3	29.3	-	16.2	16.4	0.2	24.1	21.6	5.2
Intuniv[®]	13.6	13.6	-	9.0	9.2	0.2	5.3	157.2	8.3
Vyvanse[®]	0.38	0.05	△ 0.3	0.33	0.05	△ 0.3	-*	-*	0.05
Xofluza[®]	28.0	28.0	-	27.7	28.0	0.3	26.3	6.5	1.7
Rapiacta[®]	2.6	2.6	-	2.6	2.6	0.0	2.0	27.7	0.6
Brightpoc[®] Flu	1.8	2.2	0.3	1.6	1.8	0.2	1.2	84.0	1.0
Total of strategic products	75.7	75.7	(0.0)	57.5	58.1	0.6	58.9	28.6	16.8
OxyContin[®] franchise	6.7	6.4	(0.3)	3.1	3.2	0.1	7.3	(12.1)	(0.9)
Symproic[®]	2.3	2.3	-	1.2	1.2	0	1.6	43.8	0.7
Actair[®]	0.27	0.26	(0.0)	0.14	0.14	-	0.19	35.5	0.1
Mulpleta[®]	0.33	0.23	(0.1)	0.16	0.16	-	0.15	50.2	0.1
Pirespa[®]	6.9	7.0	0.1	3.4	3.5	0.1	5.7	23.0	1.3
Total of new products	92.2	91.9	(0.3)	65.5	66.3	0.8	73.8	24.5	18.1
Crestor[®]	10.0	9.5	(0.5)	4.8	4.9	0.1	9.9	(4.0)	(0.4)
Irbetan[®] franchise	4.9	4.6	(0.3)	2.3	2.4	0.1	5.4	(13.5)	(0.7)
Others	36.9	38.1	1.1	17.7	18.0	0.3	39.6	(4.0)	(1.6)
Total	144.1	144.1	-	90.4	91.6	1.3	128.7	12.0	15.4

3. Shareholder Return

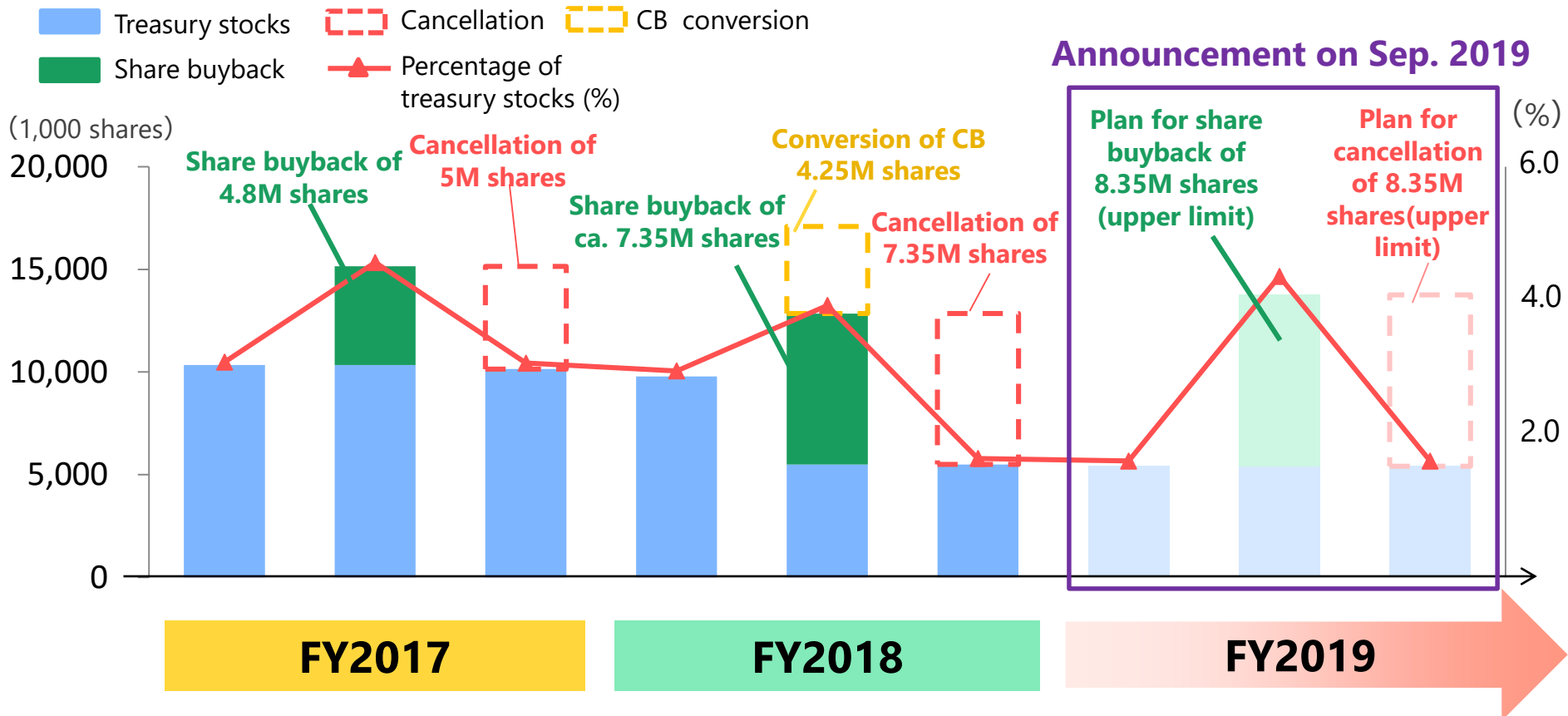
Flexible and Prompt Capital Policy

Share buyback

- Share buyback: 8.35M shares (upper limit)
- Total amount of buyback: 50 B yen (upper limit)
- Period: Oct. 1, 2019~Feb. 28, 2020

Cancellation of treasury shares

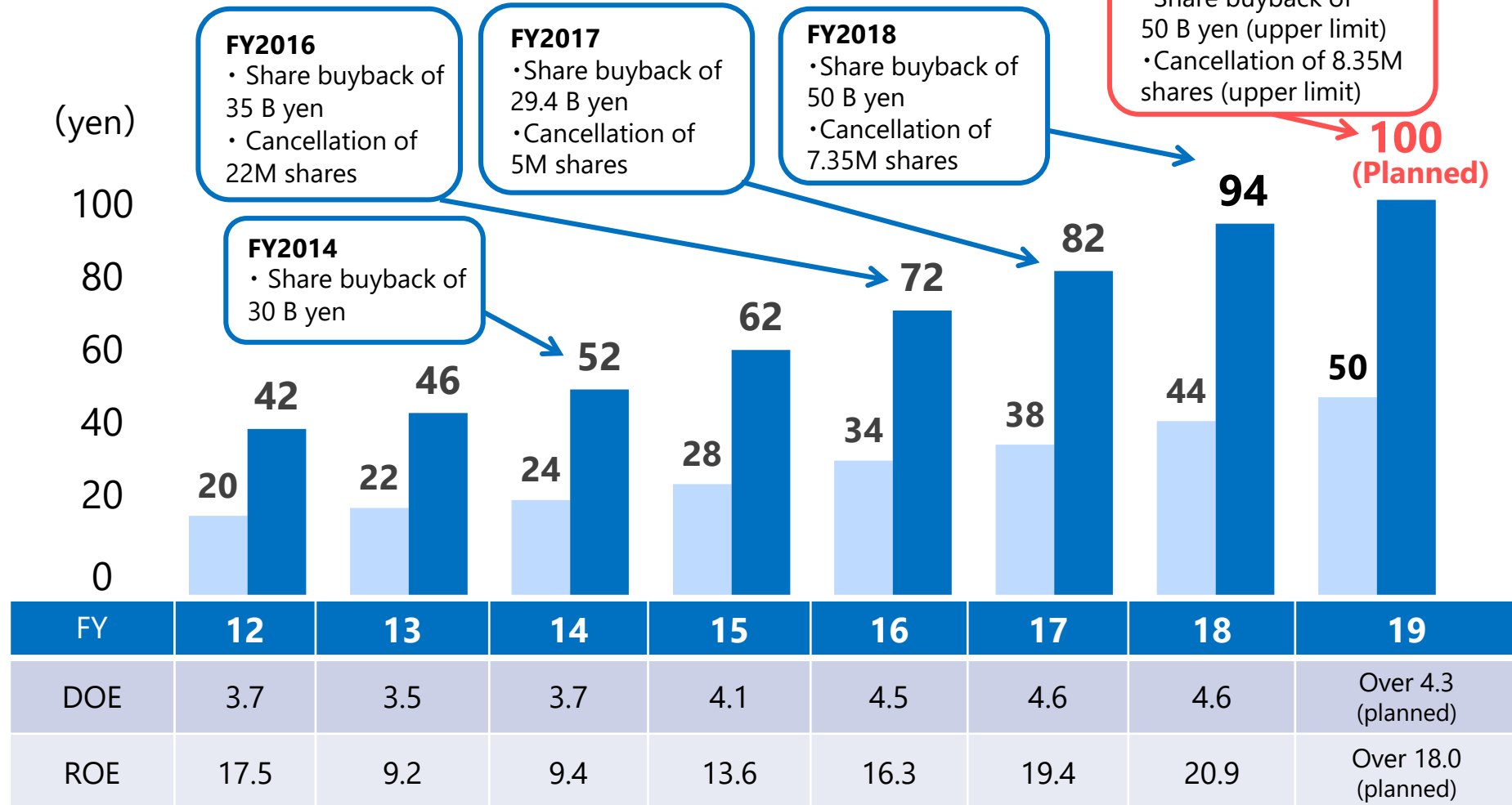
- Total shares to be cancelled: 8.35M shares (upper limit)
- Date for cancellation: Mar. 13, 2020



Shareholder Return Policy Through Which Shareholders Can Feel Our Growth

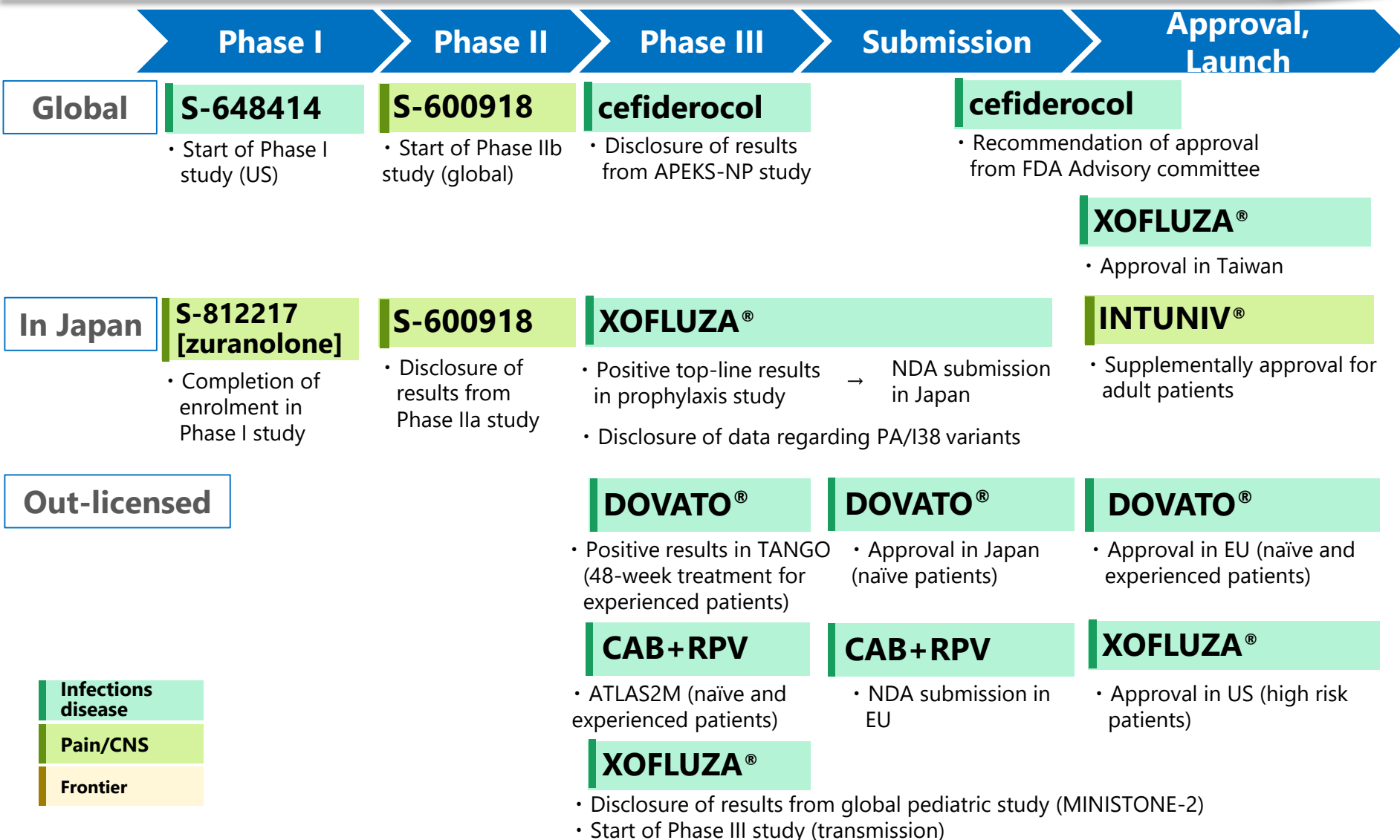


- Plan to **increase dividend for 8 consecutive years and reach 100 yen in FY2019**
- Continuously increase dividend in alignment with our growth



Appendix

Major Progress in 1H FY2019* (Pipeline)



Infections disease
Pain/CNS
Frontier

Major Progress in 1H FY2019* (Others)



- **May**
 - Contract agreement with Molteni for the commercialization of Rizmoic® (naldemedine), an opioid-induced constipation therapeutic agent in Italy and Poland
- **June**
 - Purchase all outstanding shares of Pionnier following the conclusion of the joint study
 - Contract agreement with Ferrer for the commercialization of Rizmoic® (naldemedine), an opioid-induced constipation therapeutic agent in Spain
 - Out-licensing agreements with Eddingpharm and EOC Pharma for lusutrombopag, a thrombopoietin receptor agonist and Epertinib, an HER2/EGFR Inhibitor
- **July**
 - Out-licensing agreement with AMR Centre on COT-143, a humanized monoclonal antibody targeting the PcrV protein of *Pseudomonas aeruginosa*
- **August**
 - Participate in the United Nations Global Compact
- **October**
 - M3 and Shionogi established a new joint venture "Stream-I, Inc."
 - New license agreement with Hsiri regarding a collaborative research and development program to discover and develop additional novel therapeutics for non-tuberculous mycobacterial (NTM) diseases and tuberculosis (TB)
 - Shionogi, Janssen, and Alzheimer's Drug Discovery Foundation Announced a "Clinical Sample Access Agreement" at WDC 2019 Summit

Statement/Guidelines for the use of Xofluza® in Japan

Statement of the Japanese Association for Infectious Diseases (JAID) regarding the use of Xofluza® (Announced on October, 2019)

1. ≥12 to 19 years of age and adults: No decision on a recommendation for Xofluza® use has been made at present due to limited clinical data.
2. Children <12 years of age: Careful consideration of the use of Xofluza®, taking into account the high rates of emergence of variant viruses with reduced susceptibility to Xofluza® in children observed in clinical studies to date.
3. Immunocompromised and severe influenza patients: No recommendation on active use of Xofluza® as monotherapy.*

Upon careful analysis of the available clinical data for Xofluza®, JAID has decided not to provide a definitive recommendation for Xofluza® use at present, but has confirmed multiple seasons of data are normally required before a recommendation for Xofluza® can be issued.

Guidelines of the Japanese Pediatric Society (JPS) regarding the use of Xofluza® for the 2019-2020 season (Announced on October, 2019)

1. The committee does not actively recommend the use of Xofluza® in pediatric patients <12 years of age, as the reports of the clinical experience of Xofluza® in this population are currently limited and the emergence of resistant viruses has been observed.
2. While the use of Xofluza® is not to be restricted for the time being, the emergence and potential transmission of resistant viruses needs to be carefully monitored.
3. For the treatment of immunocompromised patients, Xofluza® should not be used as monotherapy as the shedding of resistant viruses may be prolonged. In the case of severe influenza or influenza complicated with pneumonia, combination therapy with Xofluza® and other anti-flu drug(s) could be considered, although the committee views that the current level of clinical evidence is insufficient and are in the process of collecting and assessing such data.*

About PA/I38X-substituted viruses

Data from clinical studies announced to date

- **Incidence of PA/I38X-substituted viruses**

- The incidence was high in younger pediatric patients
- The incidence was higher in adults, adolescent and pediatric patients infected with A/H3N2

- **Association between the incidence of PA/I38X-substituted viruses and clinical symptoms**

- **Adult and adolescent patients**

There was no clear association between the incidence of PA/I38X-substituted viruses and the median time to alleviation or improvement. These data suggest clinical benefit of Xofluza in these populations irrespective of the substitution.

- **Pediatric patients**

It is important to continue to obtain additional data about PA/I38X-substituted viruses because the available analysis data are limited as of this moment especially in pediatric patients.



Shionogi will continue to proactively monitor and characterize PA/I38X-substituted viruses, and will communicate findings to medical institutions and academic conferences

Xofluza®: Data About PA/I38X-Substituted Viruses



Incidence of PA/I38X-substituted viruses in each clinical study

Clinical study	Age	A/H1N1pdm		A/H3N2		B	
		Sequence Population*	ITTI population**	Sequence Population*	ITTI population**	Sequence Population*	ITTI population**
Pediatric study in Japan (granule, tablet) ¹	< 6 years	20.0% (1/5)	11.1% (1/9)	52.2% (12/23)	44.4% (12/27)	0.0% (0/13)	0.0% (0/16)
	>=6 years, < 12 years	0.0% (0/2)	0.0% (0/4)	18.9% (10/53)	14.5% (10/69)	0.0% (0/3)	0.0% (0/4)
Study in OwH adults and adolescents (Phase II, CAPSTONE-1) ²	>=12 years	3.4% (4/116)	2.0% (4/205)	10.3% (35/341)	8.3% (35/423)	0.0% (0/87)	0.0% (0/106)
Study in HR adults and adolescents (CAPSTONE-2) ²	>=12 years	5.9% (1/17)	3.6% (1/28)	9.3% (13/140)	7.1% (13/182)	0.8% (1/129)	0.6% (1/167)

- The incidence was high in younger pediatric patients under 6 years of age
- The incidence was higher in patients infected with A/H3N2 for adults, adolescents, and pediatric patients

Patients with single infection were included in this analysis.

*Sequence population: Of ITTI population, patients had paired baseline and follow-up RT-PCR-positive samples evaluable for Sanger sequencing.

**ITTI population: All patients who received Xofluza with a confirmed diagnosis of influenza virus infection based on RT-PCR on Day 1.
(Patients whose influenza virus after treatment was not detected were included in this population)

Association between the incidence of PA/I38X-substituted viruses and clinical symptoms in adult and adolescent patients

Clinical study in OwH adults and adolescents (CAPSTONE-1) ¹

	Xofluza®*		Placebo**
	W/ PA/I38X-substituted viruses	W/O PA/I38X-substituted viruses	
N	36	334	230
Time to alleviation of symptoms (hours)	63.1	51.0	80.2
95% CI (hours)	52.2, 87.7	46.0, 56.0	72.6, 87.1

The median time to alleviation of symptoms tended to be longer in patients with PA/I38X-substituted viruses after treatment with Xofluza® than in patients without PA/I38X-substituted viruses. However, the median time to alleviation of symptoms in patients with PA/I38X-substituted viruses after treatment with Xofluza® was shorter than that in those treated with placebo.

Clinical study in HR adults and adolescents (CAPSTONE-2) ²

	Xofluza®*		Placebo**
	W/ PA/I38X-substituted viruses	W/O PA/I38X-substituted viruses	
N	15	275	385
Time to improvement of influenza symptoms (hours)	62.5	73.2	102.3
95% CI (hours)	28.3, 87.7	65.4, 86.9	92.7, 113.1

The median time to improvement of influenza symptoms tended to be shorter in patients with PA/I38X-substituted viruses after treatment with Xofluza® than in those without PA/I38X-substituted viruses.

There was no clear association between the incidence of PA/I38X-substituted viruses and the median time to alleviation or improvement. These data suggest clinical benefit of Xofluza® in these populations irrespective of the substitution.

HIV Franchise: Progress of 2-Drug Regimens



Tivicay[®], Triumeq[®] Launch: 2013~

- **Key drug for 3-drug regimen**

Juluca[®] (DTG/RPV) Launch: 2017~

- **First 2-drug regimen for maintenance therapy**

DTG/3TC Launch: 2019~

- **First 2-drug regimen for naïve patients**
- Apr. 2019: Approved in US (naïve patients)
- Jul. 2019: Approved in EU (naïve patients and switch patients)
 - : TANGO 48-week results (switch patients)
 - : GEMINI 96-week results (naïve patients)
- Oct.-Dec. 2019: Start SALSA (switch patients)

CAB+RPV Launch: 2019~

- **First long acting injection (monthly or bimonthly)**
- Apr. 2019: NDA submission in US (monthly injection, naïve patients and switch patients),
PDUFA date: Dec. 29, 2019 (priority review designated)
- Jul. 2019: MAA submission in EU (monthly)
- Aug. 2019: ATLAS 2M results (bimonthly injection for switch patients)

CAB prophylaxis Launch: 2021~

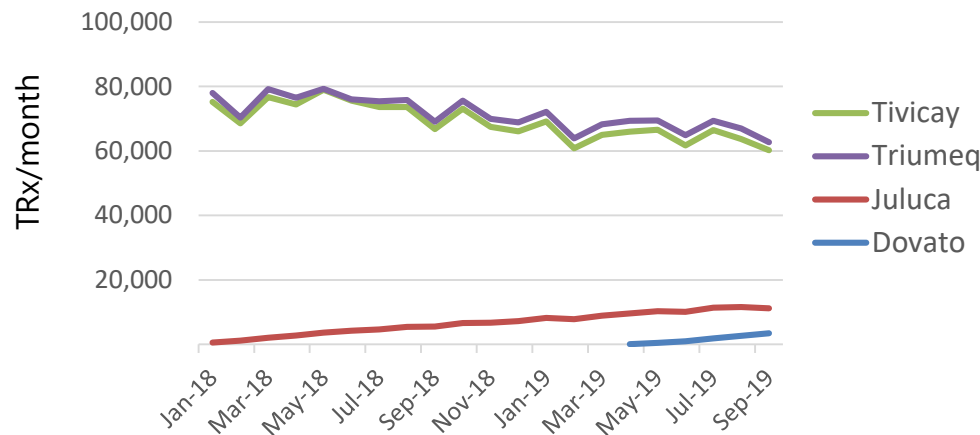
- **First long-acting injectable for prophylaxis (bimonthly injection)**

Progress of HIV Franchise



Changes in total prescriptions of DTG franchise

Changes in TRx for DTG franchise in the US*



- Growth of our two Drug Regimens is encouraging in that it more than offsets the decline in our 3 Drug Regimen Triumeq® as we transition to the new portfolio.
- Dovato® uptake will take time as access and physician acceptance increases supported by our data and updated treatment guidelines.

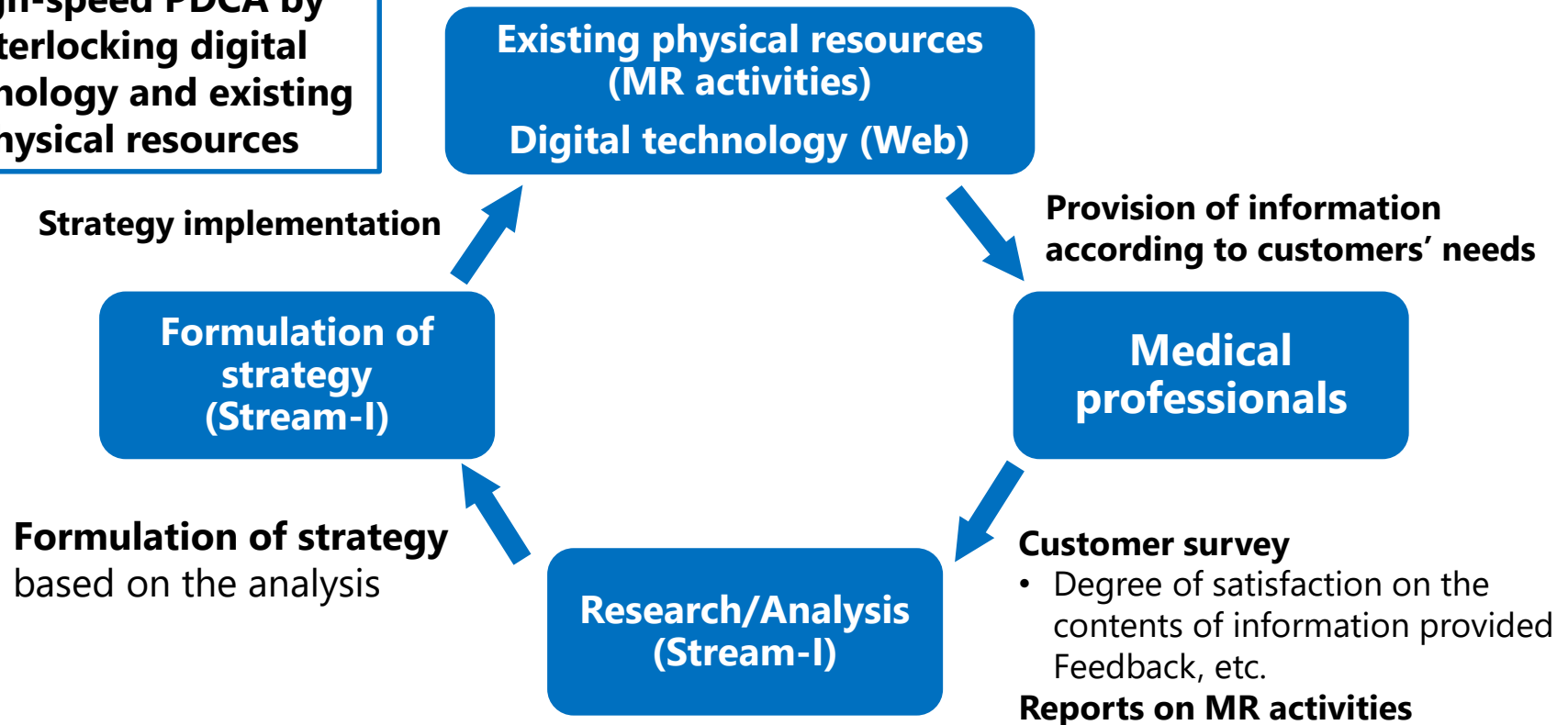
Expectations for the growth of HIV franchise by CAB+RPV

- Once approved, it will become the first long-acting regimen for HIV infection.
- According to patient satisfaction assessment in the Phase III studies, 97% (266/273) of patients in ATLAS and 99% (257/259) of patients in FLAIR answered that they preferred long-acting injections of CAB+RPV over their previous oral regimen.**
- Provide patients with a new value proposition that is different from oral medications
 - People who have concerns with disclosure
 - People who struggle to swallow the relatively large pills
 - People who struggle with compliance
 - People who suffer from the psychological burden of being reminded daily of their HIV status



Establishment of "Stream-I", a joint venture between M3 and Shionogi

High-speed PDCA by
interlocking digital
technology and existing
physical resources



**Establishment of an information delivery model
for improving productivity and supporting proper treatment**

Establishment of “Stream-I”

Stream-I’s contribution to the treatment of influenza

Potential of Stream-I

Prevention

- **Continuous increase in infection with influenza virus at homes and schools**

Diagnosis

- **Difficulty in diagnosis in early stages of infection**

Treatment

- **Existence of patients in serious condition**

- Prompt provision of information on the results of surveillance, promotion of precautionary measures, and proposal of new options
- Development of a new simplified diagnosis method and examination of a new medical treatment model
- Prevention of serious conditions by offering a tool to promote communication between patients and medical staff

Offer a new, optimal option in the treatment of influenza, leading to a disease solution

Pipeline (as of Oct. 30, 2019)



Preclinical (target indication*)	Phase I	Phase II	Phase III	Submission
Influenza virus infection HIV infection RS virus infection Bacterial infection Mycobacterium disease Fungus infection Vaccine for prevention Peptide ADHD Opioid Alzheimer's disease Cognitive and memory deficits Post-stroke spasticity Peptide Obesity S-723595 NASH Cancer metastasis S-540956 Nucleic acid adjuvant Peptide	Global <div>S-648414 HIV infection</div> <div>S-117957 Insomnia</div> <div>S-237648 Obesity</div> <div>S-588210 Solid tumor</div> <div>Rizmoic® Opioid-induced constipation (pediatric)</div> In Japan <div>S-812217 [Zuranolone] Depression</div> <div>S-600918 Neuropathic pain</div> <div>S-637880 Neuropathic pain</div> <div>S-010887 Neuropathic pain</div> <div>S-770108 Idiopathic pulmonary fibrosis</div>	<div>S-600918 Refractory/unexpected chronic cough</div> <div>S-120083 Inflammatory pain</div> <div>S-707106 Type2 diabetes</div> <div>S-488210 Head and neck squamous cell carcinoma</div> <div>epertinib Malignant tumor</div> <div>S-588410 Bladder cancer</div> <div>Cefiderocol Multidrug-resistant Gram-negative bacterial infections</div> <div>S-600918 Refractory/unexpected chronic cough</div> <div>S-005151 [Redasemtide] Acute ischemic stroke</div> <div>S-005151 [Redasemtide] Epidermolysis bullosa</div> <div>S-237648 Obesity</div> <div>S-525606 Allergic rhinitis caused by Japanese cedar allergen</div> <div>S-588410 Bladder cancer</div> <div>SR-0379 Cutaneous ulcer</div> <div>ADR-001** Decompensated liver cirrhosis</div>	<div>Cefiderocol Multidrug-resistant Gram-negative bacterial infections</div> <div>Cefiderocol Multidrug-resistant Gram-negative bacterial infections</div> <div>Xofluza® Influenza virus infection (High-dose for children)</div> <div>Cymbalta® Depression (pediatric)</div> <div>S-588410 Esophageal cancer</div>	<div>Cefiderocol (US) Complicated Urinary Tract Infections (cUTI), including Pyelonephritis</div> <div>Cefiderocol (EU) Multidrug-resistant Gram-negative bacterial infections</div> <div>Oxycontin®TR Moderate to severe chronic pain</div> <div>Xofluza® Influenza virus infection (prophylaxis)</div> <div>Xofluza® Influenza virus infection (granule, <20 kg)</div> <div>• Infectious diseases</div> <div>• Pain/CNS</div> <div>• Other</div>

Pipeline

- Major Out-Licensed Pipeline (as of Oct. 30, 2019)



Preclinical	Phase I	Phase II	Phase III	Submission
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		Dovato® Treatment for HIV infection TANGO study (maintenance)	Dovato® (Japan) Treatment for HIV infection (naïve patients)
			CAB LAP Prevention for HIV infection	CAB+RPV LAP Treatment for HIV infection
			Xofluza® Severe influenza virus infection	
			Xofluza® Influenza virus infection (pediatric)	
			Xofluza® Influenza virus infection (transmission)	
				<ul style="list-style-type: none"> • Infectious diseases • Pain/CNS • Others

Stage progression
(from Jul. 29
2019)

Xofluza® (Influenza virus infection): Submission→Approval (Taiwan)
 Xofluza® (prophylaxis): Phase III→Submission (Japan)
 S-600918 (Refractory/unexpected chronic cough): Phase IIb initiated (Global)
 S-005151 [Redasemtide] (Epidermolysis bullosa): Follow-up study of Phase II initiated (Global)
 S-648414 (Treatment for HIV infection): Phase IIb initiated (US)
 Dovato®: Phase III→Submission (Japan)
 Xofluza® (High risk patients): Submission→Approval (US)
 Xofluza® (transmission): Phase III initiated

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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- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, inavailability of raw materials, and failure to gain market acceptance.
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