1st Half of Fiscal 2019
Financial Results

October 31, 2019

Isao Teshirogi, Ph.D.
President and CEO

SHIONOGI

Agenda

1. **Overview of 1st Half FY2019 Financial Results (P.3-12)**
2. **Actions and Progress in 1st Half FY2019 (P.13-21)**
3. **FY2019 Financial Forecasts (P.22-26)**
4. **Actions in 2nd Half FY2019 for Growth Beyond 2020 (P.27-41)**
5. **Shareholder Return (P.42-44)**

Appendix

- Financial Statement (Consolidated) (P.46)
- Major Progress in 1st Half FY2019 (P.47, 48)
- Xofluza® : Data about PA/I38X-Substituted Viruses (P.49, 50)
- Target Milestones for Development of Pipeline in FY2019 (P.51-53)
- Progress of Pipeline (P.54, 55)
- Launch Plan (P.56)
- Definition of New Products (P.57)

1. Overview of 1st Half FY2019 Financial Results

1st Half Fiscal 2019 Financial Results

1. Overview of 1st Half FY2019 Financial Results
2. Actions and Progress in 1st Half FY2019
3. FY2019 Financial Forecasts
4. Actions in 2nd Half FY2019 for Growth Beyond 2020
5. Shareholder Return

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

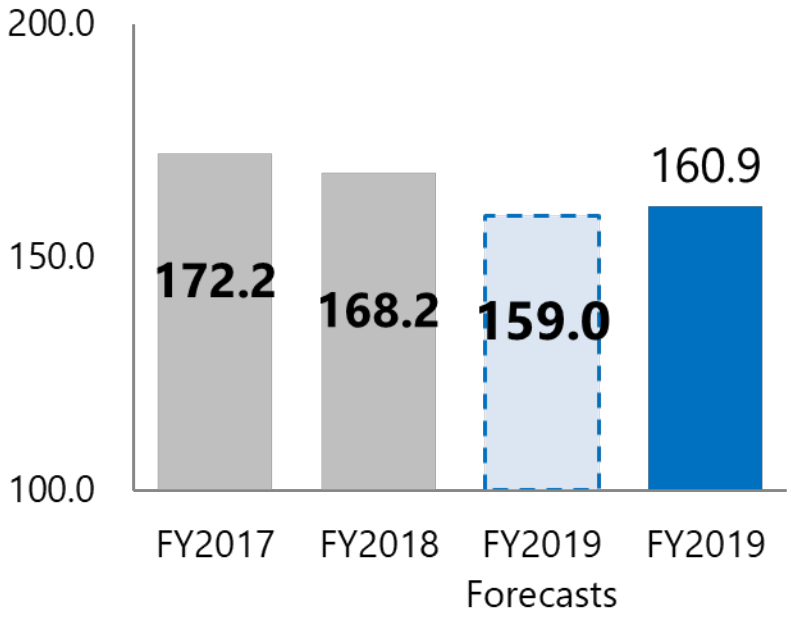
- Sales: **160.9 B yen** (YonY -4.4%, vs 1H forecast +1.2%)

For HIV franchise

- Royalty income: **61.1 B yen** (YonY +7.1%)

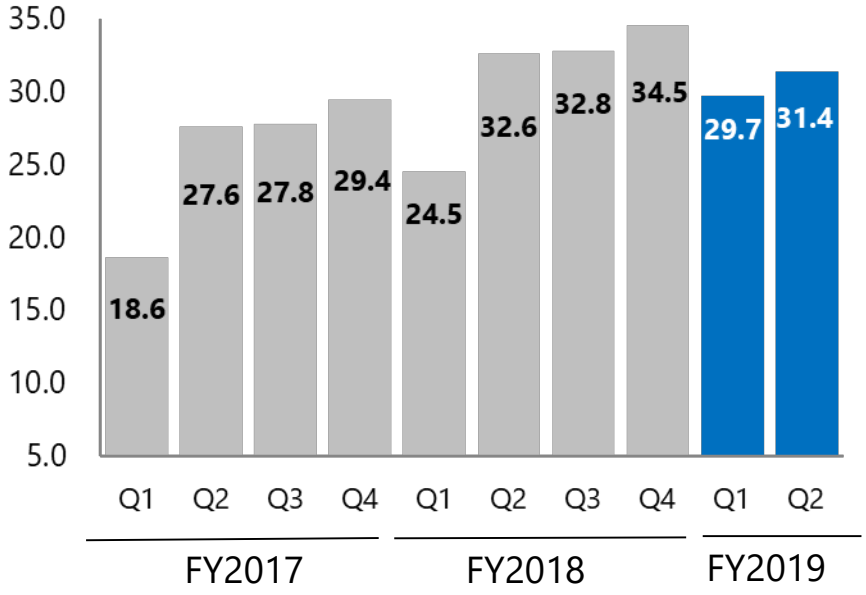
(Billions of yen)

Net Sales (1H)



(Billions of yen)

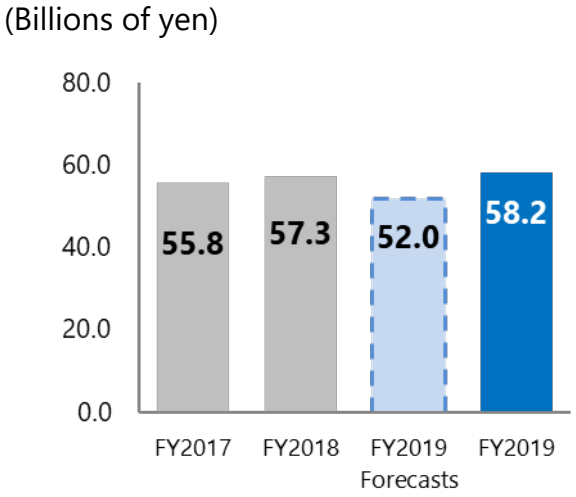
Quarterly Royalty Income from HIV Franchise



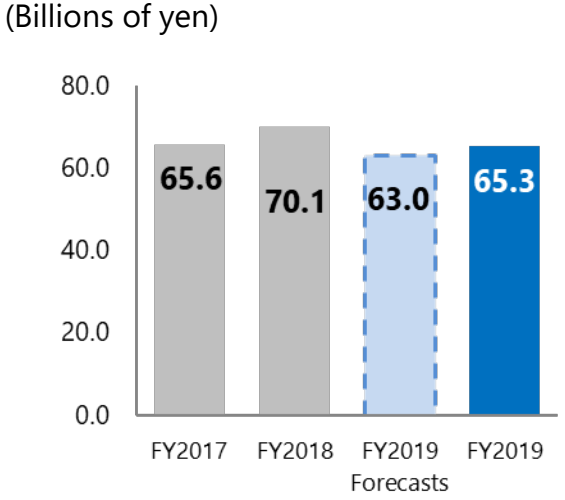
Highlight(2) Each Profit Measure Has Smoothly Progressed vs 1H Forecasts

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

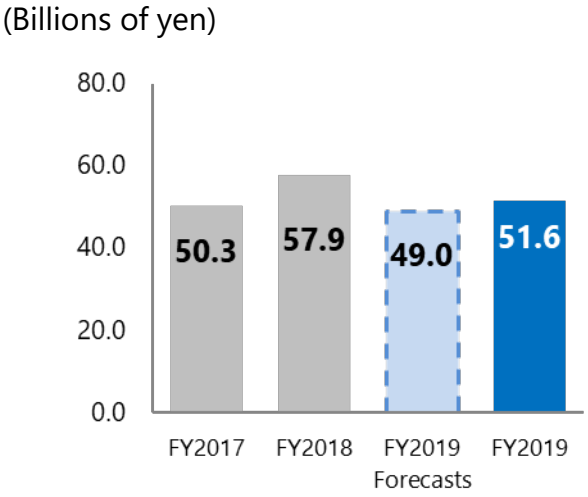
Operating Income (1H)



Ordinary Income (1H)



Profit attributable to owners of parent (1H)



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

* Forecasts announced on May 9, 2019 (Revision was announced on October 30, 2019)

Statement of Income

(Unit: B yen)

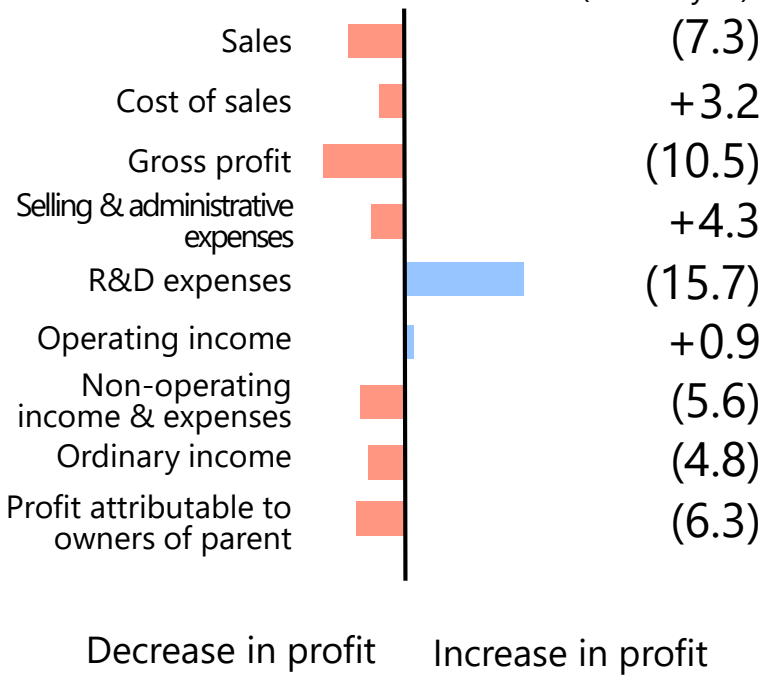
	FY2019				FY2018	Y on Y	
	Forecasts*		1H results	Achievement (%)	1H results	Change (%)	Change (B yen)
	Full year	1H					
Sales	**365.5**	**159.0**	**160.9**	101.2	168.2	(4.4)	(7.3)
	14.6	16.0	17.3		14.7		
Cost of sales	**53.5**	**25.5**	**27.9**	109.4	24.7	12.8	3.2
Gross profit	**312.0**	**133.5**	**133.0**	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)
	31.6	35.5	32.2		28.3		
Selling & administrative expenses	**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)

* Forecasts announced on May 9, 2019 (Revision was announced on October 30, 2019)
** Ordinary R&D expenses: Total R&D expenses excluding strategic investment

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

- **Y on Y comparison**

(Unit: B yen)



- **Progress vs 1H Forecasts**

(Unit: B yen)



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

* Royalty income from Roche as milestones of R&D achievement

Sales by Segment

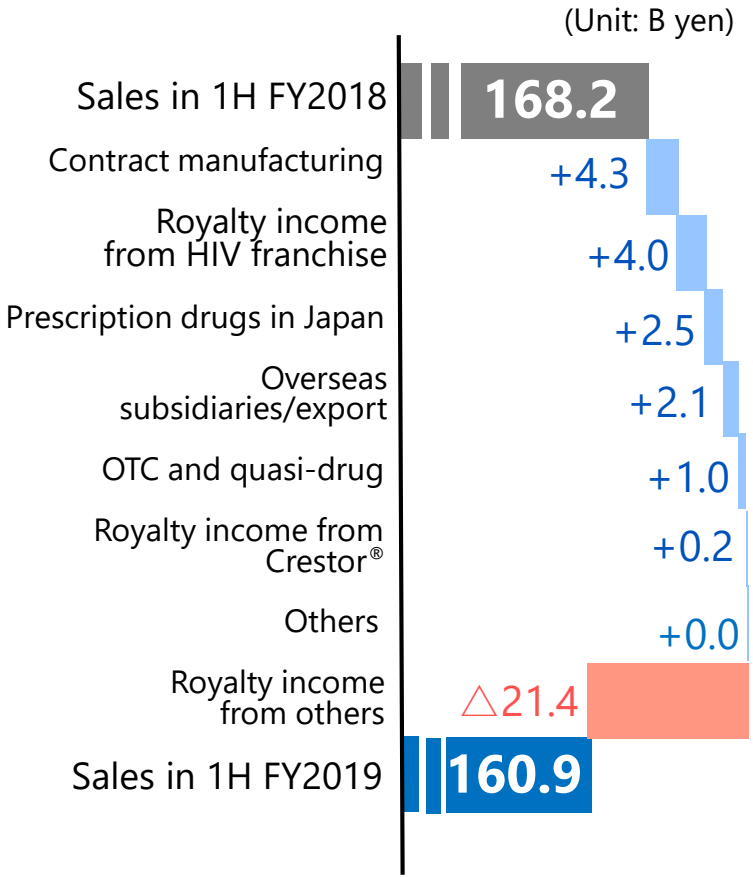
(Unit: B yen)

	FY2019				FY2018	Y on Y	
	Forecasts*		1H results	Achievement (%)	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)**

* Forecasts announced on May 9, 2019 (Revision was announced on October 30, 2019)
** The full-scale promotion was initiated in Dec. 2018.

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**

* Royalty income from Roche as milestones of R&D achievement
** BioDelivery Sciences International Inc.

Sales of Prescription Drugs in Japan

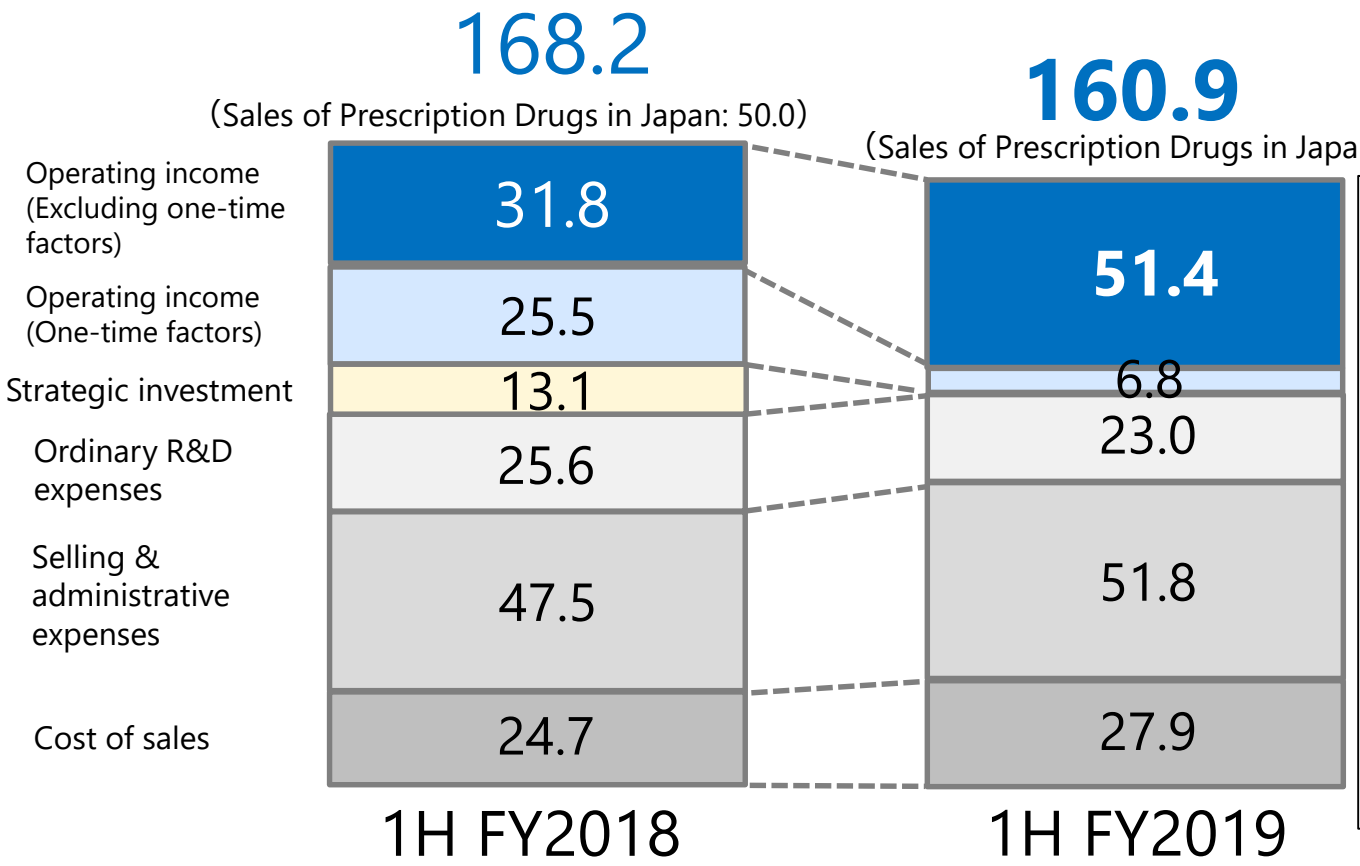
(Unit: B yen)

	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

* Forecasts announced on May 9, 2019 (Revision was announced on October 30, 2019)

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

Sales (Unit: B yen)



＜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

* BioDelivery Sciences International Inc.

2. Actions and Progress in 1st Half FY2019

1st Half Fiscal 2019 Financial Results

1. Overview of 1st Half FY2019 Financial Results
2. **Actions and Progress in 1st Half FY2019**
3. FY2019 Financial Forecasts
4. Actions in 2nd Half FY2019 for Growth Beyond 2020
5. Shareholder Return

Basic Strategy and Progress of 1st Half in FY2019

Driving for sustainable growth beyond 2020, while demonstrating our own earning power created during SGS2020

1. Sales

Increasing sales and profits, demonstrating own earning power by expanding sales of new products and further increasing management efficiency

- **Sales increase of Cymbalta® and Intuniv®**

2. Investment

- Progression of pipeline products as growth drivers beyond 2020
- Establish a global presence in priority regions

- **Further selection and concentration on high-priority projects**
- **Novel HIV drug: Initiation of a clinical trial**
- **Progress in the development of Cefiderocol and Xofluza®**

Japanese Business - Cymbalta®, ADHD family -

Cymbalta®

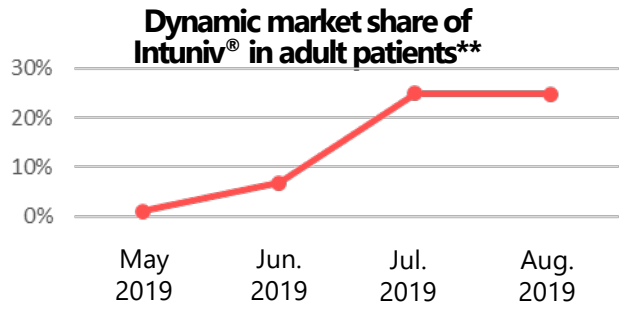
- **Improving awareness of the mechanism of Cymbalta® supported by guideline recommendations and clinical evidence**
- **Improving awareness of the direct analgesic effects of Cymbalta®, rather than through the mediation of its antidepressant effects**

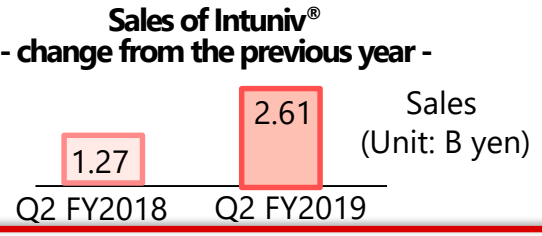
⇒ The proportion of patients prescribed Cymbalta® with chronic low back pain increased by about 10% from Feb 2019 to Sep. 2019*

（naïve patients：Feb. 12.8%→Sep. 23.8%, all patients：Feb. 14.3%→Sep. 23.6%）

ADHD family（Intuniv®, Vyvanse®）

- **Intuniv® ：Share capture in adult market**
  - **Adult：**
    - > **Sales increased about 2 times after approval for the treatment of adult patients(Y on Y, from Jul. 2019 to Sep. 2019)**
  - **Pediatric：**
    - > Seeking to expand share in naïve patient market by making the mechanism and efficacy fully understood
- **Vyvanse®: Preparation for proper use after launch**
  - Promoting understanding of the efficacy and safety profile and establishing distribution management system





SHIONOGI

* Company data

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R&D - Progress of 8 High-Priority Projects

		Pipeline	Major Progress in 1H FY2019
Infectious disease	In-house	**S-648414** (HIV infection)	Start of Phase I study (US)
		S-004992 (Tuberculosis)	Stopped development and returned the right to C&O based on the results of pre-clinical studies (Further details to be mentioned later)
Pain/CNS	In-house	**S-600918** (Refractory/unexpected chronic cough)	Completion of Phase IIa study (Japan) Presentation of positive results of Phase IIa study in ERS 2019 Start of Phase IIb study (global)
		S-637880 (Neuropathic pain)	Preparation for Phase I MAD study (Japan) and Phase II study (global)
	Collaboration	**S-812217 [Zuranolone]** (Depression)	Completion of enrollment in Phase I study (Japan) Preparation for Phase II study (Japan)
Others	In-house	**S-540956** (Nucleic acid adjuvant)	Conducted pre-clinical studies before the start of clinical trials in FY2020
		S-770108 (Idiopathic pulmonary fibrosis)	Preparation for lung deposition study (UK)
	Collaboration	**Peptide projects**	Running research programs utilizing PDPS technology for finding pre-clinical candidates in FY2020

Prompt decision of the priority in drug candidates
⇒ Effective investment in next growth drivers

R&D_Efforts for Elimination of Tuberculosis

Changes in environment in the 1st half FY2019

- FDA has approved a combination therapy using Pretomanid, Bedaquiline, and Linezolid as a treatment for drug-resistant tuberculosis
- Obtained new non-clinical data on S-004992

Have ceased research & development of S-004992 at Shionogi and returned development rights to C&O given differentiation and pricing challenges

License agreement and research collaboration with Hsiri regarding the research and development of drugs to treat mycobacterial* diseases

- In May 2018, executed a contract for collaborative research on a candidate on a mycobacterial disease drug with a new mechanism
- In October 2019, executed another contract to pursue collaborative research on another mycobacterial disease drug with another new mechanism

Continue to pursue elimination of tuberculosis by pursuing research on mycobacterial* disease drugs with novel mechanisms and the potential for a superior profile

* Diseases caused by infection of mycobacteria (tuberculosis, non-tuberculous mycobacteria)

Global Development

Progress in the Development of Cefiderocol

- **Development progress in the U.S.**
  - Submitted a New Drug Application to FDA* for the "treatment of complicated urinary tract infections, including pyelonephritis**."
    →On October 16, 2019, the Advisory Committee voted to recommend approval (14:2)

* Patients with limited or no alternative treatment options
** Based on the data from the complicated urinary tract infection study

- **Progress in clinical studies**
  - **Phase III clinical study in patients with infections caused by CR Gram-negative pathogens (CREDIBLE-CR) completed**
    - ✓ Cefiderocol showed similar clinical and microbiological outcomes as those of the best available therapy (primary endpoint).
    - ✓ The rate of all-cause mortality (secondary endpoint) was higher in the cefiderocol arm. However, patients enrolled in the study had various underlying critical illnesses. It was concluded by investigators, a data safety monitoring board, and an independent blinded adjudication committee that there was no association between the treatment with cefiderocol and the higher rate of all-cause mortality. The cause of the mortality difference is unknown and could be due to chance.
  - **Phase III clinical study in patients with nosocomial pneumonia (APEKS-NP) completed**
    - ✓ Efficacy: Cefiderocol met the primary endpoint of non-inferiority compared to high-dose meropenem in all-cause mortality at 14 days after the end of treatment. Cefiderocol also showed clinical and microbiological outcomes similar to high-dose meropenem.
    - ✓ Safety: The incidence of treatment-emergent adverse events was similar to high-dose meropenem.

* Patients with limited or no alternative treatment options
** Based on the data from the complicated urinary tract infection study

Global Development

Expansion of Xofluza® (baloxavir marboxil)

- **Pursued new indications to expand share in the U.S. (collaboration with the Roche Group)**
  - **On October 16, 2019, Received approval for additional indication for "the treatment of acute, uncomplicated influenza in people 12 years of age and older who are at high risk of developing influenza-related complications"**
    - ✓ Xofluza® is the first medicine indicated specifically for the treatment of influenza in high-risk patients*.
  - **Positive results from the Global Pediatric Phase III study (MINISTONE-2)**
- **August 28, 2019, Received approval in Taiwan of indication for the treatment of acute influenza Types A and B in patients 12 years of age and older**
- **October 16, 2019, Submitted the Supplemental New Drug Application of XOFLUZA® in Japan for Post-Exposure Prophylaxis of Influenza Virus Infection**

*High-risk patients: Patients at high risk for influenza-related complications

About Xofluza®

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.*

*Please note the potential usage of XOFLUZA in this patient population(s) is not approved by the PMDA

About Xofluza®

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**

    See appendices for details

    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

3. FY2019 Financial Forecasts

1st Half Fiscal 2019 Financial Results

1. Overview of 1st Half FY2019 Financial Results
2. Actions and Progress in 1st Half FY2019
3. **FY2019 Financial Forecasts**
4. Actions in 2nd Half FY2019 for Growth Toward Beyond 2020
5. Shareholder Return

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	**367.0**	**1.5**	206.5	**206.1**	**(0.4)**	363.7	**0.9**	**3.2**
Cost of sales	14.6 53.5	15.3 **56.0**	**2.5**	13.6 28.0	13.6 **28.1**	**0.1**	15.1 54.9	**2.0**	**1.1**
Gross profit	312.0	**311.0**	**(1.0)**	178.5	**178.0**	**(0.5)**	308.8	**0.7**	**2.2**
SG&A expenses	45.1 165.0	43.9 **161.0**	**(4.0)**	40.4 83.5	41.8 **86.2**	**2.7**	46.8 170.3	**(5.5)**	**(9.3)**
Selling & administrative expenses	31.6 115.5	30.5 **112.0**	**(3.5)**	28.6 59.1	29.2 **60.2**	**1.1**	28.0 102.0	**9.8**	**10.0**
R&D expenses	13.5 49.5	13.4 **49.0**	**(0.5)**	11.8 24.4	12.6 **26.0**	**1.6**	18.8 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	40.2 147.0	40.9 **150.0**	**3.0**	46.0 95.0	44.6 **91.8**	**(3.2)**	38.1 138.5	**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	46.6 170.5	46.7 **171.5**	**1.0**	52.1 107.5	51.5 **106.2**	**(1.3)**	45.8 166.6	**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**

* Ordinary R&D expenses: Total R&D expenses excluding strategic investment

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**

* N/A: Not applicable because Mulpleta® was sold only for 7 months in FY2018.

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**

* To be launched in 2H FY2019

4. Actions in 2nd Half FY2019 for Growth Beyond 2020

1st Half Fiscal 2019 Financial Results

1. Overview of 1st Half FY2019 Financial Results
2. Actions and Progress in 1st Half FY2019
3. FY2019 Financial Forecasts
4. **Actions in 2nd Half FY2019 for Growth Beyond 2020**
5. Shareholder Return

Toward Growth Beyond 2020

Progress in achievement of KPIs in the current mid-term business plan (SGS2020)

➢ **Most KPIs have been achieved**

		FY2020 Target	FY2019 Target	FY2018 Results
Growth	Sales of new products*	200.0 billion yen	100.6 billion yen	83.1 billion yen
	Ordinary income	150.0 billion yen	170.5 billion yen	**166.6 billion yen**
Efficacy	ROIC**	13.5% or more	15.0% or more	**16.5%**
	CCC***	Less than 7.0 months	Less than 7.6 months	8.9 months
	Original pipeline ratio	50% or more	50% or more	**69%**
Shareholder Return	ROE	15.0% or more	18.0% or more	**20.9%**
	DOE	4.0% or more	4.3% or more	**4.6%**

Set new targets for further growth and formulate a new mid-term business plan, one year earlier than scheduled, to prepare for the dolutegravir cliff. (release scheduled for the end of April 2020)

Focus on solving pending issues to transit to a new med-term business plan in the second half of FY2019.

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* New products: See the Appendix
New Products were defined in Updates to SGS2020 issued on October 31, 2016

** Return on invested capital
*** Cash conversion cycle

Efforts in 2H FY2019

1. Sales

Increasing sales and profits, demonstrating own earning power by expanding sales of new products and further increasing management efficiency

- **Evolution of sales activities in Japan**

2. Investment

- Progression of pipeline products as growth drivers beyond 2020
- Establish a global presence in priority regions

- **Progress of R&D for high-priority projects and new candidates**
- **Establish specialized sales base in the U.S. and EU market initiating with Cefiderocol**
- **Continued excellent progress of HIV Franchise**

3. Business innovation

- **Establishment of "Stream-I", M3 and Shionogi Joint Venture**
- **Improve operating processes by introducing international accounting standards (IFRS) and increasing transparency**
- **Promote activities related to ESG* and diversity & inclusion**
- **Advance business of group companies including Shionogi Pharma**

Proceed consistently to sustainable growth after FY2020

* ESG (Environment, Society, Governance) : Non-financial information to evaluate corporate sustainability and risk

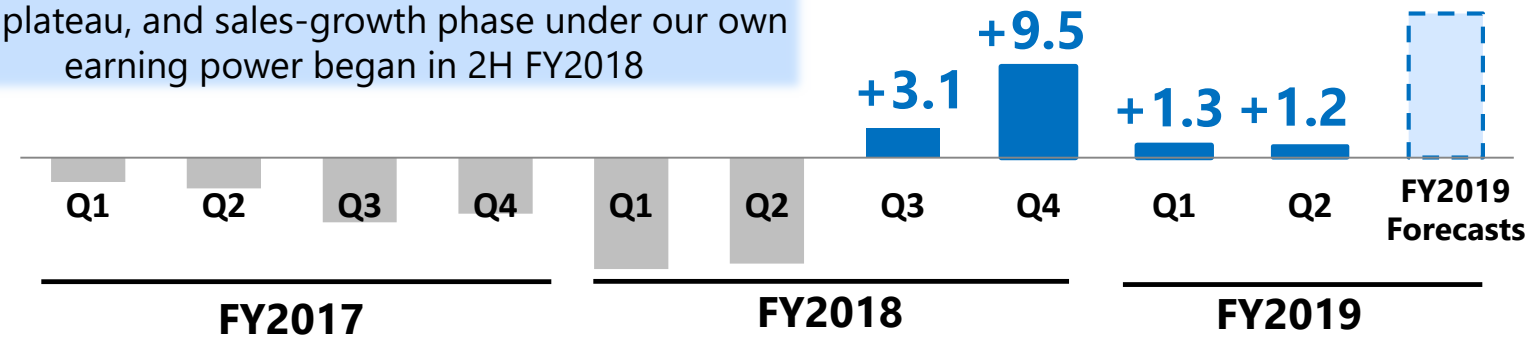
Evolution of Sales Activities in Japan

Further evolution of sales activities in Japan using IT

Sales of prescription drugs in Japan (Y on Y comparison)

The impact of share capture by generic competitors hit a plateau, and sales-growth phase under our own earning power began in 2H FY2018

(Unit: B yen)



Use of IT

Creation of a database of sales promotion activities (Using iPads)

Analysis of an effective sales promotion methods and formulation of optimized strategy

Implementation of sales promotion based on the analysis results

Improvement by implementing the PDCA cycle

Realization of effective sales promotion via the use of information provided based on data and a reformed activities

Progress in Development of Next Growth Drivers

S-812217 [general name: Zuranolone] (depression)

Promising profile including remission of depression after short-term treatment is anticipated

- **Rapid onset**: in 24 hours after first dosing
- **Greater efficacy**: superior to currently available antidepressants
- **Durable efficacy**: remission following treatment discontinuation
- **Better medication adherence**: No need for dose adjustment such as titration and tapering, once daily dosing for 14 days

➢ **Breakthrough profiles with novel mechanism**

➢ **Novel antidepressant candidate to follow Cymbalta®**

Original development plan:

Rapid development with utilizing US clinical data to the greatest extent possible

In parallel with SAGE's development in the US, Discussion with PMDA

Current development plan:

- **Conduct Phase II study, expect to start in FY2019**
- **Build evidence base to maximize value**

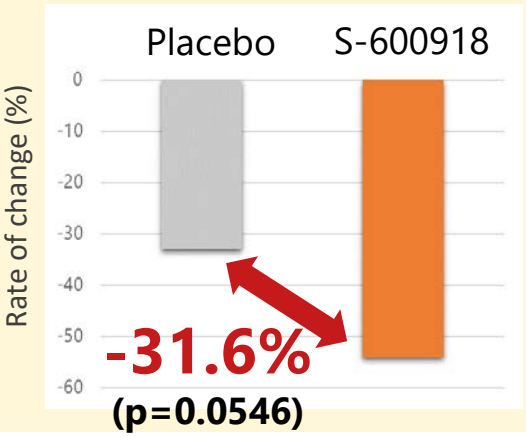
Progress in Development of Our Next Growth Drivers

S-600918 (Refractory/unexpected chronic cough)

- **Results of Phase IIa study in Japan**[1]
  - Double-blind, cross-over, placebo and S-600918 (150 mg)
  - QD for 2 weeks, N=31

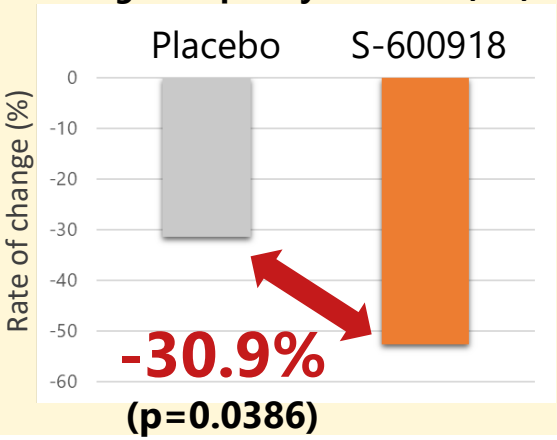
Efficacy

Cough Frequency in Daytime (/hr)



(p=0.0546)

Cough Frequency in 24 hrs (/hr)



(p=0.0386)

Safety

- S-600918 was well-tolerated and showed favorable safety

The incidence of taste disturbance, an adverse event seen at high frequency with similar drugs

Placebo	S-600918
0% (0/31)	6.5% (2/31)

- **Design of global Phase IIb study**
  - Double-blind, placebo-controlled, parallel group
  - S-600918 (50, 150, 300 mg) or Placebo, QD for 4 weeks, N=93/arm

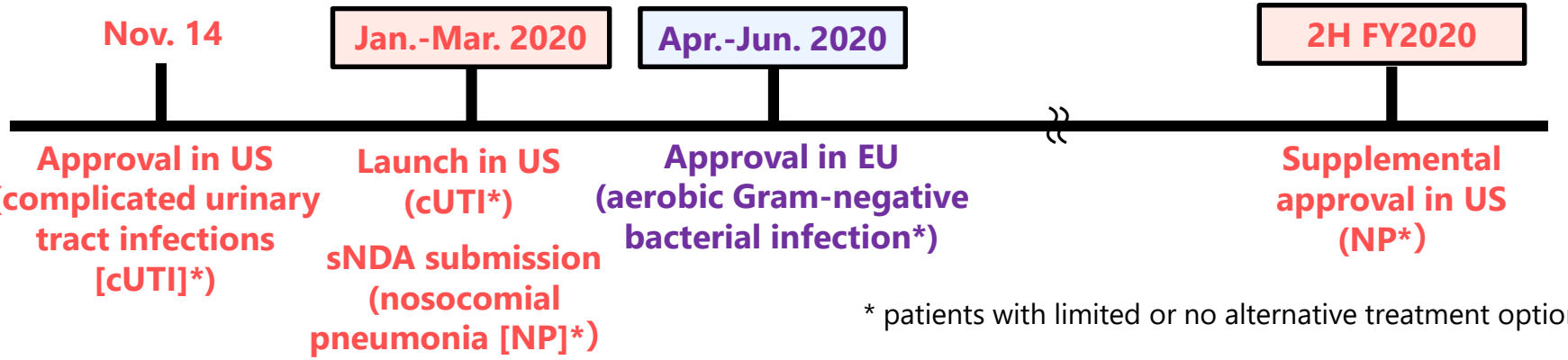
⇒To determine the optimal dose of S-600918

1 Akio Niimi et al., ERS2019

Establish A Global Presence

Strengthen own sales structure in US/EU by starting with Cefiderocol

Cefiderocol Development Schedule (Planned)



* patients with limited or no alternative treatment options

Future Major Products in US/EU, and Sales Structure

	US	EU
Cefiderocol	**Own sales (Planned)**	**Own sales (Planned)**
Lustrombopag (Product name in the US: Mulpleta®)	Own sales	Own sales (Planned)
Naldemedine (Product name in the US: Symproic®, in the EU: Rizmoic®)	Partnering with BDSI* commercialization	Partnering with Sandoz, Molteni, and Ferrer for commercialization

Strengthen own sales structure in HP/specialty market

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)

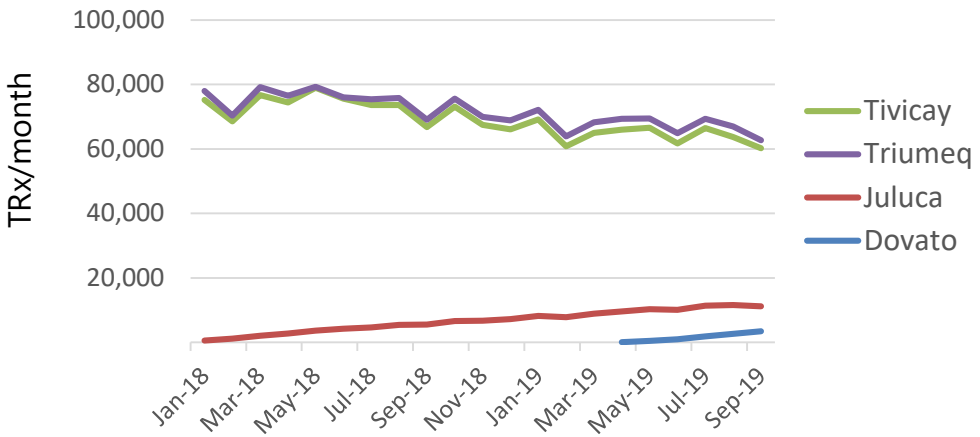
Progress from Jul. 29. 2019 to Oct. 30. 2019

DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine , CAB: cabotegravir

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

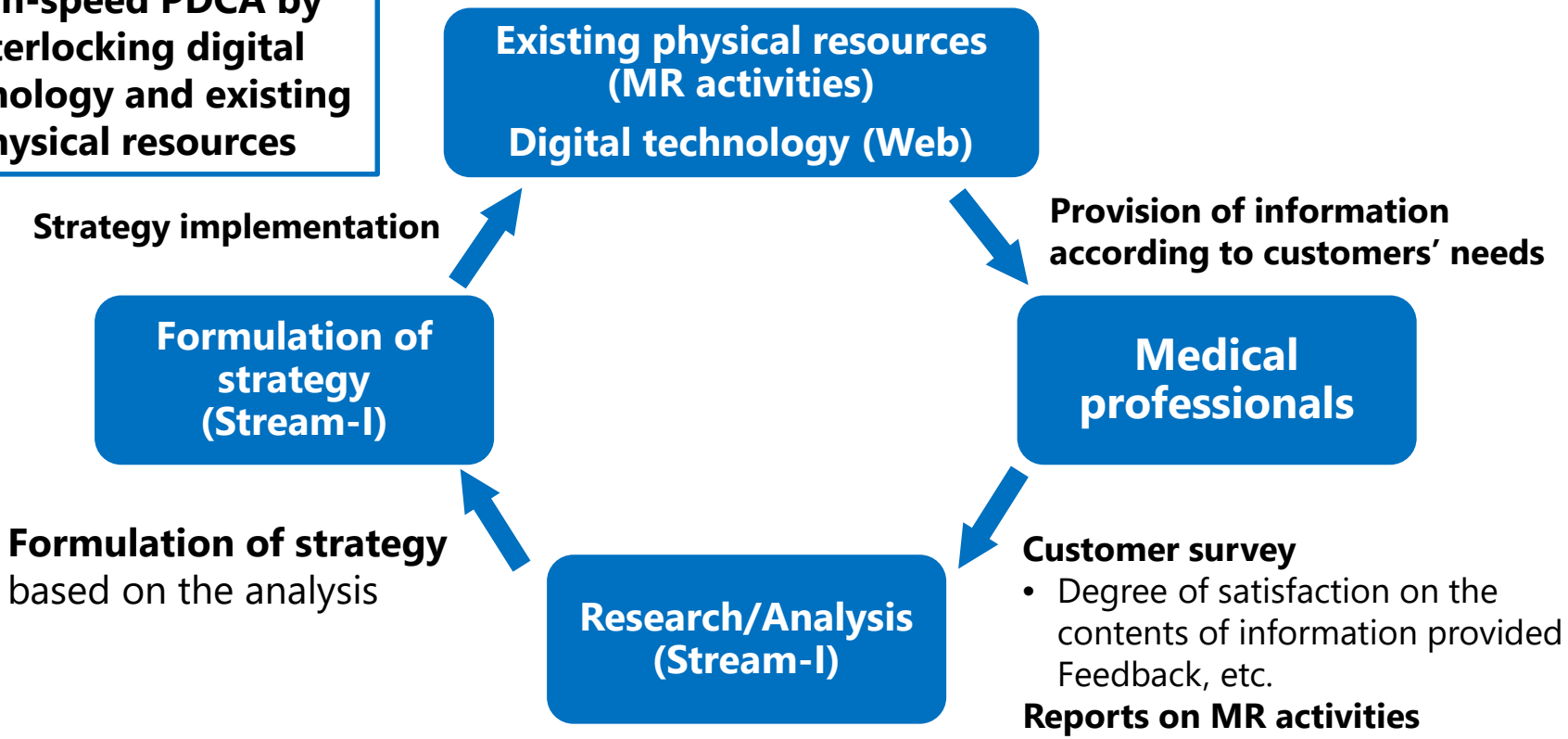
- Once approved, it will become the first long-acting regimen for HIV infection.
- According to patient satisfaction assessment in the Phase III studies, 97% (266/273) of patients in ATLAS and 99% (257/259) of patients in FLAIR answered that they preferred long-acting injections of CAB+RPV over their 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

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**April 30, 2019 ViiV Healthcare analyst call https://www.gsk.com/media/5411/fuelling-our-future-growth-slides.pdf
DTG: dolutegravir、3TC: lamivudine、CAB: cabotegravir、RPV: rilpivirine

Business Innovation

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

* Stream-I: Shionogi, Transformation, Real-world, E-Detail, AI, M3, IT / Intelligence

Establishment of “Stream-I”

Stream-I’s contribution to the treatment of influenza

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**

Potential of Stream-I

- 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

Commencement of Tender Offer for Certificates of Shares, etc. in UMN Pharma Inc.

Purpose and Outline of the Tender Offer (announced on Oct 30, 2019)

【Purpose】

- **Entering the vaccine business by acquiring 100% ownership of UMN Pharma**

【Outline】

- Target for the tender offer : common shares and issued share warrants of UMN Pharma
- Capital relationship : holding 5,500,000 target company shares which represent 31.08% of the total issued through capital and business alliance entered in Oct 2017, as of today
- Number of shares and warrants to be purchased : upper limit; none, lower limit; 6,322,000
- Tender offer period : from Oct 31, 2019 to Dec 12, 2019 (30 business days)
- Tender offer price : 540 yen per share (a premium of 70% on 318 yen, which was the simple average closing price over the six-month period preceding October 29, 2019)
- Total amount of the tender offer* : approx. 6.6 B yen
- Plan to acquire 100% ownership through the prescribed procedures after completion of the tender offer
- The board of directors of UMN Pharm express its support for the tender offer

* Estimated when the company acquires total common shares and issued share warrants of UMN Pharma.

Achievements of the Capital and Business Alliance with UMN Pharma Inc.

Entered into the Capital and Business Alliance Agreement on Oct 31, 2017

- Implementation of planned 1st Phase activities and funding to achieve those goals
- Decide the transition to the 2nd Phase conditional upon an establishment of their own core technologies

1st Phase

Core technology improvement

Establish core technologies for drug discovery, including the discovery of vaccines for the prevention of infectious diseases in humans

Basic research toward 2nd Phase

Conduct basic research on development candidates

Re-establishment of Akita plant

Restructuring of GMP facility

Milestone payment	third-party allotment	Convertible bond
0.3 B yen*	0.178 B yen	1.46 B yen

2nd Phase

Driving development pipelines

Develop promising pipeline(s) selected in the 1st Phase

Achievements in the 1st Phase

- Almost established a technology platform utilizing genetic recombination technology for manufacturing proteins to be drug substances for biopharmaceuticals, including human infectious disease vaccines
- Basic research has been progressed steadily for prioritization of development pipeline(s)

* Including an upfront fee at the time of execution of agreement

Addressing the Issues in the Capital and Business Alliance

Issues with the transition to the 2nd Phase in the business alliance

- Need to conclude the license agreement for each development candidate in the current framework
  - Limited benefit in investment of Shionogi's management resources and integration of the strengths of both companies
- Strengthening revenue stream of UMN Pharma
  - Continued payment is necessary for ensuring their sales enough to maintain the listing
  - Necessity of additional capital increases, etc. in order to achieve early approval and launch of development candidates

Framework such as forming a business alliance is not enough to drive forward vaccine business actively, flexibly and globally in drastic changes of external environment surrounding pharmaceutical industry

To invest Shionogi's management resources in the promising vaccine-related assets in UMN Pharma's more actively and flexibly than before,
we consider it is essential to revitalize UMN Pharma's project(s) and improve its efficiency by consolidating R&D, manufacture and marketing systems of both companies

Proposal to UMN Pharma for the Transaction of a wholly owned subsidiary

Synergistic business benefit of a wholly owned subsidiary

SONG for you!

Social Challenges that Shionogi Strives to Address

"Protecting people from the threat of infectious diseases"

・UMN Pharma: Strengths and features
- Knowledge, know-how and technology regarding biopharmaceutical-drug platform which will be the core of next-generation vaccines*
- Development of anti-infective vaccines
- Possession of R&D facilities for API manufacturing, CMC research etc.

×

• Shionogi: Strengths and features
- R&D for infectious diseases
- R&D of small to mid sized molecules
- Focused on development of novel drug discovery platforms
- Development of in-house adjuvants

Integrate UMN Pharma's biopharmaceutical drug platform into Shionogi's strategy for infectious diseases

- Acquiring new strengths for our research targets (influenza, RSV**, herpes viruses, etc.)
- Synergistic benefit by applying our in-house adjuvants
- Addressing emerging and re-emerging infectious diseases

Mid-to-long term goals

- Expanding our product portfolio from pre-symptomatic to treatment
- Strengthening infectious disease pipeline

Pre-symptomatic diseases	Prevention	Diagnosis	Treatment
Public awareness and education programs	Vaccine	Technology for diagnostic agent and image diagnostic system	Hard-to-treat bacterial infections, three major infectious diseases, influenza, etc.

- Promoting proper use of anti-infective drugs
- Gathering accurate epidemiological data

SHIONOGI

* Vaccines combining adjuvants and product/drug delivery technologies using novel basic technologies for drug development

** Respiratory syncytial virus (RSV): one of RNA viruses

5. Shareholder Return

1st Half Fiscal 2019 Financial Results

1. Overview of 1st Half FY2019 Financial Results
2. Actions and Progress in 1st Half FY2019
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4. Actions in 2nd Half FY2019 for Growth Beyond 2020
5. **Shareholder Return**

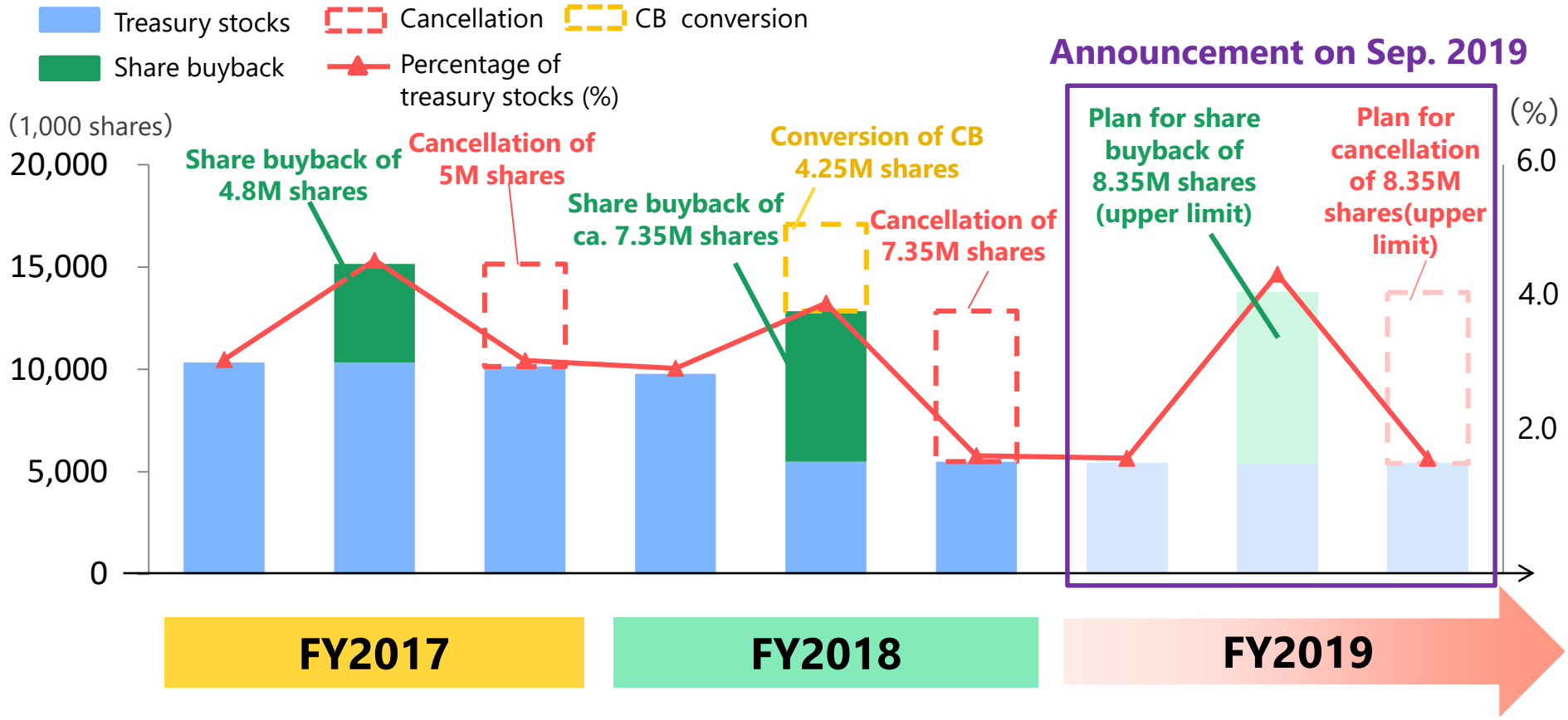
Flexible and Prompt Capital Policy

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

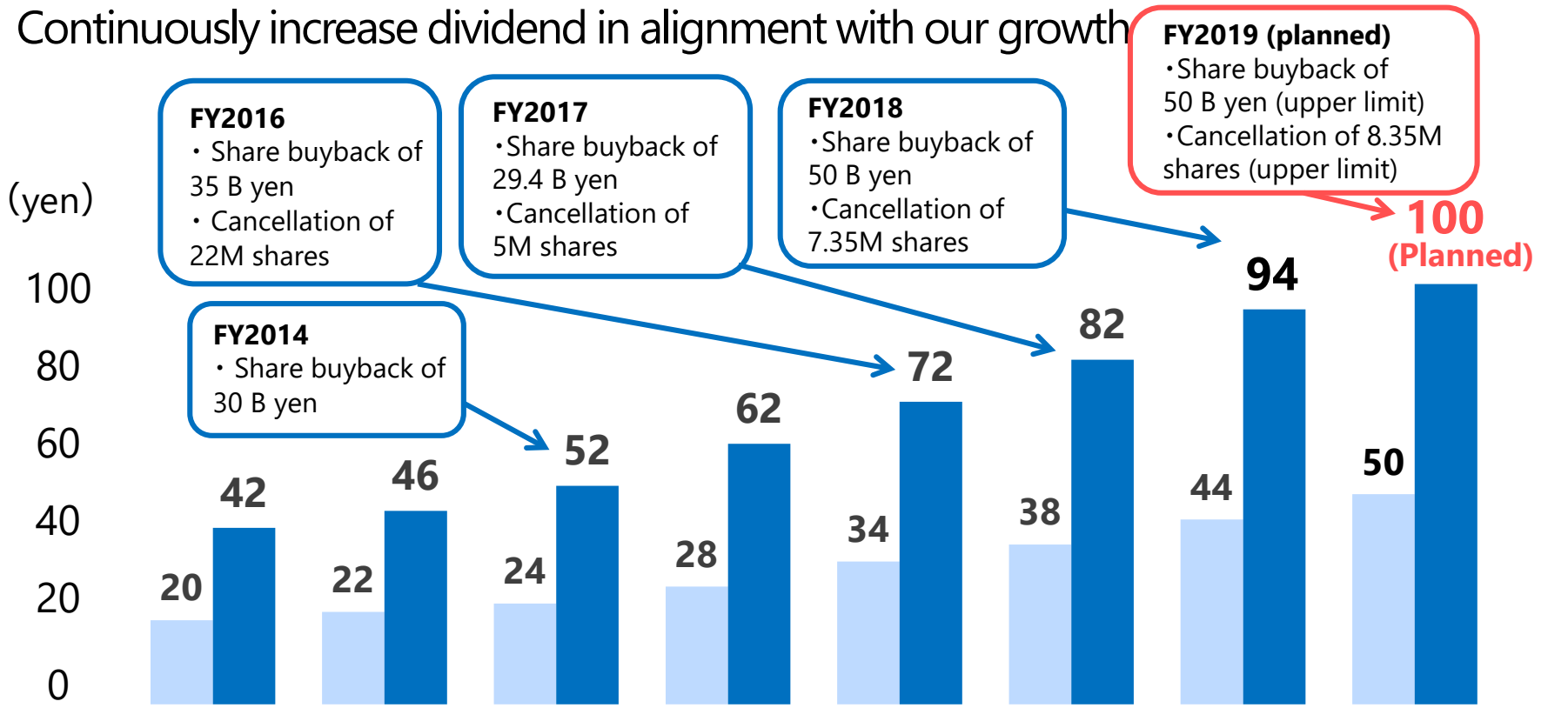
- Total shares to be cancelled: 8.35M shares (upper limit)
- Date for cancellation: Mar. 13, 2020



CB（Convertible Bond）

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

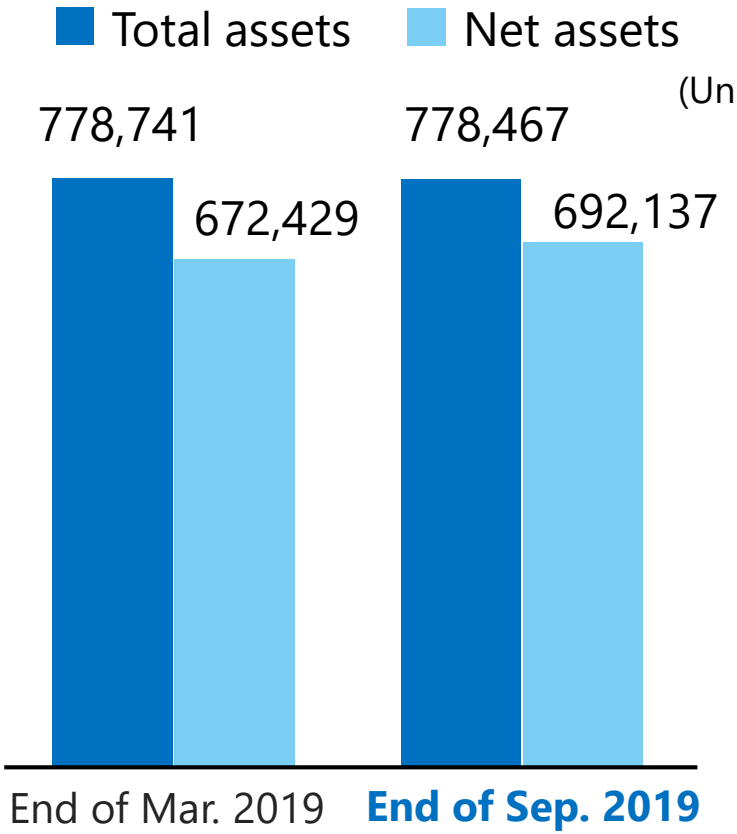


FY	12	13	14	15	16	17	18	19
DOE	3.7	3.5	3.7	4.1	4.5	4.6	4.6	Over 4.3 (planned)
ROE	17.5	9.2	9.4	13.6	16.3	19.4	20.9	Over 18.0 (planned)

Appendix

- Financial Statement (Consolidated) -
- Major Progress in 1st Half FY2019 -
- Xofluza® : Data about PA/I38X-Substituted Viruses -
- Target Milestones for Development of Pipeline in FY2019 -
- Progress of Pipeline -
- Launch Plan -
- Definition of New Products -

Financial Statements (Consolidated)



Unit: M yen		End of Mar. 2019	End of Sep. 2019	Change
Total assets	Current assets	461,743	480,300	18,556
	Non-current assets	316,997	298,167	(18,830)
Liabilities	Current liabilities	89,107	69,511	(19,595)
	Non-current liabilities	17,203	16,818	(385)
Net assets	Shareholders' equity	652,371	688,890	36,519
	Others	20,058	3,246	(16,811)

	End of Mar. 2019	End of Sep. 2019
Shareholders' equity ratio	85.7%	**88.3%**

Major Progress in 1H FY2019* (Pipeline)

	Phase I	Phase II	Phase III	Submission	Approval, Launch
Global	**S-648414** ・Start of Phase I study (US)	**S-600918** ・Start of Phase IIb study (global)	**cefiderocol** ・Disclosure of results from APEKS-NP study	**cefiderocol** ・Recommendation of approval from FDA Advisory committee	**XOFLUZA®** ・Approval in Taiwan
In Japan	**S-812217 [zuranolone]** ・Completion of enrolment in Phase I study	**S-600918** ・Disclosure of results from Phase IIa study	**XOFLUZA®** ・Positive top-line results in prophylaxis study → NDA submission in Japan ・Disclosure of data regarding PA/I38 variants		**INTUNIV®** ・Supplementally approval for adult patients
Out-licensed			**DOVATO®** ・Positive results in TANGO (48-week treatment for experienced patients) **CAB+RPV** ・ATLAS2M (naïve and experienced patients) **XOFLUZA®** ・Disclosure of results from global pediatric study (MINISTONE-2) ・Start of Phase III study (transmission)	**DOVATO®** ・Approval in Japan (naïve patients) **CAB+RPV** ・NDA submission in EU	**DOVATO®** ・Approval in EU (naïve and experienced patients) **XOFLUZA®** ・Approval in US (high risk patients)

Infections disease
Pain/CNS
Frontier

* Progress from May 10, 2019 to Oct. 30. 2019
CAB: cabotegravir, RPV: rilpivirine

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

* Progress from May 10, 2019 to Oct. 30. 2019

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)

1 Takeki Uehara et al., OPTIONS X 2019
2 Takeki Uehara et al., ECCMID 2019

Xofluza®: Data About PA/I38X-Substituted Viruses

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.

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1 Takeki Uehara et al., ECCMID 2019
2 Simon Portsmouth et al., OPTIONS X 2019

*Of Xofluza® ITTI population, patients had paired baseline and follow-up RT-PCR-positive samples evaluable for Sanger sequencing, and data for time to alleviation of symptoms or time to improvement of influenza symptoms.
**Of ITTI population, patients had data for time to alleviation of symptoms or time to improvement of influenza symptoms.

Target Milestones for FY2019 : Approval and Submission

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Vyvanse® (ADHD(pediatric))			Achieved (Mar.)	Japan(2017.4)	Japan
Intuniv® (ADHD(adult))			Achieved (Jul.)	Japan(2018.8)	Japan
Cefiderocol (US: Complicated urinary tract infections, including pyelonephritis , EU: Aerobic Gram-negative bacterial infection)	CR study: completion Nosocomial pneumonia study: completion of enrolment		Global: CR study completion Global: Nosocomial pneumonia study completion	US(2018.12) EU(2019.3)	US EU
Xofluza® (Influenza virus infection) ①granule (weight under 20kg) ②prophylaxis	Prophylaxis study: NDA submission		Japan： High-dose study for children: completion Prophylaxis study completion	①Japan(2018.8) ②Japan(2019.10)	①Japan
OxyContin®TR (Treatment of moderate to severe chronic pain)	Achieved (May)		Japan： Completion	Japan	

Progress from Jul. 30, 2019 to Oct. 30, 2019　Planned　Completed

Target Milestones for FY2019 : Phase I~III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
S-812217 [zuranolone] (Depression)	Japan: Single and multiple dose study completion	Japan: initiate			
Rizmoic® (Opioid-induced constipation(pediatric))	EU: Phase I/II study Initiate				
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections(pediatric))			Global: Safety and PK study initiate		
S-600918 (Neuropathic pain or Refractory Chronic Cough)	**Achieved** (Sep.)	Japan: POC* study completion Global: Dose-finding Study initiate			
SR-0379 (Skin ulcers (Pressure ulcers, diabetic ulcers, etc))	Completion of enrolment	Japan: POC* study completion			
S-770108 (Idiopathic Pulmonary Fibrosis)	UK: Lung deposition study initiate				

Progress from Jul. 30, 2019 to Oct. 30, 2019

* Proof of concept

Planned

Target Milestones for FY2019 : Phase I~III

Product (indication)	Phase I	Phase II	Phase III	Submission	Approval
Redasemtide [S-005151] (stroke)	Japan：Study in Healthy adults (Including the elderly) completion	Japan：initiate	Achieved (Q1)		
S-637880 (Neuropathic pain)	Japan：Multiple dose study completion	Global：initiate			
Naldemedine (POI*)		Global：initiate			
Novel HIV Drug (HIV virus infection)	US：initiate	Achieved (Sep.)			
SDT-001 (ADHD)		Japan：initiate			

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Progress from Jul. 30, 2019 to Oct. 30, 2019

Planned Completed

* Post operative ileus

Pipeline (as of Oct. 30, 2019)

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

- Infectious diseases
- Pain/CNS
- Other

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Progress from Jul. 30, 2019 to Oct. 30, 2019

** In Phase I/II

* Target indication may include some projects

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)	

- **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

Progress from Jul. 30, 2019 to Oct. 30, 2019

DTG: dolutegravir 3TC: lamivudine CAB：cabotegravir RPV: rilpivirine

Target Milestones for Launch of Products

FY2017 (Achieved)	FY2018 (Achieved)	FY2019
In Japan		
Symproic® **Intuniv®** ADHD (pediatric) **Oxycodone** Tamper resistant formulation **Actair®** Pediatric allergic rhinitis caused by house-dust mite allergen **Xofluza® (adult, pediatric)**		**Intuniv®** ADHD (adult) **Launched** **Vyvanse®** ADHD (pediatric)
Global		
Symproic® (US)	**Mulpleta®** (US)	**Cefiderocol (US)** **Lusutrombopag (EU)** **Baloxavir marboxil (Taiwan)** **Rizmoic® (EU)**
Out-licensed		
Juluca® (DTG/RPV) (US)	**Juluca® (DTG/RPV)** (EU, Japan) **Osphena®** (US) Vaginal dryness associated with postmenopausal VVA **Xofluza®** (US, OwH*)	**Dovato® (DTG/3TC)** (US, EU) **Launched** **CAB+RPV** (US) **Xofluza®** (US, HR**) **Launched**

DTG: dolutegravir, RPV: rilpivirine, 3TC: lamivudine

*OwH: Otherwise healthy patients ** HR: High risk (patients at high risk for influenza-related complications)

Definition of New Products (in Updates to SGS2020)

Pain/ CNS

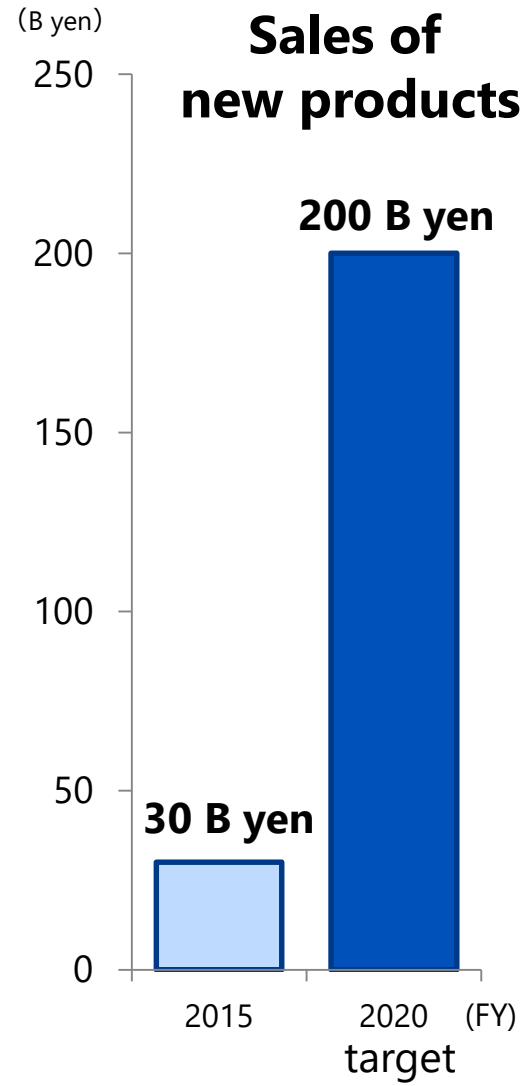
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine*
- Intuniv®, Vyvanse®

Infectious diseases

- Xofluza®
- Cefiderocol
- Rapiacta®, flu diagnosis kit

Others

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



* Product name of naldemedine: Symproic® in Japan and US, Rizmoic ® in EU

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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