SHIONOGI 140th Anniversary

S-O-N-G for you!

1st Half of Fiscal 2018 Financial Results

October 30, 2018

Isao Teshirogi, Ph.D.
President and CEO

SHIONOGI

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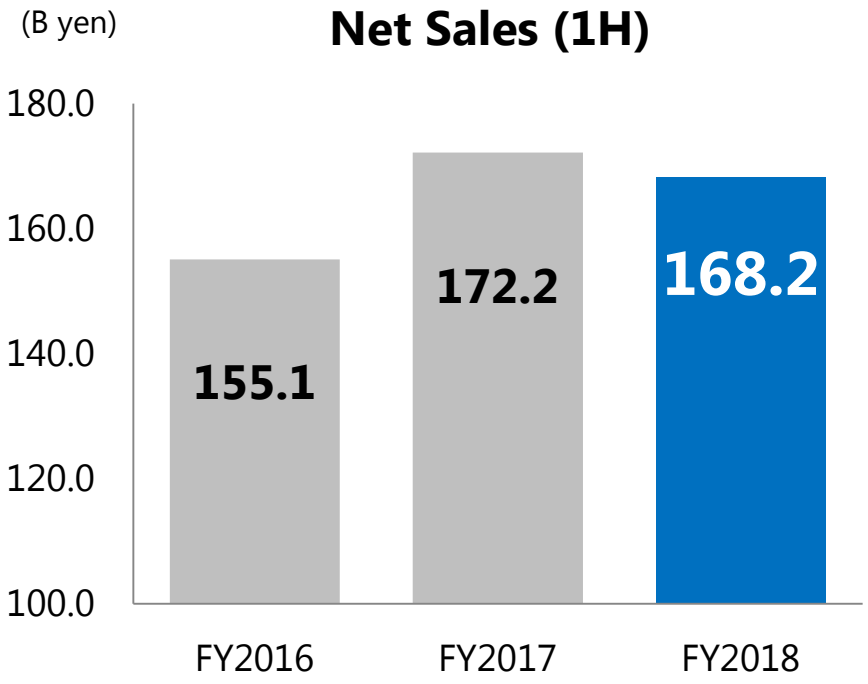
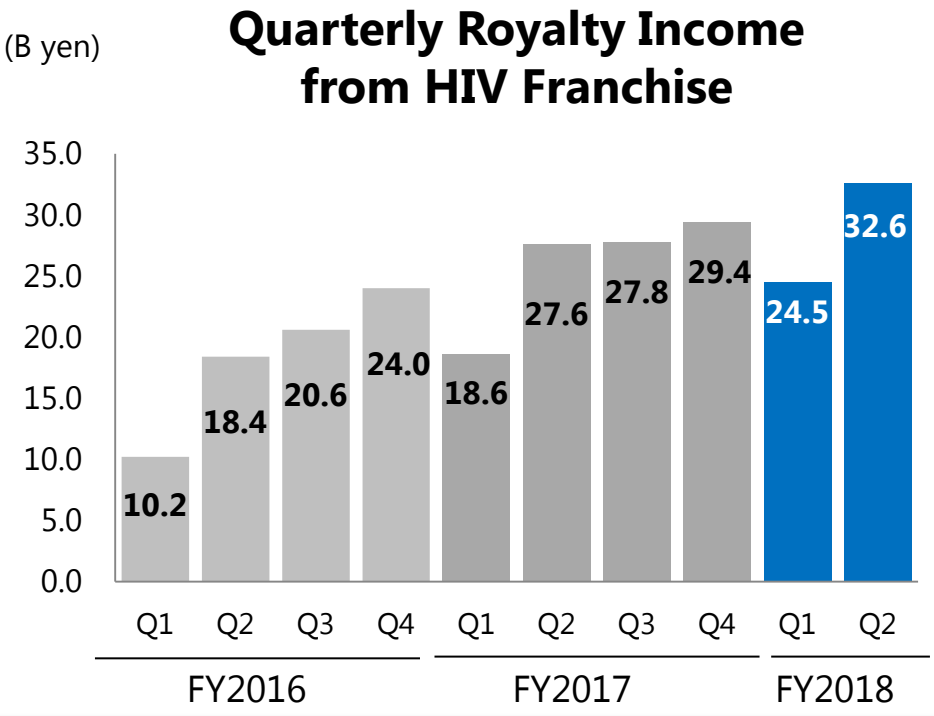
1. 1st Half FY2018 Financial Results

Highlight (1) Top-line Growth vs Forecasts

- Net Sales : **168.2 B yen** (-2.3%, vs. 1H FY2017 +0.1% vs. 1H Forecasts*)
- Royalty Income: **57.1 B yen** (+23.5% vs. 1H FY2017)
  from HIV franchise



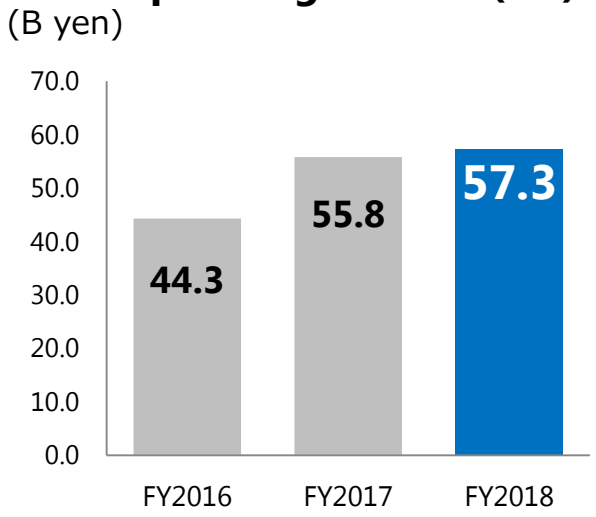


* Forecasts revised on Jul. 23, 2018

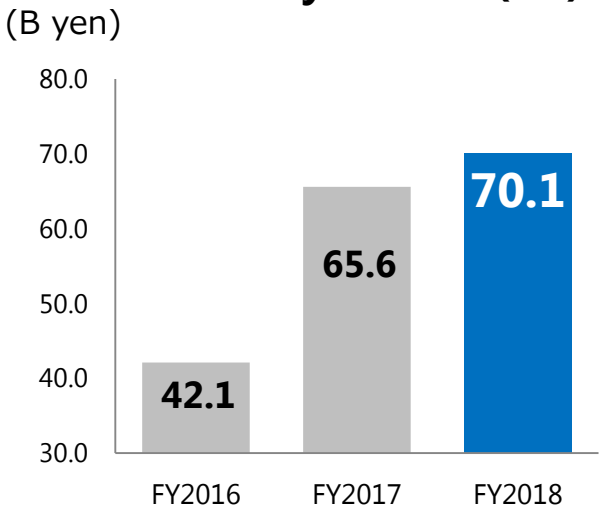
Highlight (2) All Profit Measures Were Higher than the Levels Achieved in Prior Years

- Operating income: **57.3 B yen** (+2.8%) vs 1H FY2017
  - **Record-high levels for 4 consecutive years**
- Ordinary income: **70.1 B yen** (+6.8%) vs 1H FY2017
  - **Record-high levels for 7 consecutive years**
- Profit attributable to owners of parent: **57.9 B yen** (+15.0%) vs 1H FY2017
  - **Record-high levels for 4 consecutive years**

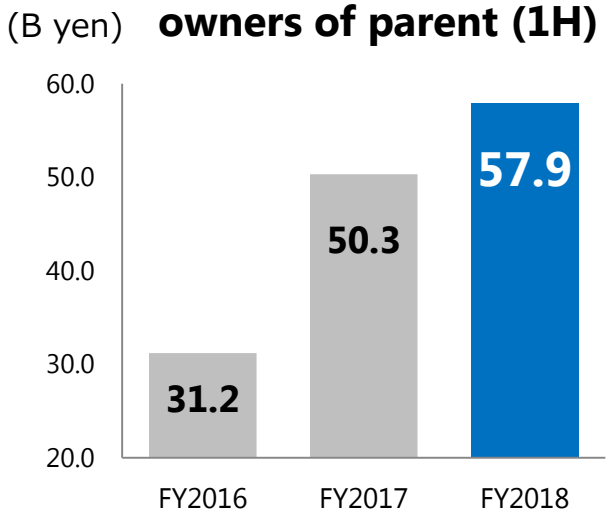
Operating income (1H)



Ordinary income (1H)



Profit attributable to owners of parent (1H)



Financial Results (Consolidated)

(Unit: B yen)

	FY2018				FY2017	Y on Y	
	Full year forecasts*	1H forecasts**	1H results	Progress vs 1H forecasts	1H results	Change (%)	Change (B yen)
Sales	**348.0**	**168.0**	**168.2**	**100.1%**	172.2	**(2.3)**	**(4.0)**
Operating income	**120.0**	**48.0**	**57.3**	**119.4%**	55.8	**2.8**	**1.5**
Ordinary income	**144.0**	**61.0**	**70.1**	**114.9%**	65.6	**6.8**	**4.5**
Profit attributable to owners of parent	**114.5**	**48.6**	**57.9**	**119.1%**	50.3	**15.0**	**7.6**

- **Sales and each profit measure have progressed smoothly toward 1H forecasts****
- **Operating income was higher than 1H FY2017, although the original 1H FY2018 forecast was lower than 1H FY2017**
- **Each profit measure was higher than the levels achieved in prior 1H results**

Exchange Rate (average)	FY2018 Forecasts	FY2018 1H Results
USD ($) – JPY (¥)	**105.0**	**110.27**
GBP (£) – JPY (¥)	**145.0**	**146.84**
EUR (€) – JPY (¥)	**130.0**	**129.80**

*Forecasts announced on Jul. 23, 2018 (Revision was announced on Oct. 29, 2018)

** Forecasts revised on Jul. 23, 2018

Statement of Income

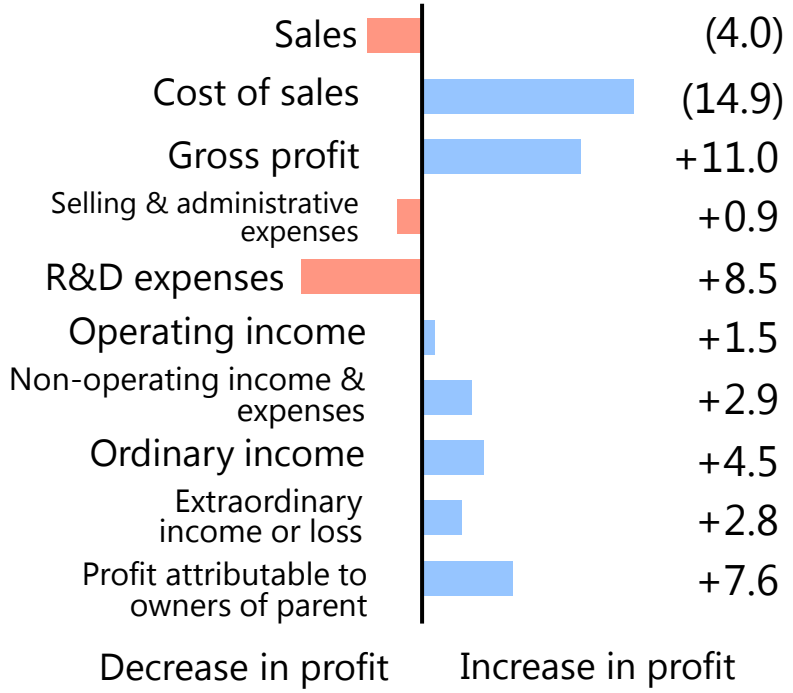
(Unit: B yen)

	FY2018 Forecasts Full year*	FY2018 Forecasts 1H**	FY2018 1H results	Achievement (%)	FY2017 1H results	Y on Y Change (%)	Y on Y Change (B yen)
Sales	**348.0**	**168.0**	**168.2**	100.1	172.2	(2.3)	(4.0)
	16.5	15.8	14.7		23.0		
Cost of sales	**57.5**	**26.5**	**24.7**	93.3	39.7	(37.7)	(14.9)
Gross profit	**290.5**	**141.5**	**143.5**	101.4	132.5	8.3	11.0
	49.0	55.7	51.2		44.6		
SG&A expenses	**170.5**	**93.5**	**86.2**	92.2	76.7	12.3	9.4
Selling & administrative expenses	29.3 **102.0**	31.0 **52.0**	28.3 **47.5**	91.4	27.1 46.6	1.9	0.9
	19.7	24.7	23.0		17.5		
R&D expenses	**68.5**	**41.5**	**38.6**	93.1	30.1	28.4	8.5
Ordinary R&D expenses***	**48.5**	**26.5**	**25.6**	96.6	30.1	(15.0)	(4.5)
Strategic investment	**20.0**	**15.0**	**13.1**	87.0	-	-	13.1
	34.5	28.6	34.1		32.4		
Operating income	**120.0**	**48.0**	**57.3**	119.4	55.8	2.8	1.5
Non-operating income & expenses	**24.0**	**13.0**	**12.8**	98.3	9.8	29.9	2.9
	41.4	36.3	41.7		38.1		
Ordinary income	**144.0**	**61.0**	**70.1**	114.9	65.6	6.8	4.5
Profit attributable to owners of parent	**114.5**	**48.6**	**57.9**	119.1	50.3	15.0	7.6

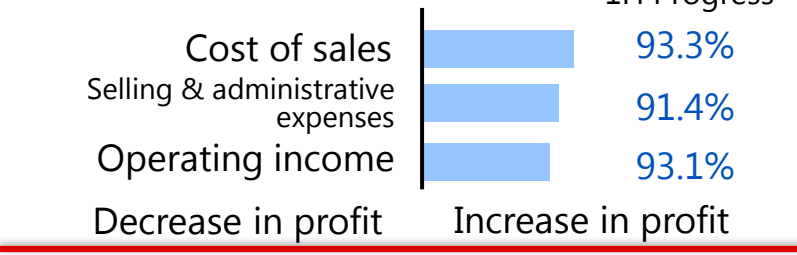
*Forecasts announced on Jul. 23, 2018 (Revision was announced on Oct. 29, 2018)
** Forecasts revised on Jul. 23, 2018
*** Ordinary R&D expenses: Total R&D expenses excluding strategic investment

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

- **Y on Y comparison** (Unit: B yen)



- **Progress vs 1H Forecasts***



Main Variation Factors (Y on Y)

- **Sales**
  - Increase in royalty income from HIV franchise
  - Income from Roche for Xofluza®
  - One-time payment from Purdue upon the termination of privious alliance for Symproic®
  - Decrease in sales of prescription drugs in Japan
- **Cost of sales**
  - Japan business: sales decline and changes in the lineup of major products
- **SG & A expenses**
  - **Selling & administrative expenses**
    - › Investment in new products (preparation for launch etc.)
    - › Advance investment in IT
  - **R&D expenses**
    - › Ordinary R&D expenses: decreased due to early completion of Xofluza® HR study
    - › Strategic investment: net increase (13.1 B yen)
- **Non-operating income & expenses**
  - Increase in ordinary dividend due to sales growth of HIV franchise, including one-time event
- **Extraordinary income or loss**
  - Sale of the Nanjing Factory of C&O in China

Main Variation Factors (vs 1H Forecasts*)

- **Cost of sales**
  - Sales decline and changes in the lineup of major products
- **SG&A expenses**
  - Termination of the contract with Purdue regarding Symproic®
- **R&D expenses**
  - Decrease in strategic investment through effective negotiation

* Forecasts revised on Jul. 23, 2018

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

Sales by Segment

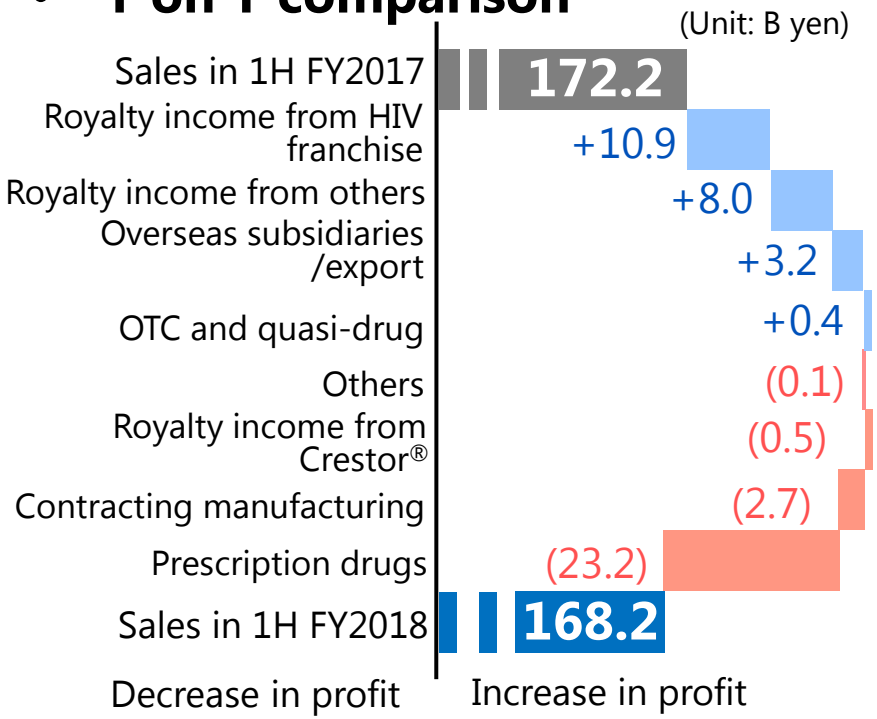
(Unit: B yen)

	FY2018				FY2017	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change (B yen)
	Full year*	1H**					
Prescription drugs	**119.3**	**52.3**	**50.0**	95.5	73.2	(31.7)	(23.2)
Overseas subsidiaries/export	**31.3**	**15.1**	**15.4**	101.8	12.2	26.2	3.2
Shionogi Inc.	**12.4**	**6.5**	**7.4**	112.9	6.0	22.3	1.3
Osphena®	**4.1**	**2.1**	**1.4**	69.3	2.0	(27.8)	(0.6)
C&O	**12.4**	**5.8**	**5.0**	86.7	3.4	49.0	1.6
Contract manufacturing	**12.1**	**5.6**	**5.7**	103.1	8.4	(31.9)	(2.7)
OTC and quasi-drug	**7.4**	**3.4**	**3.8**	111.0	3.4	12.3	0.4
Royalty income	**175.5**	**90.3**	**92.2**	102.1	73.8	24.9	18.4
HIV franchise	**124.9**	**58.7**	**57.1**	97.2	46.2	23.5	10.9
Crestor®	**21.1**	**10.6**	**10.9**	102.8	11.4	(4.1)	(0.5)
Others	**29.5**	**21.0**	**24.2**	115.2	16.2	49.2	8.0
Others	**2.5**	**1.3**	**1.1**	90.6	1.2	(7.0)	(0.1)
Total	**348.0**	**168.0**	**168.2**	**100.1**	**172.2**	**(2.3)**	**(4.0)**

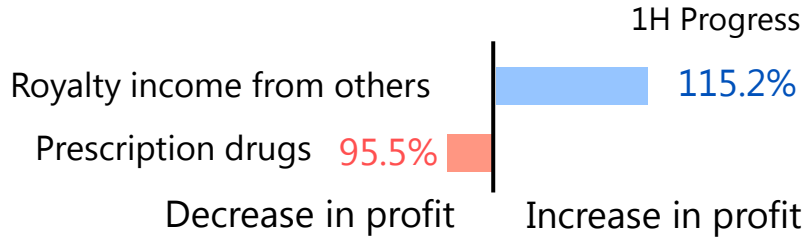
*Forecasts announced on Jul. 23, 2018 (Revision was announced on Oct. 29, 2018)
** Forecasts revised on Jul. 23, 2018

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

- **Y on Y comparison**



- **Progress vs 1H Forecasts***



Main Variation Factors (Y on Y)

- **Royalty income**
  - Sales growth of HIV franchise
  - Income from Roche from Xofluza®
- **Overseas subsidiaries/export**
  - **US business**
    - One-time payment from Purdue upon the termination of the prior alliance for Symproic®
    - Decrease in royalty income from an authorized generic
- **Prescription drugs**
  - Sales growth of strategic products
  - Sales decrease of Crestor® and Irbetan® due to share capture by generic drugs
  - Sales decrease due to NHI price revision

Main Variation Factors (vs 1H forecasts*)

- **Royalty income (Others)**
  - Income from Roche from Xofluza®
- **Prescription drugs in Japan**
  - Xofluza®: The big influenza outbreak in 2017-2018 ended quickly
  - Other prescription drugs: Sales decrease due to share capture by generic drugs

* Forecasts revised on Jul. 23, 2018

Sales of Prescription Drugs in Japan

(Unit: B yen)

	FY2018				FY2017	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change (B yen)
	Full year*	1H**					
Cymbalta®	26.0	12.1	11.9	98.4	11.7	1.9	0.2
Intuniv®	5.0	1.9	2.4	123.0	0.69	246	1.7
Xofluza®	13.0	1.3	0.46	35.8	-	-	0.5
Rapiacta®	1.1	0.06	0.01	11.4	0.07	(91.2)	(0.1)
Brightpoc® Flu	1.1	0.11	0.23	221.3	0.14	73.2	0.1
OxyContin® franchise	9.1	4.2	3.8	90.1	4.6	(16.0)	(0.7)
Symproic®	1.2	0.48	0.72	150.5	0.16	339	0.6
Total of strategic products	56.4	20.3	19.6	96.6	17.3	12.9	2.2
Actair®	0.15	0.06	0.09	144.8	0.06	55.4	0
Mulpleta®	0.23	0.12	0.08	69.2	0.08	1.6	0
Pirespa®	6.0	3.1	2.9	93.7	3.1	(8.0)	(0.2)
Total of new products	62.8	23.5	22.6	96.2	20.6	9.8	2.0
Crestor®	9.7	5.3	5.2	97.0	22.0	(76.5)	(16.8)
Irbetan® franchise	6.4	3.6	3.1	86.1	7.8	(60.4)	(4.7)
Others	40.4	19.9	19.1	96.0	22.9	(16.2)	(3.7)
Prescription drugs	**119.3**	**52.3**	**50.0**	**95.5**	**73.2**	**(31.7)**	**(23.2)**

*Forecasts announced on Jul. 23, 2018 (Revision was announced on Oct. 29, 2018)
** Forecasts revised on Jul. 23, 2018

Growth of Strategic Products

Cymbalta®

- Sales increased from the previous year (up 1.9% vs 1H FY2017)
- Prescriptions steadily increased mainly in the pain field

→15% or more increase from the previous year

Opioid family*

- OxyContin® franchise:
  - Switching to OxyContin®TR
  - Sales decrease due to share capture by generic drugs (down 16.0% vs 1H FY2017)
- Symproic®:
  - Sales increase from the previous year (ca. 4.4-fold vs 1H FY2017)

Intuniv®

- Sales increase from the previous year (ca. 3.5-fold vs 1H FY2017)
- Steady sales increase after the ban on long-term treatment was lifted on Jun. 1, 2018

Influenza family**

- Enhanced the influenza family prior to the 2018–19 flu season

→Around 65% of influenza drug market share* in 1H FY2018**

Sales of new products steadily increased with new sales organization & strategy to maximize the value of each product

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* OxyContin® , OxyContin®TR, OxiNorm®, OxiFast®, Methapain®, Symproic®
** Xofluza®, Rapiacta®, Brightpoc®Flu, Brightpoc®Flu・Neo
*** IQVIA Data

Basic Strategy in FY2018 and Major Progress in 1H FY2018

1. Sales: Enhance our sales capability and increase sales of new products

- **Japan: Steadily increased sales of new products, up 9.8% from the previous year**
- **U.S.: Initiated own marketing of Symproic® and Mulpleta®**

2. Investment: To ensure continuous growth

- Drive prioritized projects through selection and concentration
- Continuously pursue new compounds for in-licensing

- **R&D, mainly of high-priority projects, has progressed**
  - Achieved NDA submission and approval of Xofluza™, and advanced 8 high-priority projects*
- **Strategic investment to ensure sustainable growth toward beyond 2020: 4 investments in 1H FY2018**
  - Obtained new pipeline assets: S-812217, ADR-001

Accelerate reform to enhance our sales capability

*Novel HIV drug, S-004992, S-812217, S-600918, S-637880, Adjuvant, S-770108, Peptide drugs

Xofluza™ : Phase III Study (HR* Study)

HR* Study

(CAPSTONE-2)

- High-risk patients aged ≧12 years
- 0-48 hours from onset
- 17 countries (Japan/US/EU/ Asia/Southern Hemisphere)
- N=2,184

Randomization

Patients with a confirmed diagnosis of influenza virus infection

Xofluza™ 40 mg or 80 mg, single dose (80 mg, body weight≧80 kg)	N=388
Placebo	N=386
Oseltamivir 75 mg, twice daily for 5 days	N=389

Total N=1163

Common risk factors for influenza-related complications in CAPSTONE-2 (Definition by Centers for Disease Control and Prevention)**

Asthma and chronic lung disease, Adults of 65 years of age and older, , Endocrine disorders, Heart disease, Extreme obesity

Influenza virus type/subtype

- A/H3N2: 47.9%
- A/H1N1pdm: 6.9%
- B: 41.6%

* HR: High risk (patients at high risk for influenza-related complications)
** CDC website https://www.cdc.gov/flu/about/disease/high_risk.htm

Xofluza™: Positive HR Study Results

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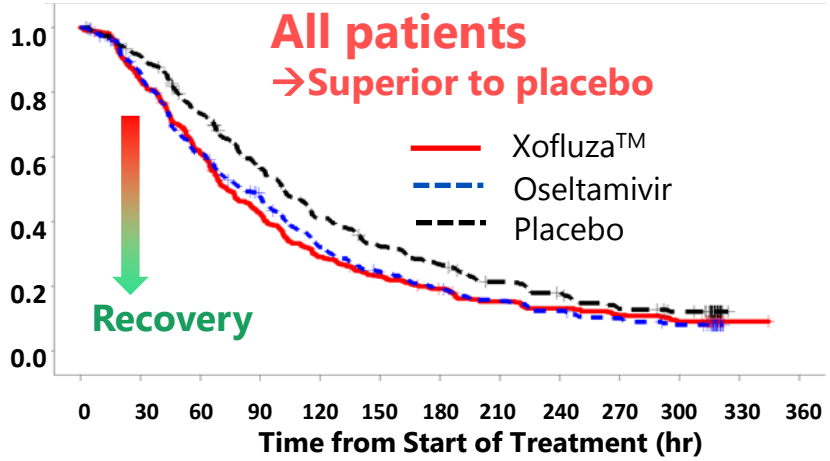
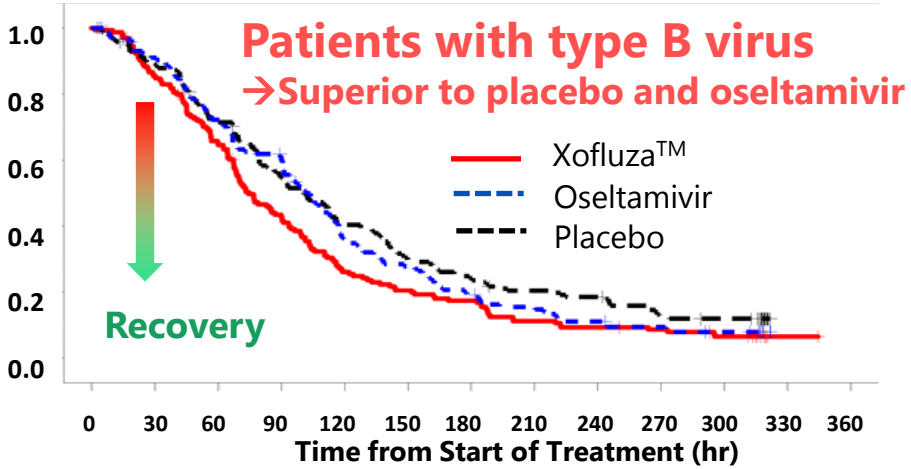
Time to improvement of influenza symptoms (TTIIS)



	Xofluza™	Placebo	Oseltamivir
TTIIS (median value, hr)	73.2*	102.3	81.0

*p<0.0001 vs placebo



	Xofluza™	Placebo	Oseltamivir
TTIIS (median value, hr)	74.6*#	100.6	101.6

*p<0.05 vs placebo
#p<0.05 vs oseltamivir

- **Significantly reduced the length of time that the virus continued to be released from the body (vs. Placebo, Oseltamivir)**
- **Significantly reduced the incidence of influenza-related complications (vs. Placebo)**
- **Well-tolerated, no new safety signals**

Provide a better therapeutic option for patients at a high risk for influenza-related complications

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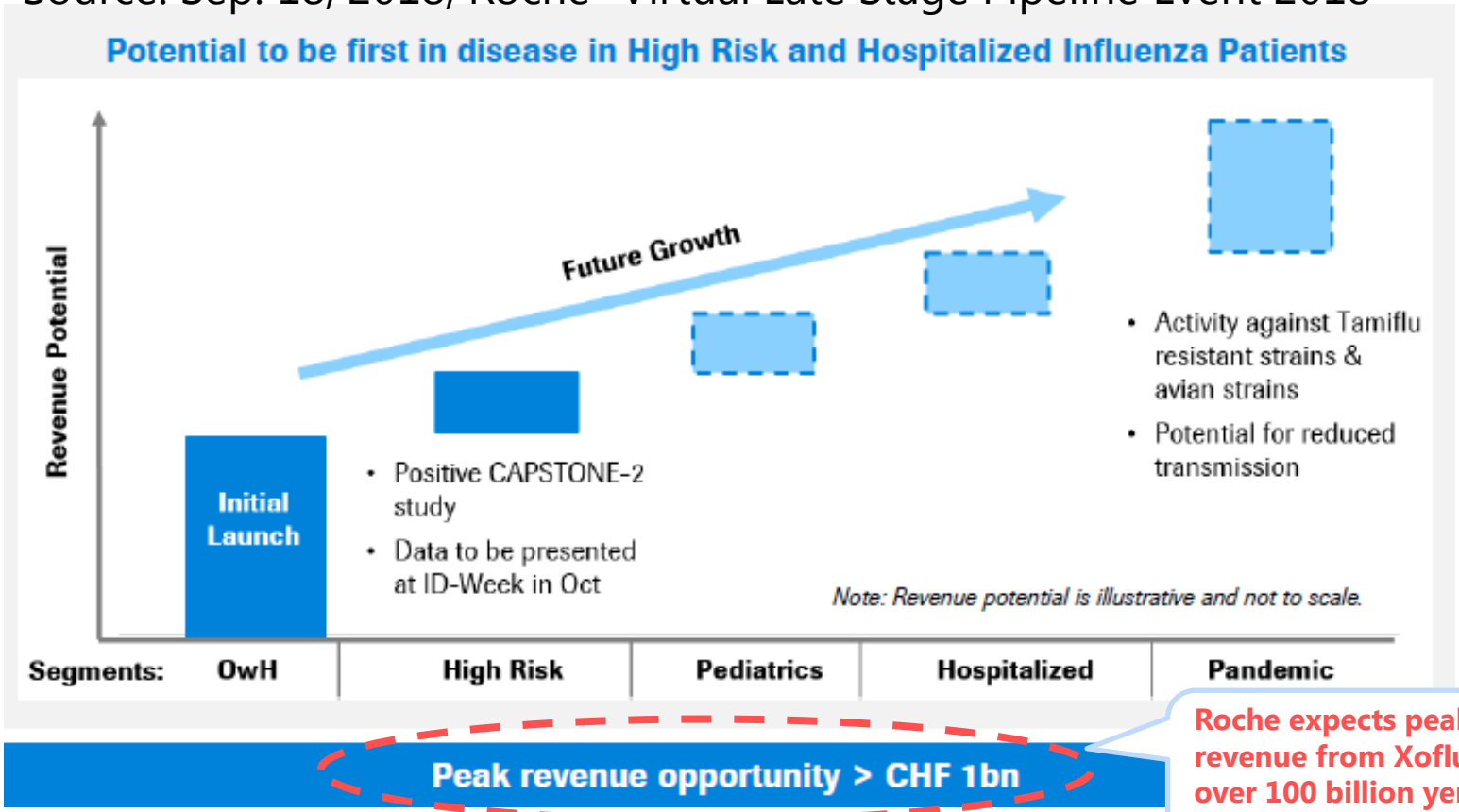
Source: Ison M, et al. Phase 3 Trial of Baloxavir Marboxil in High Risk Influenza Patients (CAPSTONE-2 Study), IDWeek 2018, Oct 3-7, Abstract #LB16

Xofluza™: Approved in the U.S.

- Approved on Oct. 24, 2018 (two months ahead of schedule) and to be launched in Nov. 2018*
  - Indication: **For the treatment of acute, uncomplicated influenza in patients 12 years of age and older"**

Source: Sep. 18, 2018, Roche "Virtual Late Stage Pipeline Event 2018"



* Shionogi and the Roche, which includes Genentech in the U.S., are in a license and collaboration agreement to further develop and commercialize baloxavir marboxil globally. Under the terms of this agreement, the Roche Group holds worldwide rights to baloxavir marboxil excluding Japan and Taiwan where the rights are retained exclusively by Shionogi.

Mulpleta®: Approved and Launched in the U.S.

- Approved on Jul. 31, 2018 and launched on Aug. 30, 2018 (1 month ahead of schedule)
  - Indication: **for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure**
- Aim for strong market through a support program for patients access, *Mulpleta Assist*

Market size (U.S.)

>125,000 procedures/year

Annual number of invasive procedures for adult patients with chronic liver disease and platelet number <50,000/μl* in the U.S.

Medical need

Avoid disadvantages of platelet transfusion

- **Infection, allergic reaction**
- **Burden on healthcare workers and patients**

Drug that satisfies unmet medical need

- Favorable safety and efficacy
- No need for transfusion
- No need to change dose depends on platelet count
- No interaction with food

Establish specialized sales base in the U.S. market

Mulpleta Assist https://www.mulpleta.com/assist/index.html

* Decision Resource Group, Real-World Data (RWD) © 2018

Progress of Strategic Investment

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See appendices for more details

- **May 31, 2018 In-licensing & research collaboration with Hsiri**
  - **Novel therapeutics for mycobacterial infection**
    - Exclusive global rights for discovery and development
    - Effective on both tuberculosis and non-tuberculous mycobacterial diseases (non-clinical data)

Hsiri Therapeutics

- **Jun. 14, 2018 In-licensing from SAGE**
  - **S-812217, antidepressant with novel mechanism of action**
    - Exclusive rights for development & commercialization in Japan, Taiwan and South Korea
    - Favorable Phase II study data, break-through therapy designation in the U.S.
    - Plan to start Phase I study in Japan from 2H FY2018

SAGE THERAPEUTICS

- **Jun. 18, 2018 Investment in Nemesis**
  - Gain knowledge about **a novel modality to solve the problem of AMR** (non-clinical data)

NEMESIS BIOSCIENCE

- **Sep. 13, 2018 In-licensing from Rohto**
  - **ADR-001, regenerative medicine for liver cirrhosis**
    - Exclusive rights for development & commercialization in Japan
    - Expectations for improvement of fibrosis and stable supply (Phase I/II study is ongoing)

NEVER SAY NEVER ロート製薬

Progress in Shionogi Healthcare

シオノギヘルスケア

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Changes of Environment Surrounding OTC Drugs

- Super-aging society
- Pressure on national finances due to increasing healthcare costs
- Need to extend healthy life expectancy through healthcare by each individual

→ **Expanded need for self-care***

➢ Jun. 25, 2018 **Strategic collaboration with Rohto**

- Initiate collaboration to **build on the strengths of each company**
- Create new business opportunities for the self-care of the future

➢ Sep. 20, 2018 **Acquire health food business from Takara**

- **Acquire infrastructure of mail-order business**
- **Supporting the pre-frail**** to promote long-term health of elderly people for the coming super-aging society

Grow and expand presence in developing self-care area

*Self-care: Health care provided by oneself often without the consultation of a medical professional
**Pre-frail: Pre-stage of frailty. Frailty is a condition seen particularly in elderly people, characterized by a vulnerability as a result of decreased physiological reserves.

2. FY2018 Financial Forecasts

Major Factors Driving Forecast Changes Since the Beginning of FY2018

Announced on Jul. 23, 2018

- **Acceleration of Xofluza™ HR* study completion**
  - Potential for income from Roche to be received ahead of schedule(2H → 2Q)
  - Increase in R&D expenses (1H)
- **US business**
  - Income from Purdue upon the termination of the prior alliance for the co-commercialization of Symproic® in US
  - Decrease in royalty income from an authorized generic
- **HIV franchise: Increase in dividend from ViiV, including one-time event (1Q)**

Revised on Oct. 29, 2018

- **Xofluza™ was approved in the U.S. on Oct. 24, 2018, ahead of schedule**
  - Income from Roche and export to the U.S. are planned in 2H
- **Increase in selling expenses to strengthen domestic and overseas sales**
  - Japan: Additional investment to promote new products
  - Overseas: Additional investment to promote Symproic®
- **Increase in ordinary R&D expenses: Additional investment in high-priority pipeline compounds**

Second upward revision of full year forecasts due to strengthening sales of new products and expanding investment in next growth-drivers

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

Upward Revision of Forecasts
(Announced on Oct 29, 2018)

(Unit: B yen)

	FY2018 Forecasts				FY2017	Y on Y	
	Original (May 9)	Revised (Jul 23)	Revised (Oct 29)	Change* (B yen)	Results	Change (%)	Change (B yen)
Sales	346.5	348.0	354.0	6.0	344.7	2.7	9.3
Operating income	119.0	120.0	124.5	4.5	115.2	8.1	9.3
Ordinary income	140.0	144.0	148.5	4.5	138.7	7.1	9.8
Profit attributable to owners of parent	111.0	114.5	118.5	4.0	108.9	8.8	9.6

Increase in sales and profit over the forecasts revised in 1Q FY2018

◆ Y on Y change (B yen)

- Sales: 3.3 → 9.3
- Ordinary income: 5.3 → 9.8
- Operating income: 4.8 → 9.3
- Net Profit: 5.6 → 9.6

Exchange rate (average)	FY2018 forecasts	1H FY2018 results
USD ($) – JPY (¥)	105.0	110.27
GBP (£) – JPY (¥)	145.0	146.84
EUR (€) – JPY(¥)	130.0	129.80

*Difference between forecasts announced on Oct. 29, 2018 and forecasts announced on Jul. 23, 2018

Revision of Statement of Income

(Unit: B yen)

	FY2018 Forecasts				FY2017	Y on Y	
	Original (May 9)	Revised (Jul 23)	Revised (Oct 29)	Change*	Results	Change (%)	Change (B yen)
Sales	346.5	348.0	**354.0**	**6.0**	344.7	**2.7**	**9.3**
	16.7	16.5	**16.1**		21.4		
Cost of sales	58.0	57.5	**57.0**	**(0.5)**	73.9	**(22.9)**	**(16.9)**
Gross profit	288.5	290.5	**297.0**	**6.5**	270.8	**9.7**	**26.2**
	48.9	49.0	**48.7**		45.1		
SG&A expenses	169.5	170.5	**172.5**	**2.0**	155.5	**10.9**	**17.0**
Selling & administrative expenses	29.6	29.3	**29.4**		27.7		
	102.5	102.0	**104.0**	**2.0**	95.6	**8.8**	**8.4**
	19.3	19.7	**19.4**		17.4		
R&D expenses	67.0	68.5	68.5	0	59.9	14.3	8.6
Ordinary R&D expenses**	47.0	48.5	**50.4**	**1.9**	59.9	**(15.9)**	**(9.5)**
Strategic investment	20.0	20.0	**18.1**	**(1.9)**	-	**-**	**18.1**
	34.3	34.5	**35.2**		33.4		
Operating income	119.0	120.0	**124.5**	**4.5**	115.2	**8.1**	**9.3**
Non-operating income & expenses	21.0	24.0	24.0	0	23.5	2.2	0.5
	40.4	414	**41.9**		40.2		
Ordinary income	140.0	144.0	**148.5**	**4.5**	138.7	**7.1**	**9.8**
Profit attributable to owners of parent	111.0	114.5	**118.5**	**4.0**	108.9	**8.8**	**9.6**

*Difference between forecasts announced on Oct. 29, 2018 and forecasts announced on Jul. 23, 2018

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

Revision of Sales by Segment

(Unit: B yen)

	FY2018 Forecasts				FY2017	Y on Y	
	Original (May 9)	Revised (Jul 23)	Revised (Oct 29)	Change*	Results	Change (%)	Change (B yen)
Prescription drugs	119.3	119.3	**119.3**	0	139.2	(14.3)	(19.9)
Overseas subsidiaries/export	29.8	31.3	**31.3**	0	23.6	32.5	7.7
Shionogi Inc.	10.9	12.4	**12.4**	0	10.6	17.0	1.8
Osphena®	4.1	4.1	**4.1**	0	3.7	12.0	0.4
C&O	12.4	12.4	**12.4**	0	6.9	80.1	5.5
Contracting manufacturing	12.1	12.1	**12.9**	**0.8**	16.9	**(23.8)**	**(4.0)**
OTC and quasi-drug	7.4	7.4	**7.4**	0	7.2	1.7	0.1
Royalty income	175.5	175.5	**180.6**	**5.2**	155.0	**16.5**	**25.6**
HIV franchise	124.9	124.9	**124.9**	0	103.5	20.7	21.4
Crestor®	21.1	21.1	**21.1**	0	22.6	(6.6)	(1.5)
Others	29.5	29.5	**34.6**	**5.2**	29.0	**19.5**	**5.7**
Others	2.5	2.5	**2.5**	0	2.6	(4.5)	(0.1)
Total	**346.5**	**348.0**	**354.0**	**6.0**	**344.7**	**2.7**	**9.3**

*Difference between forecasts announced on Oct. 29, 2018 and forecasts announced on Jul. 23, 2018

3. 2nd Half FY2018 Business Plan

Efforts in 2H FY2018 – in Mid- to Long-term Plan

(1) Japan Business

Rebuilding foundation to achieve greater strength in Japan (P.27-30)

- New approach to expand sales of new products, such as Cymbalta®, Intuniv®, and Xofluza®

(2) Overseas Business

Strengthen presence in the U.S. (P.31)

- Improve efficiency by combining partnering and our own promotion
- Intensive investment of resources in the hospital/specialty market

(3) R&D

Promote development of the next growth drivers (P.32-35)

- Intensive investment of capital in high-priority projects
- Expanding range of treatment options in the HIV franchise that supports earnings base

(1) Japan Business
Sales Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2018 Forecasts						FY2017	Y on Y	
	Full year			2H					
	Revised (Jul 23)	Revised (Oct 29)	Change*	Revised (Jul 23)	Revised (Oct 29)	Change*	Results	Change (%)	Change (B yen)
Cymbalta®	26.0	26.0	0	13.8	**14.0**	**0.2**	23.5	**10.5**	**2.5**
Intuniv®	5.0	**6.1**	**1.1**	3.1	**3.8**	**0.7**	1.9	**223.1**	**4.2**
Xofluza®	13.0	13.0	0	11.7	**12.5**	**0.8**	2.4	**439.1**	**10.6**
Rapiacta®	1.1	1.1	0	1.1	**1.1**	**0**	3.3	**(66.4)**	**(2.2)**
Brightpoc® Flu	1.1	**1.3**	**0.2**	1.0	**1.0**	**0.1**	1.1	**11.8**	**0.1**
OxyContin® franchise	9.1	**8.7**	**(0.4)**	4.8	**4.8**	**0**	8.7	**0**	**0**
Symproic®	1.2	**1.6**	**0.4**	0.69	**0.85**	**0.2**	0.60	**162.5**	**1.0**
Total of strategic products	56.4	**57.7**	**1.3**	36.2	**38.2**	**2.0**	41.6	**38.9**	**16.2**
Actair®	0.15	**0.18**	**0**	0.09	**0.10**	**0**	0.12	**48.3**	**0.1**
Mulpleta®	0.23	**0.19**	**(0)**	0.11	**0.11**	**(0)**	0.16	**19.1**	**0**
Pirespa®	6.0	**5.9**	**(0.1)**	2.9	**3.0**	**0.1**	6.5	**(9.2)**	**(0.6)**
Total of new products	62.8	**64.0**	**1.2**	39.3	**41.4**	**2.1**	48.3	**32.5**	**15.7**
Crestor®	9.7	9.7	0	4.3	**4.5**	**0.2**	29.3	**(67.0)**	**(19.6)**
Irbetan® franchise	6.4	**6.0**	**(0.4)**	2.8	**2.9**	**0.1**	14.6	**(58.8)**	**(8.6)**
Others	40.4	**39.6**	**(0.8)**	20.5	**20.5**	**0**	47.0	**(15.8)**	**(7.4)**
Total	119.3	**119.3**	**0**	67.0	**69.3**	**2.3**	139.2	**(14.3)**	**(19.9)**
Y on Y	(19.9)	**(19.9)**	**-**	0.9	**3.3**	**-**	-	**-**	**-**

*Difference between forecasts announced on Oct. 29, 2018 and forecasts announced on Jul. 23, 2018

(1) Japan Business: Building Sales Growth by Our Own Earning Power

(Unit: B yen)

Prescription Drugs in Japan	2H FY2017 Results	2H FY2018 Forecasts (Revised on Oct 29)	Y on Y comparison
New products (including strategic products)	27.7	41.4	**+13.7**
Crestor®, Irbetan® franchise	14.1	7.4	(6.7)
Others	24.2	20.5	(3.7)
Total	**66.0**	**69.3**	**+3.3**

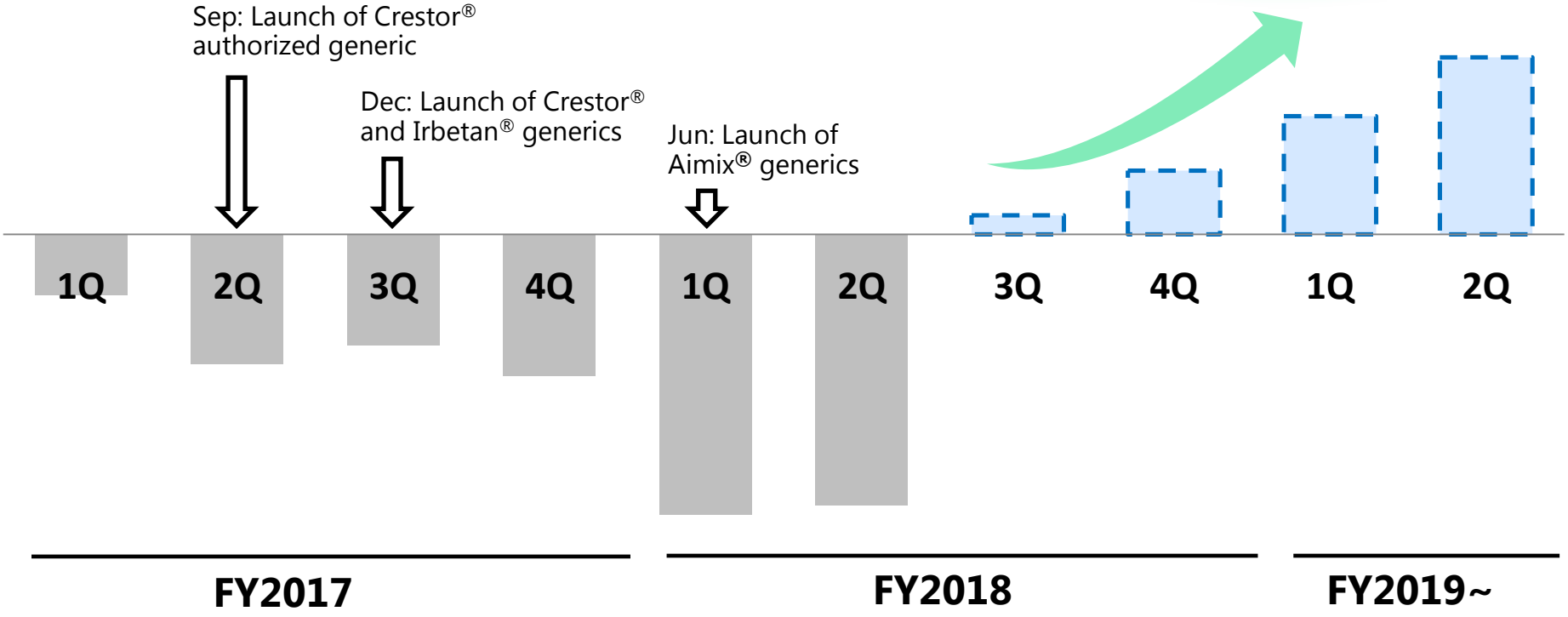
Increase sales in 2H FY2018 compared to year prior through growth in sales of strategic products

(1) Japan Business: Building Sales Growth by Our Own Earning Power

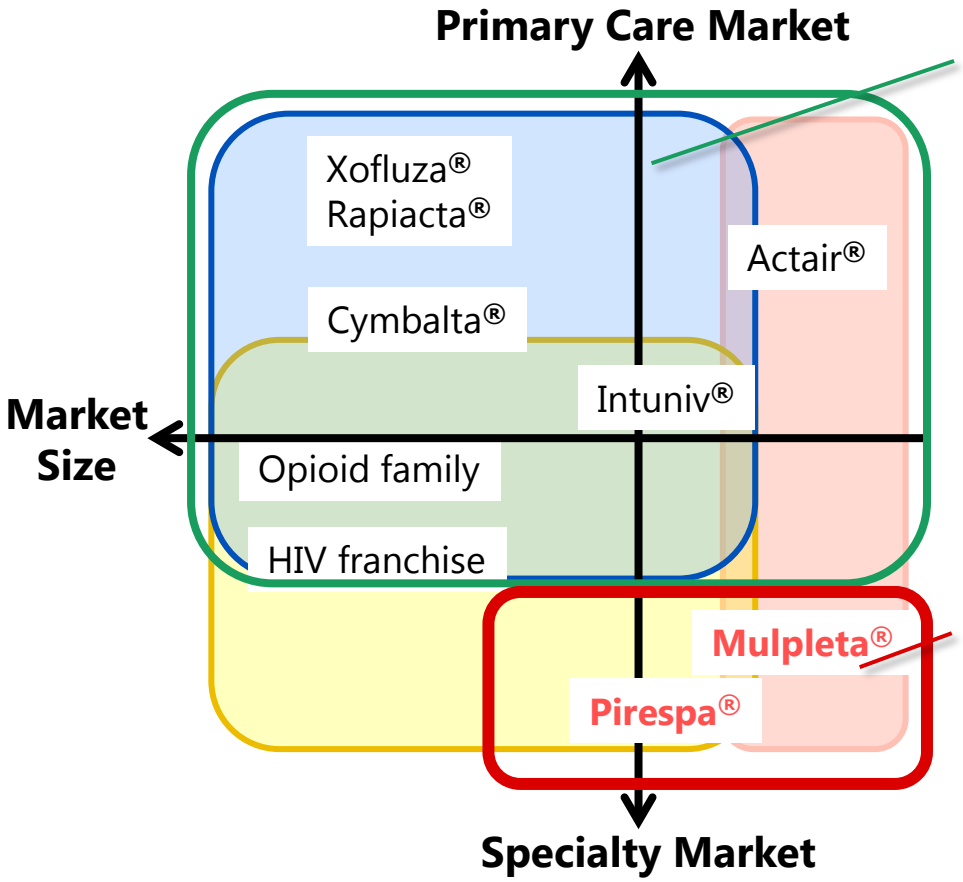
Sales of prescription drugs in Japan (Y on Y comparison)

The impact of share capture by generic competitors hit a plateau in 1H FY2018

Sales-growth phase by our own earning power



(1) Japan Business: Rebuild and Strengthen Sales Division



◆ **Promotion by general sales reps**

Focus resources on primary drugs with large market size

- Cymbalta®: Focus on chronic pain treatment
- Xofluza®: Focus on efficacy and convenience and to establish a new standard of care in influenza
- Intuniv®: Expand market through understanding of ADHD

◆ **Promotion by specialized sales reps**

Set up "Specialty Product Office" for specialty products which require high-level expertise

- One-stop service that offers everything from marketing research to information provision
- Concentrate on targeted hospitals

Pursue suitable resource allocation and deploy expertise based on each market's characteristics

(2) Overseas Business _to Strengthen the U.S. Business

Infectious disease

- **Cefiderocol: NDA submission in the U.S. in CY2018**
  - Continued accumulation of CR* study data for NDA submission in the U.S.
  - Steady Progress of Phase III studies (CR*, HAP/VAP/HCAP**)

Pain/CNS

- **Symproic® : Smooth transition to our own promotion**
  - Minimize disruption and focus on improved strategies
  - Selection of a new business partner is ongoing

Frontier

- **Mulpleta® : Use focused resources to achieve market uptake**
  - Support program "Mulpleta Assist"
- **Osphena® : Continue to support our collaborator, Duchesnay**
  - Building information base and supporting pursuit of U.S. dryness indication

Growth of top-line, total cost management, and further collaboration with business partners

→Achieve break-even in FY2018

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* CR : Carbapenem-resistant
** HAP/VAP/HCAP: hospital-acquired pneumonia/ventilator-associated pneumonia /health care-associated pneumonia

(3) R&D- Progress of Next Growth Drivers

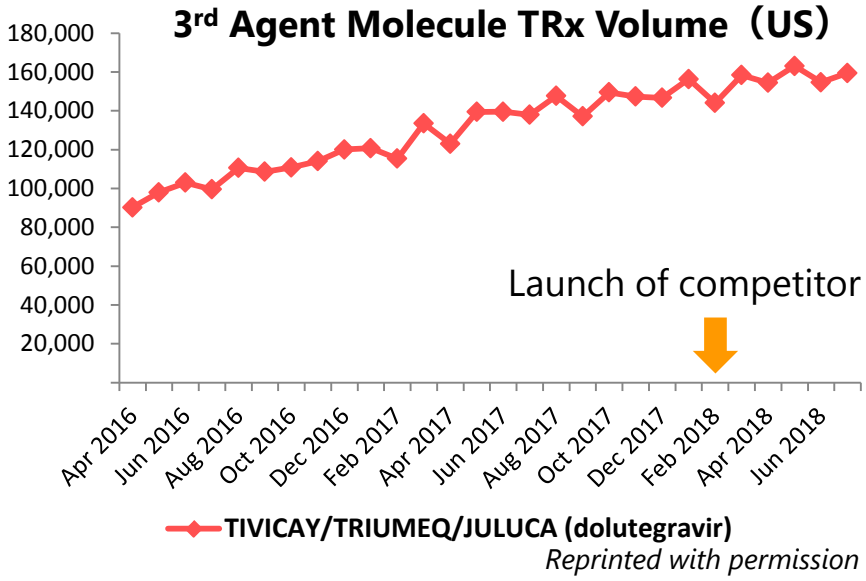
		Pipeline	Target in 2H FY2018
Infectious disease	In house	**Novel HIV drug**	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
Pain/CNS	In house	**S-004992** (Tuberculosis)	Non-clinical studies are progressing to support initiation of Phase I study (China)
	In house	**S-600918** (Refractory/unexplained chronic cough, Neuropathic pain)	Top-line results of proof of concept (Phase II) study (Refractory/unexplained chronic cough, Japan)
	In house	**S-637880** (Neuropathic pain)	Completion of Phase I study and micro-dose study (Japan)
	Collaboration	**S-812217** (Depression)	Initiation of Phase I study in Oct 2018 (Japan)
Others	In house	**Adjuvant**	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
	In house	**S-770108** (Idiopathic pulmonary fibrosis)	Completion of Phase I study (Japan)
	Collaboration	**Peptide**	Optimization of HIT peptides to initiate new drug discovery projects

Consistent progress of 8 high-priority projects

(3) R&D- Progress of HIV Franchise

Stable Prescriptions

Prescription trend in the US (TRx Volume) from Apr. 2016 to Aug. 2018



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Progress of two-drug regimen

DTG/3TC MAA/NDA submission in EU/US

- PDUFA action date is anticipated in 6 months in the US with a priority review voucher

DTG/3TC Phase III studies (GEMINI-1,2)

- Non-inferiority to three-drug regimen, and met the primary endpoint
- No emergence of resistance
- Less frequent drug-related adverse events compared with three-drug regimen

CAB+RPV Phase III study (ATLAS)

- Non-inferiority to three-drug regimen, and met the primary endpoint

Stable revenue base for our future growth with royalty income from ViiV

*Press release on Jul. 25, 2018 **Press release on Aug. 21, 2018
DTG: dolutegravir, CAB: cabotegravir, RPV: rilpivirine, 3TC: lamivudine

(3) R&D
HIV Platform Based on DTG/CAB Franchise

Tivicay®, Triumeq® **Launch: 2013~**
- **Key drug for 3-drug regimen**

Juluca® (DTG/RPV) **Launch: 2017~**
- **First 2-drug regimen for maintenance therapy**
- Nov. 2017-Jun. 2018: Approved in US, EU, CAN, AUS

DTG/3TC **Launch: 2019~**
- **First 2-drug regimen for naïve patients**
- Sep. 2018: MAA submission in EU, Oct. 2018: NDA submission in US (naïve patients)
  - ➢ PDUFA action date is anticipated in 6 months (priority review voucher)

CAB+RPV **Launch: 2019～**
- **First long acting injection** (monthly or bimonthly)
- 2H 2018~1H 2019: NDA/MAA submission in US and EU (monthly injection)

CAB prophylaxis **Launch: 2021~**
- **First long-acting injectable for prophylaxis** (bimonthly)

Provide various options for all patients' needs

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

(3) R&D
Expectations for CAB Long-Acting Injection

SONG for you!

Convenience	Medication Adherence	Reduce daily awareness of HIV	Privacy

Improvement of QOL

Interview of 27 patients enrolled in LATTE-2

Deanna Kerrigan et al, PLOS ONE, 2018

Most patients prefer long-acting injection to daily oral dosing

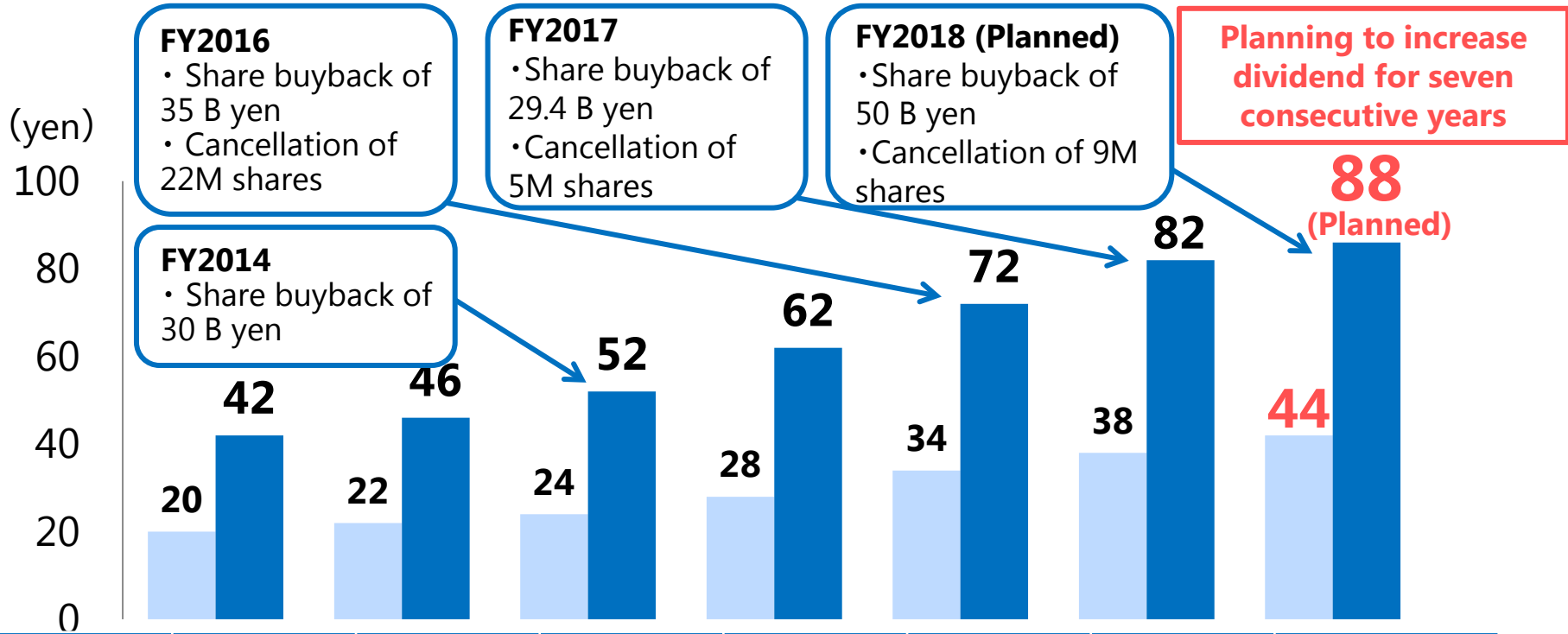
- No need to take a tablet daily
- No need to keep tablets at home
  ⇒Avoid unintentional disclosure
- No reminder of HIV status on a daily basis
  ⇒Live life like an uninfected person
- No concerns for baggage inspection at an airport

Deanna Kerrigan, et al. Experiences with long acting injectable ART: A qualitative study among PLHIV participating in a Phase II study of cabotegravir + rilpivirine (LATTE-2) in the United States and Spain. PLOS ONE . 2018

4. Shareholder Return

Shareholder Return Policy

Maximizing corporate value by balancing three key factors
: return to shareholders, investment for further growth, and strategic investment



年度	12	13	14	15	16	17	18
DOE	3.7	3.5	3.7	4.1	4.5	4.6	4.3 (planned)
ROE	17.5	9.2	9.4	13.6	16.3	19.4	18.7 (planned)

Appendix

- Progress of 1st Half FY2018
- Target Milestones for FY2018
- Progress of Pipeline
- Launch Plan
- Strategic Investment
- Share Buyback and Cancellation
- Maximizing Corporate Value Through Group Businesses

Progress in 1H FY2018* (Pipeline)

	Phase I	Phase II	Phase III	Submission	Approval, Launch
Global			**Xofluza™** • HR study top-line results	• Taiwan NDA submission	• US Approval
In Japan	**S-005151** • Start of PhI study (Acute ischemic stroke)	**S-600918** • Start of PhII study (Refractory/unexplained chronic cough) **SR-0379** • Start of PhII study (Cutaneous ulcer)	**OxyContin®TR** • Start of PhIII study (Chronic pain) **Xofluza®** • Start PhIII study (prophylaxis)	**Intuniv®** • NDA submission (adult)	**Mulpleta®** • US Approval, Launch **Brightpoc® Flu·Neo** • Approval, Launch **Xofluza®** • Approval (granule product)
Out-licensed			**DTG/3TC** • PhIII study top-line results (GEMINI) **CAB+RPV** • PhIII study top-line results(ATLAS)	• EU/US MAA/NDA submission	**Juluca®(DTG/RPV)** • Approval, Launch

Infectious diseases
Pain/CNS
Frontier

*Progress from May 10 to Oct. 29, 2018
DTG: dolutegravir RPV: rilpivirine

Progress in 1H FY2018* (Others)

- **May**
  - Collaboration with Aichi Prefecture for “Prevention of Drug Abuse”
  - Collaboration with Iwate Prefecture in “Support for Children’s Bright Future”
  - Started Shionogi’s internal use of PDPS**, a drug discovery platform developed by PeptiDream
  - Entered into a collaborative licensing, research and development program with Hsiri to discover and develop drugs for mycobacterial diseases
- **June**
  - Collaboration with SAGE to develop and commercialize S-812217
  - Investment in the clinical development of Nemesis “Symbiotics©”
  - Entered into a capital alliance between Shionogi Healthcare and Rohto
- **July**
  - Terminated the prior alliance with Purdue for the co-commercialization of Symproic® in the US (Shionogi has regained full rights to Symproic®)
- **September**
  - Shionogi and Rohto Pharmaceutical Co.,Ltd. Enter into License Agreement regarding “Cellular and Tissue-based Products” Candidate ADR-001
  - Agreement regarding acquisition of equity in Takara Healthcare and an absorption-type merger by Shionogi Healthcare, and succession of Takara Bio’s functional food business
- **October**
  - Establishment of Shionogi Pharma Co., Ltd.
  - Establishment of “Department of Biostatistics and Data Science” jointly with Osaka University

* Progress from May 10 to Oct. 29, 2018

** PDPS (Peptide Discovery Platform System) : Technology to obtain the peptide with high activity and high selectivity

Target Milestones for FY2018 : Approvals and NDA Submission

Product (indication)	Phase I	Phase II	Phase III	NDA submission	Approval
Mulpleta® (Thrombocytopenia associated with chronic liver disease)			Achieved (Aug.)	US (2017.12) EU (2018.1)	US
Rizmoic® (Opioid-induced constipation)				EU (2017.3)	EU
Lisdexamfetamine (ADHD [pediatric])				Japan (2017.4)	Japan
Xofluza™ (Influenza virus infection)		Achieved (Oct.)	Global: ongoing	US (2018.4)	US
Xofluza™, granule (Influenza virus infection)		Achieved (Sep.)	Japan: ongoing	Japan	Japan
Cefiderocol (Multidrug-resistant Gram-negative bacterial infections)			Global: ongoing	US	
Intuniv® (ADHD [adult])		Achieved (Aug.)	Japan: Extension study, ongoing	Japan	

Target Milestones for FY2018 : Phase I ~ III

Product (indication)	Phase I	Phase II	Phase III	NDA submission	Approval
Xofluza® (Influenza virus infection [prophylaxis])			Japan: initiated	Achieved (2Q)	
OxyContin®TR (Treatment of moderate to severe chronic pain)			Japan: initiated	Achieved (1Q)	
S-120083 (Inflammatory pain)		US: completed			
S-588410 (Bladder cancer)		Japan, EU: completed			
S-600918 (Refractory/unexpected chronic cough, Neuropathic pain)		Japan: initiated		Achieved (1Q) (Refractory/unexplained chronic cough)	
S-770108 (Idiopathic pulmonary fibrosis)	Japan: completed				
S-637880 (Neuropathic pain)	Japan: completed				
S-005151 (Acute ischemic stroke)	Japan: initiated			Achieved (1Q)	
S-004992 (Tuberculosis)	Asia (China) : initiated				

Progress from Jul. 31 to Oct. 29, 2018

Progress from May 10 to Jul. 23, 2018

Pipeline (as of Oct. 29, 2018)

Preclinical	Phase I	Phase II	Phase III	Filed
Global				
Influenza virus infection	**S-004992*** Tuberculosis	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Xofluza™ (Taiwan)** Influenza virus infection
HIV virus infection	**S-117957** Insomnia	**S-120083** Inflammatory pain		**Rizmoic® (EU)** Opioid-induced constipation
Bacterial infection	**S-237648** Obesity	**S-707106** Type2 diabetes		**Mulpleta® (EU)** Thrombocytopenia
Bacterial infection		**S-488210** Head and neck squamous cell carcinoma		
Mycobacterium disease		**epertinib** Malignant tumor		
Fungus infection		**S-588410** Bladder cancer		
Fungus infection				
Peptide				
Vaccine for prevention				
In Japan				
ADHD	**S-812217*** Depression	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Cefiderocol** Multidrug-resistant Gram-negative bacterial infections	**Oxycodone** Moderate to severe chronic pain
Opioid	**S-600918** Neuropathic pain	**S-600918** Refractory/unexpected chronic cough	**Xofluza™** Influenza virus infection (prophylaxis)	**Lisdexamfetamine** ADHD (pediatric)
Peptide	**S-637880** Neuropathic pain	**S-237648** Obesity	**Cymbalta®** Depression (pediatric)	**Intuniv®** ADHD (adult)
Alzheimer's disease	**S-010887** Neuropathic pain	**S-525606** Allergic rhinitis caused by Japanese cedar allergen	**Oxycodone** Moderate to severe chronic pain	
Post-stroke spasticity	**S-005151** Acute ischemic stroke	**S-588410** Bladder cancer	**S-588410** Esophageal cancer	
Obesity	**S-770108** Idiopathic pulmonary fibrosis	**SR-0379** Cutaneous ulcer		
NASH		**ADR-001**** Decompensated liver cirrhosis		
Cancer metastasis				
Adjuvant				
Peptide				

- Infectious diseases
- Pain/CNS
- Other

Progress from Jul. 31 to Oct. 29, 2018

* In preparation for Phase I
** In Phase 1/II

Pipeline -Out-licensed (as of Oct. 29, 2018)

Preclinical	Phase I	Phase II	Phase III	Filed
	GSK3342830 Multidrug-resistant Gram-negative bacterial infections		**DTG/3TC** Treatment for HIV infection TANGO study (maintenance)	**DTG/3TC (EU/US)** Treatment for HIV infection
			CAB LAP Prevention for HIV infection	**Osphena®** Vaginal dryness associated with postmenopausal VVA
			CAB+RPV LAP Treatment for HIV infection	
			Xofluza™ Severe influenza virus infection	

- **Infectious diseases**
- **Pain/CNS**
- **Others**

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Progress from Jul. 31 to Oct. 29, 2018

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

Target Milestones for Launch of Products

FY2017 (Achieved)	FY2018	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) **Lisdexamfetamine** ADHD (pediatric) **Xofluza® (granule)**
Global		
Symproic® (US)	**Mulpleta®** (US) **Launched** **Rizmoic®** (EU)	**Cefiderocol** (US) **Mulpleta®** (EU) **Baloxavir marboxil** (Taiwan)
Out-licensed		
Juluca® (DTG/RPV)(US)	**Juluca® (DTG/RPV)** (EU) **Launched** **Osphena®** (US) Vaginal dryness associated with postmenopausal VVA **Xofluza™** (US, OwH*)	**DTG/3TC** (US, EU) **CAB+RPV** (US)

DTG: Dolutegravir, RPV: Rilpivirine, 3TC: Lamivudine

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

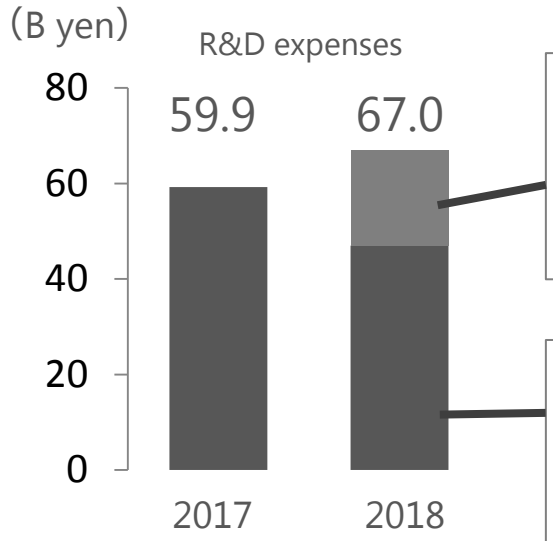
Strategic Investment for Sustainable Growth

SONG for you!

Development of Xofluza™ is in its final stage

Favorable opportunity to invest in other growth drivers

New investment to expand pipeline for sustainable growth



Strategic Investment (ca. 20 B yen)
New investment to **expand pipeline for launches beyond 2020** and to **introduce new technologies**

Focus resources on the 7 high-priority projects* by strengthening total cost management, although ordinary R&D expenses will be lower than in FY2017

Strategic investment (ca. 20 B yen) in R&D is planned for sustainable growth

* Presentation Material of R&D Meeting on Mar. 15, 2018 http://www.shionogi.co.jp/en/ir/pdf/e_p180315.pdf
1: Novel HIV drug, 2: Peptide drugs, 3: Adjuvant, 4: S-044992, 5: S-600918, 6: S-637880. 7: S-770108

Hsiri: Novel Drug for Mycobacterial Disease

- **Novel mechanism of action**, efficacy on both tuberculosis and non-tuberculosis mycobacterial disease, potential to fulfill unmet medical needs
- Start R&D for the treatment of NTM Disease

Mycobacterial Disease		
	Tuberculosis (TB)	**NTM Disease*5**
Patient number, Market potential	10.4 M new patients/year*1, ¥43.7 B market worldwide*2	Estimated 90K patients (JP); 180K patients (US) ; 9K patients (EU5)
Challenges for Mycobacterial Disease Treatment	• **One of the world's top 3 infectious diseases** • Multidrug-resistant TB and extensively drug-resistant TB • Long-term treatment • The most common presenting illness among HIV patients	• **No drugs developed for NTM disease, low effectiveness of current treatment** • Long-term treatment (>1 year) • Increased prevalence in developed countries
Action by Shionogi	S-004992, Hsiri molecules, Collaboration with TB ALLIANCE*3, GHIT*4	Hsiri molecules

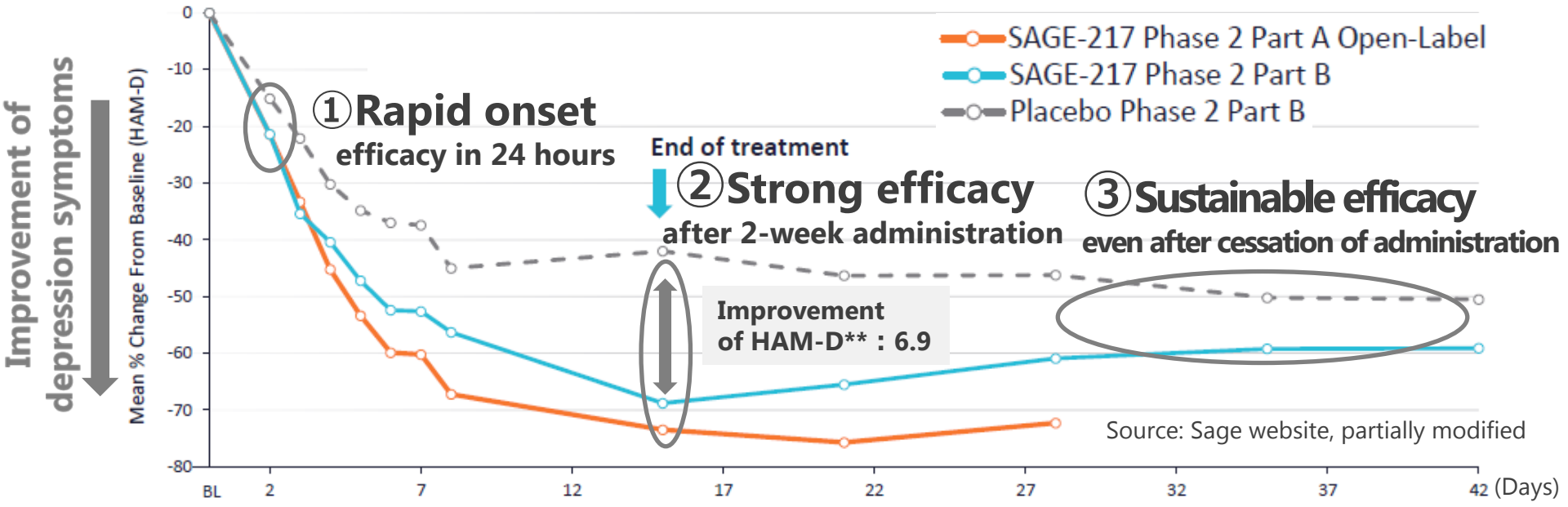
Enhance presence of Shionogi in infectious disease field including TB through development of S-004992 and Hsiri molecules for mycobacterial disease

SHIONOGI

*1 WHO: Global Tuberculosis Report 2017
*2 IQVIA Analytics Link (J4A)
*5 Epi data, company data etc.
*3 Partnership on developing medicines with support from Bill & Melinda Gates Foundation
*4 Organization to advance development of new drugs for infectious diseases in the developing countries

SAGE: Novel Antidepressant S-812217

- A potential paradigm shift in the treatment of depression through **a novel mechanism*** affecting inhibitory neurons
- FDA designated **Break-Through Therapy** in US
- **Positive placebo-controlled Phase 2 Results** demonstrate potential in depressive disorders (figure)
- Plan to start of a clinical study in Japan in CY2018

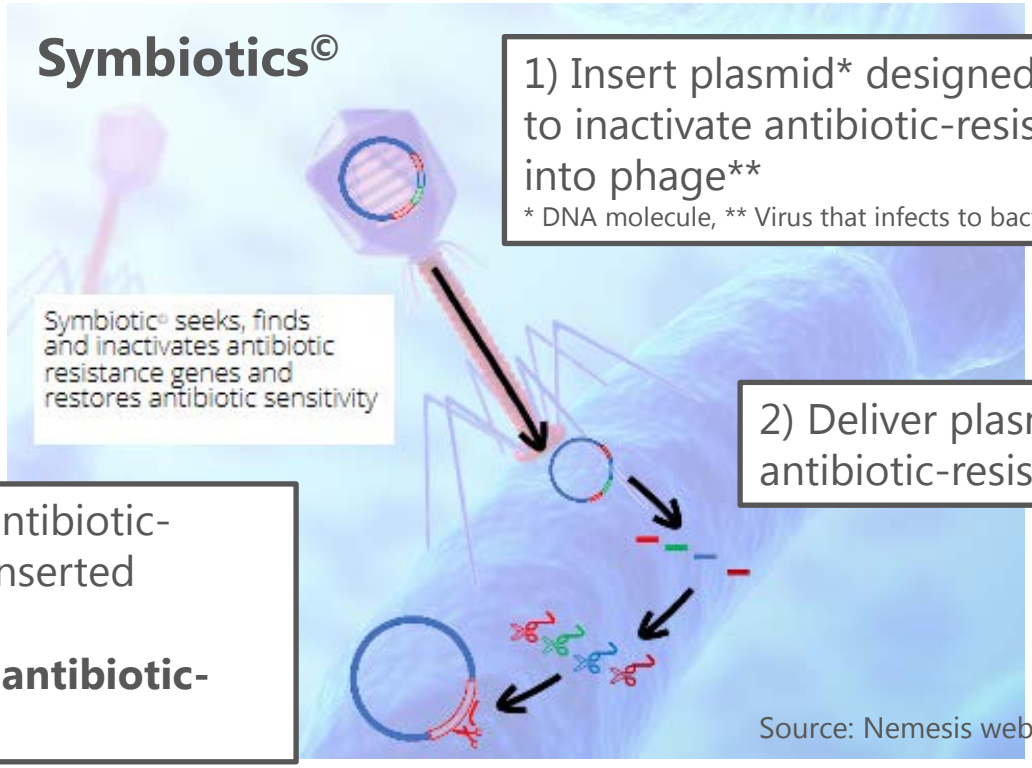


- **Novel antidepressant following Cymbalta®**
- **Launching new development products in CNS field contributing to sales beyond 2020**

* $GABA_A$ positive allosteric modulator
** HAM-D: a way of determining a patient's level of depression

Nemesis：Investment in Novel Technology for Antimicrobial Resistance (AMR)

Acquire knowledges about the novel modality “Symbiotics©” an approach to the problem of AMR



1) Insert plasmid* designed specifically to inactivate antibiotic-resistant genes into phage**

* DNA molecule, ** Virus that infects to bacteria

2) Deliver plasmid into antibiotic-resistant bacteria

3) Modification of antibiotic-resistant genes by inserted plasmid

⇒ **Inactivation of antibiotic-resistant genes**

Source: Nemesis website, partially modified

Expanding therapeutic options to AMR as a leading company in the infectious disease field

Rohto: Regenerative Medicine Products for Liver Cirrhosis

Regenerative Medicine Product Candidate: ADR-001

- **"Cellular-based products" prepared from mesenchymal stromal cells (MSC) derived from allogeneic adipose tissue** by Rohto's original technology
- Rohto is conducting Phase I/II study in patients with decompensated liver cirrhosis

➢ **Expected to reduce fibrosis** through the effect of cytokines secreted from stromal cells
➢ Prospect for **stable supply**
➢ Prospect for supply at an affordable price compared to treatment with iPS cells or ES cells

Improve QOL of patients with decompensated liver cirrhosis, for which there is no effective treatment

SHIONOGI × NEVER SAY NEVER ロート製薬

Expand our therapeutic modalities looking ahead to Beyond 2020 by reinforcing our drug discovery platform in the regenerative medicine area

From 1Q FY2018 Financial Results

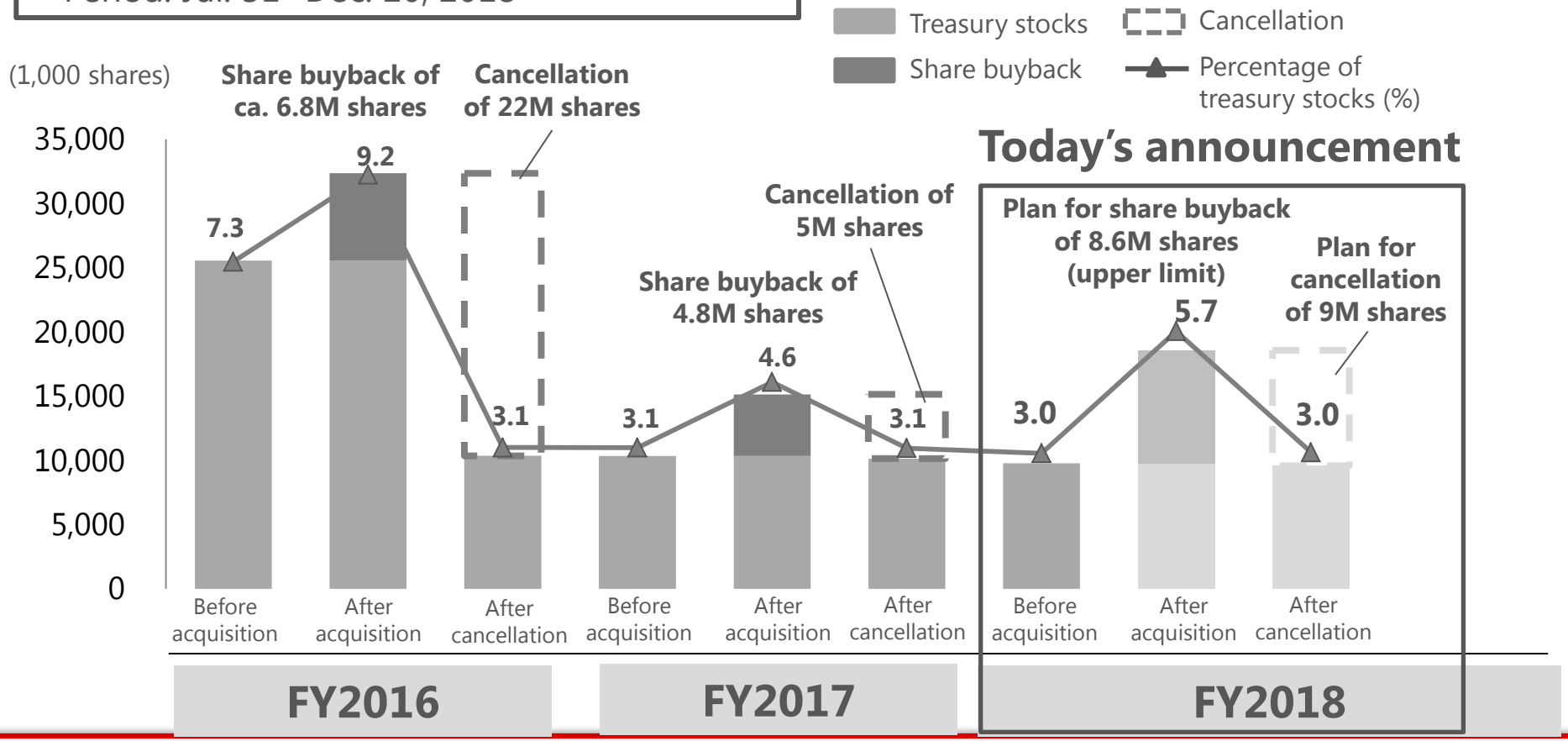
Share Buyback and Cancellation

Share buyback

- Share buyback: 8.6M shares (upper limit)
- Total amount of buyback: 50 B yen (upper limit)
- Period: Jul. 31~Dec. 20, 2018

Cancellation of treasury shares

- Total shares to be cancelled: 9M shares
- Date for cancellation: Jan. 31, 2019



From FY2017 Financial Results, Partially Revised

Maximizing Corporate Value Through Group Businesses

- **Improvement of business operations**
- **Respond to requests from society (e.g. employment extension, equal pay for equal work)**

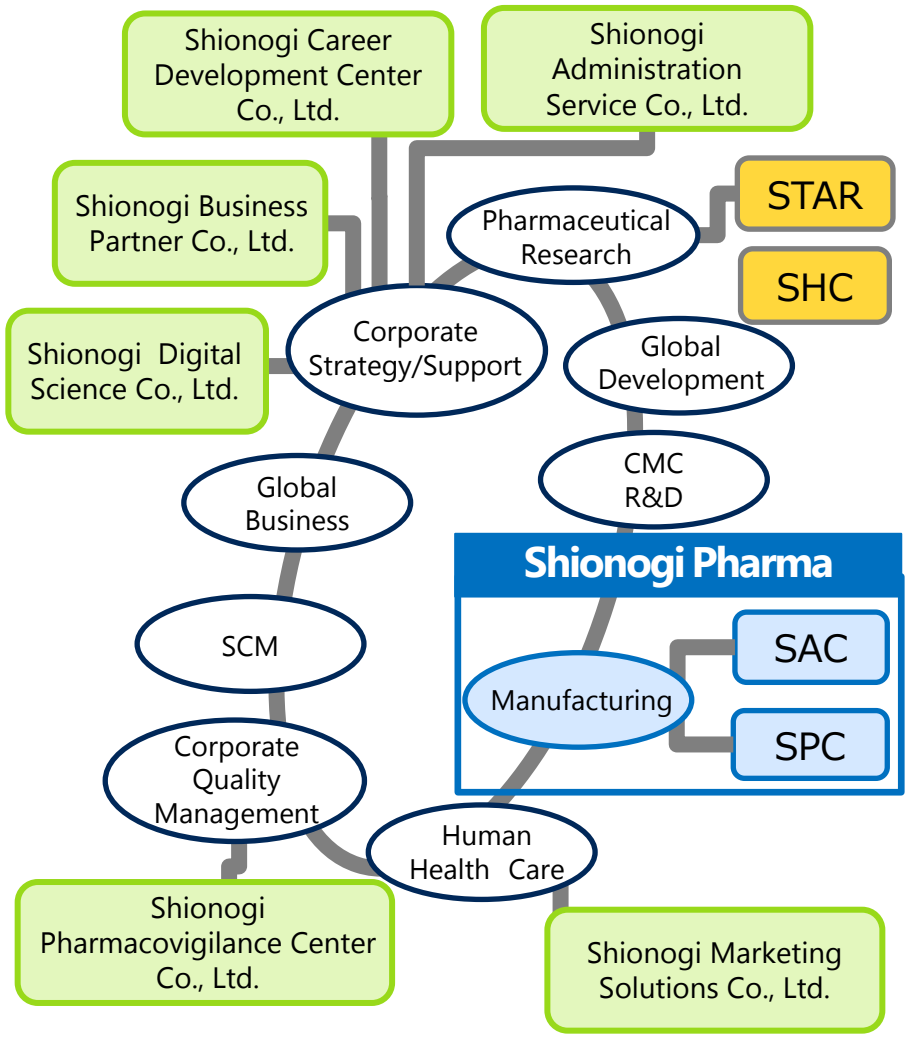
Close communication between senior management of group companies

Refine infrastructure to enhance productivity and build expertise

For further growth

Press release on Oct 1, 2018
Construction of a new manufacturing subsidiary
"Shionogi Pharma Co., Ltd."
(Start business on Apr 1, 2019)

シオノギファーマ株式会社



STAR: Shionogi Techno Advance Research Co., Ltd. SPC: Shionogi Pharma Chemicals Co., Ltd
SAC: Shionogi Analysis Center Co., Ltd. SHC: Shionogi Healthcare Co., Ltd. SCM: Supply-chain Management

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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