SHIONOGI 140th Anniversary

S-O-N-G for you!

3rd Quarter of Fiscal 2018 Financial Results

Conference Call

January 31, 2019

SHIONOGI

Agenda

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2. **Efforts and Progress in Q3 FY2018 (P.10-19)**
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   3. **R&D**
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1. Overview of Q3 FY2018 Financial Results

Financial Results (Consolidated)

(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Progress vs. forecasts	Apr.-Dec. Results	Change (%)	Change (B yen)
Sales	354.0	265.2	74.9%	263.4	0.7%	1.9
Operating income	124.5	97.4	78.3%	90.1	8.1%	7.3
Ordinary income	148.5	115.7	77.9%	105.5	9.7%	10.2
Profit attributable to owners of parent	118.5	94.3	79.6%	79.7	18.3%	14.6

<Sales and Each profit measure>

- Sales and each profit measure have progressed smoothly toward full-year forecasts
- Sales and each profit measure were higher than Apr.-Dec. FY2017

<Each profit measure>

- Apr.-Dec. results by every profit measure reached record-high levels
  - Operating income and profit attributable to owners of parent: 4 consecutive years
  - Ordinary income: 10 consecutive years

Exchange Rate (average)	FY2018 forecasts	FY2018 Apr.-Dec. results
USD ($) – JPY (¥)	105.0	111.15
GBP (£) – JPY (¥)	145.0	146.34
EUR (€) – JPY (¥)	130.0	129.48

Statement of Income

(Unit: B yen)

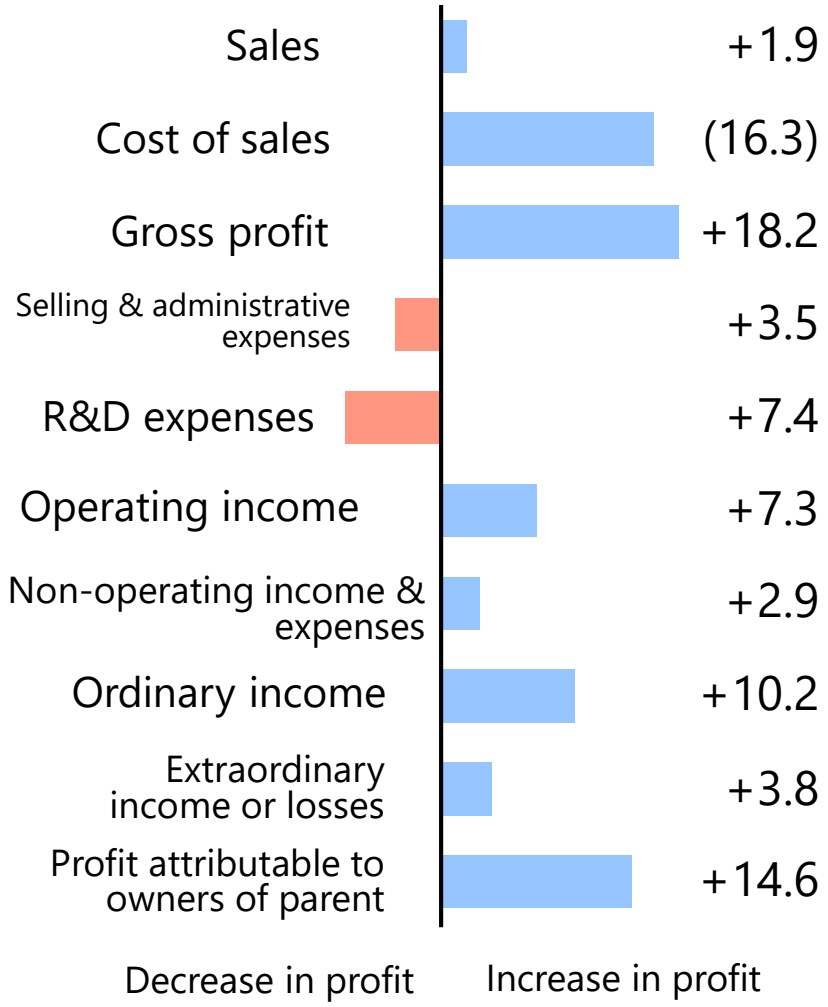
	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achieve-ment (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Sales	**354.0**	**265.2**	74.9	263.4	0.7	1.9
	16.1	15.2		21.5		
Cost of sales	**57.0**	**40.4**	70.8	56.7	(8.8)	(16.3)
Gross profit	**297.0**	**224.9**	75.7	206.6	8.8	18.2
SG&A expenses	48.7	48.0		44.2		
	172.5	**127.4**	73.9	116.5	9.4	10.9
Selling & administrative expenses	29.4	28.1		26.9		
	104.0	**74.5**	71.6	70.9	5.0	3.5
	19.4	20.0		17.3		
R&D expenses	**68.5**	**53.0**	77.3	45.6	16.2	7.4
Ordinary R&D expenses*	**50.4**	**38.2**	75.8	45.6	(16.2)	(7.4)
Strategic investment	**18.1**	**14.8**	81.8	-	-	14.8
	35.2	36.7		34.2		
Operating income	**124.5**	**97.4**	78.3	90.1	8.1	7.3
Non-operating income & expenses	**24.0**	**18.2**	75.9	15.3	18.8	2.9
	41.9	43.6		40.0		
Ordinary income	**148.5**	**115.7**	77.9	105.5	9.7	10.2
Profit attributable to owners of parent	**118.5**	**94.3**	79.6	79.7	18.3	14.6

* 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)



Main Variation Factors in Oct.-Dec. (Y on Y)

- **Sales**
  - Income from Roche for the approval of Xofluza® in the U.S.
- **SG & A expenses**
  - R&D expenses: Strategic Investments
    - › Net increase of 1.7 B yen
- **Extraordinary income or losses**
  - Profit on sale of investment securities

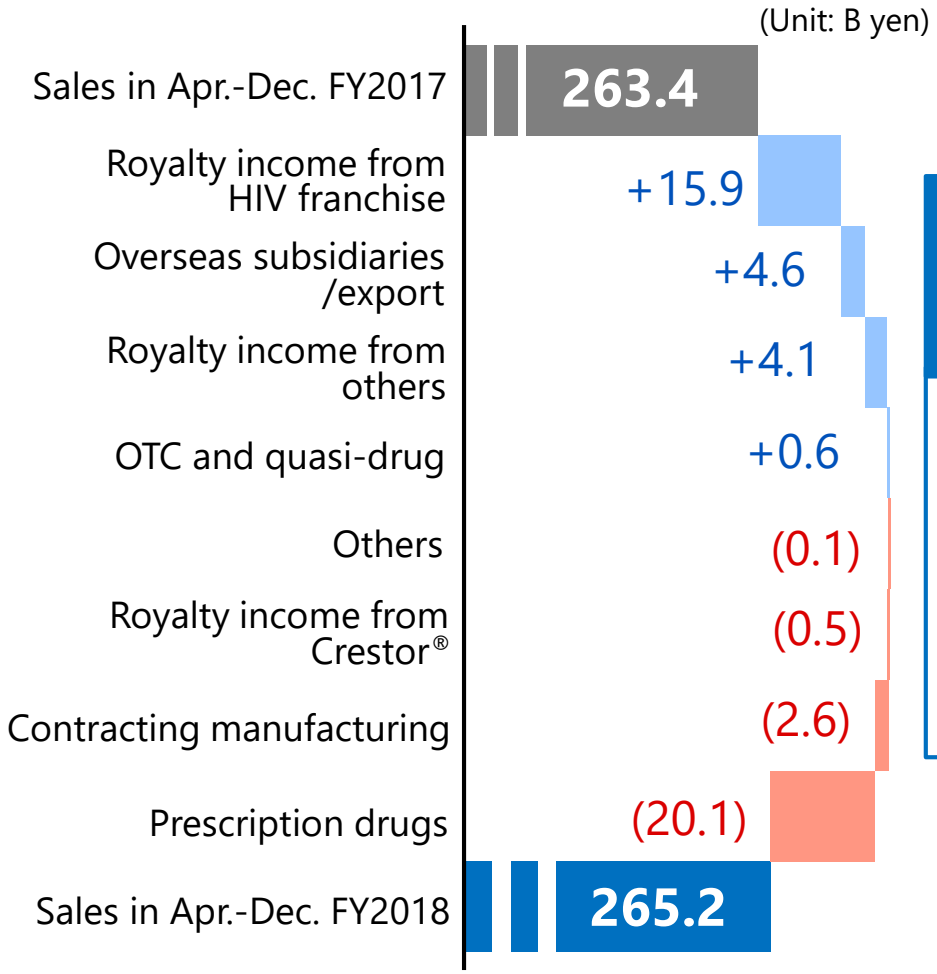
Sales by Segment

(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achieve-ment (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Prescription drugs	**119.3**	**88.3**	74.0	108.4	(18.5)	(20.1)
Overseas subsidiaries/export	**31.3**	**22.1**	70.6	17.5	26.6	4.6
Shionogi Inc.	**12.4**	**9.4**	75.6	8.4	12.0	1.0
Osphena®	**4.1**	**2.4**	58.4	3.0	(18.7)	(0.6)
C&O	**12.4**	**8.2**	66.1	4.8	71.3	3.4
Contract manufacturing	**12.9**	**9.2**	71.0	11.8	(22.1)	(2.6)
OTC and quasi-drug	**7.4**	**6.3**	85.5	5.7	10.2	0.6
Royalty income	**180.6**	**137.5**	76.1	118.1	16.4	19.4
HIV franchise	**124.9**	**89.9**	72.0	74.0	21.5	15.9
Crestor®	**21.1**	**16.4**	77.9	17.0	(3.2)	(0.5)
Others	**34.6**	**31.2**	90.0	27.1	15.1	4.1
Others	**2.5**	**1.9**	76.1	2.0	(4.5)	(0.1)
Total	**354.0**	**265.2**	**74.9**	**263.4**	**0.7**	**1.9**

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

- **Y on Y comparison**



Main Variation Factors Occurring in Oct.-Dec. (Y on Y)
(Apr.-Dec., Y on Y: +1.9 B yen, +0.7%)

- **Royalty income**
  - Income from Roche for the approval of Xofluza® in the U.S.
- **Prescription drugs**
  - Sales growth of Influenza family*

* Xofluza®, Rapiacta®, Brightpoc®Flu, Brightpoc®Flu・Neo

Sales of Prescription Drugs in Japan

(Unit: B yen)

	FY2018			FY2017	Y on Y	
	Full year forecasts (Revised on Oct. 29)	Apr.-Dec. Results	Achieve-ment (%)	Apr.-Dec. Results	Change (%)	Change (B yen)
Cymbalta®	26.0	**18.6**	71.6	18.2	1.9	0.4
Intuniv®	6.1	**3.9**	64.1	1.2	223.6	2.7
Xofluza®	13.0	**9.9**	76.4	-	-	9.9
Rapiacta®	1.1	**0.77**	68.4	1.2	(37.3)	(0.5)
Brightpoc® Flu	1.3	**0.58**	46.2	0.53	10.1	0.1
OxyContin® franchise	8.7	**5.8**	67.1	7.0	(16.9)	(1.2)
Symproic®	1.6	**1.2**	76.0	0.4	217.5	0.8
Total of strategic products	57.7	**40.8**	70.7	28.6	42.8	12.2
Actair®	0.18	**0.14**	78.7	0.09	57.6	0.1
Mulpleta®	0.19	**0.13**	65.3	0.13	0.3	0
Pirespa®	5.9	**4.5**	76.4	4.9	(9.1)	(0.4)
Total of new products	64.0	**45.6**	71.2	33.7	35.1	11.8
Crestor®	9.7	**7.8**	81.0	26.3	(70.2)	(18.5)
Irbetan® franchise	6.0	**4.4**	73.2	11.9	(63.0)	(7.5)
Others	39.6	**30.5**	76.9	36.5	(16.4)	(6.0)
Prescription drugs	**119.3**	**88.3**	**74.0**	**108.4**	**(18.5)**	**(20.1)**

2. Efforts and Progress in Q3 FY2018

Summary of Progress in Q3 FY2018

	Mid- to Long-term Plan	Major Progress
(1) Japanese Business	Rebuilding foundation to achieve greater strength in Japan	<Prescription drugs in Japan> • Focus resources on new products - Oct. to Dec. sales were increased from the previous year: 3.1 billion yen - Increase in the ratio of strategic products: 39.2% in 1H, 55.5% in Q3
(2) Overseas Business	Strengthen presence in the U.S.	<U.S. Business> • Cefiderocol: on track to meet our planned approval timelines • Selling Symproic® and Mulpleta® ourselves
(3) R&D	Promote development of next growth drivers	• Steady progress of 8 high-priority projects* • Favorable progress of HIV drugs • Four new business alliance agreements - Vast, Ube, Tetra, PeptiDream

Achieve increases in sales and profits in FY2018 and further growth in FY2019 while maintaining continuous investment for the next stage

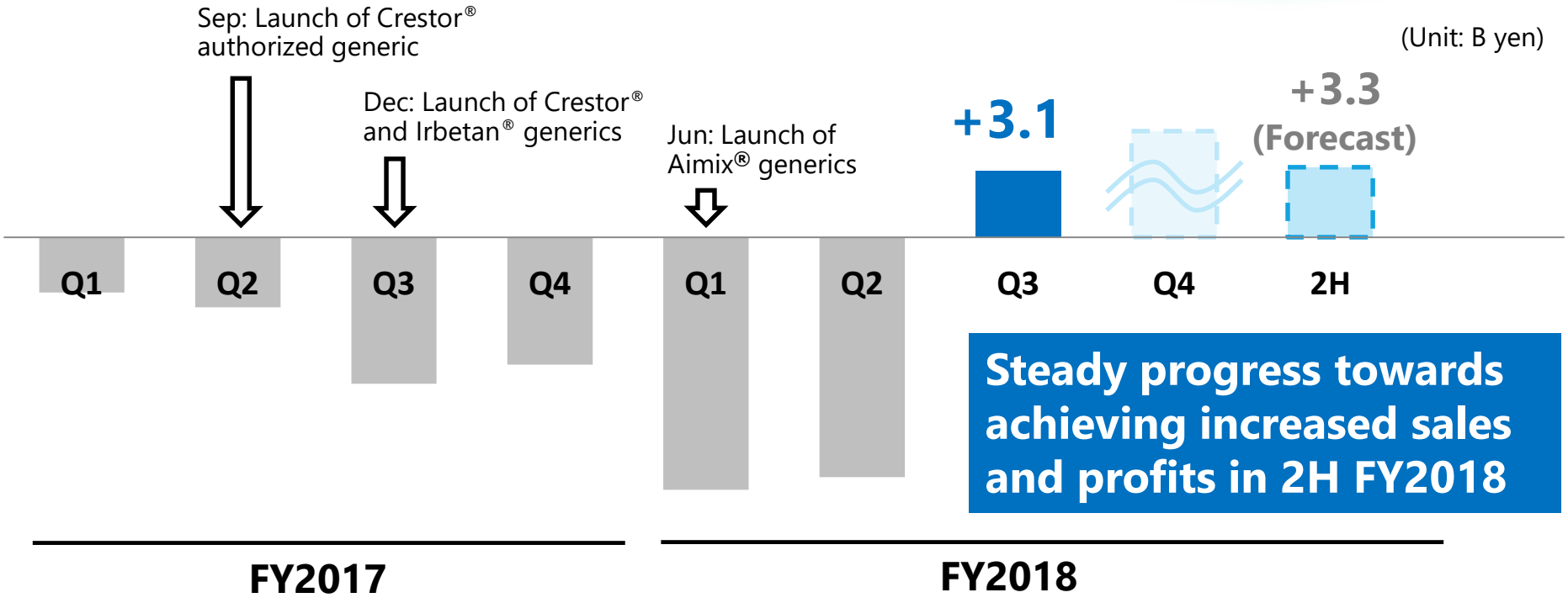
1: Novel HIV drug, 2: S-004992 (Tuberculosis), 3: S-600918 (Refractory/unexplained chronic cough, Neuropathic pain), 4: S-637880 (Neuropathic pain), 5: S-812217 (Depression), 6: Adjuvant for vaccine, 7: S-770108 (Idiopathic pulmonary fibrosis), 8: Peptide drug

(1) Japanese Business: Driving 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



Steady progress towards achieving increased sales and profits in 2H FY2018

(1) Japanese Business: Driving Sales Growth by Our Own Earning Power

Cymbalta®

- Prescriptions increased (15% or more increase from the previous year)
- Increase primarily in the pain area
  - Prescription increase in the orthopedic market
  - 29% or more increase from the previous year

Intuniv®

- Sales increase from the previous year (ca. 3.2-fold vs Oct.-Dec. FY2017)
- Top share in the non-stimulant market for pediatric ADHD for naïve and switch patients and add-on treatment*
- Advancing development to maximize the value of each product:
  - Under review by PMDA: Intuniv® (adult), lisdexamfetamine (pediatric)

Influenza family**

- Rapid sales increase due to seasonal flu outbreak
- Positive societal attention and recognition
- Clinical studies of Xofluza® are proceeding well to maximize its value

Opioid family***

- OxyContin® franchise:
  - Switching to OxyContin® TR
- Symproic®:
  - Sales increase from the previous year (ca. 3.2-fold vs Oct.-Dec. FY2017)

Sales increase driven by new sales organization and by focusing resources on strategic products

* Based on prescription volume in Nov. 2018 ** Xofluza®, Rapiacta®, Brightpoc®Flu, Brightpoc®Flu・Neo

*** OxyContin® , OxyContin®TR, OxiNorm®, OxiFast®, Methapain®, Symproic®

Xofluza®

Positive societal attention and recognition

- Profile which can change treatment of influenza
  - Single-dose, oral therapy
  - Rapid viral decrease in the body
- Positive reputation with medical experts and patients
- Coverage in various media (TV, newspaper, internet, radio, magazine etc.)

Japan

- **Providing information to physicians in an efficient and effective manner**
  - Suitable promotion in each region and usage of e-detail
- **Steady progress of two Phase 3 clinical trials (prophylaxis, new dosage for children)**

Global (the Roche Group)

- **Launched in the U.S.: middle of Nov. 2018**
  - Ongoing active promotion by the Roche group heading into the peak full season
    Sales so far: ca. 1.4 B yen (CHF 13M)
- **Steady progress of global development**
  - Steady progress of global clinical trials in pediatric and severely ill hospitalized patients

(2) Business in the U.S.

Infectious disease

- **Cefiderocol: On track to meet our planned approval timelines**
  - Steady progress of Phase III studies (CR*, HAP/VAP/HCAP**)

Pain/CNS

- **Symproic®: Sustained by our own promotion**
  - Efficient promotion by contract sales reps, Keep market exploited by Purdue
  - Selection of a new business partner is ongoing

Frontier

- **Mulpleta®: Initiated full-scale promotion in Dec.**
  - Patient access and uptake supported by “Mulpleta Assist” program
  - Tightly focused sales effort
- **Osphena®: Continue to support our collaborator, Duchesnay**
  - > Supplemental indication “moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy”: approved in Jan. 2019

Steady progress toward breakeven in FY2018 and building our foundation for expanding U.S. business

* 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	Progress in Q3 FY2018
Infectious disease	In house	**Novel HIV drug**	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
		S-004992 (Tuberculosis)	Non-clinical studies are progressing to support initiation of Phase I study (China)
Pain/CNS	In house	**S-600918** (Refractory/unexplained chronic cough, Neuropathic pain)	Proof of concept (Phase II) study (Refractory/unexplained chronic cough, Japan) is progressing ⇒Top-line results are anticipated in FY2018
		S-637880 (Neuropathic pain)	Phase I study and micro-dose study (Japan) are progressing Micro-dose studies: study 1, only PET* probe is administered; study 2, PET probe and S-637880 are administered
	Collabo-ration	**S-812217** (Depression)	Phase I study (Japan) was initiated in Oct. 2018
Others	In house	**Adjuvant**	Non-clinical studies are progressing to support initiation of Phase I study in FY2019
		S-770108 (Idiopathic pulmonary fibrosis)	Phase I study (Japan) was completed
	Collabo-ration	**Peptide**	Optimization of HIT peptides to initiate new drug discovery projects

Steady progress of 8 high-priority projects

→Details will be explained in the R&D Day scheduled for Mar. 14, 2019

*PET: Positron emission tomography

S-812217: Novel Antidepressant

Novel mechanism that differs from those of existing antidepressants

$GABA_A$ Positive Allosteric Modulator (PAM)

- Existing antidepressant: **Activate suppressed neural activity**
  - Increase of monoamine
- S-812217: **Suppress excessive neural activity**
  - Activate inhibitory neurons
  - Expected rapid onset of efficacy due to direct effect on inhibitory neurons



S-812217 binding site
=Neuroactive steroid site

GABA binding site

Extrasynaptic $GABA_A$ receptor

Steady progress of SAGE pipelines

- **SAGE-217 (S-812217)**
  - SAGE-217 met primary and secondary endpoints in Phase III clinical trial for "postpartum depression"
  - Phase III clinical trial for "major depression disorder" is proceeding
- **Injectable $GABA_A$ PAM ZULRESSO™(brexanolone)**
  - Under review by FDA for "postpartum depression"
  - FDA Advisory Committee voted 17-1 in support of benefit-risk profile
  - PDUFA date*: Mar. 19, 2019

Expected to be a novel antidepressant that can change existing treatment

(The presentation meeting will be held on Feb. 5, 2019 with SAGE)

Reference: SAGE website

* PDUFA date: deadlines for the FDA to review new drugs under the Prescription Drug User Fee Act (PDUFA)

(3) R&D
DTG/CAB Franchise - HIV Treatment Platform

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
- **Dec. 2018: Launched in Japan**

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)
- Aug. 2018: positive results from ATLAS,
  Oct. 2018: positive results from FLAIR
- 1H 2019: NDA/MAA submission in US and EU (monthly injection)

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

Continued excellent progress in expanding the platform and its value

Progress from Oct. 30, 2018 to Jan. 31, 2019

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

Progress of Strategic Investment

- **Dec. 6, 2018 Investment in Vast**
  - **Investment in Nitric Oxide Inhaled Antimicrobial Drug Platform**
    - > Obtained preferential right of negotiation for future in-license of the leading compound and subsequent compounds
- **Dec. 10, 2018 Collaboration with Ube**
  - **Collaborative research for novel anti-RS (respiratory syncytial) virus drug candidates**
    - > Accelerate development of anti-RS virus drugs through a synergistic joint SAR effort in collaboration with Ube
- **Dec. 19, 2018 In-licensing from Tetra**
  - **In-licensing of BPN14770, a drug candidate for cognitive and memory deficits**
    - > Obtained development, manufacturing, and marketing rights to BPN14770 in Japan, Taiwan and Korea
- **Jan. 23, 2019 Collaboration with PeptiDream**
  - **Novel technology which enables compounds to be selectively delivered into the brain**
    - > **Collaborative research on Peptide Drug Conjugates (PDC)**

See Appendices for details in 1H FY2018 (Hsiri, Sage, Nemesis, Rohto)

4. Shareholder Return

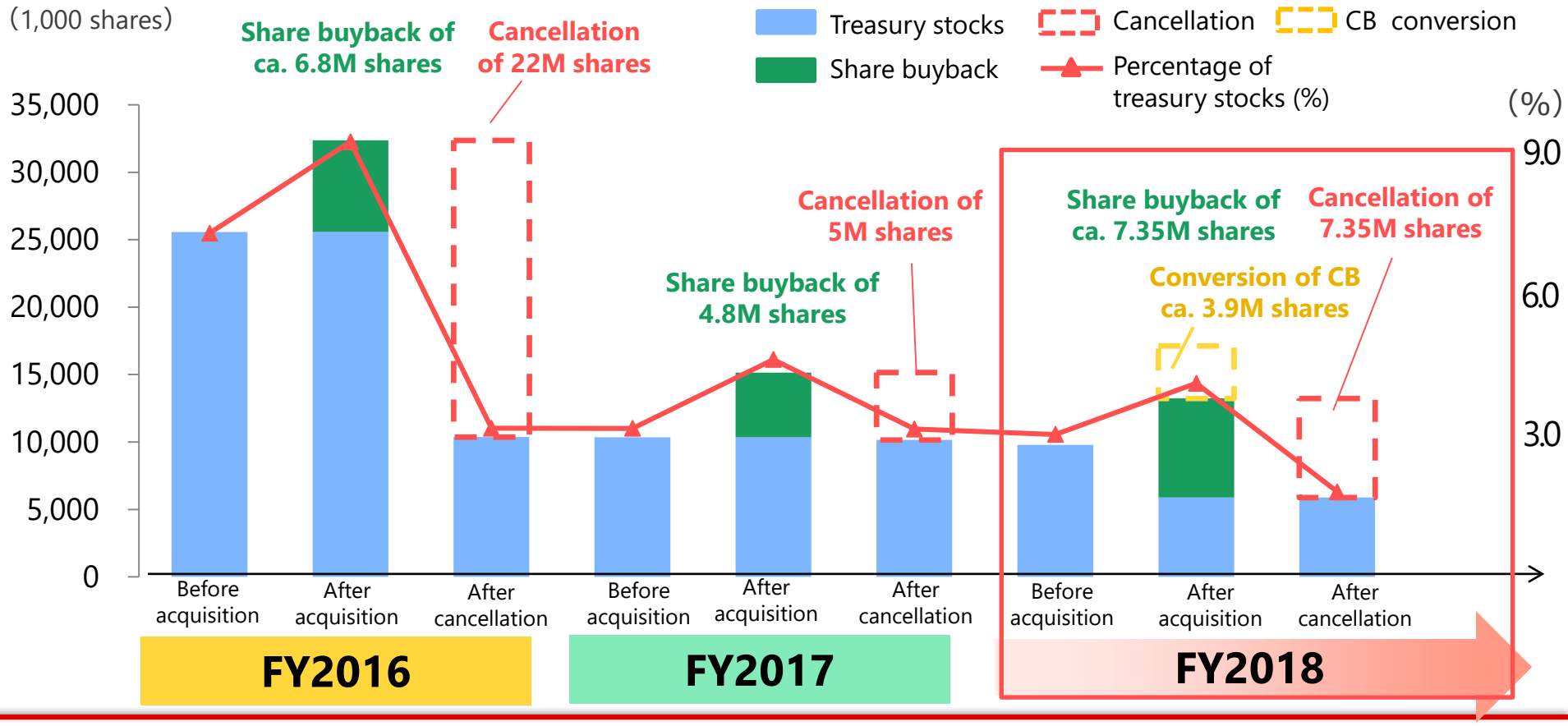
Share Buyback and Cancellation

Share buyback

- Share buyback: 7,350,400 shares
- Total amount of buyback: 49,999,850,123 yen
- Period: Jul. 31, 2018~Dec.18, 2018

Cancellation of treasury shares

- Total shares to be cancelled: 7.35M shares (planned)
- Date for cancellation: Feb. 20, 2019



CB: Convertible Bond

Appendix

- Major Progress in Q3 FY2018
- Target Milestones for FY2018
- Progress of Pipeline
- Launch Plan
- Business Plan for 2H FY2018
- Strategic Investment

Major Progress in Q3 FY2018* (Pipeline)

Phase I	Phase II	Phase III	Submission	Approval, Launch

Global

S-588210
・Start of PhI Study

Naldemedine (Rizmoic®)
・Recommendation from CHMP

Lusutrombopag
・Recommendation from CHMP

In Japan

S-812217
・Start of Ph1 Study

S-770108
・Completion of PhI Study

Xofluza®
・Start of PhIII Study
(New dosage for children)

Out-licensed

CAB+RPV
・PhIII study
top-line results
(FLAIR)

Xofluza™
・Launch (U.S.)

Juluca® (DTG/RPV)
・Approval, Launch (Japan)

Osphena®
・Approval (U.S.) (Dryness)

Infectious diseases
Pain/CNS
Frontier

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* Progress from Oct. 30, 2018 to Jan. 31, 2019
DTG: Dolutegravir 3TC: Lamivudine RPV: Rilpivirine

Major Progress in Q3 FY2018* (Others)

- **Dec.**
  - Investment in Vast Therapeutics with preferential right of negotiation for future in-license of Nitric Oxide inhaled antimicrobial drug candidates
  - Collaborative research with Ube Industries for novel anti-RS virus drug candidates
  - Collaboration with Tetra Discovery Partners on development and commercialization of BPN14770, a candidate drug for cognitive and memory deficits
- **Jan.**
  - Collaborative research with PeptiDream for new peptide drug conjugate (PDC) Discovery

* Progress from Dec. 30, 2018 to Jan. 31, 2019

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 (U.S., Aug.)	US (2017.12) EU (2018.1)	US
Naldemedine (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	

Progress from Oct. 30 to Jan. 31, 2019

Progress from May 10 to Oct. 29, 2018

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 (Q2)	
OxyContin®TR (Treatment of moderate to severe chronic pain)			Japan: initiated	Achieved (Q1)	
S-120083 (Inflammatory pain)		US: completed		Achieved (Q3)	
S-588410 (Bladder cancer)		Japan, EU: completed			
S-600918 (Refractory/unexpected chronic cough, Neuropathic pain)		Japan: initiated		Achieved (Q1) (Refractory/unexplained chronic cough)	
S-770108 (Idiopathic pulmonary fibrosis)	Japan: completed			Achieved (Q3)	
S-637880 (Neuropathic pain)	Japan: completed				
S-005151 (Acute ischemic stroke)	Japan: initiated			Achieved (Q1)	
S-004992 (Tuberculosis)	Asia (China): initiated				

Progress from Oct. 30 to Jan. 31, 2019

Progress from May 10 to Oct. 29, 2018

Pipeline (as of Jan. 31, 2019)

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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	Baloxavir Marboxil (Taiwan) Influenza virus infection
HIV virus infection	S-117957 Insomnia	S-120083 Inflammatory pain		Naldemedine (Rizmoic®) (EU) Opioid-induced constipation
Bacterial infection	S-237648 Obesity	S-707106 Type2 diabetes		Lusutrombopag (EU) Thrombocytopenia
Bacterial infection	S-588210 Solid tumor	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	Xofluza™ Influenza virus infection (New dosage for children)	Intuniv® ADHD (adult)
Alzheimer's disease	S-010887 Neuropathic pain	S-525606 Allergic rhinitis caused by Japanese cedar allergen	Cymbalta® Depression (pediatric)	
Cognitive and memory deficits	S-005151 Acute ischemic stroke	S-588410 Bladder cancer	Oxycodone Moderate to severe chronic pain	
Post-stroke spasticity	S-770108 Idiopathic pulmonary fibrosis	SR-0379 Cutaneous ulcer	S-588410 Esophageal cancer	
Obesity		ADR-001** Decompensated liver cirrhosis		
NASH				
Cancer metastasis				
Adjuvant				
Peptide				

- Infectious diseases
- Pain/CNS
- Other

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Progress from Oct. 30, 2018 to Jan. 31, 2019

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

Pipeline -Out-licensed (as of Jan. 31, 2019)

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	
			CAB+RPV LAP Treatment for HIV infection	
			Xofluza™ Severe influenza virus infection	• **Infectious diseases**
			Xofluza™ Influenza virus infection (pediatric)	• **Pain/CNS** • **Others**

Progress from Oct. 30, 2018 to Jan. 31, 2019

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) **Lusutrombopag** (EU) **Baloxavir marboxil** (Taiwan)
Out-licensed		
Juluca® (DTG/RPV)(US)	**Juluca® (DTG/RPV)** (EU) **Osphena®** (US) **Launched** Vaginal dryness associated with postmenopausal VVA **Launched** **Xofluza™** (US, OwH*) **Launched**	**DTG/3TC** (US, EU) **CAB+RPV** (US) **Xofluza™** (US, HR**)

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

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

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

(1) Japanese 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

Japanese Business: Driving Sales Growth by Our Own Earning Power

(Unit: B yen)

Prescription Drugs in Japan	2H FY2017 Results	2H FY2018 Forecasts (Revised on Oct. 29)	Oct.-Dec. FY2017 Results	Oct.-Dec. FY2018 Results	Y on Y comparison	
					2H Forecasts (Revised on Oct. 29)	Oct.-Dec. Results
New products (including strategic products)	27.7	41.4	13.1	23.0	+13.7	**+9.8**
Crestor®, Irbetan® franchise	14.1	7.4	8.4	4.0	(6.7)	**(4.4)**
Others	24.2	20.5	13.6	11.4	(3.7)	**(2.3)**
Total	**66.0**	**69.3**	**35.2**	**38.3**	**+3.3**	**+3.1**

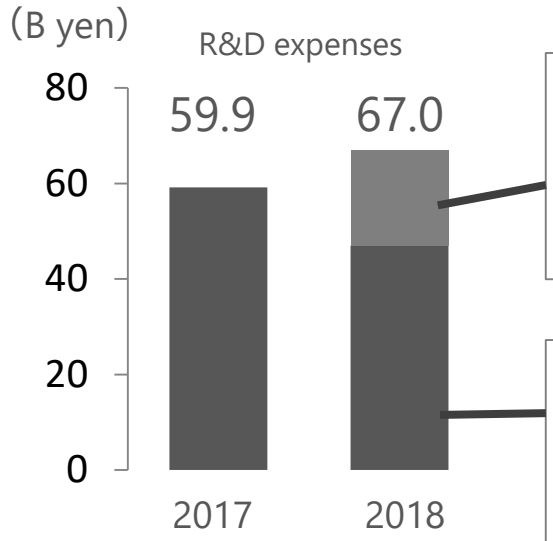
Strategic Investment for Sustainable Growth

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

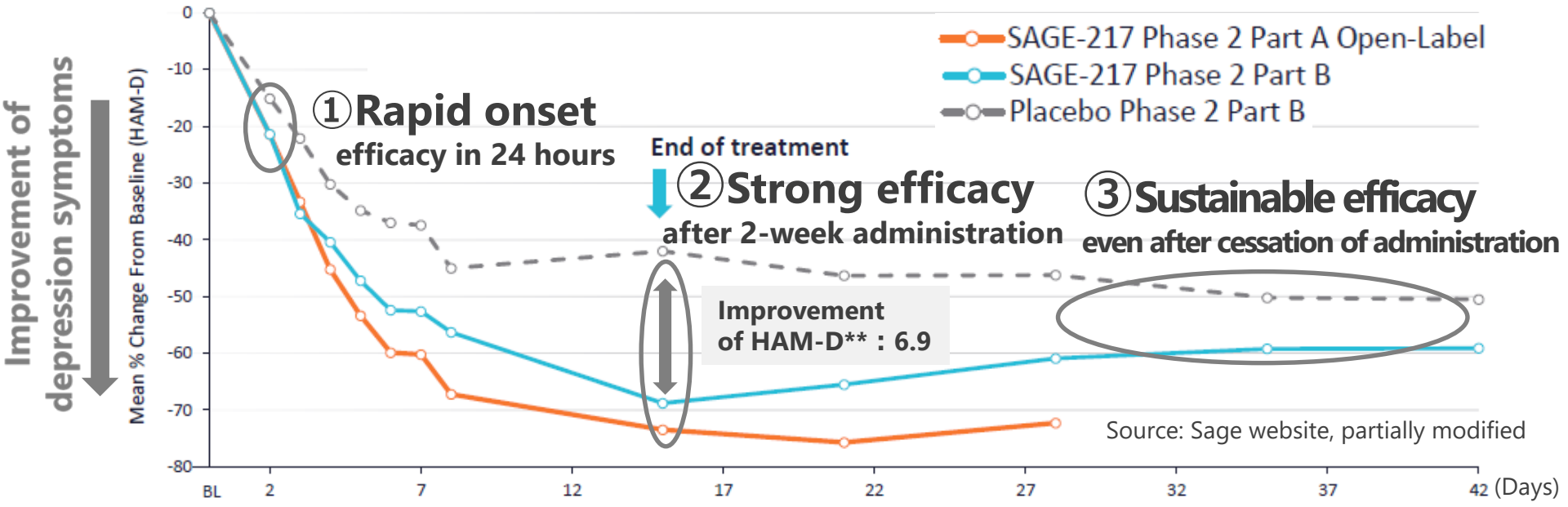
Enhance presence of Shionogi in infectious disease field including TB through development of S-004992 and Hsiri molecules for mycobacterial disease

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

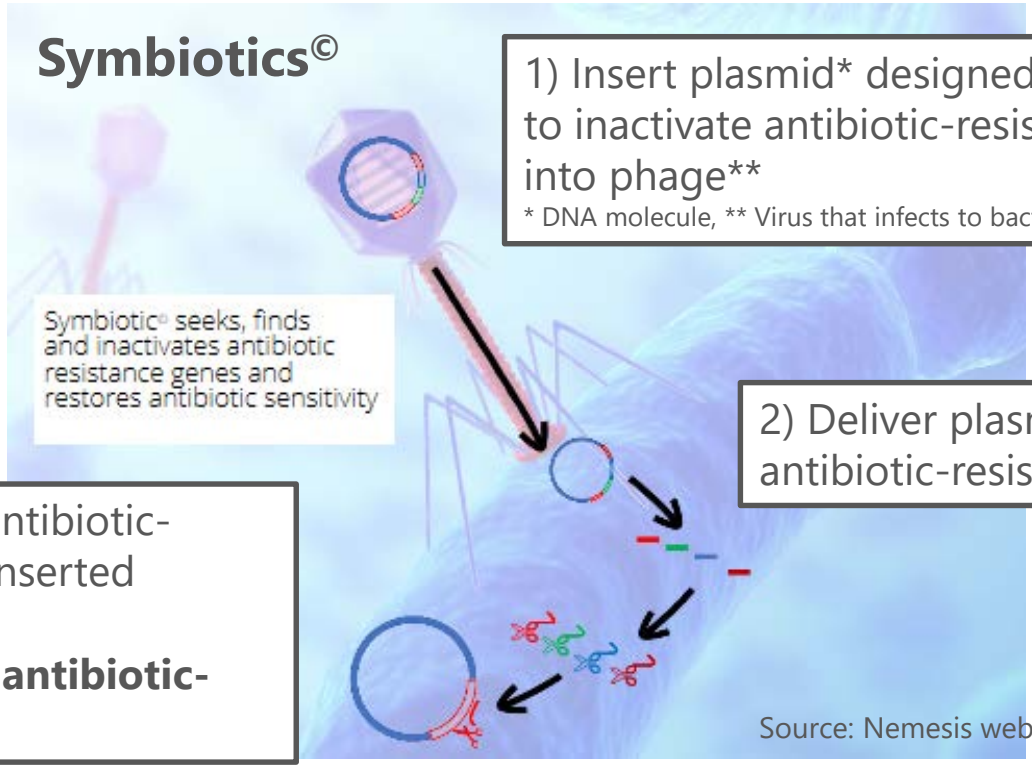


- **Novel antidepressant following Cymbalta®**
- **Launching new development products in CNS field contributing to sales beyond 2020**

* $GABA_A$ 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

From 2H FY2018 Financial Results

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

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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