1st Quarter of Fiscal 2016 Financial Results Conference Call

August 1, 2016

SHIONOGI

Agenda

- **Overview of 1st Quarter FY2016 Financial Results**

Koji Hanasaki, Ph.D.

Corporate Officer, Senior Vice President

Finance & Accounting Department

- **Action Plan to Achieve FY2016 Targets**

Takuko Sawada

Director of the Board, Senior Executive Officer,

Senior Vice President

Corporate Strategy Division

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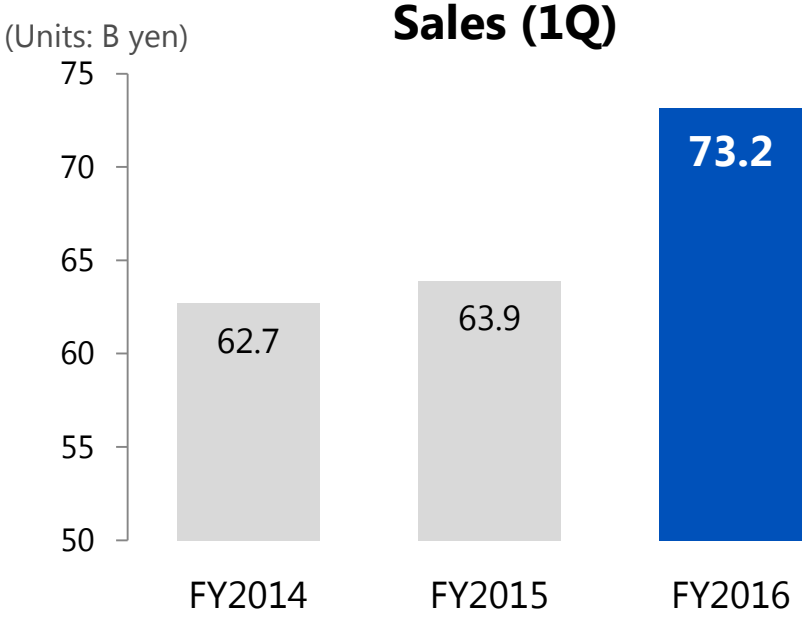
Corporate Strategy Division

Summary: Good Start to Achieve Sales Target

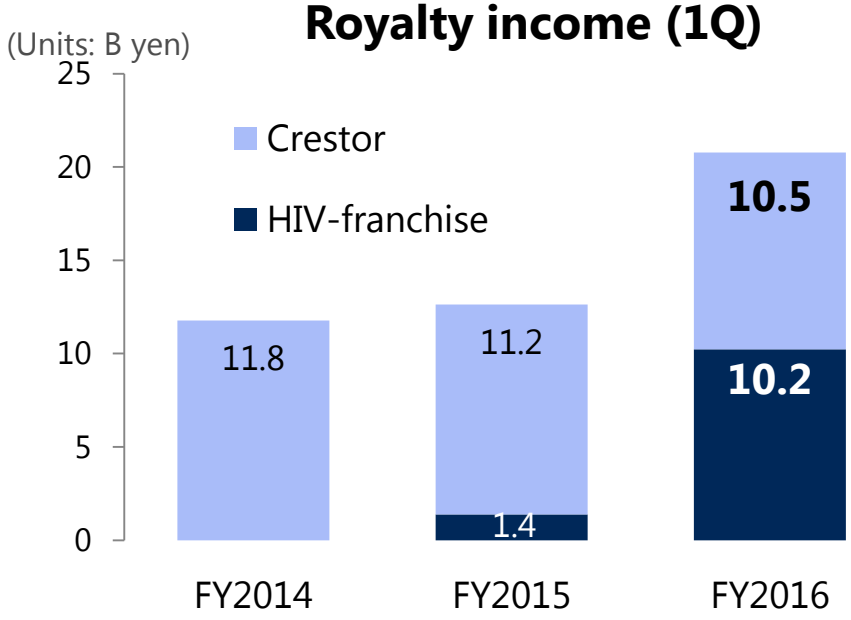
- **Sales: 73.2 B yen** (vs. 1H forecasts **50.5%**)
- **Royalty* income: 20.8 B yen** (vs. 1H forecasts **48.8%**)

(Significantly exceeded the royalty income level of FY2015 because of the strong HIV franchise sales by ViiV Healthcare)

Sales (1Q)



Royalty income (1Q)

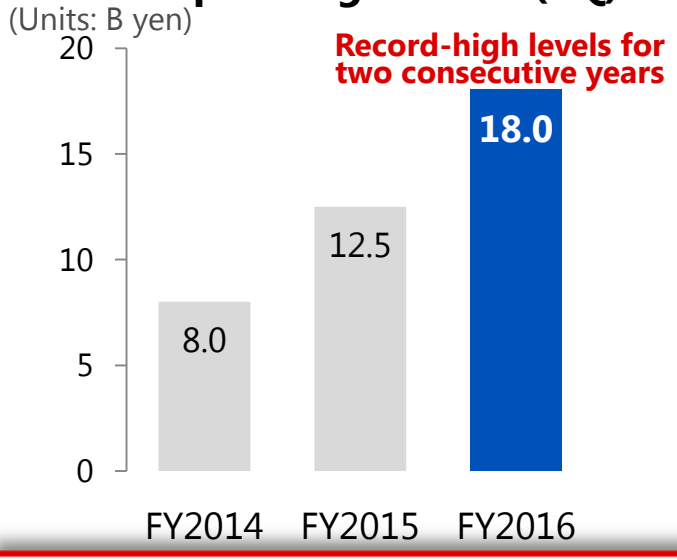


* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

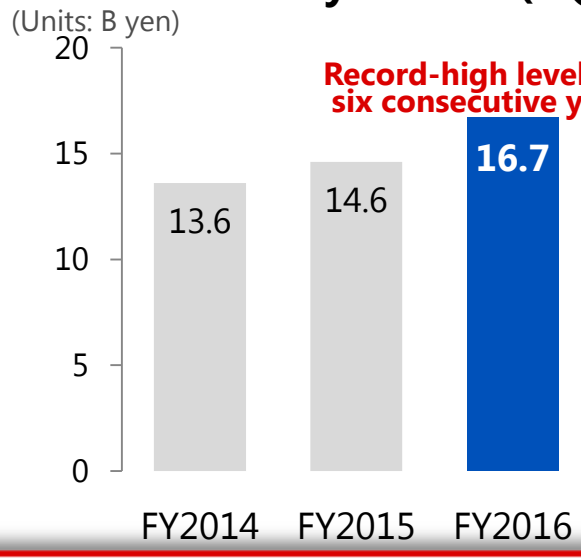
Summary: Good Start to Achieve Profit Targets

- **Operating income: 18.0 B yen** vs. 1H forecasts **(54.7%)**
- **Ordinary income: 16.7 B yen** vs. 1H forecasts **(50.6%)**
- **Profit attributable to owners of parent: 12.5 B yen** vs. 1H forecasts **(59.7%)**

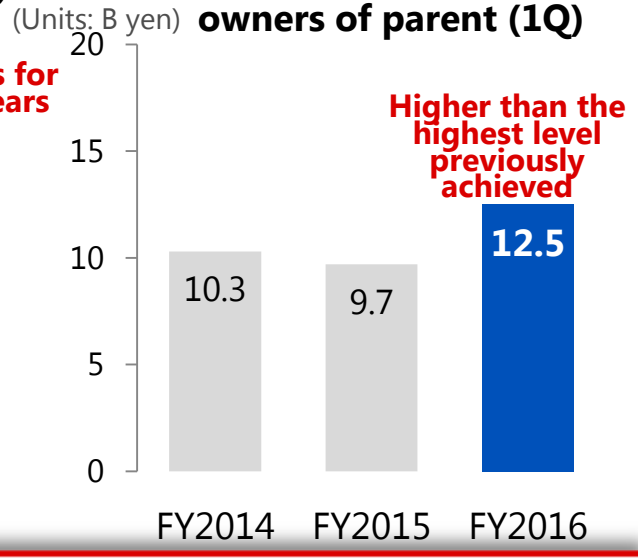
Operating income (1Q)



Ordinary income (1Q)



Profit attributable to owners of parent (1Q)



Financial Results (Consolidated)

(Units: B yen)

	FY2016				FY2015	YonY	
	full year forecasts	1H forecasts	Apr-Jun results	Progress vs. 1H forecasts (%)	Apr-Jun results	change (%)	change
Sales	318.0	145.0	**73.2**	50.5	63.9	14.6	9.3
Operating income	91.5	33.0	**18.0**	54.7	12.5	43.9	5.5
Ordinary income	101.5	33.0	**16.7**	50.6	14.6	14.3	2.1
Profit attributable to owners of parent	71.0	21.0	**12.5**	59.7	9.7	29.8	2.8

Exchange rate (average)	FY2016 forecasts	FY2016 Apr-Jun results
USD ($) – JPY (¥)	110	108.2
EUR (€) – JPY (¥)	130	122.1
GBP (£) – JPY (¥)	155	155.2

Sales of Main Merchandise and Finished Goods (Consolidated)

(Units: B yen)

	1H forecasts	FY2016 Apr-Jun results	Progress vs. 1H forecasts (%)	FY2015 Apr-Jun results	Y on Y change (%)
Prescription drugs	**76.3**	**39.9**	**52.3**	**39.7**	**0.5**
Crestor®	20.9	11.4	54.7	10.6	7.5
Cymbalta®	8.9	4.4	49.6	3.5	27.0
Irbetan franchise®	7.4	4.2	56.7	4.1	3.1
Total of 3 key products	37.2	20.0	53.9	18.2	10.2
OxyContin® franchise	5.5	2.6	46.8	2.6	(0.1)
Finibax®	2.0	0.9	46.0	1.0	(5.6)
Pirespa®	3.3	1.6	49.6	1.6	3.9
Rapiacta®	0.1	0.1	124.2	(0.0)	-
Total of 7 strategic products	48.1	25.3	52.6	23.3	8.5
[percent of sales]	[63.0%]	[63.3%]		[58.7%]	
Overseas subsidiaries/export	**12.4**	**6.5**	**52.8**	**7.2**	**(8.1)**
Shionogi Inc.	6.0	3.6	60.4	4.4	(17.4)
Osphena®	2.6	1.2	46.4	1.3	(5.4)
Contract manufacturing	**5.3**	**2.6**	**48.7**	**1.5**	**71.9**
OTC and quasi-drugs	**3.5**	**1.7**	**48.6**	**1.2**	**37.0**
Royalty income	**46.3**	**21.8**	**47.0**	**13.5**	**60.8**
Royalty income for the sales of Crestor® and HIV franchise	**42.5**	**20.8**	**48.8**	**12.6**	**64.5**
Crestor®	16.5	10.5	63.9	11.2	(6.2)
HIV franchise	26.0	10.2	39.3	1.4	637.5
Others	**1.2**	**0.6**	**52.8**	**0.7**	**(15.7)**
Total	**145.0**	**73.2**	**50.5**	**63.9**	**14.6**

◆ vs. 1Q FY2015

Prescription drugs

Increased due to growth of the seven strategic products
- Crestor® OD Tablets were launched
- Cymbalta® contributed in pain area

Shionogi Inc.

Decreased due to divestiture of existing products in FY2015

Contract manufacturing

Increased due to expansion of API for dolutegravir

OTC and quasi-drugs

Increased due to the launch of ISODINE® brands

Royalty income

Increased due to strong sales of HIV franchise worldwide

Statement of Income (Consolidated)

(Units: B yen)

	1H forecasts	FY2016 Apr-Jun results	Progress vs. 1H forecasts (%)	FY2015 Apr-Jun results	Y on Y change (%)
Sales	**145.0**	**73.2**	**50.5**	**63.9**	**14.6**
[Royalty* income]	42.5	20.8	48.8	12.6	64.5
	26.6 [37.6]	27.1 [37.8]		28.3 [35.2]	
Cost of sales	38.5	19.8	51.5	18.0	9.8
	50.7	48.3		52.1	
SG&A expenses	73.5	35.3	48.0	33.3	6.1
	33.8	31.0		35.5	
Selling & general expenses	49.0	22.7	46.3	22.7	0.2
	16.9	17.3		16.6	
R&D expenses	24.5	12.6	51.5	10.6	18.7
	22.8	24.7		19.6	
Operating income	**33.0**	**18.0**	**54.7**	**12.5**	**43.9**
[Excluding royalty* income]	**(9.5)**	**(2.7)**	**-**	**(0.1)**	**-**
Non-operating income and expenses	-	L1.4	-	P2.1	-
	22.8	22.8		22.9	
Ordinary income	**33.0**	**16.7**	**50.6**	**14.6**	**14.3**

◆ vs. 1Q FY2015

Cost of sales (Cost of sales ratio)

Cost of sales ratio: Improved 1.2%
- Increase in royalty income

Cost of sales ratio excluding royalty income: Increased 2.6%
- Product mix
- NHI price revisions
- Expansion of contract manufacturing of API for dolutegravir

SG&A expenses

Strategic investment by focusing on efficiency and prioritization and total cost management

Selling & general expenses ratio: Down 4.5%

R&D expenses ratio: Up 0.7%

Non-operating income and expenses

Foreign exchange losses of foreign-currency asset

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Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties
* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

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Director of the Board, Senior Executive Officer,

Senior Vice President

Corporate Strategy Division

Basic Strategy in FY2016 to Achieve SGS2020

SONG for you!

Key actions to complete "Evolution of core business" in SGS2020

Continue achieve bottom-line targets
and
Achieve top-line targets in Japanese/overseas businesses

Positioning for FY2016

Accelerate strengthening of business base and create future growth drivers, in preparation for upcoming patent expirations of strategic products after FY2017

Basic Strategy in FY2016

Continue growth based on increasing royalty income and improved cost management
and
Strengthen and enhance Japanese/overseas business

Strengthen and Enhance Japanese Business

◆Focus resources on growth drivers

Cymbalta®	➢ Depression and depressive symptoms – Expansion of sales as one of the first treatment options ➢ Pain associated with fibromyalgia/pain associated with chronic low back pain – Establish a partnership between psychiatrists, orthopedic surgeons, etc.

Contribute to patients and medical treatment in pain/CNS areas
Support communication between pain and CNS physicians to promote proper use

◆Strengthen business base

Crestor® OD Tablets	➢ Improve patient compliance using CMC technologies ➢ First NTE* program at Shionogi ➢ Maximize the value of Crestor®

Contribute to healthcare and maintain its growth as a top statin brand by launching Crestor® OD Tablets

* NTE (New Therapeutic Entity): Drug development for new dosage form, new administration route and new indication with existing drug

Strengthen and Enhance Overseas Business

◆Future growth driver

Naldemedine	➢ Preparing for the launch of naldemedine as a first in-house global product ➢ Start to explore partnering options to maximize the value of naldemedine

FDA: Acceptance of NDA in the US
(PDUFA date: March 23, 2017)

◆Strengthen business base

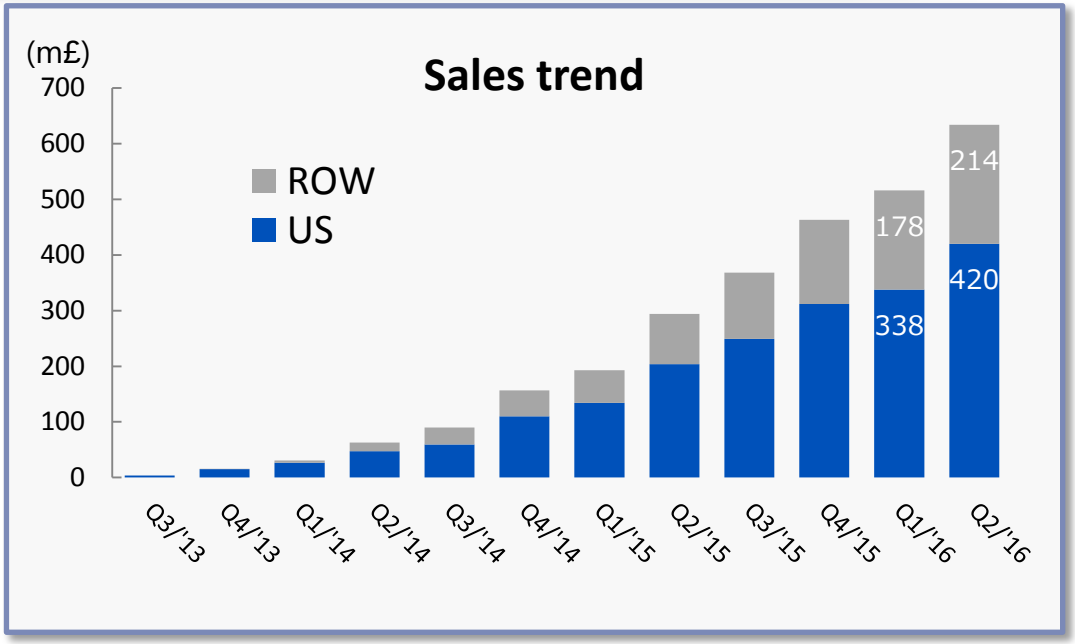
Osphena®	➢ Only product with growing market share in a declining VVA market ➢ Focusing resources on high-potential areas ➢ Phase III clinical study for vaginal dryness

Continue to optimize promotional activities in the US, launched in Italy and preparing in Spain, and creating strategy for ASEAN countries

HIV Franchise and Foreign Exchange Impact

Global sales trend

- Continuous strong global expansion exceeded forecast, reflecting its good efficacy, safety, adherence and resistance profile
- Ratio of US sales in total sales is about 2/3



Impact of foreign exchange on royalty income

- **Foreign exchange reservations** to hedge the risk of exchange rate fluctuation at the beginning of FY2016
  ⇒ **Reduced the negative impact of exchange rate** on royalty income
- Exchange rate fluctuations (£/¥ as well as $/£) impact on royalty income
- Consider foreign exchange reservations to reduce the risk of exchange rate fluctuation after next fiscal year

Target Milestones for FY2016

Areas	Product	As of Apr. 1, 2016	Target for FY2016
Infectious disease	**S-649266** Multidrug-resistant Gram-negative bacterial infections	Global: Phase II, III	US: NDA submission
	S-033188 Influenza virus infection	Japan: Phase II / US: Phase I	Japan: Phase II completed / US: Phase I completed / Japan: Phase III initiated / Global: Phase III initiated
Pain/CNS	**Guanfacine hydrochloride** ADHD (pediatric)	Japan: NDA submission	Japan: Approval
	Cymbalta® Pain associated with osteoarthritis	Japan: NDA submission	Japan: Approval
	Naldemedine Opioid-induced constipation	Japan/US: NDA submission	Japan/US: Approval
	Oxycodone Treatment of moderate to severe chronic pain	Japan: Phase III	Japan: NDA submission
	Oxycodone Tamper resistant formulation	Japan: Phase I completed	Japan: NDA submission
	Lisdexamfetamine ADHD (pediatric)	Japan: Phase III	Japan: Phase III completed
Metabolic disorder	**S-237648** Obesity	Japan: Phase II	Japan: Phase II completed / US: Phase I initiated
Frontier	**Lusutrombopag** Thrombocytopenia associated with chronic liver disease	Global: Phase III	Global: NDA submission
	S-222611 Malignant tumor	EU: Phase I/II	EU: Phase I/II completed

Appendix
- Financial Results -

Japan: Sales of Strategic Products

(Units: B yen)

	FY2016				FY2015	Y on Y	
	full year forecasts	1H forecasts	Apr-Jun results	Progress vs. 1H forecasts (%)	Apr-Jun results	change (%)	change
Crestor®	41.5	20.9	11.4	54.7	10.6	7.5	0.8
Cymbalta®	19.3	8.9	4.4	49.6	3.5	27.0	0.9
Irbetan® franchise	15.1	7.4	4.2	56.7	4.1	3.1	0.1
Total of 3 key products	**75.9**	**37.2**	**20.0**	**53.9**	**18.2**	**10.2**	**1.8**
OxyContin® franchise	10.5	5.5	2.6	46.8	2.6	(0.1)	(0.0)
Finibax®	3.9	2.0	0.9	46.0	1.0	(5.6)	(0.1)
Pirespa®	6.3	3.3	1.6	49.6	1.6	3.9	0.0
Rapiacta®	2.3	0.1	0.1	124.2	(0.0)	-	0.1
Total of 7 strategic products	99.0	**48.1**	**25.3**	**52.6**	**23.3**	**8.5**	**2.0**
[percent of sales]	**[62.5%]**	**[63.0%]**	**[63.3%]**		**[58.7%]**		
Prescription drugs	**158.2**	**76.3**	**39.9**	**52.3**	**39.7**	**0.5**	**0.2**

Sales of Main Merchandise and Finished Goods (Consolidated)

(Units: B yen)

	FY2016				FY2015	Y on Y	
	full year forecasts	1H forecasts	Apr-Jun results	Progress vs. 1H forecasts (%)	Apr-Jun results	change (%)	change
Prescription drugs	**158.2**	**76.3**	**39.9**	**52.3**	**39.7**	**0.5**	**0.2**
Overseas subsidiaries/export	**24.7**	**12.4**	**6.5**	**52.8**	**7.2**	**(8.1)**	**(0.7)**
Shionogi Inc.	12.4	6.0	3.6	60.4	4.4	(17.4)	(0.8)
Osphena®	5.3	2.6	1.2	46.4	1.3	(5.4)	(0.1)
Contract manufacturing	**10.9**	**5.3**	**2.6**	**48.7**	**1.5**	**71.9**	**1.1**
OTC and quasi-drugs	**7.0**	**3.5**	**1.7**	**48.6**	**1.2**	**37.0**	**0.5**
Royalty income	**114.9**	**46.3**	**21.8**	**47.0**	**13.5**	**60.8**	**8.3**
Royalty income for the sales of Crestor® and HIV franchise	**95.0**	**42.5**	**20.8**	**48.8**	**12.6**	**64.5**	**8.2**
Crestor®	33.0	16.5	10.5	63.9	11.2	(6.2)	(0.7)
HIV franchise	62.0	26.0	10.2	39.3	1.4	637.5	8.8
Others	**2.4**	**1.2**	**0.6**	**52.8**	**0.7**	**(15.7)**	**(0.1)**
Total	**318.0**	**145.0**	**73.2**	**50.5**	**63.9**	**14.6**	**9.3**

Statement of Income (Consolidated)

(Units: B yen)

	FY2016				FY2015	Y on Y	
	full year forecasts	1H forecasts	Apr-Jun results	Progress vs. 1H forecasts (%)	Apr-Jun results	change (%)	change
Sales	**318.0**	**145.0**	**73.2**	**50.5**	**63.9**	**14.6**	**9.3**
[Royalty* income]	**95.0**	**42.5**	**20.8**	**48.8**	**12.6**	**64.5**	**8.2**
	24.5 [35.0]	26.6 [37.6]	27.1 [37.8]		28.3 [35.2]		
Cost of sales	78.0	38.5	19.8	51.5	18.0	9.8	1.8
Gross profit	**240.0**	**106.5**	**53.3**	**50.1**	**45.8**	**16.4**	**7.5**
	46.7	50.7	48.3		52.1		
SG&A expenses	148.5	73.5	35.3	48.0	33.3	6.1	2.0
Selling & general expenses	98.5	49.0	22.7	46.3	22.7	0.2	0.0
R&D expenses	50.0	24.5	12.6	51.5	10.6	18.7	2.0
	28.8	22.8	24.7		19.6		
Operating income	**91.5**	**33.0**	**18.0**	**54.7**	**12.5**	**43.9**	**5.5**
[Excluding royalty* income]	**(3.5)**	**(9.5)**	**(2.7)**	**-**	**(0.1)**	**-**	**(2.6)**
Non-operating income and expenses	P10.0	-	L1.4	-	P2.1	-	(3.5)
	31.9	22.8	22.8		22.9		
Ordinary income	**101.5**	**33.0**	**16.7**	**50.6**	**14.6**	**14.3**	**2.1**

Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties
* Royalty income from AstraZeneca and ViiV for the sales of Crestor® and HIV franchise

Appendix
- Pipeline -

Change in Pipeline (since May 2016)

Code No.	Indication	Phase	Area	Changes
Change of phase				
S-237648	Obesity	Phase II Phase I	Japan US	Japan: Phase II → Japan: Phase II, US: Phase I
Compound added to the list				
S-600918	Neuropathic pain	Phase I	Japan	

New Products to Lead Future Growth

Target milestone for launch of new product

FY2016	FY2017	FY2018
Japanese business		
Crestor® OD tablet Cymbalta® Pain associated with chronic low back pain Pain associated with osteoarthritis ISODINE® brand ethical products	Naldemedine Guanfacine hydrochloride Oxycodone Tamper resistant formulation Moderate to severe chronic pain	S-033188 Lisdexamfetamine Actair® Pediatric patients with perennial allergic rhinitis
US business		
	Naldemedine S-649266 Lusutrombopag	Osphena® Vaginal dryness associated with postmenopausal VVA
Global out-licensed products		
		Dolutegravir + rilpivirine

®: *ISODINE* is a Registered Trademark.

Pipeline (as of Aug. 2016)

Phase I	Phase II	Phase III	NDA submission
【Global】			
S-033188 Influenza virus Infection	**S-120083** Inflammatory pain	**S-649266** Multidrug-resistant Gram-negative bacterial infections	
S-237648 Obesity	**S-117957** Insomnia	**Osphena®** Vaginal dryness associated with postmenopausal VVA	**Lusutrombopag** Thrombocytopenia
Non-clinical			
Antibody drug candidate against Pseudomonas	**Oxycodone** Tamper resistant formulation	**S-649266** Multidrug-resistant Gram-negative bacterial infections	**【In Japan】**
NTE Inhalation	**S-120083** Inflammatory pain	**Lisdexamfetamine** ADHD (pediatric)	**Guanfacine hydrochloride** ADHD (adult)
	S-010887 Neuropathic pain	**Actair®** Pediatric patients with perennial allergic rhinitis	**Oxycodone** Moderate to severe chronic pain
	S-600918 Neuropathic pain	**S-555739** Allergic rhinitis	**S-588410** Esophageal cancer

Phase I	Phase II	Phase III	NDA submission
	S-649266 Multidrug-resistant Gram-negative bacterial infections		
	S-707106 Type2 diabetes	**S-488210** Head and neck squamous cell carcinoma	
	S-222611 Malignant tumor	**S-588410** Bladder cancer	**Naldemedine** Opioid-induced constipation
	S-649266 Multidrug-resistant Gram-negative bacterial infections		**Naldemedine** Opioid-induced constipation
	S-033188 Influenza virus Infection	**S-237648** Obesity	**Cymbalta®** Pain associated with osteoarthritis
	S-525606 Allergic rhinitis caused by Japanese cedar allergen	**S-588410** Bladder cancer	**Guanfacine hydrochloride** ADHD (pediatric)

Infectious diseases | Metabolic disorder | Pain/CNS | Frontier

Red frame: change since May 2016

Pipeline (as of Aug. 2016)

Non-clinical	Phase I	Phase II	Phase III	NDA submission
【Out-licensed】		**Cabotegravir + rilpivirine LAP** Treatment for HIV infection		
GSK3342830 Multidrug-resistant Gram-negative bacterial infections		**Cabotegravir LAP** Prevention for HIV infection	**Dolutegravir + rilpivirine** Treatment for HIV infection	
Janssen/Shionogi Project compound Alzheimer's disease			**Janssen/Shionogi BACE inhibitor** Alzheimer's disease	

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Infectious diseases

Pain/CNS

LAP: Long acting parenteral formulation

Pipeline Information

Code No.	Generic name	Product name	Indication
S/GSK1349572	Dolutegravir	Tivicay®	HIV infection
–	Dolutegravir/abacavir/lamivudine	Triumeq®	HIV infection
S/GSK1265744 LAP	Cabotegravir	–	HIV infection
S-649266	–	–	Multidrug-resistant Gram-negative bacterial infections
S-033188	–	–	Influenza virus infection
S-8117	Oxycodone hydrochloride hydrate	OxyContin®	Moderate to severe chronic pain
S-297995	Naldemedine tosilate	–	Opioid-induced constipation
LY248686	Duloxetine hydrochloride	Cymbalta®	Depression and depressive symptoms, Pain associated with chronic low back pain, etc.
S-877503	Guanfacine hydrochloride	Intuniv® (US brand name)	ADHD
S-877489	Lisdexamfetamine	Vyvanse® (US brand name)	ADHD
S-888711	Lusutrombopag	Mulpleta®	Thrombocytopenia associated with chronic liver disease
S-524101	–	Actair®	Pediatric patients with perennial allergic rhinitis caused by HDM

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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