

Financial results for the second quarter
of fiscal year 2019

< Supplement >

October 30, 2019

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

(Billions of yen)

	FY2019 1H actual	FY2019 2H forecast	FY2019 forecast	FY2018 1H actual	FY2018 2H actual	FY2018 actual	Y on Y change		
							1H	2H	full-year
Net Sales	160.9	206.1	367.0	168.2	195.5	363.7	(7.3)	10.6	3.3
<i>change %</i>	(4.4)	5.4	0.9	(2.3)	13.3	5.5			
Operating Income	58.2	91.8	150.0	57.3	81.2	138.5	0.9	10.6	11.5
<i>change %</i>	1.5	13.1	8.3	2.8	36.6	20.2			
Ordinary Income	65.3	106.2	171.5	70.1	96.5	166.6	(4.8)	9.7	4.9
<i>change %</i>	(6.8)	10.0	3.0	6.8	32.0	20.1			
Profit attributable to owners of parent	51.6	83.4	135.0	57.9	74.9	132.8	(6.3)	8.5	2.2
<i>change %</i>	(10.8)	11.4	1.7	15.0	27.9	21.9			

Note: Change % shows changes from the same period of the previous fiscal year.

2. Sales of segments

(Billions of yen)

	FY2019 1H	FY2019 2H	FY2019	FY2018 1H	FY2018 2H	FY2018	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Prescription drugs	52.4	91.6	144.1	50.0	78.7	128.7	2.5	12.9	15.4
<i>change %</i>	4.9	16.4	12.0	(31.7)	19.2	(7.6)			
CYMBALTA	12.9	16.4	29.3	11.9	12.2	24.1	0.9	4.3	5.2
INTUNIV	4.5	9.2	13.6	2.4	2.9	5.3	2.1	6.3	8.3
VYVANSE	—	0.1	0.1	—	—	—	—	0.1	0.1
XOFLUZA	0.0	28.0	28.0	0.5	25.8	26.3	(0.5)	2.2	1.7
RAPIACTA	0.0	2.6	2.6	0.0	2.0	2.0	0.0	0.6	0.6
BRIGHTPOC Flu	0.3	1.8	2.2	0.2	0.9	1.2	0.1	0.9	1.0
Total of strategic products	17.7	58.1	75.7	15.0	43.9	58.9	2.6	14.2	16.8
OXYCONTIN Franchise	3.2	3.2	6.4	3.8	3.5	7.3	(0.6)	(0.2)	(0.9)
SYMPROIC	1.1	1.2	2.3	0.7	0.9	1.6	0.4	0.3	0.7
ACTAIR	0.1	0.1	0.3	0.1	0.1	0.2	0.0	0.0	0.1
MULPLETA	0.1	0.2	0.2	0.1	0.1	0.2	(0.0)	0.1	0.1
PIRESPA	3.4	3.5	7.0	2.9	2.8	5.7	0.6	0.7	1.3
Total of new products	25.6	66.3	91.9	22.6	51.2	73.8	3.0	15.1	18.1
CRESTOR	4.6	4.9	9.5	5.2	4.7	9.9	(0.6)	0.2	(0.4)
IRBETAN Franchise	2.2	2.4	4.6	3.1	2.3	5.4	(0.8)	0.1	(0.7)
Other	20.1	18.0	38.1	19.1	20.5	39.6	0.9	(2.5)	(1.6)
Overseas subsidiaries/Export	17.5	13.8	31.3	15.4	14.0	29.4	2.1	(0.2)	1.9
<i>change %</i>	13.9	(1.6)	6.5	26.2	22.8	24.6			
Shionogi Inc.	6.8	3.4	10.2	7.4	4.4	11.8	(0.6)	(1.0)	(1.6)
Mulpleta	0.3	0.7	1.0	—	0.1	0.1	0.3	0.6	0.9
C&O	7.2	7.4	14.5	5.0	6.5	11.5	2.1	0.9	3.1
Contract manufacturing	10.1	5.3	15.4	5.7	9.0	14.8	4.3	(3.7)	0.6
<i>change %</i>	75.7	(41.2)	4.1	(31.9)	6.1	(12.8)			
OTC and quasi-drugs	4.7	5.0	9.7	3.8	4.3	8.1	1.0	0.7	1.6
<i>change %</i>	25.1	15.1	19.7	12.3	11.7	12.0			
Royalty income	75.0	89.3	164.2	92.2	88.1	180.3	(17.2)	1.2	(16.0)
<i>change %</i>	(18.7)	1.3	(8.9)	24.9	8.4	16.3			
HIV Franchise	61.1	65.2	126.3	57.1	67.4	124.4	4.0	(2.1)	1.9
CRESTOR	11.1	10.8	21.8	10.9	11.1	22.0	0.2	(0.3)	(0.1)
Others	2.8	13.3	16.1	24.2	9.7	33.9	(21.4)	3.6	(17.8)
Others	1.1	1.1	2.2	1.1	1.3	2.5	0.0	(0.2)	(0.2)
<i>change %</i>	0.3	(16.4)	(8.7)	(7.0)	(4.4)	(5.6)			
Total	160.9	206.1	367.0	168.2	195.5	363.7	(7.3)	10.6	3.3
<i>change %</i>	(4.4)	5.4	0.9	(2.3)	13.3	5.5			

Note: Change % shows changes from the same period of the previous fiscal year

Sales of prescription drugs are shown on non-consolidated basis.

3. Management index

(Management index trend)

		FY2017	FY2018	FY2018 1H	FY2019 1H
Return on equity (ROE)	%	19.4	20.9	9.3	7.6
Return on asset (ROA)	%	20.2	22.4	9.6	8.4
Ratio of operating income to net sales	%	33.4	38.1	34.1	36.2
Ratio of ordinary income to net sales	%	40.2	45.8	41.7	40.6
Ratio of net income to net sales	%	31.6	36.5	34.4	32.1
Total asset turnover		0.50	0.49	0.23	0.21
Equity ratio	%	84.5	85.7	86.6	88.3
Dividend payout ratio	%	23.9	22.2	-	-
Dividend on Equity (DOE)	%	4.6	4.6	-	-
Earnings per share	yen	342.71	424.31	184.28	165.78
Earnings per share (diluted)	yen	337.43	420.67	181.64	165.56

Note: Shionogi has adopted the "Partial Amendments to Accounting Standard for Tax-Effect Accounting" etc. April 1, 2018.

Figures for FY2017 have been restated to reflect this adoption.

4. Capital investments and depreciation cost

(Billions of yen)

	FY2019 1H	FY2019 2H	FY2019	FY2018 1H	FY2018 2H	FY2018	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Investment in equipments	4.3	6.7	11.0	2.7	5.2	7.9	1.6	1.5	3.1
Depreciation cost	8.2	9.0	17.2	8.3	8.2	16.5	(0.1)	0.8	0.7
Amortization of goodwill	0.9	0.9	1.8	1.5	1.2	2.7	(0.6)	(0.3)	(0.9)

5. R&D expenses

(Billions of yen)

	FY2019 1H	FY2019 2H	FY2019	FY2018 1H	FY2018 2H	FY2018	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
R&D expenses	23.0	26.0	49.0	38.6	29.7	68.3	(15.7)	(3.7)	(19.3)
<i>change %</i>	<i>(40.6)</i>	<i>(12.3)</i>	<i>(28.3)</i>	<i>28.4</i>	<i>(0.6)</i>	<i>14.0</i>			
% to net sales	14.3	12.6	13.4	23.0	15.2	18.8			

Note: Change % shows changes from the same period of the previous fiscal year

6. Employees

	End of FY2017	End of 2018 1H	End of FY2018	End of 2019 1H	End of FY2019	Y on Y change		
	actual	actual	actual	actual	forecast	1H	2H	full-year
Employees	5,120	5,242	5,233	5,261	5,287	28	26	54

7. Consolidated statement of income

<i>(Millions of yen)</i>				
	FY2018 1H actual	FY2019 1H actual	Y on Y change	
Net sales	168,203	160,877	(7,325)	Increasing/(decreasing) in Prescription drugs: 2.5billion yen Overseas subsidiaries/Export 2.1billion yen Contract manufacturing: 4.3billion yen Royalty income: (17.2)billion yen
Cost of sales	24,724	27,898	3,173	
Gross profit	143,478	132,978	(10,499)	
Selling, general and administrative expenses	86,173	74,816	(11,356)	
Operating income	57,304	58,161	856	FY2018 1H R&D expenses by strategic business investments increased.
Non-operating income	14,563	9,949	(4,613)	
Interest income	1,009	1,540	531	
Dividends income	12,150	8,150	(3,999)	Shionogi B. V. Dividends income from ViiV decreased.
Other	1,403	257	(1,145)	
Non-operating expenses	1,790	2,805	1,015	
Interest expenses	173	51	(121)	
Foreign exchange losses	—	1,077	1,077	
Other	1,616	1,676	59	
Ordinary income	70,077	65,305	(4,772)	
Extraordinary income	2,920	2,672	(247)	FY2018 1H C&O Nanjing factory in China Shionogi Company dormitory in Omori, Tokyo
Gain on sales of investment securities	—	2,672	2,672	
Gain on sales of non-current assets	2,920	—	(2,920)	
Extraordinary losses	826	590	(235)	
Loss on valuation of investment securities	—	590	590	
Loss on disaster	826	—	(826)	FY2018 1H North Osaka earthquake
Income before income taxes	72,172	67,386	(4,785)	
Income taxes-current	12,801	17,204	4,402	
Income taxes-deferred	987	(1,389)	(2,377)	
Profit	58,382	51,572	(6,810)	
Profit (Loss) attributable to non-controlling interests	486	(43)	(529)	
Profit attributable to owners of parent	57,896	51,616	(6,280)	

8-1. Consolidated balance sheets (Assets)

(Millions of yen)

	As of Mar. 31 2019	As of Sep. 30 2019	Y on Y change	
(Assets)				
Current assets				
Cash and deposits	193,549	226,075	32,525	
Notes and accounts receivable-trade	65,918	44,269	(21,648)	Due to the collection of account receivables related to seasonal items
Short-term investment securities	133,264	139,883	6,618	Increase in NCD
Merchandise and finished goods	18,741	18,137	(603)	
Work in process	7,272	11,742	4,469	
Raw materials and supplies	14,097	11,613	(2,483)	
Other	28,942	28,624	(318)	
Allowance for doubtful accounts	(43)	(46)	(3)	
Total current assets	461,743	480,300	18,556	
Non-current assets				
Property, plant and equipment	74,653	75,045	392	
Intangible assets				
Goodwill	19,258	17,850	(1,407)	Increased / (decreased) by: Amortization: (0.9) billion yen Exchange rate fluctuations: (0.5) billion yen
Other	35,511	32,742	(2,768)	
Total intangible assets	54,769	50,593	(4,176)	
Investments and other assets				
Investment securities	151,851	133,712	(18,139)	Increased / (decreased) by: Sale / redemption: (7.3) billion yen Drop in stock prices: (6.5) billion yen Exchange rate fluctuations: (4.6) billion yen
Other	35,765	38,858	3,093	
Allowance for doubtful accounts	(42)	(42)	—	
Total investments and other assets	187,574	172,528	(15,046)	
Total non-current assets	316,997	298,167	(18,830)	
Total assets	778,741	778,467	(273)	

8-2. Consolidated balance sheets (Liabilities/Net Assets)

(Millions of yen)

	As of Mar. 31 2019	As of Sep. 30 2019	Y on Y change	
(Liabilities)				
Current liabilities				
Notes and accounts payable-trade	9,442	8,581	(861)	
Current portion of bonds	920	740	(180)	
Income taxes payable	35,870	22,984	(12,885)	
Provision for bonuses	9,058	7,420	(1,638)	
Provision for sales returns	1,428	1,085	(342)	
Other provision	166	—	(166)	
Other	32,219	28,699	(3,519)	
Total current liabilities	89,107	69,511	(19,595)	
Non-current liabilities				
Net defined benefit liability	11,930	10,816	(1,114)	
Other	5,272	6,002	729	
Total non-current liabilities	17,203	16,818	(385)	
Total liabilities	106,311	86,329	(19,981)	
(Net Assets)				
Shareholders' equity				
Capital stock	21,279	21,279	—	
Capital surplus	20,512	20,512	—	
Retained earnings	639,461	675,364	35,903	
Treasury stock	(28,882)	(28,266)	615	
Total shareholders' equity	652,371	688,890	36,519	
Accumulated other comprehensive income				
Valuation difference on available-for-sale securities	28,927	24,606	(4,321)	Due to sale of securities and the drop of stock prices
Deferred gains or losses on hedges	747	2,980	2,232	
Foreign currency translation adjustment	(18,370)	(32,522)	(14,151)	Due to the strong yen
Remeasurements of defined benefit plans	3,826	3,484	(342)	
Total accumulated other comprehensive income	15,130	(1,451)	(16,582)	
Subscription rights to shares	527	438	(88)	
Non-controlling interests	4,400	4,259	(140)	
Total net assets	672,429	692,137	19,707	
Total liabilities and net assets	778,741	778,467	(273)	

9-1. Quarterly trend for FY2018 and FY2019 (Sales of segments)

Fiscal year ended March 31, 2019

(Billions of yen)

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %	FY2018 3Q actual	Y on Y change%	FY2018 4Q actual	Y on Y change%
Prescription drugs	25.4	(31.9)	24.6	(31.5)	38.3	8.8	40.4	31.0
CYMBALTA	6.1	6.1	5.8	(2.2)	6.7	2.1	5.5	4.2
INTUNIV	1.1	209.9	1.3	284.8	1.6	194.4	1.4	100.1
XOFLUZA	0.0	-	0.4	-	9.5	-	16.4	578.7
RAPIACTA	0.0	(76.4)	(0.0)	(131.8)	0.8	(33.9)	1.3	(39.9)
BRIGHTPOC Flu	0.0	(90.5)	0.2	168.5	0.3	(11.6)	0.6	(0.9)
OXYCONTIN Franchise	2.0	(15.2)	1.8	(16.8)	2.0	(18.7)	1.5	(11.6)
SYMPROIC	0.3	526.3	0.4	257.6	0.5	123.0	0.4	72.2
Total of strategic products	9.6	11.0	10.0	14.8	21.2	88.9	27.0	107.7
ACTAIR	0.0	47.4	0.0	63.3	0.1	61.0	0.0	51.4
MULPLETA	0.0	0.6	0.0	3.0	0.0	(2.2)	0.0	(21.6)
PIRESPA	1.4	(5.1)	1.5	(10.5)	1.6	(10.8)	1.2	(22.2)
Total of new products	11.0	8.8	11.6	10.8	23.0	74.7	28.2	93.6
CRESTOR	2.6	(78.1)	2.5	(74.6)	2.7	(38.1)	2.0	(31.9)
IRBETAN Franchise	1.9	(48.5)	1.1	(71.5)	1.3	(67.7)	1.0	(63.8)
Other	9.8	(13.8)	9.3	(18.6)	11.4	(16.7)	9.1	(13.4)
Overseas subsidiaries/Export	9.9	49.3	5.5	(1.1)	6.7	27.5	7.3	18.8
Shionogi Inc.	6.1	75.7	1.3	(49.7)	2.0	(14.6)	2.4	8.3
Osphena	0.8	(32.7)	0.7	(21.4)	1.0	(0.1)	0.6	(17.6)
C&O	2.3	31.0	2.7	69.2	3.2	125.0	3.3	57.7
Contract manufacturing	2.8	(20.5)	2.9	(40.1)	3.4	2.7	5.6	8.3
OTC and quasi-drugs	1.6	1.3	2.2	21.9	2.5	7.1	1.8	18.8
Royalty income	48.3	89.7	43.9	(9.2)	45.3	2.3	42.8	15.7
HIV Franchise	24.5	31.4	32.6	18.2	32.8	18.1	34.5	17.3
CRESTOR	5.5	(4.3)	5.4	(3.9)	5.5	(1.4)	5.5	(1.9)
Others	18.3	-	5.9	(61.1)	6.9	(36.0)	2.7	43.6
Others	0.6	1.8	0.6	(14.5)	0.8	(0.5)	0.6	(9.1)
Total	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21.1

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change%	FY2019 2Q actual	Y on Y change %
Prescription drugs	26.7	5.0	25.8	4.9
CYMBALTA	6.7	10.3	6.1	5.3
INTUNIV	1.8	65.6	2.6	105.0
XOFLUZA	0.0	(100.0)	0.0	(99.7)
RAPIACTA	0.0	(89.4)	0.0	(263.2)
BRIGHTPOC Flu	0.0	97.7	0.3	31.0
Total of strategic products	8.6	18.1	9.1	16.8
OXYCONTIN Franchise	1.7	(15.5)	1.5	(17.8)
SYMPROIC	0.5	70.6	0.6	37.2
ACTAIR	0.1	42.1	0.1	37.8
MULPLETA	0.0	(31.2)	0.0	(2.5)
PIRESPA	1.7	26.2	1.7	14.8
Total of new products	12.6	14.4	12.9	11.9
CRESTOR	2.4	(7.8)	2.1	(15.4)
IRBETAN Franchise	1.2	(35.5)	1.0	(11.9)
Other	10.4	5.8	9.7	3.7
Overseas subsidiaries/Export	10.6	7.4	6.9	25.6
Shionogi Inc.	5.2	(14.0)	1.6	20.2
Mulpleta	0.2	-	0.2	-
C&O	3.8	61.1	3.4	26.6
Contract manufacturing	2.4	(12.1)	7.6	158.8
OTC and quasi-drugs	2.1	29.4	2.7	22.0
Royalty income	36.9	(23.6)	38.1	(13.3)
HIV Franchise	29.7	21.4	31.4	(3.7)
CRESTOR	5.6	1.1	5.5	1.8
Others	1.6	(91.0)	1.2	(80.1)
Others	0.5	(5.9)	0.6	6.7
Total	79.2	(10.5)	81.7	2.5

Note: Sales of prescription drugs are shown on non-consolidated basis.

9-2. Quarterly trend for FY2018 and FY2019 (Consolidated statements of income)

Fiscal year ended March 31, 2019

(Billions of yen)

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %	FY2018 3Q actual	Y on Y change %	FY2018 4Q actual	Y on Y change %
Net sales	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21.1
Cost of sales	13.5 11.9		16.1 12.8		16.1 15.7		14.7 14.5	
Gross profit	76.6	39.0	66.9	(13.6)	81.4	9.8	84.0	31.0
SG & A expenses	55.3 49.0		46.7 37.2		42.5 41.3		43.5 42.9	
Selling & administrative expenses	24.3	9.7	23.3	(5.2)	26.9	10.9	27.5	11.6
R & D expenses	24.7	45.3	13.9	6.5	14.3	(7.4)	15.3	6.8
Operating income	31.2 27.6		37.2 29.7		41.3 40.1		41.7 41.1	
Non-operating income & expenses	10.3		2.5		5.5		9.8	
Ordinary income	42.9 37.9		40.3 32.1		47.0 45.6		51.7 50.9	
Extraordinary income & losses	2.1		(0.0)		0.7		1.0	
Income before income taxes	40.1		32.1		46.2		51.9	
Income taxes and etc.	8.2		6.1		9.8		13.5	
Profit attributable to owners of parent	36.0 31.9		32.6 26.0		37.6 36.4		39.0 38.4	

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change %	FY2019 2Q actual	Y on Y change %
Net sales	79.2	(10.5)	81.7	2.5
Cost of sales	16.1 12.7		18.6 15.2	
Gross profit	66.5	(13.2)	66.5	(0.6)
SG & A expenses	47.4 37.5		45.7 37.3	
Selling & administrative expenses	25.7	5.8	26.2	12.5
R & D expenses	11.9	(51.9)	11.1	(20.4)
Operating income	36.6 29.0		35.8 29.2	
Non-operating income & expenses	3.4		3.7	
Ordinary income	40.9 32.4		40.3 32.9	
Extraordinary income & losses	(0.5)		2.6	
Income before income taxes	31.9		35.5	
Income taxes and etc.	7.5		8.3	
Profit attributable to owners of parent	30.8 24.4		33.3 27.2	

10. Group companies

<Consolidated affiliated companies (as of September 30, 2019)>

No	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi Pharma Co., Ltd.	Osaka, Japan	JPY 90 million	Mfg. of pharmaceuticals and contract manufacturing, Contract testing and analysis on medicine	October 1, 2018	March 31	100
2	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sale of OTC and quasi-drugs	January 15, 2016	March 31	85
3	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	September 8, 2010	March 31	100
4	Shionogi Administration Service Co., Ltd.	Osaka, Japan	JPY 10 million	Real estate rental and shared services	November 2, 1992	March 31	100
5	Shionogi Career Development Center Co., Ltd.	Osaka, Japan	JPY 10 million	Career development support to the group companies	April 3, 2017	March 31	100
6	Shionogi Digital Science Co., Ltd.	Osaka, Japan	JPY 10 million	ICT solution service to the group companies	April 3, 2017	March 31	100
7	Shionogi Business Partner Co., Ltd.	Osaka, Japan	JPY 10 million	Insurance agency and shared services	April 3, 2017	March 31	100
8	Shionogi Pharmacovigilance Center Co.,Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	April 3, 2017	March 31	100
9	Shionogi Marketing Solutions Co., Ltd.	Osaka, Japan	JPY 10 million	Market research, Making of the sales promotion materials, Support of the sales department	April 3, 2017	March 31	100
10	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	August 25, 2008	March 31	100
11	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	November 29, 2018	March 31	100
12	C&O Pharmaceutical Technology (Holdings) Limited	Shenzhen, China	HKD 165,840 thousand	Mfg., sale and development of pharmaceuticals	July 28, 2003	December 31	71
13	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	March 31	100
14	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	March 29, 2013	December 31	100
15	Shionogi Singapore Pte. Ltd.	Singapore	SGD 9 million	Development of pharmaceuticals	December 30, 2013	March 31	100

Note: Thirty consolidated affiliated companies are not shown on this table as the scale of their business is very small.

11. Pipeline (as of October 30, 2019)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cephem antibiotic (injection)	USA: Complicated urinary tract infections, including pyelonephritis Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global: Phase III USA: NDA submission (Dec.2018) Europe: MAA submission (Mar.2019)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Approval (Feb.2018) Taiwan: Approval (12 years of age and older) (Aug.2019)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (body weight \geq 20kg) (Sep.2018) Japan: NDA submission (body weight <20kg) (Aug.2018) Japan: Phase III (high dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: NDA submission (Oct. 2019)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Anti-HIV infection (oral)	HIV infection	USA: Phase I	In-house	In-house
Pain/CNS	S-297995 (nalmededine tosilate) [US/Japan:Symproic®] [EU: Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Japan: Phase I	In-house	In-house
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918	Antitussive agent (oral)	Refractory/unexplained chronic cough	Global: Phase II	In-house	In-house
	S-637880	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217 (Zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	Shionogi/Rohto
Frontier	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan, Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house
	S-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy (sublingual)	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes (France)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: Phase I	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house
	S-770108	Anti-fibrosis (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Cutaneous ulcer (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase II	FunPep (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Stroke (injection)	Stroke	Japan: Phase II	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Epidermolysis bullosa (injection)	Epidermolysis bullosa	Japan: Phase II	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	(DTG ^{*1} /3TC ^{*2} 2-drug fixed dose combination tablet) USA: Approval (naïve patients) (Apr.2019) Europe: Approval (naïve and switch patients) (Jul.2019) Japan: Submission (naïve patients) (Sep. 2019) Global: Phase III (switch patients)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S/GSK1265744 LAP ^{*3} (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB ^{*4} LAP+RPV ^{*5} LAP 2-drug regimen for treatment) USA: NDA submission (Apr.2019) (CAB LAP for prevention) Global: Phase III	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV, HPTN, NIAID and Gilead Sciences, Inc. (USA) for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan: Phase III	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA: Xofluza™]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) USA: Approval (high risk patients) (Oct.2019) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric) Global: Phase III (transmission)	In-house	Shionogi/Roche (Switzerland)

*1: Dolutegravir, *2: Lamivudine, *3: Long acting parenteral formulation, *4: Cabotegravir, *5: Rilpivirine

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

Generic name [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Oxycodone hydrochloride hydrate [OxyContin®]	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan; NDA re-submission (May.2019)	Napp Pharmaceuticals Limited (UK)	In-house

Since July 29, 2019

Change of phase	S-033188 (Influenza virus infection/12 years of age and older): Taiwan: NDA submission (Jun.2018)→Approval (Aug.2018)
	S-033188 (Influenza virus infection/prophylaxis): Japan: Phase III→NDA submission (Oct.2019)
	S-600918 (Refractory/unexplained chronic cough): Japan: Phase II→Global: Phase II
	S/GSK1349572 (DTG ^{*1} /3TC ^{*2} 2-drug fixed dose combination tablet/naïve patients): Japan: Submission (Sep.2019)
	S-033188 (Influenza virus infection/high risk patients): USA: sNDA submission (Mar.2019)→Approval (Oct.2019)
Compound added to the list	S-648414 (HIV infection): USA: Phase I
	S-005151 (Epidermolysis bullosa): Japan: Phase II (Follow-up study for the investigator initiated Phase II trials conducted by Osaka Univ.)
	S-033188 (Influenza virus infection/transmission): Global: Phase III
Compound erased from the list	S-877503 (ADHD/adult): Japan: Approval (Jun.2019)