



Financial Results for the First Quarter of Fiscal Year 2019(Consolidated)

July 29, 2019

Name of Listed Company: **SHIONOGI & CO., LTD.**

Listed Exchanges: Section I of Tokyo

Code: 4507 URL: <http://www.shionogi.co.jp>

Representative: Isao Teshirogi, President and CEO

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Scheduled date of quarterly securities report submission: August 7, 2019

Scheduled date of dividend payments: —

Preparation of supplemental material for the quarterly financial results: Yes

Holding of presentation for the quarterly financial results: Yes (for investment analysts)

(Note: All amounts are rounded down to the nearest million yen.)

1. Consolidated results for the period from April 1, 2019 to June 30, 2019

(1) Consolidated operating results

(% shows changes from the same period of the previous fiscal year)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended June 30, 2019	79,225	(10.5)	28,957	4.7	32,401	(14.6)	24,418	(23.4)
Three months ended June 30, 2018	88,524	18.0	27,646	72.9	37,941	80.1	31,892	99.2

Note: Comprehensive income Three months ended June 30, 2019: 15,071 million yen ((57.6)%)

Three months ended June 30, 2018: 35,562 million yen (66.5%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Three months ended June 30, 2019	78.43	78.33
Three months ended June 30, 2018	101.45	99.95

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2019	754,631	671,954	88.4
As of March 31, 2019	778,741	672,429	85.7

Reference: Shareholders' equity As of June 30, 2019: 667,092 million yen As of March 31, 2019: 667,502 million yen

2. Dividends

(Date of record)	Dividends per share				
	End of first quarter	End of second quarter	End of third quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2019	—	44.00	—	50.00	94.00
Year ending March 31, 2020	—				
Year ending March 31, 2020 (forecast)		50.00	—	50.00	100.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2020

(% shows changes from the same period of the previous fiscal year)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent		Earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Six months ending September 30, 2019	159,000	(5.5)	52,000	(9.3)	63,000	(10.1)	49,000	(15.4)	157.41
Year ending March 31, 2020	365,500	0.5	147,000	6.1	170,500	2.4	133,000	0.2	427.26

Note: Revisions of the most recent consolidated financial forecast: None

※ Notes

- (1) Significant changes in subsidiaries during the period (changes in specified subsidiaries involving changes in scope of consolidation): None
- (2) Adoption of accounting methods specific to the preparation of quarterly consolidated financial statements: None
- (3) Changes in accounting policies, changes/restatements of accounting estimates
- a) Changes in accounting policies in connection with amendments to accounting standards, etc.: None
 - b) Changes in accounting policies other than a) above: None
 - c) Changes in accounting estimates: None
 - d) Restatements: None
- (4) Number of shares issued (common stock)
- a) Number of shares issued (including treasury stock)

As of June 30, 2019:	316,786,165 shares
As of March 31, 2019:	316,786,165 shares
 - b) Number of treasury stock

As of June 30, 2019:	5,453,360 shares
As of March 31, 2019:	5,498,751 shares
 - c) Average number of shares issued during the period

Three months ended June 30, 2019:	311,329,640 shares
Three months ended June 30, 2018:	314,355,784 shares

※ *This report of financial results is unaudited.*

※ *Notes to consolidated financial forecasts and other items*

(Cautionary note concerning forward-looking statements)

The forecasts and other forward-looking statements contained in this document are based on the information currently available and certain assumptions that it judges to be reasonable. Actual results may differ materially due to a variety of factors.

For the assumptions used in forecasts and precautionary statements regarding the use of the forecasts, please refer to "1. Overview of Operating Results and Financial Position (3) Outlook" on page 2 of the accompanying materials.

(Method of Obtaining Financial Results Supplementary Materials and Details of Results Briefing Meeting)

Financial results supplementary materials are posted via TDnet on the date of disclosure. The Company plans to hold a results briefing meeting for analysts on Monday, July 29, 2019. Plans are also in place to post audio explanatory details together with financial results explanatory materials distributed to analysts on July 29, 2019 on the Company's website in a timely manner after the results briefing.

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1. Overview of Operating Results and Financial Position

(1) Operating Results for the First Quarter of the Fiscal Year Ending March 31, 2020

For the three months ended June 30, 2019 (April 1, 2019 to June 30, 2019), net sales were ¥79,225 million, operating income was ¥28,957 million, ordinary income was ¥32,401 million, and profit attributable to owners of parent was ¥24,418 million.

Net sales decreased 10.5 percent compared with the same period of the previous fiscal year. Domestic sales of prescription drugs increased 5.0 percent compared with the same period of the previous fiscal year as a result of steady expansion in sales of strategic products Cymbalta and Intuniv. Overseas subsidiary sales and exports increased 7.4 percent. In the United States, Shionogi received a one-time payment in connection with a licensing agreement with BioDelivery Sciences International, Inc. for the co-commercialization of Symproic, but sales decreased 14.0 percent, reflecting the absence of the one-time payment received from Purdue Pharma L.P. in the same period of the previous fiscal year due to the termination of the alliance for Symproic. In China, sales increased 61.1 percent as a result of steady expansion in sales of Rabeprazole. Royalty income from ViiV Healthcare Ltd. (“ViiV”) increased 21.4 percent, reflecting ViiV’s steady expansion in global sales of anti-HIV drugs Tivicay, Triumeq and Juluca. However, royalty income overall decreased 23.6 percent compared with the same period of the previous fiscal year because Shionogi received milestone payments from Roche in the same period of the previous fiscal year in connection with the global development of anti-flu drug Xofluza.

Although domestic sales of prescription drugs and royalty income from ViiV increased, gross profit decreased 13.2 percent compared with the same period of the previous fiscal year because of the substantial impact in the previous fiscal year of the milestone payments from Roche mentioned above. Operating income increased 4.7 percent as a result of a decrease in research and development expenses, reflecting the absence of the strategic business investments made in the previous fiscal year. Ordinary income decreased 14.6 percent due to a decrease in dividend income received from ViiV and fluctuations in foreign exchange rates. Profit attributable to owners of parent decreased 23.4 percent.

(2) Financial Position for the First Quarter of the Fiscal Year Ending March 31, 2020

As of June 30, 2019, total assets were ¥754,631 million, a decrease of ¥24,109 million from the end of the previous fiscal year. Current assets decreased ¥18,207 million to ¥443,535 million due to factors including progress in collection of accounts receivable related to anti-flu drug Xofluza and other seasonal products. Non-current assets decreased ¥5,901 million to ¥311,096 million, largely because of a decrease in investment securities reflecting lower stock prices and the effect of foreign currency translation.

Total liabilities decreased ¥23,633 million from the end of the previous fiscal year to ¥82,677 million. Current liabilities decreased ¥24,252 million to ¥64,855 million, mainly because income taxes payable decreased. Non-current liabilities increased ¥618 million to ¥17,822 million.

Net assets decreased ¥475 million from the end of the previous fiscal year to ¥671,954 million. Shareholders’ equity increased ¥8,960 million to ¥661,332 million as a result of factors including profit attributable to owners of parent and cash dividends paid. Accumulated other comprehensive income decreased ¥9,370 million to ¥5,760 million, mainly due to a decrease in valuation difference on available-for-sale securities reflecting lower stock prices and a decrease in foreign currency translation adjustment due to the effect of currency translation. Subscription rights to shares decreased ¥88 million to ¥438 million and non-controlling interests increased ¥23 million to ¥4,423 million.

(3) Outlook

There are no revisions to the consolidated financial forecast announced on May 9, 2019.

2. Consolidated Financial Statements and Notes

(1) Consolidated balance sheets

	<i>Millions of yen</i>	
	As of March 31, 2019	As of June 30, 2019
Assets		
Current assets		
Cash and deposits	193,549	194,995
Notes and accounts receivable-trade	65,918	44,240
Short-term investment securities	133,264	135,409
Merchandise and finished goods	18,741	18,963
Work in process	7,272	10,332
Raw materials and supplies	14,097	11,589
Other	28,942	28,056
Allowance for doubtful accounts	(43)	(52)
Total current assets	461,743	443,535
Non-current assets		
Property, plant and equipment	74,653	74,166
Intangible assets		
Goodwill	19,258	18,466
Other	35,511	34,587
Total intangible assets	54,769	53,053
Investments and other assets		
Investment securities	151,851	146,500
Other	35,765	37,418
Allowance for doubtful accounts	(42)	(42)
Total investments and other assets	187,574	183,875
Total non-current assets	316,997	311,096
Total assets	778,741	754,631
Liabilities		
Current liabilities		
Notes and accounts payable-trade	9,442	10,020
Current Portion of bonds	920	900
Income taxes payable	35,870	14,040
Provision for bonuses	9,058	10,776
Provision for sales returns	1,428	1,292
Other provision	166	—
Other	32,219	27,823
Total current liabilities	89,107	64,855
Non-current liabilities		
Net defined benefit liability	11,930	12,080
Other	5,272	5,742
Total non-current liabilities	17,203	17,822
Total liabilities	106,311	82,677

Millions of yen

	As of March 31, 2019	As of June 30, 2019
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,512	20,512
Retained earnings	639,461	648,183
Treasury stock	(28,882)	(28,643)
Total shareholders' equity	652,371	661,332
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	28,927	26,635
Deferred gains or losses on hedges	747	3,513
Foreign currency translation adjustment	(18,370)	(28,043)
Remeasurements of defined benefit plans	3,826	3,655
Total accumulated other comprehensive income	15,130	5,760
Subscription rights to shares	527	438
Non-controlling interests	4,400	4,423
Total net assets	672,429	671,954
Total liabilities and net assets	778,741	754,631

(2) Consolidated statements of income and Consolidated statements of comprehensive income

Consolidated statements of income

Millions of yen

	Three months ended June 30, 2018	Three months ended June 30, 2019
Net sales	88,524	79,225
Cost of sales	11,913	12,735
Gross profit	76,610	66,489
Selling, general and administrative expenses	48,964	37,532
Operating income	27,646	28,957
Non-operating income		
Interest income	445	807
Dividends income	9,756	4,907
Other	684	147
Total non-operating income	10,887	5,861
Non-operating expenses		
Interest expenses	89	22
Foreign exchange losses	—	1,272
Other	502	1,122
Total non-operating expenses	591	2,417
Ordinary income	37,941	32,401
Extraordinary income		
Gain on sales of non-current assets	2,462	—
Total extraordinary income	2,462	—
Extraordinary loss		
Loss on valuation of investment securities	—	530
Loss on disaster	331	—
Total extraordinary losses	331	530
Income before income taxes	40,072	31,871
Income taxes-current	12,573	8,641
Income taxes-deferred	(4,980)	(1,136)
Total income taxes	7,593	7,504
Profit	32,478	24,366
Profit (loss) attributable to non-controlling interests	586	(52)
Profit attributable to owners of parent	31,892	24,418

Consolidated statements of comprehensive income

	Millions of yen	
	Three months ended June 30, 2018	Three months ended June 30, 2019
Profit	32,478	24,366
Other comprehensive income		
Valuation difference on available-for-sale securities	5,270	(2,292)
Deferred gains or losses on hedges	1,383	2,766
Foreign currency translation adjustment	(3,975)	(9,598)
Remeasurements of defined benefit plans	405	(171)
Total other comprehensive income	3,084	(9,295)
Comprehensive income	35,562	15,071
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	35,120	15,048
Comprehensive income attributable to non-controlling interests	441	23

(3) Notes

Going concern assumption

None

Significant changes in shareholders' equity

None

Business combination

Transactions under common control

1. Overview of the transaction

(1) Name of business covered and description of its business

Name of business : Pharmaceutical manufacturing operations

Business description : Manufacturing and contract manufacturing of pharmaceutical products

(2) Date of business combination

April 1, 2019

(3) Legal form of business combination

Simplified absorption-type split with Shionogi as the splitting company and Shionogi Pharma Co., Ltd., a wholly owned subsidiary of Shionogi as the successor company

(4) Name of entity after combination

Shionogi Pharma Co., Ltd.

(5) Other information about the transaction

The transaction is for the purpose of providing stable supplies of products with high quality and at competitive prices to domestic and overseas markets, with Shionogi responsible for the Shionogi Group's production-related functions and making innovative developments in production technology.

2. Summary of accounting treatment

The transaction is treated as a transaction under common control based on the Accounting Standard for Business Combinations and the Implementation Guidance on Accounting Standard for Business Combinations and Accounting Standard for Business Divestitures.

3. Other significant items

On the same date, Shionogi Pharma Co., Ltd., the successor company, carried out an absorption-type merger of Shionogi Pharma Chemicals Co., Ltd. and Shionogi Analysis Center Co., Ltd, which were wholly owned subsidiaries of Shionogi.

Supplemental material for financial results for the 1st quarter of fiscal year 2019

July 29, 2019
Shionogi & Co., Ltd.

1. Sales of segments

(Billions of yen)

	FY2019 1H forecast	FY2019 forecast	FY2019 1Q actual	FY2018 1Q actual	change	Progress% vs. 2019 1H forecast
Prescription drugs	53.7	144.1	26.7	25.4	1.3	49.7
<i>change %</i>	7.5	12.0	5.0	(31.9)		
CYMBALTA	13.0	29.3	6.7	6.1	0.6	51.6
INTUNIV	4.6	13.6	1.8	1.1	0.7	39.9
XOFLUZA	0.3	28.0	0.0	0.0	(0.0)	0.0
RAPIACTA	0.1	2.6	0.0	0.0	(0.0)	2.6
BRIGHTPOC Flu	0.2	1.8	0.0	0.0	0.0	5.1
Total of strategic products	18.2	75.7	8.6	7.3	1.3	47.1
OXYCONTIN Franchise	3.6	6.7	1.7	2.0	(0.3)	46.7
SYMPROIC	1.1	2.3	0.5	0.3	0.2	48.6
ACTAIR	0.1	0.3	0.1	0.0	0.0	45.8
MULPLETA	0.2	0.3	0.0	0.0	(0.0)	19.7
PIRESPA	3.5	6.9	1.7	1.4	0.4	49.8
Total of new products	26.7	92.2	12.6	11.0	1.6	47.3
CRESTOR	5.2	10.0	2.4	2.6	(0.2)	46.9
IRBETAN Franchise	2.6	4.9	1.2	1.9	(0.7)	47.0
Other	19.2	36.9	10.4	9.8	0.6	54.0
Overseas subsidiaries/Export	16.0	31.4	10.6	9.9	0.7	66.0
<i>change %</i>	4.3	6.6	7.4	49.3		
Shionogi Inc.	6.3	9.9	5.2	6.1	(0.9)	83.3
Mulpleta	0.3	1.0	0.2	-	0.2	61.2
C&O	6.8	14.6	3.8	2.3	1.4	55.2
Contract manufacturing	9.1	14.3	2.4	2.8	(0.3)	27.0
<i>change %</i>	58.4	(3.0)	(12.1)	(20.5)		
OTC and quasi-drugs	4.6	9.7	2.1	1.6	0.5	44.5
<i>change %</i>	22.3	19.7	29.4	1.3		
Royalty income	74.3	163.6	36.9	48.3	(11.4)	49.6
<i>change %</i>	(19.4)	(9.2)	(23.6)	89.7		
HIV Franchise	61.3	126.5	29.7	24.5	5.2	48.5
CRESTOR	11.0	22.0	5.6	5.5	0.1	50.5
Other	2.1	15.1	1.6	18.3	(16.7)	79.1
Others	1.2	2.4	0.5	0.6	(0.0)	45.0
<i>change %</i>	5.9	(3.2)	(5.9)	1.8		
Total	159.0	365.5	79.2	88.5	(9.3)	49.8
<i>change %</i>	(5.5)	0.5	(10.5)	18.0		

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

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

2 - 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
Ospena	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%
Prescription drugs	26.7	5.0
CYMBALTA	6.7	10.3
INTUNIV	1.8	65.6
XOFLUZA	0.0	(100.0)
RAPIACTA	0.0	(89.4)
BRIGHTPOC Flu	0.0	97.7
Total of strategic products	8.6	18.1
OXYCONTIN Franchise	1.7	(15.5)
SYMPROIC	0.5	70.6
ACTAIR	0.1	42.1
MULPLETA	0.0	(31.2)
PIRESPA	1.7	26.2
Total of new products	12.6	14.4
CRESTOR	2.4	(7.8)
IRBETAN Franchise	1.2	(35.5)
Other	10.4	5.8
Overseas subsidiaries/Export	10.6	7.4
Shionogi Inc.	5.2	(14.0)
Mulpleta	0.2	-
C&O	3.8	61.1
Contract manufacturing	2.4	(12.1)
OTC and quasi-drugs	2.1	29.4
Royalty income	36.9	(23.6)
HIV Franchise	29.7	21.4
CRESTOR	5.6	1.1
Others	1.6	(91.0)
Others	0.5	(5.9)
Total	79.2	(10.5)

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

2 - 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	(40.2)	16.1 12.8	(35.1)	16.1 15.7	(8.2)	14.7 14.5	(15.6)
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	25.2	46.7 37.2	(1.1)	42.5 41.3	3.8	43.5 42.9	9.8
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	72.9	37.2 29.7	(25.4)	41.3 40.1	16.7	41.7 41.1	63.8
Non-operating income & expenses	10.3		2.5		5.5		9.8	
Ordinary income	42.9 37.9	80.1	40.3 32.1	(27.8)	47.0 45.6	14.3	51.7 50.9	53.3
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	99.2	32.6 26.0	(24.2)	37.6 36.4	24.0	39.0 38.4	31.8

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change %
Net sales	79.2	(10.5)
Cost of sales	16.1 12.7	6.9
Gross profit	66.5	(13.2)
SG & A expenses	47.4 37.5	(23.3)
Selling & administrative expenses	25.7	5.8
R & D expenses	11.9	(51.9)
Operating income	36.6 29.0	4.7
Non-operating income & expenses	3.4	
Ordinary income	40.9 32.4	(14.6)
Extraordinary income & losses	(0.5)	
Income before income taxes	31.9	
Income taxes and etc.	7.5	
Profit attributable to owners of parent	30.8 24.4	(23.4)

3. Pipeline (as of July 29, 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: Multidrug-resistant gram-negative bacterial infections	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: NDA submission (Jun.2018)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (body weight ≥20kg) (Sep.2018) Japan: NDA submission (body weight <20kg) (Aug.2018) Japan: Phase III (new dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU: Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Japan: Phase I	In-house	In-house
	S-877503 (guanfacine hydrochloride) [Intuniv®]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan:Approval (Jun.2019)	Shire (Ireland)	Shionogi/Shire
	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	Japan: 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	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage
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

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Frontier	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	Stroke (injection)	Stroke	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 (Apr.2019, naïve patients) Europe: Approval (Jul.2019, naïve and switch patients) 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: sNDA submission acceptance (high risk patients, Mar.2019) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric)	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 May 9, 2019

Change of phase	S-877503 (adult) : Japan:NDA submission (Aug.2018) →Japan:Approval (Jun. 2019)					
	ADR-001 : Added to the list					
	S/GSK1349572(DTG/3TC 2-drug fixed dose combination tablet) : Europe:MAA submission (Sep.2018)→Europe:Approval (Jul.2019)					
	Oxycodone hydrochloride hydrate : Japan:NDA submission (Nov.2016)→Japan:NDA re-submission (May 2019)					
Compound erased from the list	S-297995 (adult) : USA, Japan: Approval (Mar.2017), Europe: Approval (Feb.2019)					
	S-877489 : Japan: Approval (Mar.2019)					
	S-888711 : Japan: Approval (Sep.2015), USA: Approval (Jul.2018), Europe: Approval (Feb.2019)					