

Financial results for the year
ended March 31, 2023

< Supplement >

May 10, 2023



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1. Financial results and forecast

(Billions of yen)

	FY2021 actual	FY2022 actual	FY2023 forecast	Change		FY2023 1H forecast
				FY2022	FY2023	
Revenue	335.1	426.7	450.0	91.5	23.3	217.0
change %	12.8	27.3	5.5			43.9
Operating profit	110.3	149.0	150.0	38.7	1.0	80.5
change %	(6.1)	35.1	0.7			185.2
Profit before tax	126.3	220.3	192.5	94.1	(27.8)	98.0
change %	(11.7)	74.5	(12.6)			44.2
Profit attributable to owners of parent	114.2	185.0	155.0	70.8	(30.0)	78.0
change %	2.1	62.0	(16.2)			36.2

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

2. Revenue by segment

(Billions of yen)

	FY2021 actual	FY2022 actual	FY2023 forecast	Change		FY2023 1H forecast
				FY2022	FY2023	
Prescription drugs	89.1	75.0	134.1	(14.1)	59.1	87.4
change %	(5.9)	(15.8)	78.7			162.1
INTUNIV	16.4	19.2	—	2.8	(19.2)	—
VYVANSE	0.8	1.4	—	0.6	(1.4)	—
Infectious Disease Drugs	11.8	7.4	65.7	(4.4)	58.3	40.0
CYMBALTA	15.9	5.4	4.2	(10.5)	(1.3)	2.1
OXYCONTIN Franchise	4.8	4.4	4.1	(0.4)	(0.3)	2.1
SYMPROIC	2.7	3.4	4.9	0.7	1.5	2.3
ACTAIR	0.5	0.5	1.0	0.0	0.5	0.4
MULPLETA	0.1	0.1	0.1	(0.0)	0.0	0.1
PIRESPA	3.8	2.5	1.9	(1.3)	(0.6)	1.1
Others	32.4	30.6	52.1	(1.8)	21.5	39.3
CRESTOR	5.9	4.1	—	(1.8)	(4.1)	—
Overseas subsidiaries/Export	34.4	42.5	96.6	8.1	54.1	28.0
change %	39.5	23.7	127.3			40.5
Shionogi Inc.	13.8	15.4	13.6	1.7	(1.8)	6.7
Ping An-Shionogi / C&O	10.2	12.0	58.0	1.8	46.0	13.2
Shionogi B.V.	5.0	9.1	11.5	4.1	2.5	5.4
Contract manufacturing	17.4	15.3	13.8	(2.1)	(1.5)	7.3
change %	(11.7)	(12.0)	(10.1)			(0.4)
OTC and quasi-drugs	11.2	13.1	15.0	2.0	1.9	6.8
change %	(4.8)	17.7	14.2			8.6
Royalty income	181.3	174.7	189.5	(6.6)	14.8	86.9
change %	25.3	(3.6)	8.5			4.4
HIV Franchise	174.0	168.5	185.0	(5.5)	16.5	86.0
CRESTOR	1.2	1.3	—	0.2	(1.3)	—
Others	6.1	4.9	4.5	(1.2)	(0.4)	0.9
COVID-19 related products	—	104.7	—	104.7	(104.7)	—
change %	—	—	—			—
Others	1.8	1.3	1.0	(0.5)	(0.3)	0.5
change %	1.7	(28.8)	(21.6)			(17.4)
Total	335.1	426.7	450.0	91.5	23.3	217.0
change %	12.8	27.3	5.5			43.9

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

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

Products included in infectious disease drugs are bellow.

• Xofluz • Rapiacta • Brightpoc Flu Neo • Finibax • Flumarin • Flomox
• Shiomarin • Vancomycin • Baktar • Flagyl • Isodine

COVID-19 related products : Revenue from XOCOVA and S-268019

Infectious Disease Drugs for FY2023 forecast include COVID-19 related products.

Others of Prescription drugs for FY2023 forecast include one-time payment related to transfer of ADHD assets to Takeda.

3. Management index

(Management index trend)

		FY2020	FY2021	FY2022
Return on equity attributable to owners of parent (ROE)	%	13.9	12.5	17.8
Ratio of profit before tax to total assets (ROA)	%	15.3	11.7	17.9
Ratio of operating profit to revenue	%	39.5	32.9	34.9
Ratio of profit before tax to revenue	%	48.1	37.7	51.6
Total assets turnover		0.32	0.31	0.35
Ratio of equity attributable to owners of parent to total assets	%	84.7	84.8	83.9
Dividend payout ratio	%	29.6	30.4	21.7
Ratio of dividends to equity attributable to owners of parent (DOE)	%	4.1	3.8	3.9
Basic earnings per share	yen	365.03	378.75	621.31
Diluted earnings per share	yen	364.89	378.63	621.10

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2021 actual	FY2022 actual	FY2023 forecast	Change		FY2023 1H forecast
				FY2022	FY2023	
Investments in equipments	27.3	12.6	10.8	(14.7)	(1.8)	3.8
Depreciation and Amortization	16.4	17.2	17.2	0.8	0.0	8.6

5. R&D expenses

(Billions of yen)

	FY2021 actual	FY2022 actual	FY2023 forecast	Change		FY2023 1H forecast
				FY2022	FY2023	
R&D expenses	73.0	102.4	99.0	29.4	(3.4)	49.5
change %	34.6	40.3	(3.3)			1.6
% to revenue	21.8	24.0	22.0			22.8

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

6. Employees

	FY2021 actual	FY2022 actual	FY2023 forecast	Change		FY2023 1H forecast
				FY2022	FY2023	
Employees	5,693	5,680	5,269	(13)	(411)	5,305

7. Consolidated statement of profit or loss

(Millions of yen)

	FY2021 actual	FY2022 actual	Y on Y change	
Revenue	335,138	426,684	91,546	Increasing/(decreasing) in Prescription drugs: (14.1)billion yen Overseas subsidiaries/Export: 8.1billion yen Contract manufacturing: (2.1)billion yen OTC and quasi-drugs: 2.0 billion yen Royalty income: (6.6)billion yen COVID-19 related products: 104.7billion yen
Cost of sales	(55,415)	(62,246)	6,831	
Gross profit	279,722	364,437	84,715	
Selling, general and administrative expenses	(91,771)	(97,775)	6,003	
Research and development expenses	(72,996)	(102,392)	29,396	
Amortization of intangible assets associated with products	(3,476)	(3,720)	244	Increasing in research and development investments for treatments and vaccines for COVID-19
Other income	3,384	3,899	514	
Other expenses	(4,551)	(15,445)	10,894	Impairment loss on in-process research and development assets
Operating profit	110,312	149,003	38,691	
Finance income	16,797	75,829	59,032	Increasing in dividend income from ViiV • Receipt of dividends from ViiV which was scheduled to be received in 4th quarter of FY 2021 • Increased dividends due to ViiV receipt of lumpsum payment from the settlement with Gilead
Finance costs	(841)	(4,500)	3,659	
Profit before tax	126,268	220,332	94,064	
Income tax expense	(12,829)	(35,836)	23,007	(FY2021) Refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau
Profit	113,439	184,496	71,056	
Profit attributable to				
Owners of parent	114,185	184,965	70,780	
Non-controlling interests	(746)	(469)	276	
Profit	113,439	184,496	71,056	

8-1. Consolidated statement of financial position (Assets)

	As of Mar. 31 2022	As of Mar. 31 2023	Y on Y change	
Assets				
Non-Current assets				
Property, plant and equipment	108,893	112,085	3,191	
Goodwill	9,638	9,819	180	
Intangible assets	81,223	96,309	15,085	Increase due to acquisition of in-process research and development assets and decrease due to impairment losses
Right-of-use assets	3,524	6,482	2,958	
Investment property	26,672	26,382	(289)	
Other financial assets	242,479	247,711	5,231	Increase in fair value of ViiV stock
Deferred tax assets	12,907	22,100	9,192	Impact of increase in in-process research and development assets and contract research expenses
Other non-current assets	6,055	6,716	661	
Total non-current assets	491,396	527,607	36,211	
Current assets				
Inventories	45,892	57,919	12,026	Increase in COVID-19-related products
Trade receivables	122,965	109,774	(13,190)	Collection of accounts receivable from ViiV
Other financial assets	210,757	254,131	43,374	Increased in time deposits over 3 months
Income taxes receivable	51	68	16	
Other current assets	25,117	53,074	27,957	Increase in advance payments
Cash and cash equivalents	254,420	309,224	54,803	
Total current assets	659,205	784,192	124,986	
Total assets	1,150,601	1,311,800	161,198	

8-2. Consolidated statement of financial position (Equity/Liabilities)

	As of Mar. 31 2022	As of Mar. 31 2023	Y on Y change	
Equity and liabilities				
Equity				
Share capital	21,279	21,279	—	
Capital surplus	14,455	15,204	748	
Treasury shares	(57,857)	(63,074)	5,217	Purchase,Dispose for establishment of the "Shionogi Infectious Disease Research Promotion Foundation"
Retained earnings	832,958	940,606	107,647	
Other components of equity	164,824	186,030	21,205	Exchange rate fluctuations
Equity attributable to owners of parent	975,661	1,100,046	124,385	
Non-controlling interests	17,624	21,832	4,207	
Total equity	993,285	1,121,878	128,592	
Liabilities				
Non-current liabilities				
Lease liabilities	3,729	6,397	2,667	
Other financial liabilities	5,616	4,844	(771)	
Retirement benefit liability	15,412	12,867	(2,544)	
Deferred tax liabilities	7,807	5,916	(1,891)	
Other non-current liabilities	354	1,343	989	
Total non-current liabilities	32,920	31,369	(1,550)	
Current liabilities				
Lease liabilities	2,945	3,014	68	
Trade payables	16,372	14,005	(2,367)	
Other financial liabilities	22,027	29,720	7,693	
Income taxes payable	17,973	42,217	24,244	
Other current liabilities	65,078	69,595	4,516	
Total current liabilities	124,396	158,552	34,155	
Total liabilities	157,316	189,921	32,605	
Total equity and liabilities	1,150,601	1,311,800	161,198	

9-1. Quarterly trend for FY2021 and FY2022 (Revenue by segment)

Fiscal year ended March 31, 2022

(Billions of yen)

FY2021	FY2021 1Q actual	Y on Y change %	FY2021 2Q actual	Y on Y change %	FY2021 3Q actual	Y on Y change %	FY2021 4Q actual	Y on Y change %
Prescription drugs	23.5	5.1	23.7	(4.6)	22.4	(9.2)	19.6	(14.3)
CYMBALTA	6.8	(1.5)	4.7	(29.0)	2.7	(62.0)	1.8	(70.7)
INTUNIV	3.6	37.3	4.0	18.2	4.5	27.4	4.2	21.6
VYVANSE	0.1	436.2	0.2	223.0	0.2	170.0	0.2	124.6
Infectious Disease Drugs	2.1	(1.6)	3.7	34.4	3.0	9.3	3.0	40.3
OXYCONTIN Franchise	1.3	(8.9)	1.2	(12.0)	1.3	(1.1)	1.0	(18.4)
SYMPROIC	0.6	24.8	0.7	11.8	0.7	26.5	0.7	9.9
ACTAIR	0.1	79.1	0.1	56.2	0.1	36.2	0.1	25.4
MULPLETA	0.0	18.0	0.0	(4.3)	0.0	21.0	0.0	(0.5)
PIRESPA	1.0	(32.2)	1.0	(27.6)	1.1	(8.5)	0.8	(31.4)
Others	7.9	8.1	8.1	(5.6)	8.7	7.4	7.8	(3.8)
CRESTOR	1.4	(7.7)	1.6	(22.4)	1.6	12.9	1.3	(20.1)
IRBETAN Franchise	0.8	(7.3)	0.8	(10.7)	0.9	0.4	0.8	(2.1)
Overseas subsidiaries/Export	9.3	70.0	8.1	46.7	8.7	35.1	8.2	14.6
Shionogi Inc.	4.7	182.7	3.2	89.2	3.3	58.6	2.6	27.8
Ping An-Shionogi / C&O	2.4	0.2	2.4	24.1	2.5	(7.4)	3.0	(5.0)
Shionogi B.V.	0.9	144.1	1.4	267.6	1.6	180.6	1.2	72.3
Contract manufacturing	3.7	30.2	4.6	21.3	3.5	(3.1)	5.6	(40.7)
OTC and quasi-drugs	2.5	9.0	3.6	11.1	2.4	(28.8)	2.8	(5.6)
Royalty income	29.6	(22.1)	35.8	(9.1)	37.0	(1.4)	78.9	164.7
HIV Franchise	28.8	(6.8)	32.4	(1.7)	35.0	12.3	77.8	174.8
CRESTOR	—	—	—	—	1.2	(78.9)	—	—
Others	0.8	(47.4)	3.3	328.6	0.9	(3.4)	1.1	(25.6)
Others	0.4	(17.3)	0.4	8.6	0.6	37.3	0.4	(14.6)
Total	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)	115.5	58.8

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

Fiscal year ended March 31, 2023

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Prescription drugs	19.0	(19.0)	14.4	(39.3)	21.3	(4.9)	20.4	4.0
INTUNIV	4.7	29.5	4.8	19.7	5.3	17.2	4.4	3.6
VYVANSE	0.3	105.8	0.3	91.0	0.4	80.1	0.4	58.6
Infectious Disease Drugs	2.1	(2.3)	(2.6)	—	3.5	15.9	4.5	49.6
CYMBALTA	1.7	(75.6)	1.4	(70.3)	1.4	(47.5)	1.0	(43.5)
OXYCONTIN Franchise	1.2	(4.4)	1.1	(10.0)	1.2	(6.9)	0.9	(9.5)
SYMPROIC	0.8	31.7	0.8	27.2	1.0	31.0	0.8	22.6
ACTAIR	0.1	18.0	0.1	3.4	0.1	11.5	0.1	4.2
MULPLETA	0.0	(12.4)	0.0	(3.0)	0.0	(23.2)	0.0	(29.1)
PIRESPA	0.7	(29.0)	0.7	(33.2)	0.7	(38.3)	0.5	(33.4)
Others	7.5	(4.4)	7.7	(4.8)	7.7	(11.7)	7.7	(0.4)
CRESTOR	1.1	(25.7)	1.1	(34.3)	1.1	(31.5)	0.9	(30.6)
Overseas subsidiaries/Export	8.8	(5.3)	11.1	37.2	10.6	21.7	11.9	45.1
Shionogi Inc.	3.0	(36.2)	4.4	38.2	4.1	25.2	4.0	50.4
Ping An-Shionogi / C&O	2.5	7.4	3.1	30.7	2.7	10.6	3.6	21.5
Shionogi B.V.	1.9	108.6	2.4	75.3	2.3	50.4	2.4	109.9
Contract manufacturing	3.4	(10.2)	4.0	(13.4)	2.9	(15.5)	5.1	(10.0)
OTC and quasi-drugs	1.9	(21.2)	4.3	20.9	3.8	60.8	3.1	11.3
Royalty income	38.4	29.7	44.9	25.4	48.5	31.0	43.0	(45.5)
HIV Franchise	37.3	29.3	43.1	32.9	46.6	33.2	41.5	(46.6)
CRESTOR	—	—	—	—	1.3	15.4	—	—
Others	1.1	42.6	1.8	(46.4)	0.6	(35.7)	1.4	28.4
COVID-19 related products	—	—	—	—	100.0	—	4.7	—
Others	0.3	(13.8)	0.3	(29.1)	0.4	(26.1)	0.2	(44.3)
Total	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)

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

9-2. Quarterly trend for FY2021 and FY2022 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2022

(Billions of yen)

FY2021	FY2021 1Q actual	Y on Y change %	FY2021 2Q actual	Y on Y change %	FY2021 3Q actual	Y on Y change %	FY2021 4Q actual	Y on Y change %
Revenue	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)	115.5	58.8
Cost of sales	17.9 (12.3)	7.3	19.2 (14.7)	28.9	17.3 (12.9)	(1.7)	13.5 (15.6)	(6.1)
Gross profit	56.6	(5.5)	61.5	(6.4)	61.7	(1.9)	99.9	77.9
SG & A expenses	31.5 (21.8)	4.2	29.6 (22.5)	0.9	29.9 (22.3)	(3.4)	21.8 (25.2)	(1.7)
R & D expenses	21.4 (14.7)	21.1	17.7 (13.4)	6.0	26.9 (20.0)	39.4	21.4 (24.8)	65.0
Amortization of intangible assets associated with products	1.2 (0.8)	1.2	1.1 (0.8)	2.6	1.1 (0.8)	5.4	0.9 (1.0)	24.1
Other income & expenses	(0.5)		(0.8)		(0.7)		0.9	
Operating profit	27.3 18.8	(34.2)	31.4 23.9	(19.6)	23.8 17.8	(62.1)	43.2 49.9	306.3
Finance income & costs	4.1	(6.7)	4.0	(45.9)	6.2	125.4	1.6	(85.4)
Profit before tax	33.3 22.9	(30.5)	36.6 27.9	(24.9)	32.1 24.0	(51.7)	44.6 51.5	121.6
Income tax expense etc.	9.3	(209.0)	(7.0)	(24.6)	(6.1)	(53.0)	(8.3)	—
Profit attributable to owners of parent	46.7 32.2	31.6	27.4 20.9	(25.0)	24.0 17.9	(51.3)	37.4 43.2	89.2

Fiscal year ended March 31, 2023

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Revenue	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)
Cost of sales	18.0 (12.9)	5.0	18.3 (14.4)	(1.6)	9.2 (17.2)	33.6	20.0 (17.7)	13.6
Gross profit	58.9	4.0	64.5	5.0	170.4	176.3	70.7	(29.3)
SG & A expenses	31.2 (22.4)	3.2	30.5 (24.1)	7.0	12.9 (24.2)	8.4	30.7 (27.1)	7.4
R & D expenses	31.4 (22.5)	53.0	33.2 (26.2)	94.8	13.9 (26.1)	30.1	31.2 (27.6)	11.3
Amortization of intangible assets associated with products	1.3 (1.0)	16.9	1.3 (1.0)	20.9	0.5 (0.9)	10.2	1.0 (0.8)	(15.2)
Other income & expenses	(0.5)		2.5		(0.9)		(12.6)	
Operating profit	17.3 12.4	(33.9)	20.0 15.8	(33.8)	63.0 118.2	565.9	2.9 2.5	(94.9)
Finance income & costs	27.9	572.5	11.9	195.1	12.6	102.7	19.0	—
Profit before tax	56.1 40.3	75.7	35.0 27.7	(0.8)	69.7 130.8	446.1	24.4 21.5	(58.2)
Income tax expense etc.	(5.6)	—	(5.1)	(26.8)	(30.3)	398.8	5.7	—
Profit attributable to owners of parent	48.3 34.7	7.7	28.6 22.5	7.9	53.6 100.5	462.2	30.8 27.2	(36.9)

10. Group companies

<Consolidated affiliated companies (as of March 31, 2023)>

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	Oct. 1, 2018	Mar. 31	100
2	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sales of OTC and quasi-drugs	Jan. 15, 2016	Mar. 31	* 51
3	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	Sep. 8, 2010	Mar. 31	100
4	Shionogi Business Partner Co., Ltd.	Osaka, Japan	JPY 10 million	Insurance agency,shared services,and real estate rental	Apr. 3, 2017	Mar. 31	100
5	Shionogi Pharmacovigilance Center Co., Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	Apr. 3, 2017	Mar. 31	100
6	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr. 20, 2004	Mar. 31	100
7	Pharmira Co., Ltd.	Hyogo, Japan	JPY 85 million	Mfg.,and analytical testing of APIs and intermediates for medicinal drugs investigational drugs	Nov. 25,2021	Mar.31	*50.05
8	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	Aug. 25, 2008	Mar. 31	100
9	Tetra Therapeutics, Inc. (official name : Tetra Discovery Partners Inc.)	Michigan, U.S.A.	USD 37 thousand	Research and development of pharmaceuticals	Jul. 21, 2016	Mar. 31	100
10	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	Nov. 29, 2018	Mar. 31	100
11	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg., and sale of pharmaceuticals	Dec. 26, 1963	Mar. 31	100
12	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	Mar. 29, 2013	Dec. 31	100
13	Ping An-Shionogi (Hong Kong) Ltd.	Hong Kong, China	HKD 361,794 thousand	Sale of pharmaceuticals	Aug. 24, 2020	Mar. 31	* 51
14	Ping An-Shionogi Co., Ltd.	Shanghai, China	RMB 1,061,224 thousand	Mfg., sale and development of pharmaceuticals	Nov. 18, 2020	Dec. 31	* 51

*Incl. Indirect ownership

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

11. Pipeline (as of May 10, 2023)

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	USA: Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options Japan: Various infectious diseases caused by Gram-negative bacteria that are resistant to carbapenem antibiotics Taiwan: Infections due to aerobic Gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) Japan: NDA submission (Mar. 2022) Taiwan: NDA submission (Dec. 2022)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018)	In-house	SHIONOGI/Roche (Switzerland)
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: NDA submission (Nov. 2022) Japan: Phase III Global: Phase III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Children, 5 to 11 years)	Japan: Phase I/II/III	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Approval under the Emergency Regulatory Approval System (Nov. 2022) Japan: Phase II/III Global: Phase III South Korea: NDA submission (Jan. 2023) Taiwan: EUA submission (Mar. 2023)	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (Children, 5 to 11 years)	Japan: Phase III	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	F901318 (Olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/F2G
	S-892216	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Phase I	In-house	In-house
	S-337395	RNA dependent RNA polymerase inhibitor (Oral)	Treatment of RSV infection	Japan: Phase I	In-house/ UBE	SHIONOGI/ UBE

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Europe: PhaseI/II	In-house	In-house
	S-812217 (Zuranolone)	GABA _A receptor positive allosteric modulator (oral)	Depression	Japan: Phase III	Sage (USA)	SHIONOGI/ Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan: PhaseIII	Akili (USA)	SHIONOGI/ Akili
	BPN14770 (Zatolmilast)	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: PhaseII/III	Tetra (USA)	SHIONOGI/ Tetra
	BPN14770 (Zatolmilast)	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA: PhaseII Japan: PhaseII	Tetra (USA)	SHIONOGI/ Tetra
	GRT7039 (Resiniferatoxin)	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	New mechanism of action	Chronic pain	Japan: Phase I	In-house	In-house
Frontier	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: PhaseI/II	Rohto	SHIONOGI/ Rohto
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: Phase II	In-house	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: PhaseIII	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe: PhaseII	OncoTherapy Science, Inc. (Japan)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: PhaseI/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: PhaseI	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (Epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: PhaseI/II	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: PhaseIII	FunPep(Japan)	SHIONOGI/ FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Global: Phase IIb	StemRIM(Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan: PhaseII	StemRIM(Japan)	In-house
	S-531011	anti-CCR8 antibody (injection)	Solid tumor	Japan,USA: PhaseIb/II	In-house	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
S/GSK1265744 LAP* ¹ (Cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB* ² LAP for prevention) Global: PhaseIII	Shionogi-ViiV Healthcare LLC	Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc (USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan: NDA submission(Dec. 2021)	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (Baloxavir marboxil) [USA:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: NDA submission (pediatric, >1 year old) (Mar. 2020) Global: PhaseIII (pediatric, < 1 year old) Global: PhaseIII (transmission)	In-house	SHIONOGI/Roche (Switzerland)
S-555739 (Asapirant)	Prostaglandin D2 DP1 receptor antagonist (oral)	Control of the aggravation of COVID-19	USA: PhaseII	In-house	BioAge Labs, Inc. (USA)
S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	OrsoBio, Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	USA: Phase I	In-house	SHIONOGI-ViiV Healthcare LLC

*1 Long acting parenteral formulation,*2 Cabotegravir

Since Jan.30, 2023

Change of phase	S-217622 : Taiwan: EUA submission (Mar.2023)
	S-309309 : USA: Phase I →Phase II
	S-005151 Stroke : Japan: Phase II→Global: Phase IIb
Compound added to the list	S-217622 (Children, 5 to 11 years) : Japan: Phase III
	S-217622 (Prevention) : Global: Phase III
	S-892216 : Japan: Phase I
	S-337395 : Japan: Phase I
	S-151128 : Japan: Phase I
Compound erased from the list	S-600918 : Closed
	S-770108 : Closed