

1st Half of Fiscal 2022 Financial Results

October 31, 2022

Shionogi & Co., Ltd.



SHIONOGI

Agenda

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- 2. FY2022 Financial Forecasts (P.11-16)**
- 3. Actions for Future Growth (P.17-24)**
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1. Overview of 1st Half FY2022 Financial Results

Financial Results

(Unit: B yen)

	FY2022		FY2021		Y on Y		
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year (May 11)	1H (May 11)					
Revenue	400.0	180.0	150.8	83.8	145.1	3.9	5.7
Operating profit	120.0	57.0	28.2	49.5	42.7	(33.8)	(14.4)
Core operating profit*	120.0	57.0	25.5	44.7	43.9	(41.9)	(18.4)
Profit before tax	168.0	86.0	68.0	79.0	50.8	33.7	17.1
Profit attributable to owners of parent	136.0	71.5	57.3	80.1	53.1	7.8	4.1

- Revenue, profit before tax, and profit attributable to owners of the parent increased year-on-year despite continued investment in COVID-19 related projects
- 1H forecast was unachieved due to a shortfall in revenue from COVID-19 related products
 - 1H forecasts excludes COVID-19-related revenue and other various profit items were achieved

Exchange Rate (average)	FY2022 Forecasts	FY2022 Apr.-Sep results
USD (\$) – JPY (¥)	125	134.04
GBP (£) – JPY (¥)	160	162.94
EUR (€) – JPY (¥)	135	138.76

Financial Results

(Excluding forecasts for COVID-19 related products)

Excludes the following items from 1H forecast

- Revenue of COVID-19 related products 45 billion yen
- Cost of sales associated with sales of COVID-19 related products

(Unit: B yen)

	FY2022			FY2021	Y on Y	
	Forecasts 1H (May 11)	1H Results	Achievement (%)	1H Results	Change (%)	Change
Revenue	135.0	150.8	111.7	145.1	3.9	5.7
Operating profit	17.5	28.2	161.3	42.7	(33.8)	(14.4)
Core operating profit	17.5	25.5	145.6	43.9	(41.9)	(18.4)
Profit before tax	46.5	68.0	146.2	50.8	33.7	17.1
Profit attributable to owners of parent	42.0	57.3	136.3	53.1	7.8	4.1

Base business achieved 1H forecast

Statement of Profit or Loss

	FY2022		1H results	Achievement (%)	FY2021 1H results	Y on Y	
	Forecasts Full year (May 11)	1H (May 11)				Change (%)	Change
Revenue	400.0	180.0	150.8	83.8	145.1	3.9	5.7
Cost of Sales	22.0	17.5	18.2		18.6		
	88.0	31.5	27.4	86.9	27.0	1.4	0.4
Gross profit	312.0	148.5	123.4	83.1	118.1	4.5	5.3
Selling, general& administrative expenses, R&D expenses total	47.5	50.6	64.5		51.0		
	190.0	91.0	97.2	106.8	74.1	31.2	23.1
Selling, general& administrative expenses	30.0	32.8	32.1		31.6		
	120.0	59.0	48.5	82.2	45.9	5.6	2.6
R&D expenses	17.5	17.8	32.3		19.4		
	70.0	32.0	48.7	152.3	28.2	72.9	20.6
Other income & expenses	(2.0)	(0.5)	2.0	-	(1.4)	-	3.4
Operating profit	30.0	31.7	18.7		29.4		
	120.0	57.0	28.2	49.5	42.7	(33.8)	(14.4)
Core operating profit	30.0	31.7	16.9		30.2		
	120.0	57.0	25.5	44.7	43.9	(41.9)	(18.4)
Finance income & costs	48.0	29.0	39.8	137.1	8.2	386.7	31.6
Profit before tax	42.0	47.8	45.1		35.0		
	168.0	86.0	68.0	79.0	50.8	33.7	17.1
Profit attributable to owners of parent	136.0	71.5	57.3	80.1	53.1	7.8	4.1

(Unit: B yen)

Main Variation Factors (Y on Y)

- **Revenue**

- Increase: Sales of Cefiderocol in the US and Europe : Royalty income (HIV franchise)
- Decrease: Domestic sales of prescription drugs

- **R&D**

- Increase: Investment in R&D activities related to COVID-19

- **Finance income & costs**

- Increase in income
 - : Increased dividend reflecting ViiV's strong business
 - : Receipt of dividends from ViiV which was scheduled to be received in 4th quarter of FY2021
 - : Increased dividends due to ViiV receipt of lump sum payment from the settlement with Gilead (Both are transient factors)

- **Profit attributable to owners of the parent**

Received in 1Q of FY2021 refund regarding favorable Judgement on the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau

Revenue by Segment

	FY2022		FY2021		Y on Y		
	Forecasts Full year (May 11)	1H (May 11)	1H results	Achieve ment (%)	1H results	Change (%)	Change
Prescription drugs	78.6	35.5	33.4	93.9	47.1	(29.2)	(13.8)
Overseas subsidiaries/export	41.6	18.1	19.9	110.4	17.4	14.5	2.5
Shionogi Inc.	13.0	6.0	7.4	123.4	7.9	(6.2)	(0.5)
Fetroja®	-	-	4.7	-	2.9	65.0	1.9
Ping An-Shionogi /C&O	14.8	6.3	5.6	88.9	4.7	19.0	0.9
Shionogi BV(Europe)	8.4	3.4	4.3	127.1	2.3	88.3	2.0
Contract manufacturing	14.8	6.3	7.4	117.4	8.4	(12.0)	(1.0)
OTC and quasi-drug	13.4	6.3	6.3	99.3	6.0	3.7	0.2
Royalty income	140.4	68.2	83.3	122.0	65.4	27.4	17.9
HIV franchise	133.9	67.0	80.4	119.9	61.2	31.2	19.1
Others	6.5	1.2	2.9	239.3	4.1	(29.6)	(1.2)
COVID-19 related products**	110.0	45.0	-	-	-	-	-
Others	1.2	0.6	0.6	98.9	0.8	(21.9)	(0.2)
Total	400.0	180.0	150.8	83.8	145.1	3.9	5.7

(Unit: B yen)

Main Variation Factors (Y on Y)

- **Prescription drugs**

- Increase: Sales of Intuniv® and Vyvanse®
- Decrease: Sales of Cymbalta®
: Returns of Xofluza® and Rapiacta®

- **Overseas subsidiaries/export**

- US: Increase: Sales of cefiderocol (Fetroja®)
: Decrease: Received in 1Q of FY2021 a one-time payment for the transfer of FORTAMET® sales rights, etc. (2.2 B yen)
- EU: Increase: Sales of cefiderocol (Fetroja®)

- **Royalty income**

- HIV franchise
: Increase: Strong sales of ViiV's HIV franchise

Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022		FY2021		Y on Y		
	Forecasts Full year (May 11)	Forecasts 1H (May 11)	1H results	Achievement (%)	1H results	Change (%)	Change
Intuniv [®]	19.5	9.0	9.5	104.8	7.6	24.3	1.8
Vyvanse [®]	1.1	0.5	0.6	138.5	0.3	97.6	0.3
Infectious disease drugs	13.4	4.3	(0.6)	-	5.8	-	(6.4)
Influenza franchise	5.1	0.3	(5.0)	-	1.5	-	(6.4)
Cymbalta [®]	6.1	3.1	3.0	98.7	11.5	(73.4)	(8.4)
OxyContin [®] franchise	4.5	2.3	2.3	100.2	2.5	(7.2)	(0.2)
Symproic [®]	3.3	1.5	1.6	106.8	1.3	29.3	0.4
Actair [®]	0.6	0.3	0.3	95.9	0.2	9.8	0.0
Mulpleta [®]	0.1	0.1	0.1	93.7	0.1	(7.9)	(0.0)
Pirespa [®]	2.4	1.2	1.4	114.3	2.0	(31.1)	(0.6)
Others	27.6	13.3	15.2	114.1	15.9	(4.6)	(0.7)
Crestor [®]	3.3	1.7	2.1	126.4	3.1	(30.3)	(0.9)
Prescription drugs	78.6	35.5	33.4	93.9	47.1	(29.2)	(13.8)

<Products included in infectious disease drugs>

- Xofluza[®]
- Rapiacta[®]
- Brightpoc[®] Flu•Neo

- FINIBAX[®]
- Flumarin[®]
- Flomox[®]

- Shiomarin[®]
- Vancomycin
- Baktar[®]

- Flagyl[®]
- ISODINE[®]

Influenza franchise

Returns of Xofluza[®] and Rapiacta[®]

Approximately 5.3 billion yen worth of products (Xofluza[®]: 4.8 billion, Rapiacta[®]: 0.5 billion) that expire this year were returned

- **Causes of wholesale inventory returns**

- Two consecutive seasons without epidemics
- Short product shelf life
 - > Three years for Rapiacta[®] Bag, two years for Xofluza[®] initially* (according to Sakigake Designation System)

Ideally, the distribution of drugs for acute infectious diseases should follow the policy “producing and delivering the required quantity of products at the required time.”

Improved sales transparency (sales \doteq prescription volume) and inventory traceability

Achieve both “stable supply” and “reduction of waste” and accelerate medium- to long-term efforts to establish sustainable drug distribution for acute infectious diseases

Results and Progress in the First Half

- **Achieved 1H forecasts for revenue and other various profit items, excluding COVID-19**
 - Steady progress in domestic business, overseas business, and royalty income, excluding the temporary decline in revenue from the influenza family
- **Progress of COVID-19 related projects**
 - Phase 3 Part of the COVID-19 treatment agent ensitrelvir met the primary endpoint
 - Various clinical trials and negotiations with governments and external support organizations are progressing for the global provision of ensitrelvir
 - > Start of Global Phase 3 study (SCORPIO-HR)
 - > Start of pre-submission of application materials in China, conclusion of the sublicensing agreement with Ildong for application in South Korea
 - > Conclusion of the licensing agreement with Medicines Patent Pool for provision to LMICs*
- **Development and acquisition of new growth drivers**
 - Development progress of major pipeline assets
 - Concluded a licensing agreement with F2G for the new antifungal agent olorofim
 - Concluded a licensing agreement with Grünenthal for resiniferatoxin, a pain treatment for knee osteoarthritis

The full-year forecast was achieved, making steady progress toward medium- and long-term growth

2. FY2022 Financial Forecasts

Regarding the Changes in Earnings Forecasts

Changes in the business environment surrounding SHIONOGI in the second half

Changes in the external environment

- Increased impact of foreign exchange fluctuations, such as yen depreciation
- Impact of the shift in GE policies in China, as well as reduced economic activity and mobility due to the impact of COVID-19

Expected events in 2H

- Approval and launch ensitrelvir in Japan and other countries
- Initiation of disease prevention and pediatric trials for ensitrelvir
- Application for approval of COVID-19 vaccine (S-268019)

Major changes from the initial earnings forecast for 2H

- **Revenue**
 - **Upward revision of royalty income**
 - > Strong sales of ViiV's HIV franchise
 - **Downward revision of China business**
 - > Focus on activities to build a manufacturing and marketing system for ensitrelvir
 - > Pivot to a business centered on new drugs
- **Cost**
 - **Increase in SG&A and R&D expenses**
 - > Aggressive investment in focus items including COVID-19
 - **Reduced cost of sales**
 - > Reflected a decrease in the cost of sales due to changes in the product mix

Revision of Earnings Forecast

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Revenue	400.0	410.0	10.0	220.0	259.2	39.2	335.1	22.3	74.9
Operating profit	120.0	120.0	-	63.0	91.8	28.8	110.3	8.8	9.7
Core operating profit*	120.0	120.0	-	63.0	94.5	31.5	110.6	8.5	9.4
Profit before tax	168.0	174.0	6.0	82.0	106.0	24.0	126.3	37.8	47.7
Profit attributable to owners of parent	136.0	142.0	6.0	64.5	84.7	20.2	114.2	24.4	27.8

- **Full-year forecasts for revenue, profit before tax, and profit attributable to owners of the parent have been revised upwards**
 - Profit attributable to owners of the parent has reached a record high
- **Operating profit remains unchanged in order to continue the aggressive investment in growth drivers**

Exchange Rate (average)	FY2022 Forecasts (May 11)	FY2022 Forecasts (Oct. 24)	FY2022 Apr.-Sep results
USD (\$) – JPY (¥)	125	138	134.04
GBP (£) – JPY (¥)	160	162	162.94
EUR (€) – JPY (¥)	135	140	138.76

Revision of Earnings Forecast: Statement of Profit and Loss

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Revenue	400.0	410.0	10.0	220.0	259.2	39.2	335.1	22.3	74.9
Cost of Sales	22.0	19.5		25.7	20.3		16.5		
	88.0	80.0	(8.0)	56.5	52.6	(3.9)	55.4	44.4	24.6
Gross profit	312.0	330.0	18.0	163.5	206.6	43.1	279.7	18.0	50.3
Selling, general& administrative expenses, R&D expenses total	47.5	50.7		45.0	42.7		50.2		
	190.0	208.0	18.0	99.0	110.8	11.8	168.2	23.6	39.8
Selling, general& administrative expenses	30.0	27.6		27.7	24.9		28.4		
	120.0	113.0	(7.0)	61.0	64.5	3.5	95.2	18.6	17.8
R&D expenses	17.5	23.2		17.3	17.8		21.8		
	70.0	95.0	25.0	38.0	46.3	8.3	73.0	30.1	22.0
Other income & expenses	(2.0)	(2.0)	-	(1.5)	(4.0)	(2.5)	(1.2)	71.5	(0.8)
Operating profit	30.0	29.3		28.6	35.4		32.9		
	120.0	120.0	-	63.0	91.8	28.8	110.3	8.8	9.7
Core operating profit	30.0	29.3		28.6	36.5		33.0		
	120.0	120.0	-	63.0	94.5	31.5	110.6	8.5	9.4
Finance income & costs	48.0	54.0	6.0	19.0	14.2	(4.8)	16.0	238.4	38.0
Profit before tax	42.0	42.4		37.3	40.9		37.7		
	168.0	174.0	6.0	82.0	106.0	24.0	126.3	37.8	47.7
Profit attributable to owners of parent	136.0	142.0	6.0	64.5	84.7	20.2	114.2	24.4	27.8

Revision of Earnings Forecast: Revenue by Segment

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Prescription drugs	78.6	76.4	(2.2)	43.1	43.1	-	89.1	(14.3)	(12.7)
Overseas subsidiaries/export	41.6	39.3	(2.3)	23.6	19.4	(4.2)	34.4	14.4	5.0
Shionogi Inc.	13.0	14.4	1.5	7.0	7.1	0.1	13.8	4.8	0.7
Ping An-Shionogi* /C&O	14.8	10.4	(4.4)	8.4	4.8	(3.7)	10.2	2.1	0.2
Shionogi BV(Europe)	8.4	8.6	0.2	5.0	4.3	(0.7)	5.0	71.7	3.6
Contract manufacturing	14.8	14.8	-	8.5	7.4	(1.1)	17.4	(15.3)	(2.7)
OTC and quasi-drug	13.4	13.2	(0.1)	7.1	7.0	(0.1)	11.2	18.7	2.1
Royalty income	140.4	155.0	14.6	72.2	71.8	(0.4)	181.3	(14.5)	(26.2)
HIV franchise	133.9	150.2	16.4	66.9	69.9	3.0	174.0	(13.6)	(23.7)
Others	6.5	4.8	(1.7)	5.3	1.9	(3.4)	7.3	(34.5)	(2.5)
COVID-19 related products**	110.0	110.0	-	65.0	110.0	45.0	-	-	110.0
Others	1.2	1.2	-	0.6	0.6	-	1.8	(32.6)	(0.6)
Total	400.0	410.0	10.0	220.0	259.2	39.2	335.1	22.3	74.9

Revision of Earnings Forecast: Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022 Forecasts Full year			FY2022 Forecasts 2H			FY2021	Y on Y	
	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Forecasts (May 11)	Forecasts (Revised on Oct. 24)	Revised amount	Results	Change (%)	Change
Intuniv [®]	19.5	20.0	0.4	10.5	10.5	-	16.4	21.7	3.6
Vyvanse [®]	1.1	1.3	0.2	0.6	0.6	-	0.8	61.4	0.5
Infectious disease drugs	13.4	8.8	(4.7)	9.1	9.3	0.2	11.8	(25.8)	(3.0)
Influenza franchise	5.1	0.1	(5.0)	4.8	5.1	0.3	3.1	(95.3)	(2.9)
Cymbalta [®]	6.1	6.1	-	3.0	3.0	-	15.9	(61.7)	(9.8)
OxyContin [®] franchise	4.5	4.5	-	2.2	2.2	-	4.8	(6.5)	(0.3)
Symproic [®]	3.3	3.4	0.1	1.8	1.8	-	2.7	28.0	0.7
Actair [®]	0.6	0.6	-	0.3	0.3	-	0.5	16.4	0.1
Mulpleta [®]	0.1	0.1	-	0.1	0.1	-	0.1	2.4	0.0
Pirespa [®]	2.4	2.4	-	1.2	1.0	(0.2)	3.8	(37.8)	(1.4)
Others	27.6	29.4	1.8	14.3	14.2	(0.1)	32.4	(9.2)	(3.0)
Crestor [®]	3.3	3.9	0.6	1.6	1.8	0.2	5.9	(33.4)	(2.0)
Prescription drugs	78.6	76.4	(2.2)	43.1	43.1	-	89.1	(14.3)	(12.7)

<Products included in infectious disease drugs>

- Xofluza[®]
- Rapiacta[®]
- Brightpoc[®] Flu•Neo

- FINIBAX[®]
- Flumarin[®]
- Flomox[®]

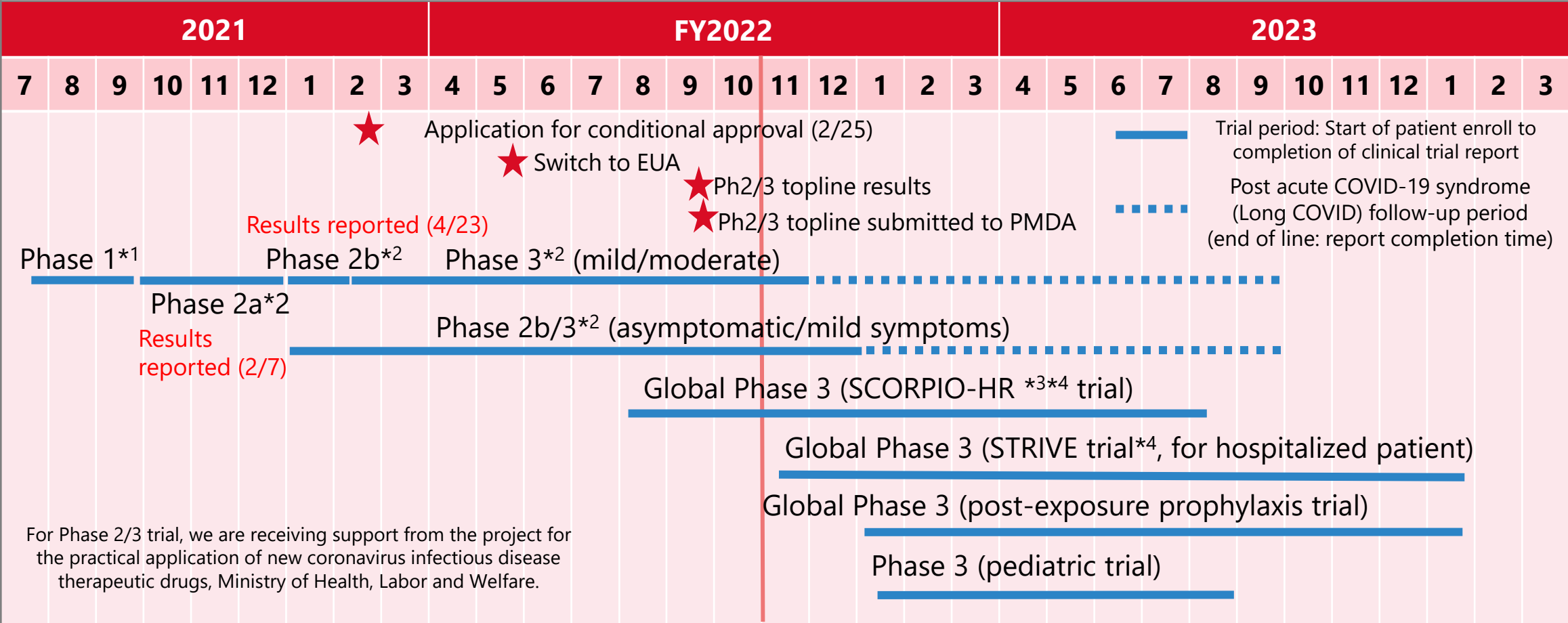
- Shiomarin[®]
- Vancomycin
- Baktar[®]

- Flagyl[®]
- ISODINE[®]

Influenza franchise

3. Actions for Future Growth

Ensitrelvir: Progress Summary



As of October 31, 2022

For Phase 2/3 trial, we are receiving support from the project for the practical application of new coronavirus infectious disease therapeutic drugs, Ministry of Health, Labor and Welfare.

*1 [jRCT2031210202](https://www.clinicaltrials.gov/ct2/show/study/NCT02031210)、*2 [jRCT2031210350](https://www.clinicaltrials.gov/ct2/show/study/NCT02031210350)、*3 [NCT05305547](https://www.clinicaltrials.gov/ct2/show/study/NCT05305547)、*4 NIH sponsored trial



Ensitrelvir

Continuation of Phase 2/3 trial

- Obtained Top-Line results of Phase 3 part (September 28, 2022)
 - Demonstrating a significant reduction vs placebo in the time to resolution of five typical Omicron-related symptoms:
Achieved the Primary Endpoint
 - Ensitrelvir also showed a significant reduction in viral RNA on day 4 (following the third dose) relative to placebo: Key Secondary Endpoint

Registration in Japan

- Discussions are underway with MHLW and PMDA regarding future approval reviews and deliberations

Global registration

- Korea : Execution of Sub-license Agreement for ILDONG
 - In consultation with authorities for approval process
- China : Ping An-Shionogi Co., Ltd. has initiated the submission of preparatory materials for an application
- US/EU : Under discussion with FDA,EMA and MHRA
- Low- and middle-income countries (LMICs): Execution of License Agreement with Medicines Patent Pool
 - Activities to provide access to 117 countries

Supply

- Building a global supply system
 - Since April 2022, production has been expanding to supply more than 10 million people annually
 - Plans to manufacture in China and the United States for further supply expansion

Ensitrelvir

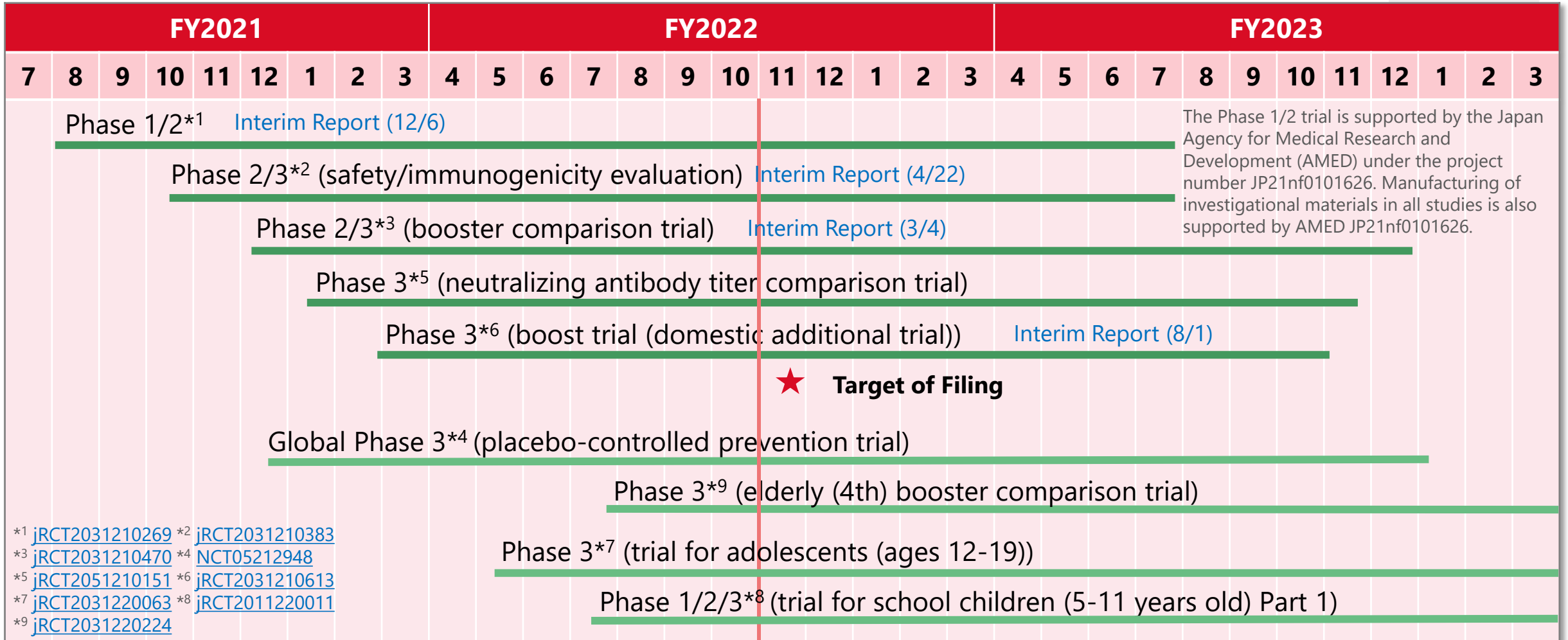
Global Phase 3 trial

- **SCORPIO-HR**
 - Patients : SARS-CoV-2 infected patients that are not hospitalized
- **STRIVE trial**
 - Patients: SARS-CoV-2 infected patients that are hospitalized
 - Start: Nov 2022 (planned)
- **SCORPIO-PEP trial**
 - Patients: Household members living with SARS-CoV-2 infected individuals
 - Start: Dec 2022 (planned)

Pediatric trial

- To seek approval using the Phase 2/3 trial data in adolescents (12 to 18)
- To conduct a clinical trial for 6 to 12 year olds in JP
 - Start: Nov 2022 (planned)
- To plan a separate global clinical trial in 0 to 12 year olds

S-268019: Progress Summary



*1 [jRCT2031210269](#) *2 [jRCT2031210383](#)
 *3 [jRCT2031210470](#) *4 [NCT05212948](#)
 *5 [jRCT2051210151](#) *6 [jRCT2031210613](#)
 *7 [jRCT2031220063](#) *8 [jRCT2011220011](#)
 *9 [jRCT2031220224](#)

As of October 31, 2022

Trial period: Start of patient enroll to completion of clinical trial report

S-268019: Development Status

Adult: Filing preparation

- **Preconsultation completed**
 - Nonclinical Part: Pharmacology & Toxicology
- **Preconsultation in Progress**
 - Clinical Part: Phase 1/2 trial, Phase 2/3 trial, Booster comparison trial
- **CTD preparation**
 - CMC Part, Clinical Part: Neutralizing antibody titer comparison trial, Boost trial (domestic additional trial)



Filing Planned by the end of 2022

Pediatric: Clinical studies on-going

- Started study in adolescents and currently conducting dose finding trial in school children

Performance against new variants

- **Confirmed increase of neutralizing antibody titers against various variants in S-268019 clinical trial specimens**
 - Neutralizing antibody titer after S-268019 booster is similar to neutralizing antibody titer after Comirnaty booster
- **Preparation of new variant antigen production**
 - Development of the antigen production process based on the genetic information of the Omicron variant is in the final stage
 - Mouse booster immunogenicity test confirmed increased of neutralizing antibody titer against new variants

Domestic and Overseas Business Initiatives

Domestic business

- **Infectious disease business**
 - Preparation for an influenza and COVID-19 twindemic
 - > Promote of combo kits that can diagnose both
 - > Provide information on Xofluza® and Rapiacta® in preparation for an influenza epidemic
 - Efforts to provide encitrelvir in Japan
- **ADHD family**
 - Started nationwide deployment of E-MR dedicated to web-based activities
 - > Increase understanding in adult-focused and low-market-share practices
 - Increase ADHD target doctors through digital detailing

Overseas business

- **COVID-19 related products**
 - Progress discussions with relevant parties regarding approval requirements and process
- **European and American businesses**
 - Maximize the value of cefiderocol
 - > Further growth in launched countries
 - > Expansion to further countries
- **China business**
 - Construct a manufacturing and marketing system for ensitrelvir
 - Progress clinical development and construct a marketing system for new drugs
 - Expand research approaches utilizing AI technology
 - Further promote collaboration with Ping An and ping An Good Doctor from research through to sales

Progress of HIV Franchise by ViiV Healthcare

Expanding growth portfolio centered on HIV integrase inhibitors

- **Dovato (two-drug regimen)**
 - Reached annualized sales of £1bn+
 - Maintains leading share of EU and US switch market
- **Cabenuva (long-acting injection: treatment)**
 - Positive results of CARISEL study* in EU
 - > Implementation of the complete long-acting regimen was acceptable, appropriate, and feasible
 - > 81% of subjects reported less stigma than existing oral regimens
 - Mid- to long-term safety and efficacy confirmed
 - > 152-week follow-up data from the ATLAS-2M study**
- **Apretude (long-acting injection: prevention)**
 - The first and only option for long-acting injectables prevention
 - Steady progress after the US launch
- **S-365598 (ultra long-acting injection)**
 - 3rd generation integrase inhibitor with potential for dosing intervals of three months or longer***
 - Phase 1 trial scheduled to start by the end of 2022

Drive short-term and medium- to long-term growth

* CARISEL study: To examine various implementation strategies of LA injectables in European clinics and evaluate their acceptability, appropriateness, and feasibility for healthcare teams and patients ([NCT04399551](https://clinicaltrials.gov/ct2/show/study/NCT04399551))

** ViiV press release [ViiV Healthcare to present new long-term findings from its innovative 2-drug and long-acting HIV medicines portfolio at CROI 2022](https://www.viiv.com/newsroom/viiv-healthcare-to-present-new-long-term-findings-from-its-innovative-2-drug-and-long-acting-hiv-medicines-portfolio-at-croi-2022)

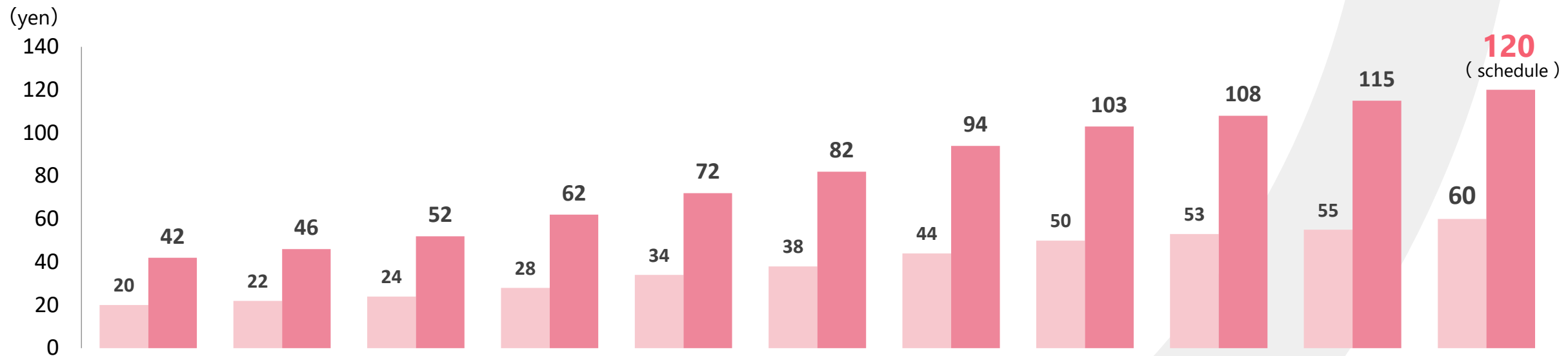
*** Shionogi R&D Day 2021 p38 https://www.shionogi.com/content/dam/shionogi/global/investors/ir-library/presentation/2021/e_20210929_4.pdf

4. Shareholder Return

Flexible Capital Policy

- **Shareholder return policy that allows you to experience SHIONOGI's growth directly**

- Improve capital efficiency by repurchasing and canceling treasury stock and reducing cross-shareholdings
- Plan to increase dividends for the 11th consecutive fiscal year in FY2022



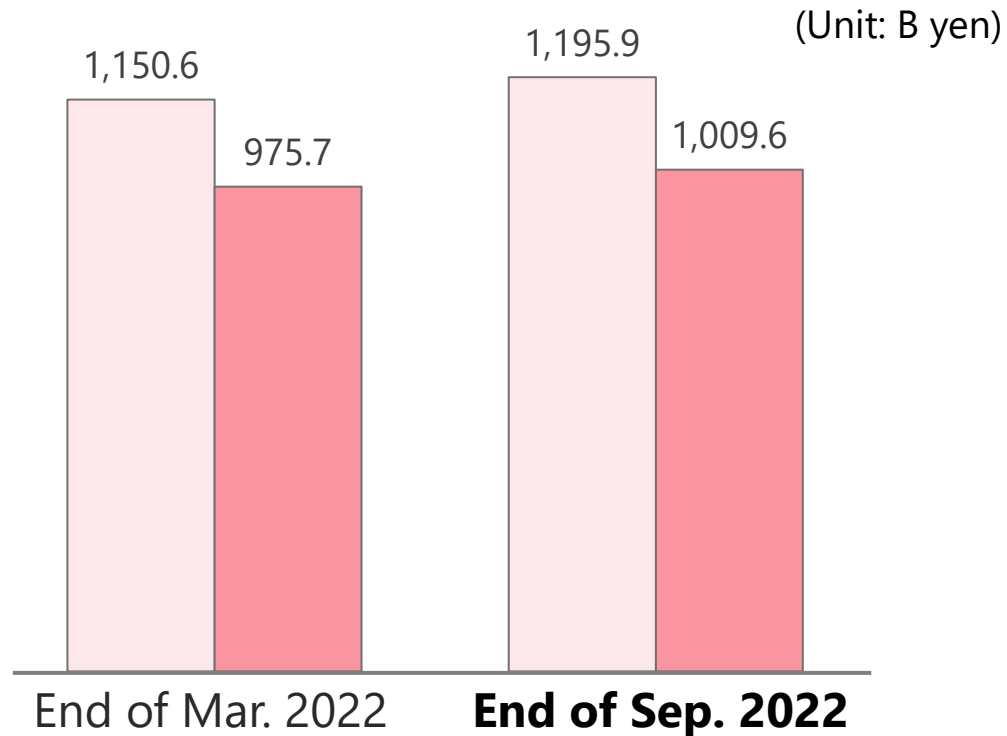
年度		12	13	14	15	16	17	18	19	20	21	22
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	50 B yen**
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.6 (Predict)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	13.8 (Predict)

Values calculated based on IFRS after 2019

Appendix

Financial Position (Consolidated, IFRS)

■ Total Assets
 ■ Equity attributable to owners of parent



	End of Mar. 2022	End of Sep. 2022
Ratio of equity attributable to owners of parent to total assets	84.8%	84.4%

Unit: B yen		End of Mar. 2022	End of Sep. 2022	Change
Total Assets	Non-current Assets	491.4	516.0	24.6
	Current Assets	659.2	679.9	20.7
Equity attributable to owners of parent		975.7	1,009.6	33.9
Total Liabilities	Non-current Liabilities	32.9	35.9	3.0
	Current Liabilities	124.4	127.0	2.6

Disposal, Acquisition and Cancellation of Treasury Stock Associated with the Establishment of the New Foundation

Disposal of treasury stock (advantageous issuance)

Total shares to be disposed: 3M
Disposal date: September 1, 2022

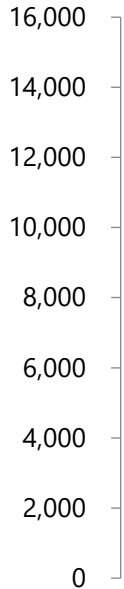
Share buyback

- Total number of shares to be acquired: 7.2M (maximum)
- Total purchase price for acquisition of shares: 50 billion yen (maximum)
- Period of acquisition: From June 24, 2022 to December 30, 2022 (scheduled)
- **Total number of shares acquired: 3,389,700 shares (on September 30, 2022)**
- **Total value of shares acquired: 23,322,547,662 yen (on September 30, 2022)**

Cancellation of treasury shares

- Total shares to be cancelled: 4.2M shares
- Date for cancellation: February 10, 2023

(1,000 shares)



Beginning of
FY2022

After treasury
stock disposal

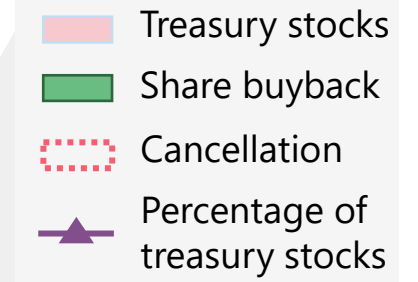
After share
buyback

After cancellation
of treasury shares

Share buyback of
ca. 7.2M shares

Cancellation of
4.2M shares

(%)



Upcoming Pipeline Events 1/2

As of Oct. 12, 2022 Not all plans are listed

Pipeline	Indication	Stage	FY2022 3Q-4Q	FY2023	FY2024
olorofim (F901318)	Invasive Aspergillosis	Phase 2b, Phase 3	★ Ph2b Interim report (3Q)		★ Ph3 Completion of case registration (4Q)
S-337395	RSV infection	Preclinical		● Ph1 start (1Q)	
S-365598 (HIV franchise, out license)	HIV infection	Preclinical	● Ph1 start (3Q)		
resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3			★ Ph3 topline results (2Q) ◆ Submission (3Q)
zatolmilast (BPN14770)	①Fragile X Syndrome ②Alzheimer's disease	①Phase 2/3 ②Phase 2	①	★ Ph2b3 topline results (4Q)	
zulanolone (S-812217)	Depression	Phase 3		★ Ph3 topline results (3Q) ◆ Submission (4Q)	
S-151128	Chronic pain	Preclinical		● Ph1 start (4Q)	

● Timing of trial start ★ Timing of topline results ◆ Timing of submission

Upcoming Pipeline Events 2/2

As of Oct. 12, 2022 Not all plans are listed

Pipeline	Indication	Stage	FY2022 3Q-4Q	FY2023	FY2024	
redasemtide (S-005151)	①Epidermolysis bullosa ②Acute ischemic stroke ③Knee osteoarthritis ④Chronic liver disease ⑤Cardiomyopathy	①Preparing for additional clinical trial ②Preparing for Phase 3 trial ③④Investigator initiated clinical trial (Phase 2 trial) in progress ⑤Preparing for Investigator initiated clinical trial	①			Submission (3Q)
			②	Ph3 start (4Q)		
			⑤		Ph2 start (2Q)	
S-309309	Obesity	Phase 1	Ph1 topline results (3Q) ★	Ph2 start (4Q)	Ph2 topline results (3Q) ★	
S-531011	Solid tumor	Phase 1b/2			Ph2 start (4Q)	
S-770108	Idiopathic pulmonary	Phase 1		Ph2 start (1Q)		

● Timing of trial start ★ Timing of topline results ◆ Timing of submission

Pipeline: Infectious Disease

as of October. 31, 2022

Preclinical

Phase 1

Phase 2

Phase 3

Submission

S-872600

Influenza nasal vaccine

S-540956

Nucleic acid adjuvant

S-875670

COVID-19 nasal vaccine

S-337395

RSV infections

S-554110

Nontuberculous
mycobacterial infection

S-892216

COVID-19 treatment

Stage change (change from October. 12, 2022)

S-892216 (COVID-19 treatment): Preclinical



: Global development



Out license

S-365598

HIV infection

S-555739

Treatment by suppressing
aggravation of COVID-19

Xofluza®

Influenza virus infection
(Pediatric, < 1 year old)

Xofluza® (US)

Influenza virus infection
(Pediatric, < 1year old)

Xofluza®

Influenza virus infection
(Transmission)

S-217622*

[Ensitrelvir]
COVID-19 treatment

S-217622 **

[Ensitrelvir]
COVID-19 treatment

S-268019

COVID-19
Prophylactic vaccine

* Phase 2/3, Phase 3
** Phase 2/3

S-268019

COVID-19
Prophylactic vaccine

cefiderocol

Various infectious diseases

cefiderocol

Aerobic Gram-negative
bacterial infection (Pediatric)

Xofluza®

Influenza virus infection
(Granules, < 20kg)

F901318

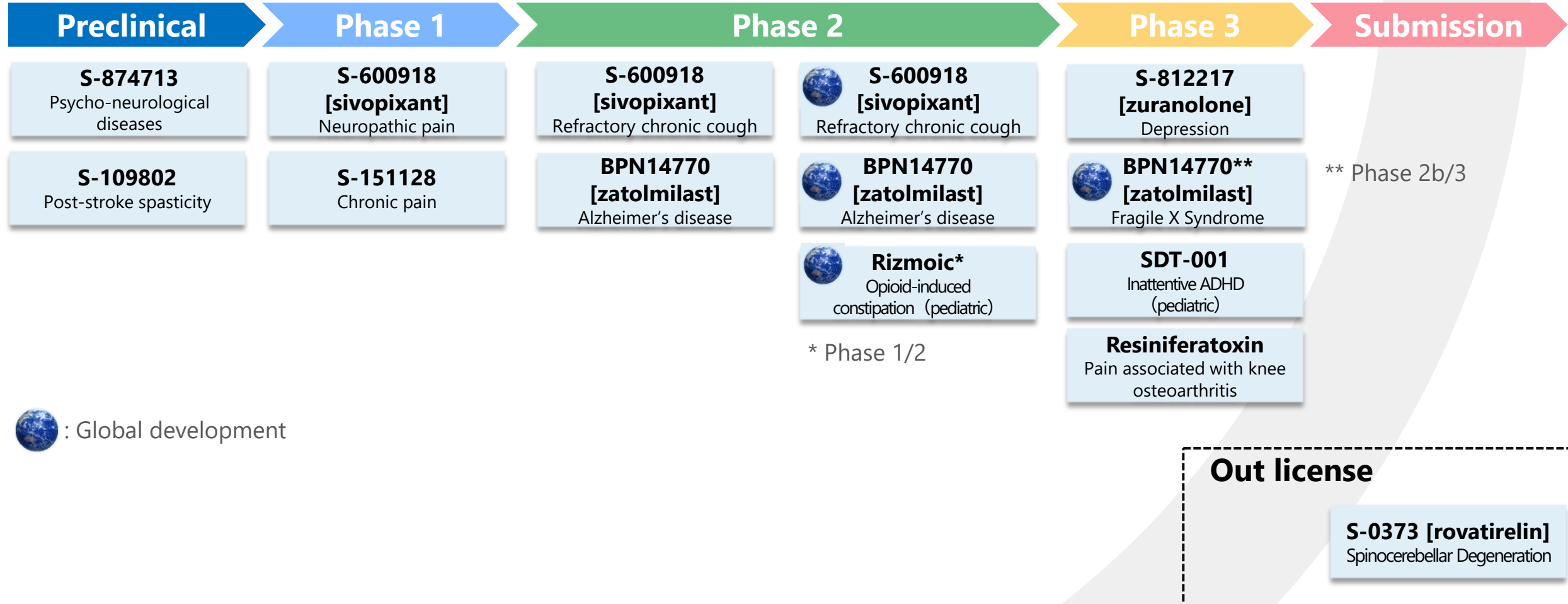
[olorofim]

Invasive Aspergillosis

: Progress from October. 12, to October. 31, 2022

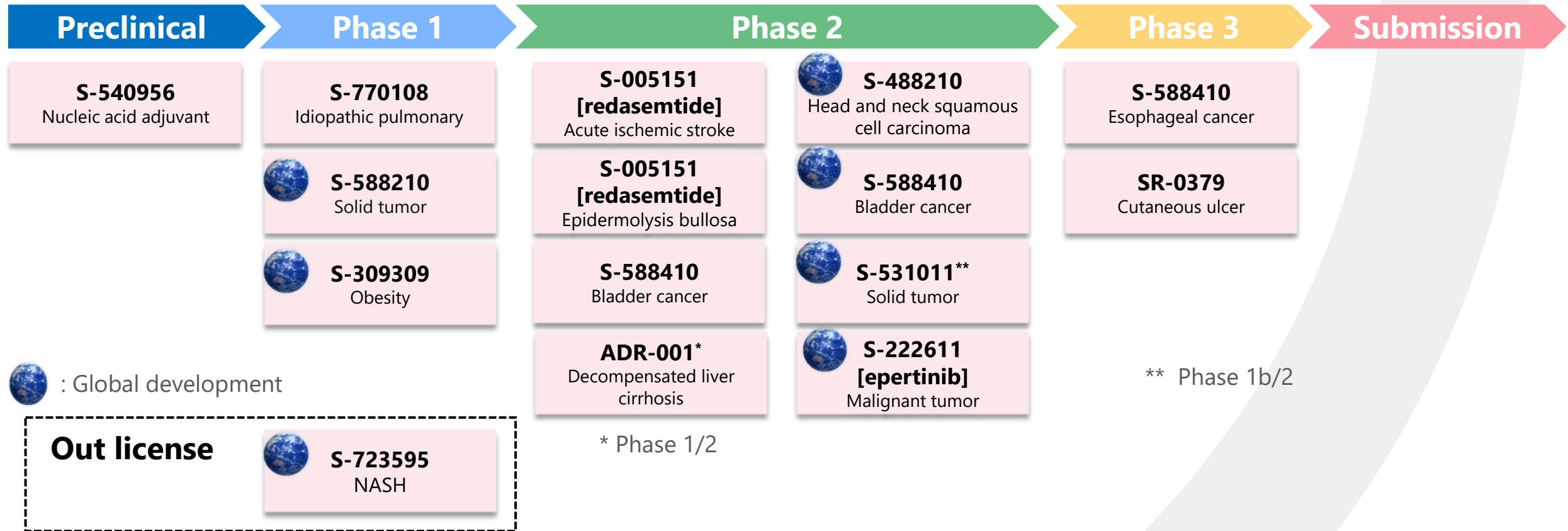
Pipeline: Psycho-Neurological Disease, Pain

as of October. 31, 2022



Pipeline: New Growth Areas

as of October. 31, 2022



Other Major Progress*

• August

- Development of an automatable highly sensitive method to detect coronavirus in wastewater for wider use (EPISENS-S method)
- Achieve the goal of crowdfunding for the communication barrier free project
- Selecting for inclusion in all ESG indices adopted by the Government Pension Investment Fund (GPIF)

• September

- Collaboration with Panasonic Holdings Corporation, the beginning of solar power generation at a health facility in Kilifi county, Kenya under the "Mother to Mother SHIONOGI Project"
- Entering a business partnership agreement among Shionogi Healthcare, Shionogi, and Pixie Dust Technologies to launch business involving brain activation through sound stimulation

• October

- Development of an automatable highly sensitive method for coronavirus detection in wastewater (COPMAN method)
- Partnership agreement between SHIONOGI and Hirakata City, Osaka for support and increased awareness of infectious disease control
- Real-World Evidence Showing Strong Efficacy with Fetroja® (cefiderocol) Against Treatment Resistant Bacterial Infections at IDWeek 2022
- Establishes of Yui Connection Co., Ltd. and launch of its business

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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