1st Half of Fiscal 2021 Financial Results

November 1, 2021
Shionogi & Co., Ltd.

SHIONOGI

Agenda

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2. FY2021 Financial Forecasts (P.11-15)
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   - Progress of other growth projects
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1. Overview of 1st Half FY2021 Financial Results

Financial Results (Consolidated)

(Unit: B yen)

	FY2021				FY2020	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year	1H					
Revenue	290.0	135.0	**145.1**	**107.5**	148.5	**(2.3)**	**(3.4)**
Operating profit	90.0	38.5	**42.7**	**110.8**	58.3	**(26.8)**	**(15.6)**
Core operating profit*	90.0	38.5	**43.9**	**113.9**	55.8	**(21.4)**	**(12.0)**
Profit before tax	115.0	48.5	**50.8**	**104.8**	70.1	**(27.5)**	**(19.3)**
Profit attributable to owners of parent	100.0	49.5	**53.1**	**107.3**	52.3	**1.5**	**0.8**

- **Revenue and profit items are achieved 1st half forecasts**
  - Both domestic and overseas businesses achieved the 1st half forecasts
  - New business opportunities contributed to business performance
- **Profit attributable to owners of parent increased compared to the same period of the previous year**
- **Continue to actively invest in R&D and new businesses**

Exchange Rate (average)	FY2021 forecasts	FY2021 Apr.-Sep. results
USD ($) – JPY (¥)	**105**	**109.82**
GBP (£) – JPY (¥)	**145**	**152.49**
EUR (€) – JPY (¥)	**128**	**130.89**

* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

Statement of Profit or Loss (Consolidated)

(Unit: B yen)

	FY2021				FY2020	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year	1H					
Revenue	290.0	135.0	**145.1**	**107.5**	148.5	**(2.3)**	**(3.4)**
Cost of sales	19.8 57.5	18.5 25.0	18.6 **27.0**	**107.9**	15.4 22.9	**18.1**	**4.1**
Gross profit	232.5	110.0	**118.1**	**107.4**	125.6	**(6.0)**	**(7.5)**
Selling, general & administrative expenses	30.7 89.0	32.6 44.0	31.6 **45.9**	**104.3**	30.2 44.8	**2.5**	**1.1**
R&D expenses	17.9 52.0	18.5 25.0	19.4 **28.2**	**112.7**	16.7 24.9	**13.4**	**3.3**
Other income & expenses	(1.5)	(2.5)	**(1.4)**	**54.9**	2.3*	**(159.7)**	**(3.7)**
Operating profit	31.0 90.0	28.5 38.5	29.4 **42.7**	**110.8**	39.2 58.3	**(26.8)**	**(15.6)**
Core operating profit**	31.0 90.0	28.5 38.5	30.2 **43.9**	**113.9**	37.6 55.8	**(21.4)**	**(12.0)**
Finance income & costs	25.0	10.0	**8.2**	**81.7**	11.9	**(31.3)**	**(3.7)**
Profit before tax	39.7 115.0	35.9 48.5	35.0 **50.8**	**104.8**	47.3 70.1	**(27.5)**	**(19.3)**
Profit attributable to owners of parent	100.0	49.5	**53.1**	**107.3**	52.3	**1.5**	**0.8**

Main Variation Factors (1st Half Forecast Comparison***)

- **Revenue**
  - Increase: Prescription drugs, overseas subsidiaries/export, contract manufacturing and royalty income
- **Cost of sales**
  - Increase: Product mix due to growth in overseas subsidiaries/export and contract manufacturing
- **Selling, general & administrative expenses**
  - Increase: Launch and sales activity costs associated with strong sales of Fetroja® and Fetcroja® in Europe and the United States
- **R&D**
  - Increase: Accelerating of R&D activities centered on COVID-19 related (S-268019, S-217622) and 8 core projects
- **Finance income & expenses**
  - Decrease in income: Dividend from ViiV

* The provisional accounting for business combinations with Tetra was finalized in FY2020, the financial results for 1H of previous fiscal year have been retroactively adjusted ** Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)
*** Appendix p.31: Year-on-Year Comparison

Revenue by Segment

(Unit: B yen)

	FY2021 Forecasts Full year	FY2021 Forecasts 1H	FY2021 1H results	FY2021 Achievement (%)	FY2020 1H results	Y on Y Change (%)	Y on Y Change
Prescription drugs	94.4	46.1	**47.1**	**102.2**	47.2	**(0.0)**	**(0.0)**
Overseas subsidiaries/export	31.1	12.2	**17.4**	**142.7**	11.0	**58.2**	**6.4**
Shionogi Inc.	8.4	4.2	**7.9**	**186.8**	3.3	**135.7**	**4.5**
Fetroja®	-	-	**2.9**	**-**	0.4	**573.3**	**2.4**
Ping An-Shionogi* /C&O	14.3	3.9	**4.7**	**121.5**	4.2	**10.9**	**0.5**
SBV(Europe)	3.5	1.4	**2.3**	**163.1**	0.7	**207.0**	**1.5**
Contract manufacturing	17.8	7.4	**8.4**	**112.7**	6.7	**25.1**	**1.7**
OTC and quasi-drug	15.4	6.9	**6.0**	**88.1**	5.5	**10.3**	**0.6**
Royalty income	129.8	61.7	**65.4**	**106.0**	77.3	**(15.5)**	**(11.9)**
HIV franchise	125.2	60.8	**61.2**	**100.8**	63.9	**(4.2)**	**(2.7)**
Crestor®	1.1	-	**-**	**-**	11.1	**-**	**(11.1)**
Others	3.5	0.9	**4.1**	**447.1**	2.3	**82.5**	**1.9**
Others	1.4	0.7	**0.8**	**108.5**	0.8	**(5.4)**	**(0.0)**
Total	290.0	135.0	145.1	**107.5**	148.5	**(2.3)**	**(3.4)**

Main Variation Factors (1st Half Forecast Comparison**)

- **Prescription drugs**
  - Increase: Sales of Cymbalta®
  - Increase: Recorded part of stockpile of Rapiacta® to the government in the 1st half
- **Overseas subsidiaries/export**
  - US: Increase: Strong sales of Fetroja®
  - : Increase: Received a one-time payment for the transfer of FORTAMET® sales rights, etc.
  - China: : Increase: Increased stocking due to concerns about potential interruption of distribution by COVID-19
  - EU: Increase: Strong sales of Fetcroja®
- **Contract manufacturing**
  - Increase: Active pharmaceutical ingredient export of dolutegravir in 2nd Quarter partially included requirements for 3rd Quarter
- **OTC and quasi-drug**
  - Decrease: Sales of ISODINE®
- **Royalty income**
  - Increase: Out-licensing agreement with ViiV for S-365598

* OTC and quasi-drugs also include in revenue of joint venture

** Appendix p.32: Year-on-Year Comparison

Revenue of Prescription Drugs in Japan

(Unit: B yen)

	FY2021				FY2020	Y on Y	
	Forecasts		1H results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Cymbalta®	15.1	10.0	**11.5**	**114.6**	13.5	**(14.9)**	**(2.0)**
Intuniv®	18.2	8.5	**7.6**	**89.0**	6.0	**26.5**	**1.6**
Vyvanse®	1.0	0.4	**0.3**	**82.8**	0.1	**293.5**	**0.2**
Infectious disease drugs	17.0	4.8	**5.8**	**120.3**	4.9	**18.5**	**0.9**
Influenza franchise	7.9	0.2	**1.5**	**-**	0.1	**-**	**1.4**
OxyContin® franchise	5.0	2.6	**2.5**	**95.3**	2.8	**(10.5)**	**(0.3)**
Symproic®	3.1	1.3	**1.3**	**96.7**	1.1	**17.7**	**0.2**
Actair®	0.4	0.2	**0.2**	**133.4**	0.1	**65.6**	**0.1**
Mulpleta®	0.1	0.1	**0.1**	**88.3**	0.1	**6.2**	**0.0**
Pirespa®	3.5	1.8	**2.0**	**111.2**	2.8	**(29.9)**	**(0.8)**
Others	30.9	16.4	**15.9**	**96.9**	15.8	**0.7**	**0.1**
Crestor®	6.5	3.8	**3.1**	**81.4**	3.7	**(16.2)**	**(0.6)**
Irbetan® franchise	3.1	1.7	**1.5**	**92.8**	1.7	**(9.0)**	**(0.2)**
Prescription drugs	94.4	46.1	**47.1**	**102.2**	47.2	**(0.0)**	**(0.0)**

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole
- ISODINE®

1st Half Results and Progress of New Business Opportunities

Expansion of infectious disease-related business

- Providing COVID-19 related products and services
- Changes in each country's response to prepare for emergencies such as flu and AMR, etc.

- **Progress in development of therapeutic drugs and vaccines**
  - Progress of clinical trials
    - S-217622: Phase 2/3 in progress, S-268019: Phase 2/3 in progress
  - In negotiation for partnering of S-217622
- Expanded indications for HISCL® TARC* reagent
- Launched LumiraDx SARS-CoV-2 Ag Test and LumiraDx Instrument
- Initiated sewage epidemiology surveillance service for detecting SARS-CoV-2
- In discussion with governments for stockpiling of influenza drugs

Generating new growth drivers

- Product introduction, M&A
- Aggressive investment for early expansion of new business
- Maximization of assets and franchises, consideration of partnering

- **Out-licensing agreement with ViiV for S-365598**
  - Upfront payment： £20M
  - Agreed on the same royalty levels in existing Integrase Inhibitors agreement by paying a certain development cost
- Milestone for Osphena® approval (Canada)
- Considering product introduction and M&A

Others

- One-time payment for the transfer of FORTAMET® ($ 18M)

Steady progress toward realization and expansion of new businesses

* TARC（thymus and activation-regulated chemokine）
One of the chemokines driving migration of Th2 cells, a type of lymphocyte, to the site of inflammation

Summary of the 1st Half

Results of the 1st Half

Smooth progress for COVID-19 projects, Core 8 projects

- Initiated Phase 2/3 trials of S-217622 and S-268019

Achievement for 1st half forecasts of revenue and each profit item

- Achievement for 1st half forecasts of domestic and overseas businesses

Creating value through new business opportunities

- Out-licensing agreement with ViiV for S-365598

Achieved the 1st half targets for revenue and profit items while aggressively investing to address the COVID-19 pandemic and to drive medium to long term growth

2. FY2021 Financial Forecasts

Major Changes from the Beginning of the 2nd half Earnings Forecast

Revenue

- **Increased sales in Western business**
  - Strong sales of cefiderocol
- **Decreased sales in China business**
  - Delay in contributing to sales using the online platform
- **Decreased sales in Influenza franchise**
  - Considering the current influenza pandemic situation
  - Recorded part of stockpile of Rapiacta® to the government in the 1st half

Selling general and administrative expenses, R&D expenses

- **Reduction of selling, general and administrative expenses by improving productivity**
- **Increased R&D expenses**
  - Active investment in focus areas including COVID-19

Revision of Earnings Forecast
（Announced on November 1, 2021）

(Unit: B yen)

	FY2021 Forcasts Full year			FY2021 Forecasts 2H			FY2020	Y on Y	
	Forecasts (May 10)	Forecasts (Revised on Nov. 1)	Revised amount	Forecasts (May 10)	Forecasts (Revised on Nov. 1)	Revised amount	Results	Change (%)	Change
Revenue	290.0	**294.0**	**4.0**	155.0	**148.9**	**(6.1)**	297.2	**(1.1)**	**(3.2)**
Operating profit	90.0	**90.0**	**-**	51.5	**47.3**	**(4.2)**	117.4	**(23.4)**	**(27.4)**
Core operating profit*	90.0	**90.0**	**-**	51.5	**46.1**	**(5.4)**	94.0	**(4.2)**	**(4.0)**
Profit before tax	115.0	**115.0**	**-**	66.5	**64.2**	**(2.3)**	143.0	**(19.6)**	**(28.0)**
Profit attributable to owners of parent	100.0	**100.0**	**-**	50.5	**46.9**	**(3.6)**	111.9	**(10.6)**	**(11.9)**

- **Achieve the full year forecasts and aim to further increase revenue and profits**
  - **leave profit items unchanged, since there are many uncertainties in the business environment**
  - **New business opportunities contribute to business performance**

Exchange Rate (average)	FY2021 Forecasts (May 10)	FY2021 Forecasts (Nov. 1)	FY2021 Apr.-Sep. results
USD ($) – JPY (¥)	105	110	109.82
GBP (£) – JPY (¥)	145	150	152.49
EUR (€) – JPY (¥)	128	130	130.89

* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

Revision of Earnings forecast Statement of Profit and Loss (Consolidated)

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(Unit: B yen)

	FY2021 Forecasts Full year			FY2021 Forecasts 2H			FY2020	Y on Y	
	Forecasts (May 10)	Forecasts (Revised on Nov. 1)	Revised amount	Forecasts (May 10)	Forecasts (Revised on Nov. 1)	Revised amount	Results	Change (%)	Change
Revenue	290.0	**294.0**	**4.0**	155.0	**148.9**	**(6.1)**	297.2	**(1.1)**	**(3.2)**
Cost of Sales	19.8 57.5	**19.4** **57.0**	**(0.5)**	21.0 32.5	**20.2** **30.0**	**(2.5)**	17.7 52.5	**8.5**	**4.5**
Gross profit	232.5	**237.0**	**4.5**	122.5	**118.9**	**(3.6)**	244.7	**(3.1)**	**(7.7)**
Selling, general& Administrative expenses	30.7 89.0	**30.3** **89.0**	**-**	29.0 45.0	**28.9** **43.1**	**(1.9)**	32.0 95.1	**(6.4)**	**(6.1)**
R&D expenses	17.9 52.0	**18.9** **55.5**	**3.5**	17.4 27.0	**18.3** **27.3**	**0.3**	18.3 54.2	**2.3**	**1.3**
Other income & expenses	(1.5)	**(2.5)**	**(1.0)**	1.0	**(1.1)**	**(2.1)**	22.1	**(111.3)**	**(24.6)**
Operating profit	31.0 90.0	**30.6** **90.0**	**-**	33.2 51.5	**31.8** **47.3**	**(4.2)**	39.5 117.4	**(23.4)**	**(27.4)**
Core operating profit	31.0 90.0	**30.6** **90.0**	**-**	33.2 51.5	**31.0** **46.1**	**(5.4)**	31.6 94.0	**(4.2)**	**(4.0)**
Finance income costs	25.0	**25.0**	**-**	15.0	**16.8**	**1.8**	25.6	**(2.3)**	**(0.6)**
Profit before tax	39.7 115.0	**39.1** **115.0**	**-**	42.9 66.5	**43.1** **64.2**	**(2.3)**	48.1 143.0	**(19.6)**	**(28.0)**
Profit attributable to owners of parent	100.0	**100.0**	**-**	50.5	**46.9**	**(3.6)**	111.9	**(10.6)**	**(11.9)**

Revision of Earnings Forecast Revenue by Segment

(Unit: B yen)

	FY2021 Forecasts Full year			FY2021 Forecasts 2H			FY2020	Y on Y	
	Forecasts (May 10)	Forecasts (Revised on Nov.1)	Revised amount	Forecasts (May 10)	Forecasts (Revised on Nov. 1)	Revised amount	Results	Change (%)	Change
Prescription drugs	94.4	**94.4**	-	48.3	**47.3**	**(1.0)**	94.7	**(0.3)**	**(0.3)**
Overseas subsidiaries/export	31.1	**35.0**	**3.8**	18.9	**17.5**	**(1.4)**	24.6	**41.8**	**10.3**
Shionogi Inc.	8.4	**12.7**	**4.3**	4.2	**4.8**	**0.6**	7.5	**70.1**	**5.2**
Ping An-Shionogi* /C&O	14.3	**12.3**	**(2.0)**	10.4	**7.6**	**(2.8)**	10.1	**22.3**	**2.2**
SBV(Europe)	3.5	**5.0**	**1.5**	2.1	**2.7**	**0.6**	2.0	**154.2**	**3.0**
Contract manufacturing	17.8	**17.8**	-	10.4	**9.5**	**(0.9)**	19.7	**(9.7)**	**(1.9)**
OTC and quasi-drug	15.4	**13.4**	**(2.0)**	8.6	**7.4**	**(1.2)**	11.7	**14.8**	**1.7**
Royalty income	129.8	**132.0**	**2.2**	68.1	**66.6**	**(1.5)**	144.6	**(8.8)**	**(12.7)**
HIV franchise	125.2	**125.2**	-	64.5	**64.0**	**(0.5)**	123.4	**1.5**	**1.9**
Crestor®	1.1	**-**	**(1.1)**	1.1	**-**	**(1.1)**	16.6	**-**	**(16.6)**
Others	3.5	**6.7**	**3.2**	2.6	**2.6**	**0.0**	4.7	**43.0**	**2.0**
Others	1.4	**1.4**	-	0.7	**0.7**	**(0.1)**	1.8	**(18.2)**	**(0.3)**
Total	290.0	**294.0**	**4.0**	155.0	**148.9**	**(6.1)**	297.2	**(1.1)**	**(3.2)**

* OTC and quasi-drugs also include in revenue of joint venture

Revision of Earnings Forecast Revenue of Prescription Drugs in Japan

	FY2021 Forecasts Full year			FY2021 Forecasts 2H			FY2020	Y on Y	
	Forecasts (May 10)	Forecasts (Revised on Nov.1)	Revised amount	Forecasts (May 10)	Forecasts (Revised on Nov.1)	Revised amount	Results	Change (%)	Change
Cymbalta®	15.1	**17.1**	**2.0**	5.1	**5.6**	**0.5**	26.5	**(35.3)**	**(9.3)**
Intuniv®	18.2	**16.6**	**(1.6)**	9.7	**9.0**	**(0.7)**	13.1	**27.3**	**3.6**
Vyvanse®	1.0	**1.0**	**-**	0.7	**0.7**	**0.1**	0.3	**288.1**	**0.8**
Infectious disease drugs	17.0	**16.6**	**(0.4)**	12.2	**10.9**	**(1.4)**	9.8	**70.4**	**6.9**
Influenza franchise	7.9	**7.9**	**-**	7.7	**6.4**	**(1.3)**	0.3	**-**	**7.6**
OxyContin® franchise	5.0	**5.0**	**-**	2.4	**2.5**	**0.1**	5.3	**(6.2)**	**(0.3)**
Symproic®	3.1	**3.1**	**-**	1.8	**1.9**	**0.0**	2.3	**37.4**	**0.8**
Actair®	0.4	**0.4**	**-**	0.2	**0.1**	**(0.1)**	0.3	**12.1**	**0.0**
Mulpleta®	0.1	**0.1**	**-**	0.1	**0.1**	**0.0**	0.1	**18.3**	**0.0**
Pirespa®	3.5	**3.5**	**-**	1.7	**1.5**	**(0.2)**	5.1	**(31.8)**	**(1.6)**
Others	30.9	**30.8**	**(0.0)**	14.4	**14.9**	**(0.5)**	32.0	**(3.5)**	**(1.1)**
Crestor®	6.5	**5.7**	**(0.8)**	2.7	**2.6**	**(0.1)**	6.7	**(14.5)**	**(1.0)**
Irbetan® franchise	3.1	**3.1**	**-**	1.4	**1.5**	**0.1**	3.3	**(7.7)**	**(0.3)**
Prescription drugs	94.4	**94.4**	**-**	48.3	**47.3**	**(1.0)**	94.7	**(0.3)**	**(0.3)**

(Unit: B yen)

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu・Neo
- FINIBAX®
- Flumarin®
- Flomox®
- Shiomarin®
- Vancomycin
- Baktar®
- Flagyl®
- Fluconazole
- ISODINE®

3. Actions for Future Growth

Shionogi's Actions for Total Care of COVID-19

SONG for you!

Epidemic forecasting

- Sewage epidemiology surveillance service for early detection of COVID-19 incursion and outbreak trends
  - **Conclude contracts with multiple local governments and expand services**
  - Under Discussion on business alliance with SHIMADZU that leverages the strengths of both parties

Prevention

- Development of a recombinant vaccine for COVID-19（**S-268019**）
  - **initiated Phase 2/3 trial (Oct. 20)**
  - Global Phase 3 trial planned
  - Planning booster test (Japan and Global)

Diagnosis

- Differential diagnosis: Antigen-test kit
- Severity prediction: Th2 chemokine TARC* kit for assisting in predicting exacerbations
- Shionogi discontinues efforts to commercialize by SATIC* method
  - Basic research continues in academia
  - Shionogi continues to hold licenses for the SATIC method

Treatment

- Discovery and development of novel antiviral drug（**S-217622**）
  - **Phase 2/3 trial in progress**
  - initiated discussions with FDA and EMA to conduct Global Phase 3 trial
- Discovery of developmental candidate peptide

Exacerbation suppression

- Licensing out asapiprant, an exacerbation controlling candidate
  - **Global phase 2 trial in progress**

Providing solutions for overwhelmed medical systems

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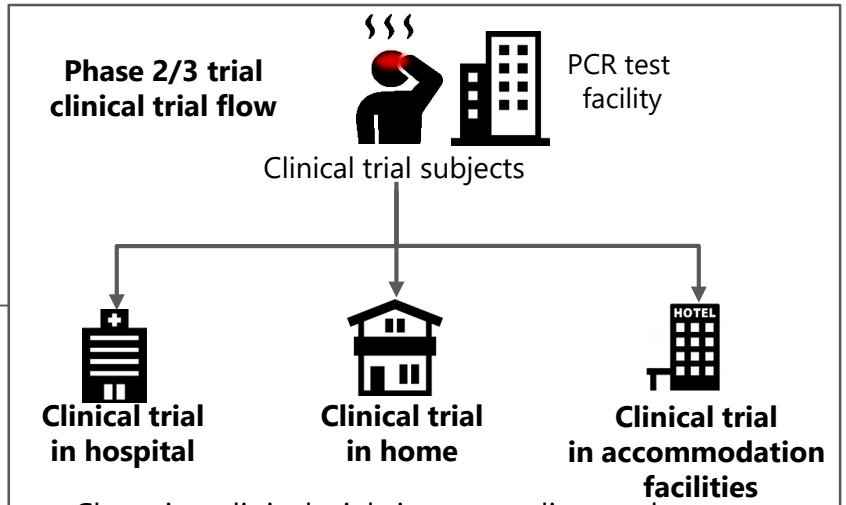
* SATIC ：Signal Amplification by Ternary Initiation Complexes

Action for COVID-19：S-217622

Development of oral therapeutic drugs (S-217622)

- **Result of phase 1 trial in japan**
  - Confirmed good safety and tolerability
  - The target drug plasma concentration required for the viral reduction effect (as predicted from non-clinical studies) was achieved by oral administration once a day for 5 days
- **Phase 2/3 trial**
  - Phase 2a part (primary endpoint is change in virus titer from baseline) in progress
    - > initiated clinical trials primarily at accommodation facilities in cooperation with local governments
    - > Conducting flexible clinical trials in response to changes in the external environment
  - **Opening overseas sites to accelerate recruitment and registration**
    - > Candidate counties are South Korea, Singapore, Vietnam, UK, etc.



- Changing clinical trial sites according to the status of medical institutions, the number of infected people, and the disease situation
- Telemedicine＋HNV*
- Ensuring sufficient response by investigative doctors and nurses outside hospital setting

* HNV： Home Nursing Visit （Home-visit nursing stations or home-visit doctors / home-visit nurses at home medical institutions provide visit support at the subject's home）

Action for COVID-19 : S-217622

Development of oral therapeutic drugs (S-217622)

- **Global Phase 3 trial**
  - In discussions with FDA and EMA to initiate the global Phase 3 trial
- **Supply preparation**
  - Smooth progress toward completion of domestic supply preparation by the end of 2021
- **Partnering**
  - Currently negotiating with multiple companies
  - Prioritize companies that can generate synergies in launch speed and global production and supply

Phase 2/3 trial drug of S-217622

Action for COVID-19：S-268019

Development of recombinant protein vaccine(S-268019)

Summary of Phase 1/2 trial dosing with new adjuvant

：Detailed results will be disclosed at the Japan Society for Vaccinology (December 4, 2021)

Completion of Day 50 observation of all 60 subjects

- **Tolerability, Safety**
  - Confirmed tolerability and absence of major safety issues
- **Immunogenicity**
  - Confirmed increase in neutralizing antibody titer equal to or higher than that of convalescent serum

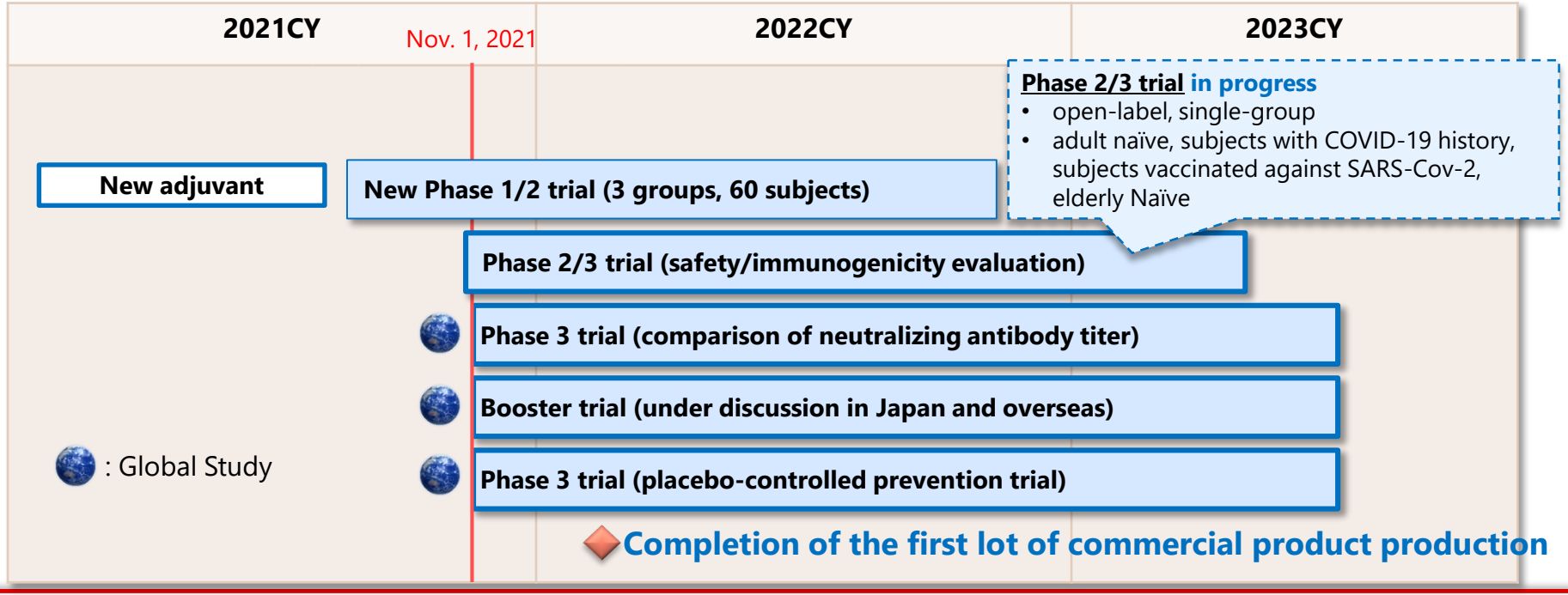
Based on the above results, domestic phase 2/3 trial initiated on October 20

⇒ Recruitment of clinical trial participants has proceeded very well (Scheduled to complete recruitment in early November 2021)

Action for COVID-19 : S-268019

Development of recombinant protein vaccine（S-268019）

Aim to begin pivotal trials within the year and supply by next March



Phase 1/2 studies are supported by AMED under Grant Number JP21nf0101626

Action for COVID-19：S-268019

Clinical Efficacy Trial

- **Placebo controlled onset prevention trial**
  - Scheduled to be implemented mainly in Asia, using the onset prevention effect, which is the true endpoint, as an evaluation index
- **Phase 2/3 trial**
  - Accumulation of unvaccinated subjects mainly in Japan
    - > Initiated from October 20, 2021, and the accumulated more than 3,000 cases (including about 100 cases each for the elderly, vaccinated subjects, and subjects with COVID-19 history)
  - Assessing safety and immunogenicity
- **Active Control Neutralizing Antibody Comparative Study Alternative trial**
  - Adjustments at ICMRA* have begun, and the direction was agreed on the comparison with the approved vaccine when using the neutralizing antibody titer as an index

Future Topics of Discussion

- **Safety evaluation in Japanese**
  - Implementation of long-term safety monitoring using the app after launch
  - Evaluation of safety information at the time of booster vaccination
    - > Comparison of safety assessment with RNA vaccine in exploratory booster trial in Japanese
- **Realization of “100 DAYS MISSION”**
  - Be prepared for any pandemic, beyond COVID-19
    - > Importance of developing organizational capability as country

* ICMRA：International Coalition of Medicines Regulatory Authorities

Initiatives to Strengthen Domestic and Overseas Businesses

Domestic business

- **Executing our disease strategy**
  - Dissemination of product and disease information to local and national areas by hospital medical representatives
  - Cooperation between Pharmaceutical Commercial Division and Integrated Disease Care Division
- **ADHD franchise, Influenza franchise**
  - Increase Intuniv® prescriptions for adult patients by strengthening information provision to psychiatrists
  - Activities to prepare for influenza outbreaks

Overseas business

- **US and Europe**
  - **Cefiderocol**
    - > Continue efforts to maximize value in the US and Europe
    - > Implementing access framework for low- and middle-income countries
- **China**
  - **Ping An-Shionogi**
    - > Increase sales via online medical platform
    - > Focus on activities for early launch of new drugs
    - > Expansion of research approaches utilizing AI technology

Achieving top-line growth through an optimal strategy for each region

Progress of HIV franchise by ViiV Healthcare

Actions to maximize value with two-drug regimens and long-acting regimens

Dovato (DTG/3TC*)

CABENUVA (CAB/RPV**)

Dovato

- Switch share expansion in EU and US
  - Leading share of switch in EU
  - Confirmed long-term effectiveness and safety that reinforce switching
    - 144 weeks data in TANGO study
- On track to reach>£1bn in 2022 with further potential

CABENUVA cabotegravir

- Treatment
  - >80% market access in the US
  - >2,000 PLHIV*** taking Cabenuva
  - Potential US approval of 2-monthly dosing; launch early 2022
- PrEP
  - FDA Priority Review granted for cabotegravir LA
  - PDUFA action date of 23 January 2022

S-365598

- Characteristics
  - 3rd gen integrase strand transfer inhibitor (INSTI)
  - Potential for ultra long dose intervals (3 months+)
  - Excellent resistance profile
- Phase 1 trial scheduled to initiate by 2023

TANGO study: designed to compare switching to Dovato versus TAF****-based regimen

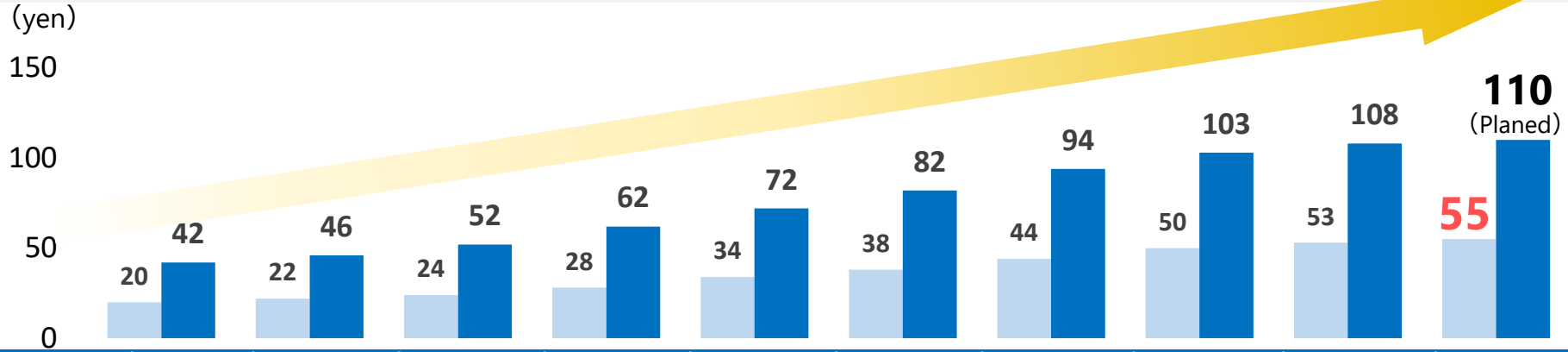
Continue commitment to HIV to secure medium- to long-term growth drivers

* DTG/3TC: dolutegravir/lamivudine, ** CAB/RPV: cabotegravir/rilpivirine, *** PLHIV: patient living with HIV, ****TAF: tenofovir alafenamide

4. Shareholder Return

Flexible and Prompt Capital Strategy

- **Shareholder return policy through which shareholders can feel our growth**
  - ➢ Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
  - ➢ **Plan to increase dividend again** in FY2021 **for the tenth consecutive year**

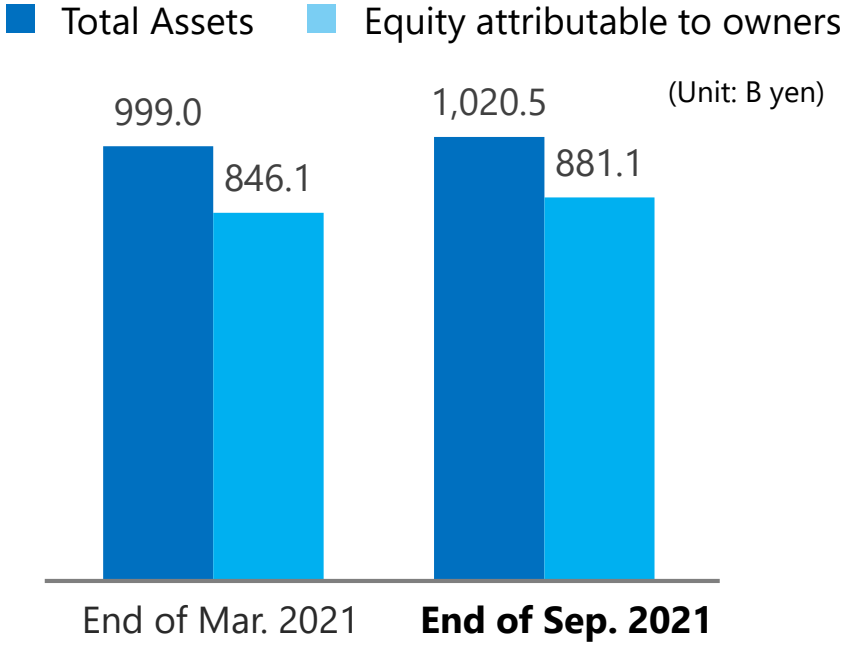


FY	12	13	14	15	16	17	18	19	20	21
Treasury stocks Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	
Treasury stocks Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	
DOE (%)	3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	over4.0 (Predict)
ROE (%)	17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	over11.5(Predict)

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020
Values calculated based on IFRS after 2019

Appendix

Financial Position (Consolidated, IFRS)

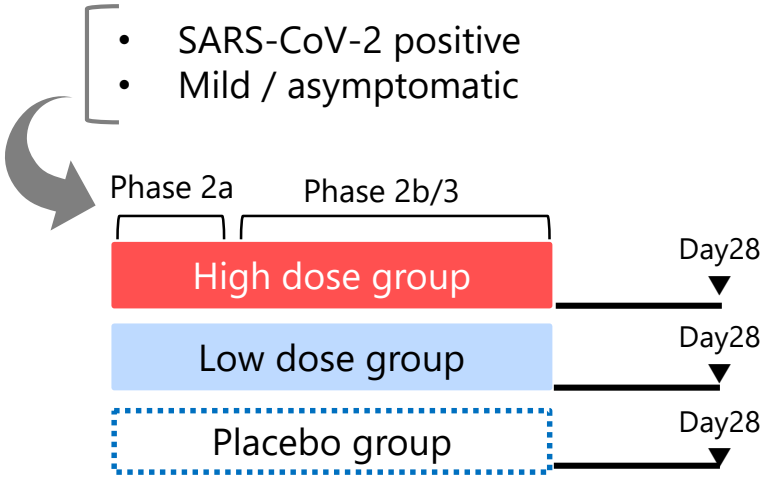


	End of Mar. 2021	End of Sep. 2021
Ratio of equity attributable to owners of parent to total assets	84.7%	**86.3%**

Unit: B yen		End of Mar. 2021	End of Sep. 2021	Change
Total Assets	Non-current Assets	442.8	438.5	(4.2)
	Current Assets	556.2	581.9	25.7
Equity attributable to owners of parent		846.1	881.1	35.0
Total Liabilities	Non-current Liabilities	34.3	31.7	(2.6)
	Current Liabilities	100.2	89.9	(10.3)

S-217622: Design of Domestic Phase 2/3 Trial

Study title	A Phase 2/3 Trial of S-217622 in Participants Infected with SARS-CoV-2
subject	Asymptomatic or mild COVID-19 patients
Clinical trial design	Multicenter, randomized, double-blind, placebo-controlled study
Treatment group	High dose group, low dose group, placebo
Primary endpoint	Phase 2a: Change in virus titer from baseline Phase 2b/3: Mild: Time to resolution of COVID-19 symptoms, Asymptomatic: Proportion of participants with occurrence of COVID-19 symptoms
Dosage	Oral administration, once a day for 5 days (tablet)
Number of subject*	Total about 2,100 subjects



SHIONOGI

* Number of subject is TBD

jRCT：2031210350（https://jrct.niph.go.jp/latest-detail/jRCT2031210350）

S-268019: Design of Phase 2/3 Trial in Japan

Clinical trial design	Open label, single group
Subject	Japanese healthy adult men and women (20 years old and over)
Main purpose	Safety
Secondary purpose	Immunogenicity (neutralizing antibody titer, IgG antibody titer, cell-mediated immunity)
Target number of subjects	3,100 subjects
Dosing regimen	Intramuscular injection, 2 inoculations (Day 1 and Day 29)
Trial period	October 2021-December 2022

jRCT：2031210383（https://jrct.niph.go.jp/latest-detail/jRCT2031210383）

Statement of Profit or Loss (Consolidated)

(Unit: B yen)

	FY2021				FY2020	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year	1H					
Revenue	290.0	135.0	**145.1**	**107.5**	148.5	**(2.3)**	**(3.4)**
Cost of sales	19.8 57.5	18.5 25.0	18.6 **27.0**	**107.9**	15.4 22.9	**18.1**	**4.1**
Gross profit	232.5	110.0	**118.1**	**107.4**	125.6	**(6.0)**	**(7.5)**
Selling, general & administrative expenses	30.7 89.0	32.6 44.0	31.6 **45.9**	**104.3**	30.2 44.8	**2.5**	**1.1**
R&D expenses	17.9 52.0	18.5 25.0	19.4 **28.2**	**112.7**	16.7 24.9	**13.4**	**3.3**
Other income & expenses	(1.5)	(2.5)	**(1.4)**	**54.9**	2.3*	**(159.7)**	**(3.7)**
Operating profit	31.0 90.0	28.5 38.5	29.4 **42.7**	**110.8**	39.2 58.3	**(26.8)**	**(15.6)**
Core operating profit**	31.0 90.0	28.5 38.5	30.2 **43.9**	**113.9**	37.6 55.8	**(21.4)**	**(12.0)**
Finance income & costs	25.0	10.0	**8.2**	**81.7**	11.9	**(31.3)**	**(3.7)**
Profit before tax	39.7 115.0	35.9 48.5	35.0 **50.8**	**104.8**	47.3 70.1	**(27.5)**	**(19.3)**
Profit attributable to owners of parent	100.0	49.5	**53.1**	**107.3**	52.3	**1.5**	**0.8**

Main Variation Factors (Year-on-Year Comparison)

- **Revenue**
  - Increase: Overseas subsidiaries/export, contract manufacturing and OTC and quasi-drug
  - Decrease: Royalty income (mainly Crestor®)
- **Cost of sales**
  - Increase: Increase in revenue other than royalty income (about 8.6 billion yen)
    : Product mix due to growth in overseas subsidiaries/export and contract manufacturing
- **Selling, general & administrative expenses**
  - Increase: Launch and sales activity costs of Fetroja® and Fetcroja®
- **R&D expenses**
  - Increase: Accelerating of R&D activities centered on COVID-19 related (S-268019, S-217622) and 8 core projects
- **Other income & expenses**
  - Decrease in income: Recognized gain on step acquisitions for Tetra in 1Q of the previous year
- **Finance income & costs**
  - Decrease in income: Dividend from ViiV
- **Profit attributable to owners of parent**
  - Increase: Received a refund regarding a favorable Judgement on the complaint for the rescission of tax reassessment by Osaka Regional Taxation Bureau

* The provisional accounting for business combinations with Tetra was finalized in FY2020, the financial results for 1H of previous fiscal year have been retroactively adjusted

** Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

Revenue by Segment

(Unit: B yen)

	FY2021 Forecasts Full year	FY2021 Forecasts 1H	FY2021 1H results	FY2021 Achievement (%)	FY2020 1H results	Y on Y Change (%)	Y on Y Change
Prescription drugs	94.4	46.1	**47.1**	**102.2**	47.2	**(0.0)**	**(0.0)**
Overseas subsidiaries/export	31.1	12.2	**17.4**	**142.7**	11.0	**58.2**	**6.4**
Shionogi Inc.	8.4	4.2	**7.9**	**186.8**	3.3	**135.7**	**4.5**
Fetroja®	-	-	**2.9**	**-**	0.4	**573.3**	**2.4**
Ping An-Shionogi* /C&O	14.3	3.9	**4.7**	**121.5**	4.2	**10.9**	**0.5**
SBV(Europe)	3.5	1.4	**2.3**	**163.1**	0.7	**207.0**	**1.5**
Contract manufacturing	17.8	7.4	**8.4**	**112.7**	6.7	**25.1**	**1.7**
OTC and quasi-drug	15.4	6.9	**6.0**	**88.1**	5.5	**10.3**	**0.6**
Royalty income	129.8	61.7	**65.4**	**106.0**	77.3	**(15.5)**	**(11.9)**
HIV franchise	125.2	60.8	**61.2**	**100.8**	63.9	**(4.2)**	**(2.7)**
Crestor®	1.1	-	**-**	**-**	11.1	**-**	**(11.1)**
Others	3.5	0.9	**4.1**	**447.1**	2.3	**82.5**	**1.9**
Others	1.4	0.7	**0.8**	**108.5**	0.8	**(5.4)**	**(0.0)**
Total	290.0	135.0	145.1	**107.5**	148.5	**(2.3)**	**(3.4)**

Main Variation Factors (Year-on-Year Comparison)

- **Prescription drugs**
  - Increase: Sales of Intuniv®
  - Increase: Provided part of stockpile of Rapiacta® to the government ahead of schedule
  - Decrease: Sales of Cymbalta®
- **Overseas subsidiaries/export**
  - US: Increase: Sales of Fetroja®
  - : Increase: Received a one-time payment for the transfer of FORTAMET® sales rights, etc.
  - EU: Increase: Sales of Fetcroja®
- **Contract manufacturing**
  - Increase: The acquisition of Nagase Medicals as a consolidated subsidiary**
- **OTC and quasi-drug**
  - Increase: Sales of SEDES® and RINDERON®
- **Royalty income**
  - Increase: Out-licensing agreement with ViiV for S-365598
  - Decrease: Royalty income of Crestor® from Jan. 2021 based on the contract
  - Decrease: Exchange rate impact on royalty income from HIV franchise (£/$)

* OTC and quasi-drugs also include in revenue of joint venture
** From 3Q of the previous year

Pipeline: Infectious Disease

as of Nov. 1, 2021

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-872600 Influenza prophylactic vaccine		**S-217622*** Up COVID-19 treatment **S-268019*** Up COVID-19 Prophylactic vaccine	**cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Xofluza®** Influenza virus infection (Granules, < 20 kg)

* Phase 2/3

: Global development

Out license

Phase 2	Phase 3	Submission
S-365598 Up HIV infection	**S-555739** Treatment by suppressing aggravation of COVID-19	**cabotegravir LAP** Prophylaxis of HIV infection **Xofluza®** Influenza virus infection (Pediatric, < 1 year old) **Xofluza®** Influenza virus infection (Transmission)	**Xofluza® (US)** Influenza virus infection (Pediatric, over 1 year old)

Stage change (Changes from Aug. 2, 2021)
S-217622 (COVID-19 Treatment) : Phase 2/3 start (Japan) S-268019 (COVID-19 Prophylactic vaccine) : Phase 2/3 start (Japan) S-365598 (HIV infection) : Out license S-648414 (HIV infection) : Closed

Pipeline: Psycho-neurological Disease

as of Nov. 1, 2021

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-874713 Psycho-neurological diseases	**S-600918 [sivopixant]** Neuropathic pain	**S-812217 [zuranolone]** Depression	**S-600918 [sivopixant]** Refractory chronic cough	
S-872881 Alzheimer's dementia	**S-010887** Neuropathic pain	**S-600918 [sivopixant]** Refractory chronic cough	**Rizmoic®*** Opioid-induced constipation(pediatric)	
S-109802 Post-stroke spasticity	**S-120083** Inflammatory pain	**S-600918 [sivopixant]** Sleep Apnea Syndrome	**S-120083** Inflammatory pain	
	S-117957 Insomnia	**BPN14770 [zatolmilast]** Alzheimer's disease	**BPN14770 [zatolmilast]** Alzheimer's disease	
		S-637880 Neuropathic low back pain	**BPN14770 [zatolmilast]** Fragile X Syndrome	
		SDT-001 Inattentive ADHD (pediatric)		

* Phase 1/2

Out license

** Preparing for application

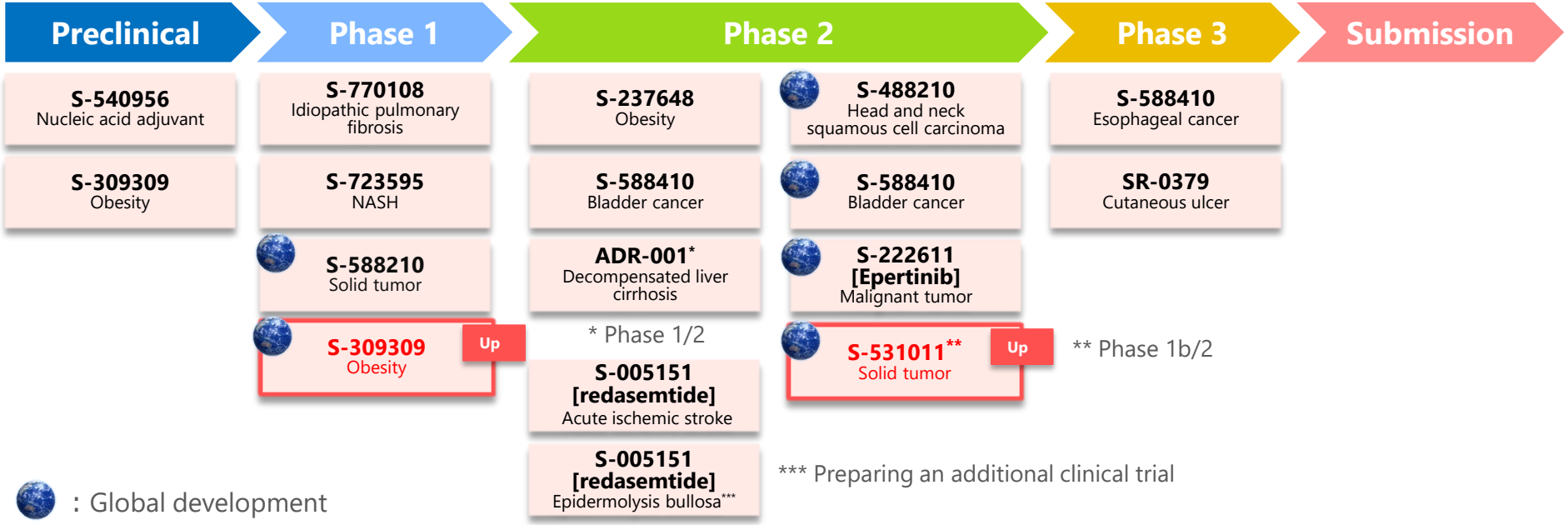
S-0373[rovatirelin]**
Spinocerebellar Degeneration

: Global development

SHIONOGI : Progress from Aug. 2, 2021 to Nov. 1, 2021

Pipeline: New Growth Area

as of Nov. 1, 2021



* Phase 1/2

** Phase 1b/2

*** Preparing an additional clinical trial

: Global development

Stage change (Changes from Aug. 2, 2021)
S-309309 (Obesity): Phase1 start (USA) S-531011 (Solid tumor): Phase 1b/2 start (Japan,USA)

: Progress from Aug. 2, 2021 to Nov. 1, 2021

Other Major Progress in Q2 FY2021*

- **August**
  - Completion of the First Term of the Mother to Mother Project in Illaramatak, Narok County, Kenya with Transfer of a Health Facility to the County Government
  - Selected for the Global ESG Investment Index 'FTSE4Good Index Series' and 'FTSE Blossom Japan Index', for the second consecutive year
- **September**
  - Agreement with AVITA for a Capital and Business Alliance to provide new solutions utilizing robots in the medical and welfare fields
- **October**
  - Conclude a Memorandum of Understanding (MOU) with Hitachi ** for the Medium- to Long-Term Strategic Partnership for Shionogi Group IT Operations

* Progress from Aug. 3, 2021to Nov. 1. 2021
** Hitachi, Ltd. and Hitachi Pharma Information Solutions, Ltd.

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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