



1st Quarter of Fiscal 2021 Financial Results

Conference Call

August 2, 2021
Shionogi & Co., Ltd.



Agenda



- 1. Overview of Q1 FY2021 Financial Results (P.3-9)**
- 2. Main Activities and Achievements in Q1 FY2021(P.10-19)**

1. Overview of Q1 FY2021 Financial Results

Financial Results (Consolidated)



(Unit: B yen)

	FY2021		FY2020		Y on Y		
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change
	Full year	1H					
Revenue	290.0	135.0	69.0	51.1	71.4	(3.4)	(2.4)
Operating profit	90.0	38.5	18.8	48.8	28.6	(34.2)	(9.8)
Core operating profit*	90.0	38.5	19.4	50.3	25.9	(25.0)	(6.5)
Profit before tax	115.0	48.5	22.9	47.3	33.0	(30.5)	(10.1)
Profit attributable to owners of parent	100.0	49.5	32.2	65.1	24.5	31.6	7.7

- **Revenue and profit at each level is in line with the forecast for 1H**

- Continued to actively invest primarily in European launches of cefiderocol and in projects related to COVID-19

- **Profit attributable to owners of parent was higher than the same period actuals a year earlier**

- Reflecting a refund resulting from finally prevailing in court regarding cancellation of correction disposition from Osaka Regional Taxation Bureau

Exchange Rate (average)	FY2021 forecasts	FY2021 Apr.-Jun. results
USD (\$) – JPY (¥)	105	109.52
GBP (£) – JPY (¥)	145	153.20
EUR (€) – JPY (¥)	128	131.94

Statement of Profit or Loss (Consolidated)



(Unit: B yen)

	FY2021		FY2020		Y on Y		
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change
	Full year	1H					
Revenue	290.0	135.0	69.0	51.1	71.4	(3.4)	(2.4)
Cost of sales	19.8	18.5	17.9		16.1		
	57.5	25.0	12.3	49.3	11.5	7.3	0.8
Gross profit	232.5	110.0	56.6	51.5	59.9	(5.5)	(3.3)
Selling general & administrative expenses	30.7	32.6	32.7		30.4		
	89.0	44.0	22.6	51.3	21.7	4.1	0.9
R&D expenses	17.9	18.5	21.4		17.0		
	52.0	25.0	14.7	58.9	12.2	21.1	2.6
Other income & expenses	(1.5)	(2.5)	(0.5)	21.7	2.5*	(121.6)	(3.0)
Operating profit	31.0	28.5	27.3		40.0		
	90.0	38.5	18.8	48.8	28.6	(34.2)	(9.8)
Core operating profit**	31.0	28.5	28.1		36.2		
	90.0	38.5	19.4	50.3	25.9	(25.0)	(6.5)
Finance income & costs	25.0	10.0	4.1	41.5	4.4	(6.7)	(0.3)
Profit before tax	39.7	35.9	33.3		46.2		
	115.0	48.5	22.9	47.3	33.0	(30.5)	(10.1)
Profit attributable to owners of parent	100.0	49.5	32.2	65.1	24.5	31.6	7.7

Main Variation Factors (Y on Y)

- Revenue**
 - Increase in sales of prescription drugs and overseas subsidiary/export
 - Decrease in royalty income (mainly Crestor®)
- Cost of sales**
 - Increased due to the acquisition of Nagase Medicals (contracted manufacturing) as a consolidated subsidiary in 3Q of the previous year
- Selling general & administrative expenses**
 - Increase in preparation for launch and sales activity costs for Fetrocja® in Europe
- R&D**
 - Accelerating of R&D activities centered on COVID-19 vaccine (S-268019), COVID-19 therapeutic drugs and 8 core projects
- Other income & expenses**
 - Recognized gain on step acquisitions for Tetra in 1Q of the previous year (about 2.9 B yen)
 - Interest on refund from Osaka Regional Taxation Bureau (about 0.9 B yen)
- Profit attributable to owners of parent**
 - Received a refund regarding a favorable Judgement on the complaint for the rescission of tax reassessment by Osaka Regional Taxation Bureau (about 13.5 billion yen)

* The provisional accounting for business combinations with Tetra was finalized in FY2020, the financial results for 1Q 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		FY2020		Y on Y		
	Forecasts		Apr.-Jun. Achieve results ment (%)	Apr.-Jun. results	Change (%)	Change	
	Full year	1H					
Prescription drugs	94.4	46.1	23.5	50.9	22.4	5.1	1.1
Overseas subsidiaries/export	31.1	12.2	9.3	76.2	5.5	70.0	3.8
Shionogi Inc.	8.4	4.2	4.7	111.5	1.7	182.7	3.0
Fetroja®	-	-	1.2	-	0.1	835.9	1.1
Ping An-Shionogi* /C&O	14.3	3.9	2.4	60.8	2.4	0.2	0.0
SBV(Europe)	3.5	1.4	0.9	63.7	0.4	144.1	0.5
Contract manufacturing	17.8	7.4	3.7	50.5	2.9	30.2	0.9
OTC and quasi-drug	15.4	6.9	2.5	36.0	2.3	9.0	0.2
Royalty income	129.8	61.7	29.6	48.0	38.0	(22.1)	(8.4)
HIV franchise	125.2	60.8	28.8	47.5	31.0	(6.8)	(2.1)
Crestor®	1.1	-	-	-	5.6	-	(5.6)
Others	3.5	0.9	0.8	84.4	1.5	(47.4)	(0.7)
Others	1.4	0.7	0.4	51.4	0.4	(17.3)	(0.1)
Total	290.0	135.0	69.0	51.1	71.4	(3.4)	(2.4)

Main Variation Factors (Y on Y)

- **Prescription drugs**
 - Increase in sales of Intuniv®
- **Overseas subsidiaries/export**
 - US : Increase in sales of Fetroja®
 - : Received a one-time payment for the transfer of FORTAMET® sales rights, etc.
 - EU : Increase in sales of Fetcroja®
- **Contract manufacturing**
 - Revenue on Nagase Medicals consigned manufacturing
- **OTC and quasi-drug**
 - Increase in sales of SEDES® and RINDERON®
 - > vs. forecasts for 1H : weak sales trends for ISODINE®
- **Royalty income**
 - Exchange rate impact on royalty income from HIV franchise (£/\$)
 - Decrease in income due to sales trends by country
 - Decrease in royalty income of Crestor® from Jan. 2021 based on the contract

Revenue of Prescription Drugs in Japan



(Unit: B yen)

	FY2021				FY2020		Y on Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change	
	Full year	1H						
Cymbalta®	15.1	10.0	6.8	68.1	6.9	(1.5)	(0.1)	
Intuniv®	18.2	8.5	3.6	42.0	2.6	37.3	1.0	
Vyvanse®	1.0	0.4	0.1	37.3	0.0	436.2	0.1	
Infectious disease drugs	17.0	4.8	2.1	43.9	2.1	(1.6)	(0.0)	
Influenza franchise	7.9	0.2	0.0	19.6	0.0	290.0	0.0	
OxyContin® franchise	5.0	2.6	1.3	48.1	1.4	(8.9)	(0.1)	
Symproic®	3.1	1.3	0.6	46.1	0.5	24.8	0.1	
Actair®	0.4	0.2	0.1	58.8	0.1	79.1	0.0	
Mulpleta®	0.1	0.1	0.0	46.0	0.0	18.0	0.0	
Pirespa®	3.5	1.8	1.0	54.2	1.4	(32.2)	(0.5)	
Others	30.9	16.4	7.9	47.8	7.3	8.1	0.6	
Crestor®	6.5	3.8	1.4	37.8	1.5	(7.7)	(0.1)	
Irbetan® franchise	3.1	1.7	0.8	47.1	0.8	(7.3)	(0.1)	
Prescription drugs	94.4	46.1	23.5	50.9	22.4	5.1	1.1	

<Products included in infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu·Neo

- FINIBAX®
- Flumarin®
- Flomox®

- Shiomarin®
- Vancomycin
- Baktar®

- Flagyl®
- Fluconazole
- ISODINE®

Summary of 1st Quarter



Smooth progress in domestic and overseas business

- Growth of Intuniv[®] and cefiderocol

Making progress in activities for total care of COVID-19

- Vaccines
- Therapeutic drugs
- Sewage epidemiology
- Diagnostic products

Active investment in growth drivers

- COVID-19
- 8 Core projects
- Cefiderocol

1H & FY2021 Earnings Forecasts



Making smooth progress toward achieving the 1H forecast

- **Revenue progressed 51.1% compared to 1H forecast**
 - Favorable progress was made in domestic and overseas business
 - Continuing to implement cost management through cost structure reforms
- ⇒ **Considered possibility of upward revision based on 1H, but not revising at present**

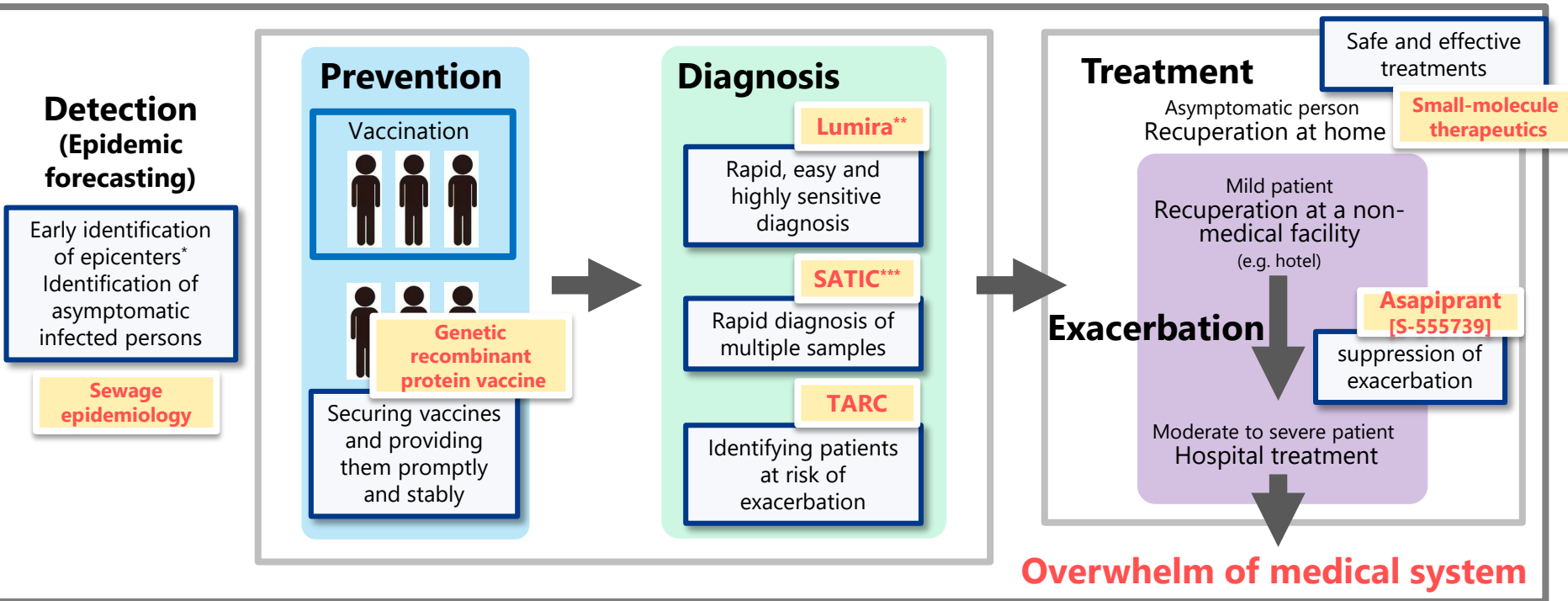
In parallel with focusing resources on providing solutions for COVID-19, achieve growth in revenue and profits by attaining FY2021 earnings forecast through strengthening existing businesses and establishing and growing new businesses

Making smooth progress toward the realization/expansion of new businesses

- **New business opportunities in FY2021**
 - Providing COVID-19 related products and services
 - Changes in each country's response to prepare for emergencies such as flu and AMR, etc.
 - Product introduction, M&A
 - Aggressive investment for early expansion of new business
 - Maximization of assets and franchises, consideration of partnering
- ⇒ **The above business opportunities, which are not factored into forecasts, are progressing as planned**

2. Main Activities and Achievements in Q1 FY2021

Providing solutions for the overwhelmed medical system



* Epicenter: A center where many infected people gather and a large amount of virus is continuously shed

** Joint Sales with LumiraDx Japan Co., Ltd

*** SATIC : Signal Amplification by Ternary Initiation Complexes

Action for COVID-19 1/5



Development of recombinant protein vaccine

Change adjuvant to accelerate development

Current formulation	New formulation
Antigen	Antigen
Current adjuvant	New adjuvant

Background on selection of initial adjuvant

- Considering the importance of Th1>Th2 type balance from research results on SARS* and MERS*²
 - Nonclinical data
 - Increased neutralizing antibody titer
 - Clear prevention of lethal exacerbations
- ⇒ Considering the clinical administration results, emphasis is placed on the Th1>Th2 balance

Result

- <Clinical data>
- Conducted clinical trials with a wide range of doses
 - No safety issue at any dose
 - A certain induction of cell-mediated immunity was confirmed
 - However, the neutralizing antibody titer was not high
- <Nonclinical data>
- Neutralizing antibody titer increased significantly in the new formulation with modified adjuvant compared with initial formulation (next page)

Consideration

- **Accumulation of evidence balancing the importance of cell-mediated immunity with the high correlation between neutralizing antibody titer and prevention of the onset of infection**
 - Although it will take some time to establish an internationally recognized standard, a certain increase in the neutralizing antibody titer is essential for a priming vaccine
 - There are few reports of VDE/ADE so far with approved vaccines, but the Th1>Th2 balance is important
- ⇒ **Need to switch to an adjuvant that can achieve higher neutralizing antibody titer induction while avoiding VDE/ADE risk**

Action for COVID-19 2/5



Development of recombinant protein vaccine

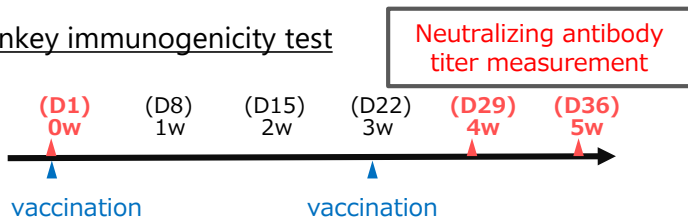
Reexamine with a combination of various adjuvants

- Monkey immunogenicity test
 - 2 vaccinations (3 weeks intervals)
 - Measure neutralizing antibody titers 29 and 36 days after vaccination
 - Very high correlation with clinical data accumulated so far

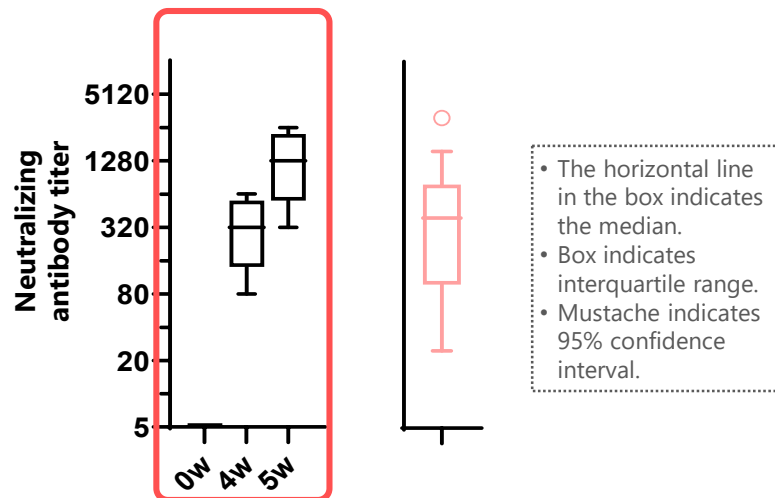
Design of monkey immunogenicity test



Macaque
N=4/group



New formulation



New formulation
clinical equivalent
(N=4/group)

Estimated value
of convalescent
serum* (N=59)

Confirmed higher neutralizing antibody titer compared to the prior formulation (Similar to recovered patient serum)



Development of recombinant protein vaccine

- **The new formulation can be expected to higher neutralizing antibody titer induction in humans while avoiding VDE/ADE risk**
 - Good data confirmed in immunogenicity tests using monkey models well correlated with humans
 - › High neutralizing antibody titer (equal to or better than recovery patient serum)
 - › Expect to maintain a favorable Th1>Th2 type balance

• Domestic clinical trial plan using new formulation

- Initiated Phase 1/2 trial (July 2021)
 - › Consider reducing the amount of antigen
- Immediately shift to the next phase after the above trial
 - › Scheduled to evaluate safety and efficacy in around 3,000 cases

• Aim to begin pivotal trials within the year with data by next March

- Preparing a comparative study with an approved vaccine based on discussions at ICMRA*
- In addition to the above, preparing a placebo controlled trial in Asia and Africa
- Continued discussions with regulators and ministries for domestic provision based on the earliest pivotal trial results
- Production capacity is in preparation



Development of therapeutic drugs with superior efficacy and safety

- **COVID-19 therapeutic drugs (S-217622) initiated phase 1 trial in Japan**
 - In-house created small molecule **oral antiviral drug, 3CL protease inhibitor**
 - › Efficacy: Rapid and statistically significant reduction in viral load in nonclinical studies
 - › Safety: there are no major safety concerns so far
 - › **Does not require PK booster***
- Efforts for early provision
 - **Plan to start large-scale clinical trials in Japan by the end of the year**
 - › Discussions with regulators and ministries for domestic provision
 - **Preparing for global development**
 - **Preparing production capacity**

Aiming for early provision of safe and easy-to-use therapeutic drugs to bring the pandemic situation to a close



Diagnostic markers that can predict exacerbation

- **HISCL® TARC*** reagent
 - Approved for an additional indication (June 7, 2021) as an auxiliary for detection of COVID-19 aggravation; launched with insurance coverage (June 11, 2021)
 - Conduct clinical research post-marketing to accumulate additional evidence



Rapid and highly sensitive antigen test

- **LumiraDx SARS-CoV-2 Ag Test and LumiraDx Instrument**
 - Launched at the end of May 2021
 - Going forward, planning for the broad application of the same device for the diagnosis and monitoring of other infections and diseases



Establishment of analysis system for SARS-CoV-2 in sewage

- **Initiated sewage epidemiology surveillance service for detecting SARS-CoV-2**
- **Concluded the basic agreement for business partnership to support early implementation**
- **In discussions with several municipalities to expand services**
 - Launched in June 2021

R&D Progress : 8 Core Projects



	Pipeline	Indication	現状
Infectious disease	S-540956	HIV infection, cancer	Preparing Phase 1 study
Psycho-neurological diseases	S-600918 [sivopixant]	①Refractory chronic cough ②sleep apnea syndrome	①Phase 2b study in progress ②Phase 2a study in progress
	S-637880	Neuropathic low back pain	Phase 2a study in progress
	S-812217 [zuranolone]	Depression	Phase 2b study in progress
	BPN14770 [zatolmilast]	①Alzheimer's disease ②Fragile X Syndrome	①Phase 2 study in progress ②Preparing Phase 2b and Phase 3 study (US)
	S-874713	Psycho-neurological diseases	Preparing Phase 1 study
New growth areas	S-531011	Solid tumor	Preparing Phase 1b/2 study
	S-005151 [redasemtide]	①Epidermolysis bullosa ②Acute stroke ③Osteoarthritis ④Chronic liver disease	①Preparing for application ②Phase 2 study in progress ③④Investigator initiated clinical trial (Phase 2 trial) in progress

**Steady progress of 8 core projects and COVID-19 project
(Details to be reported at R&D day on Sep. 29, 2021)**

Domestic business

- **2 strategic products contribute to top line growth**
 - **Cymbalta®**
 - › Continue to introduce resources to realize sustainable stable supply given the various changes in social conditions
 - **Intuniv®**
 - › Growth in the pediatric field
 - › Progression of efforts to expand the adult domain
- **Improve productivity by reorganizing domestic operations**
 - Ripple effect to regions and nationwide by strengthening hospital business

Overseas business: Acceleration of US, European and Chinese business

- **Cefiderocol**
 - Strong uptake of cefiderocol in US and Europe
 - Implementing initiatives to improve access to cefiderocol in low- and middle-income countries*
- **Ping An-Shionogi**
 - Expanding product range for sale on online platform "Ping An Good Doctor"
 - Acceleration of data-driven drug discovery and development utilizing Real World Data (RWD) collection and analysis research

Driving Growth of HIV Franchise with ViiV



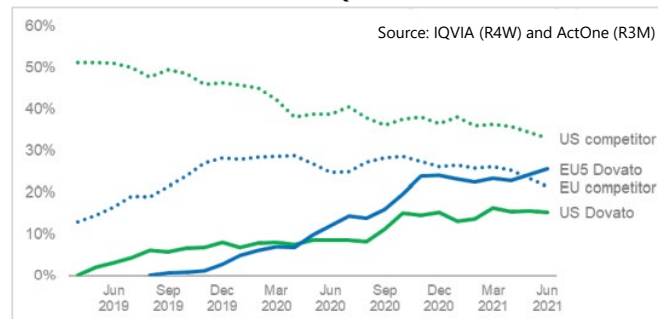
Driving growth through market penetration of Dovato and Cabenuva



- **Dovato and Cabenuva drive growth**
 - ViiV expects mid-single digit sales CAGR through 2026
- **Cabenuva**
 - Strong interest by HCPs and proactive approach to expand long-acting treatment
 - › CUSTOMIZE study has shown Cabenuva can be successfully implemented in a broad range of US healthcare practices, even during COVID-19 pandemic
 - ViiV anticipates approval of two-monthly dosing in the US by year-end with launch in early 2022
- **Cabotegravir (PrEP)**
 - Submitted NDA in the US with expected launch in early 2022
- **Ultra long-acting formulation**
 - Ultra long-acting formulation, which only needs to be administered once every 3-6 months, under development. Market launch is projected for 2028 or thereafter

- **Dovato**
 - Steady growth in switch patients in the US and Europe (graph below)
 - Confirmed good efficacy and safety at 48 weeks in SALSA study and 144 weeks in TANGO study
 - 150 billion yen sales or more projected after 2022

From GSK Q2 2021 results



- CUSTOMIZE: designed to assess the most effective strategies and facilitators for successful implementation in real-world setting
- SALSA: assessing switch to Dovato in HIV-1 infected adults who are virologically suppressed on a broad range of regimens of at least 3 drugs, including 2 NRTIs*3
- TANGO: designed to compare switching to Dovato versus TAF*4-based regimen

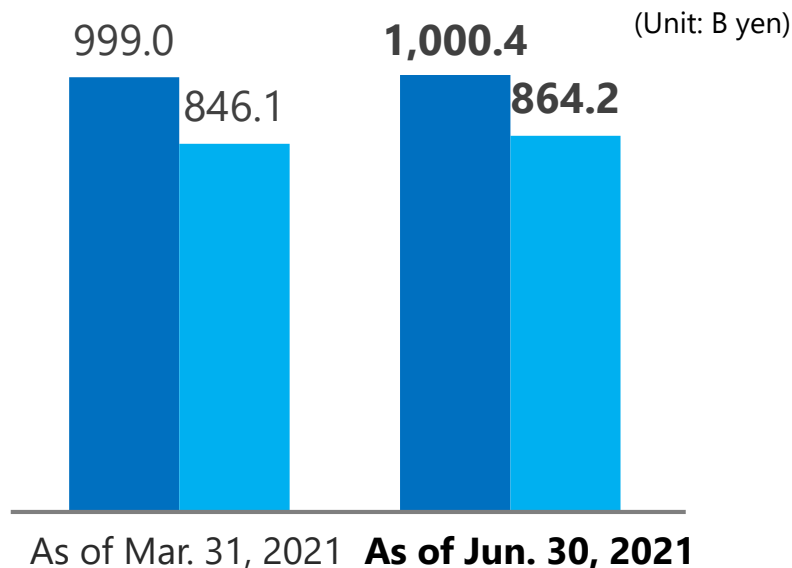


Appendix

Financial Position (Consolidated, IFRS)



■ Total Assets ■ Equity attributable to owners of parent



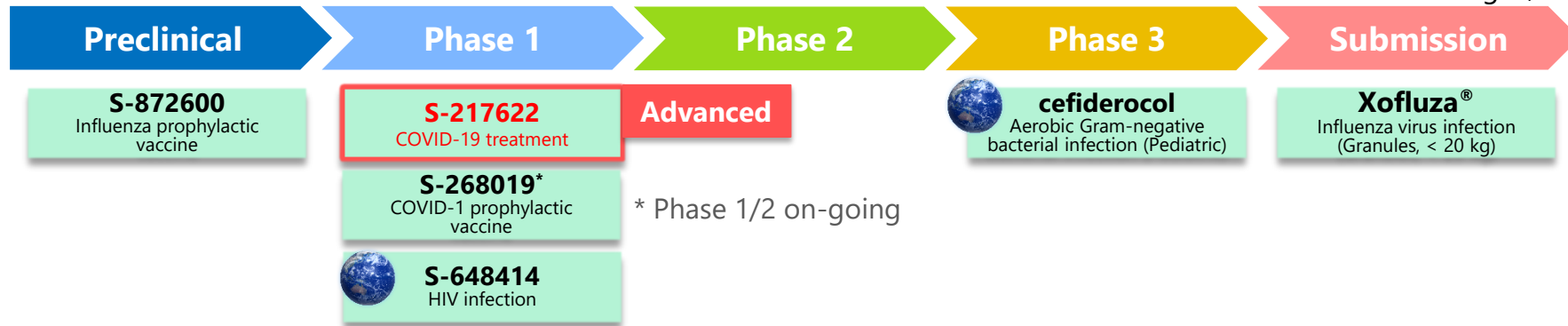
Unit: B yen		As of Mar. 31, 2021	As of Jun. 30, 2021	Change
Total Assets	Non-current Assets	442.8	442.2	(0.6)
	Current Assets	556.2	558.2	1.9
Equity attributable to owners of parent		846.1	864.2	18.1
Total Liabilities	Non-current Liabilities	34.3	32.3	(2.0)
	Current Liabilities	100.2	86.2	(14.0)

	As of Mar. 2021	As of Jun. 2021
Ratio of equity attributable to owners of parent to total assets	84.7%	86.4%

Pipeline: Infectious Disease



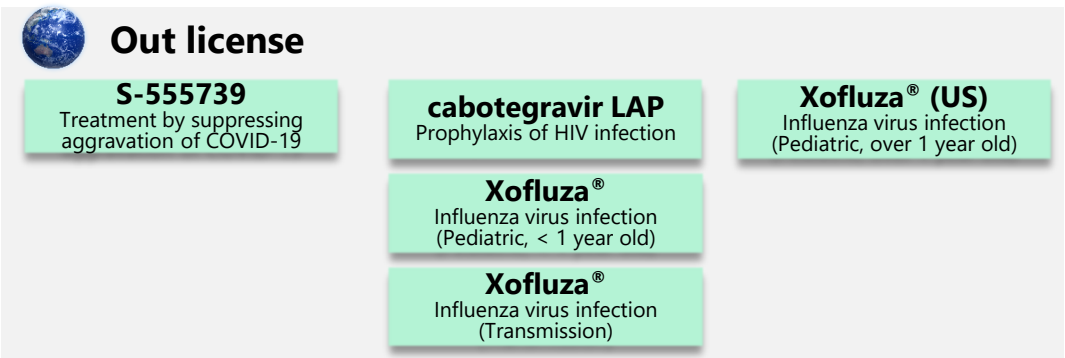
as of Aug. 2, 2021



Stage change (Changes from May. 10, 2021)

S-217622 (COVID-19 Treatment): Phase 1 start (Japan)

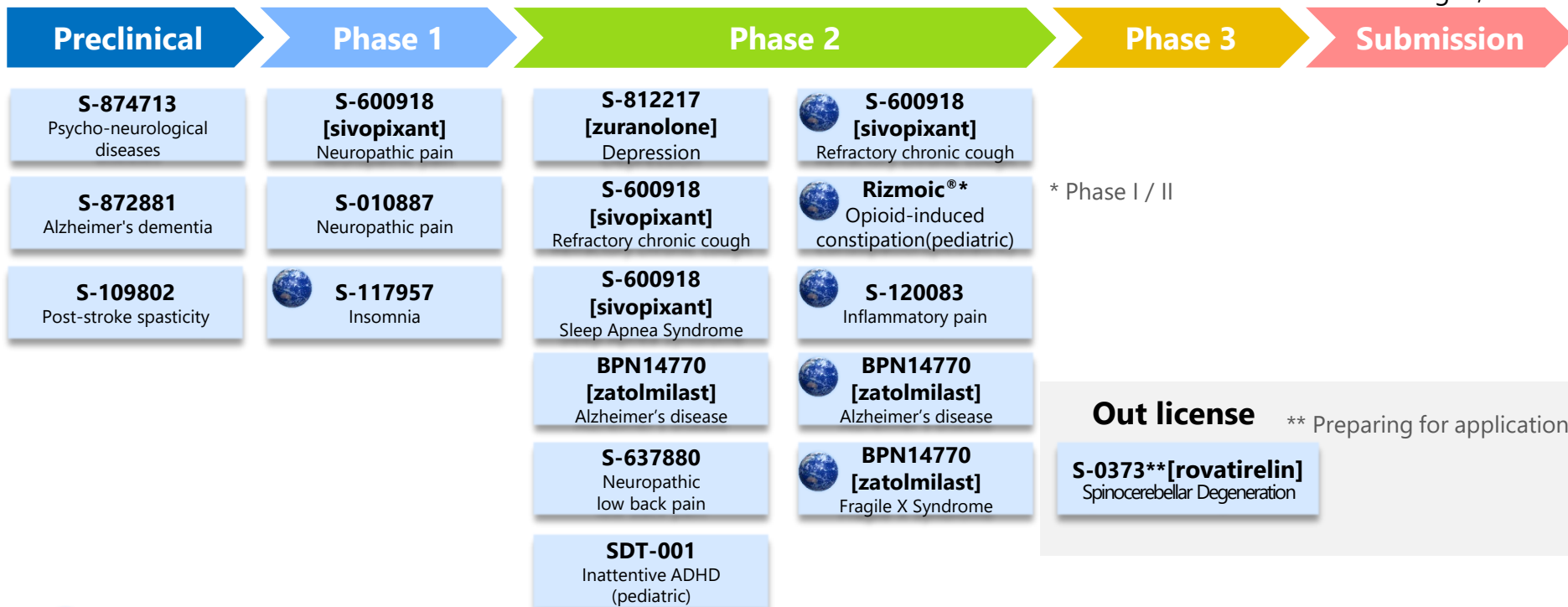
: Global development



Pipeline: Psychological and Neurological Disease



as of Aug. 2, 2021



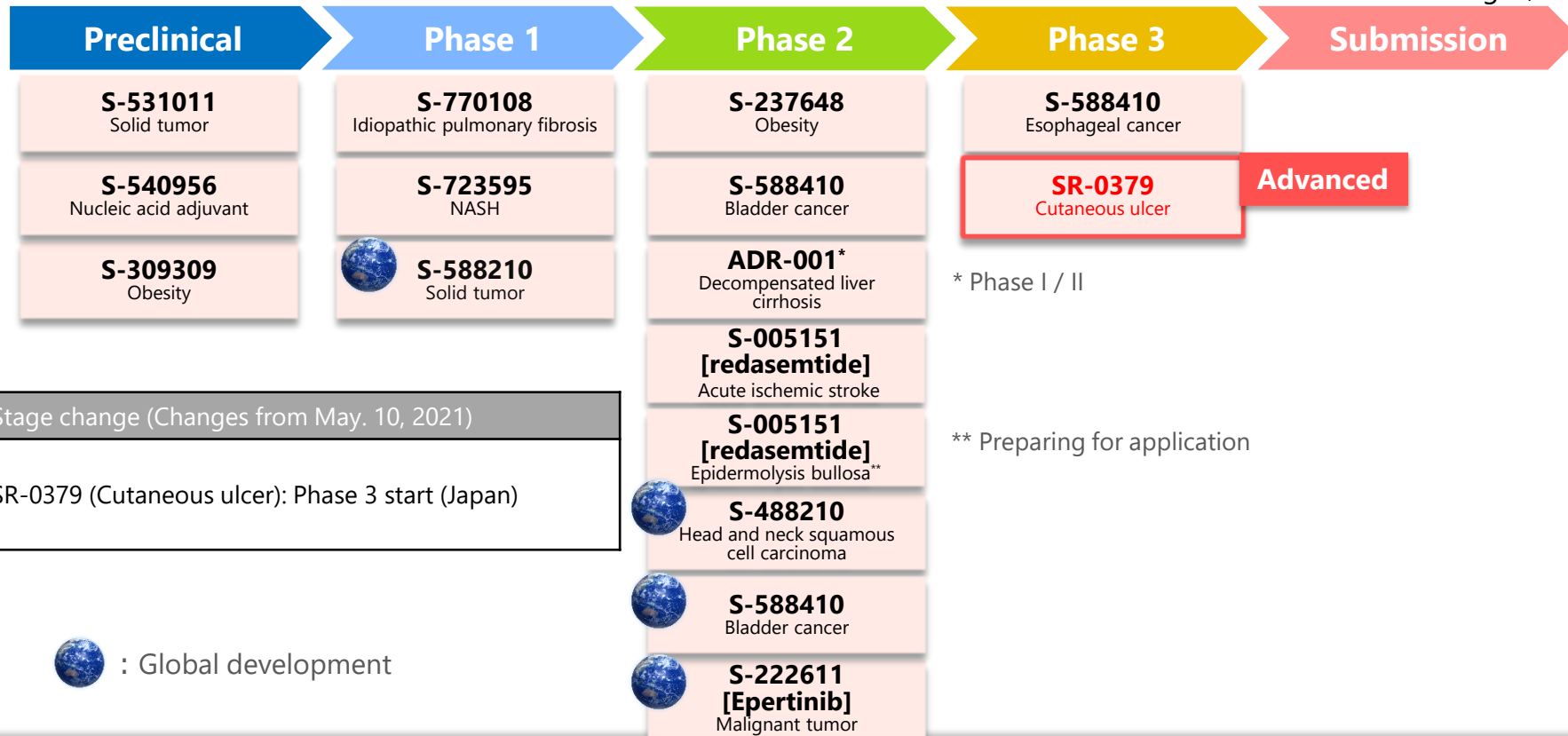
: Global development

: Progress from May 10, 2021 to Aug. 2, 2021

Pipeline: New Growth Area



as of Aug. 2, 2021



Stage change (Changes from May. 10, 2021)

SR-0379 (Cutaneous ulcer): Phase 3 start (Japan)

 : Global development

* Phase I / II

** Preparing for application

MOU with GARDP, CHAI and Shionogi to increase access to antibiotic to treat antimicrobial resistant infections in low- and middle-income countries (July 6, 2021)

Through this MOU, GARDP, CHAI and Shionogi will use their collective expertise to increase access to cefiderocol in low- and middle-income countries. Together, the collaboration will aim to assist governments and partners to introduce cefiderocol into health systems, with a focus on providing clinical guidance to physicians, training and other measures to ensure appropriate use.

* AMR currently kills 700,000 people worldwide and there is a need for new treatment options. In addition to improving access, it is important to address environment health challenges, improve diagnosis and secure appropriate use. GARDP and CHAI have tremendous local knowledge and infrastructure which will be critical to help address AMR on a global basis. We believe that this initiative will make a significant contribution to resolving this difficult problem.

Other Major Progress in Q1 FY2021*



- **Jun**

- Greenhouse Gas Reduction Target Approved by “Science Based Targets (SBT) Initiative”
- Signed an MoU with World Anti-Doping Agency (WADA) to Prevent Misuse and Abuse of Medicines for Doping in Sports

- **July**

- Opened a dedicated YouTube channel for the virtual YouTuber "Shionogi Kanade"
 - > ▼ YouTube account : Shionogi Kanade
<https://www.youtube.com/channel/UCpjB41cfRYglxskhHNo-BQQ>
 - > ▼ Shionogi Kanade Web Page
[Shionogi Kanade | Social Media | Shionogi & Co., Ltd.](#)
- selected as a member of the “SOMPO Sustainability Index” for the 10th consecutive year
- Sign a license agreement with HanaVax for COVID-19 vaccine development using cationic nanogel delivery system

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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