3rd Quarter of Fiscal 2021 Financial Results

Conference Call

January 31, 2022
Shionogi & Co., Ltd.

SHIONOGI

Agenda

1. Overview of Q3 FY2021 Financial Results (P.4-7)
2. Achievements in Q3 FY2021 and Activities for Future Growth (P.9-21)
   - Progress of COVID-19 projects
   - Progress of other projects

1. Overview of Q3 FY2021 Financial Results

Financial Results (Consolidated)

(Unit: B yen)

	FY2021			FY2020	Y on Y	
	Full year Forecasts (revised on Nov. 1)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results	Change (%)	Change
Revenue	294.0	**219.6**	**74.7**	224.4	**(2.1)**	**(4.8)**
Operating profit	90.0	**60.4**	**67.1**	105.2	**(42.5)**	**(44.7)**
Core operating profit*	90.0	**61.9**	**68.8**	80.0	**(22.6)**	**(18.1)**
Profit before tax	115.0	**74.8**	**65.0**	119.8	**(37.6)**	**(45.0)**
Profit attributable to owners of parent	100.0	**71.0**	**71.0**	89.0	**(20.3)**	**(18.0)**

- **Revenue and each profit category progressing steadily toward full year forecast**
- **Continued aggressive investment in COVID-19 related projects**
  - R&D expenses: R&D expenses related to COVID-19 include expenses that are the subject of grant negotiations with the Japanese government (Progress against the full year forecast is 86.9%, an increase of 9 B yen year on year)
  - The main reason for the decrease in profits other than the above was the gain on the exchange of the Shionogi Shibuya Building (22.9 B yen) in 3Q FY2020

Exchange Rate (average)	FY2021 forecasts (revised on Nov. 1)	FY2021 Apr.-Dec. results
USD ($) – JPY (¥)	**110**	**111.14**
GBP (£) – JPY (¥)	**150**	**152.76**
EUR (€) – JPY (¥)	**130**	**130.60**

* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)
Achievement excluding a gain on exchange of Shionogi Shibuya Building (22.9 B yen) is in Appendix p.23

Statement of Profit or Loss (Consolidated)

(Unit: B yen)

	FY2021			FY2020	Y on Y	
	Full year Forecasts (revised on Nov. 1)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results	Change (%)	Change
Revenue	294.0	**219.6**	**74.7**	224.4	**(2.1)**	**(4.8)**
Cost of sales	19.4 57.0	18.1 **39.9**	**69.9**	16.0 35.9	**10.9**	**3.9**
Gross profit	237.0	**179.8**	**75.9**	188.5	**(4.6)**	**(8.7)**
Selling, general & administrative expenses	30.3 89.0	31.4 **69.0**	**77.6**	30.6 68.6	**0.6**	**0.4**
R&D expenses	18.9 55.5	22.0 **48.2**	**86.9**	17.5 39.2	**22.9**	**9.0**
Other income & expenses	(2.5)	**(2.1)**	**84.4**	24.6	**(108.6)**	**(26.7)**
Operating profit	30.6 90.0	27.5 **60.4**	**67.1**	46.9 105.2	**(42.5)**	**(44.7)**
Core operating profit*	30.6 90.0	28.2 **61.9**	**68.8**	35.6 80.0	**(22.6)**	**(18.1)**
Finance income & costs	25.0	**14.4**	**57.4**	14.6	**(1.8)**	**(0.3)**
Profit before tax	39.1 115.0	34.1 **74.8**	**65.0**	53.4 119.8	**(37.6)**	**(45.0)**
Profit attributable to owners of parent	100.0	**71.0**	**71.0**	89.0	**(20.3)**	**(18.0)**

Main Variation Factors (Y on Y) ※ Special Notes for 3Q

- **Revenue**
  - Increase: Overseas subsidiaries/export, contract manufacturing
  - Decrease: Royalty income (Crestor®)
- **Cost of sales**
  - Increase: Increase in revenue other than royalty Income (about 7.7 B yen)
    Increase: Product mix due to growth in overseas subsidiaries/export, contract manufacturing
- **Selling, general & administrative expenses**
  - Increase: Launch and sales activity costs of cefiderocol in Europe and the United States
  - Decrease: greater efficiency in domestic sales and in general & administrative expenses
- **R&D expenses**
  - Increase: Concentrated investment in R&D activities related to COVID-19 ※
    ⇒Includes R&D expenses under negotiation with the Japanese government for grants
- **Other income & expenses**
  - Decrease in income: Recognized a gain on the exchange of the Shionogi Shibuya Building in 3Q of the previous year (22.9 B yen) ※

* 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	
	Full year Forecasts (revised on Nov. 1)	Apr.-Dec. results	Achievement (%)	Apr.-Dec. results	Change (%)	Change
Prescription drugs	94.4	**69.5**	**73.7**	71.8	**(3.2)**	**(2.3)**
Overseas subsidiaries/export	35.0	**26.2**	**74.8**	17.5	**49.7**	**8.7**
Shionogi Inc.	12.7	**11.1**	**87.6**	5.4	**106.2**	**5.7**
Fetroja®	-	**4.7**	**-**	0.9	**425.1**	**3.8**
Ping An-Shionogi* /C&O	12.3	**7.2**	**58.5**	6.9	**3.8**	**0.3**
SBV(Europe)	5.0	**3.8**	**76.7**	1.3	**195.7**	**2.5**
Contract manufacturing	17.8	**11.8**	**66.3**	10.3	**15.3**	**1.6**
OTC and quasi-drug	13.4	**8.4**	**62.5**	8.8	**(4.5)**	**(0.4)**
Royalty income	132.0	**102.4**	**77.6**	114.8	**(10.8)**	**(12.5)**
HIV franchise	125.2	**96.2**	**76.8**	95.1	**1.2**	**1.1**
Crestor®	0.0	**1.2**	**-**	16.6	**(93.1)**	**(15.4)**
Others	6.7	**5.0**	**74.8**	3.2	**57.3**	**1.8**
Others	1.4	**1.3**	**93.3**	1.2	**8.7**	**0.1**
Total	294.0	**219.6**	**74.7**	224.4	**(2.1)**	**(4.8)**

Main Variation Factors (Y on Y)

- **Prescription drugs**
  - Decrease: Sales of Cymbalta®
- **Overseas subsidiaries/export**
  - US: Increase: Sales of cefiderocol (Fetroja®)
    Increase: Received a one-time payment for the transfer of FORTAMET® sales rights, etc.
  - Europe: Increase: Sales of cefiderocol (Fetcroja®)
- **Contract manufacturing**
  - Increase: The acquisition of Nagase Medicals as a consolidated subsidiary**, increased supply of dolutegravir API
- **OTC and quasi-drug**
  - Decrease: Sales of ISODINE®
- **Royalty income**
  - HIV franchise: Increase: Sales of Dovato
  - Crestor®: Decrease: Based on the contract
  - Others: Increase: Out-licensing agreement with ViiV for S-365598

* OTC and quasi-drugs also include in revenue of joint venture
** Made a consolidated subsidiary from 3Q of the previous year

Results up to the 3rd Quarter and Outlook for Full Year Forecasts

Achievements up to the 3rd Quarter

- **Revenue progressing and each profit category steadily toward full year forecasts**
  - Domestic and overseas businesses, royalty income
  - **Concentrated investment in COVID-19 related projects**
  - R&D expenses related to COVID-19 include expenses that are the subject of grant negotiations with the Japanese government
  - As for the forecasts, it excludes unconfirmed COVID-19-related sales and R&D expenses

To achieve the full year forecasts

- **Continuation of concentrated investment in COVID-19 related projects in the 4th Quarter**
- Reduction of selling, general and administrative expenses by improving productivity
- **Creating value through new business opportunities**
  - Provision of COVID-19 therapeutic drugs/ vaccines
  - Conclusion of partnering contract, etc.

Aim to achieve full year forecasts and increase revenue and profits by creating through new business opportunities in parallel with concentrating resources necessary for the early termination of COVID-19

2. Achievements in Q3 FY2021 and Activities for Future Growth

Actions for COVID-19: S-217622

Development of oral therapeutic drug (S-217622)

- Nonclinical efficacy: activity against omicron variant

In vitro assay using VeroE6T cells

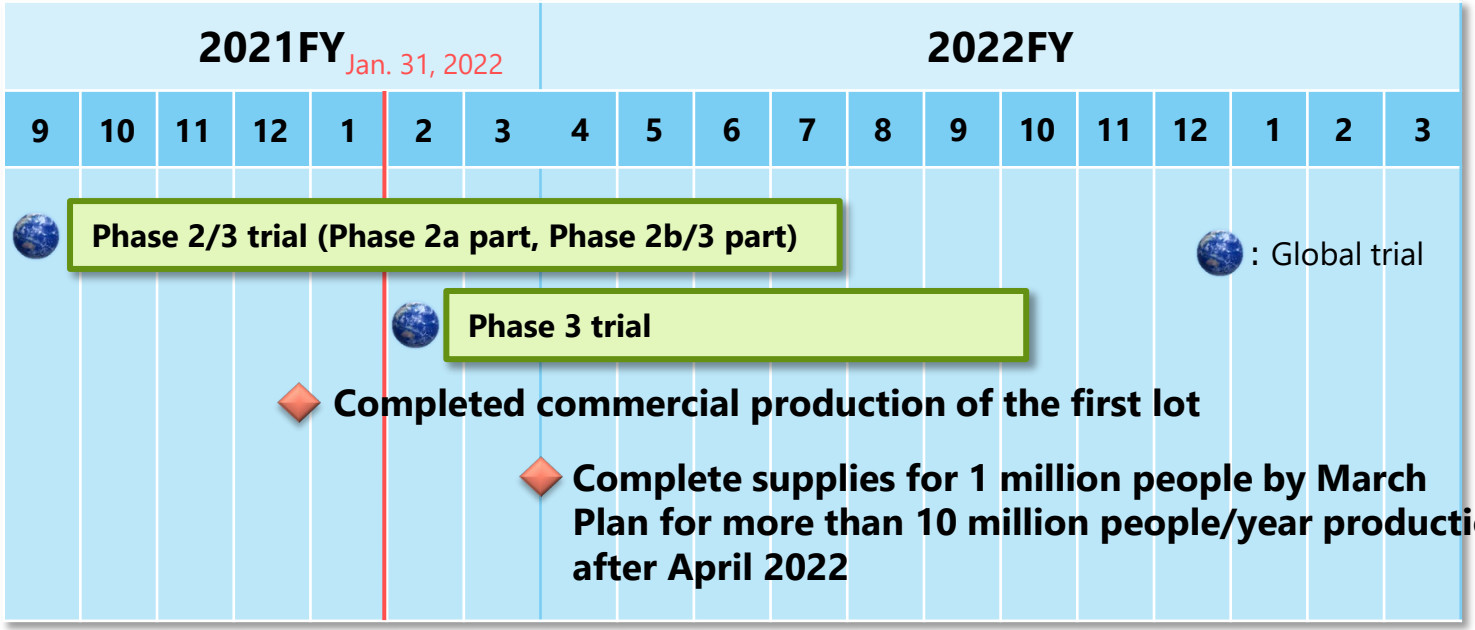
SARS-CoV-2 variant	EC_{50} (μM)	Major mutation site	
		Spike-protein	3CL-protease
WK-521 strain	**0.37**	-	-
α variant (QHN001/QHN002/QK002)	**0.31/0.46/0.33**	N501Y, D614G	-
β variant (TY8-612)	**0.40**	K417N, E484K, N501Y, D614G	K90R*
Γ variant (TY7-501/TY7-503)	**0.50/0.43**	K417T, E484K, N501Y, D614G	-
δ variant (TY11-927-P1)	**0.41**	L452R, T478K, D614G	-
ο variant (TY38-873)	**0.29**	K417N, K440K, G446S, S477N, T478K, E484A, Q493K, G496S, Q498R, N501Y, Y505H	P132H

Antiviral activity retained across various strains, including the current globally problematic omicron variant

* Inhibitory assessment using K90R enzyme confirmed no effect on drug efficacy

Actions for COVID-19: S-217622

Development of oral therapeutic drug (S-217622)

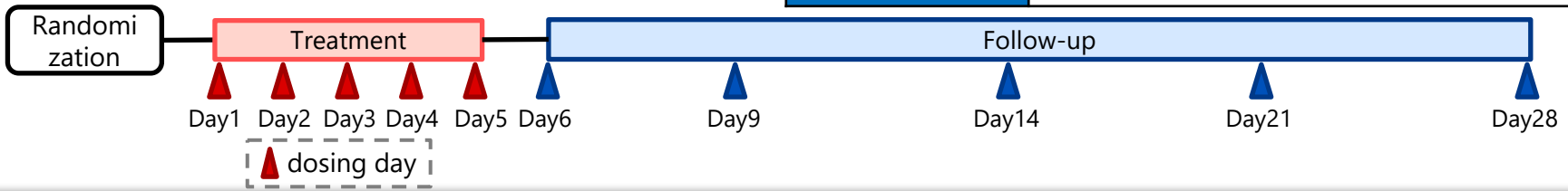


Actions for COVID-19: S-217622
- Design of Phase 2a part of Phase 2/3 trial -

Development of oral therapeutic drug (S-217622)

- Outline of Phase 2a part
  - **Purpose**
    - > Antiviral effect of repeated administration of S-217622 for 5 days to mild/moderate and asymptomatic SARS-CoV-2 infected patients
  - **Measurement of antiviral effect**
    - > **Viral titer**
      - = Amount of infectious virus (living virus) contained in the sample
    - > **Viral RNA**
      - = Amount of viral RNA (including fragments of the dead virus genome) contained in the sample

Subjects	Asymptomatic or mild/moderate COVID-19 patients
Clinical trial design	Multicenter, randomized, double-blind, placebo-controlled study
Endpoints	Efficacy, Safety
Primary endpoint	Change from baseline in SARS-CoV-2 viral titer at each time point
Secondary endpoint	• Change from baseline in amount of SARS CoV-2 viral RNA at each time point • Proportion of participants with positive SARS-CoV-2 viral titer at each time point • Change from baseline in total score of COVID 19 symptoms at each time point, etc.
Age	12 to 70 years old

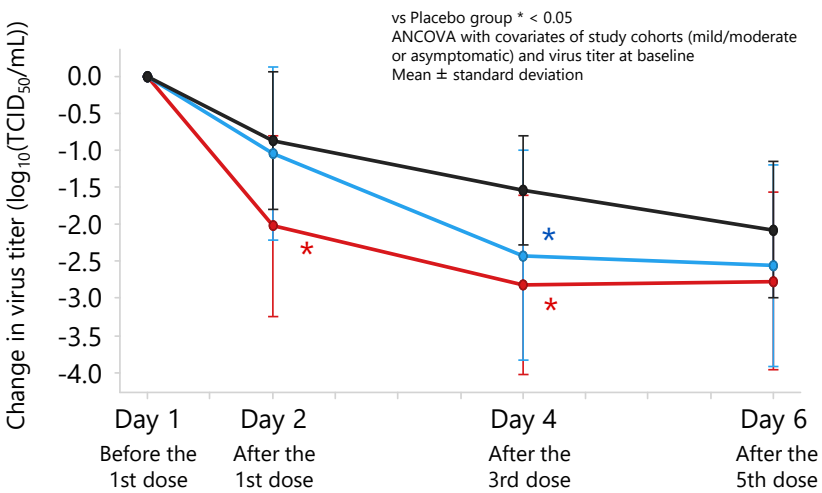


Actions for COVID-19: S-217622
- Antiviral effect: Phase 2a part of Phase 2/3 trial -

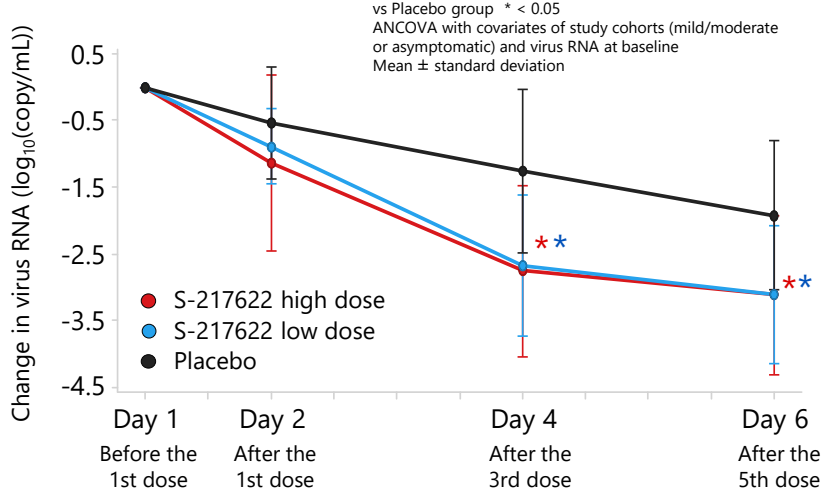
Development of oral therapeutic drug (S-217622)

- Antiviral effect

Mean change from baseline in **viral titer**



Mean change from baseline in amount of **viral RNA**

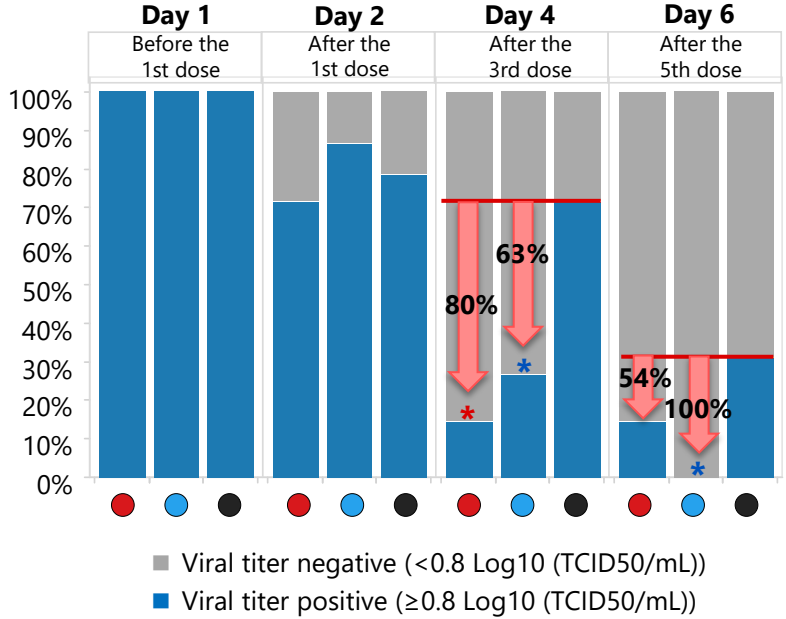


Rapid reduction of viral titer and RNA load compared to placebo group

Actions for COVID-19: S-217622
- Antiviral effect: Phase 2a part of Phase 2/3 trial -

Development of oral therapeutic drug (S-217622)

- Proportion of patients** with viral titer positivity



vs Placebo group *< 0.05
Mantel-Haenszel test stratified by study cohorts (mild/moderate or asymptomatic)

- S-217622 high dose
- S-217622 low dose
- Placebo

- **Decrease in proportion of patients with viral titer positivity in the active group compared to the placebo**

S-217622 rapidly reduces the number of patients shedding infectious virus

** Patients with a virus detected in the nasopharyngeal swab

Actions for COVID-19: S-217622

Development of oral therapeutic drug (S-217622)

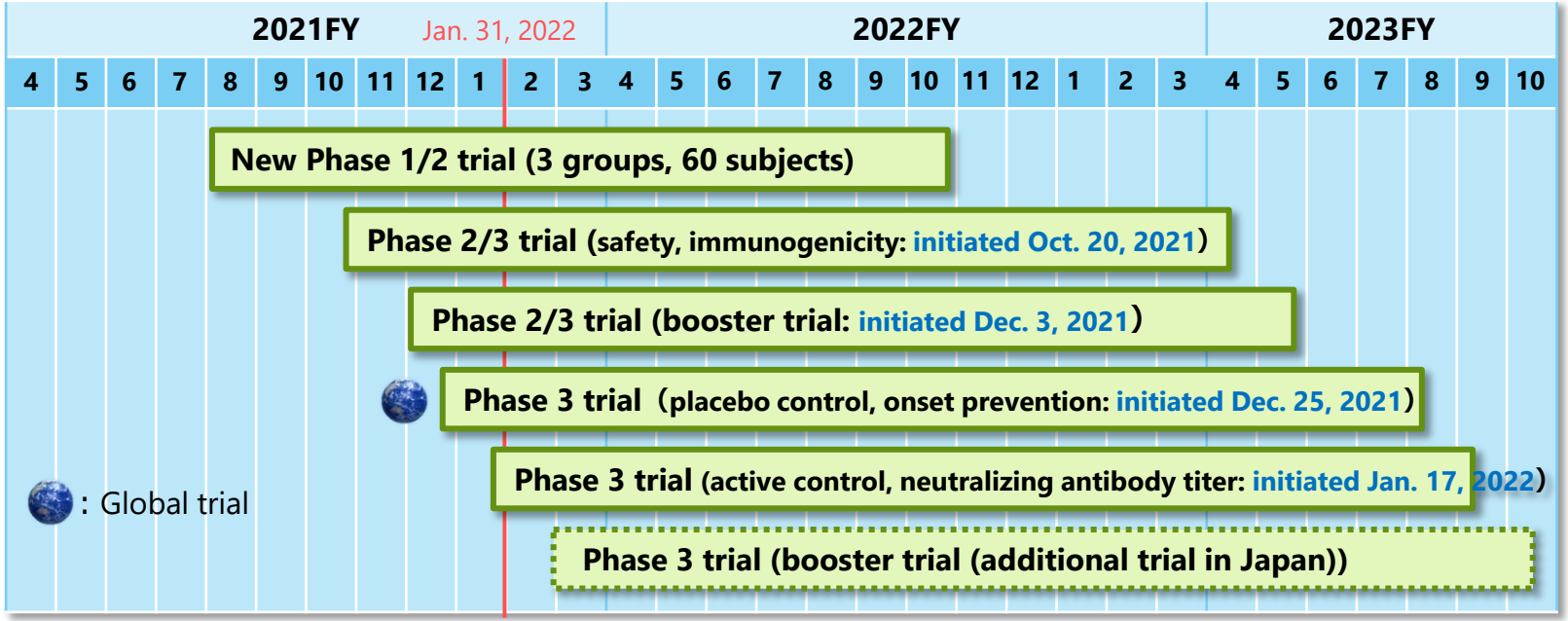
- **Phase 2/3 trial**
  - Phase 2a part, interim evaluation
    - > Confirmed prompt antiviral effect
    - > No major safety concerns, and no serious adverse events have been observed
  - Phase 2b/3 part in progress
    - > Patients enrollment goes smoothly in January 2022 with increased COVID-19 positive cases
    - > Site activation completed in global countries to accelerate patients enrollment
- **Global Phase 3 trial**
  - Under discussion with FDA and EMA to initiate trial
- **Commercial production**
  - Completed commercial production of the first lot in December 2021
- **Partnering**
  - Under discussion with candidate companies

Documents necessary for application are continuously submitted to the authorities, aiming for the fastest domestic provision

Actions for COVID-19: S-268019

Development of recombinant protein vaccine (S-268019)

Pivotal 4 clinical trials in progress



Phase 1/2 studies and all clinical trial materials are supported by AMED under Grant Number JP21nf0101626

Actions for COVID-19: S-268019

Development of recombinant protein vaccine (S-268019)

Pivotal 4 clinical trials in progress

- **Phase 2/3 trial**
  - Completed the 2nd inoculation of all subjects
  - Completed observation through Day 57 with no major safety concerns
  - Topline results including GMT of neutralizing antibody will be presented at Annual Meeting of Japanese Association for Infectious Diseases in April 2022
- **Active control, neutralizing antibody titer trial**
  - Superiority trial to compare GMT of neutralizing antibody to a licensed vaccine (VAXZEVRIA intramuscular injection)
  - Completed the 1st inoculation of all subjects
- **Booster trial**
  - Non-inferiority trial with COMIRNATY intramuscular injection with booster immunization after priming of COMIRNATY intramuscular injection
  - Completed observation through Day 29 with no major safety concerns
  - Topline results will be announced early March 2022
- **Placebo control, onset prevention trial**
  - Initiated in Vietnam from December 2021
  - Subject registration is progressing smoothly

All trials are progressing steadily,
aiming for initiation of prior consultation in February and early commercialization

All clinical trial materials are supported by AMED under Grant Number JP21nf0101626

R&D Progress: 8 Core Projects

	Pipeline	Indication	Status
Infectious disease	**S-540956**	Infectious disease, cancer	Preparing for Phase 1 trial
Psycho-neurological diseases	**S-600918 [sivopixant]**	①Refractory chronic cough ②Sleep apnea syndrome	**①Preparing for Phase 3 trial** **②Closed**
	S-637880	Neuropathic low back pain	Phase 2a trial in progress
	S-812217 [zuranolone]	Depression	**Phase 3 trial in progress**
	BPN14770 [zatolmilast]	①Alzheimer's disease ②Fragile X syndrome	①Phase 2 trial in progress ②Phase 2b trial in progress, Preparing for Phase 2b/3 trial
	S-874713	Psycho-neurological diseases	Preparing for Phase 1 trial
New growth areas	**S-531011**	Solid tumor	Phase 1b/2 trial in progress
	S-005151 [redasemtide]	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

Steady progress of 8 core projects in parallel with COVID-19 projects

R&D Progress: 8 Core Projects

Steady progress in development of projects for medium to long term growth

Zuranolone
-Efficacy that changes existing concepts of depression treatment-

- **Phase 3 trial in Japan in progress**
  - Development as an acute therapeutic drug characterized by rapid onset based on the favorable results of the Phase 2 trial in Japan and the global Phase 3 trial
    - > New positioning that can differentiate from existing antidepressants
- **Smooth progress in overseas (Sage/ Biogen) development**
  - **Preparing for NDA submission to FDA**
    - > Early 2022: Rolling submission scheduled to start

Redasemtide
-Changing the regenerative medicine paradigm-

- **Acute ischemic stroke**
  - **Preparing for the global Phase 3 trial**
    - > **Achieved primary endpoint* in Phase 2 trial**
    - > The implementation rate of revascularization therapy** is low in various countries around the world, and unmet medical needs are large
- **Epidermolysis bullosa**: Preparing for additional clinical trial
- **Knee osteoarthritis**: Completion of recruitment of Investigator initiated clinical trial (Phase 2 trial)
- **Chronic liver disease**: Recruitment of Investigator initiated clinical trial (Phase 2 trial) in progress
- **Cardiomyopathy**: Preparing for Investigator initiated clinical trial

* To evaluate the efficacy compared to placebo in patients with acute ischemic stroke with respect to modified Rankin Scale (mRS : A scale commonly used to measure the degree of disability or dependence in the daily activities of people suffering from stroke or other causes of neuropathy) 90 days after the first dose

** Thrombolytic therapy or mechanical thrombectomy

R&D Progress: DTx* Approach for Insomnia

Introducing a digital therapeutic App for insomnia from SUSMED

- **Insomnia market is expanding**
  - Estimated number of patients: About 22 million*2
  - Number of definitive diagnosed patients: About 10 million*3
- **Results of Phase 3 trial**
  - Significant improvement in the Athens insomnia scale*4, the primary endpoint
  - **Based on the results of this trial, scheduled to submit for NDA as a first digital therapeutic App for insomnia (February 2022)**

- **Features of traditional insomnia treatment and expectations for therapeutic Apps**

	Strengths	Weaknesses
Drug therapy	- Early improvement	- Monotherapy may not provide satisfactory long-term prognosis and adherence
Cognitive behavioral therapy	- Effect that continues after treatment - Fewer side effects	- Lack of feasible professional staff - takes a long time to implement, and the burden on medical institutions is large

Cognitive behavioral therapy with the App

① **Overcome the challenges of face-to-face cognitive behavioral therapy and facilitate patient access**

② Acquire daily data and reflect it in the medical treatment of doctors

③ Possibility of monotherapy and in combination with drug therapy

* Digital Therapeutics: Therapeutic software (App) used by the patient under the supervision of a doctor
*2 Ministry of Health, Labor and Welfare 2018 "National Health and Nutrition Survey" *3 JMDC 2020
*4 A scale for measuring the severity of insomnia created by the WHO

Initiatives to Strengthen Domestic and Overseas Businesses

Domestic business

- **ADHD franchise**
  - Continued efforts to increase Intuniv® share of the adult ADHD market
- **Influenza franchise**
  - Flexible efforts according to the influenza epidemic situation

US and Europe business

- **Cefiderocol**
  - Continue efforts to maximize value in the US and Europe
  - Implementing access framework for low- and middle-income countries

China business

- **Ping An-Shionogi**
  - Increase sales via new sales channels, including online medical platforms
  - Focus on activities for early launch of new drugs
  - Expansion of research approaches utilizing AI technology

To achieve full year forecasts,
accelerate the execution of optimal top-line strategies for each region

Progress of HIV franchise by ViiV Healthcare

Maximize the value of cabotegravir with PrEP and new treatment options in the US

Cabotegravir: PrEP

Apretude（cabotegravir）
- Approval of new PrEP option -

- **The first and only long-acting injectable option (every two months dosing)**
  - Freedom from daily oral administration
- **Paradigm shift in the HIV PrEP market**
  - Higher convenience and superior efficacy to a daily oral PrEP (FTC/TDF)*
  - Improved adherence through high convenience and tolerability
    - > The US government targets the reduction of new infections by 75% by 2025

Cabotegravir：Treatment

CABENUVA（CAB/RPV**）
- New options for greater convenience -

- **Treatment dosing once every two months**
  - New options to reduce the burden of continuing treatment
- **Choice of initiation options (injection or oral)**
  - Reduced complexity at the time of introduction

※ Both are scheduled to be approved in the US early in 2022. Already approved in Europe

Expand the market share of cabotegravir with approval of PrEP and more convenient treatment options

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* FTC/TDF: emtricitabine/tenofovir disoproxil fumarate
** CAB/RPV: cabotegravir/rilpivirine

Appendix

Financial Results (Consolidated)

- excluding the gain on the exchange of the Shionogi Shibuya Building (22.9 B yen)-

(Unit: B yen)

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Profit attributable to owners of parent	100.0	**71.0**	**71.0**	73.1	**(2.9)**	**(2.1)**

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

Revenue from Prescription Drugs in Japan

(Unit: B yen)

	FY2021			FY2020	Y on Y	
	Full year Forecasts (revised on Nov. 1)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. results	Change (%)	Change
Cymbalta®	17.1	**14.1**	**82.6**	20.5	**(31.0)**	**(6.3)**
Intuniv®	16.6	**12.1**	**73.0**	9.6	**26.8**	**2.6**
Vyvanse®	1.0	**0.6**	**53.7**	0.2	**228.9**	**0.4**
Infectious disease drugs	16.6	**8.8**	**52.7**	7.6	**15.2**	**1.2**
Influenza franchise	7.9	**2.0**	**25.4**	0.2	**718.8**	**1.8**
OxyContin® franchise	5.0	**3.8**	**75.5**	4.1	**(7.5)**	**(0.3)**
Symproic®	3.1	**2.0**	**64.5**	1.7	**20.8**	**0.3**
Actair®	0.4	**0.4**	**95.8**	0.2	**53.6**	**0.1**
Mulpleta®	0.1	**0.1**	**75.1**	0.1	**11.3**	**0.0**
Pirespa®	3.5	**3.1**	**88.0**	4.0	**(23.6)**	**(0.9)**
Others	30.8	**24.6**	**79.8**	23.9	**2.9**	**0.7**
Crestor®	5.7	**4.7**	**82.0**	5.1	**(8.2)**	**(0.4)**
Irbetan® franchise	3.1	**2.4**	**78.5**	2.6	**(5.8)**	**(0.1)**
Prescription drugs	94.4	**69.5**	**73.7**	71.8	**(3.2)**	**(2.3)**

<Products included in infectious disease drugs>

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

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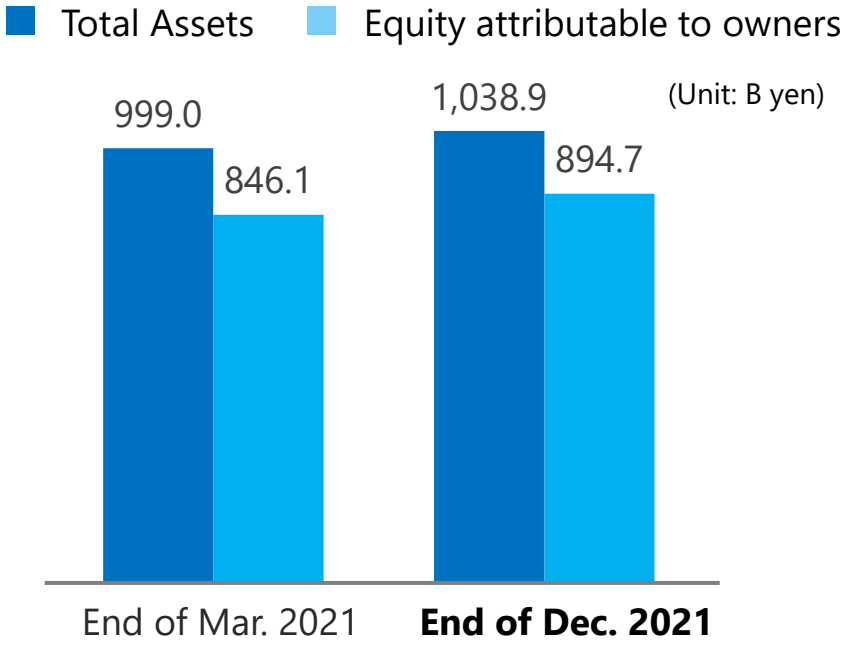
Influenza franchise

Financial Position (Consolidated, IFRS)



	End of Mar. 2021	End of Dec. 2021
Ratio of equity attributable to owners of parent to total assets	84.7%	86.1%

Unit: B yen		End of Mar. 2021	End of Dec. 2021	Change
Total Assets	Non-current Assets	442.8	452.2	9.5
	Current Assets	556.2	586.7	30.4
Equity attributable to owners of parent		846.1	894.7	48.6
Total Liabilities	Non-current Liabilities	34.3	32.1	(2.2)
	Current Liabilities	100.2	94.5	(5.7)

Pipeline: Infectious Disease

as of Jan. 31, 2022

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-872600 Influenza prophylactic vaccine			**S-268019** Up COVID-19 Prophylactic vaccine	**Xofluza®** Influenza virus infection (Granules, < 20 kg)
S-880008 Up COVID-19 treatment (peptide)			**S-268019** Up COVID-19 Prophylactic vaccine	
			S-217622* COVID-19 treatment	
			cefiderocol Aerobic Gram-negative bacterial infection (Pediatric)	
Out license		**S-555739** Treatment by suppressing aggravation of COVID-19	**cabotegravir LAP** Prophylaxis of HIV infection	**Xofluza® (US)** Influenza virus infection (Pediatric, over 1 year old)
S-365598 HIV infection			**Xofluza®** Influenza virus infection (Pediatric, < 1 year old)	
			Xofluza® Influenza virus infection (Transmission)	

: Global development

* Phase 2b/3

Stage change (Changes from Nov. 1, 2021)

S-268019 (COVID-19 Prophylactic vaccine) : Phase 3 start (Japan, Global)
S-880008 (COVID-19 Treatment peptide) : Preclinical

: Progress from Nov. 1, 2021 to Jan. 31, 2022

Pipeline: Psycho-neurological Disease

as of Jan. 31, 2022

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

: Global development

Out license

Up

S-0373[rovatirelin]
Spinocerebellar Degeneration

Stage change (Changes from Nov. 1, 2021)
S-812217 (Depression) : Phase 3 start (Japan) S-600918 (Sleep Apnea Syndrome) : Closed S-872881 (Alzheimer's dementia) : Closed S-0373 (Spinocerebellar Degeneration) : Submission

Pipeline: New Growth Areas

as of Jan. 31, 2022

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-770108** Idiopathic pulmonary fibrosis	**S-237648** Obesity	**S-005151 [redasemtide]** Acute ischemic stroke	**S-588410** Esophageal cancer
S-309309 Obesity	**S-723595** NASH	**S-588410** Bladder cancer	**S-005151 [redasemtide]** Epidermolysis bullosa	**SR-0379** Cutaneous ulcer
	S-588210 Solid tumor	**ADR-001*** Decompensated liver cirrhosis	**S-488210** Head and neck squamous cell carcinoma	
	S-309309 Obesity		**S-588410** Bladder cancer	
			S-222611 [epertinib] Malignant tumor	
			S-531011 ** Solid tumor	

* Phase 1/2

** Phase 1b/2

: Global development

Other Major Progress in Q3 FY2021*

- **November**
  - The signing of a Memorandum of Understanding with Vietnam for Infectious Disease Control, including COVID-19
  - Agreement for Joint Sales with Towns Co., Ltd. for Novel Coronavirus Antigen Test Kit Products in Japan
- **December**
  - Symproic® Tablets 0.2mg Approved for the Treatment of Opioid-Induced Constipation in adult patients in Taiwan
  - Launch of Mutational Analysis Services for Wastewater-based Epidemiological Surveillance of the Novel Coronavirus
  - Shionogi Has Been Recognized for Leadership in Corporate Sustainability by CDP - Rated as A- for “Climate Change” and for“Water security” -

* Progress from Nov. 2, 2021 to Jan. 31, 2022

Reference: Mean Change from Baseline in Virus RNA (other antivirals)

		Molnupiravir Phase 2 *1		PAXLOVID HR Phase 3 *2		REGEN-COV HR Phase 3 *3	
		Molnupiravir 800 mg	Placebo	Nirmatrelvir 300 mg ritonavir 100 mg	Placebo	REGEN-COV 2,400 mg	Placebo
Day 3	N	51	56				
	Mean*	-1.050	-0.847				
	Diff* vs placebo	**-0.203**	---				
Day 5	N	52	57	211	240		
	Mean*	-1.867	-1.320	-2.69			
	Diff* vs placebo	**-0.547**	---	**-0.93**	---		
Day 7	N	49	56			1355	1341
	Mean*	-2.485	-1.952			-3.32	-2.47
	Diff* vs placebo	**-0.534**	---			**-0.86**	---

* Least square mean

*1 Fischer W. et al. (2021). Molnupiravir, an Oral Antiviral Treatment for COVID-19.
*2 Analyst and Investor Call to Discuss the First COVID-19 Comprehensive Approach: Pfizer-BioNTech Vaccine and Pfizer's Novel Oral Antiviral Treatment Candidate
*3 Weinreich D. M. et al. (2021). REGEN-COV Antibody Combination and Outcomes in Outpatients with Covid-19.

Forward-Looking Statements

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