# 3<sup>rd</sup> Quarter of Fiscal 2022 Financial Results

January 30, 2023 Shionogi & Co., Ltd.



# **Agenda**

- 1. Overview of Q3 FY2022 Financial Results (P.3-8)
- 2. FY2022 Financial Forecasts (P.9-13)
- 3. Achievements in Q3 FY2022 and Actions for Future Growth (P.14-21)



1. Overview of Q3 FY2022 Financial Results



## **Financial Results**

		FY2022		FY2021	Y on	Υ
	Forecasts Full Year (Oct. 24)	AprDec. Results	Achievement (%)	AprDec. Results	Change (%)	Change
Revenue	410.0	338.3	82.5	219.6	54.1	118.7
Operating profit	120.0	146.5	122.1	60.4	142.4	86.1
Core operating profit*	120.0	144.0	120.0	61.9	132.6	82.1
Profit before tax	174.0	198.8	114.2	74.8	165.8	124.0
Profit attributable to owners of parent	142.0	157.7	111.1	71.0	122.2	86.7

- Significant year-on-year increases in revenue and all profit categories
- All profit categories, including operating profit, exceeded full year record highs\*\* as of 3Q

Exchange Rate (average)	FY2022 Forecasts (Oct. 24)	FY2022 AprDec. results
USD (\$) – JPY (¥)	138	136.51
GBP $(£)$ – JPY $(¥)$	162	163.96
EUR (€) – JPY (¥)	140	140.62

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



<sup>\*\*</sup> Record-highs Revenue: 420.2 B yen (FY2001,J-GAAP), Operating profit: 145.1 B yen (FY2018,IFRS), Profit before tax: 174.0 B yen (FY2018,IFRS), Profit attributable to owners of parent: 137.2 B yen (FY2018,IFRS)

## **Statement of Profit or Loss**

(Unit: B yen)

		FY2022		FY2021	Y on	Υ
	Forecasts Full Year (Oct 24)	AprDec. Results	Achievement (%)	AprDec. Results	Change (%)	Change
Revenue	410.0	338.3	82.5	219.6	54.1	118.7
Cost of Sales	19.5	13.2		18.1		
Cost of Sales	80.0	44.6	55.7	39.9	11.8	4.7
Gross profit	330.0	293.8	89.0	179.8	63.4	114.0
Selling, general&	50.7	43.9		53.4		
administrative expenses, R&D expenses total	208.0	148.4	71.3	117.2	26.6	31.1
Selling, general&	27.6	21.7		31.4		
administrative expenses	113.0	73.6	65.1	69.0	6.6	4.5
DOID armanas	23.2	22.1		22.0		
R&D expenses	95.0	74.8	78.7	48.2	55.1	26.6
Other income & expenses	(2.0)	1.1	-	(2.1)	-	3.2
0	29.3	43.3		27.5		
Operating profit	120.0	146.5	122.1	60.4	142.4	86.1
	29.3	42.6		28.2		
Core operating profit	120.0	144.0	120.0	61.9	132.6	82.1
Finance income & costs	54.0	52.3	96.9	14.4	264.2	38.0
Profit before tax	42.4	58.8		34.1		
	174.0	198.8	114.2	74.8	165.8	124.0
Profit attributable to owners of parent	142.0	157.7	111.1	71.0	122.2	86.7

## Main Variation Factors (Y on Y) \*Special Notes for 3Q

#### Revenue

- Increase: COVID-19 related products ※, Royalty income, Overseas subsidiaries/export
- Decrease: Prescription drugs

#### R&D expenses

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

#### Finance income & costs

- Increase in income
  - : Increased dividend reflecting ViiV's strong business

# Profit attributable to owners of the parent

 Receipt of refund in 1Q FY2021 in respect of a favorable judgement regarding the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau



# **Revenue by Segment**

(Unit: B yen)

		FY2022		FY2021	Y on Y		
	Forecasts Full Year (Oct 24)	AprDec. Results	Achieve ment (%)	AprDec. Results	Change (%)	Change	
Prescription drugs	76.4	54.7	71.5	69.5	(21.4)	(14.9)	
Overseas subsidiaries/export	39.3	30.6	77.8	26.2	16.9	4.4	
Shionogi Inc.	14.4	11.5	79.4	11.1	3.1	0.3	
Fetroja <sup>®</sup>	-	7.3	-	4.7	53.3	2.5	
Ping An-Shionogi <sup>*</sup> /C&O	10.4	8.4	80.5	7.2	16.1	1.2	
Shionogi BV	8.6	6.6	77.4	3.8	72.9	2.8	
Contract manufacturing	14.8	10.3	69.6	11.8	(13.0)	(1.5)	
OTC and quasi-drug	13.2	10.1	76.0	8.4	19.8	1.7	
Royalty income	155.0	131.7	85.0	102.4	28.7	29.4	
HIV franchise	150.2	126.9	84.5	96.2	31.9	30.7	
Crestor <sup>®</sup>	-	1.3	-	1.2	15.4	0.2	
Others	4.8	3.5	72.8	5.0	(30.7)	(1.5)	
COVID-19 related products**	110.0	100.0	90.9		-	100.0	
Others	1.2	1.0	85.0	1.3	(23.6)	(0.3)	
Total	410.0	338.3	82.5	219.6	54.1	118.7	

## Main Variation Factors (Y on Y) **X**Special Notes for 3Q

#### **Prescription drugs**

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

#### **Overseas subsidiaries/export**

- Shionogi Inc. (US)
  - > Increase: Sales of cefiderocol (Fetroja®)
  - > Decrease: Received in 1Q of FY2021 a one-time payment for the transfer of FORTAMET® sales rights (2.2 B yen)
- Shionogi BV(Europe)
- > Increase: Sales of cefiderocol (Fetcroja®)

#### **Royalty income**

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

#### **COVID-19 related products**

- Increase: Purchase of 2 million courses of Xocova® by the Japanese government 💥



# Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

		FY2022		FY2021	Y on	Υ
	Forecasts Full year (Oct 24)	AprDec. Results	Achievement (%)	AprDec. Results	Change (%)	Change
Intuniv <sup>®</sup>	20.0	14.8	74.0	12.1	21.6	2.6
Vyvanse <sup>®</sup>	1.3	1.1	84.4	0.6	90.1	0.5
Infectious disease drugs	8.8	2.9	32.8	8.8	(67.2)	(5.9)
Influenza franchise	0.1	(3.8)*	-	2.0	-	(5.8)
Cymbalta <sup>®</sup>	6.1	4.4	73.0	14.1	(68.6)	(9.7)
OxyContin <sup>®</sup> franchise	4.5	3.5	78.3	3.8	(7.1)	(0.3)
Symproic <sup>®</sup>	3.4	2.6	76.4	2.0	29.9	0.6
Actair <sup>®</sup>	0.6	0.4	70.2	0.4	10.4	0.0
Mulpleta <sup>®</sup>	0.1	0.1	68.9	0.1	(13.6)	(0.0)
Pirespa <sup>®</sup>	2.4	2.0	85.7	3.1	(33.7)	(1.0)
Others	29.4	22.9	77.8	24.6	(7.1)	(1.7)
Crestor <sup>®</sup>	3.9	3.2	81.9	4.7	(30.7)	(1.4)
Prescription drugs	76.4	54.7	71.5	69.5	(21.4)	(14.9)
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<Products categorized as infectious disease drugs>

Influenza franchise



<sup>•</sup> Xofluza®

Rapiacta<sup>®</sup>

<sup>•</sup> Brightpoc®Flu•Neo

<sup>•</sup> FINIBAX® • Flumarin®

Flumarin®Flomox®

<sup>•</sup> Shiomarin®

Vancomycin

vancomyci
 Baktar<sup>®</sup>

Flagyl®

<sup>•</sup> ISODINE®

<sup>\*</sup> Approximately 5.3 B yen worth of products that expire this year were returned in the second quarter. Sales of 1.5 billion yen recorded for influenza family in April-December

# **Results and Progress in Q3 FY2022**

# Bringing COVID-19 treatment drug Xocova® to patients Outcome from our COVID-19 investment contributed to earnings

#### Providing new treatment options

- Antiviral drugs play an important role in normalizing society
- Xocova<sup>®</sup> is an oral antiviral drug that can be used in a wide range of patients, regardless of immunizations status or risk level
- Global registration of Xocova<sup>®</sup> is progressing

#### Progression of a purely domestic vaccine

Filed for manufacturing and sales approval of S-268019

#### Contribution to earnings

- Exceeded each profit category in the full-year revised forecast
  - > There are many uncertainties regarding COVID-19related products, so the initial guidance was set conservatively

Aiming to achieve the highest profit since our founding and expected to continue to contribute to business performance from the next fiscal year forward

Redeploy the learnings and profits obtained from COVID-19 related projects into creation of our next growth drivers

# 2. FY2022 Financial Forecasts



# Regarding the Changes in Earnings Forecasts

- Key Points of Earnings Forecast Revision
- In the initial forecast, the profit contribution of Xocova® was estimated conservatively, but following the emergency approval in Japan, various profit items including operating profit have been revised substantially upwards.
- The revised forecast may be further surpassed depending on global registration progress of Xocova®
- Main points of earnings forecast revision
- Upward revision of revenue and financial income
  - Strong sales from ViiV
- Reduced cost of sales
  - Reflected changes in the product mix

- Reduction in selling, general & administrative expenses
  - In order to prioritize COVID-19 related businesses, some of the originally planned growth investments will be shifted to the next fiscal year
- Increase in R&D expenses
  - Aggressive investment in product development including COVID-19 related projects

SHIONOGI

# **Revision of Earnings Forecast**

		FY2022 Forec	asts Full year		FY2021	Y on Y		
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts (Revised on Jan. 30)	Revised amount	Results	Change (%)	Change	
Revenue	400.0	410.0	421.0	11.0	335.1	25.6	85.9	
Operating profit	120.0	120.0	147.0	27.0	110.3	33.3	36.7	
Core operating profit*	120.0	120.0	144.5	24.5	110.6	30.7	33.9	
Profit before tax	168.0	174.0	210.0	36.0	126.3	66.3	83.7	
Profit attributable to owners of parent	136.0	142.0	170.0	28.0	114.2	48.9	55.8	

- Reflecting the government purchase of Xocova® and the strong HIV business, implement the second upward forecast revision in this fiscal year to achieve the highest performance since our founding
- Further increase in sales may be expected from overseas progression of Xocova®

Exchange Rate (average)	FY2022 Forecasts (Oct 24)	FY2022 Forecasts (Jan. 30)	FY2022 AprDec. results
USD (\$) – JPY (¥)	138	135	136.51
GBP (£) – JPY (¥)	162	162	163.96
EUR (€) – JPY (¥)	140	140	140.62

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



<sup>\*\*</sup> Record-highs Revenue: 420.2 B yen (FY2001,J-GAAP), Operating profit: 145.1 B yen (FY2018,IFRS), Profit before tax: 174.0 B yen (FY2018,IFRS), Profit attributable to owners of parent: 137.2 B yen (FY2018,IFRS)

# Revision of Earnings Forecast: Statement of Profit and Loss

		Y2022 Foreca	sts Full year		FY2021	Y on	Y
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts (Revised on Jan. 30)	Revised amount	Results	Change (%)	Change
Revenue	400.0	410.0	421.0	11.0	335.1	25.6	85.9
Cost of Sales	22.0 88.0	19.5 80.0	15.7 66.0	(14.0)	<sup>16.5</sup> 55.4	19.1	10.6
Gross profit	312.0	330.0		25.0	279.7	26.9	75.3
Selling, general&	47.5	50.7	48.9		50.2		
administrative expenses, R&D expenses total	190.0	208.0	206.0	(2.0)	168.2	22.4	37.8
Selling, general& administrative expenses	<sup>30.0</sup> 120.0	<sup>27.6</sup> 113.0	24.5 103.0	(10.0)	<sup>28.4</sup> 95.2	8.1	7.8
R&D expenses	17.5 70.0	<sup>23.2</sup> 95.0	24.5 103.0	8.0	<sup>21.8</sup> 73.0	41.1	30.0
Other income & expenses	(2.0)	(2.0)	(2.0)	-	(1.2)	71.5	(0.8)
Operating profit	<sup>30.0</sup> 120.0	<sup>29.3</sup> 120.0	34.9	27.0	32.9 110.3	33.3	36.7
Core operating profit	<sup>30.0</sup> 120.0	<sup>29.3</sup> 120.0	<sup>34.3</sup> 144.5	24.5	<sup>33.0</sup> 110.6	30.7	33.9
Finance income & costs	48.0	54.0		9.0	16.0	294.8	47.0
Profit before tax	<sup>42.0</sup> 168.0	<sup>42.4</sup> 174.0	49.9	36.0	<sup>37.7</sup> 126.3	66.3	83.7
Profit attributable to owners of parent	136.0	142.0		28.0	114.2	48.9	55.8



# **Revision of Earnings Forecast: Revenue by Segment**

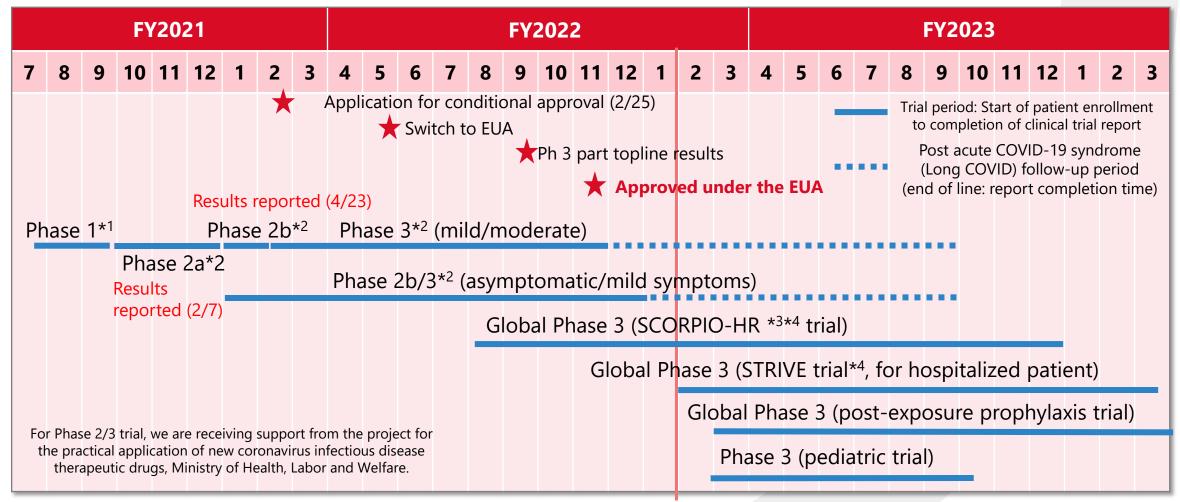
		FY2022 For	ecasts Full year		FY2021	Y on Y	
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts Revised (Revised on amount Jan. 30)		Results	Change (%)	Change
Prescription drugs	78.6	76.4	76.4	-	89.1	(14.3)	(12.7)
Overseas subsidiaries/export	41.6	39.3	39.3	-	34.4	14.4	5.0
Shionogi Inc.	13.0	14.4	14.4	-	13.8	4.8	0.7
Ping An-Shionogi <sup>*</sup> /C&O	14.8	10.4	10.4	-	10.2	2.1	0.2
Shionogi BV	8.4	8.6	8.6	-	5.0	71.7	3.6
Contract manufacturing	14.8	14.8	14.8	-	17.4	(15.3)	(2.7)
OTC and quasi-drug	13.4	13.2	13.2	-	11.2	18.7	2.1
Royalty income	140.4	155.0	166.0	11.0	181.3	(8.4)	(15.2)
HIV franchise	133.9	150.2	159.9	9.7	174.0	(8.1)	(14.0)
Crestor <sup>®</sup>	_	-	1.3	1.3	1.2	15.4	0.2
Others	6.5	4.8	4.8	-	6.1	(22.2)	(1.4)
COVID-19 related products**	110.0	110.0	110.0	-	-	-	110.0
Others	1.2	1.2	1.2	-	1.8	(32.6)	(0.6)
Total	400.0	410.0	421.0	11.0	335.1	25.6	85.9



3. Achievements in Q3 FY2022 and Actions for Future Growth



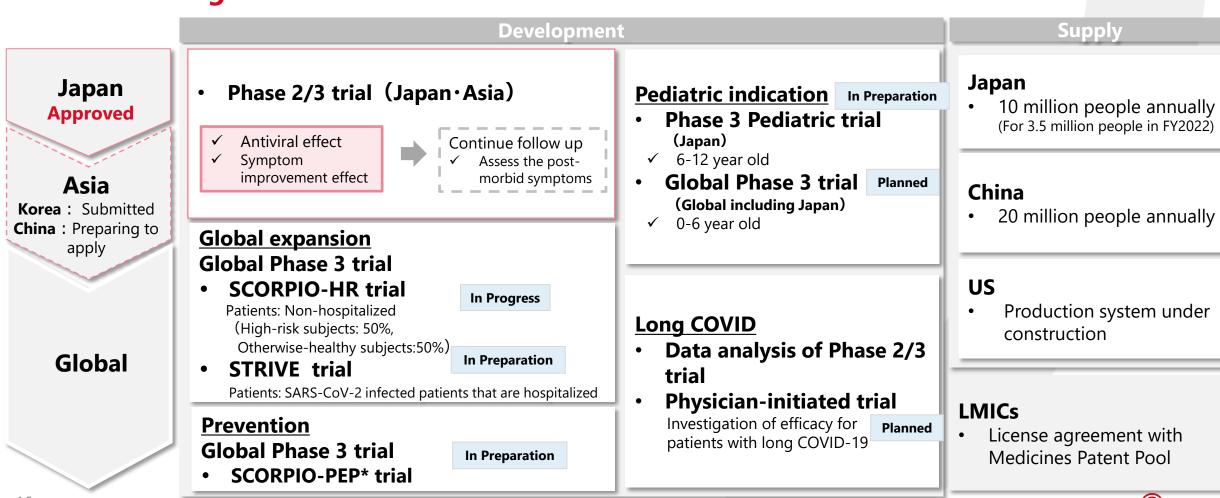
# **Xocova®: Progress Summary**





# **Xocova®: Overall picture of the current situation and future plans**

With the emergence of new mutant strains, the need for antiviral drugs remains Accumulating various evidence for the role of Xocova® in coexistence with COVID-19



# **Xocova®: Japan/Global Progress (1)**

## Japan

- Supply from government purchase, which is different from normal sales
- Collection and evaluation of safety information
  - Over 20,000 patients have taken Xocova<sup>®</sup>, and no major safety concerns have been identified
- Under discussion with MHLW and PMDA for general approval
- Additional data from Phase 3 Part of Phase 2/3 trial (Japan/Asia)
   will be announced at academic conferences, etc.
  - Antiviral reduction effect and long COVID follow-up Interim analysis results (around February 2023)

## Korea

- Submitted an approval application (January 3, 2023)
  - Aiming to obtain approval by 4Q FY2022
- Continuing discussions with the Korean government and regulatory authorities

## **Global Studies**

#### SCORPIO-HR

- Aiming for completion in 2023
- Accelerating patient enrollment by expanding sites

#### STRIVE trial

- Start: Feb. 2023 (planned)

#### SCORPIO-PEP\* trial

- Continuing protocol discussions with PMDA and FDA
- Start: Feb. 2023 (planned)



# Xocova®: Japan/Global Progress (2)

## China

- Ping An-Shionogi is preparing to apply for NDA
  - First of all, provide products manufactured in Japan
  - Switch to domestic production in China as soon as preparations are complete

### Construction of production system

- Completed PV at drug substance and formulation plants
  - > Building a production system aiming to supply more than 20 million people a year

### Construction of supply/sales system

- License agreement for import and distribution with Shanghai Pharmaceutical Co., Ltd (SHAPHAR)
- License agreement for promotion with Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (CTTQ)

#### Roles in supply/sales of Xocova® imported from Japan



- Import/customs clearance
- Storage (for bonded areas)
- Delivery to wholesalers and returns
- Storage
- Delivery to medical institutions
- Responding to orders
- Price negotiation
- Marketing plan drafting and information provision activities



# **Pipeline progress**

## Development updates from 3Q\*1

Pipeline	Indication	Progress
S-309309	Obesity	Confirmed favorable safety, tolerability and PK profile in Phase 1 interim report Phase 2 trial scheduled to start in 4Q FY2022
Olorofim (F901318)	Limited treatment options for invasive fungal infections	High efficacy and tolerability confirmed by date from the first 100 subjects in Phase 2b
	Invasive Aspergillosis	Phase 3 trial (ongoing)

## Phase 2b Initial Results\*2

- Study 32: Open-Label Study in Patients with Limited Treatment Options (NCT03583164)
- 75% significantly immunosuppressed

	Invasive Aspergillosis (n=53 of 1st 100)	External Control (n=46)
Month 3 ACM*3	32%	<b>87</b> %
95% CI	20-46%	75-95%

- Olorofim showed efficacy, including high survival rates, in infections due to a range of invasive rare molds
- Olorofim was well tolerated, even with dosing to ~2 years

New Drug Application (NDA) based on positive results is under review by FDA

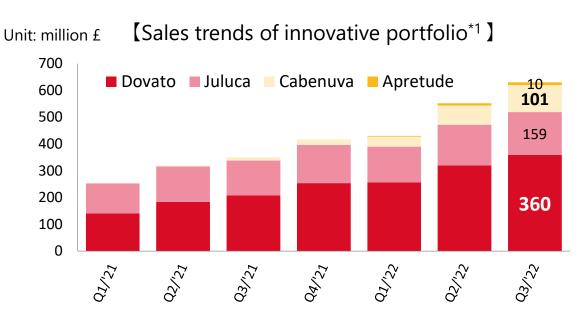
## Making steady pipeline progress



# **Progress of HIV Franchise by ViiV Healthcare**

## Strong uptake of innovative portfolio and continued pipeline progress

Growth led by Dovato and long-acting regimens



- Dovato (two-drug regimen)
  - Sales of £360 million in Q3 2022 (increase 73% YoY)
- Cabenuva (LA injection: treatment)
  - Sales of over £100 million in Q3 2022
- Apretude (LA injection: prevention)
  - Submitted NDA to EMA (Oct. 2022)\*2
- S-365598 (VH4524184\*3, ultra LA injection)
  - Initiated Phase 1 trial (Dec. 2022)\*4
    - > Oral administration

Steady growth of innovative portfolio and development progress of next-generation long-acting products to drive medium- to long-term growth

\*1 Created by SHIONOGI from GSK financial results

<sup>\*2</sup> GSK press release: European Medicines Agency validates ViiV Healthcare's marketing authorisation application for cabotegravir long-acting injectable for HIV Prevention | GSK



# **Progress of HIV Franchise by ViiV Healthcare**

Development status of combination candidates for ultra LA injections\*

Phase 1

VH3739937
maturation inhibitor

VH4004280
capsid protein inhibitor

VH4011499
capsid protein inhibitor

From GSK financial results in Q3 2022
Phase 2

VH3640254
maturation inhibitor

VH3640254
maturation inhibitor

VH4011499
capsid protein inhibitor

## **Broadly neutralizing antibody N6LS\*\***

- By blocking HIV's entry into human CD4+ cells, the HIV transmission process may be prevented
- Positive results of Phase 2a
  - A single infusion of N6LS demonstrated strong antiviral efficacy while also being well-tolerated by trial participants
  - Expect to begin a phase 2b trial of N6LS in combination with other anti-retrovirals in 2023

Accelerate development of combination candidates for the creation of ultra LA injections



# **Appendix**



# **Xocova®: Antiviral effect against mutant strains\***

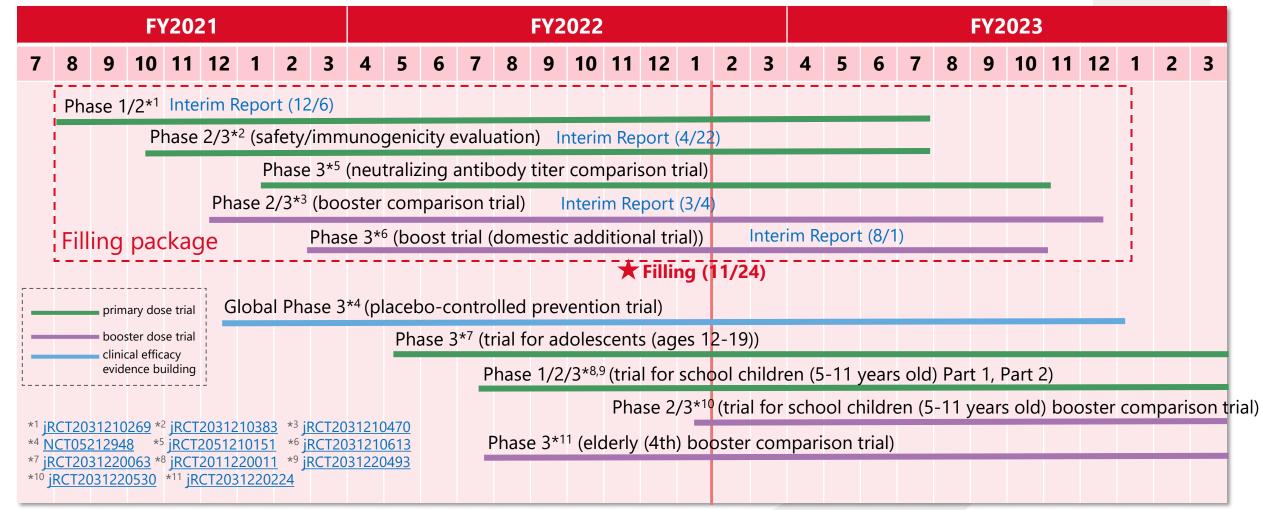
In vitro antiviral evaluation using VeroE6T cells

virus	Ancest alpha beta gamm	gamm	delta				omi	cron str	ain					
strain	or	strain	strain	a strain	strain	BA.1	BA.1.1	BA.2	BA.2.7 5	BA.4	BA.5	BQ.1.1	XBB.1	XE
ΕC <sub>50</sub> (μΜ)	0.37	0.46	0.40	0.50	0.41	0.29	0.36	0.52	0.30	0.22	0.40	0.48	0.33	0.44

- Xocova® shows antiviral efficacy against a wide range of strains, including past prevalent strains and recent Omicron mutant strains (BQ.1.1, XBB.1, XE).
- Xocova® shows antiviral efficacy against existing drug-resistant viruses (no cross-resistance)



# S-268019: Progress Summary

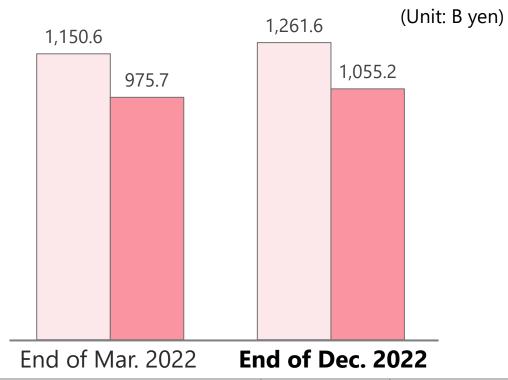


As of January 30, 2023 Trial period: Start of patient enroll to completion of clinical trial report



# **Financial Position (Consolidated, IFRS)**

Total Assets Equity attributable to owners of parent



	End of Mar. 2022	End of Dec. 2022
Ratio of equity attributable to owners of parent to total assets	84.8%	83.6%

Uni	t: B yen	End of Mar. 2022	End of Dec. 2022	Change
Total Assets	Non-current Assets	491.4	512.1	20.7
	Current Assets	659.2	749.6	90.3
Equity attributable to owners of parent		975.7	1,055.2	79.6
Total Liabilities	Non-current Liabilities	32.9	37.8	4.8
	Current Liabilities	124.4	145.3	20.9



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

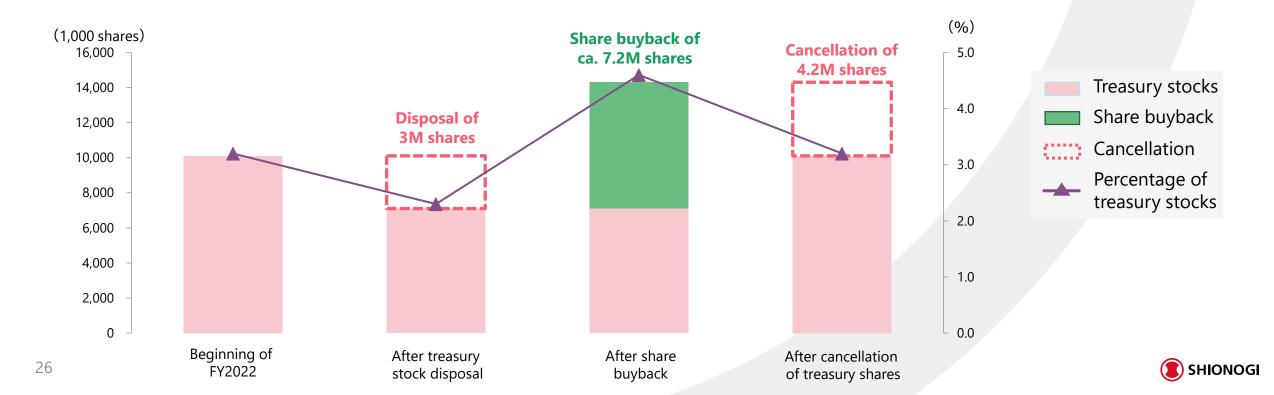
Disposal of treasury stock (advantageous issuance)

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: 7,200,000 shares (completed)
- Total value of shares acquired: 49,405,344,948 yen(completed)

Cancellation of treasury shares

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



## From the FY2022 R&D Day

# **Upcoming Pipeline Events 1/2**

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

				713 01 000. 12, 20	22 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	(3Q)	Ph1 start (1Q)	(4Q)
S-365598 (HIV franchise, out license )	HIV infection	Preclinical	Ph1 start (3Q)		
resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3			Submission (3Q) (2Q)
zatolmilast (BPN14770)	①Fragile X Syndrome ②Alzheimer's disease	①Phase 2/3 ②Phase 2	1		o3 topline results (4Q)
zulanolone (S-812217)	Depression	Phase 3		results (	mission 4Q)
S-151128	Chronic pain	Preclinical	P	(3Q) h1 start (4Q)	

Timing of trial start

Timing of topline results

Timing of submission



## From the FY2022 R&D Day

# **Upcoming Pipeline Events 2/2**

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

Pipeline	Indication	Stage	FY2022 3Q-4Q	FY2023	FY2024
Tipellie	Indication	Stage	112022 3Q-4Q	112025	112024
redasemtide (S-005151)	<ul><li>①Epidermolysis bullosa</li><li>②Acute ischemic stroke</li><li>③Knee osteoarthritis</li><li>④Chronic liver disease</li><li>⑤Cardiomyopathy</li></ul>	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	2 Ph3 s (40)		Submission (3Q)
S-309309	Obesity	Phase I re	topline Ph2 s sults (40		ne
S-531011	Solid tumor	Phase 1b/2			2 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 January. 30, 2023

#### Phase 1 Phase 2 **Preclinical** Phase 3 **Submission** S-217622 \*2 S-217622\* S-872600 S-540956 [Ensitrelvir] [Ensitrelvir] Influenza nasal vaccine Nucleic acid adjuvant COVID-19 treatment COVID-19 treatment \*2 Korea \*,\*3 Phase 2/3, Phase 3 S-268019 S-875670 S-337395 COVID-19 S-268019\*3 COVID-19 nasal vaccine **RSV** infections Prophylactic vaccine COVID-19 Prophylactic vaccine S-268019 S-554110 S-892216 COVID-19 **Nontuberculous** COVID-19 treatment Cefiderocol\*4 : Global development (Ages 5-19) mycobacterial infection Various infectious diseases cefiderocol Stage change (change from October. 31, 2022) \*4Japan, Taiwan Aerobic Gram-negative S-217622 (COVID-19 Treatment) → Japan: Approved under the EUA, Korea: Submission bacterial infection (Pediatric) Xofluza<sup>®</sup> S-268019 (COVID-19 Prophylactic vaccine): Submission Influenza virus infection F901318 Cefiderocol (Various infectious disease): Taiwan: Submission (Granules, < 20kg) [olorofim] S-365598 (HIV infection): Phase1 start Invasive Aspergillosis S-555739 Xofluza<sup>®</sup> Xofluza® (US) **Out license** S-365598 Treatment by suppressing Influenza virus infection Influenza virus infection **HIV** infection aggravation of COVID-19 (Pediatric, < 1 year old) (Pediatric, < 1year old) Xofluza® Influenza virus infection (Transmission)

# Pipeline: Psycho-Neurological Disease, Pain

as of January. 30, 2023

**Preclinical** 

Phase 1

Phase 2

**Submission** 

S-874713

Psycho-neurological diseases

S-109802

Post-stroke spasticity

S-600918 [sivopixant] Neuropathic pain

S-600918 [sivopixant]

Refractory chronic cough

**BPN14770** 

S-600918 [sivopixant] Refractory chronic cough

S-812217 [zuranolone]

Depression

**BPN14770** [zatolmilast]

Alzheimer's disease



\*\* Phase 2b/3

S-151128

Chronic pain

[zatolmilast] Alzheimer's disease

> Rizmoic\* Opioid-induced constipation (pediatric)

\* Phase 1/2

**SDT-001** 

Inattentive ADHD (pediatric)

**GRT7039** 

Resiniferatoxin

Pain associated with knee osteoarthritis

Global development

Add Code No. (change from October. 31, 2022)

GRT7039 (resiniferatoxin)

**Out license** 

S-0373 [rovatirelin]

Spinocerebellar Degeneration



# **Pipeline: New Growth Areas**

as of January. 30, 2023

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



# Other Major Progress\*

#### November

- Entering Into a Capital Alliance Agreement with LIFESCAPES
- SHIONOGI Integrated Report 2022 Won Silver Award in the WICI Japan Integrated Report Award 2022

#### December

- Shionogi Recognized with Double A list for Leadership in Corporate Transparency and Performance on Climate Change and Water Security by CDP
- New Drug Application of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol Accepted for Review in Taiwan
- Launch of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol in Spain

## January

- Approval of anti-influenza virus agent XOFLUZA® for pediatric indication in Europe
- Initiation of a Phase1/2/3 Clinical Trial (Part 2) and Phase 3 Additional Dose Clinical Trial in Japanese Pediatric Subjects of the COVID-19 Recombinant Protein-based Vaccine, S-268019



## **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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