

3rd Quarter of Fiscal 2023 Financial Results

January 31, 2024

Shionogi & Co., Ltd.



SHIONOGI

Agenda

- **Overview of Q3 FY2023 Financial Results (P.3-9)**
- **Achievements in Q3 FY2023 and Actions for Future Growth (P.10-20)**
 - Current Status of SHIONOGI's Infectious Disease Business
 - Progress of Major Development Products

Overview of Q3 FY2023 Financial Results

Financial Results

(Unit: B yen)

	FY2023			FY2022		Y on Y	
	Forecasts Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Revenue	450.0	336.8	74.8%	338.3	(0.5)	(1.5)	
Operating profit	150.0	138.7	92.5%	146.5	(5.3)	(7.7)	
Profit before tax	192.5	164.5	85.4%	198.8	(17.3)	(34.3)	
Profit attributable to owners of parent	155.0	127.2	82.1%	157.7	(19.3)	(30.5)	
EBITDA*	-	160.2	-	157.0	2.0	3.2	

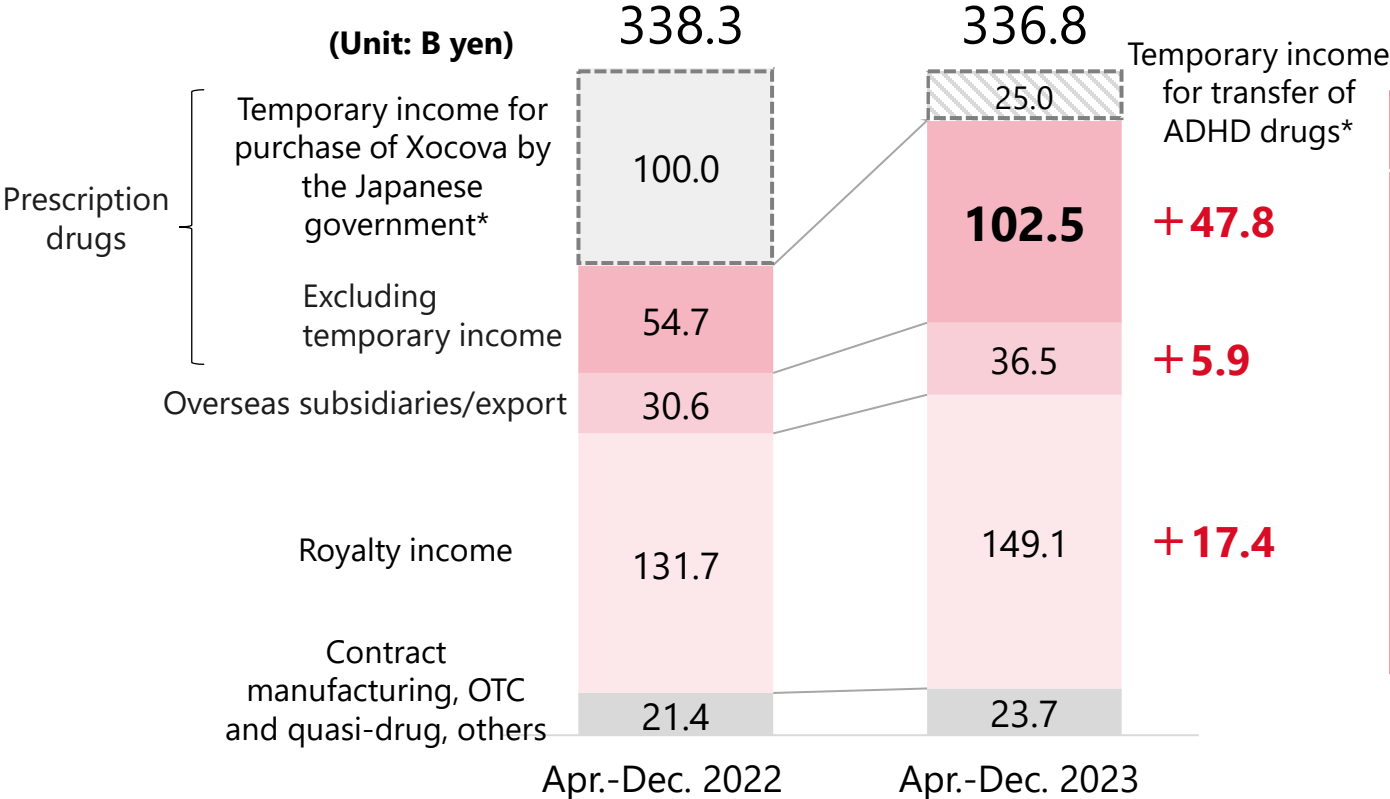
- Revenue and all profit items are on track to achieve full-year forecasts
- Expanding sales centered on infectious disease drugs will alleviate the 100 billion yen impact from the Japanese government's purchase of Xocova recorded in the same period of the previous year

Exchange Rate (average)	FY2023 Forecasts (Oct. 31)	FY2023 Apr.-Dec. Results
USD(\$) – JPY(¥)	141	143.33
GBP(£) – JPY(¥)	173	179.59
EUR(€) – JPY(¥)	151	155.33

Expansion of In-house Sales Centered on Infectious Disease Drugs

Exceeded the previous year's revenue in all business segment (excluding temporary factors) due to sales growth of in-house developed infectious disease drugs

Revenue by Segment (Y on Y)



Main sales increase factors

- **Prescription drugs (Excluding temporary income)**
 - Sales of Xocova and Xofluza
- **Overseas subsidiaries/export**
 - Sales of cefiderocol (Fetroja, Fetroja)
- **Royalty income**
 - Strong sales of ViiV's HIV franchise

* Temporary factors that affected revenue

Statement of Profit or Loss

(Unit: B yen)

	FY2023		FY2022	Y on Y		
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	450.0	336.8	74.8	338.3	(0.5)	(1.5)
Cost of Sales	13.2	12.6		13.2		
	59.5	42.4	71.3	44.6	(4.9)	(2.2)
Gross profit	390.5	294.4	75.4	293.8	0.2	0.6
Selling, general & administrative expenses, R&D expenses total	51.3	43.6		43.9		
	231.0	146.9	63.6	148.4	(1.0)	(1.5)
Selling, general & administrative expenses	26.4	22.1		21.7		
	119.0	74.3	62.4	73.6	1.0	0.7
R&D expenses	24.9	21.6		22.1		
	112.0	72.6	64.9	74.8	(2.9)	(2.2)
Other income & expenses	(9.5)	(8.8)	92.2	1.1	-	(9.8)
Operating profit	33.3	41.2		43.3		
	150.0	138.7	92.5	146.5	(5.3)	(7.7)
Finance income & costs	42.5	25.7	60.6	52.3	(50.8)	(26.6)
Profit before tax	42.8	48.8		58.8		
	192.5	164.5	85.4	198.8	(17.3)	(34.3)
Profit attributable to owners of parent	155.0	127.2	82.1	157.7	(19.3)	(30.5)

Main Variation Factors (Y on Y)

Revenue

- Increase
 - Overseas subsidiaries /export, Royalty income
- Decrease
 - Purchase of Xocova by the Japanese government in Q3 FY2022

Other income & expenses

- Increase in expenses
 - Costs related to implementation of early retirement program in Q2 FY2023 (6.6 B yen)

Finance income & costs

- Decrease in income
 - Received dividend from ViiV (FY2022 dividend increased temporarily)
 - ⇒ Dividends are progressing as planned, excluding temporary factors

Revenue by Segment

(Unit: B yen)

	FY2023			FY2022		Y on Y	
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Prescription drugs	167.0	127.5	76.4	154.7	(17.5)	(27.1)	
Excluding temporary income	-	102.5	-	54.7	87.5	47.8	
Temporary income	-	25.0	-	100.0	-	(75.0)	
Overseas subsidiaries/export	49.2	36.5	74.3	30.6	19.4	5.9	
Shionogi Inc.(US)	17.0	13.1	77.2	11.5	14.1	1.6	
Fetroja	-	10.6	-	7.3	45.4	3.3	
Shionogi B.V.(EU)	13.0	10.1	77.4	6.6	52.0	3.4	
Fetcroja	-	7.9	-	5.1	56.0	2.8	
Ping An Shionogi/C&O	12.1	8.3	68.8	8.3	(0.7)	(0.1)	
Others	7.1	5.1	70.7	4.1	22.3	0.9	
Contract manufacturing	16.4	11.7	71.7	10.3	14.2	1.5	
OTC and quasi-drug	14.8	10.6	71.7	10.1	5.1	0.5	
Royalty income	201.2	149.1	74.1	131.7	13.2	17.4	
HIV franchise	196.5	146.1	74.3	126.9	15.1	19.2	
Others	4.7	3.0	63.8	4.8	(37.1)	(1.8)	
Others	1.5	1.4	93.8	1.0	33.2	0.3	
Total	450.0	336.8	74.8	338.3	(0.5)	(1.5)	

Main Variation Factors (Y on Y)

Prescription drugs

- Increase
 - Sales of Xocova and Xofluza
 - Receipt of lump-sum income for transfer of ADHD drugs in Q1 FY2023 **(Temporary income)**
- Decrease
 - Sales of ADHD drug
 - Purchase of Xocova by the Japanese government in Q3 FY2022 **(Temporary income)**

Overseas subsidiaries/export

- Increase
 - Sales of cefiderocol (Fetroja, Fetcroja)

Royalty income

- Increase
 - Strong sales of ViiV's HIV franchise

Prescription Drugs in Japan

(Unit: B yen)

	FY2023		FY2022		Y on Y	
	Forecast Full year (Oct. 31)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Infectious disease drugs	97.5	69.0	70.8	102.9	(32.9)	(33.8)
COVID-19 related products	88.6	62.0	70.0	96.2	(35.6)	(34.2)
+ Influenza franchise	-	62.0	-	(3.8)*	-	65.8
Excludes purchase of Xocova by the Japanese government	-	-	-	-	-	-
Cymbalta	4.2	3.1	75.4	4.4	(29.5)	(1.3)
OxyContin franchise	4.3	3.3	77.7	3.5	(5.3)	(0.2)
Symproic	4.9	3.3	67.3	2.6	27.5	0.7
Actair	1.0	0.5	50.5	0.4	28.4	0.1
Mulpleta	0.1	0.1	53.7	0.1	(19.9)	(0.0)
Pirespa	1.9	1.6	81.3	2.0	(23.3)	(0.5)
Others	53.1	46.6	87.7	38.7	20.3	7.8
ADHD drugs (Intuniv and Vyvanse)**	25.0	25.0	100.0	15.8	57.8	9.2
Prescription drugs	167.0	127.5	76.4	154.7	(17.5)	(27.1)
Excluding temporary income	-	102.5	-	54.7	87.5	47.8

COVID-19 related products

- Xocova
- COVID-19 vaccines

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs

- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja

Results and Progress in Q3 FY2023

Achieved expansion of in-house sales centered on infectious disease drugs while accelerating investment to achieve global sales expansion and to advance growth drivers

Results up to Q3 FY2023

- Revenue and all profit items made steady progress against full-year forecasts
 - Domestic/overseas business and royalty income drove top line
- Expansion of in-house sales of in-house developed products contributed to performance
 - Growth in sales of Xocova, influenza family and cefiderocol
- Active R&D activities and business investment
 - Steady progress in focused pipelines
 - Built external networks to acquire new capabilities

Activities in Q4 FY2023

- Preparing for the spread of acute infectious diseases
 - Promote test-and-treat for COVID-19
 - Continue activities to improve the treatment rate with oral antiviral drugs
- Flexible cost management according to top line
- Stable supply of pharmaceuticals
 - Continue efforts to increase production mainly for infectious disease-related products such as antitussives*

Achievements in Q3 FY2023 and Actions for Future Growth

- Current Status of SHIONOGI's Infectious Disease Business
- Progress of Major Development Products

Strategies for the Infectious Disease Business

Establish a business model for each area to achieve continuous growth Contribute to global health and stable supply

Build a sustainable business model

Acute infectious diseases (COVID-19, influenza, etc.)

Therapeutic drugs: Ensitrelvir, Xofluza

- Achieve growth of ensitrelvir in the global market

Total care actions

- Achieve growth in the diagnosis, vaccine, and wastewater monitoring businesses

Antimicrobial resistance (AMR)

Work with society to create sustainable markets

- Roll out cefiderocol globally
- Introduce push and pull incentives
- Introduce rapid diagnosis that identifies antimicrobial-resistant bacteria and the mechanism of resistance

Build a stable business base by contributing to large numbers of patients

Infectious diseases requiring a long period of treatment (three major infectious diseases, etc.)

Cultivate new markets that address unmet needs

- Provide new solutions for HIV infection
- Develop a new drug (olorofim) against highly lethal fungal infections
- R&D of new treatments for infectious diseases with high unmet needs (tuberculosis, malaria, nontuberculous mycobacterial diseases)

Total care, including vaccines

Grow vaccines into the next earnings driver as a core business

- Launch COVID-19 and influenza vaccines
- Expand the business to Asia and across the world
- Establishment of new technologies that will be our strength (nasal, universal vaccines)

Strengthen diagnostic capabilities

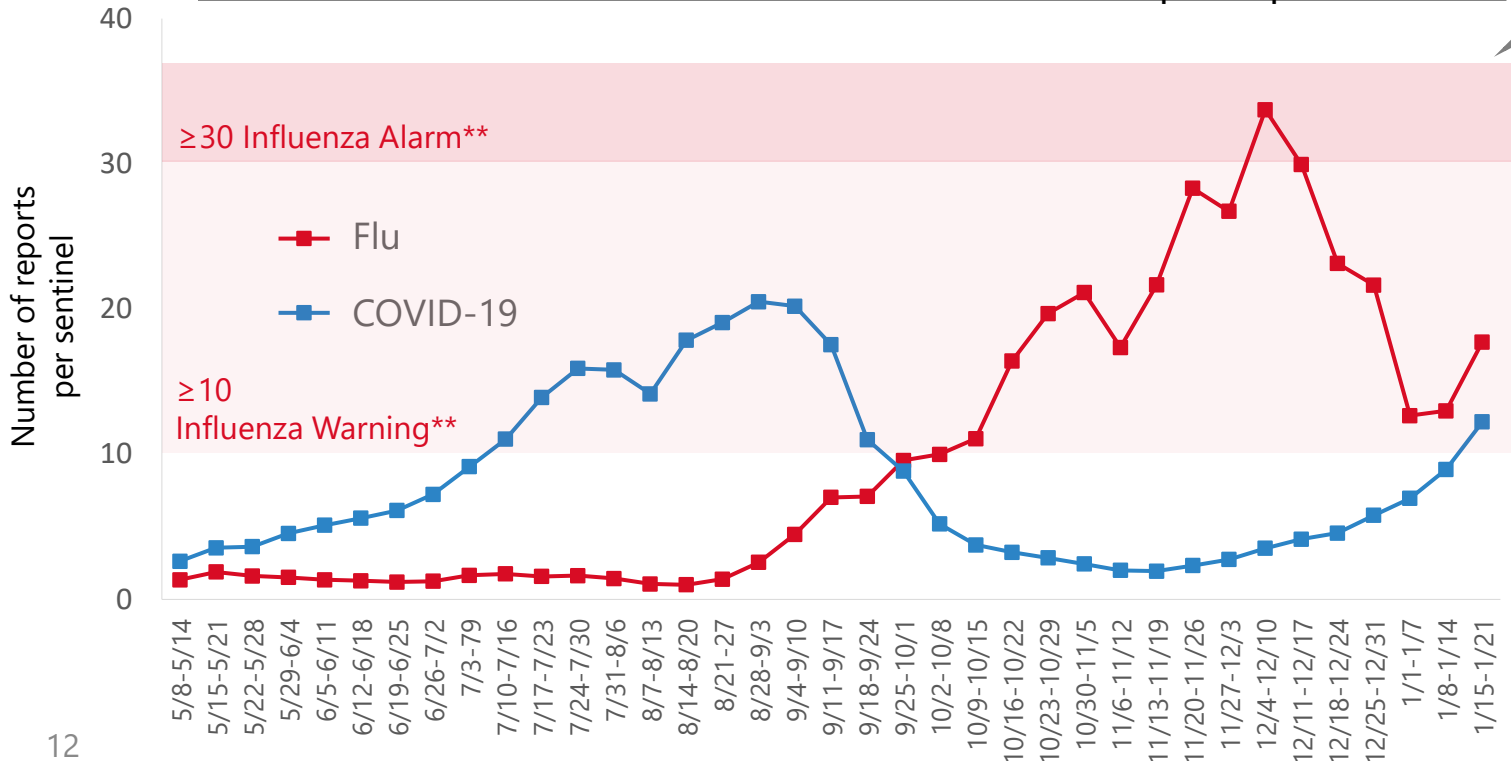
- Provide simple diagnostic solutions (home diagnosis kits, etc.)

Acute Infectious Diseases: Establishment of Sustainable Business

Having a multi-drug respiratory infectious disease portfolio can increase the stability of the business

Acute Infectious disease epidemic status in Japan

Trends in the number of influenza and COVID-19 reports per sentinel*



Either influenza or COVID-19 continued to spread above a certain level throughout the year

Achieved stable performance with two acute infectious disease drugs (Influenza and COVID-19)

Seeking to establish a sustainable global business model

* After changing the status of COVID-19 to Category 5 infectious disease
[Press materials about influenza |Ministry of Health, Labour and Welfare](#)
[Press materials about new-style coronavirus infectious disease |Ministry of Health, Labour and Welfare](#)

** Standards for influenza

Acute Infectious Diseases (Influenza): SHIONOGI's Anti-influenza Drugs

Contribute to flu treatment by providing anti-flu drugs with different routes of administration

Xofluza: Cap-dependent endonuclease inhibitor

- Indications: Treatment and prevention of influenza A and B virus infections*¹
- Mechanism of action: Suppression of virus proliferation ⇒ Suppression of viral mRNA synthesis
- Administration route: Single-time oral
- Launch date: March 2018



Recommended for adults and children 12 years and older through continued evidence accumulation*^{2,3}

Rapiacta: Neuraminidase inhibitor

- Indications: Treatment of influenza A and B virus infections
- Mechanism of action: Suppression of virus proliferation ⇒ Keep the virus on the cell surface
- Administration route: intravenous injection
- Launch date: January 2010



Contributes to the treatment of patients who are difficult to administer orally or require hospitalization

*¹ Xofluza Tablets 20mg has Indication for treatment and prevention, Xofluza tablets 10mg has Indication for treatment

*² [New recommendations regarding the use of cap-dependent endonuclease inhibitor baloxavir marboxil \(Xofluza\) \(revised on November 27, 2023\)](#)

*³ [Influenza treatment and prevention guidelines for the 2023/24 season](#)

Acute Infectious Diseases (COVID-19): Xocova Development Plan

Advance development for adult and pediatric treatment globally and for obtaining prevention indication

Progress of clinical trials

- SCORPIO-HR trial: **The enrollment was completed in December 2023**

Subject	Outpatient COVID-19 cases, including patients at risk of developing severe illness
Target number of subjects	2,000 cases (Xocova group: 1,000 cases, Placebo group: 1,000 cases)
Primary endpoint	Time to resolution of 15 COVID-19 symptoms*1
Secondary endpoints	<ul style="list-style-type: none">• Incidence rate of Long COVID*2 after 12 weeks• Change in viral RNA amount from baseline• Hospitalization rate and mortality rate related to COVID-19

- SCORPIO-PEP*3 trial: Completed enrollment of over 1,000 subjects
 - To verify the effectiveness of suppressing the onset of COVID-19 symptoms in close contacts
 - Target number of subjects: 2,200
- Pediatric trial: Promote subject enrollment in Japan

*1 Cough, sore throat, stuffy nose, runny nose, shortness of breath (difficulty breathing), feverishness or fever, chills, malaise (feeling of fatigue), muscle pain or body pain, diarrhea, nausea, vomiting, headache, taste abnormality, anosmia

*2 Malaise (feeling of fatigue), shortness of breath (difficulty breathing), decreased concentration/thinking ability, decreased logical thinking/problem-solving ability, memory impairment, taste and smell disorders

*3 PEP: Post Exposure Prophylaxis *4 Submit application materials in stages. The FDA can proceed with the review sequentially starting with the submitted data without waiting for all data to be submitted

*5 Special Access Route approval: Singapore's own regulatory system for importing and supplying unapproved therapeutic drugs

Current status in each country

- US:
 - The rolling submission*4 will start in Q1 FY2024 under discussion with FDA
- Japan:
 - Discussions with MHLW and PMDA to obtain early regular approval
 - > Application completed in June 2023
- Singapore:
 - The Filing for regular approval was submitted by Juniper
 - Based on the Special Access Route approval*5, prescription of Xocova started
- South Korea:
 - Application for manufacturing license by Ildong for production and supply in South Korea

Antimicrobial Resistance (AMR): Cefiderocol

Advancing appropriate use while resolving global access issues

Ensure broader understanding of appropriate use in already launched countries and expand launched countries

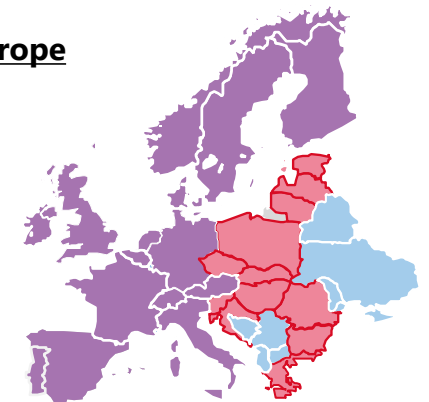
- **Europe and America**
 - Expand sales in approved countries
- **Japan**
 - Obtained manufacturing and sales approval and started sales
 - Antibiotic procurement support project (Japanese pull type incentive)*
- **China**
 - Obtained approval for clinical use in Boao Lecheng International Medical Tourism Pilot Zone
 - Phase 3 study underway to obtain regular approval

Expansion of supply countries through partnering

- **Conclusion of sales contract with Sobi**
 - Signed sales agreements in 13 countries in Central and Eastern Europe
- **Collaboration with GARDP/CHAI**
 - Started transfer of manufacturing technology to GARDP sublicensee, Orchid Pharma

Countries targeted for cooperation in Europe

- Partner countries with Sobi
- Countries licensed to GARDP
- Countries where SBV conducts sales



Total Care, including Vaccines: Progress of Vaccine Development

Establishing a platform*, Commercial manufacturing, Next generation vaccine, are progressing

S-268023 (Omicron XBB1.5 strain vaccine)

- Domestic phase 3 booster immunization trial started
 - **Registration completed**
 - > S-268023: 300 cases, Comirnaty RTU intramuscular injection (monovalent: XBB.1.5): 300 cases
 - Topline scheduled for the end of the fiscal year

Trial Overview

Subject	Subjects aged 20 years or older who have completed their first immunization
Purpose	- Verification of non-inferiority to Comirnaty RTU intramuscular injection (monovalent: XBB.1.5) • Safety evaluation and clinical efficacy study of S-268023
Primary endpoint	Geometric mean antibody titer and antibody response rate of neutralizing activity against XBB.1.5 strain 28 days after vaccination

Vaccine antigen commercial manufacturing

- Constructing stable vaccine manufacturing facilities at a commercial manufacturing scale
 - optimize the manufacturing process in line with attributes of cells and antigens

Consistently achieved antigen production meeting quality standards at 16,000L scale

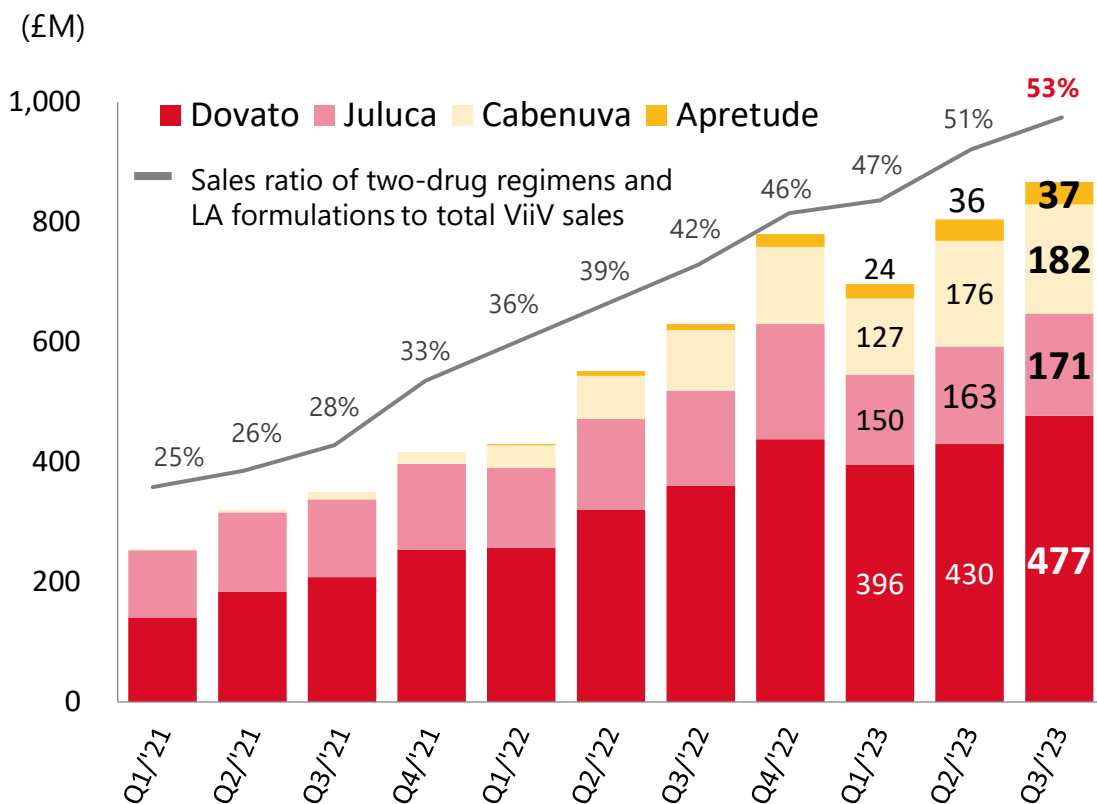
Universal Vaccine

- On track for the start of clinical trials in 2024
 - Neutralizing antibody titer increase has been confirmed not only with the original strain of SARS-CoV-2 but also with various mutant strains and even with the strain of SARS-CoV-1 that caused a pandemic in 2003
 - Data to be published at next R&D Day in June 2024

Infectious Diseases Requiring a Long Period of Treatment(HIV) : Progress of HIV Business by ViiV

HIV business is strong due to growth in oral two-drug regimens*1 and LA formulations*2

ViiV sales trend of oral two-drug regimens and LA formulations*3



Growth in oral two-drug regimens and LA formulations

- Steady progress towards sales forecast of £7 billion in 2026
 - Sales ratio of two-drug regimens and LA formulations increased to 53%
 - Dovato drives sales
 - Cabenuva, Apretude market continues to expand

ULA*4 milestones for growth drivers

- Achieving sustainable growth by continuing to roll out new products beyond 2026

	2026年	2027年	2028-2030年
ULA (PrEP)	Q4M file•launch		Q6M file•launch
ULA (Treatment)		Q4M file•launch	Q6M file•launch
Self-injection (Treatment)			file•launch

Progress of Major Development Products

as of January 30, 2024

Disease area	Pipeline	Indication	Current stage	FY2023	FY2024	Note
COVID-19 Family	S-268019	COVID-19 (Vaccine)	Submission			
	Ensitrelvir	COVID-19	Submission, Phase 3	→		SCORPIO-HR registration completed
	S-268023	COVID-19 (XBB 1.5, Vaccine)	Phase 3	→		Start Phase 3 (registration completed)
	S-892216	COVID-19	Phase 1	→		
	Universal Vaccine	COVID-19 (Vaccine)	Preclinical	→		
Infection diseases	Olorofim	Invasive aspergillosis	Phase 3	→		Announced Phase2b results*
	S-337395	RSV infections	Phase 2	→		Start Phase 2
	S-743229	AMR (Urinary tract infection)	Phase 1	→		Start Phase 1 overseas
	S-649228	AMR (Various infectious diseases)	Preclinical	→		
QOL Diseases with High Social Impact	Zuranolone	Depression	Phase 3	Phase 3 topline results (3Q)	Submission (4Q)	
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	→		Submission (4Q)
	SDT-001	ADHD	Phase 3	→		Submission
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline results (FY24 3Q)	Submission (FY25 1Q)	
	Redasemtide	Acute ischemic stroke	Phase 2b	→		
		Dystrophic epidermolysis bullosa	Phase 2	→		Submission (3Q)
	S-309309	Obesity	Phase 2	Obtain Phase 2 data (FY24 1Q)	Phase 3 start	Phase 2 registration completed
	S-531011	Solid tumor	Phase 1b/2	→		Phase 2 start (2Q)
S-151128	Chronic pain	Phase 1	→		Phase 1 topline results	
						Start of Phase 1b for OA patients

SHIONOGI R&D Day 2024 scheduled to be held on June 7 2024

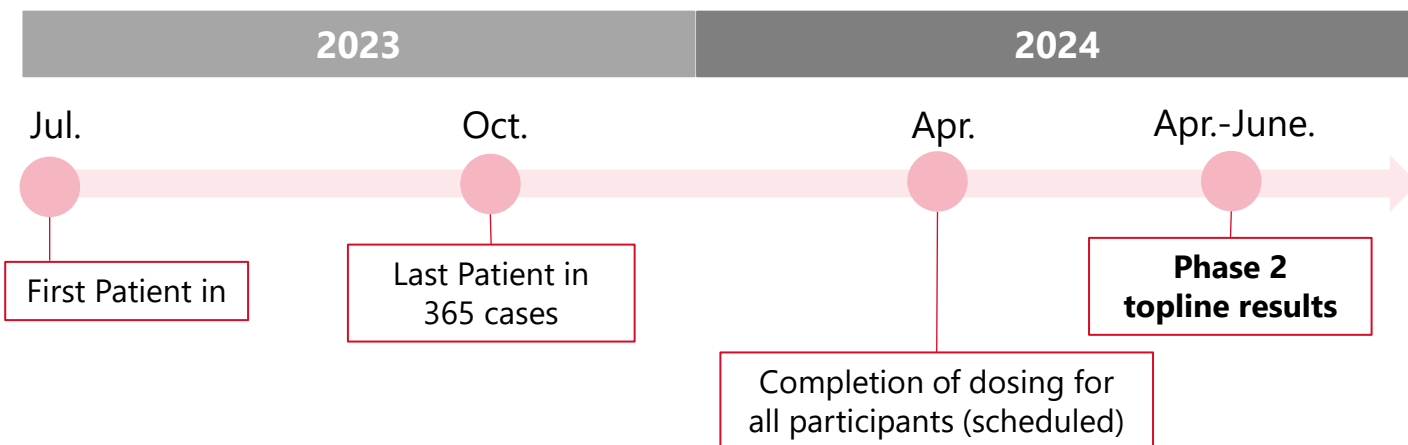
S-309309 (MGAT2* inhibitor) Development Progress

Phase 2 trial progressing as planned

Trial Overview**

Country	The U.S.
Subject	Adults with a BMI of 30 or higher
Trial design	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
Dosage number of cases	<ul style="list-style-type: none"> Oral once daily for 24 weeks S-309309: 3 doses, placebo, 80 in each group (320 in total)
Primary endpoint	Percent change in body weight from baseline (week 24)
Secondary endpoint	<ul style="list-style-type: none"> Percentage of subjects achieving $\geq 5\%/10\%/15\%/20\%$ weight loss Waist circumference, waist/hip ratio, BMI, abdominal fat/lean mass

Status of progress



- **Participant registration was completed in October, with a total of 365 cases registered**
- No adverse events that would affect the continuation of the trial have been reported
- After 24 weeks of treatment and follow-up period, we plan to provide topline results in April to June.

Further Strengthening R&D Capabilities in the Infectious Disease Field

Through Qpex, a wholly owned subsidiary, we have expanded our capabilities

Evolution of infectious disease R&D

- **Enhanced global R&D capabilities**
 - Smooth collaboration with Qpex Inc.
 - > Robust R&D activity including xeruborbactam*
 - Progress in strengthening external networks
 - > Enhancing collaboration with external organizations, including regulatory authorities and government agencies like BARDA
- **Maximizing antibacterial research**
 - Commenced research and development of novel infectious disease therapeutics with Qpex Inc.
 - Strengthen research in the field of infectious disease therapeutics to address remaining unmet needs

Progress of two development products



S-649228: xeruborbactam + cefiderocol

- Injection in combination with cefiderocol
- Progress is being made in non-clinical trials, and transition to the clinical stage is scheduled for 1Q FY2024



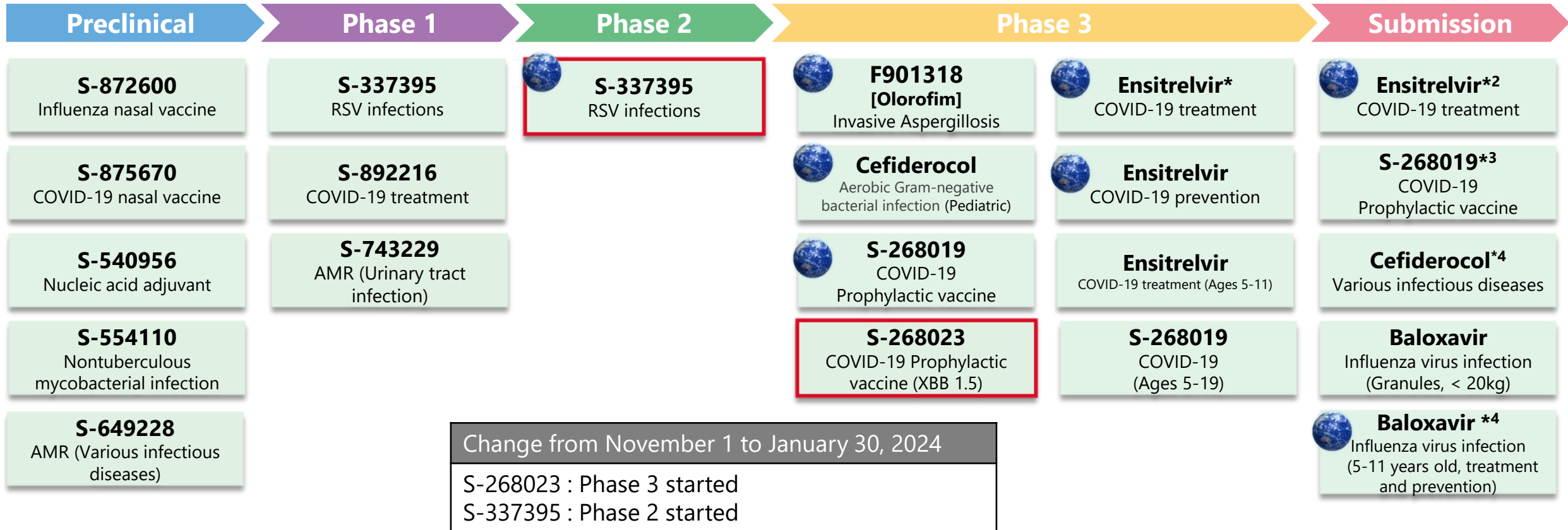
S-743229: xeruborbactam + ceftibuten

- Oral formulation in combination with the cephem antibiotic, ceftibuten
- Phase 1 trial ongoing

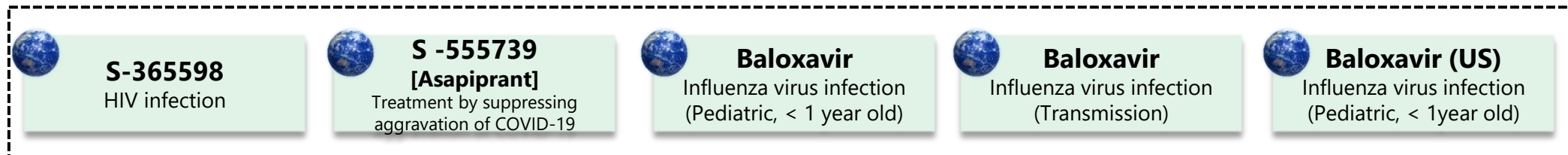
Appendix

Pipeline: Infectious Disease

as of January 30, 2024



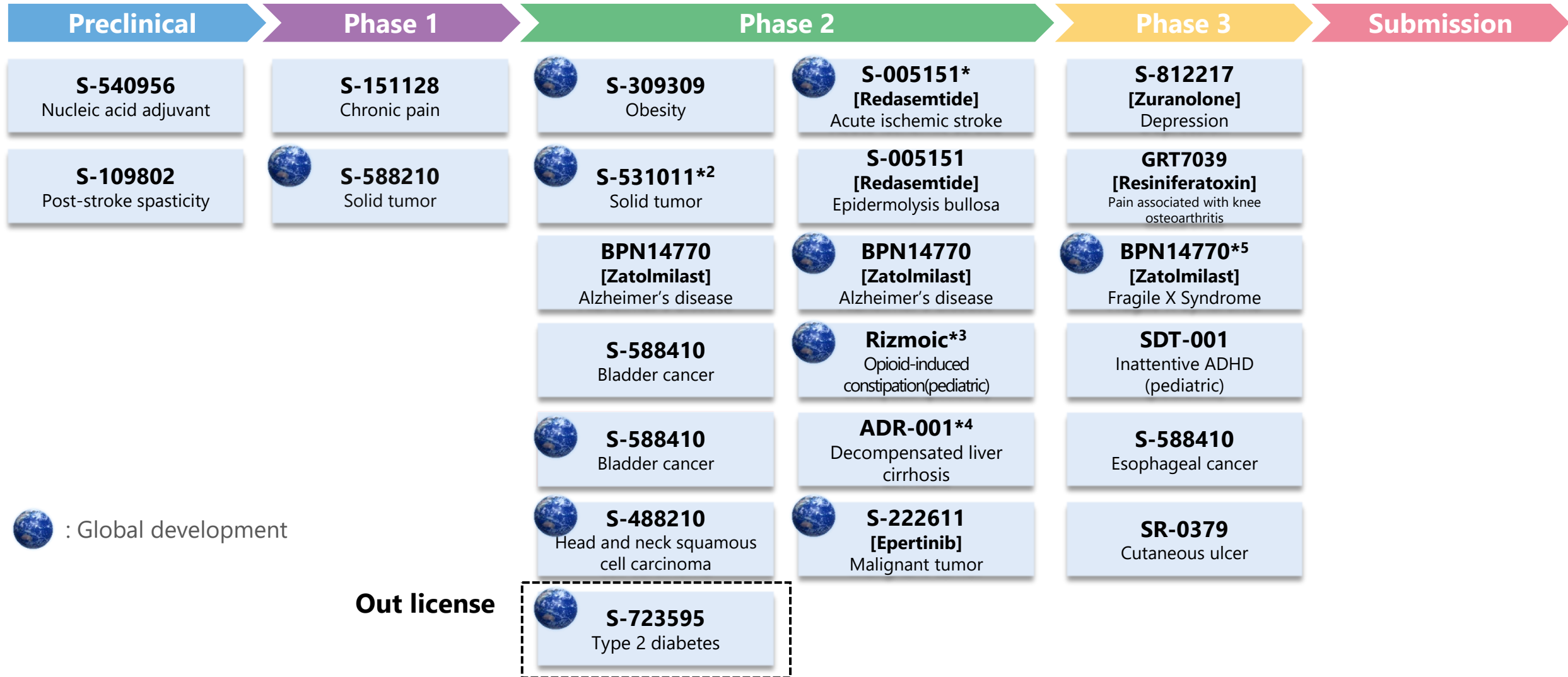
Out license



: Global development

Pipeline: QOL Diseases with High Social Impact

as of January 30, 2024



: Global development

Other Major Progress*

- **November**

- The Sales Partnership Agreement in Japan between Shionogi and Mochida regarding Insomnia Treatment Drug Daridorexant
- Investment with J.P. Morgan Asset Management's Life Sciences Private Capital
- Stream-I, Inc. Launches New Home Palliative Care Support Service 'Home Care Base'

- **December**

- Investment Agreement with AN Venture Partners
- Signing of Collaboration Agreement in the Third Phase of the "Mother to Mother SHIONOGI Project"
 - App Development for Diarrhea Prevention in Tanzania -

- **January**

- Commencement of DTx Distribution Platform Construction for the Promotion of Digital Therapeutic Services
- Investment Agreement with Niremia Collective

Creation of Universal Vaccine Antigens

Aiming to create vaccine antigens that are effective for novel variant strains and even the next pandemic

Design of universal antigens

Concepts

- Design a novel antigen using back-calculation from immune factors shown to be induced in humans
- Create vaccines that cover both the then-prevailing SARS-CoV-2 and the next (and next, and next) strain

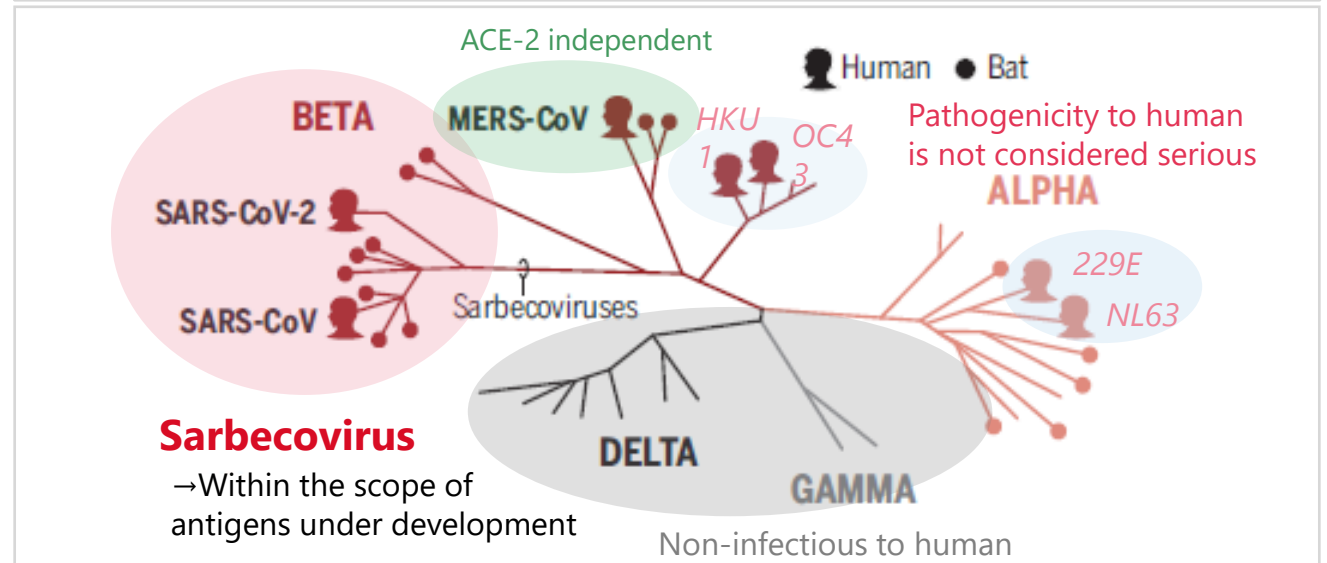
Current status

- Identification of universal sarbecovirus vaccine antigens under development has completed
- On track towards the start of clinical trials in 2024

Effects

- Neutralizing antibody titer increase has been confirmed not only in the original strain of SARS-CoV-2 but also in various mutant strains and even in the strain of SARS-CoV-1 that caused pandemic in 2003
- Data to be published at next R&D Day

Evolutional tree of coronavirus



Points to consider in the design universal antigens

Stabilization of protein structure	Change of dynamic characteristics of proteins
Optimization of versatility	Regulation of epitope

Shionogi Pharma's Efforts to Increase Production of Medicon

Response so far

- Adjustments to bring forward the delivery date of active pharmaceutical ingredients

Responses from January to March 2024 (4Q of 2023)

- Adjustments to bring forward delivery of APIs and increase production volume
- Reduce production of other products and transfer resources to Medicon
- Start manufacturing during testing, etc.

Medium- to long-term response (from April 2024)

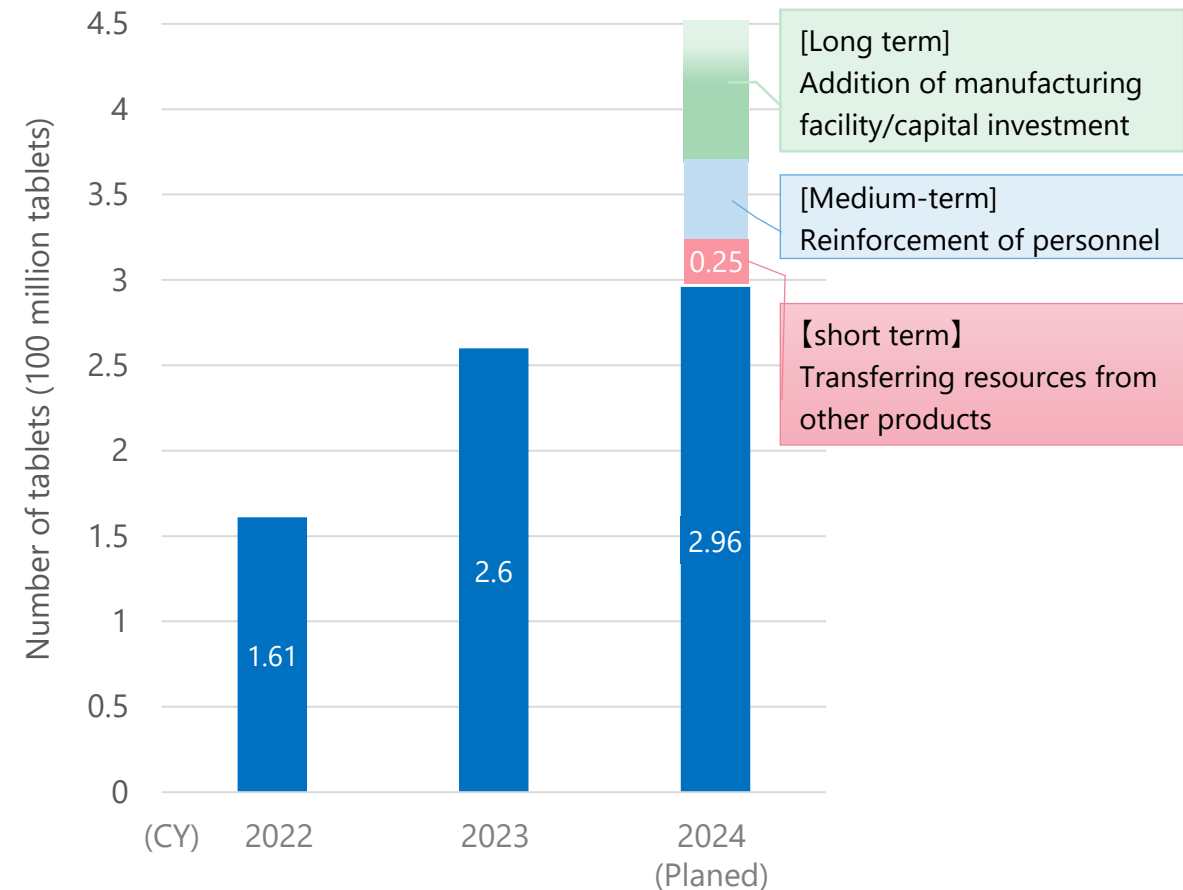
【Middle period】

- Increase in personnel (under consideration)

【Long term】

- Addition of manufacturing facility/capital investment (under consideration)

Number of tablets production of Medicon



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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- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials, and failure to gain market acceptance.
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