1st Quarter of Fiscal 2023 Financial Results

July 31, 2023

Shionogi & Co., Ltd.

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Agenda

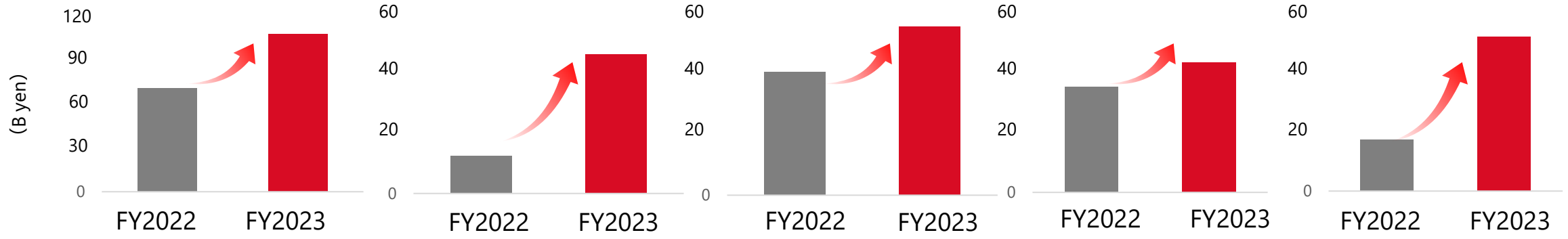
1. **Overview of Q1 FY2023 Financial Results (P.3-9)**
2. **Main Activities and Achievements in Q1 FY2023 (P.10-17)**
3. **Shareholder Return (P.18-19)**

1. Overview of Q1 FY2023 Financial Results

Financial Highlights

- **Revenue and all profit categories increased YoY**
- **Despite continued aggressive investment, revenue and all profit reached record highs in 1Q**

	Revenue	Operating profit	Profit before tax	Profit attributable to owners of parent	EBITDA*
1Q	**109.3** B yen	**46.6** B yen	**55.7** B yen	**42.6** B yen	**51.3** B yen
Y on Y	**+52.2** %	**+275.0** %	**+38.2** %	**+22.6** %	**+202.4** %



* Earnings Before Interest, Taxes, Depreciation, and Amortization: Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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Financial Results

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecasts		Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
	Full year	1H					
Revenue	450.0	217.0	**109.3**	**50.4**	71.8	**52.2**	**37.5**
Operating profit	150.0	80.5	**46.6**	**57.9**	12.4	**275.0**	**34.2**
Profit before tax	192.5	98.0	**55.7**	**56.8**	40.3	**38.2**	**15.4**
Profit attributable to owners of parent	155.0	78.0	**42.6**	**54.6**	34.7	**22.6**	**7.8**

Exchange Rate（Average）

	FY2023 Forecasts	FY2023 Apr.-Jun. Results
USD($) – JPY(¥)	130	137.50
GBP(£) – JPY(¥)	160	172.13
EUR(€) – JPY(¥)	140	149.59

Statement of Profit or Loss

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		Apr.-Jun. Results	Achievement (%)	Apr.-Jun Results	Change(%)	Change
	Full year	1H					
Revenue	450.0	217.0	**109.3***	**50.4**	71.8	**52.2**	**37.5**
Cost of Sales	15.3 69.0	14.5 31.5	12.0 **13.1**	**41.6**	18.0 12.9	**1.3**	**0.2**
Gross profit	381.0	185.5	**96.2**	**51.9**	58.9	**63.3**	**37.3**
Selling, general & administrative expenses, R&D expenses total	50.9 229.0	47.7 103.5	44.9 **49.0**	**47.4**	63.9 45.9	**6.8**	**3.1**
Selling, general & administrative expenses	28.9 130.0	24.9 54.0	22.0 **24.0**	**44.5**	32.6 23.4	**2.7**	**0.6**
R&D expenses	22.0 99.0	22.8 49.5	22.9 **25.0**	**50.5**	31.4 22.5	**10.9**	**2.5**
Other income & expenses	(2.0)	(1.5)	**(0.6)**	**37.8**	(0.5)	**5.8**	**(0.0)**
Operating profit	33.3 150.0	37.1 80.5	42.6 **46.6**	**57.9**	17.3 12.4	**275.0**	**34.2**
Finance income & costs	42.5	17.5	**9.1**	**52.1**	27.9	**(67.3)**	**(18.8)**
Profit before tax	42.8 192.5	45.2 98.0	51.0 **55.7**	**56.8**	56.1 40.3	**38.2**	**15.4**
Profit attributable to owners of parent	155.0	78.0	**42.6**	**54.6**	34.7	**22.6**	**7.8**

Main Variation Factors (Y on Y)

Revenue

- Increase：Domestic sales, Overseas subsidiaries /export, Royalty income

R&D expenses

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

Finance income & costs

- Decrease in income: Received dividend from ViiV
  - FY2022 dividend increased temporarily for the following reasons
    - > Delayed receipt of dividends from ViiV which scheduled to be received in 4Q of FY2021
    - > Increased dividends due to ViiV receipt of lump sum payment from settlement with Gilead

⇒ Dividends are progressing as planned, excluding temporary factors

* Sales revenue includes Lump-sum income for transfer of ADHD drug

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Revenue by Segment

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		Apr.-Jun Results	Achievement (%)	Apr.-Jun Results	Change(%)	Change
	Full year	1H					
Prescription drugs	134.1	87.4	**45.9**	**52.5**	19.0	**141.6**	**26.9**
Overseas subsidiaries/export	96.6	28.0	**12.0**	**42.8**	8.8	**36.2**	**3.2**
Shionogi Inc.（US）	13.6	6.7	**4.0**	**60.3**	3.0	**34.5**	**1.0**
Fetroja	-	-	**3.2**	**-**	1.8	**82.1**	**1.4**
Shionogi B.V.（EU）	11.5	5.4	**3.0**	**54.9**	1.9	**61.3**	**1.1**
Fetcroja	-	-	**2.1**	**-**	1.4	**57.4**	**0.8**
Ping An Shionogi/C&O	58.0	13.2	**3.1**	**23.4**	2.5	**22.2**	**0.6**
Others	13.4	2.7	**1.9**	**69.9**	1.4	**31.7**	**0.5**
Contract manufacturing	13.8	7.3	**4.0**	**54.7**	3.4	**19.1**	**0.6**
OTC and quasi-drug	15.0	6.8	**2.3**	**33.3**	1.9	**16.6**	**0.3**
Royalty income	189.5	86.9	**44.8**	**51.6**	38.4	**16.7**	**6.4**
HIV franchise	185.0	86.0	**44.3**	**51.4**	37.3	**18.7**	**7.0**
Others	4.5	0.9	**0.6**	**65.5**	1.1	**(47.6)**	**(0.5)**
Others	1.0	0.5	**0.3**	**58.6**	0.3	**(7.3)**	**(0.0)**
Total	450.0	217.0	**109.3**	**50.4**	71.8	**52.2**	**37.5**

Main Variation Factors (Y on Y)

Prescription drugs

- Increase : Sales of Xocova
  : Receipt of Lump-sum income for transfer of ADHD drug
- Decrease: Sales of ADHD drug

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (Fetroja、Fetcroja)
- Decrease: Change in Osphena sales scheme

Royalty income

- Increase: Strong sales of ViiV's HIV franchise

Prescription Drugs in Japan

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
	Full year	1H					
Infectious disease drugs	65.7	40.0	**9.3**	**23.1**	2.1	**348.9**	**7.2**
COVID-19 related products + Influenza franchise	57.3	35.8	**7.1**	**19.8**	0.1	**-**	**7.0**
Cymbalta	4.2	2.1	**1.1**	**52.6**	1.7	**(32.4)**	**(0.5)**
OxyContin franchise	4.1	2.1	**1.1**	**52.7**	1.2	**(6.8)**	**(0.1)**
Symproic	4.9	2.3	**1.0**	**45.2**	0.8	**29.7**	**0.2**
Actair	1.0	0.4	**0.1**	**35.0**	0.1	**13.9**	**0.0**
Mulpleta	0.1	0.1	**0.0**	**44.2**	0.0	**5.8**	**0.0**
Pirespa	1.9	1.1	**0.5**	**47.9**	0.7	**(25.7)**	**(0.2)**
Others	52.1	39.3	**32.7**	**83.2**	12.5	**162.5**	**20.3**
ADHD drug (Intuniv and Vyvanse)	25.0	25.0	**25.0**	**100.0**	4.9	**405.3**	**20.1**
Prescription drugs	134.1	87.4	**45.9**	**52.5**	19.0	**141.6**	**26.9**

COVID-19 related products

- Xocova
- COVID-19 vaccines

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs

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

* Includes Lump-sum income from transfer of ADHD drug

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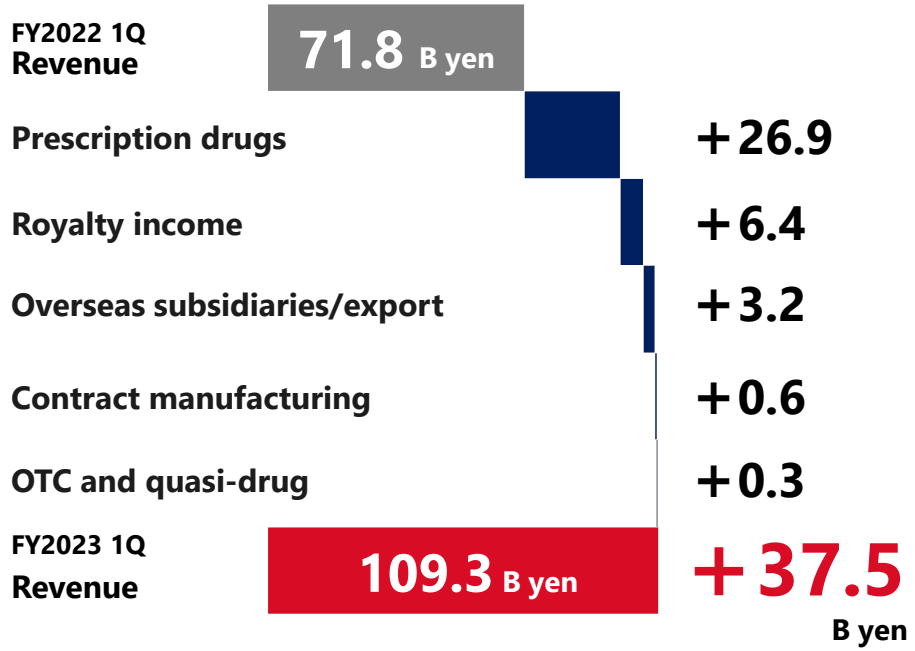
First Quarter Results and Progress

All businesses are strong, with top-line growing significantly year-on-year

- **Domestic**
  - Increased sales of Xocova outweighed decreased sales of ADHD drugs, resulting in overall growth
- **Overseas subsidiaries**
  - Strong growth of Cefiderocol（Fetroja, Fetcroja）
- **Royalty**
  - Strong growth of Dovato, Cabenuva, Apretude
- **Others**
  - Growth of Contract manufacturing and OTC and quasi-drug



At present, the forecast for the first half is expected to be achieved without revision

- Base business is expected to remain strong
- Steady penetration of Xocova and changes in current infection status

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2. Main Activities and Achievements in Q1 FY2023

Xocova (Ensitrelvir): Current Domestic Situation and Development Plan Progress

Steady progress in each initiative toward global expansion

Current domestic situation

- Accumulation of safety and efficacy information from actual use
  - Early post-marketing surveillance:
    - > As a result of more than 70,000 prescriptions and safety evaluation results, it was evaluated that no additional safety measures were necessary in the deliberations of the Safety Measures Committee.

    ⇒We will continue to provide regular feedback on safety information collected to healthcare professionals
  - Post-Marketing Surveillance:
    - > Currently collecting safety and efficacy information on 3,000 patients

      ⇒Prepared the first interim report*1(June 2023)
      - Patient background: Over 80% do not have risk factors
      - Safety and efficacy: Results similar to clinical trials were obtained
- Under review by MHLW and PMDA for regular approval

Development plan progress

- First patients enrolled in further trials
  - Prevention: Global Phase 3 trial (SCORPIO-PEP trial)
  - Pediatric indication: Phase 3 Pediatric trial（Japan）
- Asia
  - China: Inquiries from authorities are being addressed
  - Korea: Under MFDS*2 review for approval
  - Taiwan: Under TFDA*3 discussion for approval
- US/UK,EU
  - Global Phase 3 trials supported by NIH*4 progressing smoothly
    - > SCORPIO-HR trial、STRIVE trial

*1 Interim report of cases with fixed data by March 1, 2023 (1,579 cases were registered and 234 cases where survey were collected),
*2 Ministry of Food and Drug Safety、*3 Taiwan Food and Drug Administration、*4 National Institutes of Health

Progress of Vaccine Business

Various efforts toward building a sustainable business model are progressing

COVID-19 Vaccine：S-268019

- Scheduled for deliberation at the Second Pharmaceutical Subcommittee on July 31, 2023
  - Accelerate preparations for domestic supply
- LCM Initiatives to Maximize Value
  - Adult booster immunization (fourth vaccination), clinical trials in adolescents and school children are underway

Vaccine for COVID-19 Mutant strain

- Development of a monovalent vaccine for the Omicron XBB mutant is underway
  - Scheduled to enter clinical practice promptly after S-268019 is approved in Japan

Progress in universal vaccine development

- Good ability to induce neutralizing antibody confirmed in antigen design study of universal sarbecovirus vaccine
  - Anticipated as a preparation for new pandemics originating from mutated strains of the new coronavirus (SARS-CoV-2) that evade immunity and sarbecoviruses that may occur in the future'
  - Developed with KOTAI Biotechnologies, Inc. and the National Institute of Infectious Diseases under the support of SCARDA** of AMED**
- Aiming for clinical entry in 2024

* Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
** Japan Agency for Medical Research and Development

Progress in Building Foundations for Global Expansion

Acquisition of pipeline and R&D capabilities by making Qpex Biopharma a wholly owned subsidiary

Purpose of making a subsidiary

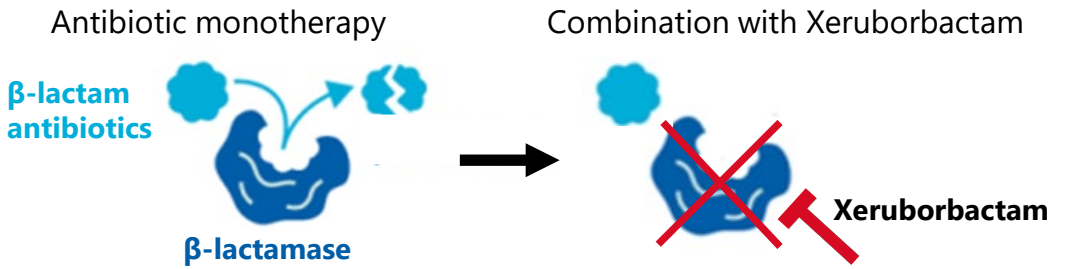
1. **Acquisition of Xeruborbactam（β-lactamase inhibitor）**
   ⇒ Preparing for strains with low susceptibility to β-lactam antibiotics*
   ⇒ Broad inhibition spectrum that can inhibit a wide range of β-lactamases
2. **Further strengthening of drug discovery and development of antibacterial drugs**
   ⇒ Acquisition of human resources with unique chemistry and deep US antibacterial development knowledge
3. **Strengthening external networks and cooperation**

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OTA number HHSO100201600026C.

Need for Xeruborbactam

- One mechanism of bacterial drug resistance is the degradation of β-lactam antibiotics by bacterial β-lactamase.
- Xeruborbactam inhibits degradation of antimicrobials by β-lactamase

Combined use of β-lactam antibacterial drug and Xeruborbactam makes it possible to demonstrate broad antibacterial activity against drug-resistant bacteria



Partially modified core presentation material of FDA Advisory Committee Meeting (October 16, 2019)

* Cephalosporin, Carbapenem, Cephems, Penicillin, Monobactam

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Progress of Major Development Products

as of July 30, 2023

Disease area	Pipeline	Indication	Current stage	FY2023	FY2024	Note
Infection	**Olorofim**	Invasive aspergillosis	Phase 3		Completion of Phase 3 case registration (4Q)	
	S-337395	RSV infections	Phase 1	Phase 1 topline results		FPI*1 (April 2023)
	S-892216	COVID-19	Phase 1	Phase 1 topline results		FPI*1 (May 2023)
QOL Diseases with High Social Impact	**Zuranolone**	Depression	Phase 3	Phase 3 topline results (3Q)	Submission (4Q)	Add on trial LPI*2 (July 2023)
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3		Submission (4Q)	Breakthrough therapy designation*3
	SDT-001	ADHD	Phase 3	Submission		
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline results (2Q)	Submission (3Q)	
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2		Submission (3Q)	Orphan drug designation*4
	S-309309	Obesity	Phase 2	Phase 2 topline results (4Q)	Phase 3 start	FPI*1 (July 2023)
	S-531011	Solid tumor	Phase 1b/2	Phase 2 start (4Q)		
	S-151128	Chronic pain	Phase 1	Phase 1 topline results		FPI*1 (April 2023)

topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

*1 First Patient In *2 Last Patient In *3 May 22, 2023 Grünenthal Press release *4 May 24, 2023 SHIONOGI Press release

Development Progress of Medium- to Long-term Growth Drivers

S-309309: Phase 2 trial overview*1 and future plans

MGAT2*2 inhibitor, novel mechanism of action

Country	U.S.
Subject	Adults with a BMI of 30 or higher
Design	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
Dosage Number of cases	• 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	• Percentage of subjects achieving ≥5%/10%/15%/20% weight loss • Waist circumference, waist/hip ratio, BMI, abdominal fat

Plan to start global Phase 3 study immediately after obtaining POC*3 and determining optimal dose in this trial

Resiniferatoxin: favorable clinical trial results

TRPV1*4 agonist, non-opioid novel mechanism of action

Results from Phase 1 and 2

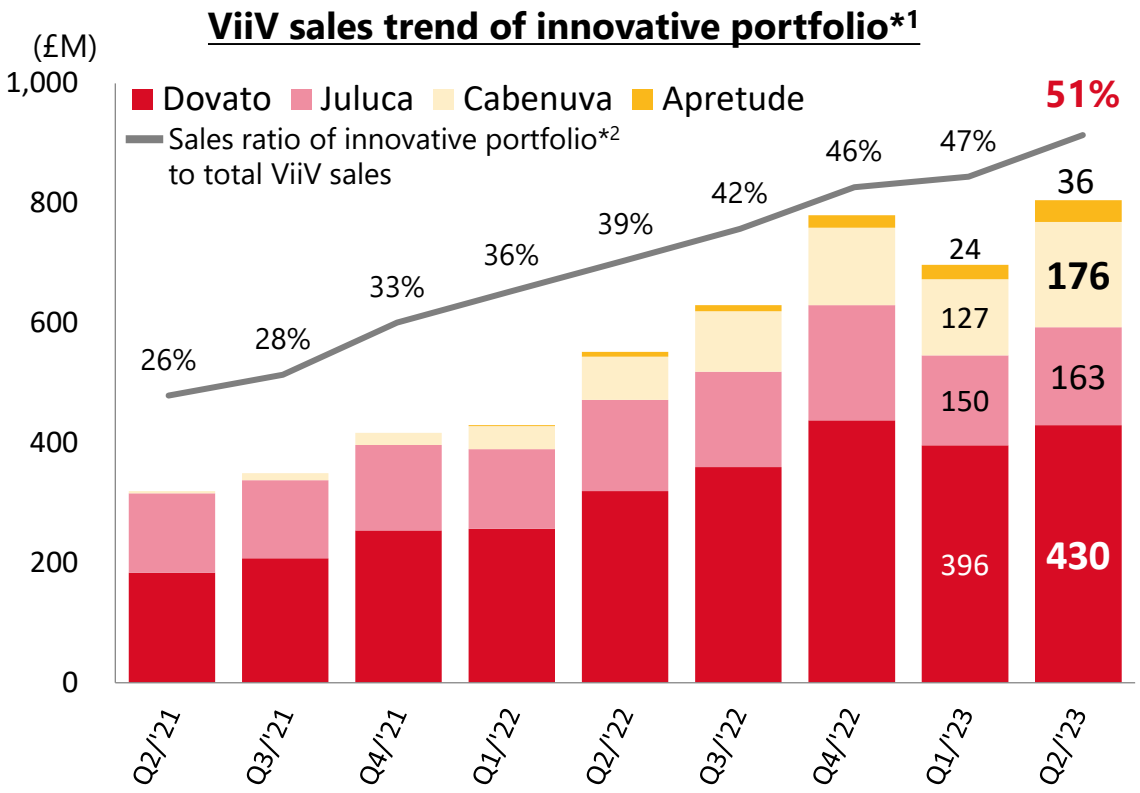
High efficacy	Long-lasting effect	High safety
Significant analgesic effect and functional improvements	An injection that can reduce pain and improve functionality by injecting once every six months on average	Favorable safety profile

Grünenthal received breakthrough therapy designation from FDA based on significant pain relief and favorable safety profile

*1 ClinicalTrials.gov: NCT05925114 *2 Monoacylglycerol transferase 2 (Appendix p.23) *3 Proof of Concept *4 Transient Receptor Potential Vanilloid 1 (Appendix p.24)

Progress of HIV Business by ViiV

Strong growth of oral two-drug regimens and LA formulations



- Sales ratio of innovative portfolio increased to 51%
- LA formulations
  - Cabenuva
    - > Compelling prescription growth driven by SOLAR study results*3
      ⇒ > 70% of sales from competitor regimens
  - Apretude
    - > Strong sales build in US
    - > Received positive CHMP opinion in Europe*4
- R&D pipeline includes multiple combination candidates for the creation of next-generation LA formulations
- Granted pediatric exclusivity by US FDA extending LOE by six months to April 2028

*1 Source: GSK financial statement *2 Oral two-drug regimens (Dovato, Julca) and LA formulations (Cabenuva, Apretude) *3 GSK press release (February 23, 2023)
*4 GSK press release (July 24, 2023)

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Human Capital Management Efforts to Achieve the 2030 Vision

Accelerate review of human resources portfolio to realize “global growth” and “establishment and growth of new businesses”

Initiatives introduced in the last few years

- New personnel system
- Re-grade
- Measures to improve work comfort
  (working from home, 3 days off per week, permission to work as a side job, etc.)
- Reskilling, retraining
  (DX training, self-investment support, etc.)
- Establishment of JV with Accenture for back-office operations
- Early Retirement Program

Continue to promote the following initiatives to build a human resource portfolio that enables growth

- Appointment of external human resources (Strategic recruitment)
- Develop human resources who can respond to globalization
- Transform into an organizational culture prepared to address the challenges of the future

3. Shareholder Return

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Acquisition of Own Shares and Cancellation of Treasury Shares

- **Acquisition of own shares in consideration of the stock price level, which we believe is undervalued, and of our performance trend**
- **A record high of 75 billion yen (upper limit)**

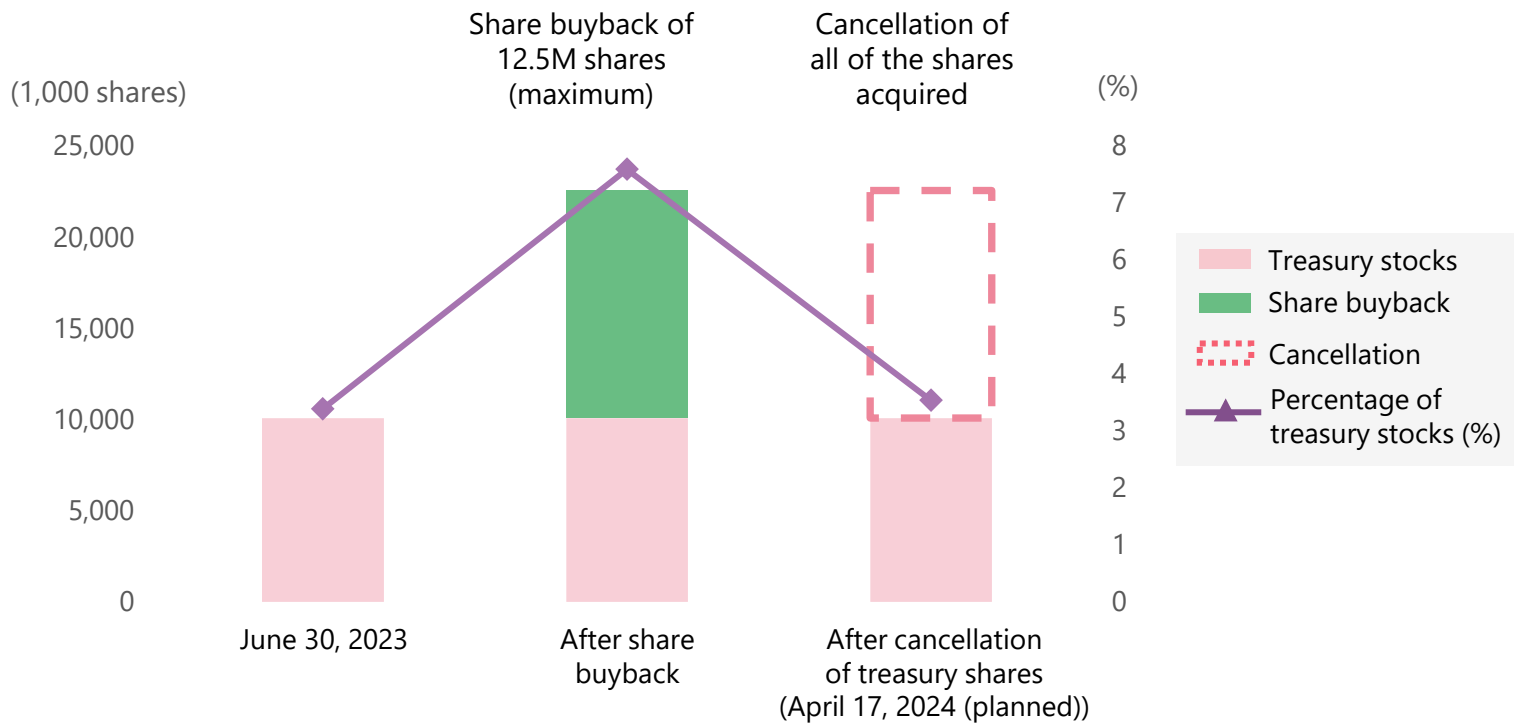
Share buyback

- Total number of shares to be acquired: 12,500,000 shares (maximum)
- Total amount of acquisition cost: 75 billion yen (maximum)
- Period of acquisition: August 1, 2023, to March 31, 2024

Depending on investment opportunities, market environment and other factors, it is possible that no share repurchase, or a share repurchase of only a portion of the above, will be carried out.

Cancellation of treasury shares

- Number of shares to be cancelled：All of the shares acquired
- Scheduled date of cancellation: April 17, 2024 (planned)



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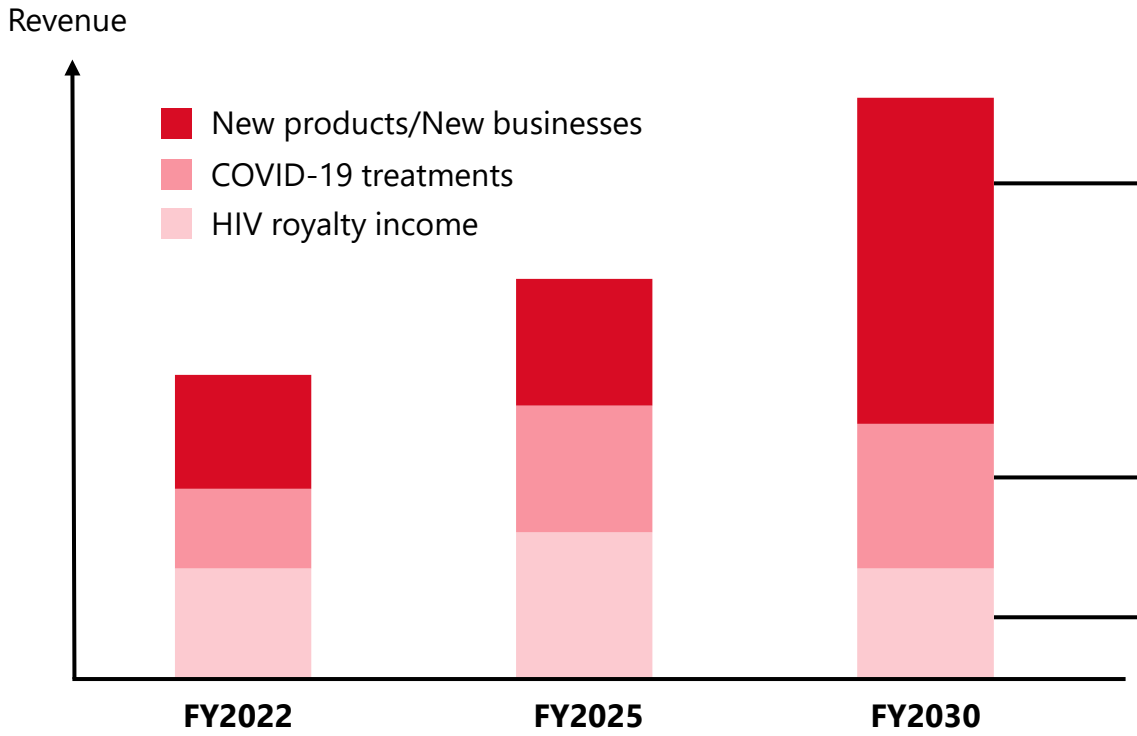
Reposted of Medium-Term Business Plan SHIONOGI Transformation Strategy 2030 (STS2030) Revision

STS2030 Revision: New Growth to Realize the 2030 Vision

- **Continued growth of HIV franchise**
- **Growth centered around ensitrelvir (STS Phase 2: 2023-25)**
- **Growth toward realizing the 2030 Vision through aggressive investment (R&D, business investments) (-2030)**



Expansion of new products and new businesses

- Approval and launch of infectious disease, psychoneurological disease, and pain products under development
- Portfolio enhancement
  - Investment in the discovery and development of drugs for unmet needs as future growth drivers
- Growth of the vaccine business

COVID-19 treatment

- Establishment of a business model leveraging the strengths of COVID-19 therapeutic drugs, including ensitrelvir and successor drugs

Revision of HIV royalty forecast

- Growth of long-acting formulations

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Ensitrelvir: Overall Picture of the Current Situation and Future Plans

From the Fiscal 2022 Financial Results (Partially revised)

With the emergence of new mutant strains, the need for antiviral drugs remains
Accumulating further evidence for the role of Xocova in "with COVID" phase

Japan
Approved

Asia
Korea：Submitted
China：
Preparing to apply

Global
US: Fast Track designation

Development

- **Phase 2/3 trial（Japan･Asia）**
  - ✓ Antiviral effect
  - ✓ Symptom improvement effect
  - Continue follow up
    - ✓ Assess the post-acute symptoms
    - CROI 2023
  - Regarding viral rebound and symptom recurrence
    - Phase 2b/3 part
    - 33rd ECCMID

Global expansion
Global Phase 3 trial
- **SCORPIO-HR trial*** — In Progress
  Patients: Non-hospitalized
- **STRIVE trial*** — In Progress
  Patients: SARS-CoV-2 infected patients that are hospitalized

Prevention
Global Phase 3 trial
- **SCORPIO-PEP*2 trial** — FPI*3 (June) — In Progress

FPI*3 (June) — In Progress

Pediatric indication
- **Phase 3 Pediatric trial (Japan)**
  - ✓ 6-12 year old
- **Global Phase 3 trial**
  - ✓ 0-12 year old — Planned

Long COVID
- **Data analysis of Phase 2/3 trial**
- **Physician-initiated trial**
  Investigation of efficacy for patients with long COVID-19 — Planned

Propagation suppression effect
- Propagation suppression evaluation — under consideration

Supply

Japan
- 10 million people annually

China
- 20 million people annually

US
- Production system under construction

LMICs
- License agreement with Medicines Patent Pool

* NIH sponsored trial *2Post Exposure Prophylaxis Study *3 First Patient In

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From SHIONOGI R&D Day 2022
(partially revised)

S-309309: Profile

Indication

- Obesity

Product characteristics

- Best-in-class efficacy among existing oral drugs (weight loss of 10% or more per year) with no safety concern
- Lower economic burden compared to GLP-1[*1] injectables

Market

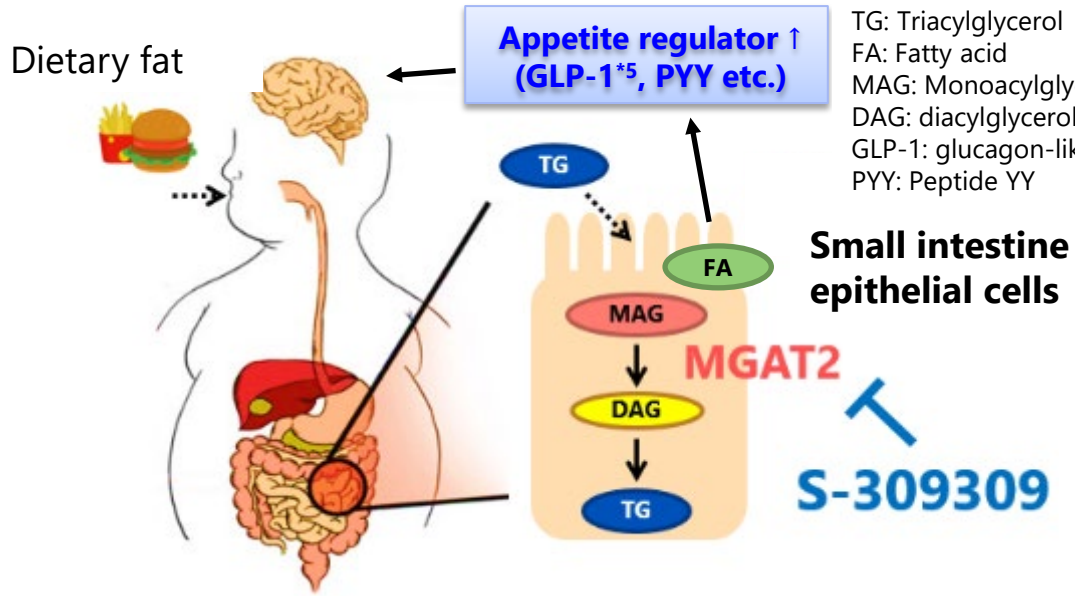
- Obese patients[*2]: 245 million (7MM[*3]), 125 million (U.S.)
- Market size[*4]: $ 1,692 MM (2021) (including 93% in the US)

Unmet needs

- There is a demand for a drug that has no safety concerns, shows a sufficient weight loss effect over a long period of time, and has a low out-of-pocket cost

Mechanism of action

- Monoacylglyceroltransferase 2 (MGAT2[*5]) inhibitor



TG: Triacylglycerol
FA: Fatty acid
MAG: Monoacylglycerol
DAG: diacylglycerol
GLP-1: glucagon-like peptide-1
PYY: Peptide YY

*1 glucagon-like peptide-1
*2 © 2021 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.
*3 7 major markets; US, France, Germany, Italy, Spain, UK and Japan
*4 Copyright © 2022 IQVIA. Calculated by SHIONOGI based on IQVIA Analytics Link 2021.1-12 , Reprinted with permission *5 monoacylglycerol acyltransferase 2

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From SHIONOGI R&D Day 2022
(partially revised)

Resiniferatoxin: Profile

Indication

- Osteoarthritis of the knee

⇒ Moderate to severe pain associated with knee osteoarthritis in patients who have failed one or more prior therapies

Special characteristics

- An injection that can reduce pain and improve functionality by injecting into the knee joint once every six months on average

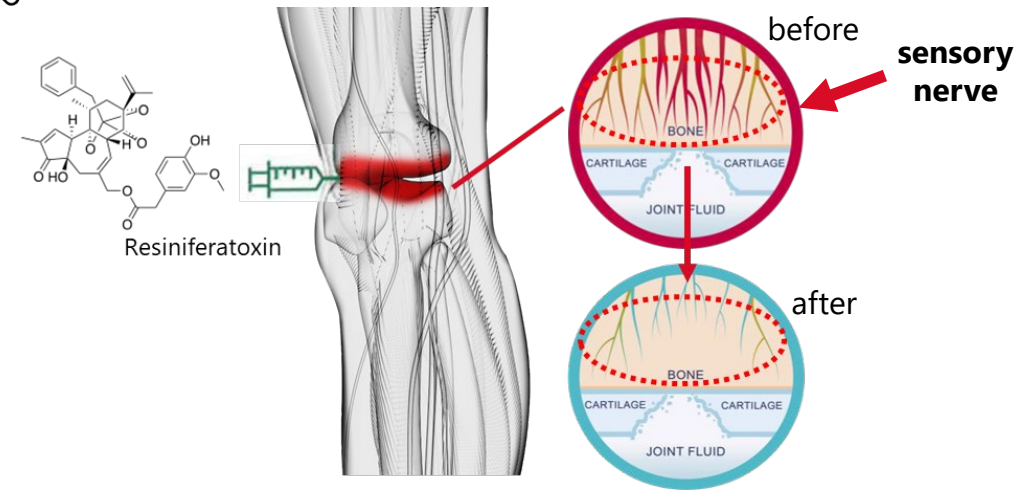
Market

- Number of symptomatic people: 25 million (Japan)

Unmet needs

- Insufficient efficacy or short duration of effect is a problem with existing drugs, and there is a need for drugs that can control pain for a long time
- Drugs with strong analgesic effects are required as adjuvants for exercise therapy

Mechanism of action



1. Resiniferatoxin acts on TRPV1* on sensory nerves projecting into the knee surface
2. Causes strong desensitization and retraction of sensory nerves from the knee (pain is suppressed)

* Transient Receptor Potential Vanilloid 1

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Pipeline: Infectious Disease

as of July 30, 2023

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-872600 Influenza nasal vaccine	**S-337395** RSV infections		**Olorofim [F901318]** Invasive Aspergillosis	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-875670 COVID-19 nasal vaccine	**S-892216** COVID-19 treatment		**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Ensitrelvir** COVID-19 prevention	**S-268019*3** COVID-19 Prophylactic vaccine
S-540956 Nucleic acid adjuvant			**S-268019** COVID-19 Prophylactic vaccine	**Ensitrelvir** COVID-19 treatment (Ages 5-11)	**Cefiderocol*4** Various infectious diseases
S-554110 Nontuberculous mycobacterial infection			**S-268019** COVID-19 (Ages 5-19)		**Baloxavir** Influenza virus infection (Granules, < 20kg)
					Baloxavir *5 Influenza virus infection (5-11 years old, treatment and prevention)

: Global development

Change from May 10 to July 31, 2023

Baloxavir: Additional application for pediatric indication in Taiwan
Ensitrelvir (Taiwan) : Discussions with TFDA on switching from EUA submission to regular submission

Out license

S-365598 HIV infection	**S -555739 [Asapiprant]** Treatment by suppressing aggravation of COVID-19	**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)	**Baloxavir** Influenza virus infection (Transmission)	**Baloxavir (US)** Influenza virus infection (Pediatric, < 1year old)

: Progress from May 11 to July 30, 2023 *,*3 Phase 2/3、Phase 3 ongoing *2 Korea *4 Japan, Taiwan *5 Taiwan

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Pipeline: QOL Diseases with High Social Impact

as of July 30, 2023

Preclinical	Phase 1	Phase 2		Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-151128** Chronic pain	**S-309309** Obesity	**S-005151*** **[Redasemtide]** Acute ischemic stroke	**S-812217** **[Zuranolone]** Depression	
S-109802 Post-stroke spasticity	**S-588210** Solid tumor	**S-531011**[*2] Solid tumor	**S-005151** **[Redasemtide]** Epidermolysis bullosa	**GRT7039** **[Resiniferatoxin]** Pain associated with knee osteoarthritis	
		BPN14770 **[Zatolmilast]** Alzheimer's disease	**BPN14770** **[Zatolmilast]** Alzheimer's disease	**BPN14770**[*5] **[Zatolmilast]** Fragile X Syndrome	
		S-588410 Bladder cancer	**Rizmoic**[*3] Opioid-induced constipation(pediatric)	**SDT-001** Inattentive ADHD (pediatric)	
		S-588410 Bladder cancer	**ADR-001**[*4] Decompensated liver cirrhosis	**S-588410** Esophageal cancer	
		S-488210 Head and neck squamous cell carcinoma	**S-222611** **[Epertinib]** Malignant tumor	**SR-0379** Cutaneous ulcer	
		Out license **S-723595** Type 2 diabetes			

Change from May 10 to July 31, 2023
S-723595: Phase 2 started and indication changed (NASH⇒Type 2 diabetes) S-0373 [Rovatirelin]: Submission withdrawn (Considering the feasibility of additional clinical trials)

: Global development

: Progress from May 11 to July 30, 2023

* Global Phase 2b ongoing *2 Phase 1b/2 ongoing *3,4 Phase 1/2 ongoing *5 Phase 2b/3 ongoing

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Other Major Progress*

- **May**
  - Orphan Drug Designation for Redasemtide for Dystrophic Epidermolysis Bullosa
  - Concluded a comprehensive partnership agreement with the Rohto Children's Future Foundation
  - Contribution to the Global Health Innovative Technology Fund (GHIT Fund) for the Third Phase
- **June**
  - Selected as a new “DX Featured Company 2023”
  - Launch of the Third Phase for the Mother to Mother SHIONOGI Project New Activities to Support Maternal and Child Health in Kenya and Ghana
  - Concluded a business alliance agreement with Allm, a medical ICT company, aiming to build a total care for infectious diseases
  - Seven manufacturers sign sublicence agreements with the Medicines Patent Pool to produce generic versions of Shionogi's COVID-19 oral antiviral ensitrelvir to increase access in low- and middle-income countries
  - Eddingpharm Announces Approval of Mulpleta® (Lusutrombopag) in China
- **July**
  - Shionogi Filed for a Supplemental New Drug Application of XOFLUZA® (Baloxavir Marboxil) in Taiwan for Pediatrics Aged 5 to Under 12 for the Treatment and Prevention of Influenza Infection

* Progress from May 11, 2023 to July 30, 2023

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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