Fiscal 2023 Financial Results

May 13, 2024

Shionogi & Co., Ltd.

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Agenda

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- QOL Diseases with High Social Impact

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Overview of FY2023 Financial Results

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Financial Results

Highlight

- We achieved a record-breaking revenue and operating profit last fiscal year, surpassing our previous best performance
  - The sales of Xocova and Xofluza in the domestic market, along with our HIV business, have grown into a stable revenue base
- Our profit before tax and profit attributable to owners of parent decreased compared to the previous year
  - Excluding the temporary increase in dividends from ViiV in the previous term, we continue to achieve year-on-year profit growth
- We have met the revised forecasts for all profit items*

(Unit : B yen)

	FY2023			FY2022	Y on Y	
	Forecasts (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Revenue*2	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**
Operating profit	150.0	**153.3**	**102.2**	149.0	**2.9**	**4.3**
Profit before tax	192.5	**198.3**	**103.0**	220.3	**(10.0)**	**(22.0)**
Profit attributable to owners of parent	155.0	**162.0**	**104.5**	185.0	**(12.4)**	**(22.9)**
EBITDA*3	167.0*4	**188.7**	**113.0**	175.6	**7.5**	**13.1**

Exchange Rate (Average)

	FY2023 Forecasts (Oct. 31)	FY2023 Results
USD($) – JPY(¥)	141	144.56
GBP(£) – JPY(¥)	173	181.72
EUR(€) – JPY(¥)	151	156.76

* The revised budget will be announced on October 31st

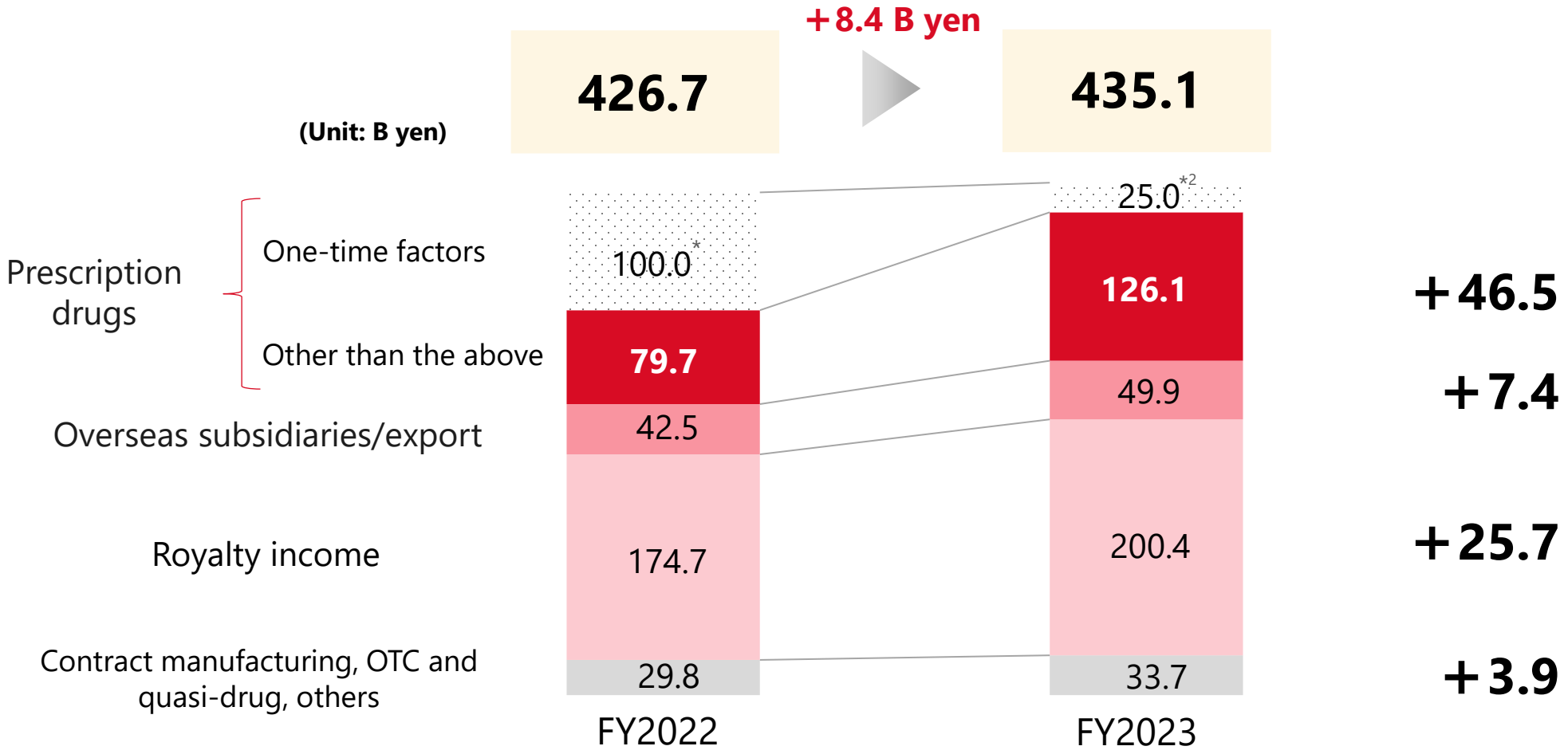
*3 Earnings Before Interest, Taxes, Depreciation, and Amortization: Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

*2 Includes temporary income from transfer of ADHD drugs

*4 Targets in the Medium-Term Management Plan

Growth of Topline

We achieved growth across all businesses, centered around a dramatic expansion in our direct sales



* Purchase of Xocova by the Japanese government in Q3 FY2022 *2 Includes temporary income from transfer of ADHD drugs

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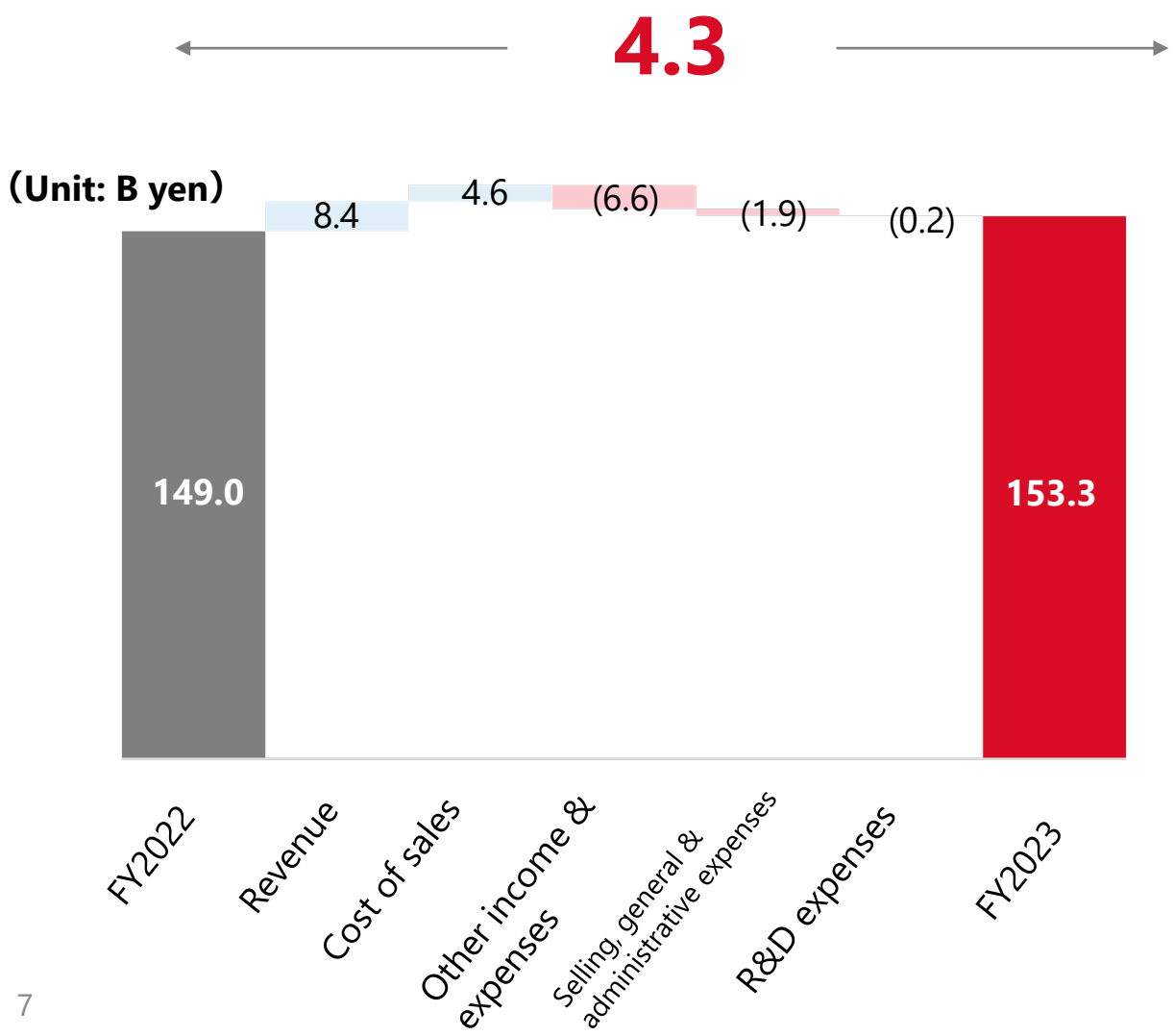
Statement of Profit or Loss

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Revenue	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**
Cost of Sales	13.2 59.5	13.2 **57.6**	**96.8**	14.6 62.2	**(7.5)**	**(4.6)**
Gross profit	390.5	**377.5**	**96.7**	364.4	**3.6**	**13.0**
Selling, general & administrative expenses, R&D expenses total	51.3 231.0	47.4 **206.0**	**89.2**	47.8 203.9	**1.0**	**2.1**
Selling, general & administrative expenses	26.4 119.0	23.8 **103.4**	**86.9**	23.8 101.5	**1.9**	**1.9**
R&D expenses	24.9 112.0	23.6 **102.6**	**91.6**	24.0 102.4	**0.2**	**0.2**
Other income & expenses	(9.5)	**(18.1)**	**-**	(11.5)	**-**	**(6.6)**
Operating profit	33.3 150.0	35.2 **153.3**	**102.2**	34.9 149.0	**2.9**	**4.3**
Finance income & costs	42.5	**45.0**	**105.8**	71.3	**(37.0)**	**(26.4)**
Profit before tax	42.8 192.5	45.6 **198.3**	**103.0**	51.6 220.3	**(10.0)**	**(22.0)**
Profit attributable to owners of parent	155.0	**162.0**	**104.5**	185.0	**(12.4)**	**(22.9)**

Main Variation Factors of Operating Profit (Y on Y)



Revenue

Increase Overseas subsidiaries/export, Royalty income

Decrease Purchase of Xocova by the Japanese government in FY2022

Cost of Sales

Decrease in expenses

- Changes in product mix

Other income & expenses

(One-time factors)

Increase in expenses

- Costs related to implementation of early retirement program
- Impairment due to revision of development plan of Zatolmilast (BPN14770) in Alzheimer's disease

※ Impairment charges were recorded due to a revision of the development plan in the previous term

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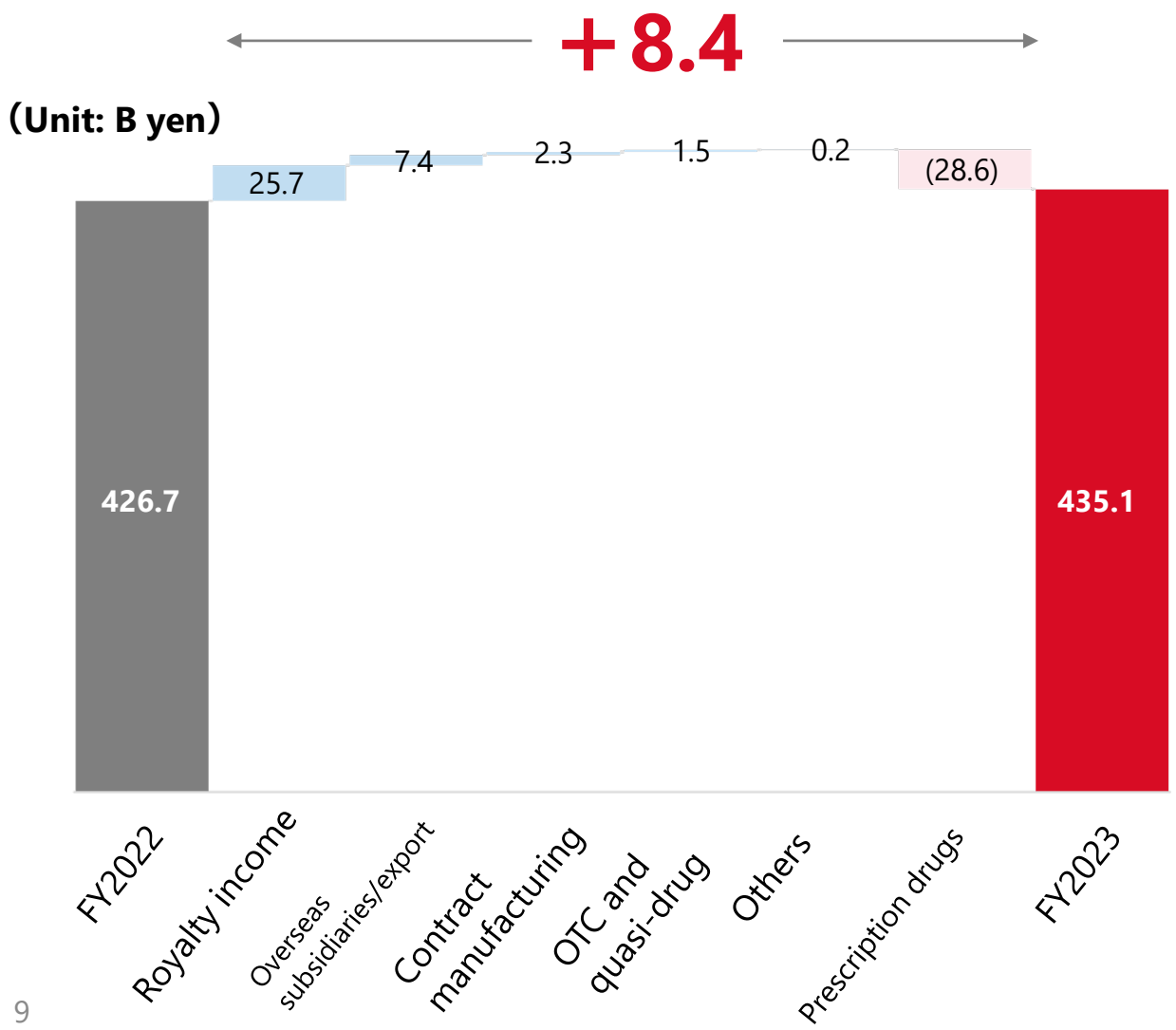
Revenue by Segment

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Prescription drugs	167.0	**151.1**	**90.5**	179.7	**(15.9)**	**(28.6)**
Excluding temporary income	-	**126.1**	**-**	79.7	**58.1**	**46.4**
Temporary income	-	**25.0**	**-**	100.0	**-**	**(75.0)**
Overseas subsidiaries/export	49.2	**49.9**	**101.5**	42.5	**17.4**	**7.4**
Shionogi Inc.(US)	17.0	**17.9**	**105.6**	15.4	**15.9**	**2.4**
Fetroja	-	**14.5**	**-**	10.0	**45.4**	**4.5**
Shionogi B.V.(EU)	13.0	**13.6**	**104.3**	9.1	**49.9**	**4.5**
Fetcroja	-	**10.7**	**-**	6.6	**62.0**	**4.1**
Ping An Shionogi/C&O	12.1	**10.6**	**88.1**	12.0	**(11.3)**	**(1.4)**
Others	7.1	**7.8**	**109.7**	6.0	**29.8**	**1.8**
Contract manufacturing	16.4	**17.6**	**107.5**	15.3	**14.8**	**2.3**
OTC and quasi-drug	14.8	**14.6**	**99.3**	13.1	**11.6**	**1.5**
Royalty income	201.2	**200.4**	**99.6**	174.7	**14.7**	**25.7**
HIV franchise	196.5	**195.8**	**99.6**	168.5	**16.2**	**27.3**
Others	4.7	**4.6**	**96.6**	6.2	**(26.7)**	**(1.7)**
Others	1.5	**1.4**	**98.6**	1.3	**12.6**	**0.2**
Total	450.0	**435.1**	**96.7**	426.7	**2.0**	**8.4**

Main Variation Factors of Revenue (Y on Y)



Prescription drugs

Increase

- Sales of Xocova and Xofluza
- Receipt of lump-sum income for transfer of ADHD drugs in Q1 FY2023 (One-time factors)
- Returns of Xofluza and Rapiacta in FY2022

Decrease

- Sales of ADHD drug
- Purchase of Xocova by the Japanese government in Q3 FY2022 (One-time factors)

Royalty income

Increase Strong sales of ViiV's HIV franchise

Overseas subsidiaries/export

Increase Sales of cefiderocol (US: Fetroja, EU: Fetcroja)

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Prescription Drugs in Japan

(Unit: B yen)

	FY2023			FY2022	Y on Y	
	Forecast (Oct. 31)	Results	Achievement (%)	Results	Change (%)	Change
Infectious disease drugs	97.5	**82.9**	**85.1**	112.1	**(26.0)**	**(29.2)**
COVID-19 related products + Influenza franchise	88.6	**73.4**	**82.9**	103.6	**(29.1)**	**(30.2)**
Excludes purchase of Xocova by the Japanese government	-	**73.4**	**-**	3.6*	**-**	**69.8**
Cymbalta	4.2	**3.8**	**92.5**	5.4	**(29.3)**	**(1.6)**
OxyContin franchise	4.3	**4.2**	**97.1**	4.4	**(6.3)**	**(0.3)**
Symproic	4.9	**4.5**	**91.5**	3.4	**32.3**	**1.1**
Actair	1.0	**0.7**	**67.9**	0.5	**29.6**	**0.2**
Others	55.1	**55.0**	**99.7**	53.8	**2.2**	**1.2**
ADHD drugs (Intuniv and Vyvanse)*2	25.0	**25.0**	**100.0**	20.6	**21.4**	**4.4**
Prescription drugs	167.0	**151.1**	**90.5**	179.7	**(15.9)**	**(28.6)**

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

* Returns of Xofluza and Rapiacta (Recognized -5.3 billion yen in 2Q of FY2022)

*2 Includes temporary income from transfer of ADHD drugs

Achievements in FY2023

Achieved revenue and profit growth through top-line growth and meticulous cost management

Top-line growth

Domestic business: Successfully expanded our own sales mainly in the category of infectious disease drugs

- Revenue from domestic business increased by **46.5 billion yen from the previous fiscal year excluding non-recurring factors**

Royalty income: Oral two-drug regimens and LA formulations grew dramatically

- Increased by **25.7 billion yen from the previous fiscal year as ViiV achieved steady business growth**

Overseas business: Steady progress in Cefiderocol

- Revenue increased by **7.4 billion yen from the previous fiscal year mainly through growth in the European and US business**

Profit growth

Flexible cost management in response to changes in top line

- Achieved growth in operating profit after recognizing several non-recurring expenses
- Invested aggressively toward establishing growth drivers*

* The results of the major development projects for FY2023 are described on page 39

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Reflections on First Year of STS2030 Revision Phase2

The KPIs set forth in the STS2030 Revision have shown a promising start in alignment with the objectives of STS Phase2

	STS Phase2			STS Phase3
	FY2023 (Target)	**FY2023 (Results)**	FY2025	FY2030
Revenue	**450.0 B yen**	**435.1 B yen**	**550.0 B yen**	**800.0 B yen**
Overseas sales CAGR*	–	**17.4%** Starting from FY2022	**50%** Starting from FY2022	**15%** Starting from FY2025
EBITDA	**167.0 B yen**	**188.7 B yen**	**200.0 B yen**	–

* CAGR (Compound Annual Growth Rate)

FY2023 fiscal year initiatives and FY2024 outlook

Infectious Diseases

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Ensitrelvir: Summary of Results on the SCORPIO-HR trial

Primary endpoint	**Symptom improvement effect**	• Although ensitrelvir demonstrated a numerical reduction in the time to symptom resolution compared to placebo among participants treated within 3 days of symptom onset, the difference was not statistically significant. → A pre-defined supportive analysis of resolution of six symptoms for one day using a statistical method similar to that used in the SCORPIO-SR Study (Phase 3 part of the Phase 2/3 study of ensitrelvir conducted in Asia) yielded a significant difference ($p<0.05$) in the time to resolution of symptoms
Secondary endpoints	**Effect for Long COVID**	• Ensitrelvir did not demonstrate a statistically significant reduction in the proportion of participants with post COVID-19 symptoms (Long COVID) at three months, but there was a tendency for a higher proportion of participants to report "having returned to pre-COVID health" and "felt no fatigue" compared to placebo. → Further detailed analysis is planned, including additional follow-up at six months.
	Antiviral effects	• Ensitrelvir demonstrated a potent antiviral effect for both viral RNA and culture, compared to placebo. • Symptomatic viral rebound was not observed in this study, supporting previous findings from SCORPIO-SR.
	Hospitalization and death prevention	• No deaths were observed in either group up to Day 29 of follow up, and very few cases of COVID-19 related hospitalization were observed in either arm.
Safety		• No new safety concerns were identified. • Ensitrelvir had similar tolerability to placebo and there were no reports of taste disturbance.

Ensitrelvir: Development Direction and Progress of each Clinical Trials

Aiming to provide ensitrelvir globally as an oral antiviral drug with potent antiviral and symptom-improving effects

Future development direction

- **Discussions with regulatory bodies including FDA and Asia have begun**
- **Accelerating ongoing clinical trials**

Progress in Japan

Obtained standard approval for ensitrelvir in Japan, based on positive results from SCORPIO-SR trial

- Ensitrelvir has become the first medication to receive standard approval following an emergency regulatory approval
- Accumulated safety information from over 900,000 patients (estimated) under emergency regulatory approval

Current status of each clinical trials

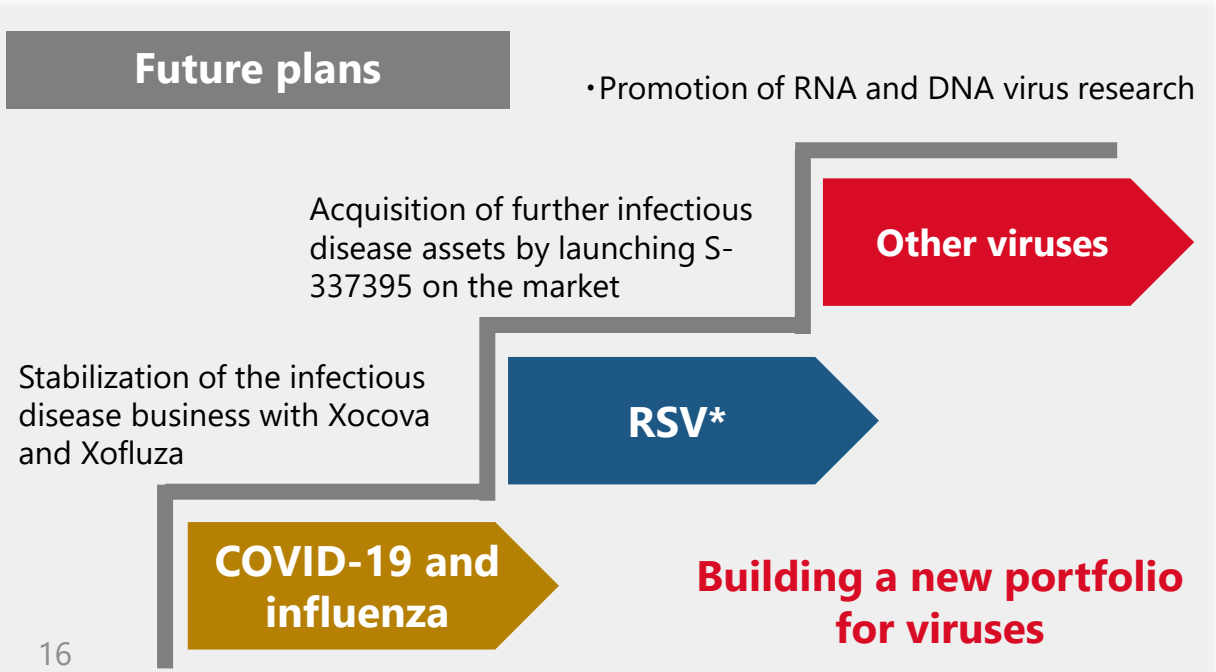
- **SCORPIO-PEP trial**
  - Verify the effectiveness of suppressing the onset of COVID-19 symptoms in close contacts
  - Completed enrollment over 1,800 subjects (Target: 2,400 subjects)
    - > Aiming to complete enrollment during the first half of FY2024
- **STRIVE trial**
  - Verification of efficacy, including mortality prevention effect in hospitalized patients
  - Continue to promote enrollment (Target: 1,500 subjects)
- **Japanese Pediatric trial**
  - Confirming safety, pharmacokinetics, and effectiveness in pediatrics
  - Promoting enrollment of subjects aged 6 to 12 years

Toward Further Stabilization of Acute Infectious Disease Business Model

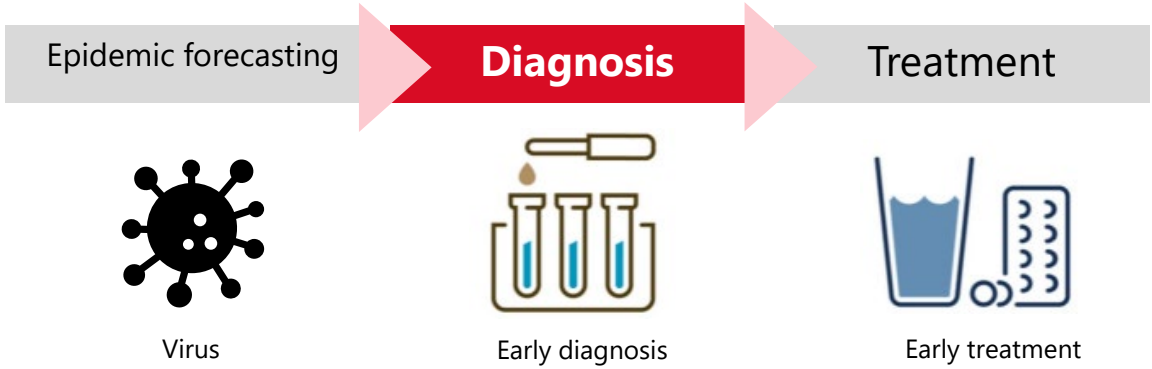
Aim to realize a "diagnosis and treatment" paradigm with a comprehensive virus treatment portfolio

Acute infectious disease business model

- Need to offer multiple infectious disease therapeutics for acute virus infections
  - Early market launch of S-337395



Importance of "test to treat"



- Appeal the importance early diagnosis/treatment to society
  - Aim to prescribe appropriate antivirus drugs
  - Promote early diagnosis until it becomes a standard practice worldwide
- Expansion and increased convenience of tests for simultaneous detection of multiple viruses
  - A reasonably priced, simple test system with excellent operability, sensitivity, and simultaneous testing capability

* RSV: Human respiratory syncytial virus

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Addressing the global issue of AMR

Progress in accumulating real-world evidence for cefiderocol and improving global access

Published Real-world evidence*

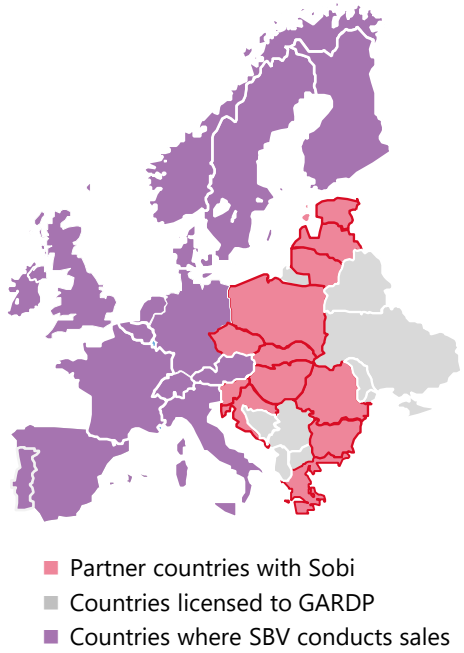
It is important to build evidence post-marketing to evaluate the clinical utility of cefiderocol

Subject	Patients with Gram-negative infections and limited treatment options • 64.8% were resistant to all tested antibiotics and 44.4% experienced treatment failure with prior antibiotics before receiving cefiderocol • 63.2% in the intensive care unit
Primary endpoint	clinical success rate (defined as the composite of clinical cure and/or survival at Day 28) of 84.3% and a 28-day all-cause mortality of 21.5%

Confirmed the importance of cefiderocol in clinical care

Expanding global access

- Expansion of cefiderocol (Fetcroja) suppliers in Europe
  - SBV stat to sale in Finland, Portugal and Belgium
  - Expands coverage to 13 countries in Central and Eastern Europe, through collaboration with Sobi



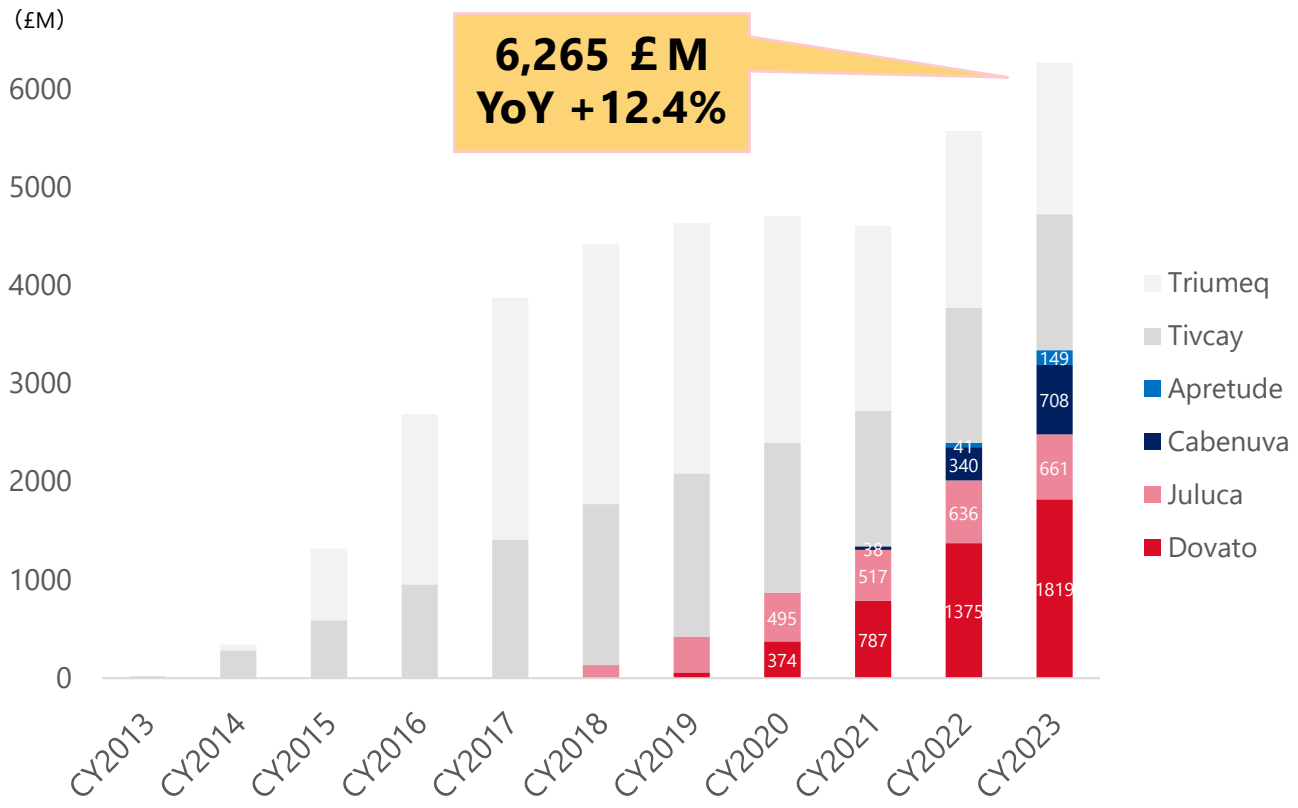
- Promoting collaboration with GARDP and CHAI
  - Transfer of manufacturing technology to Orchid Pharma for the provision to LMICs in 2027 is progressing smoothly

* A retrospective observational study evaluating the efficacy and safety of cefiderocol in real-world clinical trials conducted as part of Shionogi's Early Access Program in Spain Published at ESCMID Global

Progress of HIV Business by ViiV

Our HIV business has made steady progress based on growth of LA formulations* oral two-drug regimens*2

ViiV sales trend of Dolutegravir and Cabotegravir products*3



Growth of oral two-drug regimens **YoY +23.3%**

- Dovato continues to contribute to growth of HIV business
- The patent protection period is expected to continue through the end of 2029

Strong growth is expected to continue going forward

Growth of LA formulations **YoY +124.9%**

- Market penetration of LA formulations (treatment / PrEP) is expanding rapidly
- Switching from competing products accounts for 70% of Cabenuva sales

Establish a position of LA formulations through further market expansion

* Long acting (Product name: Cabenuva, Apretude) *2 Product name: Dovato, Juluca *3 Source: Prepared by SHIONOGI based on GSK financial statements

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CROI 2024* Update

ViiV reported excellent tolerability and safety of CAB-ULA*2 at CROI 2024

Summary of CAB-ULA Phase 1 trial results

Part	CAB-ULA dose	Administration	N
1	800 mg (2 mL)	SC*3	8
2	800 mg (2 mL)	IM*4	8
3	1200 mg (3 mL)	SC	8
4	1200 mg (3 mL)	Im	8
5	1600 mg (3 mL)	IM	16

Endpoints

- Safety
- PK profile
- Possibility of low administration frequency

- Confirmed a long half-life of SC and IM of CAB-ULA
  - Coverage from IM injection: More than twice that of Cabenuva
- No adverse events leading to discontinuation

PK profile supports administration every four months or longer

The future development of CAB-ULA

PrEP*5

- Following the favorable results of the Phase 1 trials, we are proceeding to the registration study

Treatment

- We will select partner drug in 2024 and prepare for registration studies
  - Planning further clinical trials after the selection of concomitant drugs

* Conference on Retroviruses and Opportunistic Infectious 2024 *2 Cabotegravir Ultra Long Acting
*3 SC: Subcutaneous injection, *4 IM: Intramuscular injection *5 PrEP: Pre-Exposure Prophylaxis

Progress of Major Development Products - Infection diseases -

※The bar starts from FPI and ends at CSR,　Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

	Pipeline	Indication	Current stage	FY2024	FY2025
COVID-19 Family	S-268019	COVID-19 (Vaccine)	Submission		
	Ensitrelvir	COVID-19	Submission・Phase 3 Phase 3（Pediatric）	Phase 3 topline results（FY24 4Q）	
	Ensitrelvir	COVID-19 (prevention)	Phase 3 † Data analysis in progress	Phase 3 topline results （FY24 3Q）	
	S-268023	COVID-19 （XBB1.5,Vaccine）	Phase 3		
	S-892216	COVID-19	Phase 1	Phase 2 start（FY24 2Q） topline results （FY24 4Q）	
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	Phase 1/2 start （FY24 4Q） topline results （FY25 2Q）	
Infection diseases	Olorofim	Invasive aspergillosis	Phase 3		
	S-337395	RSV infections	Phase 2		
	S-743229	AMR (Complex urinary tract infection)	Phase 1	Phase1 (combined use) topline （FY24 3Q）	
	S-649228	AMR (Gram-negative bacteria infection)	Preclinical	Phase1 (combined use) start（FY24 2Q） topline results （FY24 3Q）	

FY2023 fiscal year initiatives and FY2024 outlook

QOL Diseases with High Social Impact

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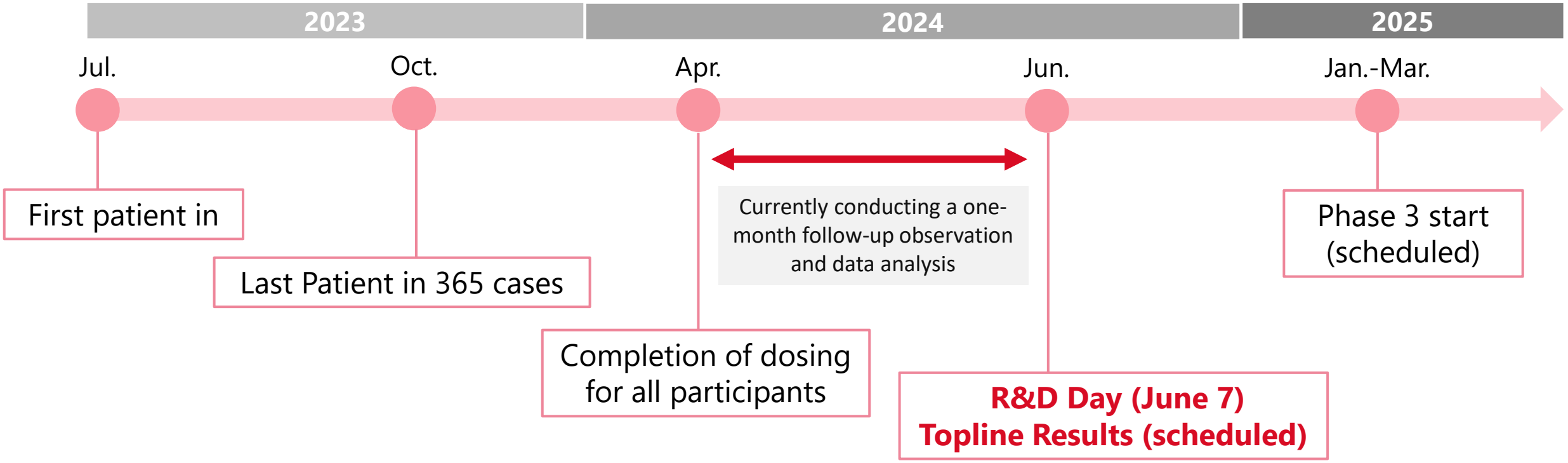
S-309309 Development Progress

Top-line disclosure is scheduled for R&D Day

Status of progress



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Introduction of MZE001, a New Therapeutic Drug Candidate for Pompe Disease

Aim to cause a paradigm shift by a low-molecular therapeutic drug for Pompe disease whose unmet needs are high

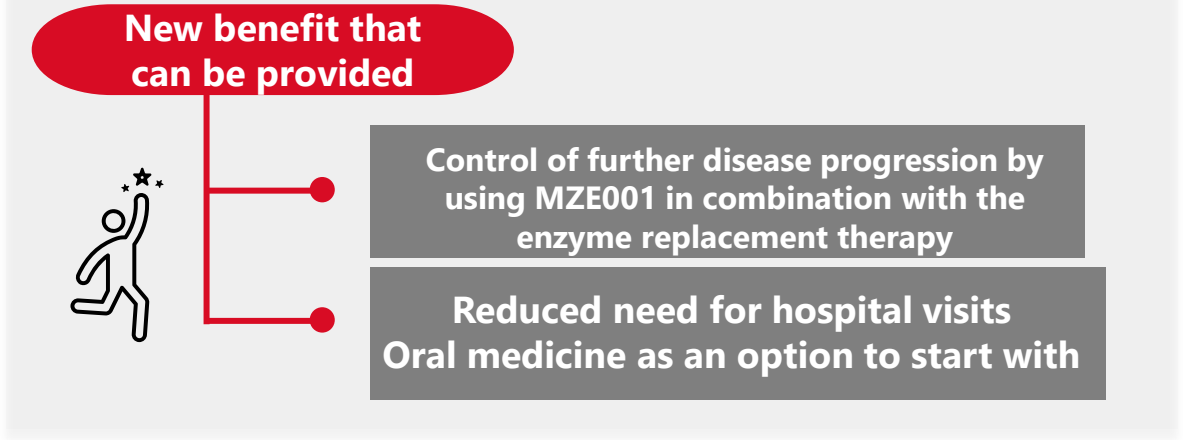
What is Pompe disease?

- A genetic disorder characterized by dysfunction of acid α-glucosidase
  - It causes an accumulation of glycogen in cells due to a deficiency in glycolysis
    - > Symptoms include motor dysfunctions, respiratory disorders, and cardiac dysfunctions
- Enzyme replacement therapy (intravenous drip) is the only existing therapy
- The market size for therapeutic drugs is estimated about $1.0 billion and is expected to increase going forward

Characteristics of MZE001

- Novel oral GYS1* inhibitor
  - It inhibits the synthesis of glycogen, which is the cause of accumulation in cells
- The only small molecular drug in the clinical development stage
  - As its mechanism of action and route of administration are different from those of the existing therapy, it may be able to provide new benefit to patients





* Glycogen synthase1 *2 Can genes influencing muscle function affect the therapeutic response to enzyme replacement therapy (ERT) in late-onset Type II Glycogenosis?
*3 Questionnaire survey on home enzyme replace therapy for lysosomal storage disease patients (N = 23, 2020)

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Promoting the global development of treatments for diseases affecting QOL

Progress in global initiatives for pediatric diseases and rare diseases



Obesity

- Development of anti-obesity drug S-309309



Dementia

- Business partnership with FRONTEO regarding diagnostic support in Japan



Hearing impairment

- Implementing business development activities to acquire new assets



Pediatric・Rare diseases

- Implementing efficient initiatives that leverage synergies



Sleeping disorder

- Development in a joint venture with Apnimed

Promote the development of two products with synergistic effects globally

MZE001 (Pompe disease) × **zatolmilast** (Fragile X syndrome)

Phase 2 application is scheduled in FY2024

Phase 2/3 in progress

Medications that have both been designated as orphan drugs

Synergistic effects of developing and marketing two agents globally

- Efficient sales: Most of target facilities overlap
- Efficient research and development using the expert center network

Progress of Major Development Products - QOL Diseases with High Social Impact -

※The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025
QOL Diseases with High Social Impact	SDT-001	ADHD	Submission	Approval（FY24 4Q）	
	Zuranolone	Depression	Preparation for application	Submission （FY24 1Q）	Approval（FY25 1Q）
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3		Submission （FY25 3Q）
	Zatolmilast	Fragile X Syndrome	Phase 2/3		Phase 2/3 topline（FY25 1Q） Submission （FY25 3Q）
	Redasemtide	Acute ischemic stroke	Phase 2b		
		Dystrophic epidermolysis bullosa	Phase 2		
	S-309309	Obesity	Phase 2	Phase 2 topline（FY24 1Q）	Phase 3 start（FY24 4Q）
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start（FY24 2Q）	
	MZE001	Pompe	Phase1		Phase 2 start（FY25 1Q）
	S-151128	Chronic pain	Phase 1	Phase 1b topline（FY24 2Q）	

FY2024 Financial Forecasts

FY2024 Financial Plan

While accelerating investments, we will achieve increased revenue and profits through top-line growth

Top-line growth mainly through our own sales

- Expand sales of infectious disease drugs in Japan
  - Improve the presence of Xocova and Xofluza
- Strong growth of overseas businesses
  - Increase the number of countries where Cefiderocol is sold
- Stable growth of the HIV business

Acceleration of investment toward achieving STS2030

- Build a sales system to achieve full-fledged expansion of own products in the US and Europe
- Establish global sales capabilities for new growth drivers
  - Proactive investment towards the progress of global in-house developed products
- Globalization of corporate functions and promotion of digital transformation

Domestic Business Progression in FY2024

Aiming to further grow domestic business by continuously introducing new products to the market

Focus items

Xocova
COVID-19 treatment

Xofluza
Influenza virus infecion treatment

- Promote early diagnosis and treatment
- Aim for continued stable growth as an important asset for acute respiratory infections

Fetroja
Various infectious diseases treatment

- Obtain regular domestic approval in FY2023
- Providing a new option for patients suffering from infections caused by drug-resistant bacteria

Symproic
Opioid-induced constipation

- Expanding market share through switching from other drugs
- Promoting efforts to raise awareness of opioid-induced constipation

NEW

Daridorexant
Insomnia Treatment

Sales Timing	**Sales are scheduled to begin in the second half of 2024**
Mechanism	A dual orexin receptor antagonist that selectively blocks the binding of wake-promoting neuropeptides
Product Characteristics	There is a possibility that it could become a best-in-class treatment that meets the unmet needs of insomnia patients

After Nxera Pharma Japan obtains manufacturing and sales approval, we will begin sales together with Mochida Pharmaceutical*

* Announcement of the Sales Partnership Agreement in Japan between Shionogi and Mochida regarding Insomnia Treatment Drug Daridorexant

Enhancing Global Sales System

Further accelerate globalization by unifying sales systems in both in Japan and overseas

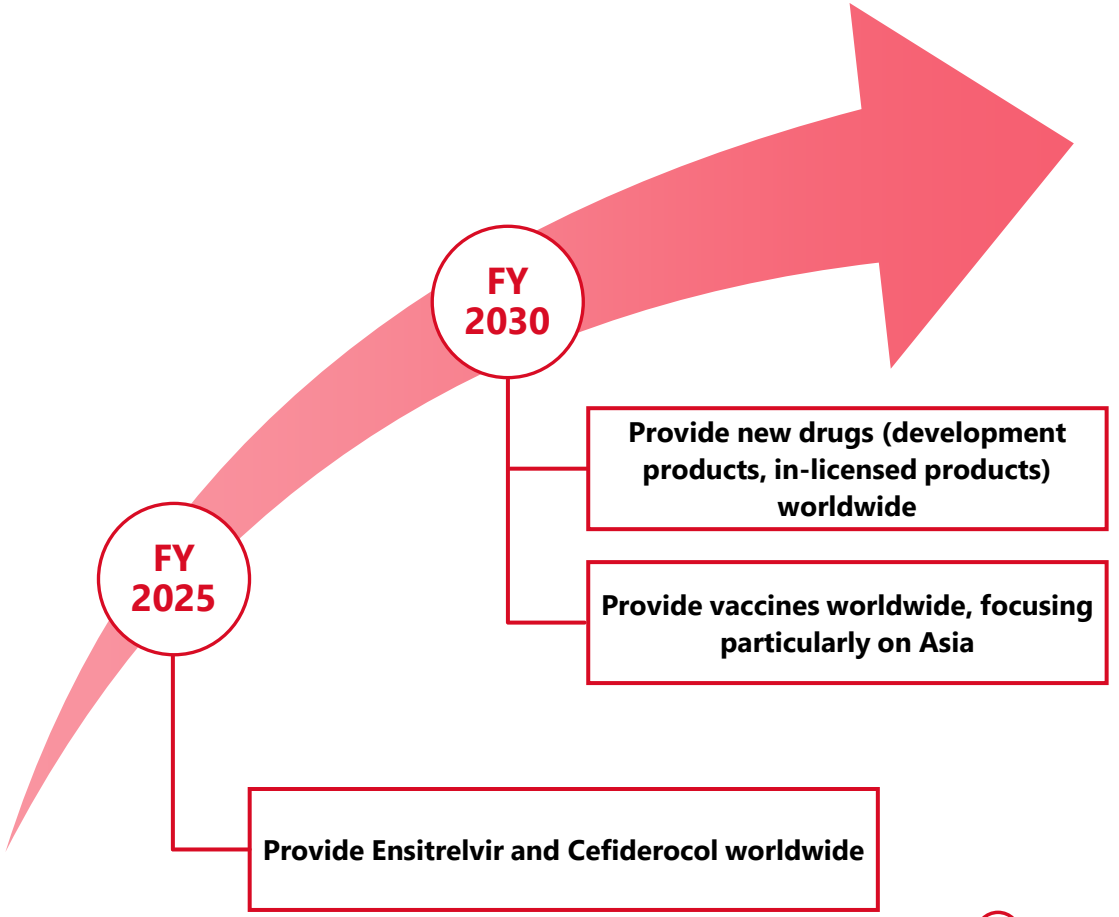
FY2023

- **Domestic sales**
  - Achieved growth and stabilization of profit with Xocova and the influenza family
- **Overseas sales**
  - Established a presence in the infectious disease area through the growth of Cefiderocol

Future Initiatives

Integration of our global sales system into the Healthcare Business Supervisory Unit

- Centralization of various functions from marketing to sales on a global basis
- Global maximization of product value by sharing product sales knowhow centered on Ensitrelvir and Cefiderocol



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Initiatives to Become a Globally Competitive Leader

Strengthening the company platform and human resources in order to be a globally competitive leader

Strengthening the company platform

- **Strengthen global corporate functions**
  - Change in the structure of the Corporate Strategy Division
    It now also oversees also the Human Resources Department to globally manage the effective use of budgets and human capital

Building a platform to support group-wide optimization of management resources of the SHIONOGI Group in response to the globalization of its business

×

Strengthening human resources

- **Reform of the human resources system**
  - Ensuring appropriate treatment by re-grading all employees
  - Competitive compensation plans
- **Implementation of a special early retirement program**
- **Securing and retaining human resources necessary for growth**
  - Enhancing mid-career recruitment
    Hiring excellent human resources related to globalization, establishment of vaccine business, and digital transformation

Financial Results

Earnings forecast

- **Both revenue and operating profit are expected to achieve record highs for the third consecutive year**
- **We plan to increase profits in all profit items**
  - **Profit before tax and profits attributable to owners of parent will also post increases**
- **Investment toward achieving STS2030 will be accelerated further**

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Results	Change (%)	Change
Revenue	455.0	210.0	435.1	4.6	19.9
Operating profit	160.0	69.0	153.3	4.4	6.7
Profit before tax	200.0	82.5	198.3	0.9	1.7
Profit attributable to owners of parent	163.0	66.5	162.0	0.6	1.0
EBITDA*	-	-	188.7	-	-

Exchange rate (average)

	FY2024 assumptions	FY2023 results
USD ($) – JPY (¥)	145	144.59
GBP (£) – JPY (¥)	178	181.72
EUR (€) – JPY (¥)	155	156.76

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

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Statement of Profit or Loss

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change (%)	Change
Revenue	**455.0**	**210.0**	435.1	**4.6**	**19.9**
Cost of Sales	**66.0**	**28.5**	57.6	**14.6**	**8.4**
Gross profit	**389.0**	**181.5**	377.5	**3.1**	**11.5**
Selling, general & administrative expenses, R&D expenses total	**226.5**	**111.0**	206.0	**9.9**	**20.5**
Selling, general & administrative expenses	**106.5**	**52.0**	103.4	**3.0**	**3.1**
R&D expenses	**120.0**	**59.0**	102.6	**16.9**	**17.4**
Other income & expenses	**(2.5)**	**(1.5)**	(18.1)	**-**	**15.6**
Operating profit	**160.0**	**69.0**	153.3	**4.4**	**6.7**
Finance income & costs	**40.0**	**13.5**	45.0	**(11.1)**	**(5.0)**
Profit before tax	**200.0**	**82.5**	198.3	**0.9**	**1.7**
Profit attributable to owners of parent	**163.0**	**66.5**	162.0	**0.6**	**1.0**

Revenue by Segment

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change(%)	Change
Prescription drugs	**134.9**	**58.0**	151.1	**(10.7)**	**(16.2)**
Overseas subsidiaries/export	**53.7**	**24.7**	49.9	**7.6**	**3.8**
Shionogi Inc. (US)	**20.6**	**10.0**	17.9	**15.1**	**2.7**
Shionogi B.V. (EU)	**14.4**	**6.8**	13.6	**6.1**	**0.8**
Ping An Shionogi/C&O	**11.2**	**4.7**	10.6	**5.5**	**0.6**
Others	**7.5**	**3.2**	7.8	**(4.2)**	**(0.3)**
Contract manufacturing	**15.5**	**6.5**	17.6	**(12.0)**	**(2.1)**
OTC and quasi-drug	**16.6**	**8.0**	14.6	**13.3**	**2.0**
Royalty income	**232.5**	**112.2**	200.4	**16.0**	**32.1**
HIV franchise	**224.6**	**111.2**	195.8	**14.7**	**28.8**
Others	**7.9**	**1.0**	4.6	**72.6**	**3.3**
Others	**1.8**	**0.6**	1.4	**25.3**	**0.4**
Total	**455.0**	**210.0**	435.1	**4.6**	**19.9**

Prescription Drugs in Japan

(Unit: B yen)

	FY2024 Forecasts		FY2023	Y on Y	
	Full year	1H	Result	Change(%)	Change
Infectious disease drugs	**91.2**	**37.6**	82.9	**9.9**	**8.2**
COVID-19 related products + Influenza franchise	**80.1**	**32.7**	73.4	**9.1**	**6.7**
Symproic	**6.5**	**2.9**	4.5	**43.9**	**2.0**
OxyContin franchise	**5.0**	**2.3**	4.2	**20.4**	**0.8**
Actair	**1.4**	**0.5**	0.7	**100.4**	**0.7**
Cymbalta	**3.3**	**1.8**	3.8	**(13.7)**	**(0.5)**
Others	**27.5**	**12.8**	55.0*	**(49.9)**	**(27.4)**
Prescription drugs	**134.9**	**58.0**	151.1	**(10.7)**	**(16.2)**

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

* Includes temporary income from transfer of ADHD drugs

Shareholder Return

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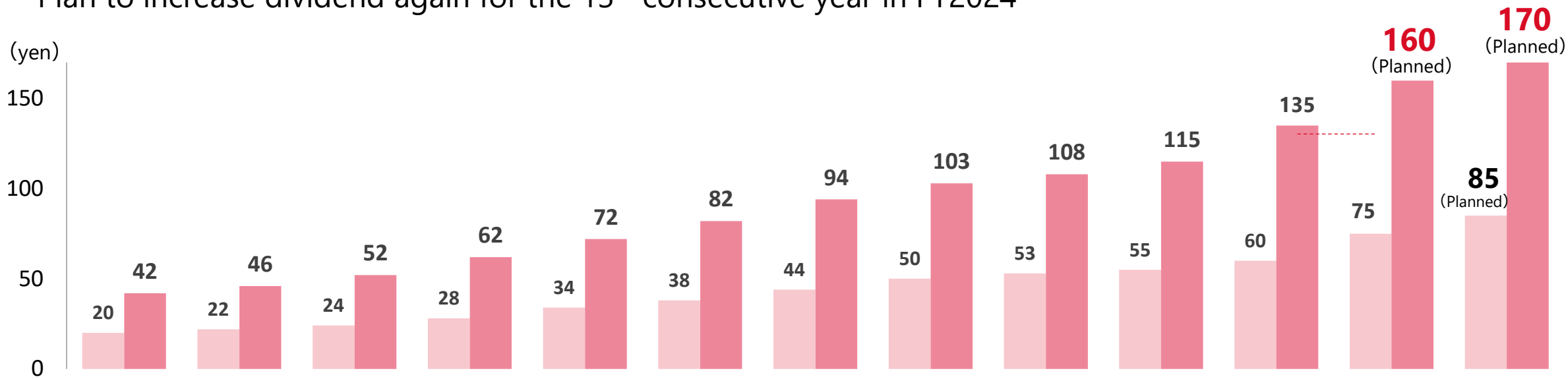
Shareholder return policy through which shareholders can feel our growth

- Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
- FY2023 is the largest annual dividend increase (+25 yen)
- Plan to increase dividend again for the 13th consecutive year in FY2024



FY		12	13	14	15	16	17	18	19	20	21	22	23	24
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	75 B yen	-
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	10.84 M Shares*2	-
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9	4.0 (planned)	4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.9	13.0 over (expected)

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020

*2 Resolution passed on July 31, 2023, and treasure shares cancelled on April 17, 2024

Values calculated based on IFRS after 2019

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Appendix

Progress in Major Development Projects concerning New Products and Businesses

As of May 12, 2024

Disease area	Pipeline	Indication	Current stage	Note
Infectious diseases	**S-268019**	COVID-19 (Origin strain vaccine)	Submission	Scheduled for deliberation at the Second Pharmaceutical Subcommittee (May 24, 2024)
	S-268023	COVID-19 (XBB 1.5 vaccine)	Phase 3	Started Phase 3 (3Q)
	S-567123	COVID-19 (Universal vaccine)	Preclinical	Started preclinical studies
	Olorofim	Invasive aspergillosis	Phase 3	Announced Phase 2b results* (3Q)
	S-337395	RSV infections	Phase 2	Started Phase 2 (3Q)
	S-892216	COVID-19	Phase 1	Obtain Phase 1 results
	S-743229	AMR (Complex urinary tract infection)	Phase 1	Start Phase 1 overseas (3Q)
	S-649228	AMR (Gram-negative bacteria infection)	Preclinical	Started preclinical studies (2Q)
QOL Diseases with High Social Impact	**SDT-001**	ADHD	Submission	Application for domestic approval has been submitted
	Zuranolone	Depression	Phase 3	Application for domestic approval is being prepared
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	Designated as a Breakthrough Therapy (1Q)
	Zatolmilast	Fragile X syndrome	Phase 2/3	Designated as an orphan drug in Europe (4Q) Designated as an Fast Track in US (2Q)
	Redasemtide	Acute cerebral infarction	Phase 2b	
		Dystrophic epidermolysis bullosa	Phase 2	Designated as an orphan drug (1Q)
	S-309309	Obesity	Phase 2	Completion of dosing for all participants
	S-531011	Solid tumor	Phase 1b/2	Dose Escalation Study (Single Agent) Determination of Maximum Tolerated Dose
	S-151128	Chronic pain	Phase 1	Started Phase 1b for OA patients (3Q)

In red: Special notes for progress made in and after 4Q of FY2023. *Announced by F2G (October 30, 2023): TIMM2023

Pipeline: Infectious Disease

as of May 12, 2024

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-567123 COVID-19 Universal Vaccine	**S-337395** RSV infections	**S-337395** RSV infections	**F901318** **[Olorofim]** Invasive Aspergillosis	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-872600 Influenza 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-875670 COVID-19 nasal vaccine	**S-743229** AMR (Complex urinary tract infection)		**S-268019** COVID-19 Prophylactic vaccine	**Ensitrelvir** COVID-19 treatment (Ages 5-11)	**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-540956 Nucleic acid adjuvant			**S-268023** COVID-19 Prophylactic vaccine (XBB 1.5)	**S-268019** COVID-19 (Ages 5-19)	
S-554110 Nontuberculous mycobacterial infection					
S-649228 AMR (Gram-negative bacteria infection)					

Out license

S-365598 HIV infection	**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)
	Baloxavir Influenza virus infection (Transmission)

: Global development

Change from January 31 to May 12, 2024

- Baloxavir（Influenza virus infection,5-11 years old）: Approval in US
- Baloxavir（Influenza virus infection,5-11 years old）: Approval in Taiwan
- Cefiderocol（AMR：Various infectious diseases） : Approval in Taiwan
- S-365598（HIV infection） : Phase 2 started
- S-567123（COVID-19 Universal Vaccine ） : Add Code No.
- S-555739（Treatment by suppressing aggravation of COVID-19） : Closed

: Progress from January 31 to May 12, 2024

*,*3 Phase 2/3, Phase 3 ongoing *2 Korea, Singapore

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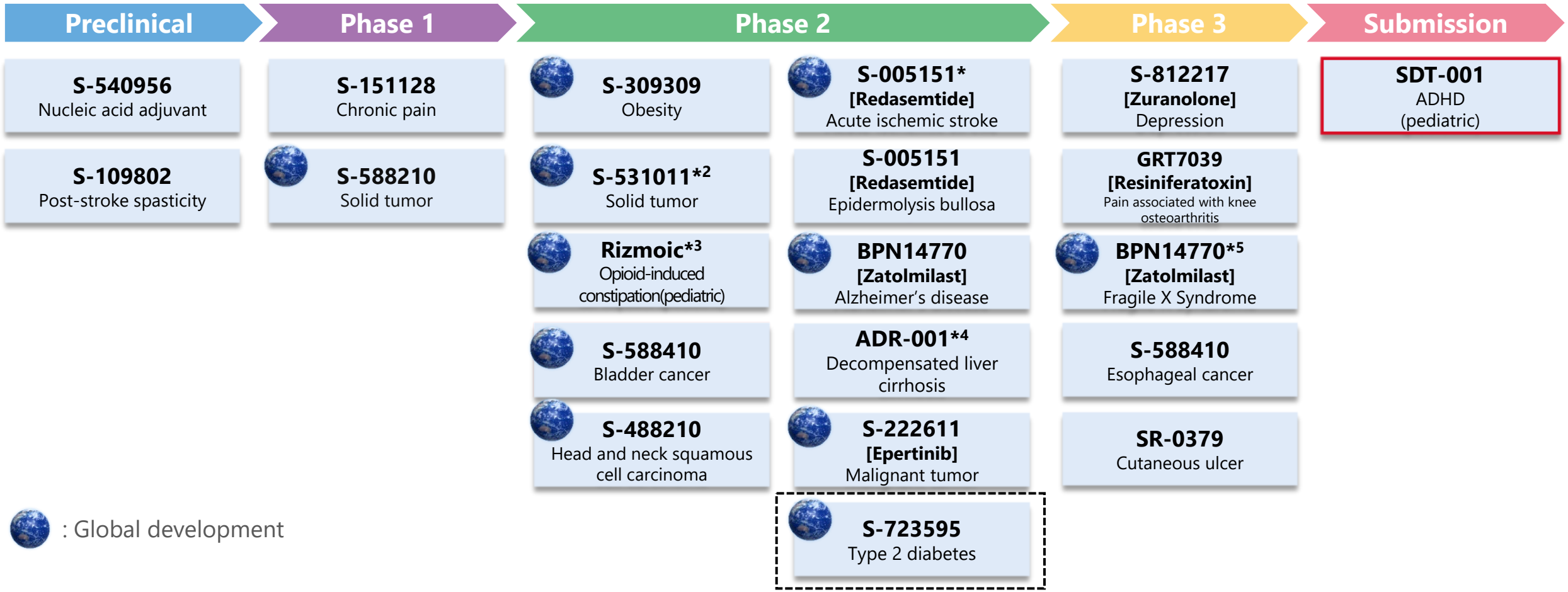
Pipeline: QOL Diseases with High Social Impact

as of May 12, 2024



: Global development

Out license

Change from January 31 to May 12, 2024
• SDT-001（ADHD, Pediatric）: Submission

: Progress from January 31 to May 12, 2024

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

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Ensitrelvir：Trial Overview

SCORPIO-HR（Global development）

－ Trial Overview －

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*
Secondary endpoints	• 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-SR

－ Trial Overview －

Subject	Mild to moderate COVID-19 patients
Number of subjects	1,821 cases
Primary endpoint	Time to resolution of 5 COVID-19 symptoms*3
Secondary endpoints	・The change from baseline in SARS-CoV-2 RNA level on day 4 ・Time to first negative SARS-CoV-2 titer

* 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 stuffy or runny nose, sore throat, cough, feeling hot or feverish, and low energy or tiredness

Partial changes to SHIONOGI R&D Day 2022 materials

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

Market

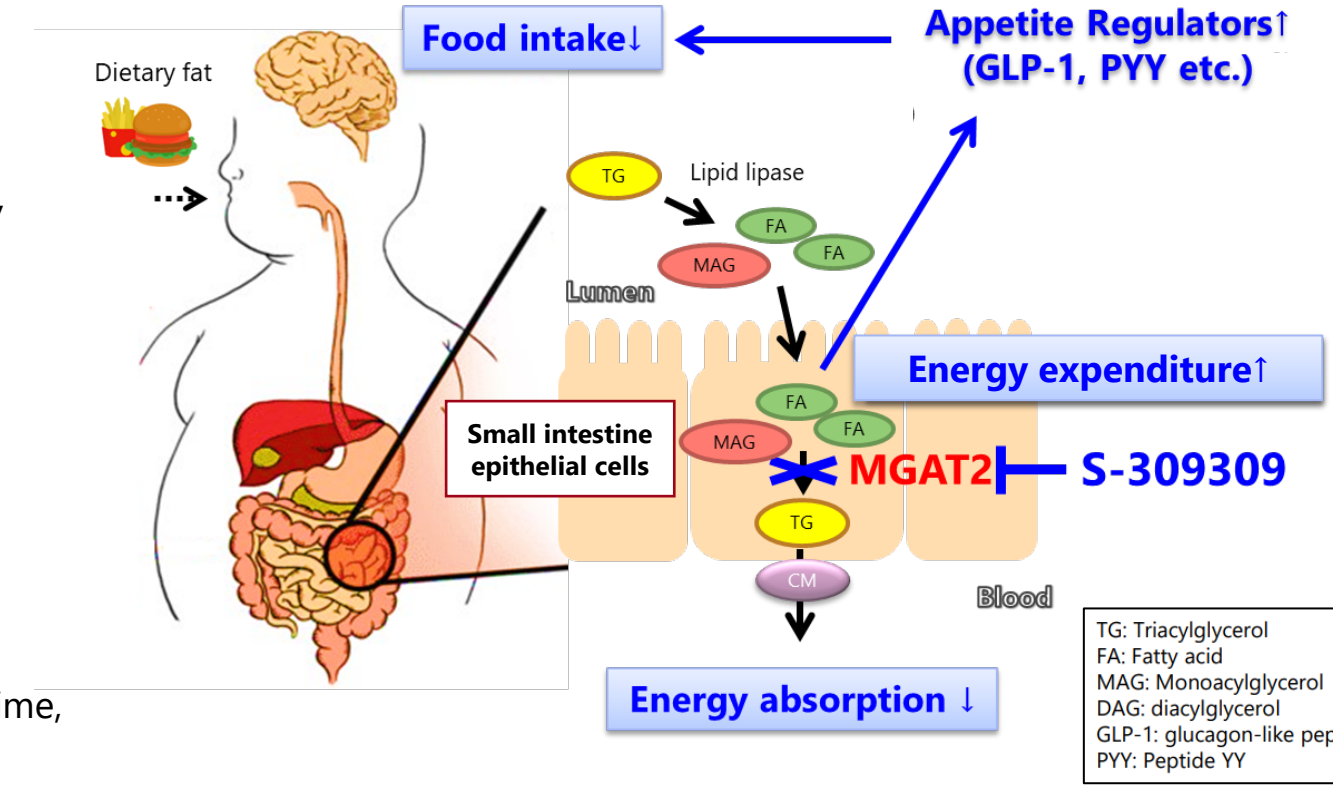
- Obese patients*：245 million（7MM*2）、125 million (U.S.)

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

- Monoacylglycerol transferase 2 (MGAT2) inhibitor



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*2 7 major markets; US, France, Germany, Italy, Spain, UK and Japan

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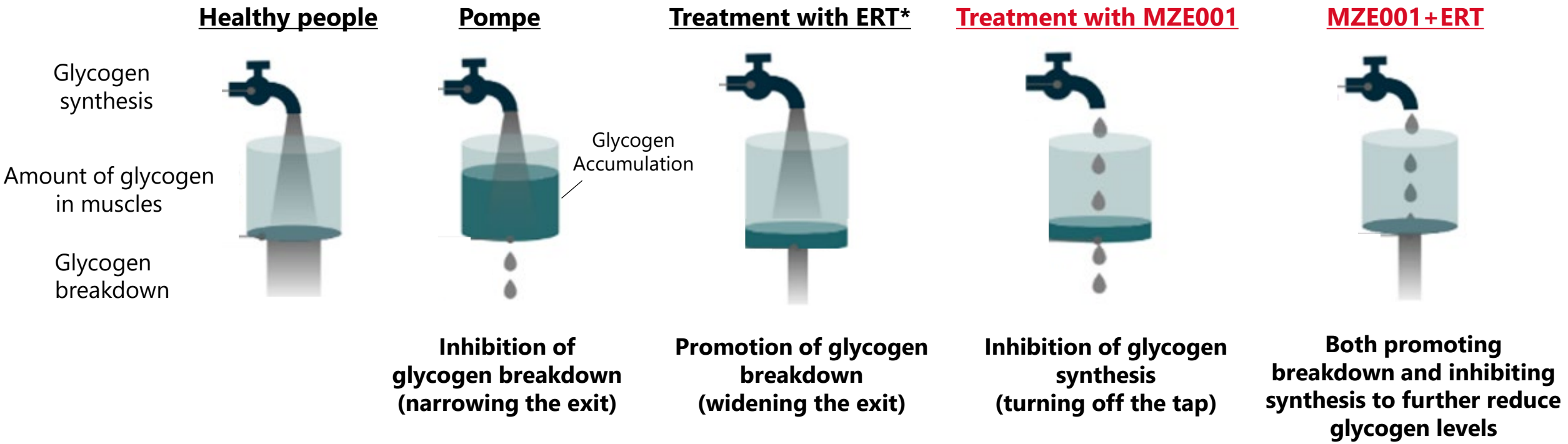
Pathophysiology of Pompe Disease and Treatment Concept with MZE001

- Pompe disease is a disorder where a mutation (activity reduction) in the lysosomal acid alpha-glucosidase (GAA) in muscles leads to abnormal accumulation of glycogen in muscle tissues, resulting in tissue destruction
- The symptoms can be improved by reducing the amount of glycogen, either by inhibiting its production or by promoting its breakdown



* Enzyme Replacement Therapy: Promotes the breakdown of glycogen in muscles by supplementing GAA

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Sustainable Growth Strategy Focusing on LA and ULA Formulations

Growth is expected to continue through and beyond 2026 through sales growth of LA formulations and market launches of ULA* formulations

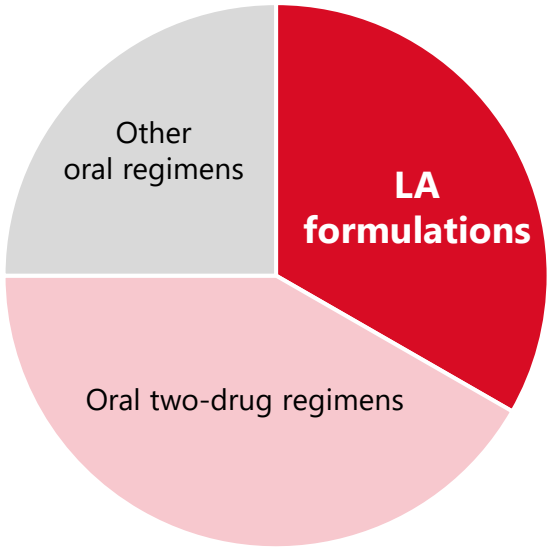
2021 – 2026

Expected to lead the growth of the overall HIV business at the compound annual growth rate of **6 to 8%**

- **Cabenuva**
  ULA formulations (treatment)
- **Apretude**
  ULA formulations (PrEP)
- **Dovato**
  Oral two-drug regimens

2026

The overall HIV business is expected to generate revenue of **up to £7.0 billion**



LA formulations account for more than 30% of overall sales

2026 – 2031

Further value enhancement of LA formulations through continuous launches of formulations for administration every four months and every six months

Q4M*2	**ULA formulations (PrEP)**	**2026**
Q4M	**ULA formulations (treatment)**	**2027**
Q6M*3	**ULA formulations (PrEP / treatment)**	**2028 and beyond**

* Ultra long acting *2 Every 4 months *3 Every 6 months

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Anti-HIV drug released by ViiV

Product name	Formulations	Compounds	Administrations	Frequency	Indications	CY2023 Sales (M £)
Cabenuva	Long Acting	CAB＋RPV	IM injection	Q2M (LA)	Treatment	708
Apretude		CAB	IM injection	Q2M (LA)	PrEP	149
Dovato	Two-drug regimens	DTG＋3TC	Oral	Evrey day	Treatment	1,819
Juluca		DTG＋RPV	Oral	Every day	Treatment	661
Tivicay	Single agent	DTG	Oral	Every day	Treatment	1,386
Triumeq	Three-drug regimen	DTG+ABC+3TC	Oral	Every day	Treatment	1,542

Building a Robust Global Supply Chain

Initiatives to ensure stable supply of antibiotics in Japan through industry-academics-government collaboration

Complex problems and issues of supply shortage of antibiotics

Reliance on raw materials and active pharmaceutical ingredients sourced from overseas	**Lack of manufacturing capacity**
Deterioration of profitability	**Quality issues**

Major issues

People

- Train engineers to maintain a certain level of production capacity in normal times
- Establish an education system

Technology

Dual sourcing and stockpiling of a certain amount of raw materials with procurement risks

Goods

Early development of technologies necessary for the manufacturing of active pharmaceutical ingredients

Equipment

Early construction of manufacturing equipment

SHIONOGI's initiatives

Kanegasaki Plant

Started to build equipment, such as solvent tanks for β-lactam raw materials
- Aim to start commercial production in 2028

Amagasaki Plant

Started to build equipment in order to establish side chain synthesis technology for active pharmaceutical ingredients and continuous manufacturing methods
- Aim to start commercial production in 2028

Adopted as part of the Project to Support Stable Supply of Pharmaceuticals of the Ministry of Health, Labour and Welfare for the resolution of various problems through industry-academics-government collaboration

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Other Major Progress*

- **February**
  - Academic Presentation at Neuroscience 2023 in the United States - Confirmation of Gamma Wave Synchronization in the Human Brain through Auditory Stimulation-
  - Recognized with the Double A List for Leadership in Corporate Transparency and Performance on Climate Change and Water Security by CDP for the second consecutive year
  - Completion of the Transfer of the "Mother to Mother SHIONOGI Project" the Second Phase to the Government of Kilifi County, Republic of Kenya
  - Strategic Business Partnership Agreement for Diagnosis Support AI Program in Dementia and Depression between FRONTEO and Shionogi
- **March**
  - Option Agreement between FunPep and SHIONOGI Regarding Allergy Vaccine
  - Initiation of the Second Phase of Comprehensive Cooperation in the Field of Infectious Diseases Focused on Malaria with Nagasaki University
  - Recognized as One of the Highest-Ranking Companies on the Supplier Engagement Rating (Climate Change) by CDP for the Fourth Consecutive Year
- **May**
  - Collaboration Agreement for the Discovery and Development of Novel Malaria Preventive Drugs with Nagasaki University, National Institute of Infectious Diseases, and MMV, Supported by the GHIT Fund

* Progress from January 31, 2024 to May 12, 2024

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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