



SHIONOGI & CO., LTD.

1st Quarter of Fiscal 2026 Financial Results

August 3, 2026

Presentation

Kyokawa: Thank you very much for your participation today despite your busy schedule. My name is Kyokawa, Corporate Communications Manager, SHIONOGI & CO., LTD.

We would like to start the Q1 of FY2026 financial results of SHIONOGI & CO., LTD.

First, let me introduce today's speakers. John Keller, Director of the Board, R&D Supervisory Unit.

Keller: I'm Keller. Thank you very much.

Kyokawa: Toshinobu Iwasaki, Senior Executive Officer, Healthcare Business Supervisory Unit.

Iwasaki: I'm Iwasaki. Thank you.

Kyokawa: Takeki Uehara, Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division

Uehara: I'm Uehara. Thank you.

Kyokawa: Masako Kudou, Corporate Officer, Head of Business Strategy Division.

Kudo: My name is Kudo. Thank you.

Kyokawa: Takuji Fujiwara, Accounting and Finance Vice President.

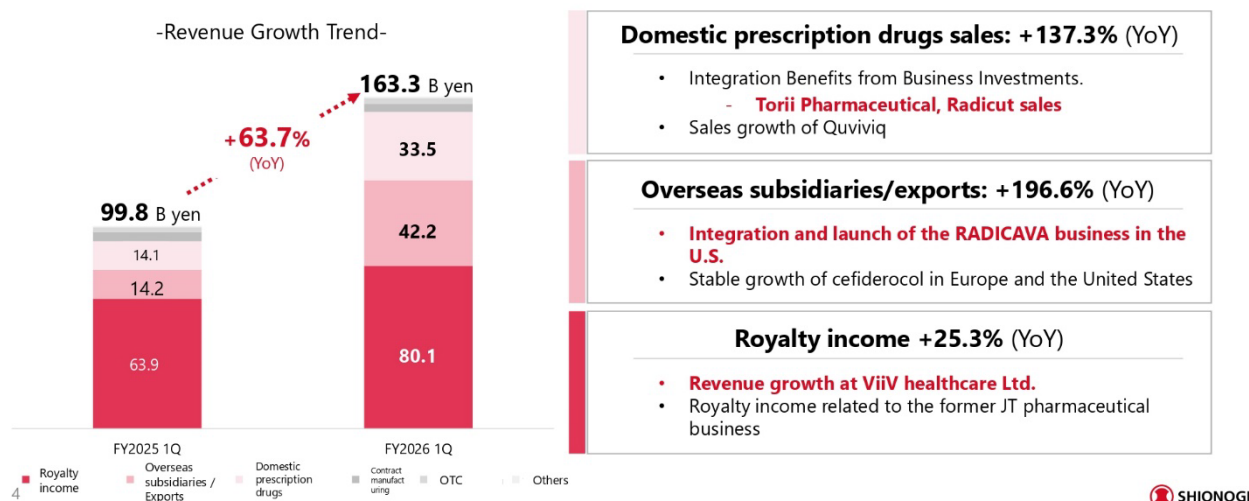
Fujiwara: My name is Fujiwara. Thank you.

Kyokawa: Today, we will begin with an explanation of our Q1 financial results by Fujiwara and the respective executive officers. Following that, John Keller will provide an update on our HIV business, based on the announcements made last week by GSK and ViiV.

Let me begin at once. Mr. Fujiwara, please start your presentation.

Significant Growth of Key Businesses

Revenue reached a record high for the first quarter, driven by growth of existing businesses and integration effects from acquired businesses



Fujiwara: I'll begin by providing an overview of our financial results for Q1 of FY2026.

During the first quarter, in addition to growth in our existing businesses, the integration benefits from a series of growth investments executed in the previous fiscal year began contributing steadily to our business performance.

Revenue reached ¥163.3 billion, representing significant growth of 63.7% year on year.

By segment, Prescription Drugs in Japan generated revenue of ¥33.5 billion, an increase of 137.3% year on year. Overseas Subsidiaries/Exports generated revenue of ¥42.2 billion, an increase of 196.6% year on year. Royalty income reached ¥80.1 billion, an increase of 25.3% year on year. All major businesses achieved substantial growth. I will provide further details on each business later.

In particular, revenue from Torii Pharmaceutical, overseas subsidiaries, the launch of the RADICAVA business in the United States, and growth of the HIV franchise resulting from increased sales at ViiV made significant contributions to performance. As a result, we recorded the highest first-quarter revenue in the Company's history.

Financial Results (Consolidated)

Year-on-year growth achieved revenue and all profit categories

(Unit: B yen)

	FY2026				FY2025	YoY	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change (%)	Change
Revenue	700.0	340.0	163.3	48.0	99.8	63.7	63.5
Operating profit	220.0	96.0	66.9	69.7	35.1	90.6	31.8
Profit before tax	220.0	96.0	73.7	76.8	46.3	59.2	27.4
Profit attributable to owners of parent	210.0	108.0	97.7	90.5	39.4	148.2	58.3
EBITDA*1	315.0	152.0	93.4	61.4	40.6	129.8	52.7

⁵ *1 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.)  SHIONOGI

Let me now explain our consolidated financial performance.

Revenue and all profit items increased year on year. Revenue totaled ¥163.3 billion, an increase of ¥63.5 billion year on year. Operating profit was ¥66.9 billion, up ¥31.8 billion year on year. Quarterly profit before tax was ¥73.7 billion, up ¥27.4 billion year on year. Quarterly profit attributable to owners of the parent was ¥97.7 billion, up ¥58.3 billion year on year. EBITDA was ¥93.4 billion, an increase of ¥52.7 billion year on year.

Against our first-half forecast, achievement rates were 48.0% for revenue, 69.7% for operating profit, 76.8% for profit before tax, and 90.5% for profit attributable to owners of the parent. Progress was particularly strong on the profit side relative to our forecast. I will explain the reasons for this in more detail on the following pages.

Statement of Profit or Loss (Consolidated) (Unit: B yen)

	FY2026		FY2025		YoY		Main variation factors (YoY)
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	
Revenue	700.0	340.0	163.3	48.0	99.8	63.7	63.5
Cost of Sales	17.1	18.8	18.9	48.1	12.3	150.0	18.5
Gross profit	580.0	276.0	132.5	48.0	87.5	51.5	45.1
SG&A*1, R&D expenses total	56.4	57.9	56.8	47.1	51.3	81.2	41.6
SG&A*1	34.3	34.7	37.3	51.7	26.4	131.8	34.7
R&D expenses	22.1	23.2	19.5	40.2	24.9	27.7	6.9
Other income & Expenses	35.0	17.0	27.2	159.8	(1.2)	-	28.3
Operating profit	31.4	28.2	41.0	69.7	35.2	90.6	31.8
Finance income & costs	-	-	6.8	-	11.2	(39.2)	(4.4)
Profit before tax	31.4	28.2	45.2	76.8	46.4	59.2	27.4
Profit attributable to owners of parent	220.0	96.0	73.7	76.8	46.3	59.2	27.4
	210.0	108.0	97.7	90.5	39.4	148.2	58.3

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*1 Selling, general and administrative expenses ** PPA: Purchase Price Allocation — provisional accounting treatment before completion
 *3 Dividends received from Viiv Healthcare, which were recognized as financial income (dividend income) in the statement of profit or loss in the previous fiscal year, are reflected in "Investments accounted for using the equity method" (non-current assets) in the statement of financial position



I will now explain our consolidated statement of profit or loss.

Revenue increased by ¥63.5 billion year on year, driven by growth in royalty income, the Prescription Drugs in Japan segment, and the Overseas Subsidiaries/Exports segment.

Regarding expenses, cost of sales was ¥30.8 billion, an increase of ¥18.5 billion year on year.

The primary factors behind this increase were higher cost of sales resulting from the consolidation of Torii Pharmaceutical as a subsidiary and a one-time inventory valuation expense related to the edaravone business acquired through business succession. We expect the impact of inventory-related expenses associated with edaravone to be limited to the first half.

Selling, general and administrative expenses totaled ¥61.0 billion, an increase of ¥34.7 billion year on year.

This increase primarily reflects amortization of intangible assets associated with the former JT pharmaceutical business and the edaravone business, selling-related expenses for our U.S. operations, which represent a key growth region, and SG&A expenses associated with Torii Pharmaceutical.

Research and development expenses totaled ¥31.8 billion, an increase of ¥6.9 billion year on year.

The principal reason for this increase was the inclusion of R&D expenses from the former JT pharmaceutical business and Torii Pharmaceutical.

Other income and expenses amounted to ¥27.2 billion, an increase of ¥28.3 billion compared with the same period of the previous year.

The primary reason for this increase is that, beginning this fiscal year, Viiv has been accounted for using the equity method, and Viiv's profits are therefore recognized as a share of profit of investments accounted for using the equity method in proportion to our ownership interest. At this point in the first quarter, however, amortization of intangible assets arising from the acquisition of Viiv shares has not yet been recorded.

Net financial income amounted to ¥6.8 billion.

Although the change in accounting treatment for dividends received from ViiV had a negative impact, foreign exchange gains contributed positively during the quarter.

Profit attributable to owners of the parent also benefited from improved expectations for future taxable income at our U.S. subsidiary following the transfer of the edaravone business.

As a result, deferred tax assets were recognized during the quarter. This generated a one-time tax effect in the first quarter, resulting in profit attributable to owners of the parent of ¥97.7 billion, an increase of ¥58.3 billion year on year.

On a full-year basis, we expect this impact to remain in line with our original assumptions.

As a result of these factors, all profit items increased compared with the same period of the previous fiscal year.

Revenue by Segment

			FY2026		FY2025	YoY		Main variation factors (YoY)
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change	
Prescription drugs	178.6	79.9	33.5	42.0	14.1	137.3	19.4	Prescription drugs - Increase: Sales of Torii Pharmaceutical, Radicut, Quviviq - Decrease: Sales of acute respiratory infection drugs
Overseas subsidiaries/export	175.2	85.4	42.2	49.4	14.2	196.6	28.0	
Shionogi Inc. (US)	138.7	68.0	32.0	47.1	6.2	417.1	25.8	Overseas subsidiaries / Exports Increase: RADICAVA, sales of cefiderocol in the U.S. and Europe (U.S.: Fetroja, Europe: Fetcroja)
RADICAVA*	101.7	51.8	24.2	46.7	-	-	24.2	
Fetroja	-	-	7.7	-	5.9	29.4	1.7	Royalty income - Increase: HIV franchise (sales by ViiV Healthcare) - Other: Royalties related to the former JT pharmaceutical business
Shionogi B.V. (EU)	22.6	11.1	6.6	59.7	4.7	40.4	1.9	
Fetcroja	-	-	5.0	-	3.4	44.9	1.5	
Shionogi China	5.3	2.5	1.5	57.8	1.5	(2.6)	(0.0)	
Others	8.7	3.8	2.1	55.2	1.8	15.5	0.3	
Contract manufacturing	14.4	7.7	4.0	51.7	4.5	(11.0)	(0.5)	
OTC and quasi-drug	18.8	8.3	2.9	34.7	2.4	19.6	0.5	
Royalty income	310.6	157.7	80.1	50.8	63.9	25.3	16.2	
HIV franchise	276.0	139.1	72.7	52.3	61.2	18.9	11.5	
Others	34.6	18.6	7.4	39.6	2.7	169.3	4.6	
Others	2.3	0.9	0.6	66.7	0.6	(4.4)	(0.0)	
Total	700.0	340.0	163.3	48.0	99.8	63.7	63.5	

7 *UP rate of RADICAVA revenue in the U.S. and Canada: 14.6%
Apr.-Jun. 2026: 151.9 MUSD (sales at SHIONOGI Group), Apr.-Jun. 2025: 132.5 MUSD (RADICAVA sales at Tanabe Pharma)



I will now explain revenue by business segment.

Revenue in the Prescription Drugs in Japan segment was ¥33.5 billion, an increase of ¥19.4 billion year on year.

This increase was driven by the addition of products acquired through last year's M&A transactions, including products from Torii Pharmaceutical and Radicut, a treatment for ALS and other conditions, as well as higher sales of Quviviq, a treatment for insomnia.

On the other hand, sales of products for acute respiratory infections declined because there was no widespread COVID-19 outbreak during the first quarter.

Revenue from Overseas Subsidiaries/Exports totaled ¥42.2 billion, an increase of ¥28.0 billion year on year.

In the United States, RADICAVA began making a meaningful contribution to sales, bringing total U.S. revenue to ¥32.0 billion.

As noted in the footnote, revenue from RADICAVA in the United States and Canada totaled US\$150 million during the April-June 2026 period, representing a 14.6% increase from US\$130 million in the same period of the previous year.

We believe that we have successfully integrated the acquired business and smoothly launched operations.

U.S. sales of Fetroja totaled ¥7.7 billion, an increase of ¥1.7 billion year on year.

European sales of Fetroja totaled ¥5.0 billion, an increase of ¥1.5 billion year on year.

Performance remained solid in both North America and Europe.

Royalty income totaled ¥80.1 billion, an increase of ¥16.2 billion year on year.

Driven by ViiV's continued growth, royalty income from the HIV franchise reached ¥72.7 billion, an increase of ¥11.5 billion year on year.

In addition, royalty income related to the former JT pharmaceutical business contributed to growth in other royalty income.

As a result, total revenue reached ¥163.3 billion.

1Q Results and Future Outlook

**Steady progress toward achievement of 1H forecast
through further growth of key businesses**

1Q results

Record-high 1Q results for revenue and all profit items

- Performance expanded through growth of key businesses and integration effects from acquired businesses
- Continued investment to drive further growth of the U.S. business

1H outlook

On track to achieve the 1H forecast

- HIV franchise and overseas business expected to continue revenue and profit growth through further expansion
- Advancing initiatives in preparation for a potential increase in COVID-19 infections
- From Q2 onward, the PPA impacts associated with Shionogi's increased shareholding in ViiV will be reflected in "Equity method income."

Let me conclude with a brief summary of our first-quarter achievements and outlook.

In the first quarter, we achieved record-high revenue and record-high levels across all profit metrics.

As I have explained, our performance expanded substantially due to growth in our core businesses and synergy benefits from the integration of acquired businesses.

We also continued to invest appropriately in our U.S. business, one of our key growth areas.

Based on our first-quarter results, we expect to achieve our first-half forecast.

For revenue, we continue to expect strong growth in both the HIV franchise and overseas businesses.

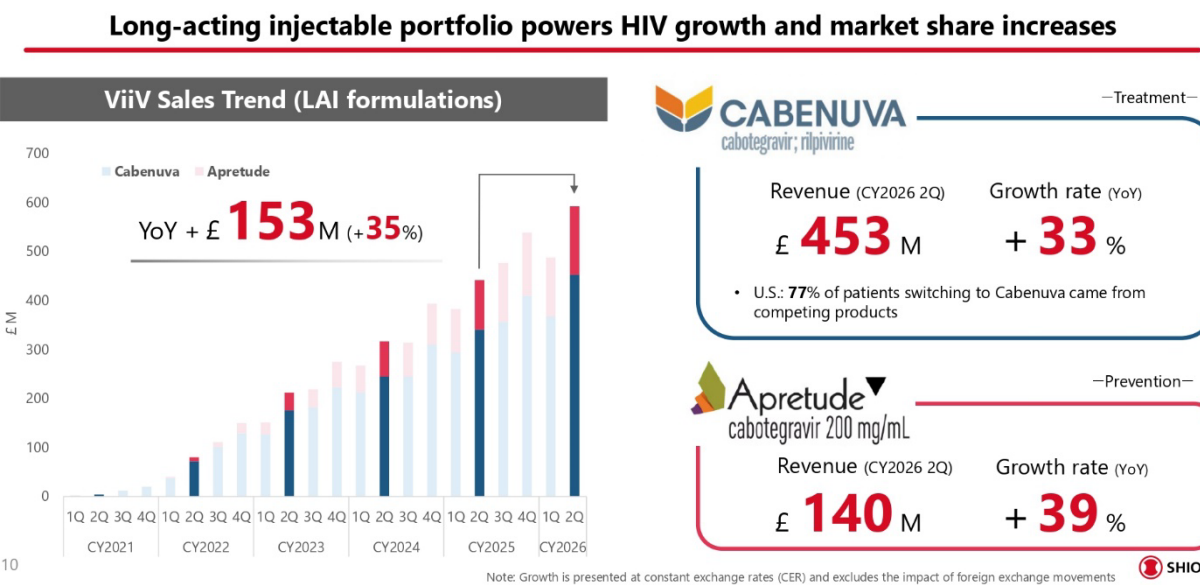
In addition, we will continue our efforts to prepare for potential future COVID-19 outbreaks in Japan.

On the profit side, beginning in the second quarter, we expect to reflect the results of the purchase price allocation associated with our additional acquisition of ViiV shares in equity-method investment income. We believe progress remains in line with our first-half plan.

Accordingly, we are making steady progress toward achieving our first-half forecast.

That concludes my presentation.

Progress of ViiV's HIV Franchise



Keller: Regarding progress in our key businesses, I would like to discuss the advancement of ViiV Healthcare's HIV franchise.

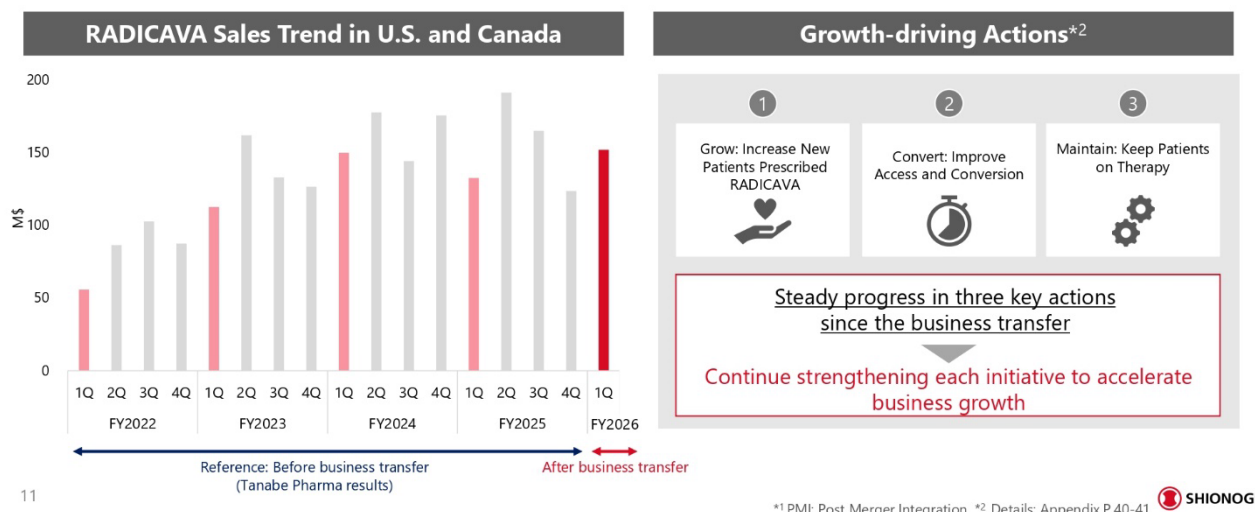
The HIV franchise continued to deliver strong growth in both the treatment and prevention segments. Total revenue from the long-acting injectable portfolio increased by GBP 153 million, representing year-on-year growth of 35%.

In the treatment segment, revenue reached GBP 453 million, up 33% year on year. In addition, 77% of newly switched patients came from competing products.

For Apretude in the prevention segment, revenue reached GBP 140 million, representing strong year-on-year growth of 39%.

RADICAVA Business Progress

Achieved record-high 1Q revenue through a smooth business transition and effective PMI*¹ execution



Iwasaki: Regarding our domestic and overseas businesses, I, Iwasaki, who oversees the Healthcare Business, will provide an update.

Let me begin with the progress of the RADICAVA business.

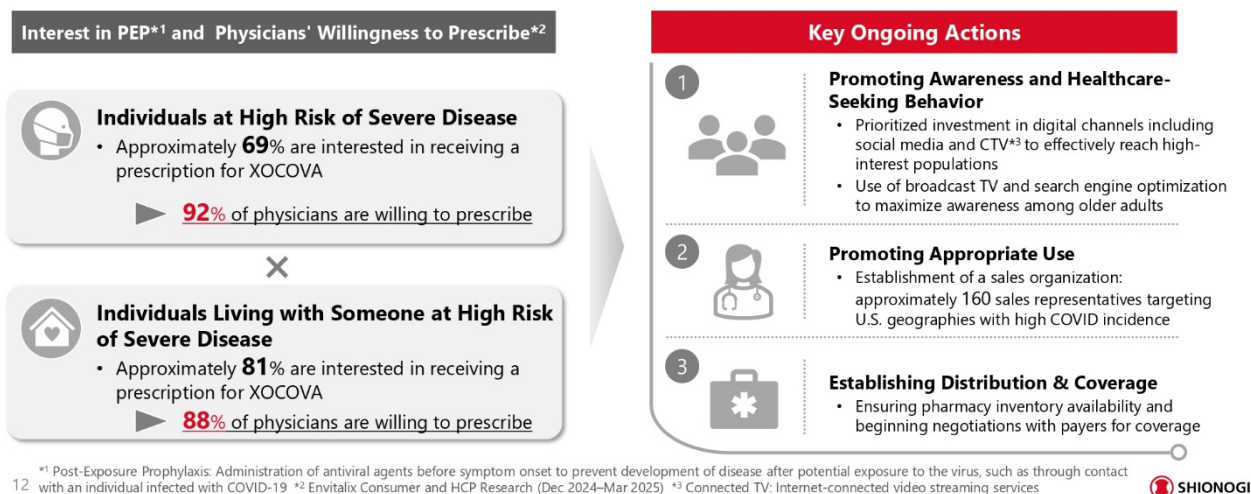
First-quarter revenue for RADICAVA totaled approximately USD 150 million in the United States and Canada combined, marking the highest first-quarter revenue in the product's history. We successfully completed the smooth transfer of the business from Tanabe Pharma Corporation and steadily advanced PMI activities, enabling stable business operations.

As we have previously communicated, we are pursuing three key initiatives to drive further business growth: providing prompt and reliable support for new patients, streamlining the treatment initiation process, and establishing a foundation that supports treatment continuation. These initiatives are progressing steadily, and we are seeing positive results both in acquiring new patients and in supporting ongoing treatment.

Going forward, we will further strengthen these initiatives to improve access to RADICAVA for more ALS patients and drive continued growth of the RADICAVA business.

U.S. Launch of XOCOVA (Post-Exposure Prophylaxis for COVID-19)

Driving adoption of post-exposure prophylaxis as a new option



Let me now explain the rollout of XOCOVA in the United States.

We launched XOCOVA in the United States on July 28.

In the U.S. COVID-19 post-exposure prophylaxis market, or PEP market, significant unmet needs have been identified. Approximately 70% of individuals at high risk of severe disease, and approximately 80% of those living with people at high risk of severe disease, have expressed interest in prevention with XOCOVA. Physicians' willingness to prescribe is also at a high level, at approximately 90% for both groups.

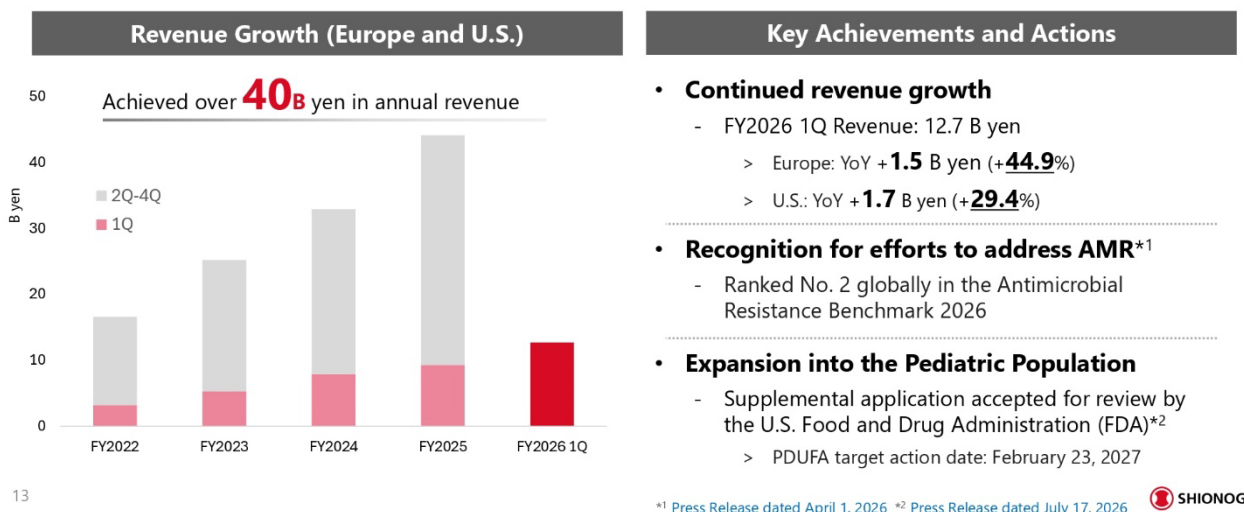
To capture this market opportunity, we are focusing on increasing awareness and encouraging medical consultations, promoting appropriate use, and establishing distribution and reimbursement infrastructure.

Specifically, in addition to awareness-building activities utilizing social media and Connected TV, we have established a nationwide commercial organization of approximately 160 sales representatives, with a focus on regions experiencing high COVID-19 incidence rates. Furthermore, we are securing adequate inventory at pharmacies and advancing discussions with payers, steadily building the foundation necessary to improve patient access.

Through these initiatives, we will work to expand adoption of this new preventive option and maximize the value of XOCOVA.

Cefiderocol Growth

Maximizing product value through the promotion of appropriate use



Let me now discuss the growth of cefiderocol.

Revenue from cefiderocol continues to expand, primarily in Europe and the United States, and the product grew to generate annual sales exceeding ¥40 billion in the previous fiscal year.

First-quarter FY2026 revenue totaled ¥12.7 billion, representing strong year-on-year growth of approximately 45% in Europe and approximately 29% in the United States.

As revenue continues to grow steadily, we have consistently focused on maximizing the value of cefiderocol through the promotion of appropriate use since its launch. These efforts have been highly recognized internationally, and in the Antimicrobial Resistance Benchmark 2026, we were ranked second among major global research-based pharmaceutical companies.

In addition, to further expand patient access, we are pursuing an additional indication in pediatric patients. In July of this year, our regulatory submission was accepted for review by the FDA.

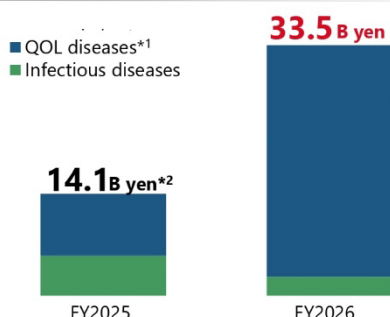
By promoting both appropriate use and broader access, we will deliver cefiderocol to more patients while achieving sustainable growth.

Progress in Domestic Business

Diversified product portfolio drives stable growth in the domestic business

Share of domestic business revenue (1Q)

YoY **+19.4B yen** (+137.3%)



*1 High social impact QOL-related diseases: sleep disorders, hearing loss, rare pediatric diseases, immunology/allergy, etc. *2 Excluding revenue from Torii Pharmaceutical-related products, Radicut, and Zurzuvae *3 YoY growth rate: 13.2% (comparison with the prior-year revenue of Torii-related products in the JT Group pharmaceutical business)** SLIT: Sublingual Immunotherapy *5 Although limited shipments remain in place, shipment volumes to wholesalers have been increasing *6

14 YoY growth rate: 2.4% (comparison with the prior-year revenue at Tanabe Pharma)*7 JAMDAS (Data from April 1 to June 30, 2026)



Products of Torii Pharmaceutical

1Q revenue: 18.8 B yen*3

- Increased shipment volume of SLIT*4
- Co-promotion in the dermatology area



Radicut 1Q revenue: 1.8 B yen*6

(Amyotrophic lateral sclerosis (ALS) treatment)

- Encouraging early diagnosis and timely treatment through awareness campaigns



Quviviq (Insomnia treatment)

1Q revenue: 1.5 B yen

- Sales growth driven by increased adoption among psychiatric institutions



Zurzuvae (MDD treatment)

1Q revenue: 0.4 B yen

- Growing number of adopting facilities, mainly clinics



Acute respiratory infection (Xocova, Xofluza, Rapiacta)

Rapiacta*

- Achieved a 67.5%*7 market share in the COVID-19 treatment market
- Providing information in preparation for infectious disease outbreaks

SHIONOGI

Let me now explain developments in our domestic business.

Domestic business revenue for the first quarter totaled ¥33.5 billion, an increase of ¥19.4 billion compared with the same period of the previous year.

This revenue increase was driven primarily by products related to Torii Pharmaceutical, as well as the addition and growth of products in the QoL disease area, including Quviviq, Zurzuvae, and Radicut.

Products related to Torii Pharmaceutical and Radicut were not recorded as revenue by SHIONOGI in the previous fiscal year. In the current first quarter, however, they generated revenue of ¥18.8 billion and ¥1.8 billion, respectively, making significant contributions to the growth of our domestic business.

Quviviq continued to grow through increased adoption at psychiatric institutions. Zurzuvae, an antidepressant, also expanded its market penetration steadily, with the number of adopting facilities increasing primarily among clinics.

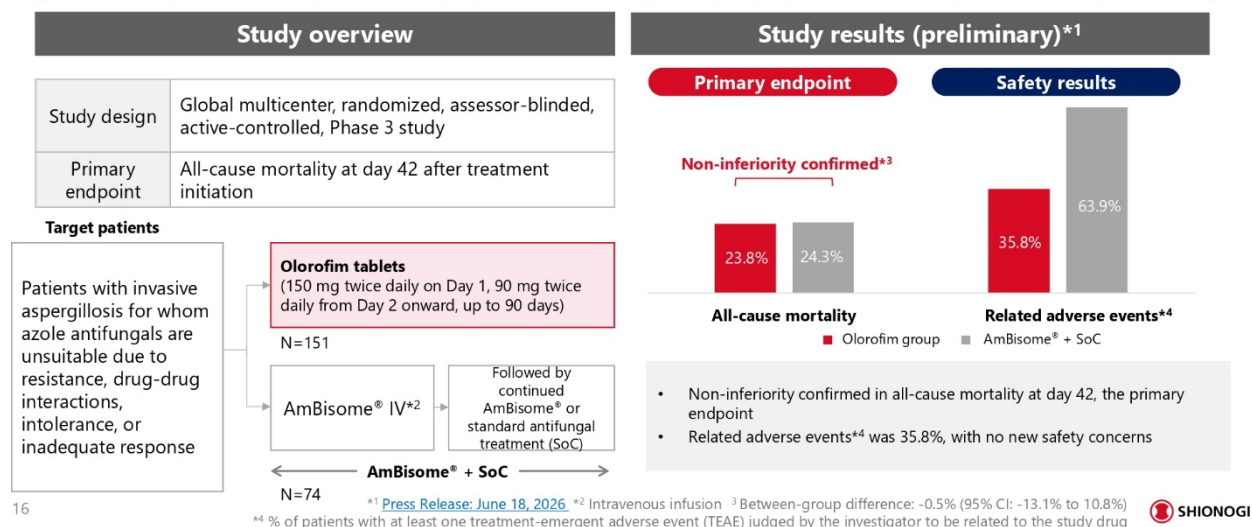
In the infectious disease area, although there was no COVID-19 outbreak during the quarter, XOCOVA maintained a market share of 67.5%, and we have already established a system that enables us to provide appropriate treatment to patients promptly when outbreaks occur.

Through the cultivation of growth drivers in multiple QoL disease areas that are not affected by fluctuations in infectious disease outbreaks, together with contributions from products acquired through M&A, our domestic business achieved stable growth.

Going forward, we will continue to pursue stable growth through diversification of our product portfolio

Olorofim: Phase 3 Study Results (Preliminary)

Achievement of the primary endpoint, with regulatory filings planned in Europe and Asia



Uehara: Next, I will continue with an update on the development pipeline.

The most significant achievement this quarter was the completion of the Phase 3 study of olorofim, a novel antifungal agent with a new mechanism of action that we are co-developing with F2G. As already announced in our press release, the study achieved its primary endpoint.

We are once again presenting the study design and its results.

The target patient population consisted of patients with resistance to azole antifungal agents, which are generally considered first-line therapies, or patients for whom such agents could not be used. In this setting, patients received oral olorofim or intravenous AmBisome®, a liposomal formulation of amphotericin B. The primary endpoint was all-cause mortality, as shown on the right side of the slide.

The study confirmed non-inferiority versus the AmBisome treatment group and, as we had expected, demonstrated that olorofim is a safe oral treatment option. This Phase 3 study successfully verified its safety profile. As we hold commercialization rights in Europe and Asia, we are planning to submit regulatory applications in those regions.

Treatment Challenges in Invasive Aspergillosis

Treatment options remain limited for patients who cannot receive azole antifungals

Current Treatment Landscape in Invasive Aspergillosis

Patient Population

- Estimated annual diagnoses exceed **200,000** patients across Europe, Japan, and China

High Mortality Risk

- Mortality rate is **100%**^{*1} if left untreated
- Mortality rate is approximately **30%** with current antifungal therapies^{*1}

Lack of Treatment Options

- Azole antifungals are preferred first-line therapy but can be inappropriate due to increasing prevalence of azole-resistant strains,^{*2} drug-drug interactions
- Alternative therapies^{*3} are urgently needed

Expectations for New Alternative Treatment Options



1. Improved Safety Profile

Treatment options that can be more readily used in high-risk patients are needed

Risk of **organ toxicity**

Risk of **drug-drug interactions**



2. Reduced Patient Burden

Need for convenient treatment options that support long-term therapy

Prolonged intravenous treatment

Transition to outpatient care

17

^{*3} Including polyene antifungals and other alternative therapies (Source: [IDSA 2016 Clinical Practice Guideline Update for the Diagnosis and Management of Aspergillosis](#))

^{*1} Walsh TJ et al. J Fungi. 2025, 11(9), 657 ^{*2} Lestrade PPA, et al. Emerg Infect Dis. 2020;26(7):1447-1455

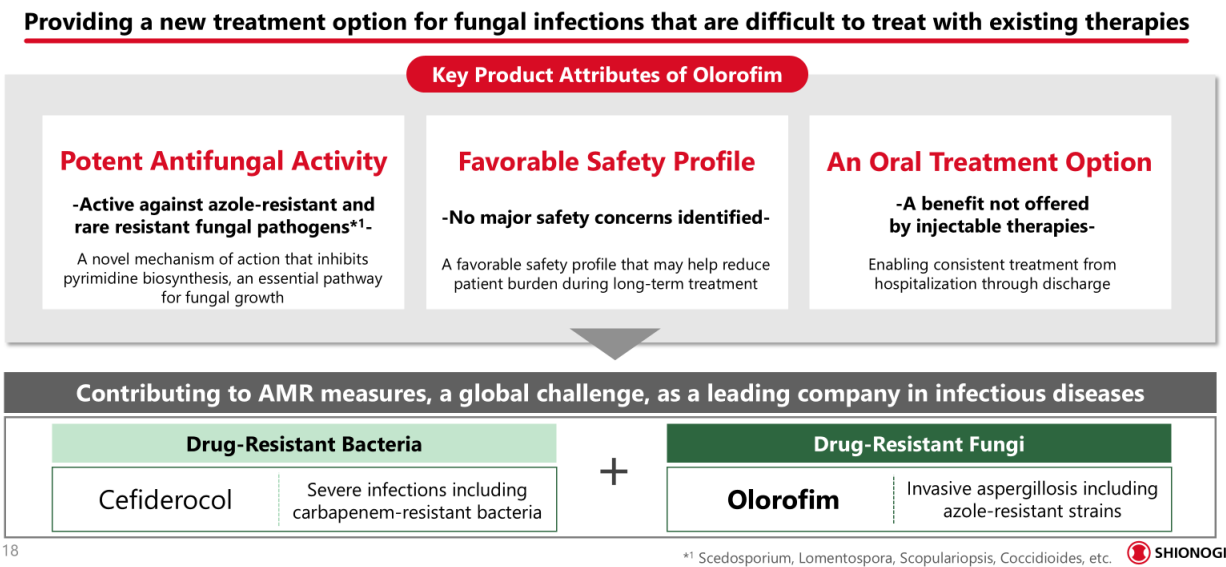


Regarding invasive aspergillosis, I would like to briefly discuss the unmet medical need in this area.

The number of diagnosed patients is estimated to exceed 200,000 annually across Japan, Europe, and China. Naturally, if left untreated, the mortality rate is 100%, and even with currently available antifungal therapies, mortality remains high.

Against this backdrop, there is a significant need for antifungal agents that can be used safely. Furthermore, existing treatments such as AmBisome require intravenous administration and therefore hospitalization. Even when patients show improvement, there remains a need for therapies that enable a transition to outpatient care and reduce the burden on patients. This continues to be an important challenge.

Contributing to AMR Measures in the Fungal Disease Area



Against this background, as mentioned at the outset, olorofim offers a new treatment option: an oral therapy with a favorable safety profile. In addition, because it has a novel mechanism of action, efficacy has been demonstrated against fungi that have developed resistance to existing therapies. Furthermore, its activity against rare fungal species suggests that it may have broad clinical utility.

As Iwasaki mentioned earlier, we have been advancing the global expansion of our cefiderocol business. Now, with the addition of olorofim as a new product, we believe these two assets together will further strengthen our infectious disease business. By contributing to efforts against antimicrobial resistance (AMR), a global healthcare challenge, we aim to continue expanding this business area.

R&D Milestones for FY2026 (Infectious Disease Areas)

Red text: Changes from May 13, 2026, to August 3, 2026, ✓: Milestone achieved

The list of applicable assets is planned to be updated on a rolling basis

Top-line results: This indicates the timing of data acquisition, and the timing of disclosure will be considered separately

Development products	Target diseases	FY2026 1H		FY2026 2H		Target launch timing*1
Ensirelvir	COVID-19 treatment	Approval (Europe)				-FY2027
	COVID-19 treatment (Pediatric ages 6-11)	Approval (Japan)	✓			
	COVID-19 treatment (Pediatric ages 0-5)			Phase 3 top-line results		
	COVID-19 PEP	Approval (U.S.*2)	✓			
Secutrelvir	COVID-19 treatment (oral)	Phase 3 starts	✓			FY2028-2030
	COVID-19 pre-exposure prophylaxis (injection)			Initiation of Phase 2 IND preparation		FY2031-
S-268024	COVID-19 (JN.1 vaccine)	Approval (Japan)				-FY2027
S-567123	Sarbecovirus*4 infections (Broadly protective coronavirus vaccine)	Phase 1 top-line results		Phase 2 starts		FY2028-2030
S-337395	RSV infections			Phase 2b top-line results		FY2028-2030
Olorofim	Invasive aspergillosis	Phase 3 top-line results	✓	Submission (Europe)		FY2028-2030
Cefiderocol	Pediatric, Gram-negative bacterial infection	Submission (U.S. and Europe)	✓	Approval (U.S.)		-FY2027
S-649228	Gram-negative bacterial infection	Phase 1 top-line results Phase 2 starts				FY2028-2030

19 *1 This indicates the timing of the initial launch in any country or region where SHIONOGI holds commercialization rights, and is not intended to refer to any specific country or region *2 Already submitted in Europe *3 IND : Investigational New Drug *4 A group of viruses including SARS-CoV (2002 SARS) and SARS-CoV-2 (COVID-19)  SHIONOGI

Next, I would like to show the progress of pipelines.

As I mentioned at the beginning, ensirelvir has also been approved in Japan for children aged 6 to 11. Furthermore, we have received approval in the United States for post-exposure prophylaxis and have begun sales.

We have initiated two global Phase III clinical trials for Secutrelvir, a next-generation COVID-19 treatment.

Furthermore, with regard to the applications for pediatric approval of Olorofim and Cefiderocol mentioned earlier, we have successfully achieved very significant milestones, and we are also making steady progress on the remaining activities.

R&D Milestones for FY2026 (QOL Disease Areas)

The list of applicable assets is planned to be updated on a rolling basis
Top-line results: This indicates the timing of data acquisition, and the timing of disclosure will be considered separately

Development products	Target diseases	FY2026 1H	FY2026 2H	Target launch timing ^{*1}
Zatolmilast	Fragile X syndrome		Phase 2 additional analysis results Phase 3 top-line results	FY2028-2030
	Jordan syndrome	Phase 2 top-line results		
S-606001	Pompe disease		Phase 2 LPI	FY2031-
S-054501 (S-600918 + Combination medicine)	Sleep apnea with a central component	Phase 2 top-line results		FY2028-2030
S-054502 (Sulthiame)	Sleep apnea	Phase 1 top-line results Phase 2b/3 starts		FY2028-2030
Redasemtide	Epidermolysis bullosa	Phase 2 top-line results	Submission (Japan)	-FY2027
	Acute ischemic stroke	Phase 2b top-line results		FY2028-2030
Naldemedine	Constipation associated with Parkinson's disease		Phase 2a top-line results	FY2031-
S-531011	Solid tumor	Phase 2 top-line results		FY2031-
SDS-881	Dementia (AI program for cognitive function testing)	Phase 3 top-line results Submission (Japan)		-FY2027

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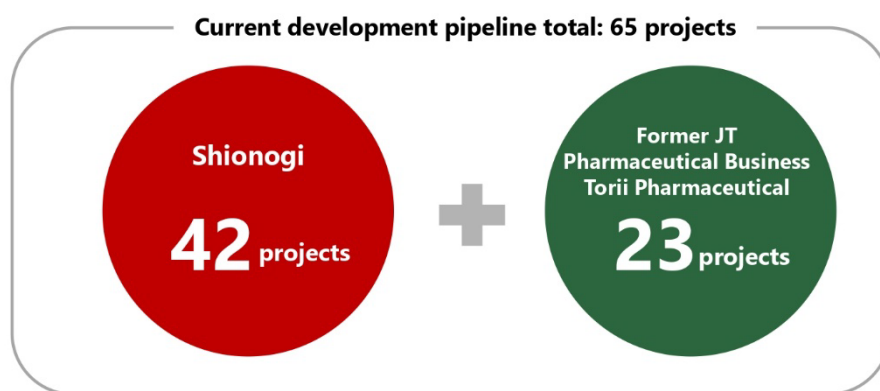
^{*1} This indicates the timing of the initial launch in any country or region where SHIONOGI holds commercialization rights, and is not intended to refer to any specific country or region ^{*2} LPI: Last Patient In  SHIONOGI

We have also listed activities related to our other QOL disease programs on this slide.

As discussed at previous earnings presentations, Zatolmilast continues in an open-label extension study. We are also conducting a Phase 2 study in Jordan syndrome, an ultra-rare disease. Based on the results of these studies, we plan to make a comprehensive assessment of the program.

In addition, several upcoming data-readout events are scheduled for our growth-driver programs, including those targeting sleep apnea syndrome and Acute ischemic stroke, as well as our oncology asset S-531011. We intend to disclose those results through appropriate channels when the time comes.

Integrated R&D pipeline to be unveiled at the R&D Day on November 18, 2026



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Finally, let me discuss our R&D outlook.

In addition to the pipeline that Shionogi has built over the years, new assets have been added through Torii Pharmaceutical and the former JT pharmaceutical business. After establishing priorities among these assets, we will determine which programs should receive more aggressive development investment.

To discuss these priorities and our future development strategy in greater detail, we plan to hold an R&D Meeting on November 18 this year. We look forward to discussing these topics further at that time.

Products containing integrase inhibitors licensed by SHIONOGI

ViiV's INSTI¹-based therapies containing dolutegravir or cabotegravir

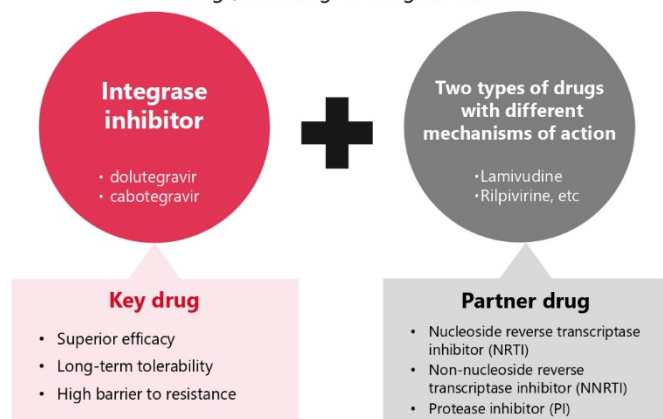
Approval ²	Formulations	Product name	Approval ²	Formulations	Product name
CY2013	Oral (single agent) Daily	 Tivicay dolutegravir	CY2019	Oral (two-drug regimen) Daily	 Dovato dolutegravir/lamivudine
CY2014	Oral (three-drug regimen) Daily	 Triumeq dolutegravir/abacavir/ lamivudine	CY2021	LAI ³ 6× a year	 CABENUVA cabotegravir; rilpivirine
CY2017	Oral (two-drug regimen) Daily	 Juluca dolutegravir/rilpivirine	CY2021	LAI ³ 6× a year	 Apretude cabotegravir 200 mg/mL ^{*4}

Keller: Following the presentations by GSK and ViiV, I would like to take a moment to look back and discuss the future business outlook for our HIV portfolio. First, let me review ViiV's portfolio. Tivicay was the starting point for our dolutegravir-based oral therapies, which subsequently evolved into two-drug regimens. In the long-acting injectable (LAI) therapies, we have Cabenuva for treatment and Apretude for prevention.

Integrase Inhibitors Are the Gold Standard for HIV Treatment

Following the launch of dolutegravir, the majority of the market was replaced by integrase inhibitor-based therapies

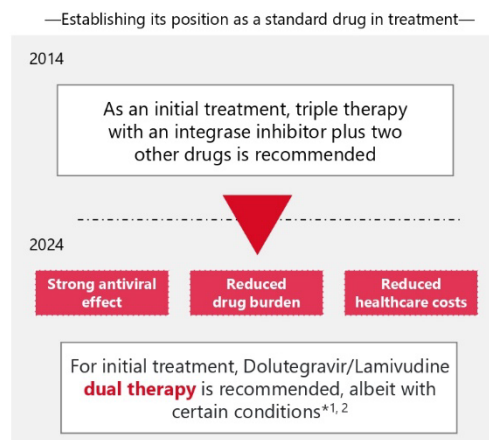
HIV treatment is now primarily based on combination therapy with 2-3 drugs, including an integrase inhibitor



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^{*1} Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV (US DHHS, Sep 12, 2024).

^{*2} European AIDS Clinical Society (EACS) Guidelines, Version 12.1-November 2024.



As we have mentioned before, integrase inhibitors form the backbone of these therapies and have become the gold standard in HIV treatment.

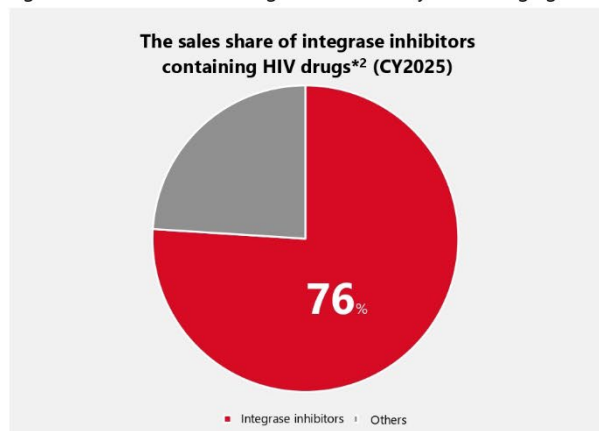
As a result, the HIV treatment market has shifted toward integrase inhibitor-based therapies. Initially, treatment consisted of integrase inhibitors combined with two partner drugs. However, leveraging the strengths of dolutegravir, treatment evolved to two-drug regimens such as Dovato and Juluca, where the addition of only one companion agent can provide sufficient therapeutic efficacy.

Sales Growth of ViiV and the Integrase Inhibitor Portfolio

ViiV's growth continues, driven by the integrase inhibitor portfolio

-Regimens with INSTI at the core driving ViiV's growth-

-Integrase inhibitors are among the most widely used drugs globally-



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*¹ Created by SHIONOGI based on GSK's financial statements *² Calculated by SHIONOGI based on sales data disclosed by companies marketing anti-HIV drugs

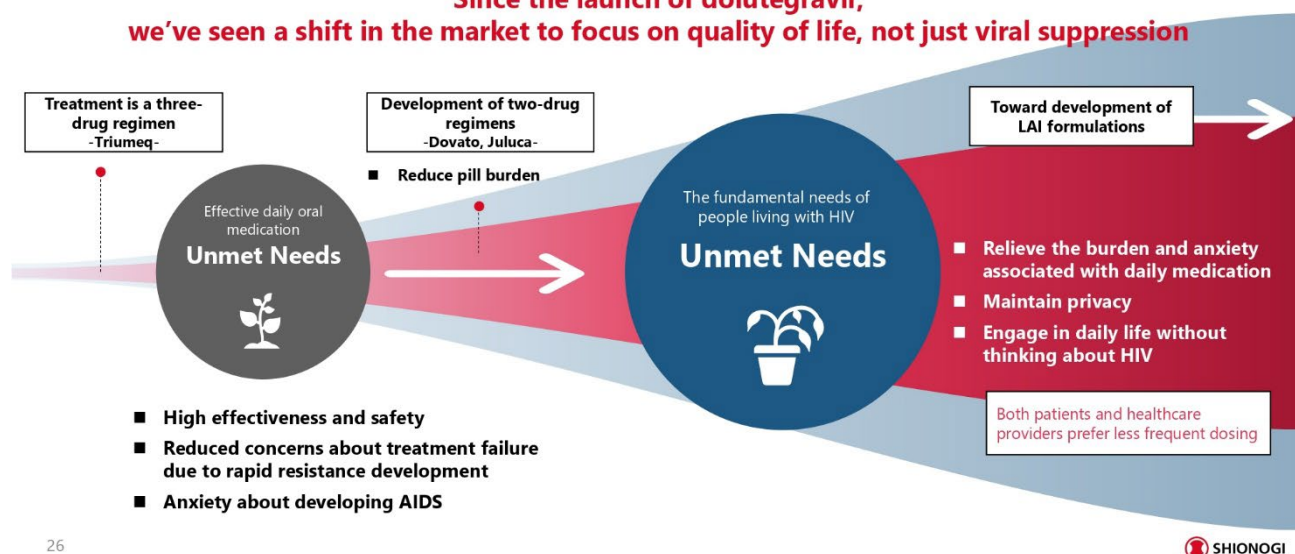


Overall revenue growth at ViiV has been driven by integrase inhibitors, supported by both oral therapies and long-acting products.

Today, medicines containing integrase inhibitors account for 76% of global HIV medication sales.

Unmet Needs of People Living with HIV Are Changing

Since the launch of dolutegravir,
we've seen a shift in the market to focus on quality of life, not just viral suppression



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As you have seen, the unmet needs of people living with HIV have evolved over time.

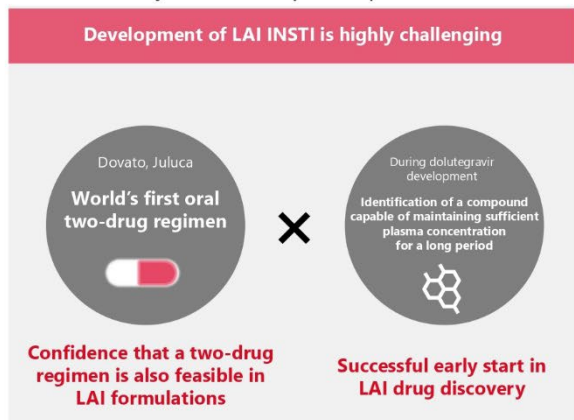
When triple-drug regimens were first introduced, the primary requirements were efficacy, safety, durability / sustained efficacy, and a high barrier to resistance.

As treatment continued to improve, two-drug regimens were developed to reduce pill burden and drug-drug interactions, leading ultimately to the development of long-acting injectable therapies. LAI therapies address additional important needs by eliminating the burden and anxiety associated with daily dosing and helping preserve privacy, allowing people living with HIV to lead increasingly normal lives without constant reminders of their condition.

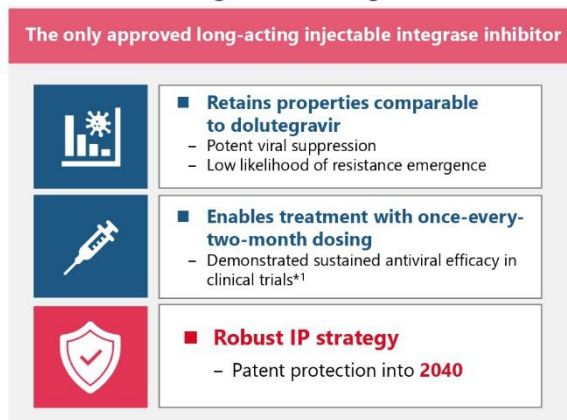
Creation of LAI Integrase Inhibitor: Cabenuva (6× a year)

No long-acting injectable integrase inhibitors other than ViiV/Shionogi INSTIs projected to be approved until after 2030

—Why was development possible?—



—Strengths of cabotegravir—



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^{*1} [SOLAR Study](#)



Cabenuva, the current LAI therapy, is administered six times per year.

We created this market, and we believe that the next generation of LAI therapies beyond Cabenuva will emerge after 2030.

The foundation for LAI therapy was established through the pioneering two-drug regimen and cabotegravir. Cabotegravir can be administered as a long-acting injectable while maintaining the key characteristics associated with dolutegravir, namely potent antiviral activity, a favorable safety profile, and a high barrier to resistance. Cabenuva has further evolved this innovation into a treatment requiring only six injections per year. In addition, we believe supplementary patents will provide patent protection through 2040.

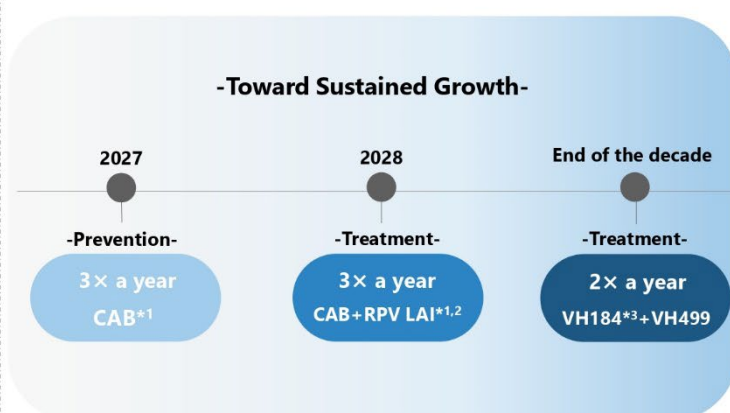
LAI Expected to Drive Growth Beyond 2030

Continued innovation in LAIs positions ViiV to lead the future of the HIV market

-Foundation for ViiV's sustained long-term growth-



-Significant near-term growth drivers-



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^{*1} New IM formulations ^{*2} RPV: Rilpivirine ^{*3} VH184 : SHIONOGI's development number: S-365598



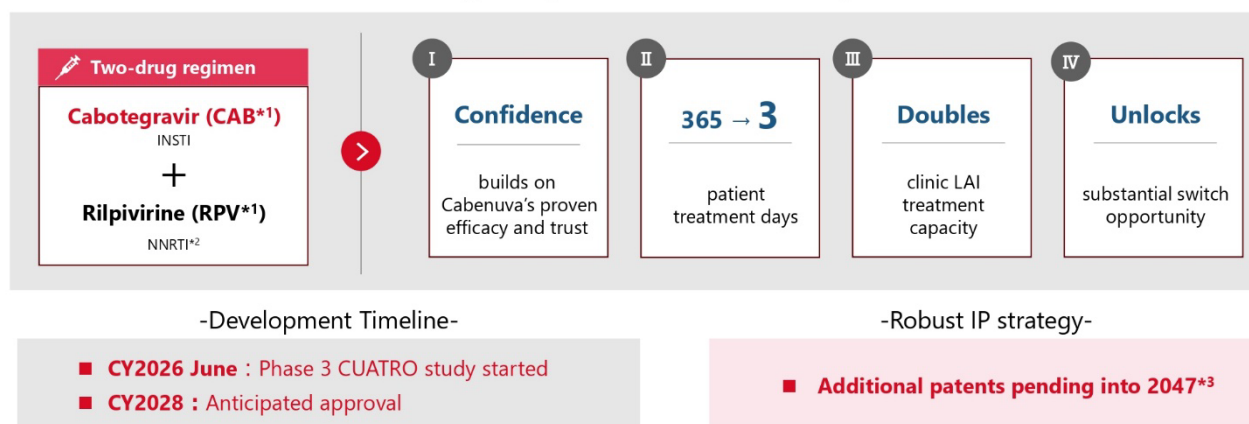
Going forward, we intend to continue improving and advancing LAI therapies to make them even more convenient and easier for patients to receive. At the same time, we will accelerate the transition toward LAI-based treatment and continue raising the standard of care for people living with HIV.

Specifically, we aim to move from the current six-times-per-year dosing schedule to three-times-per-year dosing by 2028 and ultimately twice-per-year dosing around 2030 through a combination of S-365598 (ViiV development code: VH4524184) and VH4011499. In prevention, we expect results from the three-times-per-year cabotegravir prevention study next year.

3× a year LAI Treatment (CAB+RPV)

Lowering the dosing frequency of the marketed LAI therapy Cabenuva to enhance convenience

Extending dosing intervals from 6× to 3× a year-



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*1 New IM formulations *2 NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor *3 cabotegravir NCE patent expiry 2031



Let me now talk about treatment administered three times per year.

Although this represents a new dosing schedule, the therapy itself is based on medicines whose efficacy and reliability have been demonstrated over many years. You should think of this combination as adding the new convenience of three-times-per-year dosing to a well-established treatment foundation.

For patients transitioning from oral therapy, this format reduces the number of times they need to think about HIV from 365 days per year to only three treatments annually.

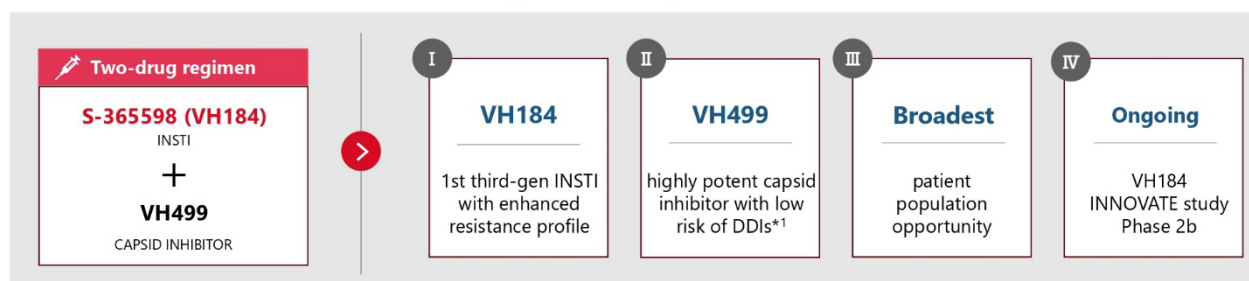
Healthcare providers will also be able to accommodate more patients. In addition, patients already accustomed to injectable treatment will have the opportunity to switch to a more convenient three-times-per-year regimen. At the same time, more patients may choose injectable therapy for the first time, which could further expand treatment access and opportunities.

Phase 3 studies began in June 2026, and approval is expected around 2028. As a three-times-per-year therapy, we aim to extend patent protection through 2047.

2× a year LAI Treatment (VH184+VH499)

Best-in-class profile transforms adherence, setting a new standard of care

-Advancing toward 2× a year LAI treatment-



-Development Timeline-

- **CY2026 H2** : VH499 CINERGY Phase 2b start
- **CY2028** : Phase 3 start

-Robust IP strategy-

- NCE*2 patent expiry into 2040s
- **Patents pending into at least 2047**

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*1 DDI: Drug-drug interaction *2 NCE: New chemical entity SHIONOGI

Turning to the twice-per-year treatment regimen, this consists of a combination of the novel compound S-365598 (ViiV development code: VH4524184) and VH4011499.

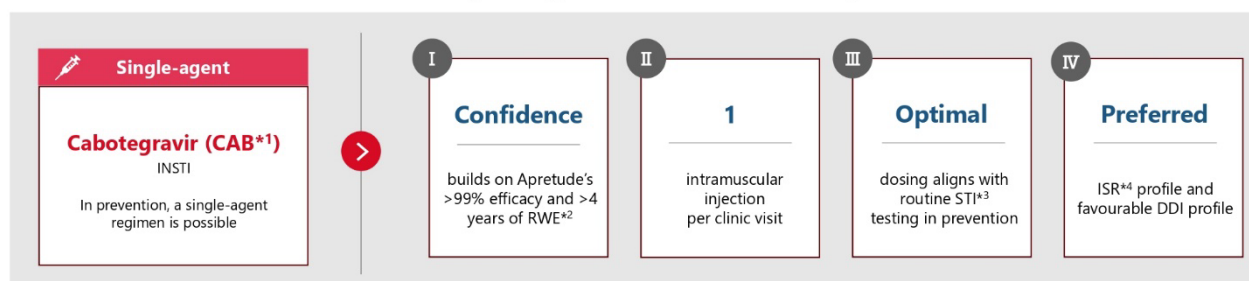
S-365598 (ViiV development code: VH4524184) is the first third-generation integrase inhibitor and offers a substantially enhanced resistance profile. By combining it with VH4011499, a capsid inhibitor with a low drug-drug interaction risk, we believe twice-per-year dosing can be achieved while providing access to a broad range of patients.

A Phase 2b study of S-365598 (ViiV development code: VH4524184) has already started, and a study of VH4011499 is expected to begin shortly. We plan to initiate Phase 3 studies in 2028 and target approval around 2030. Composition-of-matter patent protection for the novel compound extends through 2040, and when combined with additional intellectual property protection, exclusivity could extend to at least 2047.

CAB (3× a year Prevention)

3× a year Prevention : The optimal choice for patients and healthcare providers

-Extending dosing intervals from 6× to 3× a year-



-Development Timeline-

- **CY2026 H2** : EXTEND 4M pivotal data
- **CY2027** : Anticipated approval

-Robust IP strategy-

- **Patents pending into 2045^{*5}**

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^{*1} New IM formulation ^{*2} RWE: Real-world evidence ^{*3} STI: Sexually transmitted infection ^{*4} ISR: Injection site reaction ^{*5} cabotegravir NCE patent expiry 2031



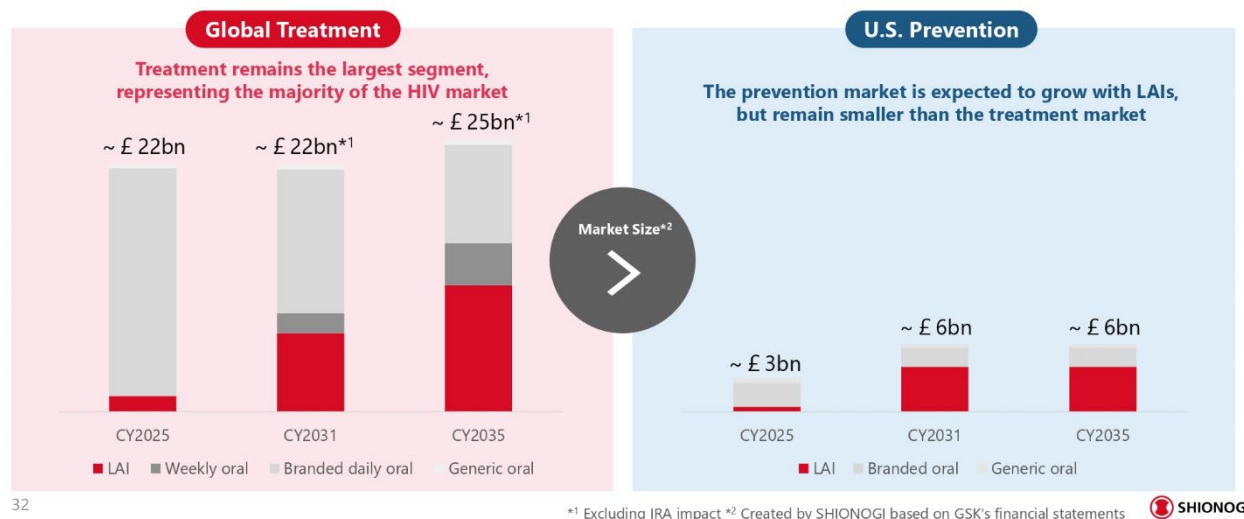
Next, let me talk about prevention administered three times per year.

We believe this is an optimal format for HIV prevention. As a reminder, this therapy aligns very well with global sexual health management strategies and HIV prevention strategies. Physicians generally want to see patients more frequently, not only to assess HIV risk but also to monitor other infectious diseases and overall health status. In addition, this product has demonstrated a favorable injection-site reaction profile and a favorable drug-drug interaction profile.

We expect pivotal data by the end of this year and are targeting approval next year. We also believe patent protection will extend through 2045.

HIV Market Size (CY2025-CY2035)

HIV market value rapidly shifting from daily orals therapies to LAIs



Finally, let me revisit the two HIV markets: treatment and prevention.

We expect the treatment market to continue growing steadily over the next decade, expanding from approximately GBP 22 billion today to approximately GBP 25 billion by 2035. At present, this market is approximately ten times larger than the prevention market.

While the prevention market is also expected to grow over the next ten years, we anticipate it will remain relatively smaller than the treatment market.

We believe the treatment market will continue expanding due to the availability of LAI therapies. More convenient formats, including three times per year and twice-per-year dosing, should drive further growth. We also see a role for once-weekly oral therapies, and we expect both branded and generic oral therapies to remain part of the treatment franchise, albeit in a gradually declining segment. What our market research clearly indicates, however, is that the LAI treatment segment will continue to accelerate significantly as these increasingly convenient treatment options become available.

Question & Answer

Kyokawa: We will now move to the Q&A session.
Mr. Ueda from Goldman Sachs, please go ahead.

Ueda: This is Ueda from Goldman Sachs.
My first question concerns HIV, which Mr. Keller just discussed.

I understand that progress has been steady, including the long patent life of the long-acting franchise, the development of the four-month cabotegravir formulation, and the favorable progress of S-365598.

However, as shown on the final slide, I would like to ask whether long-acting products can really expand to that extent over the next five to six years.

In particular, what do you think will accelerate adoption? Given that this outlook assumes substantial growth from here, what risks are you most concerned about that could affect this trajectory?

Keller: Thank you for your question.

As you can see, Cabenuva, administered six times per year, continues to deliver steady and sustained growth. However, we believe that a three-times-per-year regimen will become a major catalyst for further market expansion.

The regimen we are developing utilizes cabotegravir and rilpivirine, both of which already have established track records. Therefore, we believe the development risk is lower than that of a typical new drug development program. Both we and ViiV have extensive experience with the efficacy, safety, and real-world performance of these two agents.

Accordingly, we believe we can continue to advance development strongly and realize further market expansion.

In addition, the results of the LATITUDE study provide important evidence supporting our outlook.

Ueda: My second question concerns the financial results.

Regarding the progress of SG&A expenses and R&D expenses, it appears that SG&A expenses are progressing somewhat ahead of plan, while R&D expenses seem to be progressing below plan.

Going forward, there may be additional spending on XOCOVA and RADICAVA in the United States. Should we think about SG&A and R&D expenses being managed on a combined basis? How should we think about the risk of expenses exceeding expectations?

Fujiwara: I will take that question.

First, regarding SG&A expenses, we have already made substantial investments in ensitrelvir, including pre-launch activities. As a result, although progress may appear somewhat ahead of schedule, we do not currently expect a dramatic increase from here.

With respect to RADICAVA, we acquired an existing business that was already operating. Our understanding is that activities have been proceeding steadily in line with the original assumptions, and therefore we do not anticipate a significant increase in expenses during this fiscal year.

Regarding R&D expenses, some costs were deferred from the first quarter into the second quarter, making progress appear somewhat slower. However, development activities themselves are progressing largely as planned.

Kyokawa: Mr. Seki from UBS AG, please.

Seki: This is Seki from UBS.

My first question is for Mr. Fujiwara regarding the purchase price allocation, or PPA, related to ViiV.

I think the fact that the PPA has not been completed and the fact that the amortization related to the ViiV PPA was not recognized in the first quarter in the first quarter are two separate issues.

Comparisons between Q1 and Q2 may become difficult, and when I look at prior PPAs such as JT and Torii Pharmaceutical, the figures disclosed in the earnings reports changed considerably between year-end and subsequent reporting periods.

My question is this: SHIONOGI already owned 10% of ViiV and conducted due diligence before the transaction. Why, even six months later, has the PPA not progressed to the point where even provisional amounts can be recognized? What exactly is happening?

Fujiwara: First of all, I apologize that the figures are currently difficult to interpret.

We are working diligently on the ViiV PPA. At this stage, however, we have not yet been able to estimate the amounts based on assumptions that we consider sufficiently reasonable. We are currently reviewing the figures in preparation for the second quarter. We expect the actual PPA process to be completed during the third quarter.

As for the reason, because this transaction involved the acquisition of additional shares, communication with ViiV after the acquisition has provided us with access to information that was not previously available. As our ownership interest increased, we were able to obtain additional information, and we have therefore started by reassessing the business plan itself.

As a result, we are not yet in a position to finalize the PPA based on reasonable assumptions. For this first-quarter disclosure, we have included only those profit figures derived from the information currently available to us that we believe can be disclosed with a high degree of confidence.

Seki: My second question is somewhat unusual, and I'm not sure who is best positioned to answer it.

Recently there has been considerable discussion about the risks posed by AI. As a company, how does SHIONOGI think about medical countermeasures against biological threats?

For example, I understand that your contract with BARDA disclosed in April may be related to this area. Does that scope include countermeasures against AI-driven bioterrorism? While Fetroja may address certain Gram-negative bacterial threats, how do you view broader bioterrorism risks beyond that?

Keller: We have worked with BARDA on secutrelvir, which is being developed as a long-acting injectable for COVID-19 pre-exposure prophylaxis. This was one of the last COVID-19-related programs selected for BARDA funding.

We also continue discussions with the U.S. government regarding preventive measures against biological threats.

We have extensive experience in antiviral drug research and development built over many years. Discussions therefore extend beyond COVID-19 to other viral disease areas as well.

As a company with strong expertise in infectious diseases, we intend to further strengthen our collaboration with BARDA and the U.S. government. This includes not only preparedness for threats that may emerge in an AI-driven environment, but also providing solutions to prevent the spread of infectious diseases that threaten societal stability.

Kyokawa: Mr. Wakao from J.P. Morgan, please.

Wakao: My first question concerns RADICAVA in the United States.

Looking at Slide 11, the first-quarter performance following the transition from Tanabe Pharma to SHIONOGI appears very strong.

Should we view this as a sustainable trend rather than a one-time event? Historically, quarterly sales have fluctuated considerably, so should we assume there were temporary factors at play this quarter as well? Or is the improvement primarily due to SHIONOGI's marketing efforts?

I would appreciate your thoughts as we consider performance from the second quarter onward.

Iwasaki: I will answer your question.

The first quarter of this fiscal year coincided with the transition from Tanabe Pharma to SHIONOGI. As a result, inventories were somewhat constrained in the fourth quarter and then increased in the first quarter, which undoubtedly had some impact.

One factor behind quarterly fluctuations is the timing of reimbursement agreements. We have contracts with a wide range of payers, and once annual agreements are finalized, RADICAVA can be supplied to healthcare providers and patients covered under those plans. This timing can create some variability.

However, our sales representatives now operate under a structure in which SHIONOGI contracts directly with wholesalers. This has greatly increased the flexibility of our supply management. We are also investing in nonclinical mechanism-of-action studies, real-world clinical evidence, strengthening our commercial organization, and expanding reimbursement coverage through progress in payer negotiations.

Another important factor is accessibility. Previously, considerable time could elapse between obtaining insurance coverage and patients actually receiving a prescription. During that period, disease progression sometimes advanced to the point where treatment was no longer feasible. Accessibility has improved, which is helping to improve access for new patients as well.

Therefore, although the first quarter benefited from certain inventory-related factors, we believe continued execution of these activities will support sustainable growth going forward.

Wakao: My second question concerns olorofim.

The data appear to have been very positive. Could you provide more detail regarding its sales potential?

You explained the opportunity in terms of patient numbers, but I assume the pricing will also be relatively high. While commercialization initially focus on Asia and Europe, I believe that depending on pricing, the product could generate a meaningful level of revenue. Could you share any assumptions SHIONOGI currently has regarding its potential sales scale?

Iwasaki: First of all, these results have only recently become available, so we would like to further refine the target indication and better define the patient population.

As olorofim has received orphan drug designation, we believe we believe a relatively high price may be achievable. We will also continue evaluating pricing strategies that can maintain an appropriate global price consistency, taking into account considerations such as MFN requirements.

At this point, however, we would like to refrain from providing specific sales projections until regulatory submissions and related activities have progressed further.

Kyokawa: Mr. Yamaguchi from Citi Securities, please.

Yamaguchi (Citi): My first question concerns ViiV.

From an external perspective, the development schedules for both the three-times-per-year and two-times-per-year treatment regimens appear somewhat tight. Including yourself, Mr. Keller, as a member of ViiV's Board of Directors, do you believe these development timelines are achievable?

Keller: These timelines have been developed very carefully and have been thoroughly reviewed by the Board of Directors. While they are certainly ambitious, we believe they are fully achievable.

Yamaguchi: My second question relates to the overall earnings picture. You mentioned earlier that certain costs are weighted toward later periods. Although the infectious disease business was somewhat weak, how do you view overall performance?

From the Company's perspective, is performance broadly in line with full-year expectations, or have some areas gotten off to a better-than-expected start? This question relates to your overall assessment of the first-quarter results.

Fujiwara: With respect to revenue, we believe performance is generally tracking in line with our expectations. However, performance in the second quarter and the second half, particularly in the acute respiratory infection area, will inevitably be affected by the prevalence of infections. Therefore, our view remains unchanged, and we will continue to monitor market conditions closely.

With regard to expenses, I would again like to apologize for the lack of visibility. The main factor making this year's results difficult to interpret is that amortization related to the ViiV equity-method investment has not yet been reflected in the share of profit from investments accounted for using the equity method reported within other income and expenses.

For all other areas, we believe performance is generally progressing according to plan.

Yamaguchi: There was a question on this topic earlier. Although the amortization has not yet been reflected, is it not included in the Company's assumptions either?

Fujiwara: Regarding amortization associated with our equity-method investment in ViiV, on the business side, we do not believe the difference is large enough to warrant revising first-half or full-year forecasts. Accordingly, we have no plans at present to revise our guidance.

Yamaguchi: So a certain amount is effectively already assumed in the forecast?

Fujiwara: Yes.

Yamaguchi: But it was not included in Q1, correct?

Fujiwara: Correct. Because we were unable to incorporate it in Q1, the results were disclosed without the amortization expense being reflected.

Kyokawa: Mr. Hashiguchi from Daiwa Securities, please.

Hashiguchi (Daiwa Securities): A question for Mr. Keller. Will the combination study of VH4524184 and VH4011499 first enter clinical development as a Phase 3 study in 2028? To my understanding, a combination study has not yet been conducted. Typically, there would be a Phase 2 dose-finding study. Are there no plans for such a study? ViiV has announced the initiation of a Phase 2 study of cabotegravir combined with VH4011499. Will proof of concept for the combination be established using cabotegravir, with the combination involving VH4524184 entering Phase 3 directly?

Keller: As you noted, two Phase 2 studies have been ongoing since 2024: a monotherapy study of VH4524184 and a combination study. The Phase 3 program will combine VH4524184 and VH4011499. By the time we initiate Phase 3, we expect to have accumulated substantial experience regarding the efficacy and performance of both agents.

Across the entire program, we continue working to accelerate development wherever possible.

Hashiguchi: My second question is also for Mr. Keller. At the media briefing following the May earnings announcement, Mr. Teshirogi indicated that the Company hoped to reach conclusions regarding additional M&A opportunities as early as possible during this fiscal year.

Has that review process now concluded, with opportunities ultimately being passed over? Or is the evaluation still ongoing such that M&A remains a possibility in the near future?

Keller: At present, we would not say that the number of opportunities available is sufficient. However, that does not mean we are prepared to pursue acquisitions at excessive prices or transactions that do not make strategic sense.

We continue to evaluate multiple promising opportunities and remain prepared to act quickly if there is an appropriate balance between asset value and price.

On the other hand, if the terms are not appropriate, we will not proceed with a transaction.

Kyokawa: Mr. Yamakita from Jefferies, please.

Yamakita (Jefferies): My first question concerns SG&A expenses for XOCOVA. My understanding is that the initial strategy is to market broadly across multiple channels and then optimize spending over time.

Could that optimization process begin in the current fiscal year, including possible reductions? Earlier, you mentioned that spending is progressing according to plan, but I would like to understand whether there is a possibility that expenses ultimately come in below budget.

Iwasaki: We launched on the 28th of last month, and prescriptions have already been generated in 30 states. Although it has not yet been a full week since launch, performance appears to be tracking largely as planned.

Accordingly, we intend to continue activities through social media campaigns and direct-to-consumer initiatives. Then, around September in the second quarter, we will assess the situation at that time and decide whether to discontinue, scale back, or geographically focus those activities.

While we monitor performance on a weekly basis, decisions will be made on a quarterly basis.

Yamakita: My second question concerns Quviviq. You mentioned strong growth among psychiatrists. Since prescription restrictions have been lifted, I assume it has become easier to approach internal medicine physicians as well. How is uptake progressing outside psychiatry?

Iwasaki: As you pointed out, growth is not limited to psychiatry. In internal medicine, physicians appreciate that the 50 mg tablet can be administered as a single tablet and that physicians can use it with confidence in patients with renal impairment. These attributes have made it a highly convenient treatment option.

As a result, within psychiatry we are seeing increased prescriptions per institution due to strong physician evaluations of the product. At the same time, the number of institutions adopting the product has increased significantly in internal medicine.

Therefore, we believe Quviviq's growth is being driven by both of these factors.

Kyokawa: Mrs. Sogi from Bernstein, please.

Sogi (Bernstein): My first question concerns XOCOVA in the United States. Originally, I expected commercialization of XOCOVA for PEP to focus less on broad consumer promotion and more on settings where outbreak prevention is a major concern, such as long-term care facilities and military settings.

However, based on today's discussion, it appears you are reaching out directly to the general public through channels such as social media. Could you elaborate on your commercialization strategy going forward?

Iwasaki: Awareness of PEP remains relatively low. Therefore, rather than narrowing our focus to specific target groups, we are first seeking to raise broad awareness among the general population regarding the risks of COVID-19 and the importance of prevention. We are doing this primarily through social media and related channels.

At the same time, we have already hired 160 sales representatives, who are primarily visiting long-term care facilities in the United States.

Accordingly, we believe long-term care settings will ultimately become a key area for prescribing activity.

Sogi: My second question relates to the HIV long-acting franchise. For treatment, both three-times-per-year and two-times-per-year options are currently being developed. For PrEP, however, the focus appears to be solely on a three-times-per-year regimen.

Is this difference in dosing cadence part of a deliberate strategy reflecting differences between treatment and PrEP?

Keller: Yes. We believe the optimal dosing paradigm differs between treatment and PrEP.

For treatment, we believe a twice-yearly regimen maximizes convenience. Given the established confidence in integrase inhibitor-based treatment, physicians can feel comfortable seeing people living with HIV twice a year and confirming continued viral suppression at those visits.

PrEP is different.

In reality, a majority of PrEP users are managed not by HIV specialists but by sexual health clinics. These clinics need to evaluate a broad range of infectious disease risks that patients may face. In addition, individuals using PrEP require ongoing assessment of risks associated with sexual activity.

As a result, three visits per year provide an opportunity not only to confirm HIV status but also to conduct regular monitoring for other sexually transmitted infections.

Based on extensive feedback, we believe that a three-times-per-year regimen represents the optimal approach for PrEP.

Kyokawa: As we have reached the scheduled end time, this concludes SHIONOGI & Co., Ltd.'s FY2026 1Q Financial Results Conference Call.

Thank you all very much for joining us today despite your busy schedules.