



ONO PHARMACEUTICAL CO., LTD.

Q1 Financial Results Briefing for the Fiscal Year Ending March 2026

August 1, 2025

[Number of Speakers]

5

Masaki Itoh

Corporate Executive Officer / Division
Director, Corporate Strategy & Planning,
Business Management Division

Tatsuya Okamoto

Corporate Officer, Executive Director, Clinical
Development

Hirokazu Kitada

Corporate Officer, Executive Director, Sales
and Marketing

Hiroyuki Takahashi

Director of Oncology Business Division,
Sales and Marketing

Ryuta Imura

Senior Director of Corporate Communications

Presentation

Imura: Thank you very much for attending ONO PHARMACEUTICAL CO., LTD.'s Financial Results Meeting for Q1 of the fiscal year ending March 2026 today.

First, I would like to introduce the attendees from the Company:

Itoh, Corporate Executive Officer and Division Director, Corporate Strategy and Planning, Business Management Division; Okamoto, Corporate Officer, Executive Director, Clinical Development; Kitada, Corporate Officer, Executive Director, Sales and Marketing; and Takahashi, Director of Oncology Business Division, Sales and Marketing.

Agenda



2026年3月期第1四半期 決算概要について

Financial Results Q1 FY 2025 (14:00-14:20)

常務執行役員 経営戦略本部 経営管理統括部長
Corporate Executive Officer /
Division Director, Corporate Strategy & Planning, Business
Management Division,

伊藤 雅樹
Masaki Itoh

開発品の進捗状況

Development Pipeline Progress Status (14:20-14:30)

執行役員 開発本部長
Corporate Officer / Executive Director, Clinical Development

岡本 達也
Tatsuya Okamoto

オペジーボの動向

Trend of OPDIVO (14:30-14:40)

執行役員 営業本部長
Corporate Officer / Executive Director, Sales and Marketing

北田 浩一
Hirokazu Kitada

質疑応答

Q&A Session (14:40-15:00)

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Here are some of the details for today.

First, Itoh, Division Director of Corporate Strategy and Planning, Business Management Division, will give an overview of financial results for Q1 of the fiscal year ending March 31, 2026, followed by an update on the progress of development pipeline by Okamoto, Executive Director of Clinical Development; and finally, Kitada of Sales and Marketing will give an trend of OPDIVO.

Please refer to the materials which are already posted on the Company's website.

Now, Itoh will give an overview of the financial results for Q1 of the fiscal year ending March 31, 2026.

Highlights of Financial Results for FY2025Q1 (Core Basis)



FY2025Q1 Sales Revenue	<p><u>Revenue increased by ¥9.9 billion (8.4%) year on year to ¥127.5 billion, marking a new record high for the first quarter.</u></p> <p>Domestic Sales Results While sales of FORXIGA expanded, overall sales slightly decreased mainly due to a decline in OPDIVO sales resulting from intensified competition.</p> <p>Overseas Sales Results Sales increased mainly due to the inclusion of the sales of QINLOCK^(R) (ripretinib) and ROMVIMZA^(TM) (vimseltinib), which were not recorded in the previous period (April-June). QINLOCK sales were ¥8.9 billion, and ROMVIMZA sales were ¥1.1 billion.</p>
FY2025Q1 R&D, SG&A Expenses	<p><u>Inclusion of Deciphera's R&D and SG&A expenses resulted in an increase compared to the same period last year.</u></p> <p>R&D : Expenses, excluding Deciphera's R&D expenses, decreased compared to the previous period. SG&A : The figures are roughly at the same level as the previous period, excluding the co-promotion costs for Forxiga and Deciphera's SG&A.</p>
FY2025Q1 Core Operating Profit	<p><u>Core operating profit decreased by ¥3.5 billion (10.1%) year on year to ¥31.6 billion.</u></p> <p>The inclusion of Deciphera's operating loss, which was not recorded in the previous period (April-June), led to a decrease in core operating profit .</p>

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Itoh: Due to the acquisition of Deciphera last year, we are disclosing our core financial statements in order to show you the essential performance of our core business. Today's explanation will be given on a core basis.

Revenue increased by JPY9.9 billion, or 8.4%, from the same period last year to JPY127.5 billion, a solid performance and the highest sales ever recorded for a Q1 result.

Domestic sales decreased slightly overall, with continued growth in FORXIGA tablets offset by a decline in OPDIVO due to intensified competition. Overseas sales increased due to the inclusion of sales from Deciphera, such as QINLOCK, a treatment for gastrointestinal stromal tumors, and ROMVIMZA, a treatment for tenosynovial giant cell tumors, which were not recognized in Q1 of the previous fiscal year.

R&D and SG&A expenses also increased YoY due to the addition of Deciphera's R&D and SG&A expenses, which were not recorded in Q1 of the previous fiscal year, respectively. R&D expenses, excluding Deciphera's R&D expenses, decreased from the previous year, and SG&A expenses, excluding FORXIGA's co-promotion expenses and Deciphera's SG&A expenses, were at the same level as in the previous year.

Core operating profit decreased by JPY3.5 billion, or 10.1%, from the same period last year to JPY31.6 billion due to the inclusion of Deciphera's operating loss, which was not recorded in the previous period.

FY2025Q1 : Sales Revenue



Revenue
¥127.5 billion
 YoY +9.9 billion
 (+8.4%)



Goods and Products Sales
¥87.8 billion
 YoY +8.4 billion (+10.6%)



Royalty and Others
¥39.8 billion
 YoY +1.4 billion (+3.7%)

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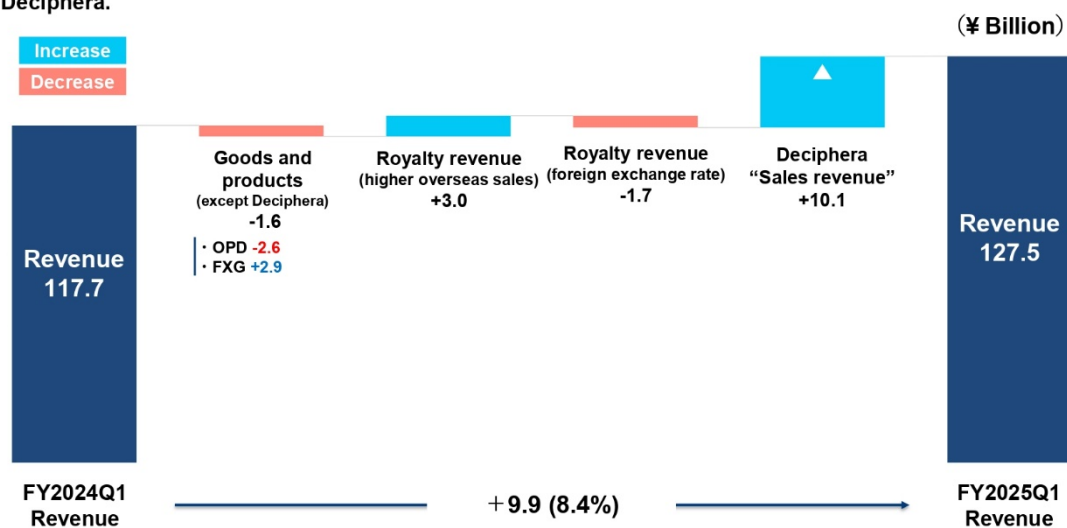
I will now explain each item in detail.

Revenue for Q1 of the fiscal year under review increased by JPY8.4 billion, or 10.6%, from the same period last year to JPY87.8 billion, and royalties and others increased by JPY1.4 billion, or 3.7%, to JPY39.8 billion, for a total of JPY127.5 billion, an increase of JPY9.9 billion, or 8.4%, from the same period last year.

FY2025Q1 : Sales Revenue (Breakdown)



Domestic sales decreased due to intensified competition affecting OPDIVO, despite the increase in sales of FORXIGA Tablet. However, overall sales increased by ¥9.9 billion year on year, driven by the revenue from Deciphera.



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The following is a breakdown of the factors that contribute to the increase or decrease in sales revenue.

The main reason for the increase was the recording of JPY10.1 billion in sales revenue from Deciphera. The three bar charts on the left, excluding this one, show that sales of domestic products decreased by JPY1.6 billion, while royalties related to OPDIVO and KEYTRUDA increased by JPY3 billion, or a net increase of JPY1.3 billion, despite the negative impact of the strong yen.

FY2025Q1 : Sales Revenue by Product (Domestic)



¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	127.5	9.9	8.4%	490.0
Goods and products	79.3	87.8	8.4	10.6%	330.0
Royalty and others	38.3	39.8	1.4	3.7%	160.0

Goods and Products (Domestic)	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	32.1	<u>29.4</u>	(2.6)	(8.2%)	125.0
FORXIGA Tablets	22.2	<u>25.1</u>	2.9	13.1%	80.0
ORENCIA for Subcutaneous Injection	6.9	<u>7.0</u>	0.1	1.8%	28.0
GLACTIV Tablets	5.0	<u>3.6</u>	(1.4)	(28.8%)	12.0
VELEXBRU Tablets	2.7	<u>3.0</u>	0.3	12.0%	11.0
ONGENTYS Tablets	1.9	<u>2.3</u>	0.3	17.2%	9.0
PARSABIV Intravenous Injection	2.1	<u>2.2</u>	0.1	5.9%	9.0
KYPROLIS for Intravenous Infusion	2.3	<u>2.0</u>	(0.3)	(12.1%)	9.0

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.

• Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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This is an overview of domestic products by category.

While sales of anti-cancer agent, OPDIVO intravenous infusion, decreased by JPY2.6 billion to JPY29.4 billion due to intensified competition, sales of FORXIGA tablet, a treatment for diabetes, chronic heart failure, and chronic kidney disease remained strong, increasing by JPY2.9 billion or 13.1% from the same period last year to JPY25.1 billion.

Other major products include rheumatoid arthritis treatment, ORENCIA, for subcutaneous injection increased by JPY0.1 billion to JPY7 billion, anti-cancer agent, VELEXBRU tablet increased by JPY0.3 billion to JPY3 billion, Parkinson's disease treatment agent, ONGENTYS tablet increased by JPY0.3 billion to JPY2.3 billion, and secondary hyperparathyroidism treatment agent for hemodialysis patients, PARSABIV, for intravenous dialysis increased by JPY0.1 billion to JPY2.2 billion.

On the other hand, sales of GLACTIV tablets, a drug for type 2 diabetes, decreased by JPY1.4 billion to JPY3.6 billion due to the NHI price cut, and sales of KYPROLIS for intravenous infusion, a drug for multiple myeloma, decreased by JPY0.3 billion to JPY2 billion.

FY2025Q1 : Sales Revenue by Product (Overseas) / Royalty



¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	<u>127.5</u>	9.9	8.4%	490.0
Goods and products	79.3	<u>87.8</u>	8.4	10.6%	330.0
Royalty and others	38.3	<u>39.8</u>	1.4	3.7%	160.0

Goods and Products (Overseas)	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO	3.1	<u>3.3</u>	0.2	5.5%	13.5
QINLOCK	—	<u>8.9</u>	—	—	34.0
ROMVIMZA	—	<u>1.1</u>	—	—	5.0

Royalty and others	FY2024Q1	FY2025Q1	YoY		
			Change	Change(%)	
OPDIVO	28.5	<u>29.2</u>	0.7	2.6%	
KEYTRUDA®	6.3	<u>6.5</u>	0.2	3.9%	

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.

• Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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These are overseas sales and royalties.

OPDIVO sales in Taiwan and South Korea combined totaled JPY3.3 billion this fiscal year, an increase of JPY0.2 billion from the same period last year. Sales of Deciphera's two products: QINLOCK, a treatment for gastrointestinal stromal tumors, totaled JPY8.9 billion, which is well in line with the initial forecast of JPY34 billion; and sales of ROMVIMZA, a treatment for tenosynovial giant cell tumors, amounted to JPY1.1 billion.

Annual sales are projected at JPY5 billion and are expected to grow as the number of patients increases. Sales by Deciphera have been a major driver in Q1.

FY2025Q1 : Core Operating Profit



Core Operating Profit
¥31.6 billion
 YoY -3.5 billion
 (-10.1%)



Revenue ¥127.5 billion

YoY +9.9 billion (+8.4%)



R&D Expense ¥36.3 billion

YoY +7.4 billion (+25.6%)



SG&A Expense ¥31.1 billion

YoY +6.1 billion (+24.4%)

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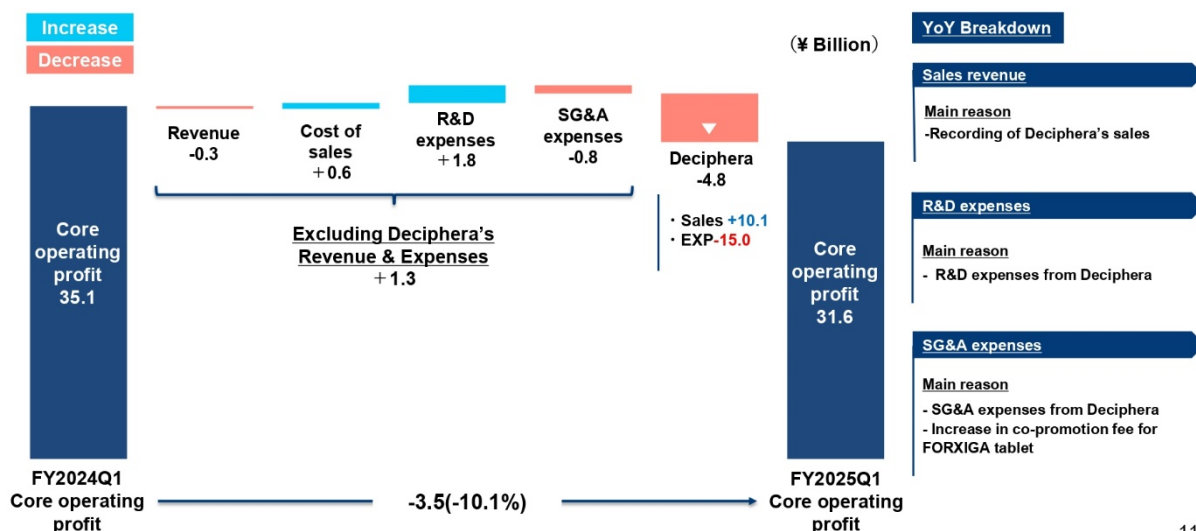
Next is core operating profit.

Core operating profit decreased by JPY3.5 billion, or 10.1%, from the same period last year to JPY31.6 billion. While revenue increased by JPY9.9 billion, R&D expenses increased by JPY7.4 billion and SG&A expenses increased by JPY6.1 billion.

FY2025Q1 : Core Operating Profit (Breakdown)



R&D and SG&A expenses have been recorded by Deciphera, which were not recorded in the first quarter of the previous fiscal year, resulting in a decrease of ¥3.5 billion from the same period last year to ¥31.6 billion.



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We have also listed them by factor here.

The major reason for the decrease in core operating profit is the JPY4.8 billion operating loss recorded by Deciphera. Excluding this, profit/loss was an increase of JPY1.3 billion.

FY2025Q1 : Financial Overview (Core)



¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*	YoY Breakdown
			Change	Change(%)		
Revenue	117.7	<u>127.5</u>	9.9	8.4%	490.0	R&D expenses +¥7.4 billion (+25.6%)
Cost of sales	28.2	<u>28.1</u>	(0.1)	(0.2%)	103.5	R&D ratio : 28.4%
R&D expenses	28.9	<u>36.3</u>	7.4	25.6%	150.0	Main reason - R&D expenses from Deciphera
SG&A expenses	25.0	<u>31.1</u>	6.1	24.4%	120.0	SG&A expenses +¥6.1 billion (+24.4%)
Other income	0.0	<u>0.1</u>	0.1	204.6%	0.5	Main reasons - SG&A expenses from Deciphera
Other expenses	0.6	<u>0.6</u>	0.0	4.2%	3.0	- Increase in co-promotion fee for FORXIGA tablet
Core operating profit	35.1	<u>31.6</u>	(3.5)	(10.1%)	114.0	
Core profit before tax	37.7	<u>32.2</u>	(5.5)	(14.6%)	114.0	
Core profit for the period (attributable to owners of the Company)	28.7	<u>24.8</u>	(3.9)	(13.7%)	91.0	

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.

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Here is an overall view of the consolidated core results.

Revenue increased by JPY9.9 billion, or 8.4%, from the previous year to JPY127.5 billion. Core operating profit, here, decreased by JPY3.5 billion, or 10.1%, from the same period last year to JPY31.6 billion. Core profit for the period decreased by JPY3.9 billion, or 13.7%, from the same period last year to JPY24.8 billion.

(Ref) FY2025Q1 : Financial Overview (Full Basis)



¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*	Breakdown
			Change	Change(%)		
Revenue	117.7	127.5	9.9	8.4%	490.0	Cost of sales +¥7.3 billion
Cost of sales	29.7	37.0	7.3	24.7%	135.0	Main reason - Amortization expenses related to intangible assets acquired through acquisitions and inventory assets evaluated at fair value
R&D expenses	28.9	36.3	7.4	25.6%	150.0	R&D expenses +¥7.4 billion R&D ratio:28.4%
SG&A expenses	27.9	31.1	3.2	11.5%	120.0	Main reason - R&D expenses from Deciphera +¥9.1 billion
Operating profit	30.7	22.0	(8.7)	(28.3%)	85.0	SG&A expenses +¥3.2 billion
Profit before tax	33.3	22.6	(10.7)	(32.0%)	85.0	Main reasons - SG&A expenses from Deciphera +¥5.3billion - Increase in co-promotion fee for FORXIGA tablet - Absence of expenses associated with the acquisition of Deciphera
Profit for the period (attributable to owners of the Company)	24.8	17.7	(7.1)	(28.7%)	67.0	

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.

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This is a summary of results on a full IFRS basis.

There are no adjustments to revenue from sales on a core basis. It is JPY9.9 billion increase, or 8.4%, to JPY127.5 billion. There will be some adjustments in the following areas.

In cost of sales, amortization of intangible assets and amortization of PPA inventory, which were excluded from the core basis, are included, so this adjustment exists between the core and full basis.

There is no major adjustment in R&D expenses, but there is a reactionary decrease in SG&A expenses due to the recording of expenses related to the acquisition of Deciphera, which were excluded from the core basis in the previous fiscal year.

Adjusted for these effects, operating profit on a full basis is JPY5.2 billion larger than on a core basis. It decreased by JPY8.7 billion, or 28.3%, from the same period last year to JPY22 billion, and profit for the period also decreased by JPY7.1 billion from the same period last year to JPY17.7 billion for the same reason.

(Ref) FY2025Q1 : Reconciliation from Full to Core Basis



¥ in Billion	IFRS (Full) basis	Adjustment				Core basis	Breakdown
		Amortization	Impairment loss	Others	Total		
Sales revenue	127.5				—	127.5	Cost of sales -¥8.9 billion <u>Main reasons</u> - Amortization expenses related to intangible assets acquired through acquisitions or in-licensing - Amortization expenses related to inventories from PPA
Cost of sales	37.0	(6.2)		(2.7)	(8.9)	28.1	
Gross profit	90.5	+6.2	—	+2.7	+8.9	99.4	R&D expenses
R&D costs	36.3				—	36.3	
SG&A expenses	31.1				—	31.1	No Adjustment
Other income /expenses	(1.2)			(0.7)	(0.7)	(0.5)	
Operating profit	22.0	+6.2	—	+3.4	+9.6	31.6	SG&A expenses and Other income&expense <u>Main reason</u> - Termination Fee for lease contract cancellation
Operating profit ratio	17.2%				—	24.8%	
Finance income / Finance cost	0.7				—	0.7	
Profit before tax	22.6	+6.2	—	+3.4	+9.6	32.2	
Income tax expense	5.0	+1.6		+0.8	+2.4	7.5	
Profit for the year	17.7	+4.6	—	+2.5	+7.1	24.8	

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This is a reconciliation from the full to core basis in Q1 for the current period.

As I mentioned earlier, the reconciliation item is mainly amortization expenses related to intangible assets in the cost of sales, which totaled JPY6.2 billion combined with the previous amount(License item's amount), and amortization expenses of JPY2.7 billion for the step-up in fair value associated with the acquisition of inventory. The total reconciliation is JPY8.9 billion.

FY2025 : Financial Forecast (Core/Compared to the Previous Year)



There is no change from the consolidated financial forecasts, announced on May 8th, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)	Breakdown
Revenue	486.9	<u>490.0</u>	3.1	0.6%	Cost of sales -¥3.4 billion <u>Main reason</u> - Decrease in sales related to FORXIGA tablets and long-term listed products
Cost of sales	106.9	<u>103.5</u>	(3.4)	(3.1%)	
R&D expenses	143.3	<u>150.0</u>	6.7	4.7%	R&D expenses +¥6.7 billion <u>Main reasons</u> - Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months) - Costs associated with Sapabursen in-licensed from Ionis Pharmaceuticals, Inc. - Promotion of cost efficiency measures
SG&A expenses	122.2	<u>120.0</u>	(2.2)	(1.8%)	
Core operating profit	112.7	<u>114.0</u>	1.3	1.2%	SG&A expenses -¥2.2 billion <u>Main reasons</u> - Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months) - Promotion of cost efficiency measures
Core profit before tax	113.9	<u>114.0</u>	0.1	0.1%	
Income tax expense	23.4	<u>23.0</u>	(0.4)	(1.8%)	
Core profit for the year	90.4	<u>91.0</u>	0.6	0.7%	

* The exchange rate assumed in the financial forecast is ¥145 per US dollar.

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Here is the full-year forecast.

As already announced in the financial results summary, there are no revisions to the earnings forecast for the current fiscal year. There is currently no change in the sales forecast for each of the products from the figures announced at the beginning of the period.

FY2025 : Financial Forecast (Full / Compared to the Previous Year)



There is no change from the consolidated financial forecasts, announced on May 8th, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	147.9	135.0	(12.9)	(8.8%)
R&D expenses	149.9	150.0	0.1	0.1%
SG&A expenses	125.7	120.0	(5.7)	(4.5%)
Operating profit	59.7	85.0	25.3	42.3%
Profit before tax	59.3	85.0	25.7	43.3%
Income tax expense	9.2	18.0	8.8	96.5%
Profit for the year	50.0	67.0	16.9	33.8%

* The exchange rate assumed in the financial forecast is ¥145 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥1.3 billion in revenue and an increase of ¥0.3 billion in operating profit for every ¥1 depreciation of the yen.

Breakdown

Cost of sales -¥12.9 billion

Main reasons

- Decrease in sales related to FORXIGA tablets and long-term listed products
- Absence of sales milestone on FORXIGA recorded in the previous fiscal year

R&D expenses +¥0.1 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Costs associated with Sapabursen in-licensed from Ionis Pharmaceuticals, Inc.
- Absence of impairment losses on development compounds in the previous fiscal year

SG&A expenses -¥5.7 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Promotion of cost efficiency measures

16/30

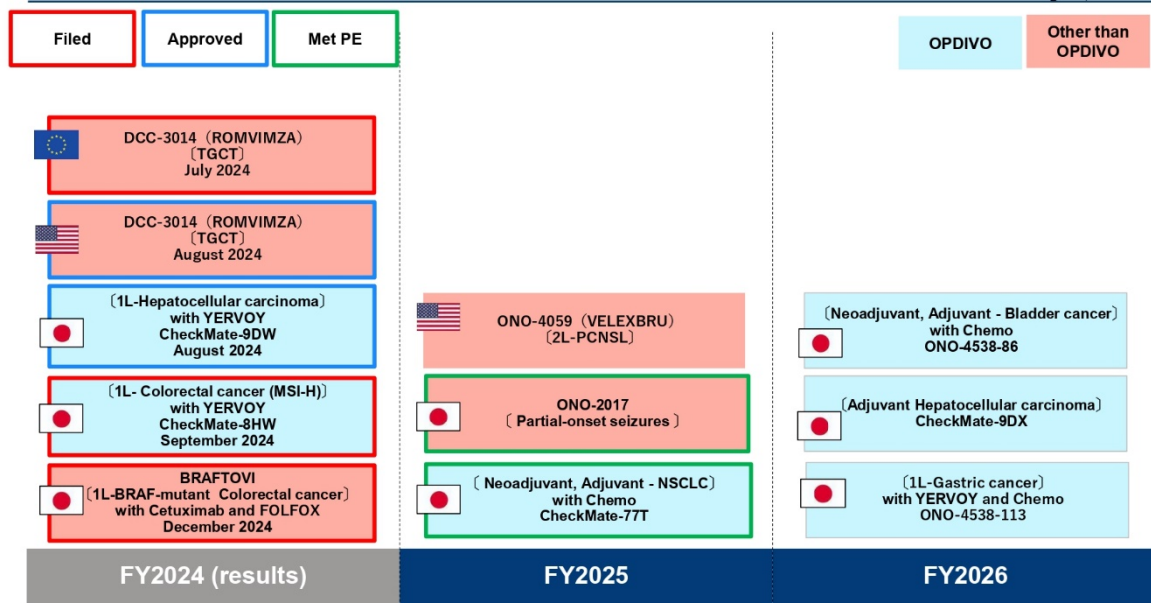
Full basis, the earnings forecast remains unchanged from the forecast announced at the beginning of the fiscal year.

Imura: Next, Okamoto, Executive Director of Clinical Development, will give an update on the progress of major development pipelines.

Okamoto: I would like to mainly explain the changes since May 8 of this year, using the development pipeline progress materials posted on our website.

Status of regulatory filing for approval in Japan, US and Europe

As of August1, 2025



PE : Primary endpoint

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First, here are the actual results and planned applications for approval.

I would like you to look at the leftmost part. As you are aware, the combination therapy of OPDIVO and YERVOY has been approved in Japan for the first-line treatment of hepatocellular carcinoma, and the approval is updated with a blue box.

The other three pending applications are ROMVIMZA in Europe, OPDIVO in combination with YERVOY for first-line colorectal cancer with MSI-H in Japan, and BRAFTOVI for the first-line BRAF-mutant colorectal cancer in Japan. The review of these three cases is currently progressing smoothly.

We announced as the press release on July 28 that we received a positive opinion from the European Commission for the approval of ROMVIMZA in Europe for the treatment of tenosynovial giant cell tumors.

Next is the schedule for future applications. There will be two changes since the last time. As for the ONO-4538-86 study, a global Phase III study for neo-adjuvant and adjuvant therapy for bladder cancer, we have changed the application period from FY2025 to the next fiscal year due to the expected delay in obtaining the results.

The application for approval based on the CheckMate 9DX study, a global Phase III study for the adjuvant therapy for hepatocellular carcinoma, has also been rescheduled for the next fiscal year because the results are now expected to be available later.

That concludes my report regarding the status and schedule of regulatory filing for approval.

Development status of OPDIVO



As of August1, 2025

- Approval or filed/awaiting approval in the past year
- Ongoing key clinical trials for approval

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Non-small cell lung cancer	Neo-adjuvant・Adjuvant	with Chemo	III	III	III	Approved	Approved
Gastric cancer	1st	with Ipi/Chemo	III	III	III	—	—
Colorectal cancer	MSI-H/dMMR (1st)	with Ipi	Filed	—	—	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant・Adjuvant	with Chemo	III	III	III	III	III
Rhabdoid tumor	2nd	Monotherapy	II	—	—	—	—
Richter transformation	2nd	Monotherapy	II	—	—	—	—
Solid tumor	—	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	—	—	Approved	Approved

※Red: Update after announcement of FY 2024 financial result in May 2025

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I would like to explain the major changes in the development status of OPDIVO.

As in the past, changes from the previous time are shown in red. First of all, the top row, neo-adjuvant and adjuvant therapy for non-small cell lung cancer, which is a combination with chemotherapy, has been approved in Europe and has been updated.

Then, about the middle section. The first-line hepatocellular carcinoma therapy in combination with ipilimumab was approved in Japan on June 24, as I mentioned earlier. In addition, we also received approval in South Korea and Taiwan in July last month, so we are updating this information.

Also, at the bottom of the page, we have updated the subcutaneous formulation of OPDIVO, which was approved in Europe at the end of May. The indication for which the drug was approved in Europe is the same as that in the US, where the drug was approved earlier, and it is approved for all solid tumors in which ipilimumab is not used in combination with continuous therapy.

These are the major development updates for OPDIVO.

Development pipeline (Oncology) ①



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	P/II	P/II	P/III	F	A	Status	Area	ID
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	BRAF-mutant thyroid cancer							FY2024.12 Filing accepted	JP, US, EU, KR, TW and others*	NCT04607421
QINLOCK (ripretinib) KIT inhibitor	Gastrointestinal Stromal Tumor 2L KIT Exon 11+17/18 (GIST)							FY2025 Primary Completion	US, EU, KR, TW and others	NCT05734105
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL)							FY2025 Primary Completion (Part A) (Actual)	US	NCT04947319
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*							FY2025 Primary Completion	JP, KR, TW	NCT06256328
	Colorectal cancer*							FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*							FY2026 Primary Completion	JP	NCT06542731
	Hormone receptor-positive, HER2-negative breast cancer							FY2026 Primary Completion	JP	NCT06570031
ONO-0530 (sapabursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia Vera							FY2025 Primary Completion	US, EU and others	NCT05143957
ONO-4482 (relatlimab) Anti-LAG-3 antibody	Melanoma*							FY2024 Primary Completion (Actual)	JP, US, EU and others	NCT01958109
ONO-7427 Anti-CCR8 antibody	Solid tumor*							FY2025 Primary Completion	JP, US, EU and others	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Solid tumor (with sotorasib)							FY2027 Primary Completion	US	NCT04892017
	Advanced Malignancies (with ripretinib)							FY2026 Primary Completion	US	NCT05957367

MOA : Mode of Action

F : Filed, A : Approval

EU : European countries

* : Combination with OPDIVO, * : Development rights countries: JP, KR
Estimated study completion date shown in JRCT or ClinicalTrials.gov

※Red: Update after announcement of FY 2024 financial result in May 2025

20/30

Next, I would like to talk about the progress of our oncology development pipeline excluding OPDIVO.

The top row BRAFTOVI, and the next row QINLOCK. The implementation countries are written in red, but this is only because there were many entries, such as Japan, the US, Europe, and Australia, we have only revised those entries.

For ONO-4059, tirabrutinib, the progress status has only been updated to data in use acquired. The US Phase II trial has two parts, Part A and Part B. Cohort Part B, which is a combination with standard treatment for first-line treatment, which is a combination with standard treatment for untreated patients, is ongoing.

Next, I would like to talk about the EP4 antagonist, ONO-4578. This is an international Phase II study, PoC trial for primary colorectal cancer. We have updated the information to include Japan and Europe as new countries participating in the trial.

In addition, regarding ONO-4578, we are currently conducting a Phase I clinical trial in Japan targeting hormone receptor-positive, HER2-negative breast cancer. We are continuing to follow up on efficacy data and have revised the timing for obtaining key data to FY2026.

This is an international Phase II clinical trial for the primary treatment of gastric cancer, and results are expected to be available around autumn. We expect to obtain the main efficacy data in the fall of this year.

For the others, ONO-0530, ONO-4482, and ONO-7427, only the description regarding the implementing country was rearranged.

Development pipeline (Oncology) ②



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	P/II	PII	PIII	F	A	Status	Area	ID
DCC-3084 Pan-RAF inhibitor	Advanced Malignancies							FY2026 Primary Completion	US	NCT06287463
DCC-3009 Pan-KIT inhibitor	Gastrointestinal Stromal Tumor							FY2028 Primary Completion	US	NCT06630234
ONO-7913 (magrolimab) Anti CD47 antibody	Pancreatic cancer*							FY2026 Primary Completion	JP	NCT06532344
	Colorectal cancer*							FY2027 Primary Completion	JP	NCT06540261
ONO-4685 PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2025 Primary Completion	US	NCT05079282
								FY2028 Primary Completion	JP	NCT06547528
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	HER2-expressing Solid tumor							FY2029 Primary Completion	US	NCT06241456
ONO-7428 Anti-ONCOKINE-1 antibody	Solid tumor							FY2029 Primary Completion	JP	NCT06816108

MOA : Mode of Action

F : Filled, A : Approval

* : Combination with OPDIVO
Estimated study completion date shown in JRCT or ClinicalTrials.gov

※Red: Update after announcement of FY 2024 financial result in May 2025

21/30

Next is the area of oncology.

Although it has been removed from the table, regarding the Axl/Mer inhibitor ONO-7475, we had been conducting a Phase I clinical trial in Japan targeting non-small cell lung cancer patients with EGFR mutation positive in combination with osimertinib, which is the standard treatment. However, due to strategic reasons, we have discontinued its development and have therefore removed it from the table.

In addition, the results of a Phase I trial of ONO-7913 as a first-line treatment for pancreatic cancer and a first-line treatment for colorectal cancer were presented at the ESMO GI conference held in Spain in early July.

Development pipeline (Non-oncology)



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PIII	PII	PIII	F	A	Status	Area	ID
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial Giant Cell Tumor							FY2024 FDA: Approval EMA: Filing accepted	US, EU and others	NCT05059262
	chronic Graft Versus Host Disease							FY2029 Primary Completion	US	NCT06619561
ONO-2017(cenobamate)Inhibition of voltage- gated sodium currents/positive allosteric modulator of GABAA ion channel	Primary generalized tonic-clonic seizures							FY2026 Primary Completion	JP	NCT06579573
	Partial-onset seizures							FY2024 Primary Completion(Actual)	JP, KR and others*1	NCT04557085
VELEXBRU Tablet (ONO-4059 : tirabrutinib) BTK inhibitor	Pemphigus							FY2027 Primary Completion	JP	NCT06696716
Povetacicept BAFF/APRIL dual antagonist	IgA Nephropathy							FY2028 Primary Completion	JP, US, EU, KR, TW and others*2	NCT06564142
ONO-2808 S1P5 receptor agonist	Multiple System Atrophy							FY2025 Primary Completion	JP, US	NCT05923866
ONO-1110 Endocannabinoid regulation	Postherpetic Neuralgia							FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia							FY2026 Primary Completion	JP	NCT06752590
	Hunner Type Interstitial Cystitis							FY2026 Primary Completion	JP	NCT06752603
	Major Depressive Disorder							FY2026 Primary Completion	JP	NCT06792136
	Social Anxiety Disorder							FY2026 Primary Completion	JP	NCT06805565
ONO-2020 Epigenetic Regulation	Alzheimer's Disease							FY2026 Primary Completion	JP, US	NCT06881836
	Agitation Associated with Dementia Due to Alzheimer's Disease							FY2026 Primary Completion	JP	NCT06803823
ONO-4685 PD-1 x CD3 bispecific antibody	Autoimmune disease							FY2024 Completion (JRCT)	JP	JRCT2071220081
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2024 Primary Completion(Actual)	EU	NCT05332704
								FY2026 Completion (JRCT)	JP	JRCT2071240056

MOA : Mode of Action

F : Filing, A : Approval

*1 : Development rights country: JP, *2 : Development rights countries: JP, KR

Estimated study completion date shown in JRCT or ClinicalTrials.gov. Shaded boxes indicate studies on healthy volunteers.

※Red: Update after announcement of FY 2024 financial result in May 2025

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Next, here is a summary of the development status of the non-oncology field.

As previously announced in a press release on June 23, we have newly added povetacicept, a BAFF/APRIL dual antagonist, for which we have acquired development and commercialization rights in Japan and South Korea from Vertex of the United States.

As for povetacicept, it is a compound that has newly entered the pipeline, and I will give you a brief overview of the compound later in this presentation.

In addition, regarding other items, the top row is ROMVIMZA, followed by cenobamate in the next row. As with cancer, we have made necessary adjustments to the information regarding the area of implementation, but there are no other changes.

In addition, we are conducting an international Phase II clinical trial of ONO-2808, an S1P5 receptor agonist, for the treatment of multiple system atrophy. As with the result for gastric cancer with ONO-4578, we expect to obtain key efficacy data for this trial in the fall of this year.

- ◆ Ono Pharmaceutical and Vertex enter into strategic agreement to develop and commercialize povetacicept in Japan and South Korea¹⁾
- ◆ Povetacicept is a recombinant fusion protein and a dual antagonist of the BAFF²⁾ and APRIL³⁾ cytokines
- ◆ Povetacicept is in development for multiple serious B cell-mediated diseases, including IgA nephropathy, primary membranous nephropathy

【IgA Nephropathy (IgAN)】

- IgAN results from deposition of circulating immune complexes consisting of autoantibodies in the renal glomerular mesangium
- Up to 72% of adult IgAN patients progress to end-stage renal disease within 20 years
- There are no approved therapies that specifically target the underlying cause of IgAN

【Povetacicept】

- Povetacicept has higher binding affinity and greater potency in preclinical studies versus other inhibitors of BAFF and/or APRIL alone
- Treatment with povetacicept 80 mg every 4 weeks subcutaneously reduced mean UPCR⁴⁾ by 66%⁵⁾ at 48 weeks
- A global Phase 3 pivotal study (RAINIER study) is currently being conducted in patients with IgAN, including in Japan

1) Ono Pharmaceutical press release (<https://www.ono-pharma.com/en/news/20250623.html>)

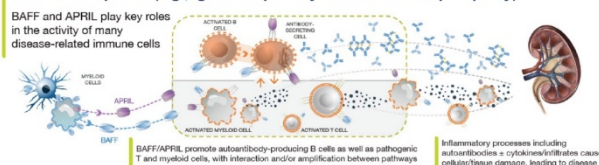
2) A Proliferation Inducing Ligand

3) B Cell Activating Factor

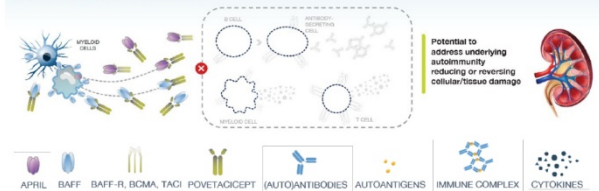
4) Urine protein/creatinine ratio

5) Ju-Young Moon, et al. Presentation at KSN 2025

Glomerulonephritis (e.g., IgAN and primary membranous nephropathy)



Dual BAFF/APRIL Inhibition



Adapted from Ju-Young Moon, et al. Presentation at the 45th Annual Meeting of the Korean Society of Nephrology (KSN), 20 June 2025, Seoul, Korea.

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As I mentioned earlier, I would like to give you a brief overview of povetacicept.

We have acquired its development and commercialization rights in Japan and South Korea from Vertex of the United States.

Povetacicept is a recombinant fusion protein. It is intended for the treatment of autoimmune diseases, particularly those caused by B cells. This is a dual antagonist of BAFF and APRIL, which are thought to play an important role in the activation of immune cells in autoimmune diseases.

We are currently developing a drug as the treatment of multiple severe B-cell-mediated diseases, including IgA nephropathy and primary membranous nephropathy. Of these, a global Phase III study for IgA nephropathy, including Japan, is underway.

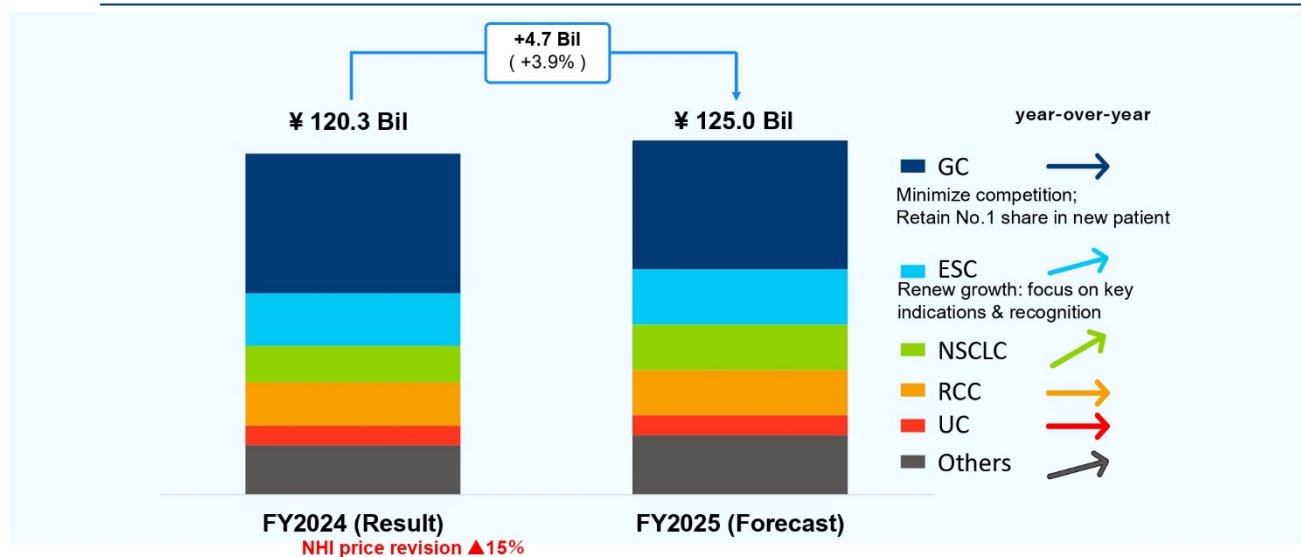
Povetacicept, in preclinical studies, has shown higher binding affinity to its target than other BAFF antagonists, drugs that inhibit only BAFF, APRIL, or both.

As a result, excellent effects on B cell proliferation, differentiation, and antibody production have been observed.

As you are all aware, a competitor's antibody against APRIL is currently being submitted to the FDA for the expected indication of IgA nephropathy. Povetacicept, as I mentioned earlier, has a different action in that it also inhibits BAFF, and we expect it to be positioned as a best-in-class treatment for IgA nephropathy.

Imura: Next, Kitada of Sales and Marketing will give an overview of OPDIVO trends.

Sales Trend of OPDIVO by Each Cancer



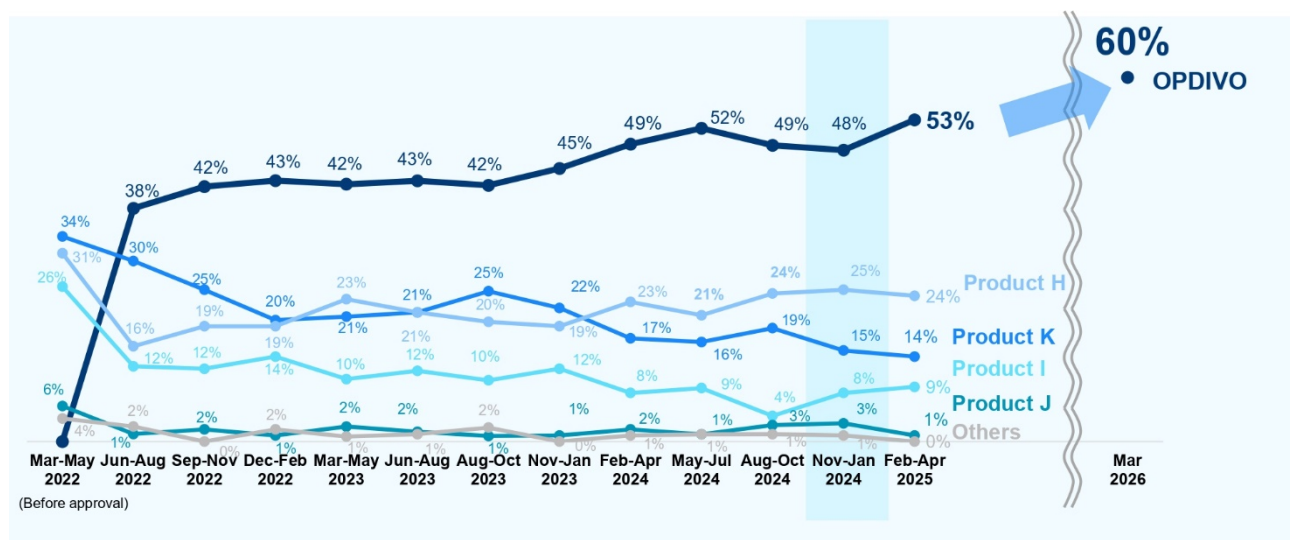
Kitada: I will explain the trend of our main product, OPDIVO.

First, we show OPDIVO sales trends by cancer type. In the current fiscal year, we project JPY125 billion, an increase of JPY4.7 billion over the previous year, after bottoming out in FY2024. In order to achieve JPY125 billion, we will focus particularly on minimizing the encroachment of competitors in the gastric cancer area, maintaining our number one share of new prescriptions, and advancing the evaluation in the non-small cell lung cancer and esophageal cancer areas to achieve renewed growth.

Although gastric cancer, which accounts for the highest percentage of sales, is facing a severe competitive environment and is affected to a certain extent by competing products, we have promoted activities to penetrate long-term follow-up data and real-world data in Japan, etc. As a result, the latest new patient prescription share is 65%. We will continue to promote activities to achieve 70% by the end of the fiscal year.

In addition, we plan to add a new indication for the first-line treatment of hepatocellular carcinoma in June and for the first-line treatment of MSI-H colorectal cancer in August this year, thereby maintaining its number one market share position in the gastrointestinal field.

Prescription Ratio in Patients Newly Treated※ for 1L ESC(Squamous Cell Carcinoma)



※Patients starting treatment within the last 3 month

Source: Primary research results
(May 2022~Apr 2025: n=150~155)

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Next, we report on the status of esophageal and lung cancers that is our goal in this year.

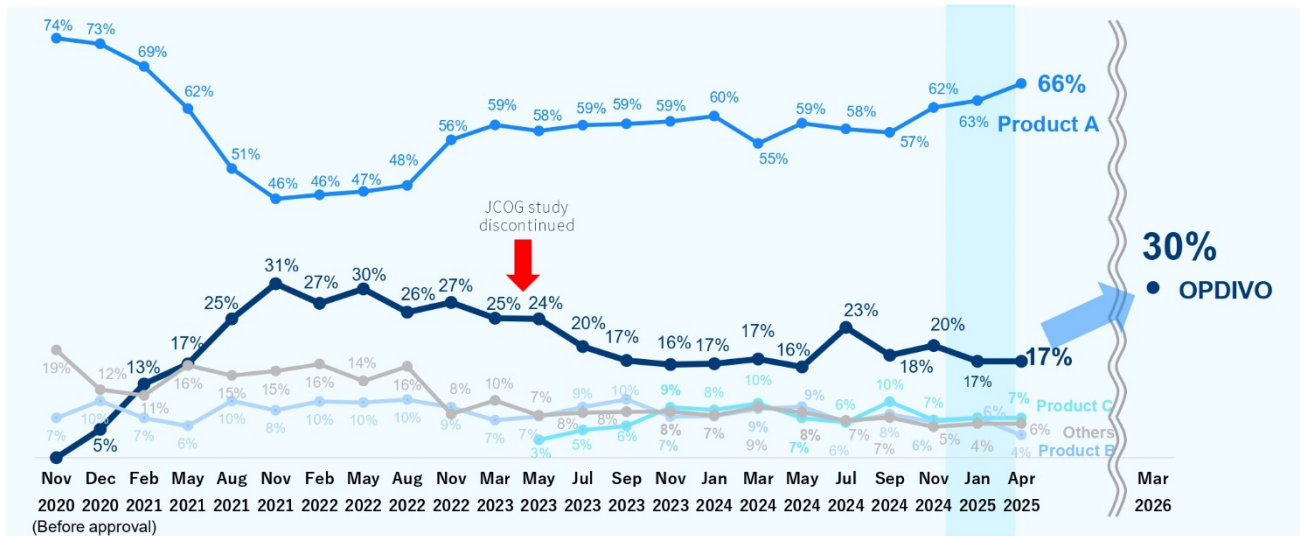
First, esophageal cancer, here is the prescription ratio in patients newly treated for first-line treatment of esophageal cancer. For the first-line treatment of esophageal cancer, we believe that our greatest strength lies in our ability to propose prescriptions for each patient based on the characteristics of the two regimens: OPDIVO plus chemotherapy, and OPDIVO plus YERVOY.

Although it entered the market six months after its predecessor, OPDIVO has been able to maintain a high share of 53% in new prescriptions.

I will now explain the factors behind the 53% growth. We believe this as a growing share of new prescriptions in surgical field.

We will continue to establish the evaluation of the two regimens through lectures, webinars, and other activities regarding the results of the CheckMate-648 study and the Japanese analysis of the 45-month follow-up, in order to increase the share of new prescriptions to 60%.

Prescription Ratio in Patients Newly Treated* for 1L NSCLC



*Patients starting 1L treatment within the last 1 month (Except Driver Mutation)

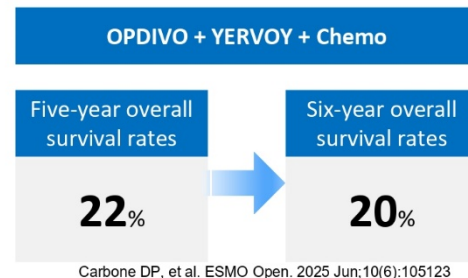
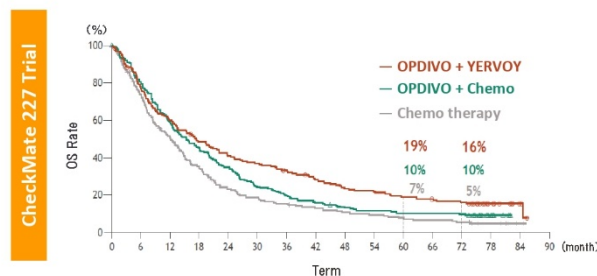
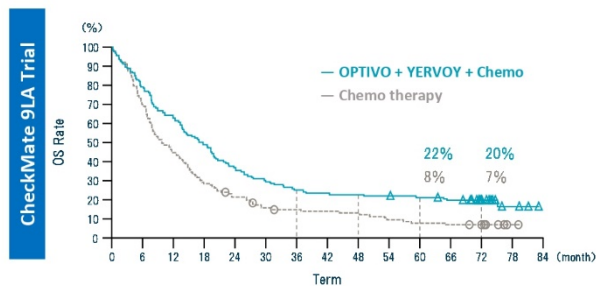
Source: Primary research results
(Nov 2020~Apr 2025: n=167~245) 27 / 30

Next, let me explain about lung cancer.

As you are aware, safety concerns were raised in an investigator-initiated clinical trial conducted by the Japan Clinical Oncology Group, hereinafter referred to as JCOG, for the OPDIVO + YERVOY + chemotherapy combination regimen, the so-called 9LA regimen, and the decision to discontinue the trial was announced in press in April 2023.

This led to a decrease in the use of OPDIVO + YERVOY + chemotherapy in the first-line treatment for lung cancer. As a countermeasure, we are working to establish the evaluation in PD-L1-negative patients in particular, as other treatment options have shown long-term survival benefits in PD-L1-negative patients with a poor prognosis. However, the current market share of new prescriptions of OPDIVO is 17% compared to the current year's target of 30%, which remains unchanged.

The result of Clinical Study - NSCLC 1L (PD-L1 negative) -



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In order to overcome this situation, we will utilize new topics in lung cancer.

In addition to the previous CheckMate-227 study, this is a paper published in June of this year. Six-year follow-up data from the CheckMate-9LA trial has been published in ESMO Open. In this analysis, in a group of PD-L1-negative patients with poor prognosis on other treatment options, the combination of OPDIVO + YERVOY + chemotherapy resulted in a 20% six-year survival rate in the overall population, indicating that the majority of patients who were alive at five years were still alive at six years.

Note that the five-year survival rate obtained with other treatment options recommended in the guidelines for PD-L1-negative patients is less than 10%. We believe that this once again proves the necessity of OPDIVO + YERVOY + chemotherapy combination therapy for long-term survival.

Based on the above, in FY2025, we will focus our activities on PD-L1-negative for which we have solid evidence, increase the share of new prescriptions to 50%, and place the highest priority on establishing an evaluation. Through these activities, we aim to recover the share of new prescriptions not only for PD-L1-negative patients, but also for PD-L1-weakly positive and PD-L1-strongly positive patients to the level before the discontinuation of the JCOG clinical trial, and as a result, increase the share of new prescriptions for first-line treatment overall to 30% and contribute to long-term survival of patients with lung cancer.

The Clinical Trial Result of HCC 1L



CheckMate 9DW Trial

	OPDIVO + YERVOY	Control Group (molecular-targeted drug)
OS	23.7 months	20.6 months
PFS	9.1 months	9.2 months
ORR	36%	13%
DOR	30.4 months	12.9 months
Three-years overall survival rates (follow-up data)	38%	24%
Steroid	29%*	-
Treatment-related death	3.6%	0.9%

* Percentage of high-dose steroid use

Lancet. 2025 May 24;405(10492):1851-1864.

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Next, we show the results of the CheckMate 9DW study for the first-line treatment for hepatocellular carcinoma, an indication that was added in June.

The OPDIVO + YERVOY group showed high efficacy in overall survival, progression-free survival, and response rate, and the efficacy in each of these categories compared to conventional therapy. On the other hand, we have started activities to address immune-related adverse events, with safety as the first priority.

As an initial response to our activities, we have received feedback indicating high expectations for their effectiveness. At the same time, we have set a target of 30% of new prescriptions in December 2026, one year and six months from now, because we need to work together to raise awareness against immune-related adverse events.

Finally, the marketability of OPDIVO and its prospects for the year 2025 are presented. In FY2025, there will be approximately 70,000 patients who have not yet received OPDIVO for existing indications. We will work to recover our share of new prescriptions, particularly in the large market for lung cancer.

In addition, we will continue to strengthen our efforts in the gastrointestinal field, particularly in gastric cancer and esophageal cancer. We anticipate additional efficacy for OPDIVO in the first-line treatment of MSI-H colorectal cancer, for which approval has not yet been obtained. As the leading company in the gastrointestinal field, we are committed to maintaining our number one position and achieving sales growth for OPDIVO in this fiscal year.

Imura: Thank you very much. That is all for our explanatory slides.

Question & Answer

Imura : Now, we would like to take your questions. First, Mr. Yamaguchi from Citigroup Securities, please go ahead.

Yamaguchi : I would like to ask you about Deciphera's products.

It seems like a good start, especially considering that both drugs will be growing in the future. QINLOCK seems to be doing well and ROMVIMZA seems like a promising product. It has only been three months since these two agents were started, but I wonder if you could tell us how you see the rate of progress against the forecast for this fiscal year, including the reputation of the local market.

Itoh : As for QINLOCK, I think both drugs are coming along at a good pace, faster than expected. In particular, ROMVIMZA sales are now JPY1.1 billion in Q1, and I believe they are coming in faster than expected.

Yamaguchi : Do you have any factors for QINLOCK? Is there a reason like Medicare Part D, Medicare re-setting, or competitors? I'm not sure.

Itoh : With regard to QINLOCK, despite the negative impact of the IRA, the number of patients is growing and continues to grow on a volume basis.

Yamaguchi : So, you were aware of the negative factor of IRA, but there has been an increase in volume that overcomes that negative factor, and has this phenomenon also been observed at other companies? How should I look at it?

Itoh : I see. Although sales growth may appear to be a little sluggish when compared to the previous year, I think we are doing well in this respect, although I am not talking about the accounting point of view. (In fact, it is growing on a volume basis.)

Yamaguchi : Thank you very much. Regarding OPDIVO, you mentioned about new indications in H2, and that the area of esophageal cancer is doing well. Regarding Q1, is it correct to say that things are not going as planned, particularly with regard to the lungs? Please tell us about the evaluation in Q1.

Takahashi : First of all, you are referring to the Q1 situation of lung cancer, right?

Yamaguchi : Overall, I think Q1 was underachieved, but I think the area where it was underachieved was probably lung cancer. Let me confirm this point.

Takahashi : As Kitada mentioned earlier, the growth in lung cancer was sluggish, which is true as a result. First, the decline in first-line gastric cancer caused a decrease in the share of new prescriptions due to the entry of competitors from last fiscal year, resulting in a delay in acquiring new patients. We have improved our current 65% share of new prescriptions, but we believe the biggest reason is that we have not yet been able to cover the reduced number of new prescriptions carryover from the last year.

In addition, although esophageal cancer has been performing well, we have yet to acquire reevaluation for lung cancer, which is a large market. I hope I have answered your question.

Yamaguchi : Thank you very much. This means that in order to achieve the full term, you have to work a little harder on the drop in the gastric cancer area, and the same goes for lung cancer. Is it correct to assume that you can recover from this for the full year?

Takahashi : The share of prescriptions for new patients with gastric cancer, which was once close to 80%, has dropped to 57%. However, we have been able to recover to 65% in Q1, and we would like to maintain our goal of reaching a 70% share of new patient prescriptions by continuing to push forward with our activities.

In addition, in the gastrointestinal field, we have hepatocellular carcinoma and MSI-H colorectal cancer for which we expect to obtain approval, and we will thoroughly try to be reevaluated in lung cancer along with them for some gains. In the PD-L1-negative segment, the OS was nearly double that of other conventional IO preparations and checkpoint inhibitor regimens.

I believe that we, as a pharmaceutical company, have a mission to deliver these products to patients in this segment. We continue to face a very difficult situation here, but we will continue to work diligently. This is all from myself.

Yamaguchi : Lastly, about the one for BAFF/APRIL from Vertex. Did it say that test continues until FY2028 for domestic applications? After this? Please provide guidance on the timing of domestic applications.

Okamoto : We are currently conducting Phase III, so we have described the main data acquisition, etc. However, we think it is too early to say when the application will be submitted at this time, so we would appreciate your patience.

Yamaguchi : Does that mean it could be faster than this, doing intermediate analysis or something? Or is it still unsure because you have just bought it?

Okamoto : Rather than "we don't know" because we have just bought it, we are still really in the process of implementing Phase III so I would like to refrain from saying when at this point.

Yamaguchi : I see. That is all. Thank you.

Imura : Next, Mr. Hashiguchi from Daiwa Securities, please go ahead.

Hashiguchi : The share of new prescriptions for OPDIVO for gastric cancer had fallen to 57% but has recovered to 65%. Where has this recovery mainly come from? First of all, please let us know which regimen you think you can take to increase the level to 70%.

Takahashi : First of all, the fact that the percentage once dropped to 57% is almost entirely due to the impact of VYLOY. Currently, OPDIVO has increased their share in new prescriptions to about 20%. If we consider the maximum possible impact, Claudin-positive patients account for approximately 40% of the total. Therefore, given the current 20% share in new prescriptions, we estimate that VYLOY accounts for about half of these prescriptions.

First, this part, clearly Claudin-positive, which does not necessarily means VYLOY, but for us, there are also patients with CPS10 or higher mixed in. The first issue is to create an environment in which patients can use the different types of drugs according to their backgrounds.

In addition, as for KEYTRUDA, new prescriptions remain around 10%. Now that the indication has been added for HER2-positive patients, I think there is a possibility that the drug will gain a little momentum.

Regarding gastric cancer, we have a lead period of two and a half years, so based on the accumulated experience of doctors. In addition, five-year follow-up data are now available. By continuing to provide reliable information based on long-term data and five-year follow-up data, we believe we can maintain OPDIVO's strong position for HER2-negative patients and achieve a 70% share of new prescriptions. This is all from myself.

Hashiguchi : From 57% to 65%, where did you take it from to recover?

Takahashi : We believe that our efforts to promote the high response rate of OPDIVO, even in Claudin-positive patients, and to encourage doctors to select treatments based on individual patients' backgrounds, such as using different approaches for those with CPS10 or higher, have become well established.

Hashiguchi : So you mean you got back what was once taken by VYLOY partly, right?

Takahashi : We believe you can think of it that way.

Hashiguchi : The second point is that you presented the data on magrolimab at the conference. Given that such data has been compiled to some extent, what are your thoughts on the future development policy? I know it is not easy since development overseas has stopped, but I would like to know what you think about it.

Okamoto : What we presented at ESMO GI regarding ONO-7913 was a pancreatic cancer first-line treatment, standard chemotherapy, and combination of this magrolimab and OPDIVO. Then, for the first-line treatment of colorectal cancer, we also added OPDIVO to the combination therapy with standard treatment, and we have announced the results of this study.

We are now in a situation where we are positively considering the next process. Regarding colorectal cancer, as for a trial targeting colorectal cancer called Trial 04, we received the Best Poster Award and received various questions on the day.

We are constantly monitoring the data, and we are actively considering the situation while keeping an eye on the Company's pipelines, portfolio, and other factors. We apologize for not being able to disclose any further information at this time.

Imura : Next, Mr. Wakao from JPMorgan Securities, please go ahead.

Wakao : First, I would like to ask you to summarize how this Q1 landing went against your company's plan and the outlook for Q2 and beyond. As for Q1, ROMVIMZA and QINLOCK performed well, but OPDIVO was slightly below the Company's plan. However, can I understand that the net result was as per your company's internal plan?

And after Q2, for example, QINLOCK and ROMVIMZA, if they go at this pace, this part will be an upswing against the plan, but then we should see how much OPDIVO can make up, is that correct?

Itoh : As you can see, domestic sales and overseas sales are as you confirmed. Overseas sales are slightly ahead of our forecast, so we hope to exceed our annual target.

As for domestic sales, we are hoping to bring OPDIVO sales in line with the plan, and we are aware that there are both positive and negative factors regarding sales as you have confirmed.

Wakao : What about in terms of operating profit?

Itoh : Regarding operating profit, even at the core operating profit, we are planning on target or for a slight increase this fiscal year. As we explained earlier, Q1 of this fiscal year saw a YoY decline, but this was due to the fact that Deciphera's performance was not included in the YoY comparison. At the moment, we have made progress at a rate of slightly more than a quarter of the total, but we would like to make a solid investment for growth and land at a level that is even with the current level. We are not at the point where we are strong, but we are almost going according to plan.

Wakao : I understand very well. Thank you. The second is about ROMVIMZA. Regarding the faster-than-expected pace, I would like to know what factors are behind it, and I would like to know more about the pace, whether it is quantitative or monthly movement, if you can give me more information.

Okamoto : First, regarding ROMVIMZA, one of the reasons for exceeding expectations is that, as you know, drugs that have been approved in advance have warnings attached to them, but ROMVIMZA does not have such warnings.

Since this is not a fatal disease, there may be patients on a waiting list, but I have heard that in addition to patients on the waiting list, prescriptions for switching from other drugs are also progressing, which was not originally anticipated.

Wakao : I understand. A bit more, what about the pace? How do you describe it? So, since you only have actual sales results for one quarter, it is difficult to see at what pace they will rise in the future, so can you give us some more tones?

Okamoto : It is difficult for us to say what the pace is. One is that, unlike cancer, we believe that the so-called long-lasting nature of the administration is a characteristic of the disease. On the other hand, although the number of diseases and the number of patients themselves are not that large, the number is steadily increasing, and the prescription period and administration period for individual cases are becoming longer. We believe that the growth will be steady.

Wakao : I understand. So, is it correct to understand that the unexpected increase in the number of patients waiting for treatment and switching from other prescriptions, as you mentioned, is continuing?

Okamoto : I hope that it will continue.

Wakao : Thank you very much. Finally, I would like you to tell me about povetacicept. I would like to know the background behind you saying, "best in class," and if it is possible to apply in Japan with the data from the interim analysis. Also, it would be helpful if you could suggest the amount of the upfront payment in this agreement.

As you mentioned in terms of whether it is best in class, I think the inhibitory activity of povetacicept is quite good. On the other hand, there is still rather little clinical data, so I am not quite sure if it is best in class or not.

If there is any data that only your company has seen, I would like you to tell us why it is best in class based on some more data. Please let me know if you can or cannot make it with the intermediate analysis of the UPCR.

Okamoto : First, I mentioned earlier that we expect it to be best in class. As you have just mentioned, clinical data cannot be compared side by side, at least in separate trials, so therefore, when considering solely from a mechanism-based perspective, we believe that it is important to inhibit BAFF in combination with APRIL, rather than inhibiting APRIL only, and we expect that this approach will enable us to be best in class on the MOA basis.

Besides, regarding whether or not it is possible to apply for approval with an interim analysis, this is a matter related to the application strategy, so as in the past, we would prefer to refrain from answering at this time. We are not currently disclosing the financial terms of the project, so we would appreciate your patience here as well.

Wakao : In the cash flow, there is a rather large amount for the acquisition of intangible assets, but is this unrelated?

Itoh : This is due to the significant impact of the sapablursen cash-out, which was announced in March.

Wakao : I understand. Thank you. That is all.

Imura : Next, Mr. Muraoka from Morgan Stanley MUFG Securities, please go ahead.

Muraoka : Regarding ROMVIMZA, in just three months, although it is still only three months' figures, Daiichi Sankyo's TURALIO grew slightly YoY to JPY1.1 billion. Your company also has JPY1.1 billion. You say that you were able to make the switch smoothly, but looking at the numbers on the surface, it's not clear to me.

For example, as a breakdown of JPY1.1 billion, what is the percentage of patients on the waiting list, what is the percentage of new patients, and what is the percentage of those who have switched the prescription, and what kind of ratio this will be in the future? I would appreciate it if you could give me a little more detail on these points.

Okamoto : We need to examine the point of your question closely within our company. According to the report from Deciphera, there were patients on the waiting list for treatment of benign diseases for which there was no other treatment available. On the other hand, as you pointed out, there are warnings attached to the preceding drugs, so they are not so widespread, but there has been some switching of such patients.

However, the problem is that the breakdown and details are currently being scrutinized internally. We do not have the data to provide you with at this time. I'm sorry.

Imura : If I may add on Okamoto's answer, as for existing treatment, not only TURALIO, but those who have been treated with TKI, there may be a switch from there.

Muraoka : It would be very helpful if you could give us some more colored information after three months.

Another question is about your future strategy in the diabetes area, where patents have just started to expire. The point is, though, what about the GLP-1 opportunity?

Both Lilly and Novo have been pursuing a partnering strategy in Japan for a long time, and your company has such a strong diabetes franchise. As for your company, I think that if there is an opportunity for co-promotion, you go for it, or better yet, you should go for it.

So far, there hasn't been any talk of that. Did you raise your hand but ultimately decide not to go for it, or did you think from the start that the conditions were unfavorable and decided not to go for it, or are you going to reduce the sales of diabetes in the future? What is your company's direction?

Imura : About the partnership. Of course, we have been focusing on diabetes, so we have a desire to do so in general, but specifically raising our hand or making a concrete proposal would involve contractual matters related to the partnerships, so I cannot comment on that here.

As you mentioned, we have been working in the diabetes field for a long time and it is an area where we are strong, but I hope you will forgive me not saying if we have raised our hand or that we are doing something about it.

Muraoka : I understood. Thank you. Lastly, just one more point. In the data book, there are sales by region, Japan, US, Asia, and Europe. Europe grew significantly from JPY500 million last year to JPY2.4 billion this fiscal year. Was this related to Deciphera, or was there an increase in royalties? It didn't sound right to me.

Itoh : In this Q1, Deciphera is newly included, so the sales in the European region are included.

Muraoka : Most of the plus JPY2 billion is from the European sales by Deciphera; is this royalty-like income?

Itoh : They do sell locally, so it is sales, not royalties.

Sato : Right. I understand that. That is all.

Imura : For next question, Mr. Ueda of Goldman Sachs Securities, please go ahead.

Ueda : I would like to start by asking about the progress of gross margin and SG&A expenses. In Q1, the gross margin was lower than planned and SG&A expenses seem to have progressed relatively well, but this is due to the product mix, such as the progress of FORXIGA, and co-promotion expenses will also decline as FORXIGA declines, so basically, progress is in line with the plan. Is that correct?

Itoh : Regarding SG&A expenses, yes, they are almost in line with the plan. Did you say gross margin or operating profit?

Ueda : I think the gross profit margin is probably a little lower for Q1 than you have planned for the full year.

Itoh : There are no major factors that would cause gross profit margins to fluctuate significantly in the future, so we do not expect to see much variation. For now, we see it as planned.

Ueda : I understand. Thank you. And secondly, I would like to know about the Povetacicept sales. Your Company's FORXIGA will also see its patent expire in the future. If you can maintain the current system for this renal field and lead to the launch of this development product. Could you tell us about your thinking on the sales structure in the renal field?

Kitada : We also have a drug called PARSABIV in the dialysis field. We are currently working in the field of nephrology, so we believe that the activities can be linked to this field.

Ueda : Thank you. In that sense, is my understanding correct that you can bring new drugs to the market without much revision of the system?

Kitada : You are right.

Ueda : I understand. That's all from me.

Imura : Thank you. For next questions, Mr. Sakai from UBS Securities, please go ahead.

Sakai : About sapablursen, I'm not sure if it will be your competitor, but Takeda has been successful with the same indication, and they are quite optimistic, projecting peak sales of USD1 billion to USD2 billion. In contrast, your contract is extremely modest, and although the application is the same, it is an orphan, but on the other hand, it is a fast-drug designation. I see from the documents that there will be a lead-out during FY2025.

Do you think it is possible to apply for this at the end of Phase II or at the end of the current trial impressions, depending on the data? This is nucleic acid, but who will be the manufacturer? In other words, the only treatment available is phlebotomy, so I think the marketability will vary greatly depending on how the price is determined.

Is that up to your company or is there still some joint work left to be done with Ionis? Could you tell me more about that?

Okamoto : First, regarding sapablursen, up to Phase II, the licensor for us which is Ionis, will conduct the trial. After that, since we have acquired the worldwide rights, we will conduct Phase III.

As you pointed out, there may not be a large number of patients, but here we are considering the strategy of implementing Phase III to obtain approval, the normal standard strategy, including past cases, etc.

As for the Takeda's case, the points to know are basically the same. We explained sapablursen in our previous opportunity, but although the modality and approach are different from Takeda's product, the target is the same as the leading drug rusfertide, so we believe that its chances of success are extremely high, in other words.

Sorry, what was the purpose of your question about the NHI price?

Sakai : I think this also has to do with manufacturing costs. I heard, partly, if phlebotomy becomes the target, the drug price becomes extremely low, so the idea behind this is that we still need to wait for Phase III to be completed.

Okamoto : Regarding the patients in this target group that we initially identified using keywords phlebotomy, we believe that the significance of this target lies in reducing the number of phlebotomy, as it significantly impairs their quality of life.

Certainly, if patients had phlebotomy, which is the end, it would be difficult to use the cost of the procedure as a basis for calculation. Usually, after all, from the perspective of improving quality of life, which is not the way to think about it.

Sakai : I see. I just counted the number of pipelines, and your company has 23 pipelines coming up. It's just the number of items, though. I wonder if it is time to narrow down the options, or should you continue with the current number for the time being and review the situation, including R&D costs control, just before the expiration of OPDIVO's US patent in 2028? Could you please let us know if you have any thoughts on that at this time?

Okamoto : First of all, we received a compliment, or should I say a compliment, about the number of pipelines. On the other hand, as Mr. Sakai pointed out the number may have increased. However, we basically believe that we urgently need to fill the late-stage pipelines first. That part will be filled in with licensing-in products.

On the other hand, in the early phase, we have been working to detect drug efficacy as reliably as possible while keeping costs to a minimum. For example, in oncology, we have conducted many trials centered on OPDIVO, so we can detect a certain level of efficacy without references, or rather, we can make in-house judgments.

We are also focusing heavily on taking biomarkers. We believe that this will allow us to determine Go/No-Go in a relatively compact study. At this point, as for the early phase, we hope that all phases will advance, but in reality, some will be eliminated. We do not think it is necessary at this time to narrow down the pipelines from a different perspective, as pointed out by Mr. Sakai.

Sakai : I understand. Thank you.

Imura : Last but not least, Mr. Wada of SMBC Nikko Securities, please go ahead.

Wada : What I would like to ask is about the OPDIVO royalty. Bristol has also launched a subcutaneous injection, and sales are reported to be around USD30 million in Q1. If the OPDIVO royalty from this is included in this term, if its royalty is included, at this point in Q1 we have been informed that there may be upward or downward revisions, and also about approval, I would like to ask whether the timing of this has been factored into your outlook, or whether your assessment is likely to change over the full year.

Itoh : Regarding royalties, it is included in this Q1, so this part is outside the scope of the forecast.

Wada : So you mean it is not included in the current term for now?

Itoh : No.

Wada : I see. So, you have actually signed a contract that you include it.

Itoh : Yes.

Wada : I understand. Am I correct in saying that it is contracted to include it, but you do not include it in the forecast?

Itoh : You're right.

Wada : I see. Thank you.

Imura : This concludes the financial results meeting for Q1 of the fiscal year ending March 31, 2026. Thank you very much for your participation today.