



## **ONO PHARMACEUTICAL CO., LTD.**

Financial Results Meeting for the Fiscal Year Ended March 2024

May 10, 2024

<b>[Number of Speakers]</b>	7	
	Gyo Sagara	Representative Director, Chairman of the Board and Chief Executive Officer
	Toichi Takino	Representative Director, President and Chief Operating Officer
	Satoshi Takahagi	Corporate Executive Officer, Executive Director, Sales and Marketing
	Tatsuya Okamoto	Corporate Officer, Executive Director, Clinical Development
	Masaki Ito	Corporate Officer, Division Director, Corporate Strategy & Planning
	Masayuki Tanigawa	Corporate Officer, Executive Director, Corporate Development & Strategy
	Ryuta Imura	Senior Director, Corporate Communications

# Presentation

**Imura:** Thank you very much for attending ONO's financial results meeting for the fiscal year ended March 2024 today.

First of all, Mr. Sagara, Chairman of the Board, would like to begin with an overview of the financial results.

## FY2023 : Financial Overview



Sales have increased for 9 consecutive fiscal years, and operating profit and net income have increased for 6 consecutive years.

¥ Billion	FY 2022	FY 2023	YoY		FY2023 (Forecast)	Progress (%)
			Change	Change (%)		
<b>Revenue</b>	<b>447.2</b>	<b>502.7</b>	<b>55.5</b>	<b>12.4%</b>	<b>500.0</b>	<b>100.5%</b>
Cost of sales	110.1	127.1	17.1	15.5%	122.0	104.2%
R&D expenses	95.3	112.2	16.8	17.7%	109.0	102.9%
Ratio of R&D to revenue	21.3%	22.3%			21.8%	
SG&A expenses	89.5	100.3	10.8	12.1%	98.0	102.3%
Other income	0.7	1.2	0.4	60.3%	1.0	117.6%
Other expenses	11.1	4.3	(6.7)	(60.8%)	5.0	86.9%
<b>Operating profit</b>	<b>142.0</b>	<b>159.9</b>	<b>18.0</b>	<b>12.7%</b>	<b>167.0</b>	<b>95.8%</b>
Net financial income	1.6	3.8	2.2	142.1%	2.0	189.9%
<b>Profit before tax</b>	<b>143.5</b>	<b>163.7</b>	<b>20.2</b>	<b>14.1%</b>	<b>169.0</b>	<b>96.9%</b>
<b>Profit for the year</b> (attributable to owners of the Company )	<b>112.7</b>	<b>128.0</b>	<b>15.3</b>	<b>13.5%</b>	<b>126.0</b>	<b>101.6%</b>

- Regarding sales revenue, sales of Opdivo increased by ¥3.1 billion to ¥145.5 billion and sales of Forxiga increased by ¥19.6 billion to ¥76.1 billion. Royalties from Bristol-Myers Squibb Company on Opdivo increased by ¥8.3 billion year on year to ¥97.9 billion, and royalties from Merck & Co., Inc. on Keytruda® increased by ¥7.9 billion year on year to ¥53.0 billion.
- Regarding expenses, combined impairment losses of ¥14.8 billion were recorded for marketing rights and intangible assets associated with compounds under development. Other expenses decreased by ¥6.7 billion year on year, mainly due to the absence of a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc.

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**Sagara:** This is a financial overview, and the sales revenue was JPY502.7 billion, exceeding JPY500 billion for the first time. Both product sales and royalty income increased. Operating profit increased by JPY18 billion to JPY159.9 billion. Cost of sales increased by JPY17.1 billion to JPY127.1 billion, R&D expenses increased by JPY16.8 billion to JPY112.2 billion, and SG&A expenses, excluding R&D expenses, increased by JPY10.8 billion to JPY100.3 billion.

Profit before taxes increased by JPY20.2 billion to JPY163.7 billion, and net profit attributable to owners of the Company, excluding income taxes, increased by JPY15.3 billion to JPY128 billion.

I would like to add a little bit to the cost of sales, R&D expenses, and SG&A expenses.

Cost of sales increased by JPY17.1 billion to JPY127.1 billion, mainly due to an increase in sales and the recording of JPY11.1 billion in impairment losses related to Joyclu and Parsabiv. Excluding impairment losses, it was an increase of JPY6 billion.

We also continue to invest aggressively in R&D. The amount increased by JPY16.8 billion to JPY112.2 billion, partly due to the recording of impairment losses on intangible assets related to development compounds. It was JPY3.2 billion more than the plan, but it was due to the impact of impairment losses. The ratio of research to development was 4:6 last year.

Other SG&A expenses increased by JPY10.8 billion, mainly due to Forxiga's co-promotion fee and IT and digital related expenses. The reason for the JPY2.3 billion increase over the plan was that sales of Forxiga exceeded expectations and so on.

## FY2023 : Sales Revenue



¥ Billion	FY2022	FY2023	YoY		FY2023 Forecast	Progress (%)
			Change	Change (%)		
<b>Revenue</b>	<b>447.2</b>	<b>502.7</b>	<b>55.5</b>	<b>12.4%</b>	<b>500.0</b>	<b>100.5%</b>
<b>Goods and products</b>	<b>295.0</b>	<b>317.0</b>	<b>21.9</b>	<b>7.4%</b>	<b>315.0</b>	<b>100.6%</b>
<b>Royalty and others</b>	<b>152.1</b>	<b>185.7</b>	<b>33.6</b>	<b>22.1%</b>	<b>185.0</b>	<b>100.4%</b>
OPDIVO	89.6	97.9	8.3	9.3%		
KEYTRUDA®	45.2	53.0	7.9	17.4%		

Sales Revenue of Main Products (Gross Sales Basis)						
Opdivo Intravenous Infusion	142.3	145.5	3.1	2.2%	150.0	97.0%
Forxiga Tablets	56.5	76.1	19.6	34.7%	75.0	101.5%
Orencia for Subcutaneous Injection	24.8	25.8	1.1	4.3%	25.5	101.3%
Glactiv Tablets	22.5	21.2	(1.3)	(5.9%)	21.0	100.9%
Velxbru Tablets	8.5	10.2	1.7	19.7%	9.5	107.5%
Kyprolis for Intravenous Infusion	8.7	9.1	0.4	5.1%	8.5	107.6%
Parsabiv Intravenous Injection	8.4	8.2	(0.2)	(2.1%)	8.0	102.9%
Ongentys Tablets	5.0	6.3	1.3	26.8%	6.5	97.1%

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This is a breakdown of sales revenue.

Sales of products increased by JPY21.9 billion to JPY317 billion, and royalty and others increased by JPY33.6 billion to JPY185.7 billion.

Royalty and others include Opdivo royalties from Bristol-Myers Squibb, up JPY8.3 billion to JPY97.9 billion, and royalties from Merck, up JPY7.9 billion to JPY53 billion. Other than that, a JPY17 billion upfront payment from the settlement of a lawsuit with AstraZeneca was recorded.

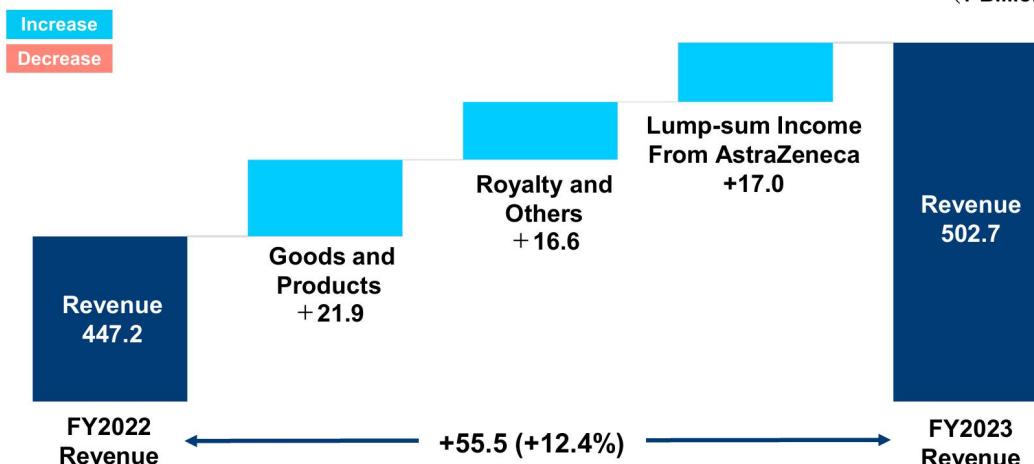
Sales of major products are as shown.

## FY2023 : Sales Revenue (Breakdown)



Revenue reached a record high due to a significant increase in sales of Forxiga, higher royalty revenue from Bristol-Myers Squibb Company, Merck & Co., Inc., and others, as well as a ¥17.0 billion upfront payment from the settlement of a patent-related lawsuit with AstraZeneca UK Limited.

(¥ Billion)



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I would like to briefly show you the breakdown of our sales revenue for FY2023.

As you can see, the previous year's sales revenue was JPY447.2 billion. Product sales added JPY21.9 billion, royalty-related sales added JPY16.6 billion, and the settlement with AstraZeneca added JPY17 billion, which added up to JPY55.5 billion, resulting in a total of JPY502.7 billion.

## FY2024 : Financial Forecasts



¥ Billion	FY2023 (Actual)	FY2024 (Forecast)	Change	Change (%)
<b>Revenue</b>	<b>502.7</b>	<b>450.0</b>	<b>(52.7)</b>	<b>(10.5%)</b>
Cost of sales	127.1	113.0	(14.1)	(11.1%)
R&D expenses	112.2	112.0	(0.2)	(0.2%)
Ratio of R&D to revenue	22.3%	24.9%		
SG&A expenses	100.3	100.0	(0.3)	(0.3%)
Other income	1.2	0.5	(0.7)	(57.5%)
Other expenses	4.3	3.5	(0.8)	(19.4%)
<b>Operating profit</b>	<b>159.9</b>	<b>122.0</b>	<b>(37.9)</b>	<b>(23.7%)</b>
Net financial income	3.8	1.0	(2.8)	(73.7%)
<b>Profit before tax</b>	<b>163.7</b>	<b>123.0</b>	<b>(40.7)</b>	<b>(24.9%)</b>
<b>Profit for the year</b> (attributable to owners of the Company)	<b>128.0</b>	<b>91.0</b>	<b>(37.0)</b>	<b>(28.9%)</b>

- Regarding revenue, sales of Opdivo is expected to decrease by ¥20.5 billion year on year to ¥125.0 billion, sales of Forxiga is expected to increase by ¥6.9 billion to ¥83.0 billion, and the royalty rate received from Merck & Co., Inc. for Keytruda® is expected to decrease by approximately 60%.
- Cost of sales is expected to decrease by ¥14.1 billion year on year, partly due to the absence of the ¥11.1 billion impairment loss on marketing rights recorded in the fiscal year ended March 31, 2024.
- R&D expenses are expected to decrease by ¥0.2 billion year on year to ¥112.0 billion, and other SG&A expenses are expected to decrease by ¥0.3 billion year on year to ¥100.0 billion.
- The annual exchange rate assumed in this forecast is 1 USD = 145 yen. Foreign exchange sensitivity in case of a depreciation of 1 yen may increase revenue and operating profit by ¥0.6 billion and ¥ 0.2 billion, respectively.

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Next is the financial forecasts for the next fiscal year.

I would like to reiterate that the impact of the Deciphera acquisition announced on April 30 is currently under scrutiny and is not included in our full-year forecast.

Revenues are projected to decrease by JPY52.7 billion from the current period to JPY450 billion. I will explain individual products later, but due to the impact of Opdivo's NHI price reduction, a decrease in royalty income due to lower royalty rates from Merck and others, and AstraZeneca's JPY17 billion being zero for the current fiscal year, these will have a reactionary impact.

Cost of sales will decrease by JPY14.1 billion to JPY113 billion in the current period, partly due to the absence of the JPY11.1 billion impairment loss on sales rights.

R&D expenses will remain mostly unchanged this year, as we intend to continue to invest aggressively in R&D. It is expected to be JPY112 billion.

SG&A expenses, excluding R&D expenses, are also almost unchanged at JPY100 billion.

Operating profit is projected to decrease JPY37.9 billion to JPY122 billion, and profit after taxes is projected to decrease by JPY37 billion to JPY91 billion.

## FY2024 : Sales Forecasts



¥ Billion	FY2023 (Actual)	FY2024 (Forecast)	Change	Change (%)
<b>Revenue</b>	<b>502.7</b>	<b>450.0</b>	<b>(52.7)</b>	<b>(10.5%)</b>
<b>Goods and products</b>	<b>317.0</b>	<b>304.0</b>	<b>(13.0)</b>	<b>(4.1%)</b>
<b>Royalty and others</b>	<b>185.7</b>	<b>146.0</b>	<b>(39.7)</b>	<b>(21.4%)</b>

Sales Revenue of Main Products (Gross Sales Basis)				
Opdivo Intravenous Infusion	145.5	125.0	(20.5)	(14.1%)
Forxiga Tablets	76.1	83.0	6.9	9.0%
Orencia for Subcutaneous Injection	25.8	27.0	1.2	4.5%
Glactiv Tablets	21.2	18.5	(2.7)	(12.7%)
Velexbru Tablets	10.2	10.0	(0.2)	(2.1%)
Kyprolis for Intravenous Infusion	9.1	9.5	0.4	3.9%
Parsabiv Intravenous Injection	8.2	8.5	0.3	3.3%
Ongentys Tablets	6.3	7.5	1.2	18.8%

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Sales forecasts by products.

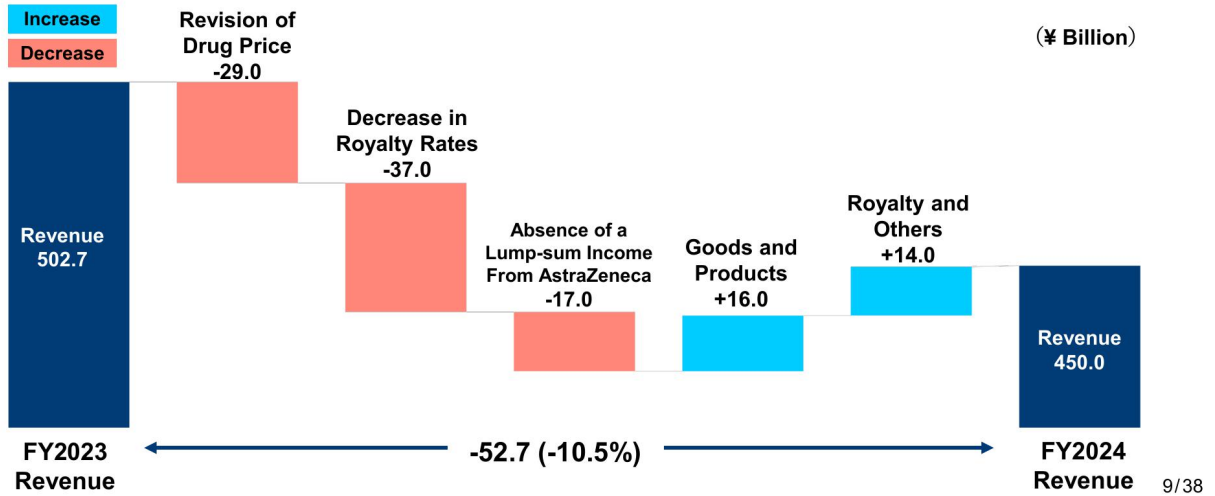
Opdivo has been affected by a 15% NHI price reduction. Forxiga is expected to continue to grow, and Orencia, Ongentys, and others are also expected to continue to grow.

As for royalty and others, we expect that royalty income from BMS will increase, but royalties from Merck, Roche, and others will decrease significantly as royalty rates decline, and with the absence of AstraZeneca's onetime payment, we are projecting a decrease of JPY39.7 billion, or about JPY40 billion, to JPY146 billion.

## FY2024 : Sales Forecasts (Breakdown)



Revenue is expected to decrease by ¥52.7 billion year-on-year due to the drug price reduction of Opdivo (down 15%), reduction in royalty rate received from Merck & Co., Inc. and others, and the absence of a ¥17.0 billion upfront payment from the settlement of a patent-related lawsuit with AstraZeneca UK Limited.



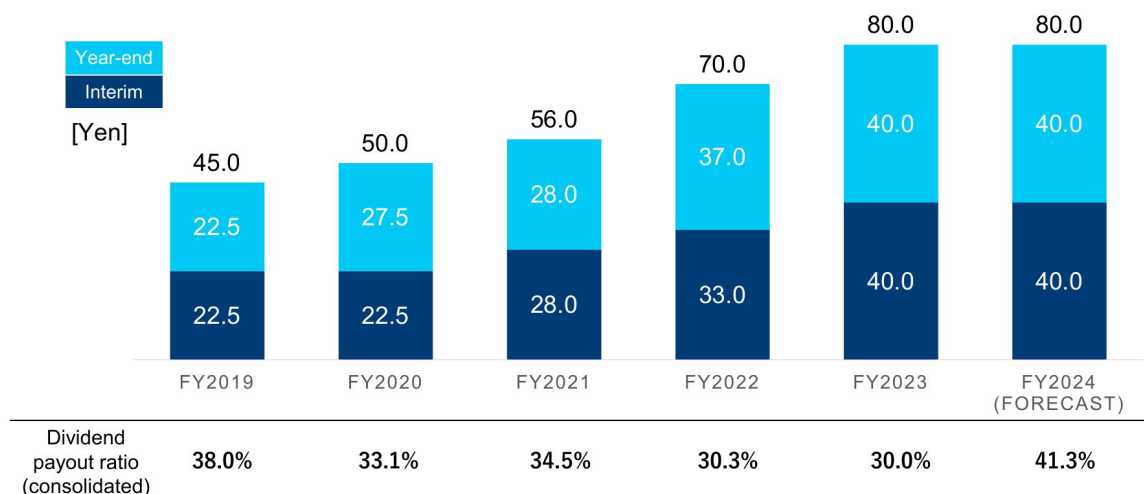
The sales decrease from the fiscal year ended March 31, 2024 to the fiscal year ending March 31, 2025 is JPY52.7 billion. Looking at the details, the impact of the NHI price revision is JPY29 billion. Also, the royalty rate will decrease, as I'm sure you are aware, but 1.625% of global sales will become 0.625%, so it will be approximately multiplied by 0.4. It affects royalties from Merck and Roche. Then, a Lump-sum Income from AstraZeneca will be gone.

The reason for this increase is a JPY16 billion increase in product sales. Royalties from BMS and others will increase by JPY14 billion, resulting in an estimated net sale of JPY450 billion.

## Profit Distribution (Dividend)



Dividends are to be paid out in accordance with a progressive policy of maintaining or increasing the annual dividend each year, with a target payout ratio of 40%, taking into account the performance of each fiscal year and various indices.



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Regarding dividends, we have continued to increase dividends in recent years, and we plan to maintain the dividend at JPY80 per share for the current fiscal year.

Regarding shareholder returns, we have added wordings to our financial statements and other documents that we had not previously mentioned. One is that the Company has a progressive dividend policy of maintaining or increasing annual dividends. That is the first point. Second is that the target dividend payout ratio is 40%. We have not mentioned these two things before, but now, we are expressing them in our financial statements.

## Reduction plan of Cross-shareholdings (published on November 1, 2021)



### ➤ Reduction plan

- Period: October 2021 to March 2025 (3 and a half years)
- Details of reduction plan:
  - 30% reduction from the end of September 2021 (141.8 billion yen)
  - ※The company plans to reduce its cross-shareholdings to less than 20% of its net assets by the end of March 2022.

	End of September 2021	Expected at the end of March 2025	Plan	
			Reduction	Reduction rate
<b>Market price at the end of September 2021</b>	<b>¥ 141.8 bil</b>	<b>¥ 99.3 bil</b>	<b>¥ 42.5 bil</b>	<b>30.0%</b>

### ➤ Medium-to long-term plan

We aim for the ratio of strategic shareholdings to net assets (on a balance sheet basis) to be less than 10%.

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Next is reduction plan of cross-shareholdings.

We are proceeding with a policy of reducing the amount by 30% from the JPY141.8 billion at the end of September 2021 over three and a half years.

## Status of reduction of Cross-shareholdings



	End of September 2021	End of March 2024	Reduction*	Reduction rate
<b>Market price at the end of September 2021</b>	<b>¥ 141.8 bil</b>	<b>¥ 95.8 bil</b>	<b>¥ 46.0 bil</b>	<b>32.4%</b>

\*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of March 2024	Reduction	Reduction rate
<b>Balance sheet accounting amount</b>	<b>¥ 141.8 bil</b>	<b>¥ 101.5 bil</b>	<b>¥ 40.3 bil</b>	<b>28.4%</b>

※End of March 2024  
Ratio of Cross-shareholdings to net assets : 12.7%

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The above chart shows the situation based on the market price at the end of September 2021.



We have already achieved a 32.4% reduction. However, the stock price is rising, so if you calculate it using the current stock price, the reduction rate is 28.4%, which means that we have to make a little more progress, but we will definitely achieve it by March 2025 as promised.

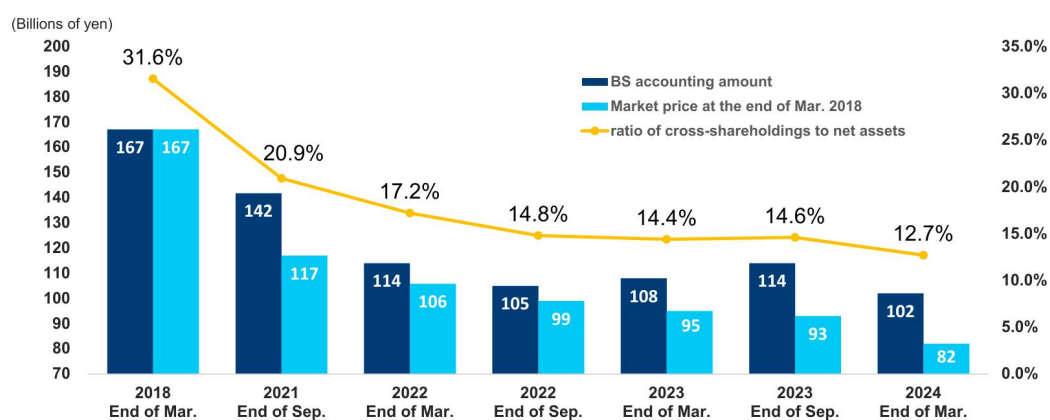
## Status of reduction of Cross-shareholdings



### ➤ Reduction plan

- 30% reduction by the end of September 2021 as of the end of March 2018 (111 brands, 167.1 billion yen)
- 30% reduction by the end of March 2025 as of the end of September 2021 (141.8 billion yen)

### ➤ Changes of reduction



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Currently, the cross-shareholdings ratio is 12.7% of net assets, but we are planning to move this ratio to less than 10%.

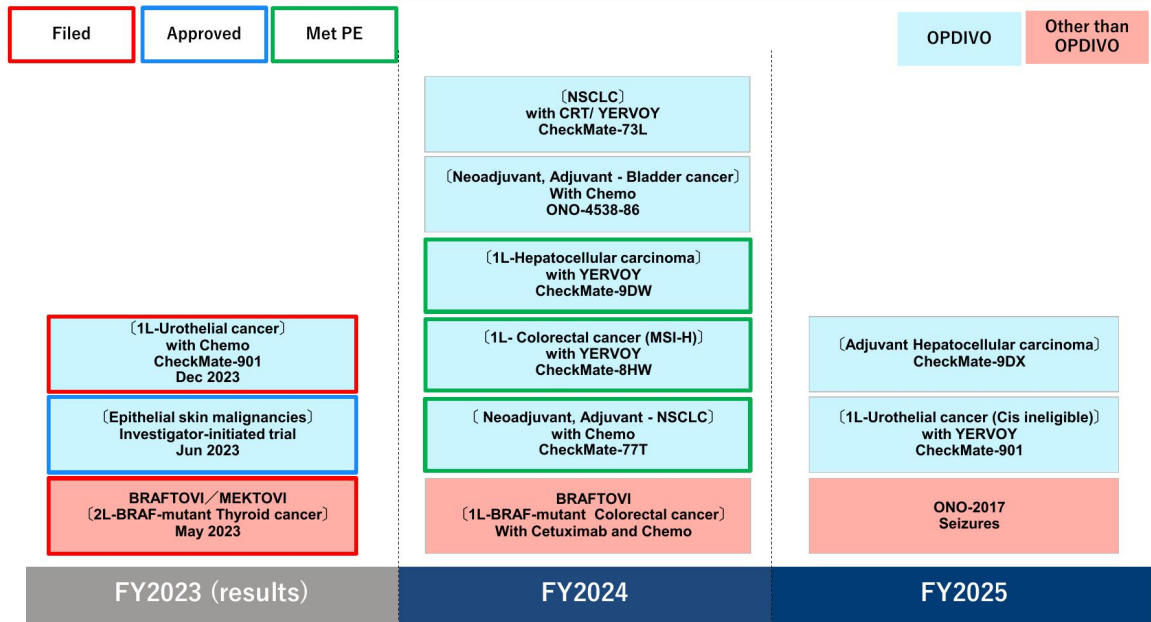
**Imura:** Mr. Okamoto, Executive Director of Clinical Development, will give an update on the progress of the development pipeline.

**Okamoto:** I would like to mainly explain the changes since January 31 of this year, using the development pipeline progress materials posted on our website.

In the new fiscal year, we have made some changes in the way we describe the progress of our development pipeline, which I will explain in turn.

# Status of regulatory filing for approval in Japan

As of May 6, 2024



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Please look at this slide.

We have changed the slide title to: Status of regulatory filing for approval in Japan.

In addition, up until now, when applying for and obtaining approval for Opdivo, we have referred to the approval of a single agent as M(monotherapy), and the approval of combination therapy as C (combination), but we omit it.

Further, in the past, H1 and H2 of the fiscal year—FY2024 in the case of this fiscal year—were listed separately, but now, they are listed together as a fiscal year.

On the other hand, applications that are filed are indicated with a red frame, those that have already been approved are indicated with a blue frame, and those that have successfully completed a validation study for application are indicated with a green frame.

Please note that our company applies for approval approximately six months after the successful completion of a verification study, but regarding the timing of the application and future plans, this is only the earliest possible schedule if things proceed as planned. Therefore, we would appreciate your understanding in advance.

Regarding the applications that are scheduled in FY2024, there are two changes from the last time.

The first is an application for domestic approval based on CheckMate-77T, an international joint Phase III study for preoperative and postoperative adjuvant therapy for non-small cell lung cancer. Until last year, we had stated that we were aiming to apply for approval in FY2023. However, during the pre-application consultation with the authorities, there were some differences of opinion between us and the authorities, and we have not been able to resolve these differences to date.

We would like to apply as soon as we reach a resolution of this issue, and at this time, we are planning to apply in FY2024. Please note that the schedule is subject to change depending on the details of the discussions with the authorities.

The other is that we have applied for domestic approval for combination therapy with Ipilimumab based on the results of the CheckMate-901 study, an international Phase III study targeting urothelial carcinoma for the first line treatment in which Cisplatin is not suitable. Due to the expected delay in obtaining the results, the application schedule has been changed from FY2024 to FY2025.

There are no other changes from the previous schedule of applications for approval in FY2024. Regarding the CheckMate-8HW, which is the first-line treatment for colorectal cancer with MSI-H, and the CheckMate-9DW trial, which is also used in combination with Ipilimumab for the first-line treatment of hepatocellular carcinoma, both of which are used in combination with ipilimumab, as I mentioned earlier, the clinical trials were successful, and the results have been obtained, so we are currently preparing to be able to apply as scheduled.

Next slide shows schedule for FY2025. We are planning to apply for approvals based on the Opdivo trial (application for approval of combination therapy with ipilimumab in Japan based on the results of the CheckMate-901 study), which I mentioned earlier that it will be postponed from this year, and the other is CheckMate-9DX, a postoperative adjuvant for hepatocellular carcinoma.

In addition, we are planning to submit an application for approval of ONO-2017 (Cenobamate), which we in-licensed from SK Biopharmaceuticals of Korea, for the treatment of partial-onset seizures in epilepsy.

In FY2025, we plan to apply for approval of Velexbu in the United States, based on the results of a Phase II study in the United States for relapsed and refractory PCNSL.

This will be the last on the slide. As an update on the applications filed for FY2023, we received approval for epithelial skin malignancies on February 9 of this year. Upon approval, a 10-year reexamination period was granted as a drug for rare diseases.

This was the explanation of the schedule for domestic applications.

## Development status of OPDIVO (1)



As of May 6, 2024

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug* (Relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	Approved	Approved
	Chemoradiotherapy	with CRT, with CRT/Ipi	III	III	III	III	III
	1st	with Ipi	Approved	Approved	Approved	Approved	–
		with Ipi/Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	–	–	–	–
	2nd	with Chemo (NSQ)	Revision of labeling	Approved	Approved	–	–
2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved	
Hodgkin's lymphoma	Relapsed /Refractory	with Brentuximab	III	–	–	III	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	SOC refractory	Monotherapy	Approved	–	–	–	–
Malignant Mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved	–	–	–	–

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482) ※Red: Update after May 2023 ※Red: Update after 3Q FY2023

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I will continue with an explanation of the major changes in the development status of Opdivo.

I apologize for repeating this, but I would like to explain the information in the table. Updates after the May 2023 financial announcement are shown in red. Of those, updates since the last time, January 31 of this year, are highlighted in yellow.

In this page, I mentioned earlier that the application for preoperative and postoperative adjuvant therapy for non-small cell lung cancer has been delayed due to some differences of opinion with the regulatory authorities in Japan. However, BMS has applied for approval in the United States and Europe, so we have updated this information.

## Development status of OPDIVO (2)

As of May 6, 2024



Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
		with Ipi/Chemo	III	III	III	-	-
	3rd	Monotherapy	Approved	Approved	Approved	-	-
Esophageal cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Colorectal cancer	MSI-H/dMMR(1st)	with Ipi	III	-	-	III	Filed
	MSI-H/dMMR(3rd)	Monotherapy	Approved	-	Approved	Approved	-
		with Ipi	Approved	Approved	Approved	Approved	Approved**
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	III	III	III	III	III
	2nd	with Ipi	II	II	Approved	Approved	II

★★2nd Line    ※Red: Update after May 2023    ※Red: Update after 3Q FY2023

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Next page.

As announced by BMS on May 6, US time, the European regulatory authorities have accepted the application based on the results of the CheckMate-8HW study in combination with Ipilimumab for the first line treatment of colorectal cancer in MSI-H, as updated here.

## Development status of OPDIVO (3)

As of May 6, 2024



Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		with Ipi/TKI	–	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant + Adjuvant	with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Filed	III	III	Approved	Filed
		with Ipi	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Dosage and Administration		240 mg (every 2 weeks)	Approved	Approved	Approved	Approved	Approved
		360 mg (every 3 weeks)	Approved	Approved	Approved	Approved	Approved
		480 mg (every 4 weeks)	Approved	Approved	Approved	Approved	Approved
Solid tumor	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	–	–	Filed	III

※Red: Update after May 2023 ※Red: Update after 3Q FY2023

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This information has been updated as BMS has obtained approval in the United States based on the results of the CheckMate-901 study, an international Phase III study targeting first-line urothelial carcinoma.

Also, at the bottom of the page, regarding the subcutaneous injection formulation of Nivolumab, BMS announced on May 6, US time, that the application for approval of the subcutaneous injection formulation of Nivolumab to the US FDA has been completed. This application covers all indications for which the intravenous formulation of Nivolumab has been approved as a single agent or in combination with chemotherapy or Cabozantinib.

Regarding combination therapy with Ipilimumab, the approval application is based on the approved efficacy of Nivolumab as a single agent for maintenance therapy. Please note that this approval application is only for adults.

As I mentioned earlier, we have received approval for epithelial cutaneous malignant tumors in Japan, so we updated this.

## Development pipeline in Japan (Oncology)



As of May 6, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
Braftovi Capsules (Encorafenib) BRAF inhibitor	JRCT2011230032/JP	BRAF-mutant thyroid cancer						FY2024 Approval
Mektovi Tablets (Binimetinib) MEK inhibitor	JRCT2011230032/JP	BRAF-mutant thyroid cancer						FY2024 Approval
ONO-4059 BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma						FY2025 Primary Completion (Part A)
ONO-4482 (Relatlimab) Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*						FY2024 Primary Completion
	NCT01968109/JP, US, EU	Melanoma*						FY2024 Primary Completion
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*						FY2025 Primary Completion
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*						FY2025 Primary Completion
	JRCT2031200215/JP	Colorectal cancer*						FY2027 Completion (JRCT)
	JRCT2031200286/JP	Pancreatic cancer*						FY2024 Completion (JRCT)
	JRCT2031200346/JP	Non-small cell lung cancer*						FY2024 Completion (JRCT)
	JRCT2031210364/JP	Hormone receptor-positive, HER2-negative breast cancer						FY2025 Completion (JRCT)
ONO-7475 (Tamnorzinib) Axl/Mer inhibitor	JRCT2031230429/JP	Pancreatic cancer*						FY2027 Completion (JRCT)
	JRCT2051210045/JP	EGFR-mutated non-small cell lung cancer						FY2024 Completion (JRCT)
ONO-7913 (Magrolimab) Anti-CD47 antibody	JRCT2031210172/JP	Pancreatic cancer*						FY2025 Completion (JRCT)
	JRCT2051210038/JP	Colorectal cancer*						FY2024 Completion (JRCT)
ONO-7914 STING agonist	JRCT2031210530/JP	Solid tumor						FY2027 Completion (JRCT)
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma						FY2025 Primary Completion
	JRCT2011230051/JP							FY2029 Completion (JRCT)
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia						FY2027 Primary Completion
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor						FY2029 Primary Completion

\* : Combination with Opdivo, Estimated study completion date shown in JRCT or ClinicalTrials.gov ※Red: Update after May 2023 ※Red: Update after 3Q FY2023 20/38

The following is the progress of the development pipeline, excluding Opdivo.

Regarding this, up until the previous meeting, we have covered the progress of the combination therapy of Opdivo and cancer immuno-chemotherapy, the progress of the domestic development pipeline in cancer fields other than Opdivo, the progress of the domestic development pipeline other than cancer, and the progress of the overseas development pipeline, summarized in a somewhat complicated manner.

Since we expect progress in the global development of our in-house development pipeline, we have summarized the progress status both domestically and internationally and have also divided it into oncology and non-oncology.

In addition, we will also provide the trial IDs as listed in the public databases ClinicalTrials.gov or JRCT and the timing of acquisition of key data or completion of the trial.

First is oncology. ONO-7427, an anti-CCR8 antibody, is a jointly developed with BMS, and we have added this as Japan has also participated in the international joint Phase I / Phase II trials conducted by BMS.

As for ONO-7913, the name Magrolimab was previously written in Roman or English letters, but now that it has been registered in Japan, it is written in Katakana.

On the other hand, ONO-7119, a PARP7 inhibitor in-licensed from Ribon Therapeutics of the US, was in Phase I trials in Japan, but its development was discontinued for strategic reasons and has been removed from the table.

We also participated in international joint Phase I trials led by BMS for ONO-7122, a TGF-β inhibitor, and ONO-7226, an anti-ILT4 antibody. However, since the development company, BMS, has decided to discontinue development, we have also considered the matter and made the decision to discontinue development. As a result, they have been removed from the table.

# Development pipeline in Japan (Non-oncology)



As of May 6, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-2017 (Cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	jRCT2031210624/JP	Primary generalized tonic-clonic seizures					FY2026 Completion (jRCT)	
	NCT04557085/JP	Partial-onset seizures					FY2024 Study completion	
Velexbru Tablets (ONO-4059 : Tirabrutinib)	jRCT2031220043/JP	Pemphigus					FY2026 Completion (jRCT)	
ONO-2910 Enhancement of Schwann cell differentiation	jRCT2061210008/JP	Diabetic polyneuropathy					FY2024 Completion (jRCT)	
	...../US		---					
	jRCT2031230173/JP	Chemotherapy-Induced Peripheral Neuropathy					FY2025 Completion (jRCT)	
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy					FY2025 Study completion	
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease					FY2024 Completion (jRCT)	
	NCT05332704/EU						FY2025 Study completion	
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease					2023.12 Study completion (Actual)	
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain					FY2024 Completion (jRCT)	

Estimated study completion date shown in jRCT or ClinicalTrials.gov. Dashed lines indicate studies on healthy adults. ※Red: Update after May 2023 ※Red: Update after 3Q FY2023 21/38

Here is a summary of the development status of the non-oncology field.

We have added ONO-2910, a drug that promotes Schwann cell differentiation, has recently been initiated in healthy adults in the United States.

Regarding the timing of obtaining the results of the trials I mentioned earlier, we will soon obtain the results of the Phase II trial as PoC trial, of ONO-2910 in patients with diabetic peripheral neuropathy, which is being conducted in Japan.

Additionally, we are participating from Japan in the Phase II trial of ONO-2808, targeting patients with multiple system atrophy, which was previously started in the United States and will be conducted in both Japan and the United States, so the information is updated.

I have explained the progress of the developed product, focusing on changes since the last time.

**Imura:** Next, Mr. Takahagi, Executive Director of Sales and Marketing, will give an overview of Opdivo trends.

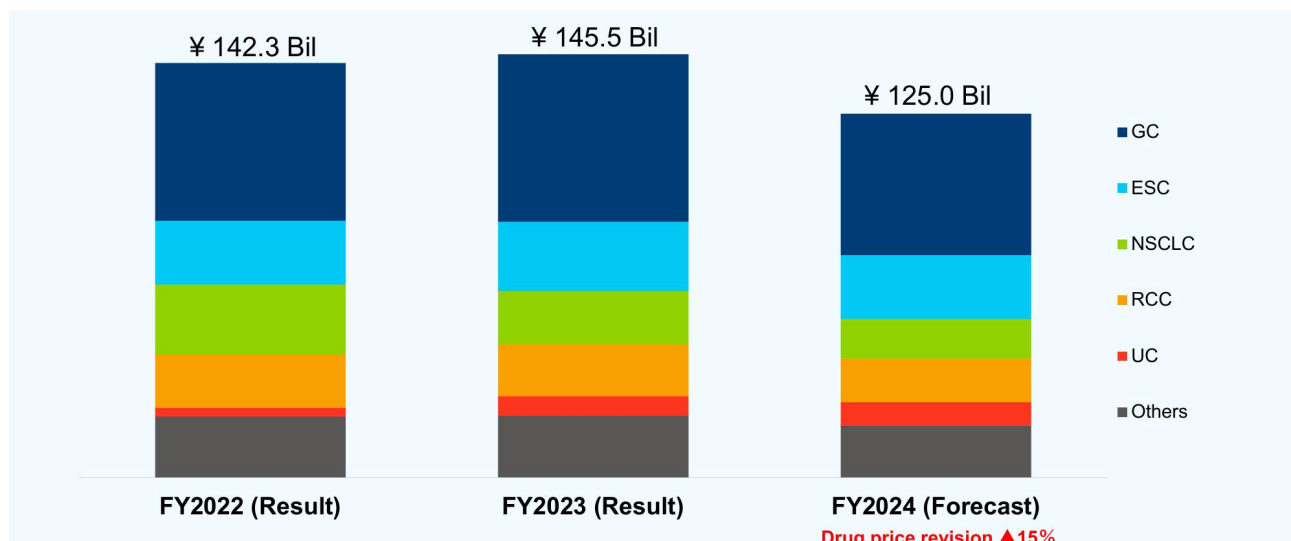
**Takahagi:** Let me explain the trends for Opdivo.

First, in FY2024, we expect a 1.1% increase in sales volume, despite negative factors, such as lower drug prices and the entry of competing products into the gastric cancer field.

In particular, in FY2024, we will build a foundation for recovery in the areas of gastric and lung cancer. Especially in the fields of gastric and lung cancer, there are positive factors, such as long-term follow-up data. For gastric cancer, we will create a barrier to entry against competitors, and for lung cancer, we will reevaluate and work to recover prescriptions.

In addition, there is still a market for existing indications, and there are positive factors for new market expansion through the addition of new indications. We are about to enter a growth phase from FY2025 onward, with the current fiscal year as the bottom.

## Sales Trend of OPDIVO by Each Cancer



Source: Estimation from external and internal data 24/38

Opdivo sales.

In FY2023, we set a goal of JPY150 billion, but we fell a little short of our target. In particular, we were unable to achieve the planned growth in urothelial carcinoma and non-small cell lung cancer.

In urothelial carcinoma, various guidelines recommended the Opdivo regimen, and it was on a growth trajectory, there were still variations in the patient population that physicians considered to be at high risk of recurrence. In addition, the lack of OS data delayed the acquisition of prescriptions to a greater extent than originally anticipated.

Also, in non-small cell lung cancer, again due to safety concerns with the Yervoy combination, the number of cases in first line treatment has decreased since 2022, and as we will show later, we believe that the decrease in new patient prescriptions has bottomed out, but recovery has been slower than originally expected.

However, as I mentioned earlier, in FY2024, we hope to make a solid recovery in gastric cancer and lung cancer to lay the foundation for a turnaround.

In particular, we have been actively working on gastric cancer since December 2021, and in dialogue with doctors, we believe that what is desired for gastric cancer treatment is long-term survival, as well as improvement of passage obstruction through tumor shrinkage, and how to maintain QOL.

Especially for Opdivo, we believe that the erosion of new prescriptions by competing products can be limited to 10% or less due to the positive factors of Opdivo, such as its usefulness, expected long-term survival, and tumor shrinkage effect. We will maintain the volume base here for the most part.

In addition, we have been appealing, doctors-to-doctors, about how to deal with cytokine release syndrome, which has been a safety concern in non-small cell lung cancer, through medical specialists.

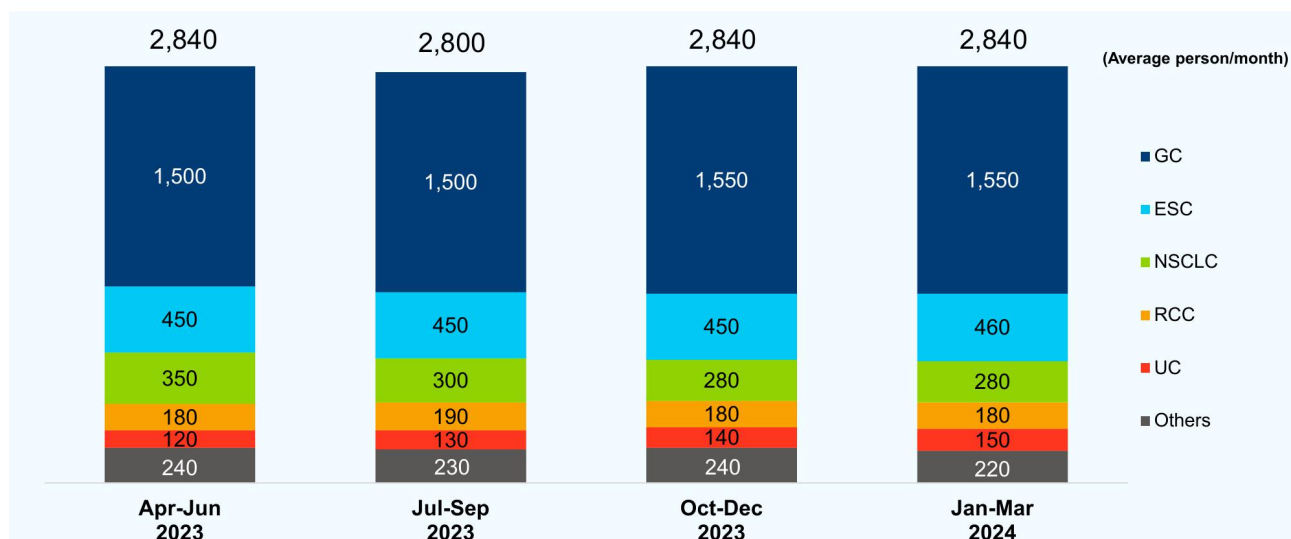
Furthermore, we believe that the decline in the number of new prescriptions of Opdivo has bottomed out because of the promotion of understanding of Opdivo's efficacy in terms of long-term follow-up data.



In FY2024, follow-up data is scheduled to be released by ASCO and other organizations, so we are confident that we will be able to reevaluate the situation, and we will work to restore the number of prescriptions.

In addition, sales for esophageal cancer and urothelial carcinoma are expected to continue to grow, with a volume-based increase of 1.1 % to 1.25billion in FY2024 compared to FY2023.

## Number of Patients Newly Prescribed with OPDIVO by Each Cancer (Estimation)

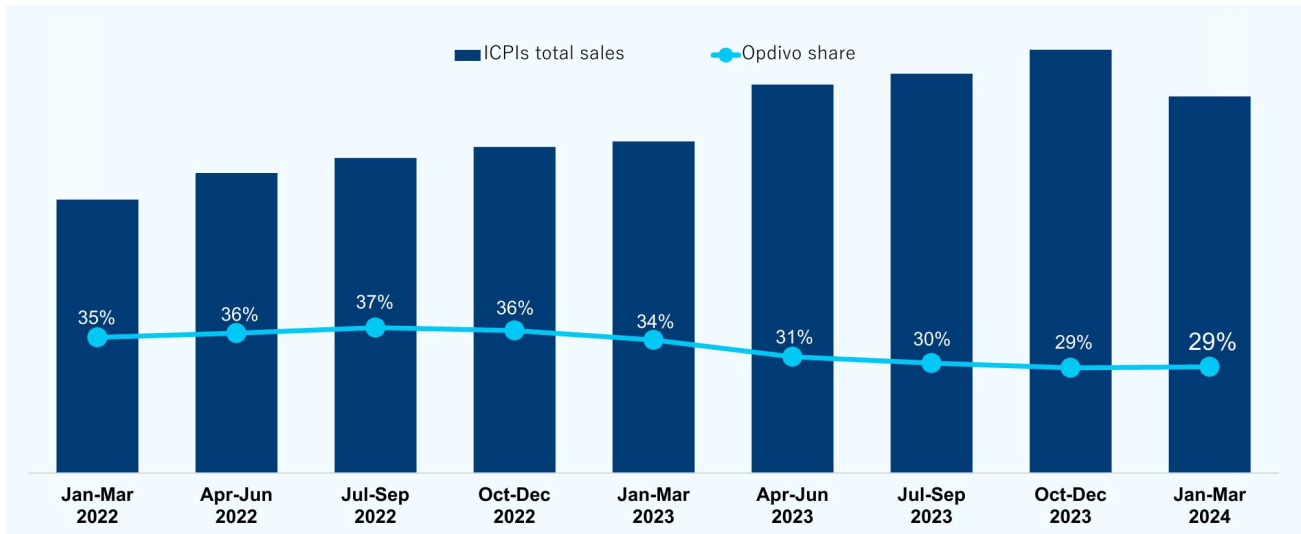


Source: Estimation from external and internal data  
25/38

The following table shows the number of patients newly prescribed with Opdivo by carcinoma, broken down by quarter.

During the most recent period from January to March, the number of patients newly prescribed was 1,550 for gastric cancer, 460 for esophageal cancer, and 280 for lung cancer, for a total of 2,840.

## Trend of total sales of ICPIs and OPDIVO share



Source: External data

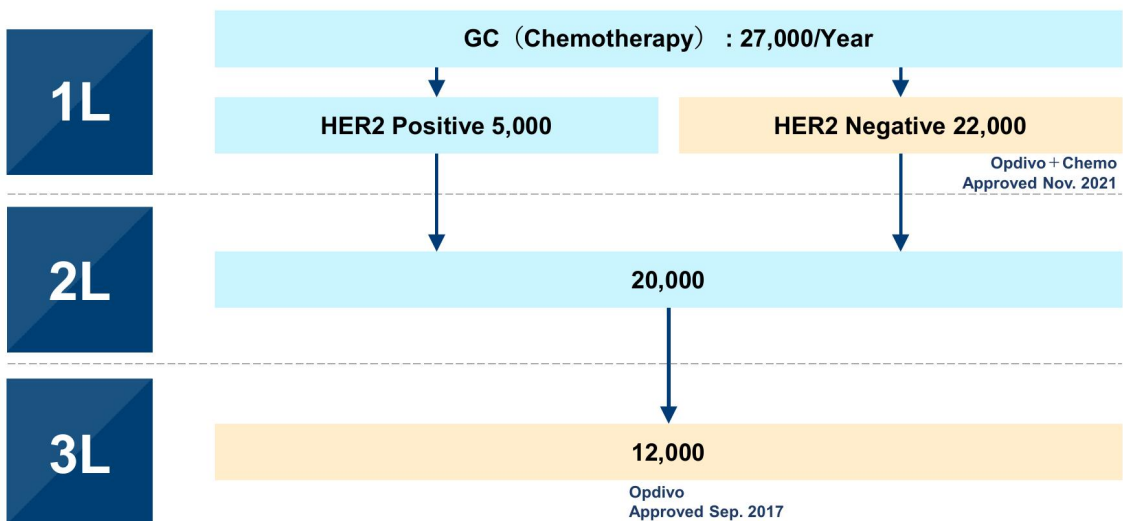
26/38

Here is the trend of total sales of immune checkpoint inhibitors launched in Japan and Opdivo's market share.

The Opdivo market share was 29% from January to March.

## Number of GC\* Patients per year in Japan

\* : Unresectable Advanced or Recurrent GC



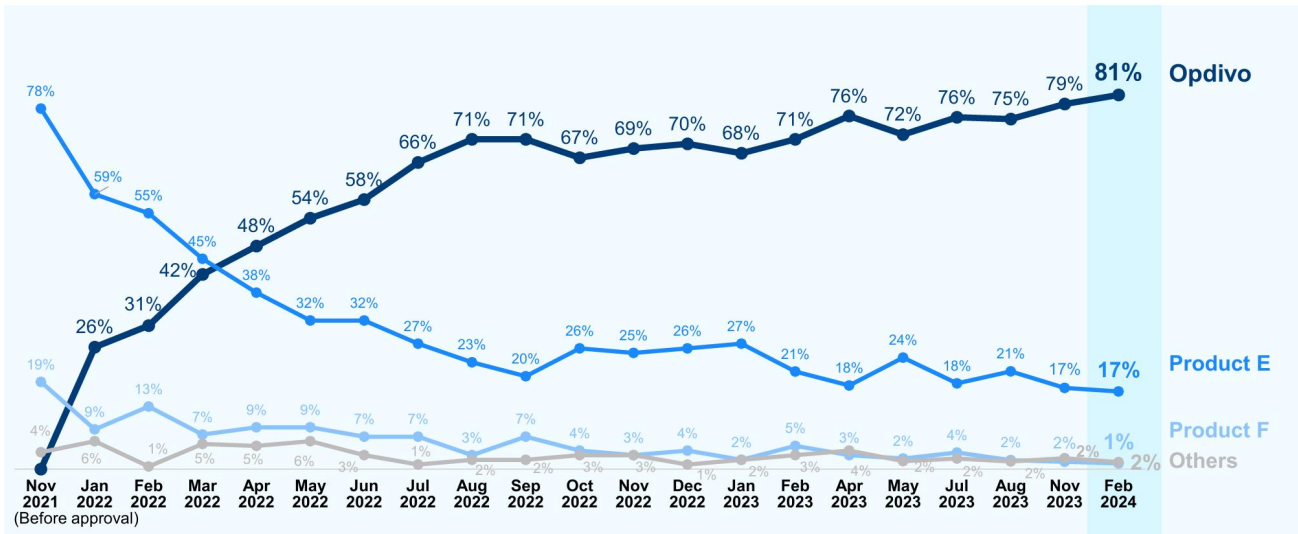
Estimation based on internal survey (2020)

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This is the first-line status of gastric cancer.

The annual number of HER2-negative patients eligible for first-line treatment with Opdivo is estimated at 22,000.

## Prescription Ratio in Patients Newly Treated\* for 1L GC



\*Patients starting treatment within the last 3 month

Source: External data (Nov 2021~Feb 2024: n=200~204)

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The status of Opdivo's share of new patient prescriptions has recently increased to 81%.

In gastric cancer treatment, as I mentioned at the beginning, physicians place great importance on long-term survival, improvement of passage obstruction due to tumor shrinkage, and maintaining QOL.

This is the four-year follow-up data for the CheckMate-649 study, arranged for two, three and four years from the time of approval. In the overall population, Opdivo was different from the control group at four years in terms of overall survival, with a survival rate of 13%, a high rate of survival of one in eight patients.

In addition, the hazard at the time of approval was 0.8, but it was 0.79 in the four-year follow-up data, which has not decreased at all. It is maintained. These results also show that Opdivo has a long-term survival and tail plateau, which is one of its strengths and has been highly evaluated by physicians.

In this regard, we believe that this will lead to a differentiation from competing products.

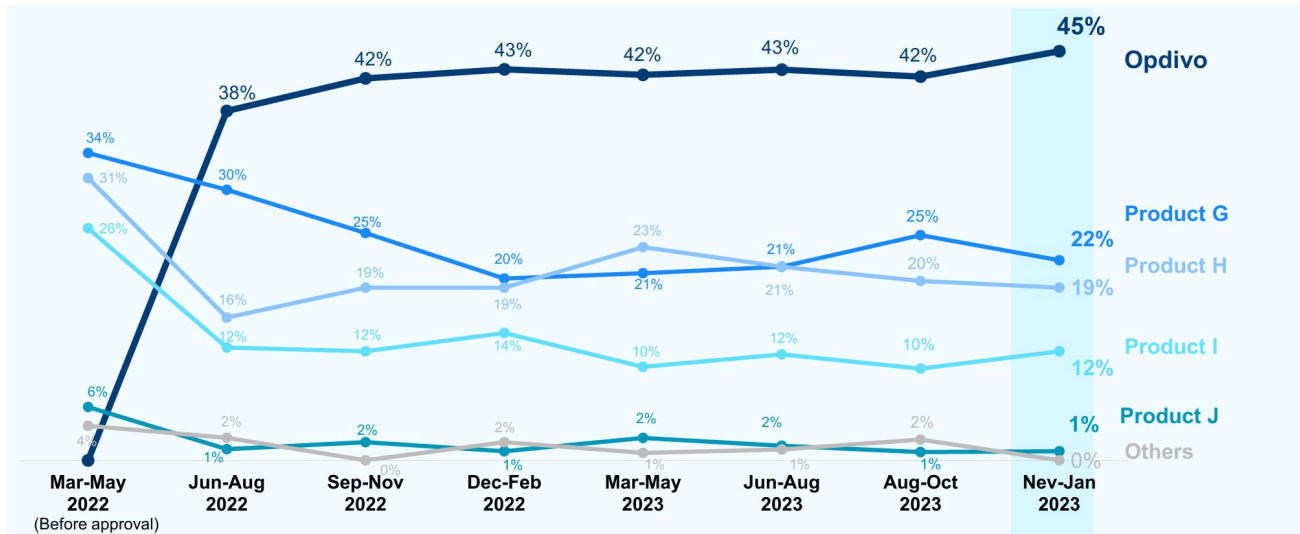
Furthermore, as you all know, this is a guideline for the treatment of gastric cancer. The improvement of symptoms associated with the progression of cancer is also described here, and this is one of the treatment goals.

In this context, let me review the test results of CheckMate-649 again. Compared to the chemo group, we can see an additional effect of 12% by adding Opdivo. This will lead to the improvement of passage obstruction and symptoms. We believe that this will also differentiate us from our competitors.. Also, QOL is extremely important to doctors when it comes to treatment.

In cancer treatment, it is important to ensure that the patient's QOL does not deteriorate during treatment. The results of the QOL data from CheckMate-649 show that the Opdivo group had better QOL results in both categories compared to the chemotherapy group.

We have obtained a lot of data that can promote the efficacy of Opdivo, and long-term follow-up data will continue to emerge. Therefore, we believe that it is possible to keep the entry of competitors limit within 10%.

## Prescription Ratio in Patients Newly Treated\* for 1L ESC(Squamous Cell Carcinoma)



\*Patients starting treatment within the last 3 month

Source: External data (May 2022~Jan 2024: n=150~155)

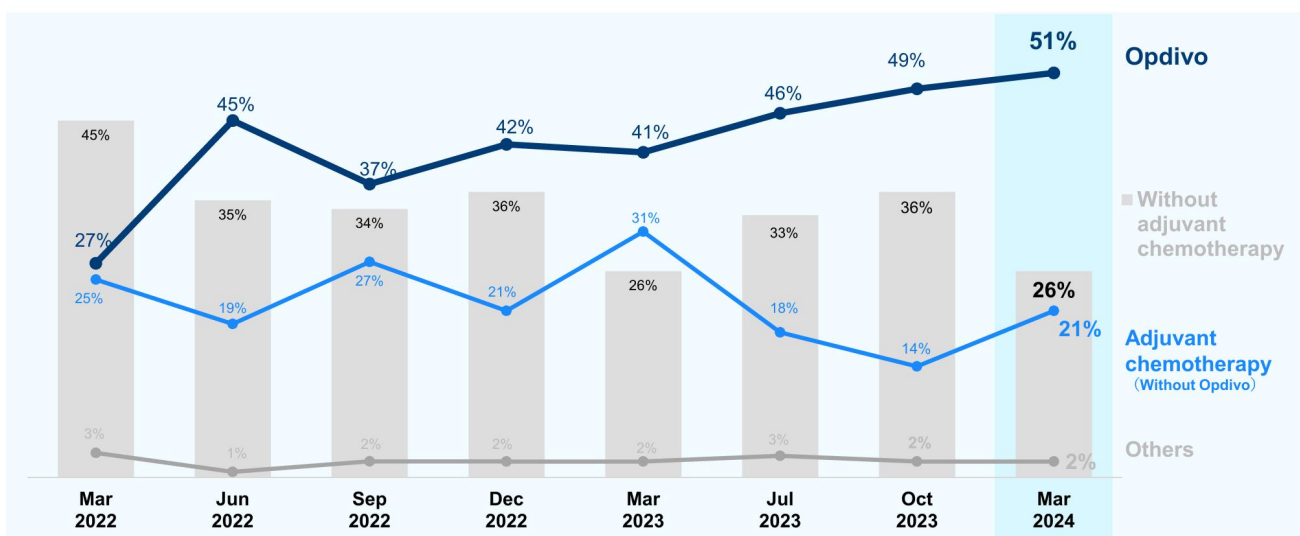
30/38

In the gastrointestinal field, this is the result of primary treatment for esophageal cancer.

Currently, it has grown to 45%.

As you all know, we entered this field late, but we have maintained the number one position by outperforming the competition from the very beginning. We believe that we have proven our strong presence in the field of gastrointestinal oncology, and we will continue our efforts in this area.

## Prescription Ratio in Patients Newly Treated\* for ESC(adjuvant chemotherapy)



\*Patients starting treatment within the last 3 months

Source: External data (Mar 2022~Mar 2024 n=130~152)

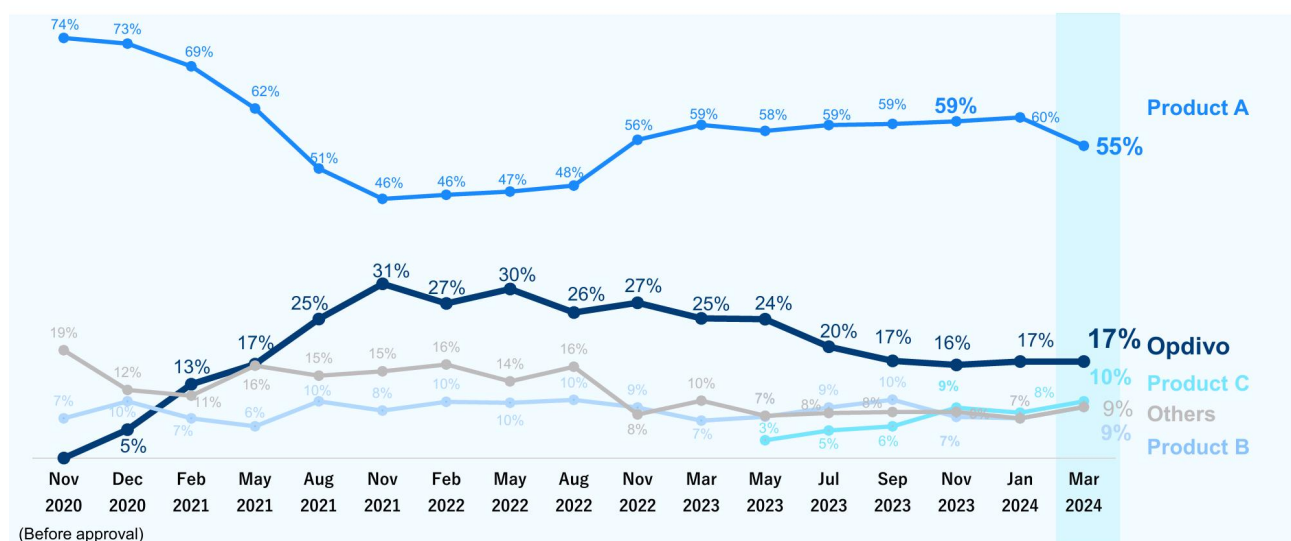
32/38

In the field of esophageal cancer, we are promoting activities for postoperative adjuvant treatment, and the current share of new prescriptions is 51%.

Since approval, lots of clinical data has been accumulated. We have been able to expand prescriptions by introducing these types of products on a doctor-to-doctor basis, so we will continue this activity in the future.

However, there are still many patients who do not receive postoperative support in this area. Therefore, we would like to further speed up the process.

## Prescription Ratio in Patients Newly Treated\* for 1L NSCLC



(Before approval)

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

Source: External data (Nov 2020–Mar 2024; n=167–245)

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In particular, we are focusing on the lung cancer area this fiscal year.

The share of new patients' prescription in the lung cancer area was 17%, and we believe that we have hit bottom with respect to the decrease in new prescriptions.

As we continue to expand from here, one of our strengths in particular is CheckMate-227, and I will show you the results of the CheckMate-9LA regimen later, but we are beginning to see a clear tail plateau, especially in the PD-L1 negative population.

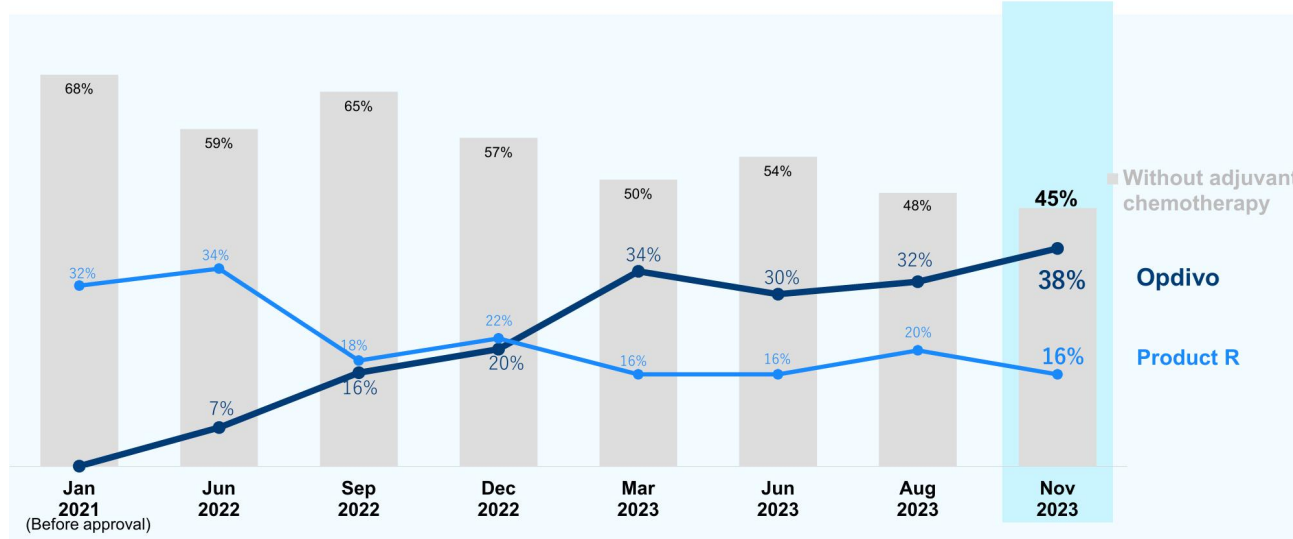
The survival rate was 16%, which is a very effective result after six years of follow-up. In addition, the CheckMate-9LA regimen has a four-year follow-up result, with a survival rate of 23% at four years.

Especially in the lung cancer field, we are seeing a trend that it is difficult to achieve long-term survival in negative cases in which PD-L1 is not expressed with PD-1 inhibitors. However, with the Opdivo and Yervoy regimens, the percentage of long-term survival has been high when Yervoy, a CTLA-4, is used in combination.

We are continuing to follow up on both regimens, and follow-up data will be released this year. We believe that we will be able to recover new prescriptions by focusing our efforts on negative cases, where unmet needs are very high.

However, we must continue to work hard on AEs and safety, as we recognize that this drug can continue to contribute to the long-term survival of many lung cancer patients. I believe we can make a comeback.

## Prescription Ratio in Patients Newly Treated\* for Bladder Cancer (adjuvant chemotherapy)



\*Patients starting treatment within the last 3 months

Source: External data (Jan 2022–Nov 2023: n=200)

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Finally, I would like to report on the field of urology.

Currently, the prescription ratio in patients newly treated for bladder cancer adjuvant therapy has increased to 45%.

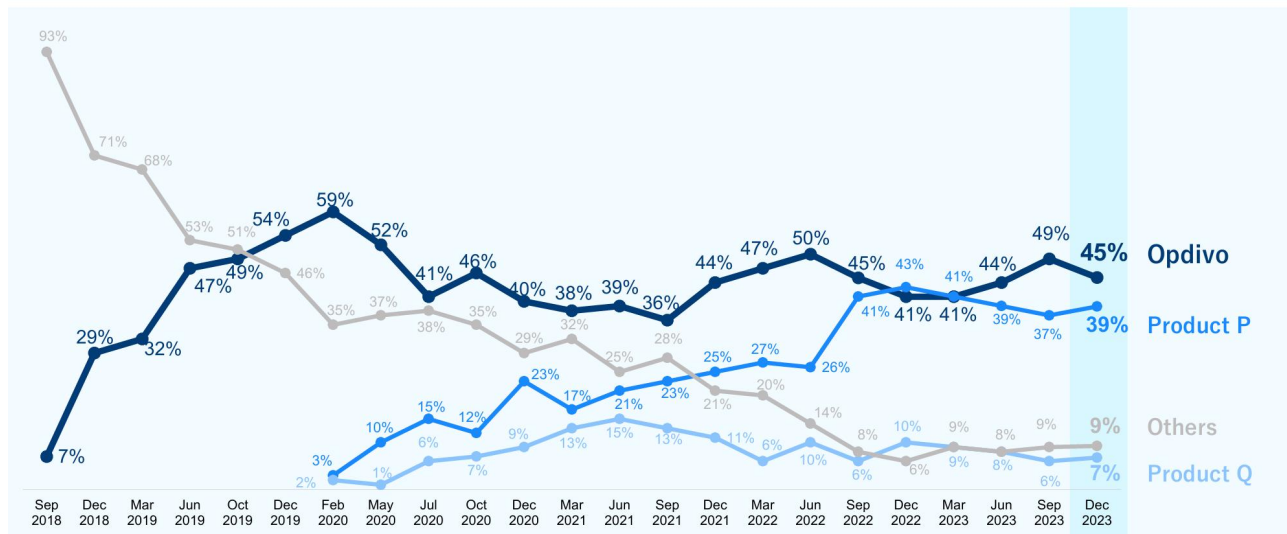
However, although this area is gradually growing, there are still issues to be addressed. In terms of overcoming this issue, I mentioned at the beginning that there are differences in the perception of high-risk patients among physicians. We will continue to work on this, as the number of confirmed prescription cases is gradually increasing due to information provision activities, such as doctor-to-doctor activities.

On the other hand, there was no OS data, which had been an issue since the initial approval. Follow-up data on CheckMate-274 were published by the European Association of Urology in April of this year. The results of DFS and OS became available.

The median DFS was 22.9 months, which is excellent, and the overall survival period was 69.5 months, which is a significant trend, although the difference is not yet significant.

Since Opdivo has shown benefits in urothelial carcinoma, which has a high risk of recurrence after curative resection with a poor prognosis, and we believe that we can expand the use of Opdivo and will continue our efforts here.

## Prescription Ratio in Patients Newly Treated\* for 1L RCC



\*Patients starting treatment within the last 3 months

Source: External data (Sep 2018-Dec 2023: n=46-150)

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Lastly, this is the area of renal cell carcinoma in the field of urology.

Currently, the market share of new patient prescriptions is 45%, and although it was once overtaken by a competitor, the Opdivo regimen has taken over the number one position by continuing to provide information without slowing down.

The competition in this area will continue to intensify in the future, but we are determined to maintain our strong presence here.

This was the last slide that I had to explain.

In FY2024, there are negative factors, but as I indicated earlier, there are also many positive factors, and we will strengthen our sales activities to eliminate the negative factors and create a foundation for a turnaround.

Especially in the gastrointestinal field, where competition is intensifying, we have been maintaining our top prescription ratio in newly treated patients, and ONO's corporate reputation is currently number one in the external evaluation by medical representatives. We will continue to be number one in terms of both quantity and quality and continue to build an entry wall against the competition.

Also, in the lung cancer field, where there are a large number of eligible patients, we will restore new prescriptions, just as we did in the kidney cancer field.

We also believe that we can expect further sales expansion by entering new areas, such as hepatocellular carcinoma, and by obtaining approval for new regimens in lung cancer, colorectal cancer, and urothelial cancer.

We will continue our activities to meet the unmet needs of cancer patients, as we hope to bottom out this fiscal year and re-enter the growth phase from FY2025 onward.

## Question & Answer

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**Imura:** Now, we would like to answer your questions. For those in the venue, if you have any questions, please raise your hand.

**Sakai:** This is Sakai from UBS Securities.

I heard Mr. Takahagi just said that Opdivo is entering the recovery phase. In yesterday's news article, it was written that Mr. Sagara said that Opdivo may have already reached its peak, and the contrast between the two was very strong. What should I think of this?

I would like to ask you again about Opdivo. I think the lung cancer area is still the key, and this should be protected. I think it is a part that should be protected rather than increasing or recovering, but I get the impression that it is still affected by the JCOG data.

Could you first tell us about these two points?

**Sagara:** I did not say that Opdivo sales would peak, nor did the article. I mentioned that royalties may have peaked, but in terms of domestic sales, I said that sales will continue to grow, as there is still hope that new efficacy will emerge.

Wasn't the article about royalty?

**Sakai:** I don't know. I only peeked at the article, but my impression was that you said last fiscal year, overall, was the peak for Opdivo.

**Sagara:** I didn't say that, so, I will tell you that this is a misunderstanding.

What I mentioned yesterday was about the royalties that exceeded JPY180 billion. From here, JPY17 billion was a onetime matter with AstraZeneca, so this will go away. There are royalties from Merck and Roche and others, which are JPY30 billion-plus. On the other hands, considering that, we will still receive royalties from BMS, and it will increase.

**Takahagi:** As for lung cancer, I believe that JCOG data has had an impact. However, after the results of the study, we had data on a large number of cases, both in clinical trials and after marketing, and we continued to carefully introduce this data to doctors.

Also, regarding cytokine release syndrome, we believe that the decline in new prescriptions has already bottomed out with the help of specialists and by organizing numerous seminars throughout the country to introduce our product in a careful manner. I believe that we are entering a phase where we can recover from the uncertainty of the Opdivo regimen regarding safety at every facility.

In this context, follow-up data that we can continue to provide is our strength, and especially for negative cases, competing IO formulations from other companies do not seem to provide very good data. The doctors' expectations for this area are still high, and if they are well matched, we will be able to achieve a recovery.

However, as you mentioned, the lung cancer field has a very large number of patients, and we believe that one of the pillars of this fiscal year is to achieve a solid recovery in this area.



**Sakai:** One more thing, regarding dividends and returns, I mean, the shareholder return policy. This time, a dividend payout ratio of 40% has been announced. On the other hand, dividends are maintained or increased on a progressive policy. Why did you announce a 40% dividend payout ratio now?

Naturally, if EPS increases, I think there is a possibility that the dividend will increase if the dividend payout ratio is 40%, but on the other hand, I am skeptical that such a situation will occur.

Then, this time, the main premise is to maintain at least JPY80, and I am not sure how I should think of the table on page 10. Can you explain this?

**Sagara:** For the time being, I think it would be good if you understand that we will maintain the minimum at about JPY80. "For the time being" means for the time being, unless there is another announcement.

**Sakai:** I understand. If I read too deeply or look ahead, if the dividend payout ratio is 40% when the Opdivo cliff comes, the dividend will be reduced, but is that not the way you think?

**Sagara:** I think you can understand from what I said that it won't occur that way.

**Sakai:** Thank you very much.

**Hashiguchi:** My name is Hashiguchi from Daiwa Securities.

At the briefing two years ago, you stated that the targets for FY2026 were an operating margin of 25% or more and R&D expenses of 20% to 25% of sales. This fits into the current earnings forecast, but I wonder how it will change if the Deciphera acquisition comes in. I feel that it may be deviating a bit from this framework. Could you tell us again what your mid-term forecast is for FY2026 and beyond?

**Sagara:** As you say, I believe that when the time comes to incorporate the Deciphera acquisition into the current year's results and to be able to announce it, it will probably be less than 25%.

Regarding how to revise it, we will announce how to revise the forecast for FY2026 when it actually occurs. By "when it actually occurs," I mean the time when the Deciphera acquisition can be incorporated into our financial results.

Until the Deciphera acquisition happens, it will not be revised. It is 25%, right?

**Hashiguchi:** Yes. Is the outlook for FY2026 unchanged on an organic basis?

**Sagara:** It hasn't changed.

**Hashiguchi:** When should we expect the update?

**Sagara:** The acquisition, or TOP, has not yet been completed, so we have to start working on it promptly after it is completed.

**Hashiguchi:** Thank you.

**Yamaguchi:** My name is Yamaguchi from Citi group.

I would like to ask more about the previous question. As for Deciphera, since it is closing in Q2, do you basically expect to include P&L from H2, or has that not been decided yet? Can you tell us a little bit about it?

**Ito:** If it happens in Q2 as planned, it will be included in this fiscal's P&L for the number of months since the acquisition.

**Yamaguchi:** I see. Also, I think impairment has been in the pipeline a bit lately. Your company still has quite a bit of intangible assets, but if you have any major items in this category, could you please disclose them to us? There should be introduced products, if any.

**Ito:** I think the big one is Forxiga, which we introduced and has a lot of goodwill. When it comes to the balance in terms of licenses, there are no big ones anymore.

**Yamaguchi:** No? Not included Forty Seven?

**Ito:** As for Forty Seven, it is included, but the balance is not much, as milestone has not yet accumulated.

**Yamaguchi:** So, it's not very big.

**Ito:** No.

**Yamaguchi:** I see.

Also, you explained various aspects of Opdivo as a whole, which were easy to understand. In terms of the current fiscal year, drug prices have been falling, and many of them are roughly 15% lower than they would have been. I think you are exactly right that only the urothelial carcinoma is a bit increased.

You mentioned that it will grow when drug prices become neutral from the next fiscal year onward. It can be just the image, but there are many kinds of growth. What is the volume growth you are looking at in your mind, Mr. Takahagi? Double digits can be tough, but will it be low single digit or high single digit?

**Takahagi:** Thank you.

I think the higher the volume growth, the better, but I would like to provide a more detailed explanation regarding next fiscal year at another time.

However, the extent of recovery in lung cancer, for example, is likely to be a factor in the increase in the next fiscal year and beyond. We also believe that there is still room for growth in esophageal cancer and urothelial cancer, so these three cancers are growth factors.

Also, there will be competition in the gastric cancer field, so depending on how well do we outperform the competition, the width of that will change, so I would like to report on that later.

**Yamaguchi:** As for gastric cancer, Keytruda is one thing, but I think it's Vyloy, which I think will come in the future. Although the drug price has not yet been decided, I think that your company's original view was that small competition may occur in only certain segments. It is still too early, but is there anything you can comment on?

**Takahagi:** The max is 10%.

**Yamaguchi:** You mentioned that, originally. Do you feel that not much has changed?

**Takahagi:** No. No change. On the contrary, I am now thinking that we can make the percentage less.

**Yamaguchi:** I see.

Lastly, the application for Nivolumab subcutaneous injection has been completed in the United States, and although it is in Phase I in Japan, I think it will be something like bridging, so I wonder if you are getting close to the time when you can apply for subcutaneous injection in Japan. What do you think about that?

**Okamoto:** Thank you.

As for the timing of the application, I would like to refrain from being more specific. There is no difference in Opdivo itself between Japan and other countries, so even if it is injected subcutaneously, we do not think there is any particular difference between Westerners and the Japanese. Once Phase I is complete, we will consider the possibility of applying at the appropriate time while also assessing various external factors.

**Yamaguchi:** When will Phase I end?

**Okamoto:** Phase I is a dose-escalation study, so it is difficult to say exactly when it will end. However, it will not take long.

**Yamaguchi:** Yes, I understand. Thank you. That's all.

**Akahane:** I am Akahane from Tokai Tokyo Intelligence lab.. I have three brief questions.

I am looking at pages 24 and 25 of the material. Opdivo is struggling because the NHI price was lowered by 15%. You mentioned esophageal cancer and non-small cell lung cancer, which have been the focus of attention, but do you think 15% cannot be absorbed, and a slight drop in sales will occur? Conversely, is it correct to think that urothelial cancer absorbs 15% and is seen as positive on a monetary basis?

**Takahagi:** First, in terms of esophageal cancer, it is seen as positive on a volume basis. However, it is still difficult to absorb the reduced drug price.

As for urothelial carcinoma, the volume base is positive, of course, but the monetary base is just a little short of reaching the target.

**Akahane:** I understand very well.

The second question is on page nine. The 15% NHI price reduction of Opdivo resulted in reducing the sales by JPY20.5 billion. Then, the chart says that the NHI price revision caused a JPY29 billion decline. Since you mentioned a 1% increase in volume, more than 80% of the decrease is due to Opdivo NHI price reductions.

What I would like to ask is, how much will this reduce Opdivo's profit as sales for your company, if not quantitatively, but qualitatively?

It simply says that profits will decrease by JPY37.5 billion, which, when calculated, is almost entirely explained by the decrease in the rate of fees. I am sure that Opdivo's profit will decline in sales, but you will increase the volume, so what kind of image do you have of profit?

**Ito:** Regarding the Opdivo profit, there are manufacturing costs and royalties paid on sales, so I don't think the actual rate or cost ratio was disclosed.

However, I don't think it is that much different from the overall cost rate, if the royalties are all included.

**Akahane:** I understand very well.

This is a bit of a vague question, but you have announced a 10.5% decrease in sales and a 23.7% decrease in operating profit in your latest forecast.

Looking at the NHI price revision this time, I think that your company is being tailgated and is receiving unreasonable price reductions.

What I would like to ask you is what you think about the NHI price revision. In creating guidance, of course, not only investors, but also the government agencies are looking at it. Since the price was lowered by 15% this time, and if sales and profits decline in the single digits even after reducing costs, I wonder how you think about the government.

Looking at your company this time, I see that some companies are withdrawing unprofitable products, and some companies are issuing drastic numbers when issuing guidance. Does this factor into your company's business forecasts?

In other words, it's frustrating if it doesn't have that much of an impact at all, and if you don't show that it had an impact in the first place, it will give the impression to the government that you are still making so much money at the time of the next drug price revision.

Is this something you take into consideration when you create guidance?

**Sagara:** I have feelings about it, but the reality is, I put the feelings aside and create guidelines.

**Akahane:** You mean creating guidance that is straightforward?

**Sagara:** Yes, that's what I mean.

**Akahane:** I understand very well. That's all.

**Imura:** The time is up, so we will conclude today's briefing.

Thank you very much for taking time.