ONO PHARMACEUTICAL CO., LTD.

Presentation of FY2023 Q3 Business Results to Institutional Investors and Business Analysts

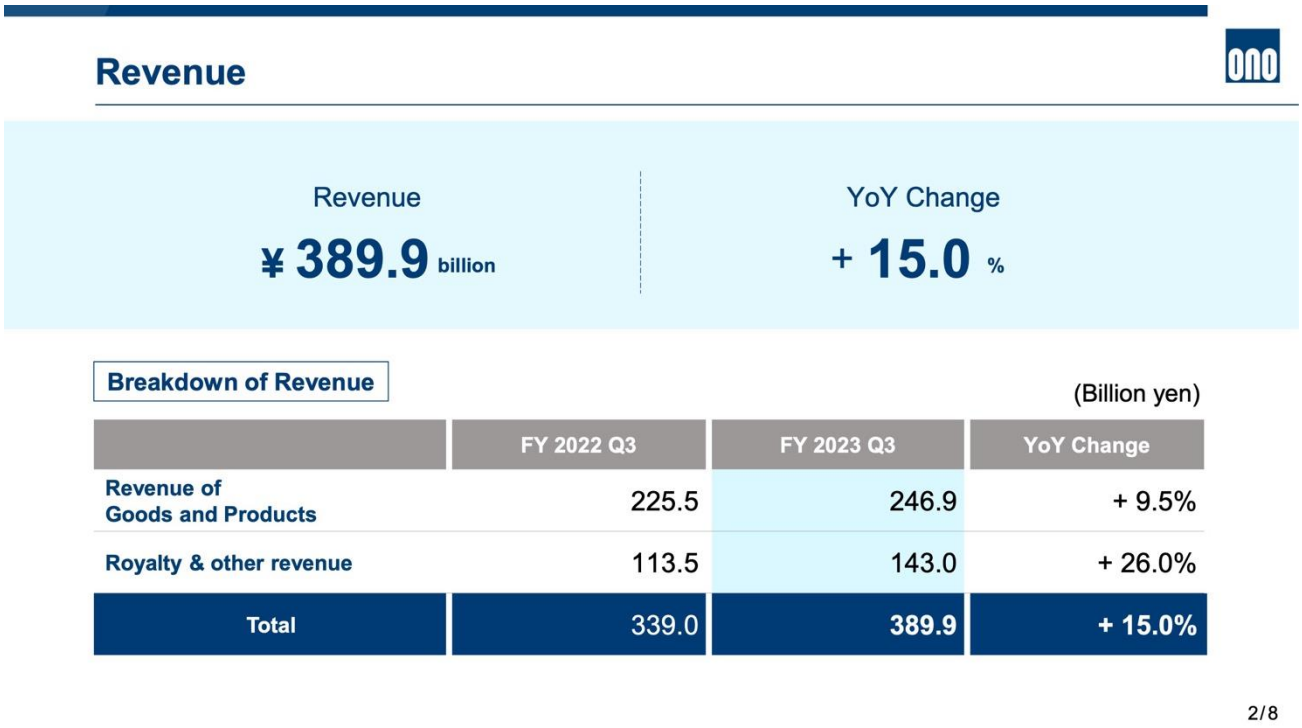
January 31, 2024

[Number of Speakers]	4	
	Satoshi Takahagi	Corporate Officer, Executive Director of Sales and Marketing
	Masaki Ito	Corporate Officer, Division Director, Corporate Strategy & Planning, Business Management Division
	Tatsuya Okamoto	Corporate Officer, Deputy Executive Director, Clinical Development
	Ryuta Imura	Senior Director, Corporate Communications

Presentation

Imura: Thank you very much for joining us today at ONO PHARMACEUTICAL CO., LTD.'s financial results briefing for Q3 of the fiscal year ending March 31, 2024.

First, Mr. Ito will provide an overview of the financial results.



Revenue

Revenue	YoY Change
¥ 389.9 billion	+ 15.0 %

Breakdown of Revenue

(Billion yen)

	FY 2022 Q3	FY 2023 Q3	YoY Change
Revenue of Goods and Products	225.5	246.9	+ 9.5%
Royalty & other revenue	113.5	143.0	+ 26.0%
Total	339.0	**389.9**	**+ 15.0%**

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Ito: I would like to present a summary of the financial results for Q3 of the current fiscal year.

First, let's look at revenue. Net sales for Q3 amounted to JPY389.9 billion, up JPY50.9 billion or 15% from the same period last year. By product, sales of Opdivo for intravenous infusion, Forxiga tablets, and other products remained solid, resulting in a YoY increase of JPY21.4 billion, or 9.5%, to JPY246.9 billion. Royalties and others increased JPY29.5 billion, or 26%, from the same period last year to JPY143 billion.

Included in this royalty and others are royalty income of JPY73.9 billion from Bristol-Myers Squibb related to Opdivo for intravenous infusion, an increase of JPY7.1 billion from the same period last year, and royalty income of JPY38.9 billion from Merck related to Keytruda, an increase of JPY5.4 billion. In addition, upfront payment income from the settlement of a patent-related lawsuit from AstraZeneca, which was already recorded in Q2, includes JPY17 billion.

Revenue

Sales of Major Products

(Billion yen)

	FY 2022 Q3	FY 2023 Q3	YoY Change
Opdivo	109.1	114.9	+5.3%
Forxiga	41.9	57.5	+37.3%
Orencia SC	19.1	20.0	+4.8%
Glactiv	17.7	16.7	-5.3%
Velexbru	6.5	8.0	+22.0%
Kyprolis	6.8	7.1	+4.8%
Parsabiv	6.5	6.4	-2.0%
Ongentys	3.8	4.9	+27.0%
Onoact	3.6	3.4	-5.2%
Braftovi	2.5	2.7	+6.2%
Opalmon	3.4	2.9	-16.0%
Mektovi	2.0	2.0	+2.1%

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The following is an overview of the status of our main products.

Sales of the anti-cancer agent Opdivo for intravenous infusion increased by JPY5.8 billion or 5.3% from the same period last year to JPY114.9 billion, due to increased use in gastric cancer, esophageal cancer, and urothelial cancer, despite intensified competition from other competing products.

Other major new products included Forxiga tablets for diabetes, chronic heart failure and chronic kidney disease, up JPY15.6 billion or 37.3% to JPY57.5 billion; Orencia subcutaneous injection for rheumatoid arthritis, up JPY0.9 billion or 4.8% to JPY20 billion; Velexbru tablets for anti-malignant tumor, up JPY1.4 billion or 22% to JPY8 billion; Kyprolis tablets for multiple myeloma, up JPY0.3 billion or 4.8% to JPY7.1 billion; and Ongentys tablets for Parkinson's disease, up JPY1 billion or 27% to JPY4.9 billion.

On the other hand, sales of Glactiv tablets, a treatment for type 2 diabetes, decreased JPY0.9 billion or 5.3% to JPY16.7 billion, and sales of Parsabiv for intravenous dialysis, a treatment for secondary hyperparathyroidism under hemodialysis, decreased JPY0.1 billion or 2% to JPY6.4 billion.

Operating Profit

Operating Profit	YoY Change
¥ 144.6 billion	+ 18.0 %

Costs, etc.

(Billion yen)

		YoY Change	
Cost of Sales	95.5	+13.9%	
R&D Expenses	76.5	+15.9%	①
SG&A Expenses	73.3	+10.8%	②
① + ② Total	149.8	+13.4%	
Other Income	1.0	+89.0%	
Other Expenses	1.0	- 3.2%	

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Next is operating profit.

Operating income increased JPY22 billion, or 18%, from the same period last year to JPY144.6 billion.

On the cost of sales side, cost of sales increased by JPY11.7 billion, or 13.9%, to JPY95.5 billion, mainly due to an increase in product sales and recording of a JPY5.4 billion impairment loss on sales rights for Joyclu joint injection and Adlumiz tablets.

R&D expenses increased JPY10.5 billion, or 15.9%, YoY to JPY76.5 billion, due to an increase in expenses related to research and development costs related to clinical trials.

Sales and general administrative expenses, excluding R&D expenses, increased JPY7.1 billion, or 10.8%, to JPY73.3 billion due to co-promotion expenses associated with the sales expansion of Forxiga tablets and increased expenses associated with the strengthening of IT and digital-related information infrastructure.

As a result of the above, operating income increased JPY22 billion, or 18%, to JPY144.6 billion.

Profit before Tax

Profit before Tax	YoY Change
¥ 147.3 billion	+ 18.4 %

Net financial income, etc.

+ ¥ 2.7 billion (YoY Change + ¥ 0.9 Billion)	
Finance income :	¥ 3.1 billion
(Dividend income, Interest income, etc.)	
Finance costs :	¥ 0.5 billion
(Exchange losses, etc.)	

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Furthermore, regarding income before income taxes, financial income was JPY3.1 billion and financial expenses were JPY0.5 billion, resulting in a positive financial balance of JPY2.7 billion, an increase of JPY0.9 billion from the same period last year, and income before income taxes was JPY147.3 billion, an increase of JPY22.9 billion or 18.4% YoY.

Profit for the Period (Owners of the Company)

Profit for the Period (Owners of the Company)	YoY Change
¥ 110.5 billion	+ 15.6 %

Income tax expense

¥ 36.7 billion (YoY Change + 28.5 %)

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Due to the increase in income before income taxes, quarterly income attributable to owners of the final parent company amounted to JPY110.5 billion, up JPY14.9 billion, or 15.6%, from the same period last year. Both sales revenue and profits at each level were the highest ever recorded for Q3.

Financial Forecast for FY 2023

Financial forecast is unchanged from that announced on November 1, 2023

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Revenue	447.2	**500.0**	**+ 11.8 %**
Operating profit	142.0	**167.0**	**+ 17.6 %**
Profit before tax	143.5	**169.0**	**+ 17.7 %**
Profit for the year (Owners of the Company)	112.7	**126.0**	**+ 11.8 %**

Exchange rate
FY 2023 (Forecast (2nd Half)): 1USD = 140 yen

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We continue with our full-year forecast for the fiscal year ending March 31, 2024. On November 1 last year, we revised our earnings forecast for Q2 of last year, but we have not revised our forecast for the full year. On the other hand, regarding the sales forecasts for each major product listed on page 12 of the financial results, the forecasts for some products have been changed.

Revenue (Forecast)

Sales Forecasts of Major Products

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Opdivo	142.3	150.0	**+5.4%**
Forxiga	56.5	75.0	**+32.7%**
Orencia SC	24.8	25.5	**+3.0%**
Glactiv	22.5	21.0	**-6.7%**
Velexbru	8.5	9.5	**+11.3%**
Kyprolis	8.7	8.5	**-2.3%**
Parsabiv	8.4	8.0	**-4.8%**
Ongentys	5.0	6.5	**+30.5%**
Onoact	4.5	4.5	**+0.4%**
Braftovi	3.2	4.0	**+23.2%**
Opalmon	4.4	3.5	**-19.9%**
Mektovi	2.5	3.0	**+18.1%**

※ The sales revenue forecast of Opdivo was revised from 155 billion yen to 150 billion yen.
The sales revenue forecast of Forxiga was revised from 70 billion yen to 75 billion yen.

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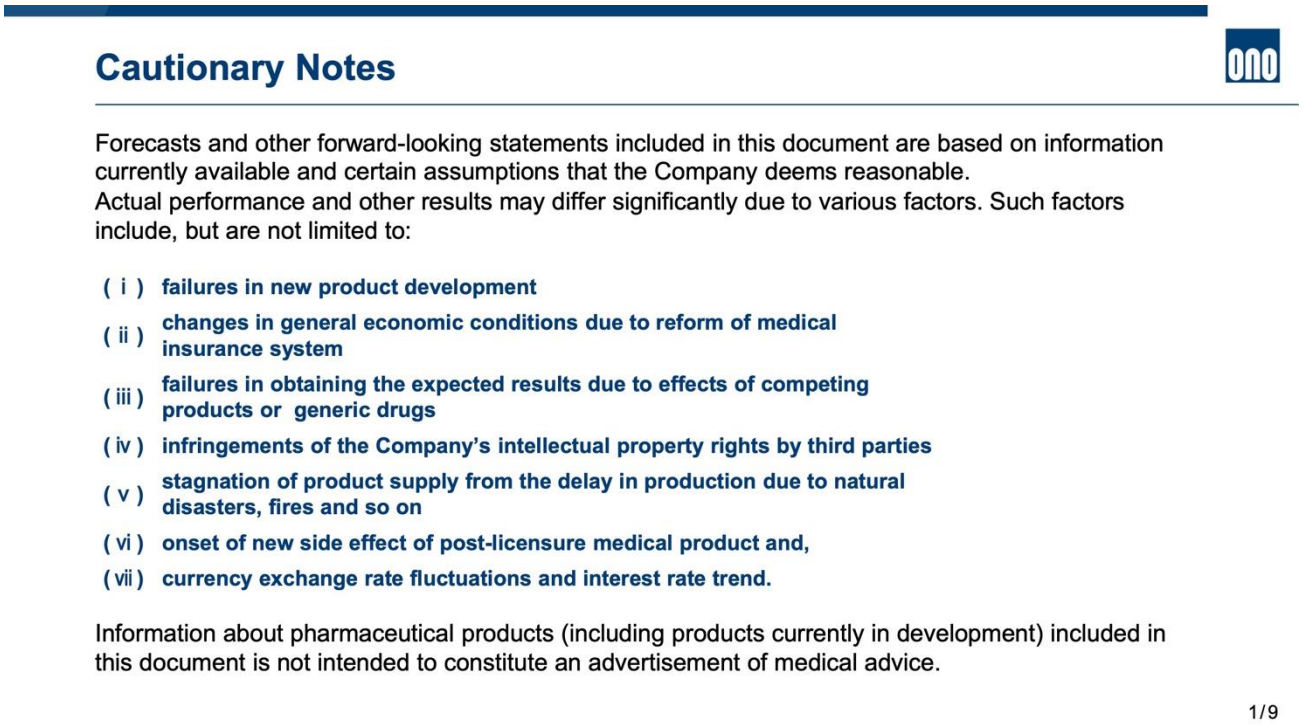
First, we have revised downward our forecast for Opdivo for intravenous infusion by JPY5 billion, and our revised full-year forecast is JPY150 billion, an increase of JPY7.7 billion or 5.4% from the previous year.

Forxiga tablets have been revised upward by JPY5 billion, and the revised full-year forecast is JPY75 billion, an increase of JPY18.5 billion or 32.7% from the previous year.

The year-end dividend will be JPY40 per share, as previously forecasted, and the annual dividend of JPY80 per share remains unchanged at present.

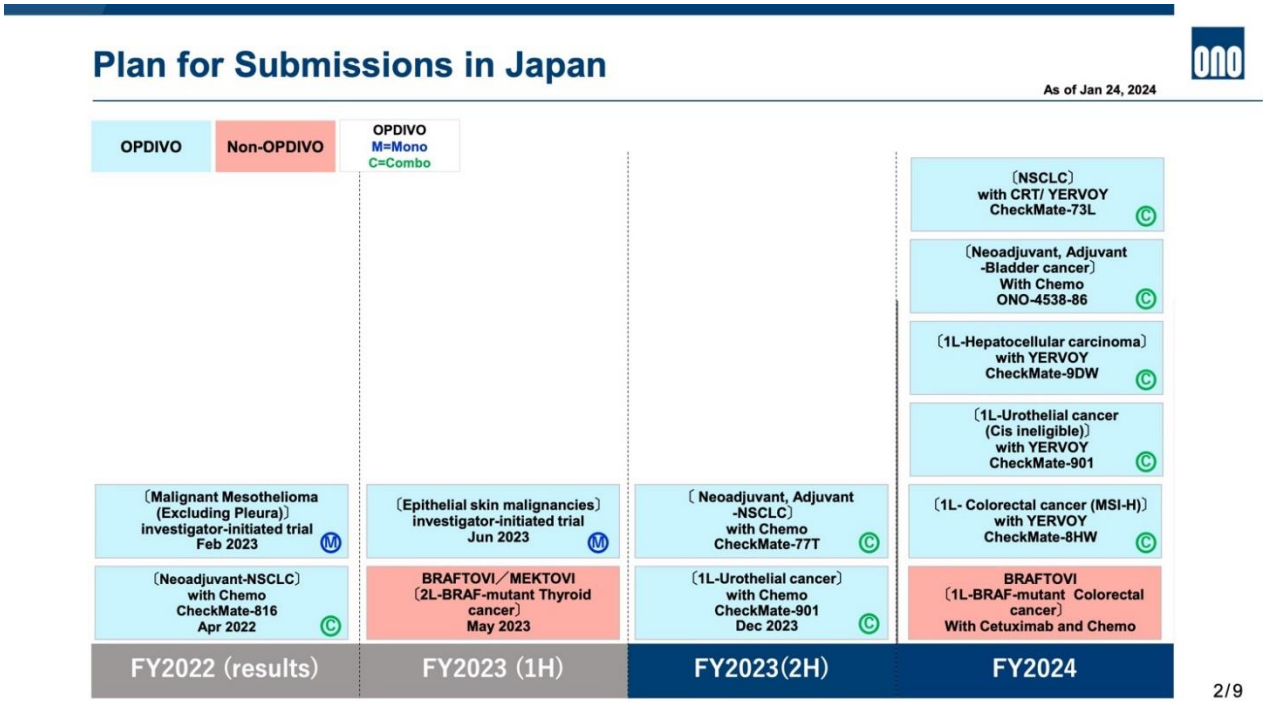
This is a summary report of the Q3 financial results.

Imura: We will continue with an explanation of the progress of our main development pipeline.



Okamoto: I would like to explain the progress of the development pipeline, using the materials on our website, focusing on the changes that have occurred since November 1 last year.

First, a general note. Please take note of this.



I will begin by explaining our plans for future and domestic applications.

The timing of the application is the earliest possible date if all goes according to plan. Therefore, please be aware that the situation may change in the future.

In H2 of FY2023, we filed an application for approval in Japan based on the CheckMate-901 study, a global Phase III study of Opdivo in combination with chemotherapy for first-line urothelial carcinoma on December 18, 2023. In addition, the Company plans to submit an application for approval in Japan based on CheckMate-77T, a global Phase III study for preoperative and postoperative adjuvant treatment of non-small cell lung cancer, during this fiscal year as planned.

There is no change in the overall schedule for other applications, but we have already announced the results of the global Phase III CheckMate-8HW study in first-line colorectal cancer with MSI-High, which is scheduled to be submitted for approval in FY2024. As already announced, the primary endpoint has been met.

The hazard ratio of PFS and progression-free survival in the chemotherapy arm of the study was 0.21, which means that it reduced the risk of death or disease progression by approximately 80%. We are currently preparing for the submission of the application so that this highly effective treatment can be delivered to the clinical field as soon as possible.

The application for malignant mesothelioma excluding pleura, on the far left, which was submitted in FY2022, was approved last year on November 24, 2023. The re-examination period is 10 years as an Orphan Drug.

This is all about the domestic application schedule.

Development status of OPDIVO (1)

As of Jan 24, 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	Ⅲ	Ⅲ
	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	–	–	–	–
		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 2Q 2023

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Next, I will explain the major changes in the development status of Opdivo. First, a note on the table, in red below. Updates since the earnings announcement in May are shown in red. Of these, updates since the last time, last November 1, are highlighted in yellow. As for this page, the changes since the last time, we have highlighted the approval for malignant mesothelioma excluding pleura in November 2023 which I mentioned earlier.

Development status of OPDIVO (2)

As of Jan 24, 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	Ⅲ
	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

※Red: Update after May 2023 ※Red: Update after 2Q 2023

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Although there are no highlights, regarding the global Phase III study of ONO-7121, a combination of Opdivo and Relatlimab, an anti-LAG-3 antibody, in third-line and later stage colorectal cancer, the study was conducted by BMS, but unfortunately BMS has decided to terminate the study because it met the pre-defined criteria for futility discontinuation. Therefore, they have been removed from the table.

Development status of OPDIVO (3)

As of Jan 24, 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	Filed	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	Filed	–	–	–	–
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（Comibination with vorhyaluronidase alfa）	Ⅰ	–	–	Ⅲ (RCC)	Ⅲ (RCC)

※Red: Update after May 2023 ※Red: Update after 2Q 2023

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Based on the results of the CheckMate-901 study in first-line urothelial carcinoma, we have filed an application for approval in Japan, so I am updating this page. In addition, BMS has filed for approval in the US and Europe, and we are updating this information as well.

The bottom line is ONO-4538HSC, development code, which is a new combination drug of nivolumab and vorhyaluronidase and is a subcutaneous injection formulation of Opdivo. We have added a note that a Phase I study of this combination drug has been started in Japan.

In the US and Europe, an overseas Phase III study, CheckMate-67T, has been conducted and it has already been announced that the primary endpoints were met.

Clinical trials in combination therapy OPDIVO & other Immuno-Oncology compounds

As of Jan 24, 2024

Development code (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
ONO-4482 (Relatlimab) Anti-LAG-3 antibody	Hepatocellular carcinoma	Ⅱ	Ⅱ	Ⅱ
	Melanoma	Ⅰ／Ⅱ	Ⅰ／Ⅱ	-
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer	Ⅱ	-	Ⅱ
	Colorectal cancer	Ⅰ	-	-
	Pancreatic cancer	Ⅰ	-	-
	Non-small cell lung cancer	Ⅰ	-	-
ONO-7475（Tamnorzatinib） Axl/Mer inhibitor	Pancreatic cancer	Ⅰ	-	-
ONO-7913 （Magrolimab） Anti-CD47 antibody	Pancreatic cancer	Ⅰ	-	-
	Colorectal cancer	Ⅰ	-	-
ONO-7119（Atamparib） PARP7 inhibitor	Solid tumor	Ⅰ	-	-
ONO-7122 TGF-βinhibitor	Solid tumor	Ⅰ	Ⅰ	-
ONO-7914 STING agonist	Solid tumor	Ⅰ	-	-
ONO-7226 Anti-ILT4 antibody	Solid tumor	Ⅰ	Ⅰ	-

※Red: Update after May 2023 ※Red: Update after 2Q 2023

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This page summarizes the status of development in combination with Opdivo, but there is no update at this time.

Development pipeline in Japan (Oncology area other than OPDIVO)

As of Jan 24, 2024

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filed】		
BRAFTOVI (Encorafenib)	BRAF-mutant thyroid cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant thyroid cancer	MEK inhibitor
【Phase Ⅱ】		
ONO-4578	Gastric cancer *	PG receptor (EP4) antagonist
【Phase Ⅰ】		
ONO-4578	Colorectal cancer *	PG receptor (EP4) antagonist
	Pancreatic cancer *	
	Non-small cell lung cancer *	
	Hormone receptor-positive, HER2-negative breast cancer	
ONO-7475（Tamnorzatinib）	Pancreatic cancer *	Axl / Mer inhibitor
	EGFR mutation-positive non-small cell lung cancer	
ONO-7913（Magrolimab）	Pancreatic cancer *	Anti-CD47 antibody
	Colorectal cancer *	
ONO-4685	T-cell lymphoma	PD-1×CD3 bispecific antibody

* Combination with Opdivo ※Red: Update after May 2023 ※Red: Update after 2Q 2023

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Similarly, there is no update on the status of development in Japan in oncology fields other than Opdivo.

Development pipeline in Japan (Non-oncology)

As of Jan 24, 2024

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase Ⅲ】		
ONO-2017（Cenobamate）	Primary generalized tonic-clonic seizures	Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel
	Partial-onset seizures	
VELEXBRU (ONO-4059 : Tirabrutinib)	Pemphigus	BTK inhibitor
【Phase Ⅱ】		
ONO-2910	Diabetic polyneuropathy	Enhancement of Schwann cell differentiation
	Chemotherapy-Induced Peripheral Neuropathy	
【Phase Ⅰ】		
ONO-4685	Autoimmune disease	PD-1 × CD3 bispecific antibody
ONO-1110	Pain	Endocannabinoid regulation

※Red: Update after May 2023 ※Red: Update after 2Q 2023

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There are no updates since the last report for areas other than oncology.

Global development projects (Other than OPDIVO)

As of Jan 24, 2024

Product name/ Development code (Generic name)	Target indication	Pharmacological action	Area
【Phase Ⅲ】			
ONO-7913（Magrolimab）	Acute myeloid leukemia	Anti-CD47 antibody	KR・TW
【Phase Ⅱ】			
ONO-4059（Tirabrutinib）	Primary central nervous system lymphoma	BTK inhibitor	US
ONO-4578	Gastric cancer	PG receptor (EP4) antagonist	KR・TW
ONO-2808	Multiple System Atrophy	S1P5 receptor agonist	US
【Phase Ⅰ】			
ONO-4685	T-cell lymphoma	PD-1 x CD3 bispecific antibody	US
	Autoimmune disease		EU
ONO-2020	Neurodegenerative disease	Epigenetic Regulation	US
ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	MALT1 Inhibitor	US
ONO-8250	HER2-expressing Solid tumor	iPSC-derived HER2 CAR T-cell therapy	US

※Red: Update after May 2023 ※Red: Update after 2Q 2023

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This is a summary of the global pipeline other than Opdivo. The Phase I study of ONO-8250, a CAR-T cell therapy targeting HER2 derived from iPS cells, has been initiated in the United States, and it was added in the bottom of the table

The above is an explanation of the progress of the developed products, focusing on the changes from the previous report.

Imura: Then, Takahagi, Executive Director of Sales and Marketing, will give an overview of the trend of Opdivo.

Cautionary Notes

Forecasts and other forward-looking statements included in this document are based on information currently available and certain assumptions that the Company deems reasonable.
Actual performance and other results may differ significantly due to various factors. Such factors include, but are not limited to:

- (i) **failures in new product development**
- (ii) **changes in general economic conditions due to reform of medical insurance system**
- (iii) **failures in obtaining the expected results due to effects of competing products or generic drugs**
- (iv) **infringements of the Company's intellectual property rights by third parties**
- (v) **stagnation of product supply from the delay in production due to natural disasters, fires and so on**
- (vi) **onset of new side effect of post-licensure medical product and,**
- (vii) **currency exchange rate fluctuations and interest rate trend.**

Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

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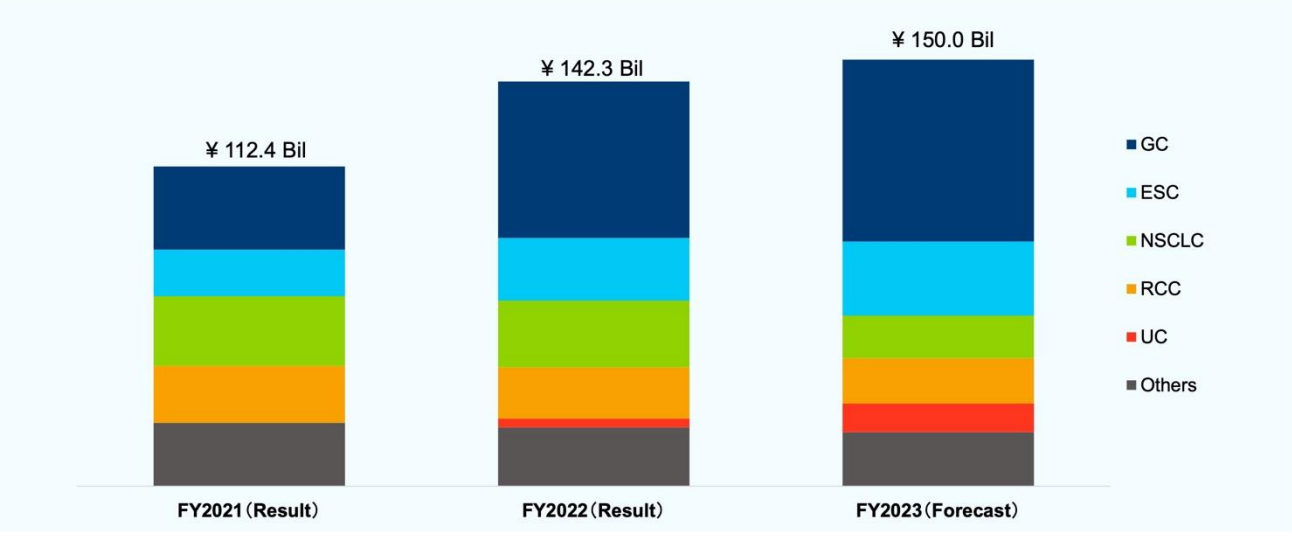
Takahagi: Now, I would like to talk about the Opdivo trend. First, a note of caution.

Sales Trend of Opdivo by Each Cancer



Source: Estimation from external and internal data

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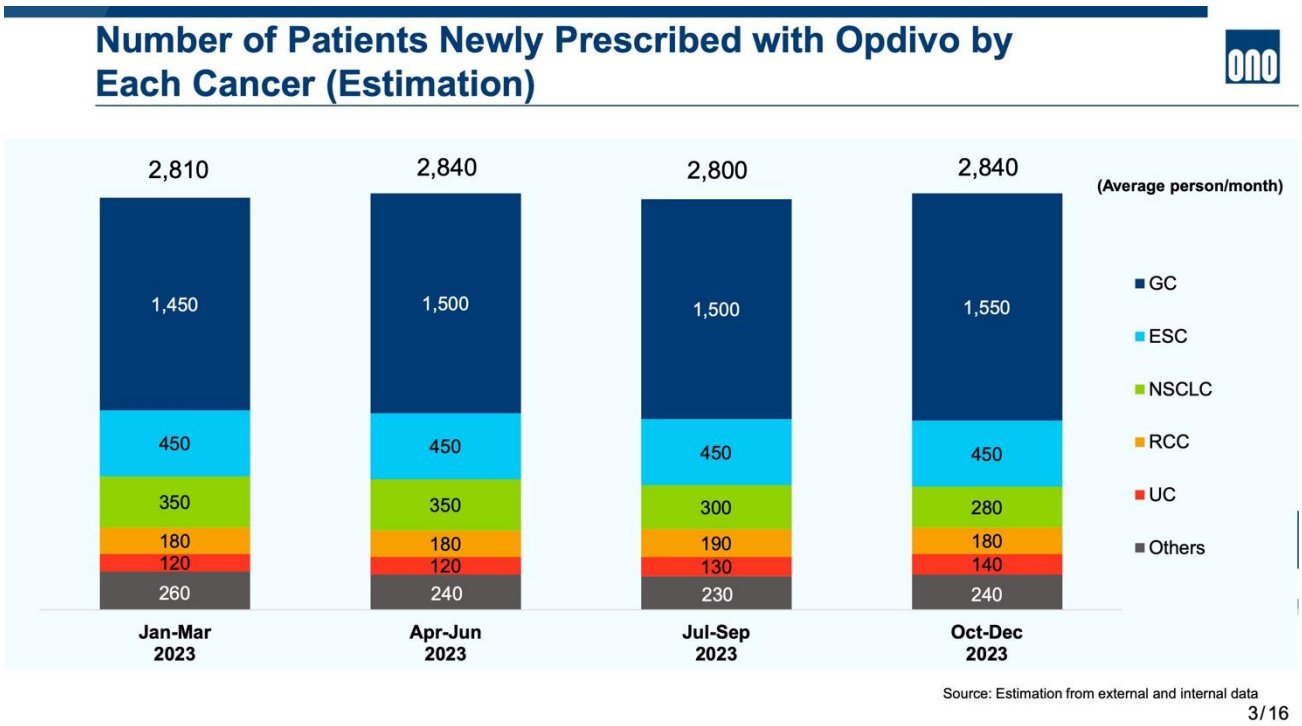
We have revised downward our forecast for Opdivo sales for FY2023. This is due to delays in urothelial carcinoma and non-small cell lung cancer.

First, in the case of urothelial carcinoma, postoperative adjuvant therapy with Opdivo is recommended in the guidelines for bladder cancer treatment, but there is still a difference in the perception of what doctors consider to be patients at high risk of recurrence, and there is a delay in obtaining new prescriptions compared to our initial expectations.

In non-small cell lung cancer, as you are aware, the number of cases of first-line treatment has decreased since last year due to growing concerns about the safety of the Yervoy combination. In 10-12, we believe that the decline in new prescriptions has bottomed out, but the recovery is still slower than originally expected.

However, new clinical data in gastric cancer and renal cell carcinoma that will support our activities are being presented at ASCO GI and ASCO GU in January 2024. We are determined to expand the use of Opdivo.



The following table shows the number of patients newly prescribed Opdivo by carcinoma.

As we have mentioned in the past, we have also presented the average number of patients for each quarter. This is only an estimate, but during October to December in 2023, prescriptions of Opdivo have started with 1,550 cases of gastric cancer, 450 cases of esophageal cancer, and 280 cases of lung cancer.

In particular, prescriptions are being expanded for primary treatment of gastric and esophageal cancer, and for postoperative adjuvant for esophageal and urothelial cancer.

On average, 2,840 new prescriptions are confirmed each month.

Trend of total sales of ICPIs and Opdivo share

Source: External data

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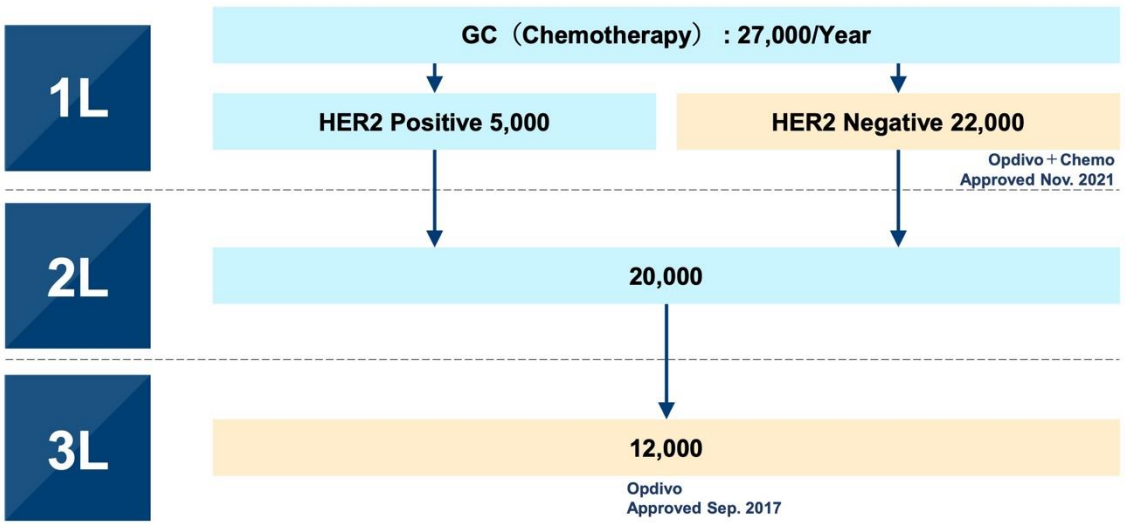
Please refer to page four of the document. This page shows trend of total sales of immune checkpoint inhibitors marketed in Japan and Opdivo's market share. The bar graph shows the total of all immune checkpoint inhibitors and the line graph shows the share of Opdivo. Overall sales of immune checkpoint inhibitors are increasing steadily. As for Opdivo, the current market share is 29%, which is an increase of 3.7% compared to October to December in the previous fiscal year.

Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC



Estimation based on internal survey (2020)

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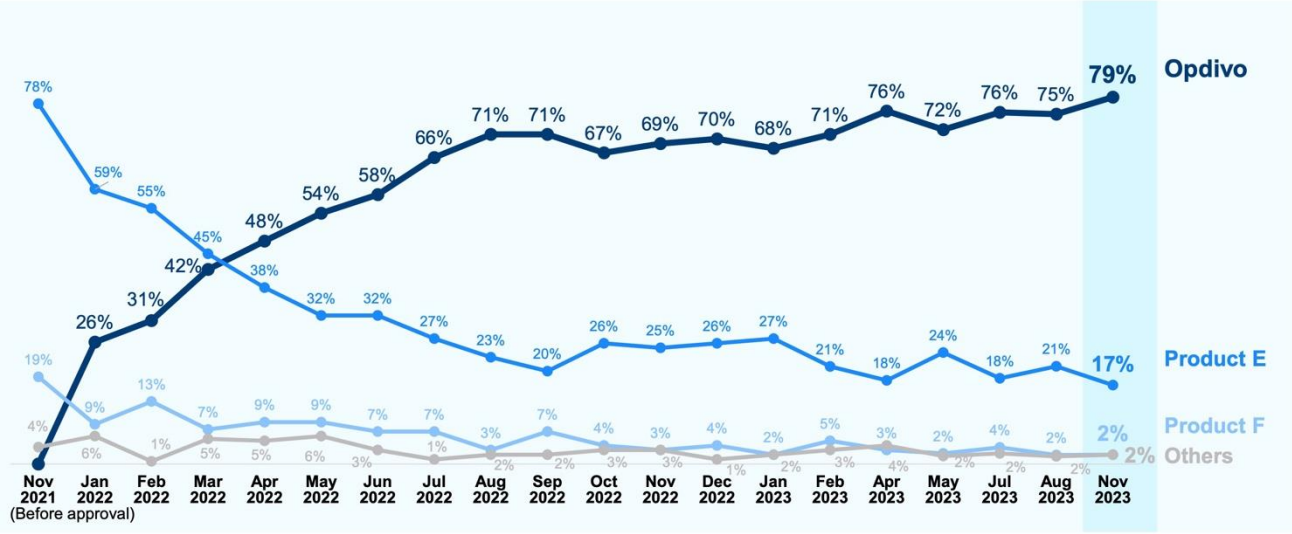
Please refer to page five. From here, we will report by carcinoma. First, in the area of gastric cancer, the number of gastric cancer patients per year. We believe that the annual number of HER2-negative patients eligible for first-line treatment with Opdivo is 22,000, although this is only an estimate.

Prescription Ratio in Patients Newly Treated※ for 1L GC



※Patients starting 1L treatment within the last 3 month

Source: External data（Nov 2021~Nov 2023: n=200~204）

6/16

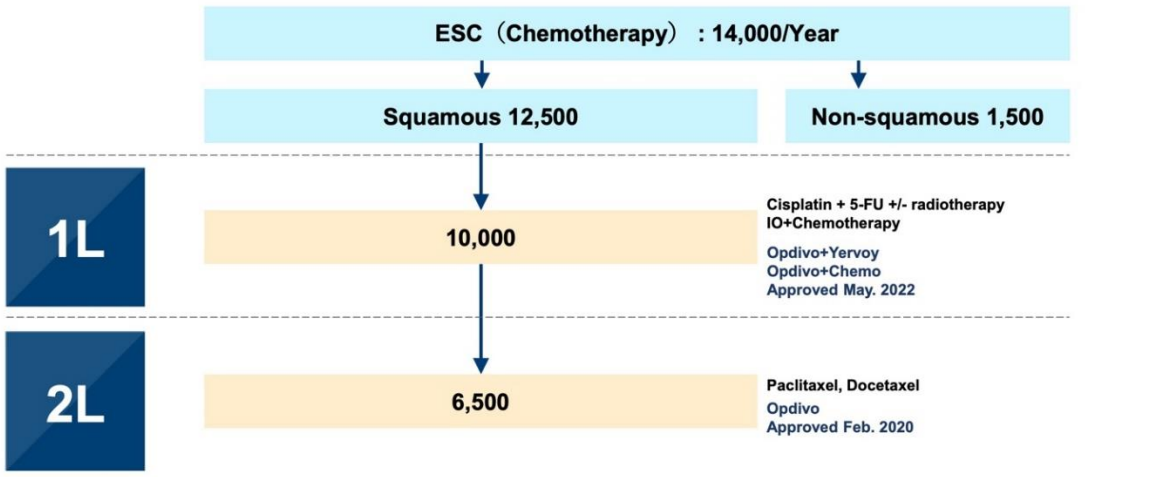
This is the changes of the share of new patient prescriptions for the first-line treatment. The share of new prescriptions has been around 70%, but has recently risen to 79%, indicating that prescriptions are expanding.

At the ASCO GI in January of this year, four-year follow-up data from the CheckMate-649 trial was presented. We believe that we have obtained very useful data that will strongly support our activities in the future.

We believe that the choice of Opdivo chemotherapy as the first-line treatment for gastric cancer patients will increase the expectation of long-term survival. Although we can see that the competitive environment will become very tough in the future, we believe that we can appeal long term benefit with this four-year long-term data, which is unique to Opdivo.

Number of ESC* Patients per year in Japan

* : Unresectable Advanced or Recurrent ESC

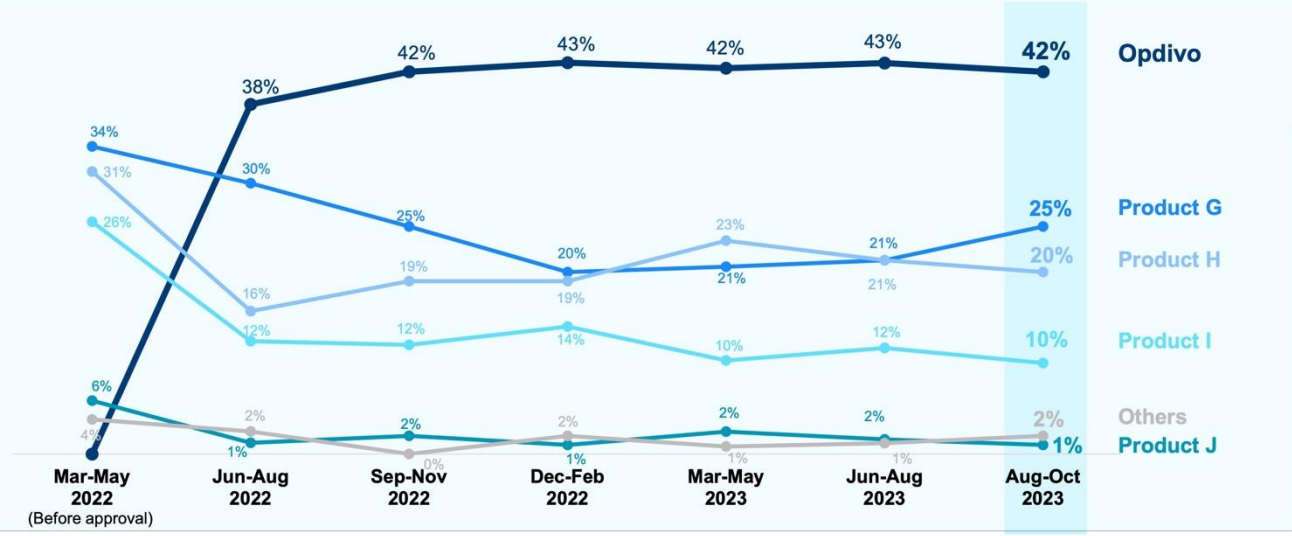


Estimation based on internal survey (2022)

7/16

I will now introduce esophageal cancer. We estimate that the number of patients eligible for first-line treatment with Opdivo per year is 10,000.

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



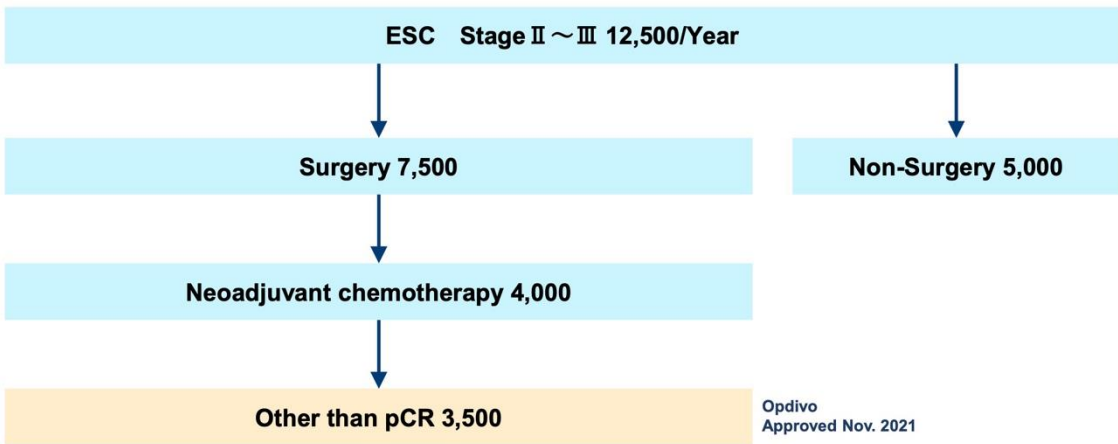
※Patients starting treatment within the last 3 month

Source: External data（May 2022~Oct 2023: n=150~155)

8/16

Opdivo regimen has entered the first line of treatment, and the share of new patient prescriptions for Opdivo regimen is currently 42%. Although I-O regimens, including competing products, have expanded to 60% of first-line therapy, chemotherapy regimens are still in use, leaving a solid segment for expansion of Opdivo regimens. In particular, with Opdivo, we can firmly propose two regimens, one in combination with chemotherapy and the other with Yervoy, as you all know, along with its efficacy. This is also an advantage in that we can make choices, and we would like to further expand this area.

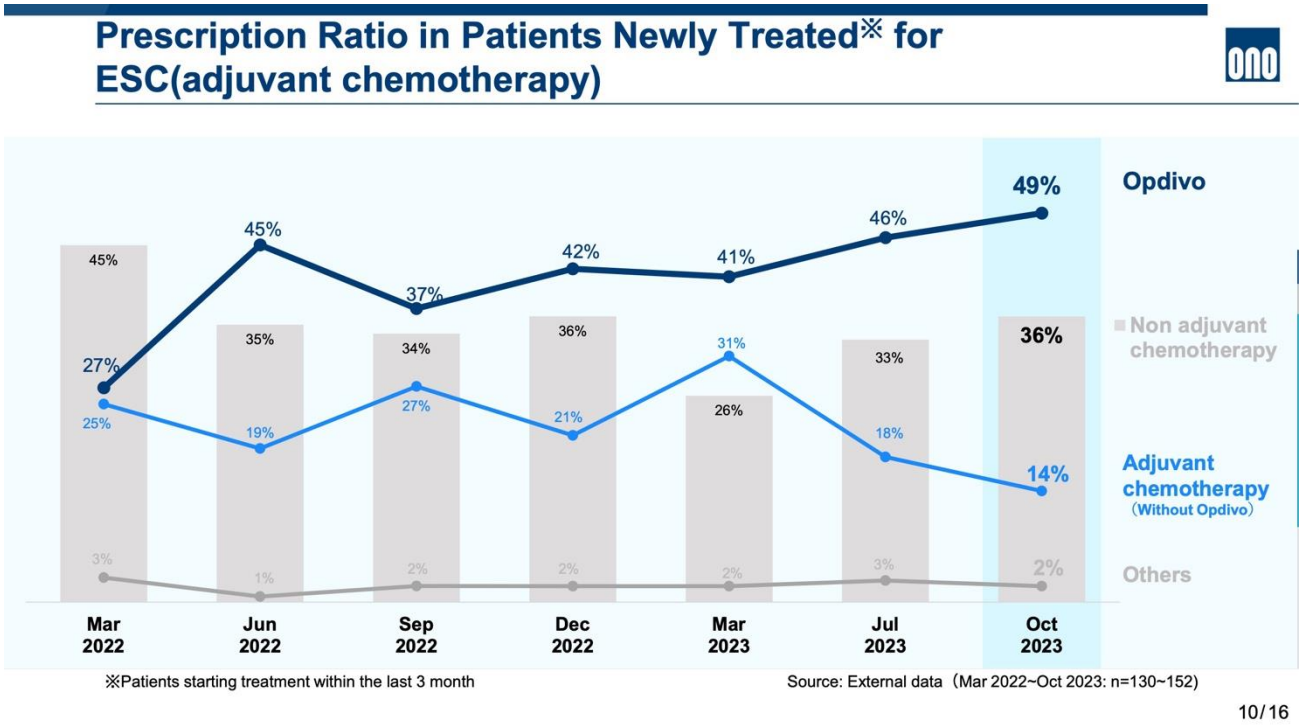
Number of ESC(Perioperative)Patients per year in Japan



Estimation based on internal survey (2022)

9/16

It is a postoperative adjuvant for esophageal cancer. We are looking at 3,500 patients per year with pathologic non-complete response eligible for Opdivo.



The share of new patient prescriptions for postoperative adjuvant for esophageal cancer is now 49% and growing.

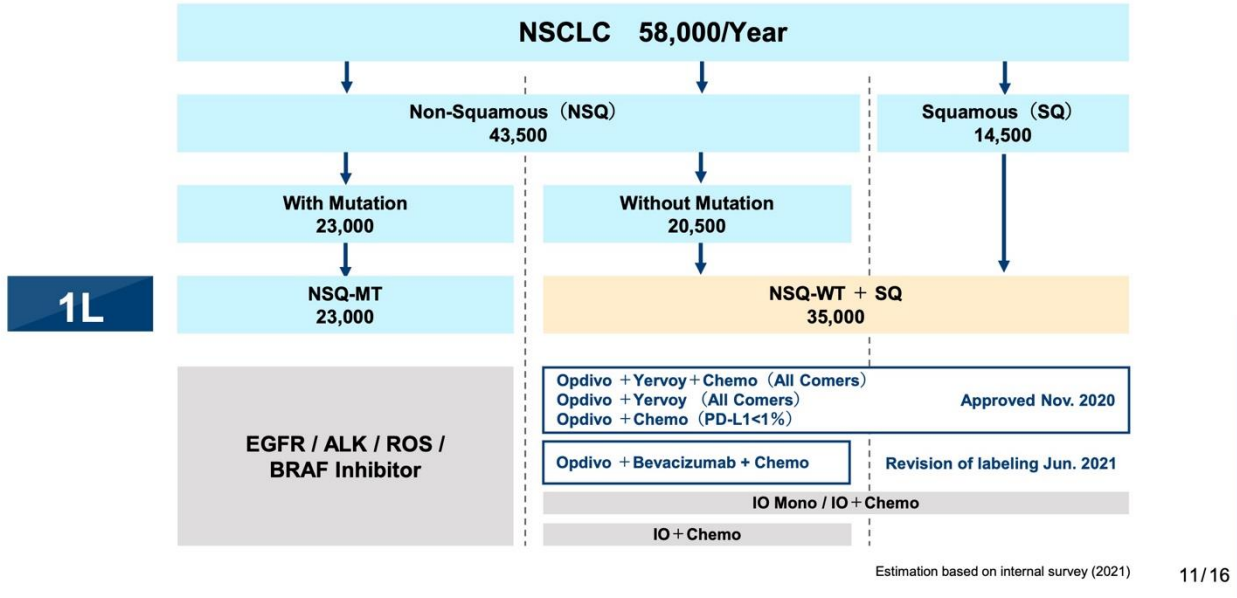
By presenting clinical data accumulated in actual clinical practice at Doctor-to-Doctor lectures, we are currently working to expand prescriptions.

However, there are still patients who receive only adjuvant chemotherapy or no adjuvant chemotherapy, and we believe that there is ample room for further expansion.

We will continue to promote the efficacy of Opdivo to speed up the expansion. In the gastrointestinal field, Opdivo is leading the field of first-line and postoperative adjuvant therapy for gastric and esophageal cancer, and we would like to make a broad-ranging effort for our activity.

Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC

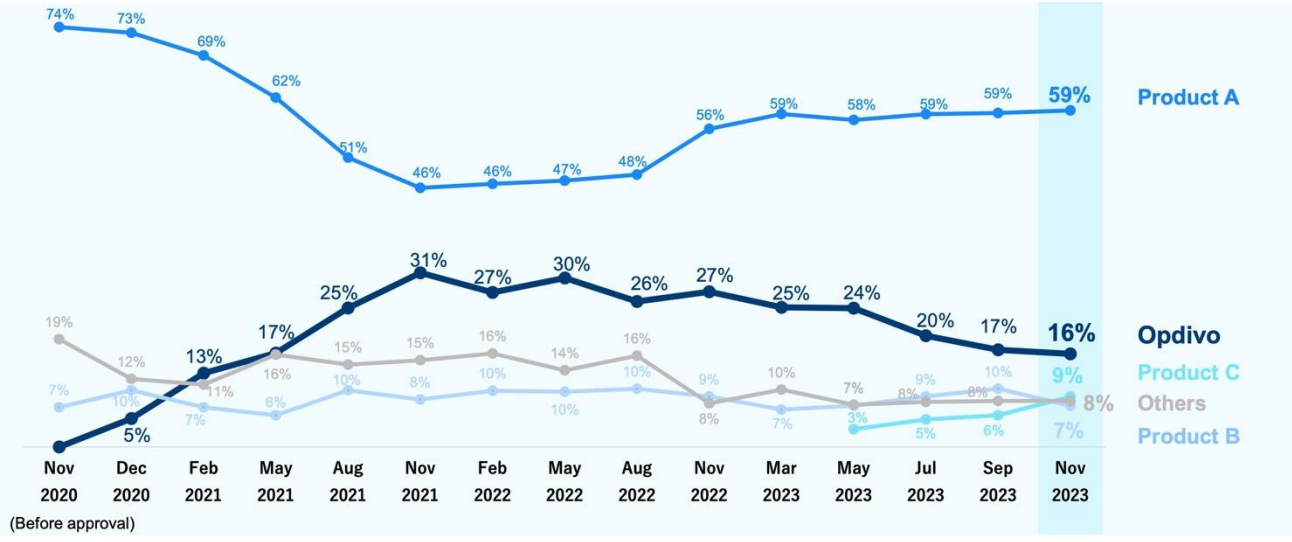


Estimation based on internal survey (2021)

11/16

I would like to continue with the area of lung cancer. We estimate that the annual number of patients eligible for the first-line treatment for lung cancer is 35,000 patients with squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



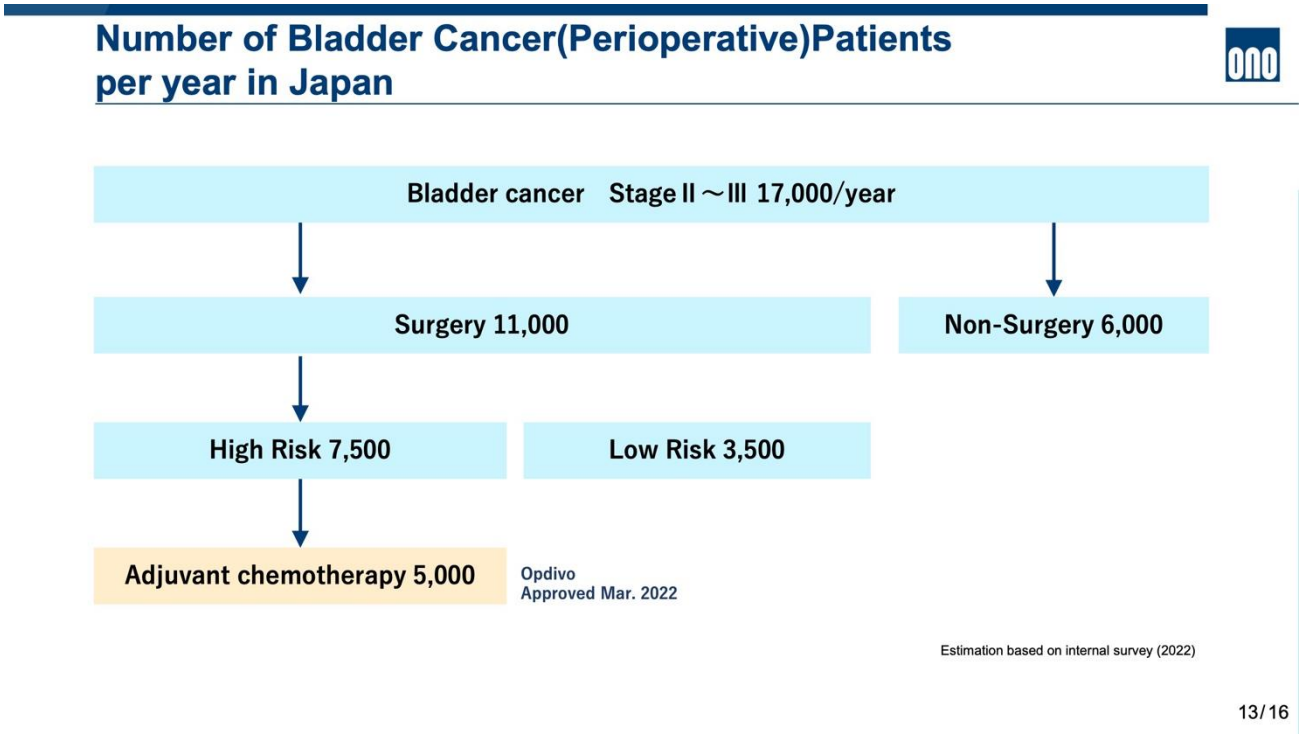
※Patients starting 1L treatment within the last 1 month (Except Driver Mutation)

Source: External data（Nov 2020~Nov 2023: n=167~245）

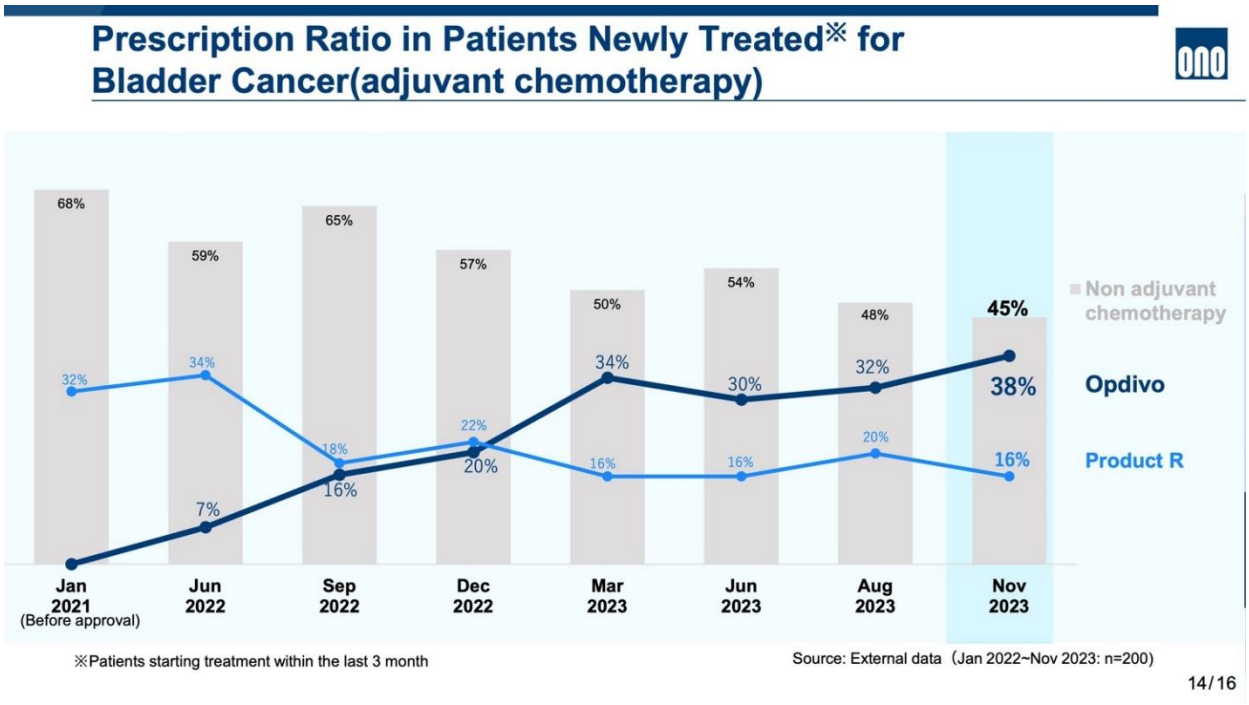
12/16

This is the share of new patients. Opdivo's share of new patients is 16%, and as I explained earlier in the introduction, the recovery in the acquisition of new prescriptions has been slower than originally expected. However, even with the Opdivo regimen, there are patients with very high unmet need for PD-L1 expression levels below 1%. We are currently working hard to support safety measures and irAE's management system, as we have recognized the very significant benefits to this area.

We are determined to expand further as we believe that the drug can contribute to long-term survival for many lung cancer patients in the future by turning both of these things around.



Next is urothelial cell carcinoma. As you all know, bladder cancer accounts for 80% of all urothelial cancers in Japan, so I will introduce this number of patients in the bladder cancer category, which has the largest number of patients. The number of patients eligible for Opdivo postoperative adjuvant is expected to be 5,000 per year.

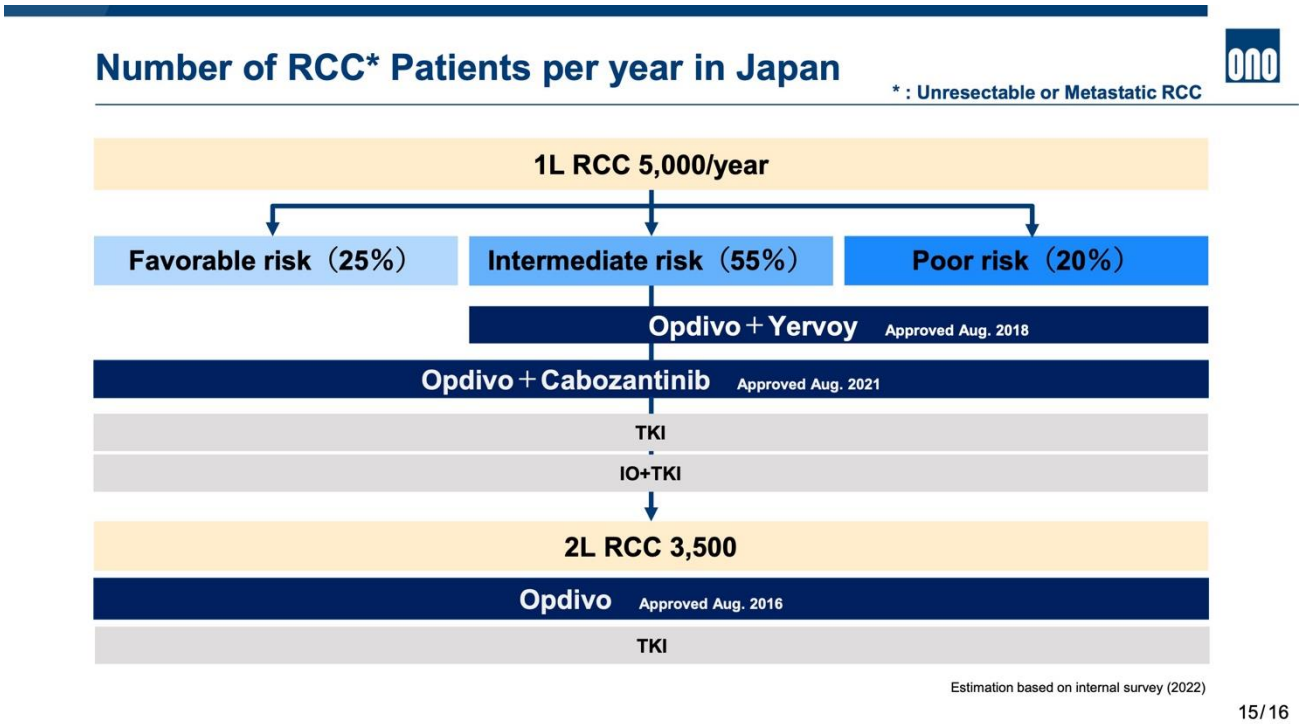


This is a new prescription share.

In July and September of last year, we strengthened our efforts to provide Doctor to Doctor information, and the number of new prescriptions has gradually begun to increase. The share of new prescriptions is on an upward trend and currently stands at 38%.

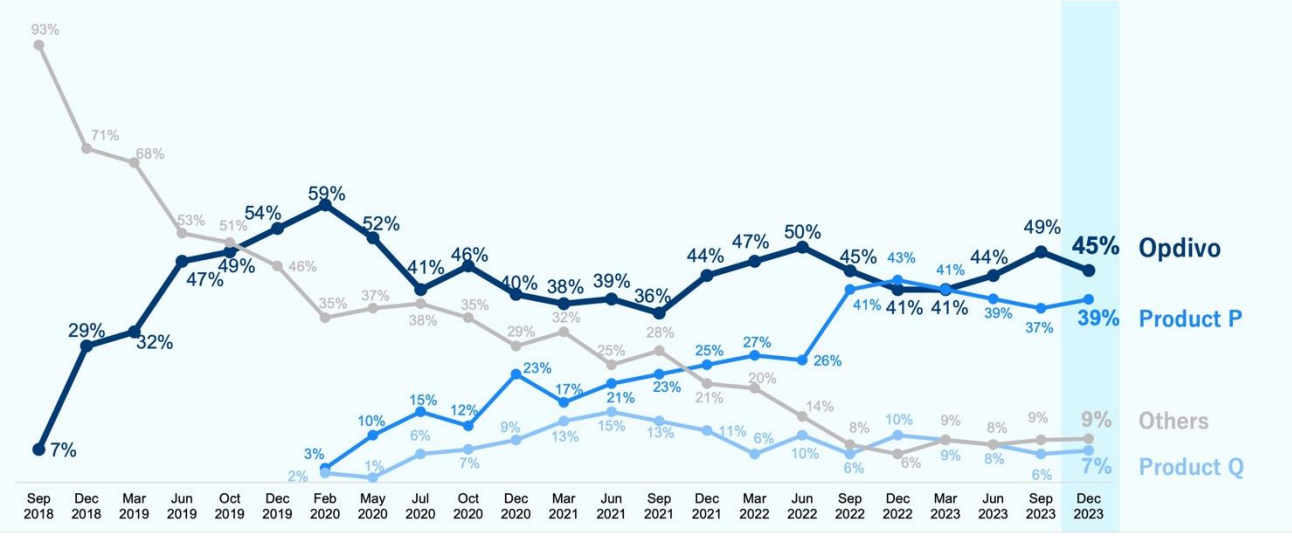
As I mentioned earlier, similar to esophageal cancer, there are still 50% of patients who have not yet undergone postoperative adjuvant. We are currently continuing to raise awareness of its usefulness so that it can be evaluated as a necessary treatment option.

As shown here, the share of prescriptions is on an upward trend, and we would like to accelerate this trend and improve the differences in the perception of physicians at high risk of recurrence, which is an issue, in order to further increase the number of prescriptions.



Finally, I would like to introduce renal cell carcinoma. The number of patients eligible for first-line treatment with the Opdivo regimen is expected to be 5,000 per year.

Prescription Ratio in Patients Newly Treated※ for 1L RCC



※Patients starting treatment within the last 3 month

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

16/16

This page shows the prescription ratio in patients newly treated for first-line renal cell carcinoma. In the first-line treatment, more than 90% of cases are already treated with I-O combination therapy, and in renal cell carcinoma, the upturn has been greater than expected. The share of new patient prescriptions for the combination of Opdivo, Yervoy, and TKI is currently 45%.

At the ASCO GU held this month, eight-year follow-up data from CheckMate-214, which is a Phase III trial of the combination of Opdivo, and Yervoy were presented. This eight-year period is a very long period of follow-up data.

In the field of renal cell carcinoma, where the competitive environment is extremely severe, we would like to further promote penetration based on data that can appeal the usefulness of this Opdivo regimen.

This is the last slide.

The development team indicated the plan of applying schedule in the future. The number of eligible patients for the Opdivo regimen to be submitted in the future, although this is only an in-house estimate, has been described. Of course, this will depend on the success of development trials, but we believe that these will be drivers for renewed growth in the future, as we plan to file for approval in FY2024 and beyond.

Although the competitive environment for Opdivo is intensifying, we will continue to expand new prescriptions of Opdivo, especially for gastric cancer, esophageal cancer, and urothelial carcinoma, and today, we have received data to demonstrate the efficacy of Opdivo, especially in the areas of gastric cancer and renal cell carcinoma. We would like to provide doctors with this kind of information and we will continue to strive to meet the unmet needs of cancer patients.

Question & Answer

Imura: Now, Mr. Muraoka from Morgan Stanley MUFG Securities, please.

Muraoka: I didn't get a chance to write down the number of patients on Mr. Takahagi's last slide, but I think it was 9DW, Yervoy combination for liver cancer, and it looks like you wrote 6,500, but I was wondering if it was more, or if it was only about the same as the other ones. I was just wondering naively, are you calculating conservatively?

Takahagi: Currently, we are estimating it based on the protocols at the current stage of development. The study was limited to patients diagnosed with unresectable advanced liver cancer, Child-Pugh A, which is a diagnostic classification, and who have not been previously treated with systemic therapy and for whom local therapy is not suitable. We estimated the number there.

Muraoka: Understood. So, if it is as labeled, it stays relatively the same as other indications?

Takahagi: This is only an estimate according to the current situation. We would like to keep a close eye on the results of the trial, and as the number of patients is updated year by year, we would like to keep a close eye on these points.

Muraoka: I understand. Thank you. Also, this is the idea of Opdivo for the next fiscal year, and you mentioned that you would extend the Opdivo in various ways, but what you did not mention in your talk today, the re-calculation due to the spillover, it is difficult to discuss because we do not know the rate, but I am almost certain that you will receive this re-calculation, but if you receive re-calculation of between 10% to 15 or 20%, is it possible to extend Opdivo sales in the next fiscal year, in Japan?

Takahagi: First, we would like to announce the forecast for the next fiscal year at the time of the announcement of financial results scheduled for May. As you mentioned, we expect the next fiscal year to be another tough one, considering the NHI price revision and the intensification of competition.

However, as I indicated earlier, we expect some drivers of renewed growth in the future, and we hope to recover in those areas.

Muraoka: Lastly, it was announced that Mr. Takino is going to be President & COO, and Mr. Sagara is still Chairman & CEO. There will be no changes in strategic direction. Is that understanding correct?

Imura: Your understanding please.

Muraoka: The medium-term plan you showed us some years ago is still effective. So, it is my understanding that both tactics and strategy are on the same track toward that one.

Imura: Yes, that's right.

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

Imura: Now, Mr. Akahane of Tokai Tokyo Research Center, please.

Akahane: First, the overall results have not been revised, but the individual products have been reviewed, Opdivo JPY5 billion minus. Basically, in the current situation, Forxiga has grown by 37%, so it will be raised, and Opdivo will be adjusted according to your earlier explanation, that lung cancer and urothelial cancer will be postponed, is that what you are saying?

As for royalties, you gave us the figures, but Bristol and Merck grew by about 16%, which is about what you expected?

Ito: Regarding royalties, things are proceeding almost as expected.

Akahane: In terms of sales, Forxiga has grown a little bit more than expected? Does this mean that the offsetting is almost zero?

Ito: Yes, that's right.

Akahane: And then, regarding Opdivo sales, this is on the second page, I think, JPY5 billion out of JPY150 billion, which was explained earlier, and if you divide this JPY5 billion, non-small cell lung cancer and urothelial cancer are in the negative.

Takahagi: Yes, we think so.

Akahane: What percentage is this?

Takahagi: I have not indicated that, so I would refrain from answering.

Akahane: I understand. On the other hand, as you explained earlier, the four-year survival rate of Checkpoint for gastric cancer and the eight-year results of CheckMate-214 for renal cell cancer have shown very good results, so can we expect that bladder cancer will also expand further in this area in the future?

Takahagi: We would like to expand our sales in this area, but on the other hand, in the field of gastric cancer, we would like to use this data to appeal against the competing products, which will enter the market next fiscal year.

Akahane: With the NHI price revision due to the spillover, I don't know the percentages, so I can't say anything, but I would say it will go down slightly. As for competing products, on the other hand, there is the issue of side effects described in the package insert, and the three areas of strategy you mentioned earlier, but these areas are growing, so it is difficult to quantify this, but what kind of image does your company have now? There are so many uncertain factors that it is difficult to make any kind of prediction, but what kind of image do you have of growth with the issue of the NHI price revision, various side-effect problems of other companies, and these three strategic areas?

Takahagi: We are currently examining these issues closely and would be happy to discuss them at the time of the next announcement of financial results.

Akahane:I understand very well. That's all from me.

Imura: Next, Mr. Yamaguchi of City group, please.

Yamaguchi: I would like to see a bit the chart that you showed us at the end earlier that contains the number of patients.

Imura: Please wait a moment.

Yamaguchi: I do not study well, but I can find out, if I look it up, especially in the last column for 2024, the number of people from the top, 5,500 and various other numbers, but looking at the competition with existing products, can you briefly introduce where you are behind and where your company is ahead? Besides the number of patients, I would appreciate it if you could tell me whether or not your company is likely to be captured in due course, as I believe that precedence will be important.

Takahagi: Are you referring to the approval of competing products or the status of clinical trials?

Yamaguchi: Yes. So, if your company enters at this time, I would be grateful if you could tell us whether you are in a chasing position or a leading position.

Takahagi: First, regarding 9DW for the first-line treatment of liver cancer, there are two drugs that have already been approved in Japan, so we will be a chasing position.

Against 77T, we have received information that a competitor has filed for approval of competing drug in Japan. Against CheckMate-73L , Imfinzi has already been approved and used. Also, you have already known the situation of unsuitable, CIS for urothelial carcinoma. Against 8HW in combination with Yervoy, a competing product is now available. However, itis the I-O mono-therapy. I hope this answers your question.

Yamaguchi: I understand. Does this mean that there will continue to be many indications that it is not quite a blue ocean and that you will continue to fight there?

Takahagi: So, it seems. We would like to scrutinize the situation, based on the results of clinical trials that will be available in the future, as well as the characteristics of each drug.

Yamaguchi: Lastly, you have raised Forxiga's sales a bit, but have you adjusted SG&A expenses accordingly? I think there is a co-promotion fee in it.

Ito: The co-promotion fee will increase, as you say, due to the increase in sales of Forxiga. However, as far as total SG&A expenses are concerned, the impact of this change is not significant at this point, so we are leaving it as it is.

Yamaguchi: I understand. You can cover it in other points. Thank you. That is all from me.

Imura: Mr. Wakao from JPMorgan Securities, please.

Wakao: The first is, I would like to confirm your thinking for the next fiscal year. As for the next fiscal year, I wonder if it will be difficult because of the price reduction of Opdivo and the reduction of royalty rate of Keytruda and other products. The consensus in the stock market is that profits will decrease, but for the next fiscal year, for example, do you think that you will make efforts to reduce the margin of profit decline by cutting SG&A and R&D expenses? Or, we do not have to consider such things at the moment. I think that now is a good time to invest aggressively, so should we assume that it is inevitable that profits will decrease in the short term?

Ito: We are currently examining the profit and loss plan and activity plan for the next fiscal year, and it will take some more time to determine how we will organize our activities for the next fiscal year. At this point, I cannot say whether we should actively invest regardless of short-term profits and losses, or whether we should prioritize profits and losses by reducing overall costs, but we are considering this while also looking at the balance.

Wakao: One more thing, please tell us about the development of Opdivo for subcutaneous formulation. I understand that Phase I has started in Japan, but is it necessary to conduct Phase III in Japan for each carcinoma?

Okamoto: First, BMS issued the press release., Upon publication of the results of the study evaluating the non-inferiority of intravenous and subcutaneous formulations for renal cell carcinoma, they announced, ``Regulating next steps for subcutaneous Opdivo in multiple cancer tumors. We plan to discuss this with the authorities." Upon publication of the results of a study to verify the non-inferiority of the subcutaneous

formulation compared to intravenous formulation in renal cell carcinoma, BMS commented that they will discuss next steps for subcutaneous formulation with health authorities across multiple cancer types .

On the other hand, in Japan, we have the results of the Phase III trial overseas, so basically, we will conduct the Phase I trial and hope to submit an application for broad approval while utilizing overseas data, but this will depend on future consultations with the authorities, at this point, we can only say that we have started Phase I trials.

Wakao: I understand. Do you mean that the timing for consultation with the authorities to proceed is after Phase I is completed?

Okamoto: We are sorry that we have traditionally refrained from responding to the part of questions concerning the strategy for application and development plan for individual study.

Wakao: Also, in relation to this SC, are there any points that you are currently doing research on, such as how much intravenous injection will be replaced by subcutaneous formulation when it is actually launched? Most recently, I think Bristol said that 60% to 70% of Opdivo in the US market will be converted to SC. How about it in Japan?

Takahagi: We believe that there is a certain level of need for subcutaneous formulation, considering the convenience for healthcare providers and the shortened administration time, etc. However, we are currently conducting a thorough examination in this area, so I would like to refrain from giving an answer today. I'm sorry.

Wakao: So, it will be a while before you can show us the potential of this area?

Takahagi: Yes. We will share more information when we know for sure. However, there are currently other manufacturers that are expanding their anticancer drug models by switching from intravenous infusion to subcutaneous formulation, so we would like to carefully scrutinize the situation while taking such factors into consideration.

Imura: Seeing no further questions, I would like to conclude the presentation of financial results for Q3 of the fiscal year ending March 31, 2024.