ONO PHARMACEUTICAL CO., LTD.

Financial Results for the Fiscal Year Ended March 2023

May 11, 2023

[Number of Speakers]	7	
	Gyo Sagara	President and Chief Executive Officer
	Toshihiro Tsujinaka	Senior Executive Officer, Executive Director, Corporate Strategy & Planning
	Toichi Takino	Senior Executive Officer, Executive Director of Discovery & Research
	Kiyoaki Idemitsu	Executive Officer, Executive Director of Clinical Development
	Satoshi Takahagi	Corporate Officer, Executive Director of Sales and Marketing, Primary Care Business Division
	Masaki Ito	Corporate Officer, Division Director, Corporate Strategy & Planning, Business Management Division
	Yukio Tani	Corporate Executive Officer, Head of Corporate Communications

Revenue

Revenue	YoY Change
¥ 447.2 billion	+ 23.8 %

Breakdown of Revenue

(Billion yen)

	FY 2021	FY 2022	YoY Change
Revenue of Goods and Products	246.0	**295.0**	+ 20.0 %
Royalty & other revenue	115.4	**152.1**	+ 31.8 %
Total	361.4	**447.2**	+ 23.8 %

Sagara:

I would now like to proceed with a summary of the financial results for the fiscal year ended March 31, 2023.

Revenue was JPY447.2 billion, up 23.8% or JPY85.8 billion from the previous year. The breakdown is JPY295 billion for revenue of goods and product and JPY152.1 billion for royalties and other revenue, representing increases of JPY49 billion YoY and JPY36.7 billion YoY, respectively.

Royalty and other revenue related to Opdivo from BMS increased by JPY19.7 billion YoY to JPY89.6 billion, and from Merck increased by JPY14.3 billion YoY to JPY45.2 billion. Others are royalties from Roche, those related to Yervoy, and co-promotion income of Orencia IV, etc.

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Revenue

Sales of Major Products

(Billion yen)

	FY 2021	FY 2022	YoY Change
Opdivo	112.4	**142.3**	+ 26.6 %
Forxiga	36.7	**56.5**	+ 54.3 %
Orencia SC	22.9	**24.8**	+ 8.1 %
Glactiv	24.5	**22.5**	- 8.3 %
Kyprolis	8.4	**8.7**	+ 4.0 %
Parsabiv	8.9	**8.4**	- 5.3 %
Velexbru	6.3	**8.5**	+ 36.2 %
Ongentys	2.9	**5.0**	+ 72.9 %
Onoact	4.9	**4.5**	- 7.9 %
Braftovi	2.7	**3.2**	+ 18.2 %
Mektovi	2.2	**2.5**	+ 13.4 %

Regarding revenue by product, Opdivo and Forxiga increased approximately JPY30 billion YoY and JPY20 billion YoY, respectively, while other products such as Orencia SC, Velexbru, and Ongentys contributed to the increase in sales. Glactiv is slightly decreased.

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Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2021	FY 2022	YoY Change
Opalmon	4.7	**4.4**	- 7.6 %
Onon capsule	3.6	**2.5**	- 30.7 %

ONO PHARMACEUTICAL CO.,LTD. 4/15

Revenue of long-term listed products were decreased, as shown.

Operating Profit

Operating Profit	YoY Change
¥ 142.0 billion	+ 37.6 %

Costs, etc.

(Billion yen)

	FY 2022	YoY Change
・Cost of Sales	110.1	(+ 17.7%)
・R&D Expenses	95.3	(+ 25.7%) ①
・SG&A Expenses	89.5	(+ 16.1%) ②
①+② Total	184.8	(+ 20.9%)
・Other Income	0.7	(- 25.1%)
・Other Expenses	11.1	(- 12.9%)

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Operating profit increased by 37.6% YoY to JPY142 billion. Cost of sales was JPY110.1 billion, an increase of JPY16.6 billion YoY, R&D expenses were JPY95.3 billion, an increase of JPY19.5 billion YoY, and other SG&A expenses increased by, JPY12.4 billion YoY.

Other expenses were JPY11.1 billion. This is a one-time payment associated with the settlement of the lawsuit with the Dana-Farber Cancer Institute, as well as some expenditure to the foundation since we decided to discontinue the scholarship endowment and establish “Ono Pharma Oncology, Immunology, Neurology Research Foundation” to provide research grants from the foundation. These are the two main other expenses.

Regarding the settlement with Dana-Farber Cancer Institute, the release announced that additional payments will be made to Dana-Farber Cancer Institute in the future if certain conditions are met. Basically, the whole issues with Dana-Farber Cancer Institute have been settled and there will be no more rights disputes in the future, but we announced that there could be additional royalties. Since this level is estimated to be up to one-digit billion yen, it is fair to say that the matter is almost over economically, and that is the way it will be. In any case, the matter has been fully resolved.

Profit before Tax

Profit before Tax	YoY Change
¥ 143.5 billion	+ 36.7 %

Net financial income, etc.

+ ¥ 1.6 billion (YoY Change - ¥ 0.3 billion)

Finance income : (Dividend income received, etc.)	¥ 2.5 billion
Finance costs : (Exchange losses, etc.)	¥ 0.9 billion

Profit before tax was JPY143.5 billion.

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Profit for the Year (Owners of the Company)

Profit for the Year (Owners of the Company)	YoY Change
¥ 112.7 billion	+ 40.0 %

Income tax expense

¥ 30.6 billion	(YoY Change + 25.8 %)	
Statutory effective tax rate	30.6 %	(30.6 % prior year)
Tax burden rate	21.3 %	(23.2 % prior year)

(Major change factors)

Increase in profit before tax

Profit for the year was JPY112.7 billion. Both revenue and each profit were record highs.

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Financial Forecast for FY 2023

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Revenue	447.2	**475.0**	+ 6.2 %
Operating profit	142.0	**153.0**	+ 7.8 %
Profit before tax	143.5	**154.0**	+ 7.3 %
Profit for the year (Owners of the Company)	112.7	**115.0**	+ 2.0 %

Exchange rate
FY 2023 (Forecast): 1USD = 130 yen

Next is the forecast for FY2023. For FY2023, revenue is forecast to be projected at JPY475 billion, an increase of 6.2% YoY.

The assumed exchange rate for FY2023 is 130 yen to the dollar.

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Revenue (Forecast)

Revenue	YoY Change
¥ 475.0 billion	+ 6.2 %

Breakdown of Revenue

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Revenue of Goods and Products	295.0	310.0	+ 5.1 %
Royalty & other revenue	152.1	165.0	+ 8.5 %
Total	447.2	475.0	+ 6.2 %

The revenue of goods and products is forecast to be JPY310 billion, an increase of JPY15 billion YoY. Royalties and other revenue will be increased to JPY165 billion, or by JPY12.9 billion YoY, totaling an increase of JPY27.8 billion.

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Revenue (Forecast)

Sales Forecast of Major Products

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Opdivo	142.3	155.0	+ 8.9 %
Forxiga	56.5	65.0	+ 15.0 %
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 %
Mektovi	2.5	3.0	+ 18.1 %

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By product, as you can see, it is forecasted that Opdivo sales will increase by JPY12.7 billion YoY to JPY155 billion, Forxiga by JPY8.5 billion YoY to JPY65 billion, and sales of Velexbru and Ongentys will also increase.

Revenue (Forecast)

Sales Forecast of Long-term listed products

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Opalmon	4.4	**3.5**	**- 19.9 %**

Opalmon is a long-term listed product. As you can see, we are projecting that the sales will decrease by JPY1 billion YoY.

As you know, last year and the year before, the supply of generics became unstable and there was a swing back to brand products, so the decline in sales of long-term listed products last year and the year before was smaller than expected.

On the other hand, we expect that the supply of generics will gradually recover this fiscal year, and our forecast is that there will be an overall negative JPY5 to JPY6 billion for long-term listed products.

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Operating Profit (Forecast)

Operating Profit	YoY Change
¥ 153.0 billion	+ 7.8 %

Costs, etc.

(Billion yen)

	FY 2023 (Forecast)	YoY Change
・Cost of Sales	113.0	(+ 2.7 %)
・R&D Expenses	109.0	(+ 14.3 %) ①
・SG&A Expenses	96.0	(+ 7.3 %) ②
①+② Total	205.0	(+ 10.9 %)
・Other Income	0.5	(- 31.8 %)
・Other Expenses	4.5	(- 59.3 %)

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Operating profit forecast is JPY153 billion, by 7.8% or JPY11 billion YoY. As you can see, the cost of sales will increase to JPY113 billion, or up JPY2.9 billion YoY; R&D expenses will be JPY109 billion, or up JPY13.7 billion YoY; and SG&A expenses will be JPY96 billion, or up JPY6.5 billion YoY.

Research and development expenses have increased significantly over the past two years. We are investing aggressively to ensure significant growth in anticipation of or overcoming the Opdivo patent cliff. We are one step ahead of the situation that this kind of expense has come out, but we are investing aggressively in R&D with the hope of delivering good news to you at the earliest opportunity.

Profit before Tax (Forecast)

Profit before Tax	YoY Change
¥ 154.0 billion	+ 7.3 %

Net financial income, etc.

+ ¥ 1.0 billion (YoY Change - ¥ 0.6 billion)

The forecast of profit before is expected to be JPY154 billion, an increase of 7.3% YoY.

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Profit for the Year /Owners of the Company (Forecast)

Profit for the Year (Owners of the Company)	YoY Change
¥ 115.0 billion	+ 2.0 %

Income tax expense

¥ 38.8 billion (YoY Change + 26.7 %)

(Major change factors)

Increase in profit before tax	¥	10.5 billion
Increase in corporate tax	¥	8.2 billion

Profit for the year is expected to be JPY115 billion, an increase of JPY2.3 billion YoY, and the ratio of income taxes here is expected to rise a bit.

These are the forecasts for the next fiscal year.

For FY 2022, we plan to increase the year-end dividend by JPY4 to JPY70 per share for the full year, from the planned JPY66 per share for FY2022. This is an increase of JPY14 from JPY56 in the previous period.

The projected dividend for the ongoing fiscal year is JPY80 per share.

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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
Market price at the end of September 2021	¥ 141.8 bil	¥ 99.3 bil	¥ 42.5 bil	-30.0%

➢ 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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I would like to report on the status of the reduction of cross-shareholdings.

We have announced and are proceeding with a plan to reduce our cross-shareholdings by 30% in three and a half years, from a market value of JPY141.8 billion as of September 2021.

Status of reduction of Cross-shareholdings

	End of September 2021	End of March 2023	Reduction*	Reduction rate
Market price at the end of September 2021	**¥ 141.8 bil**	**¥ 112.5 bil**	**¥ 29.3 bil**	**-20.7%**

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of March 2023	Change	Ratio of Cross-shareholdings to net assets
Balance sheet accounting amount	**¥ 141.8 bil**	**¥ 107.8 bil**	**¥ 34.0 bil**	**14.4%**

As of today, we have been able to reduce the amount of JPY112.5 billion at the market value at that time. We are at 20% progress against 30% planned.

Current cross-holdings amount to JPY107.8 billion on a current balance sheet basis, which is 14.4% of net assets.

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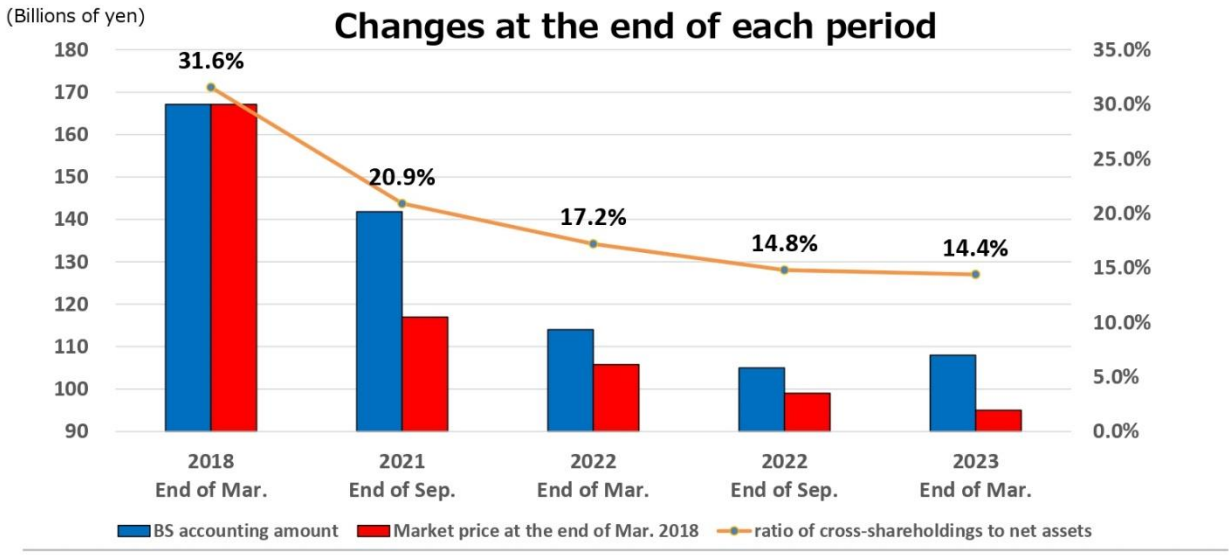
Status of reduction of Cross-shareholdings

➢ **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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The ISS, Glass Lewis, and other organizations require levels of less than 20% and 10%, respectively, and we have already met the ISS requirement. We would like to move forward step by step with the goal of reducing it to 10% or less.

Development pipeline

Idemitsu: Today, I will explain the updated development situation since Q3 of the fiscal year ended March 31, 2023.

I. Main Status of Development Pipelines (Oncology)

As of April 25, 2023

<Approved>

*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Hepatocellular carcinoma *1	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *2	Injection	S. Korea	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.
Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023
*1: An application was approved in Taiwan for combination therapy with Opdivo and Yervoy for the treatment of hepatocellular carcinoma previously treated with sorafenib.
*2: Applications were approved in South Korea for combination therapy with Opdivo and Yervoy and combination therapy with Opdivo and chemotherapy for the treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma.

<Filed>

*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Malignant mesothelioma *3 (excluding malignant pleural mesothelioma)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023
*3: An application for approval of Opdivo was filed in Japan for the treatment of malignant mesothelioma (excluding malignant pleural mesothelioma).

<Clinical Trial Stage>

<Opdivo>

*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)

<Yervoy>

*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-license (Co-development with Bristol-Myers Squibb)

First, regarding oncology area.

Opdivo was approved in combination with Yervoy in Taiwan in March for the treatment of hepatocellular carcinoma.

The combination therapies of Opdivo and Yervoy as well as Opdivo and chemotherapy were approved for the treatment of esophageal cancer in South Korea in March.

In the development products under application described in the bottom table, we filed an application of Opdivo for malignant mesothelioma (excluding pleural) in February in Japan.

II. Main Status of Development Pipelines (Areas other than Oncology)

As of April 25, 2023

<Clinical Trial Stage>

*) : "In-house" compounds include a compound generated from collaborative research.

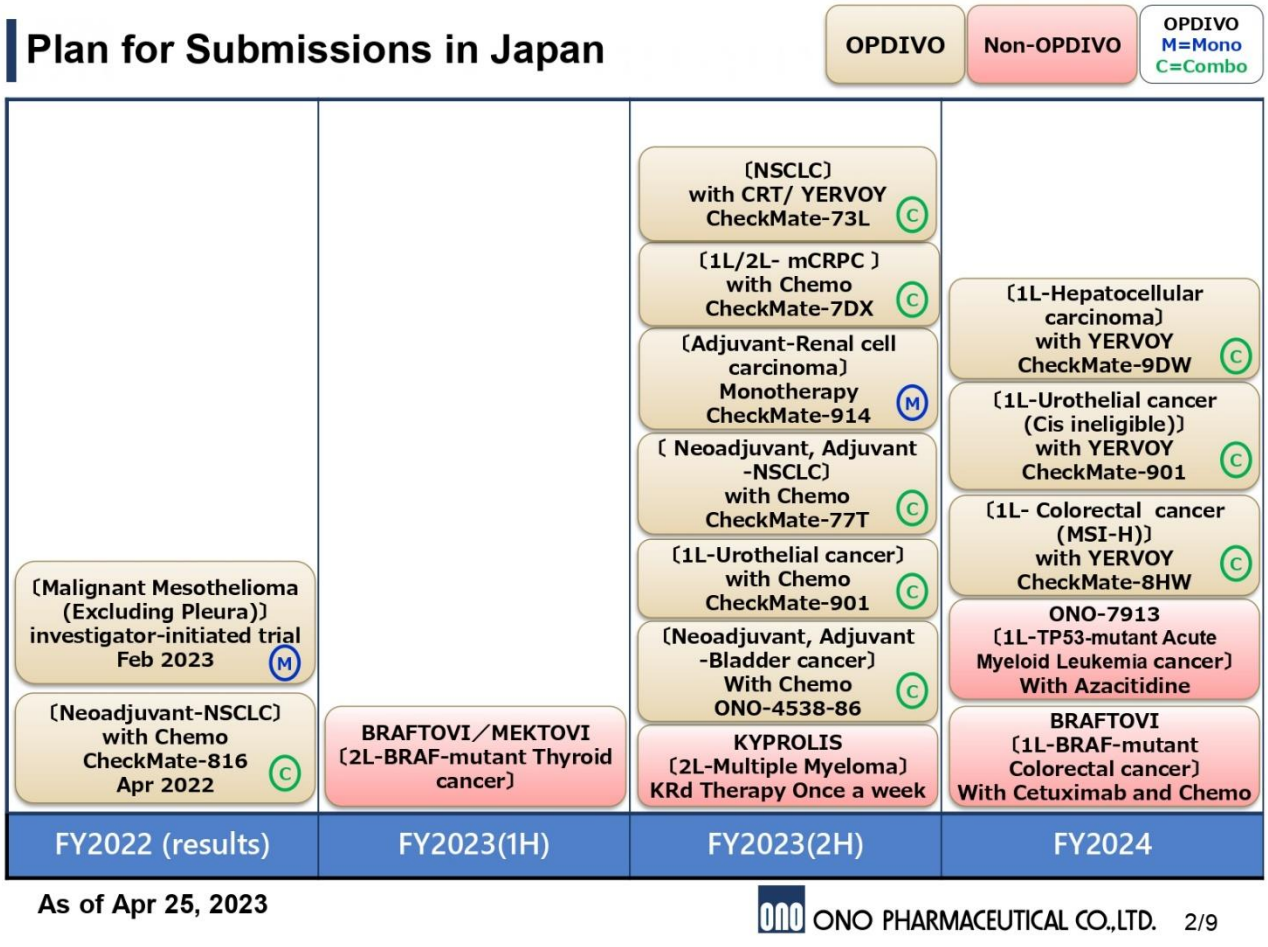
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-2017 / Cenobamate	New chemical entities	Primary generalized tonic-clonic seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
	New chemical entities	Partial-onset seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Tablet	Japan	III	In-license (SK Biopharmaceuticals)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	III	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Japan Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / S1P5 receptor agonist	Tablet	Japan Europe	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house
ONO-1110	New chemical entities	Pain / Endocannabinoid regulation	Oral	Japan	I	In-house

Changes from the announcement of financial results for the third quarter of the fiscal year ended March 31, 2023

*Phase I of Velexbru Tablets (BTK inhibitor) was conducted in Japan for the treatment of systemic sclerosis, but the project was discontinued due to the result not being able to confirm the anticipated efficacy.

This is a table of major progress of development products (other than oncology) under clinical trials. As you can see from the annotation, we had conducted a Phase I study of Velexbru for systemic scleroderma, but the expected efficacy was not observed, and the development was terminated.

This is all about the progress of development products using supplemental materials for the financial statements.



Now I will continue with an explanation using the materials on the progress of the development pipeline, which can be found on our website.

Please note that the timing of the application is the fastest possible schedule if everything goes well according to plan, and the situation is subject to change.

I will now focus on the changes made since last time, after January 2023. The left-most FY2022 result is the application for malignant mesothelioma (excluding pleural) filed in February, as explained earlier in the supplementary financial statements.

Second, we had planned to submit an application for adjuvant treatment of hepatocellular carcinoma in H2 FY2023, but due to a significant delay in obtaining the results, we have changed our application schedule to FY2025 or later.

In addition, in H2 FY2023, we added Opdivo in combination with chemoradiotherapy for non-small cell lung cancer, and in combination with chemoradiotherapy and Yervoy.

We also added filing project of Opdivo for combination therapy with docetaxel for prostate cancer, for renal cell carcinoma, and a chemotherapy combination for pre and post-operative adjuvant treatment of non-small cell lung cancer.

Further, we have now added a column with the planned applications for FY2024, describing each of the five filing projects.

This is all about the domestic application schedule. The status of the development project is shown after this page, which we hope you will check separately.

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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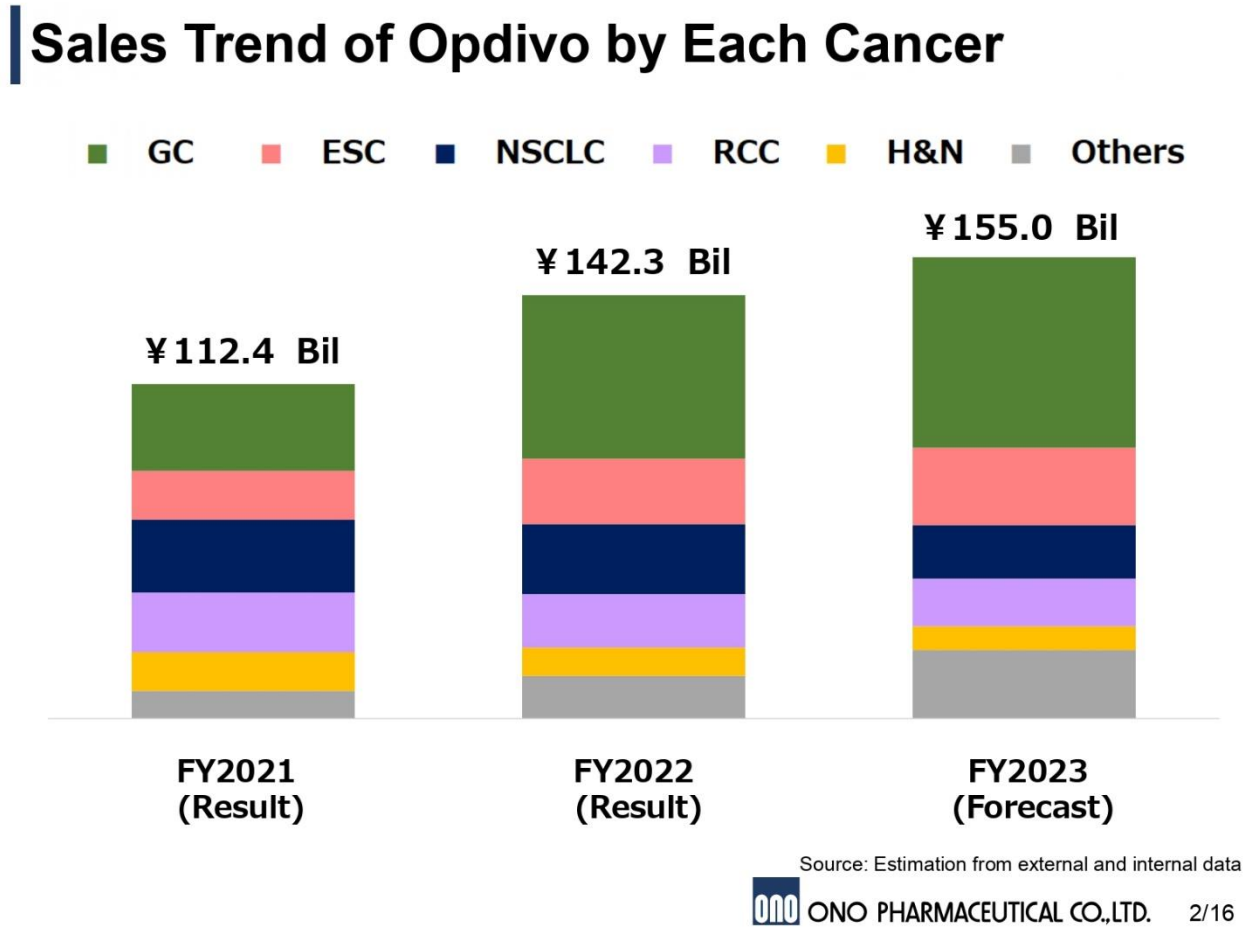
Trend of Opdivo

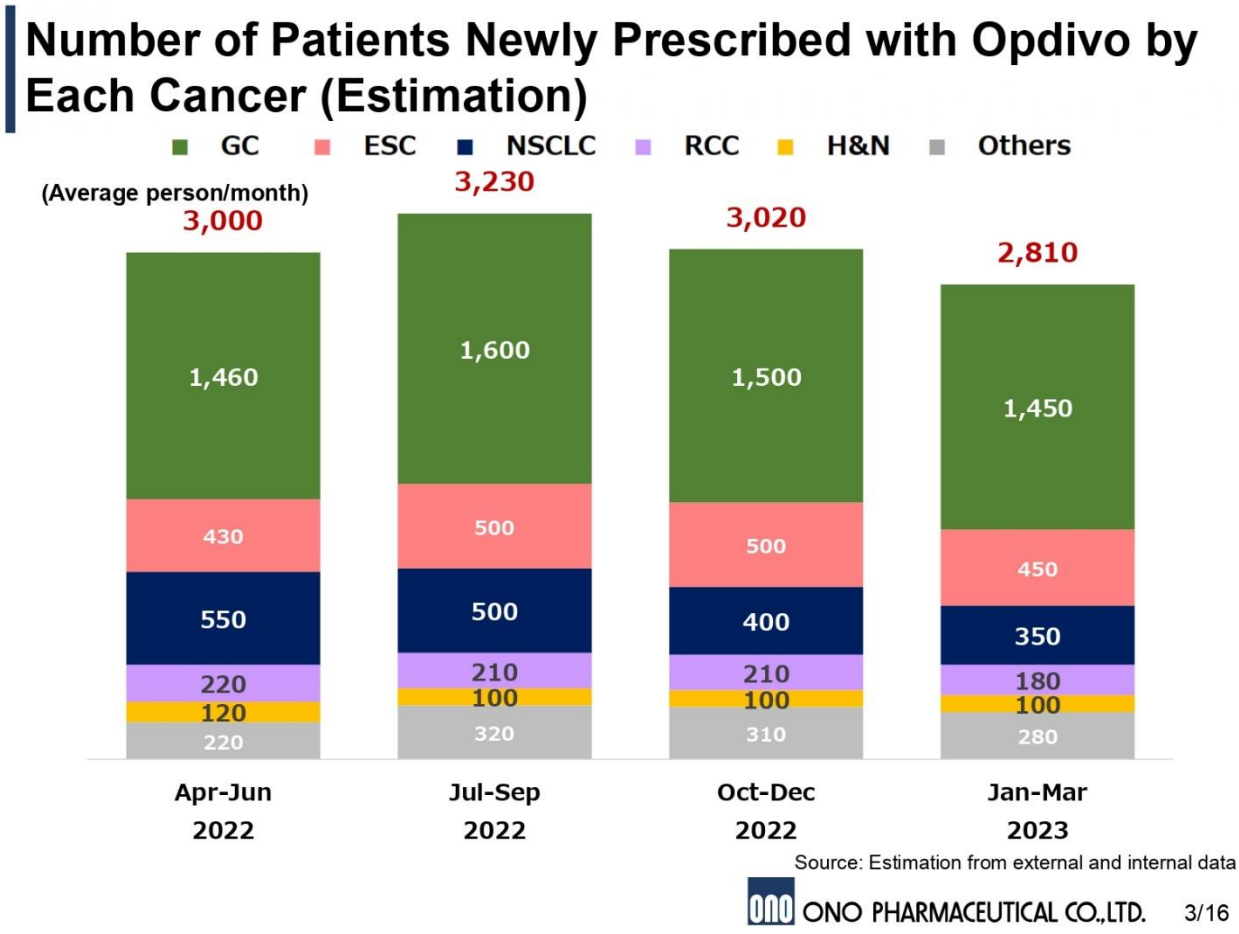
Takahagi: I would like to explain the Opdivo trend. Today, I will explain sales, new prescriptions, and status by carcinoma.



Opdivo sales.

In FY2022, sales were JPY142.3 billion, up JPY29.9 billion or 27% from the previous fiscal year. However, we had made a revised plan of JPY145 billion at the end of Q3, and we have just come in slightly below that at JPY142.3 billion. I will explain the factors later.

For the current fiscal year, we forecast JPY155 billion, up JPY12.7 billion, or about 9%, from the previous year.



This table shows the number of new prescriptions of Opdivo for each cancer type. From the bar graph on the left, we show the average number of patients per month per quarter from April to June 2022 to January to March 2023.

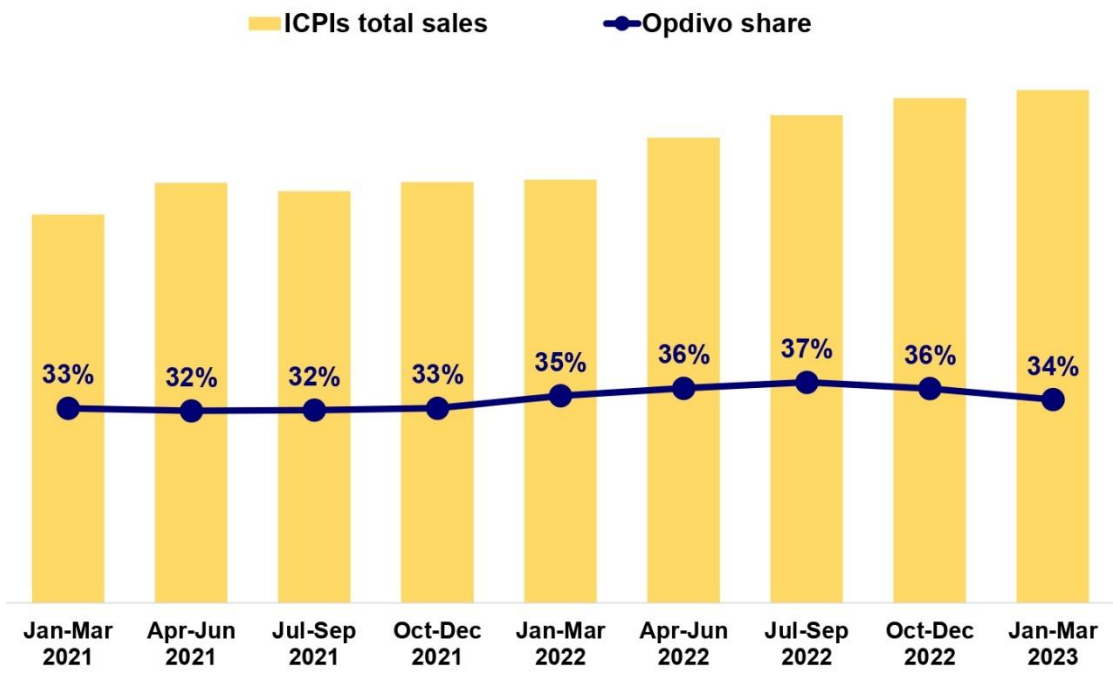
This is only an estimate, but in the January to March period of 2023, prescriptions for 1,450 cases of stomach cancer, 450 cases of esophageal cancer, and 350 cases of lung cancer have just been initiated. As a monthly average, the total number of cases is 2,810.

To give you a little more breakdown, new prescriptions for first-line treatment, especially for gastric and esophageal cancer, have increased compared to FY2021. On the other hand, the number of newly prescribed patients for second-line treatment and behind, for example, compared to the October to December period of 2022 and the January to March period of this year, has dropped by about 100 cases for gastric cancer for third-line treatment and behind, and esophageal cancer for second-line treatment and behind, combined.

Overall, this gastrointestinal area appears to be decreasing, but first-line treatment, which is expected to be administered over a longer period, is increasing. The reason for this is that Opdivo is a drug that should be used early in the line of treatment.

The total number of new prescriptions in FY2021 was approximately 28,000, and in FY2022, it was 36,000, an increase of 29%, so we would like to expand new prescriptions to patients in earlier lines well into this fiscal year, and we believe there is a good chance to expand.

Trend of total sales of ICPIs and Opdivo share



Source: External data

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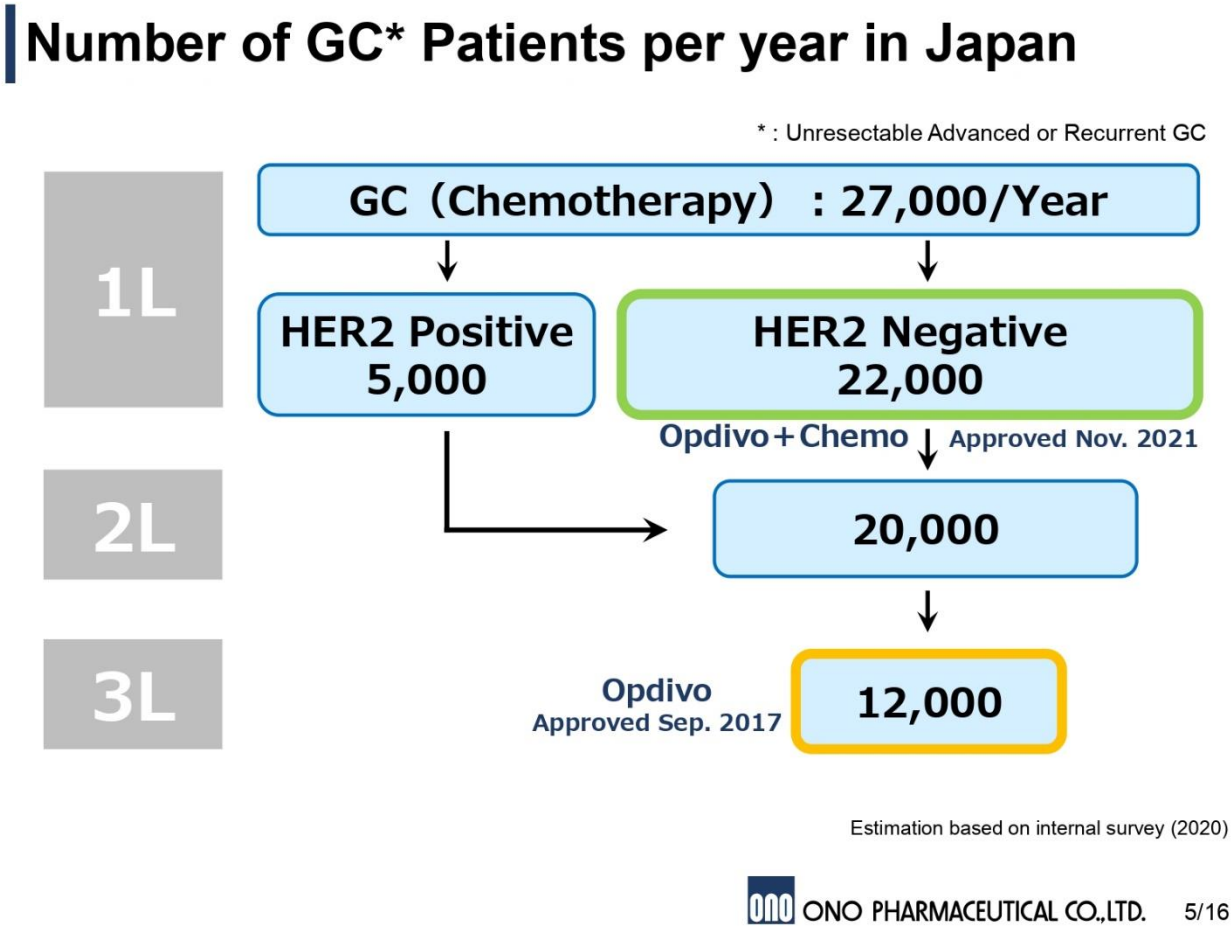
Here is trend of total sales of immune checkpoint inhibitors launched in Japan and Opdivo's market share. The yellow bar graph shows the total sales of immune checkpoints inhibitors, and the dark blue line graph shows the market share of Opdivo.

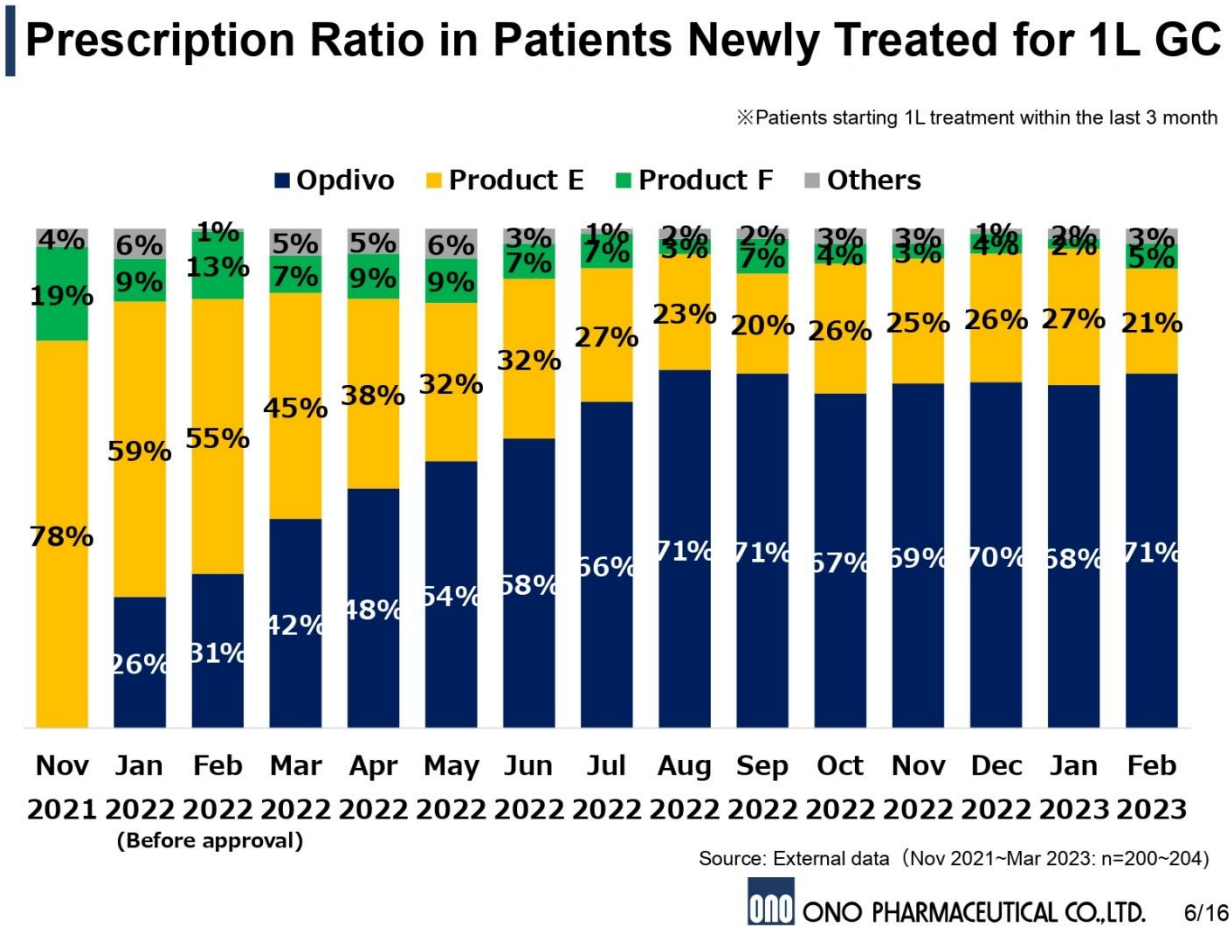
Overall sales of immune checkpoint inhibitors are increasing steadily, with a 21% increase in the overall market when comparing the first three months of 2022 to the first three months of 2023. Among them, the Opdivo market share is 34%, and sales are growing.



The following information is for each cancer type.

The first is gastric cancer of gastrointestinal cancer. As you are aware, we estimate that the total number of patients with unresectable advanced or recurrent gastric cancer per year is 27,000 in total, although this is only our own estimate.

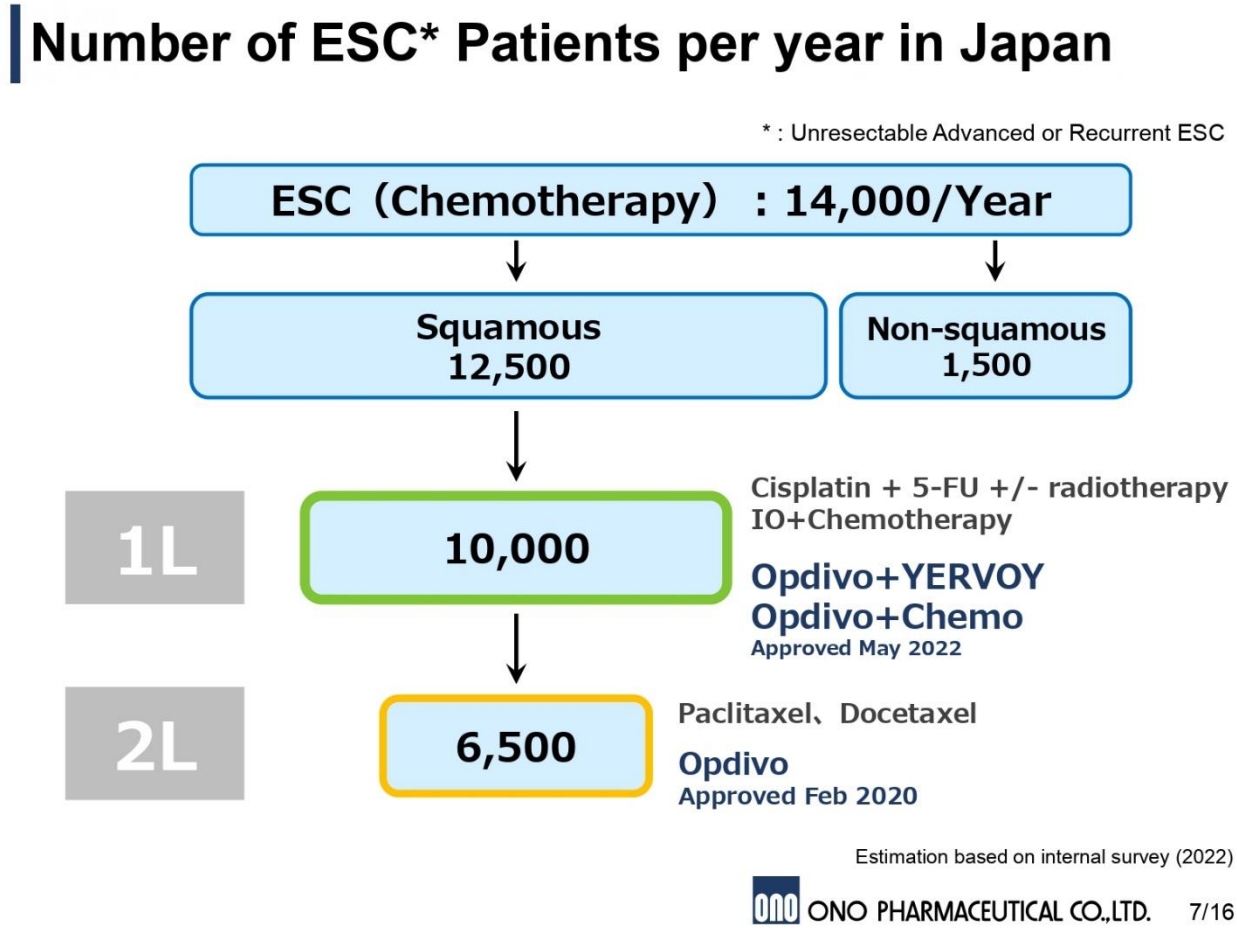
Among them, Opdivo plus chemotherapy is indicated for the first-line treatment of HER2-negative patients, and the number of patients is estimated to be 22,000 per year.



This table shows the share of new patient prescriptions for first-line treatment of gastric cancer. Opdivo's share of new patient prescriptions for first-line therapy is as high as 71%, but we would like to aim much higher.

At the ASCO GI held in January of this year, the three-year follow-up data for CheckMate -649 was presented, where the efficacy and safety of the Opdivo regimen for three years has been demonstrated. We believe that we can achieve our plan by firmly promoting the efficacy and safety of the Opdivo regimen.

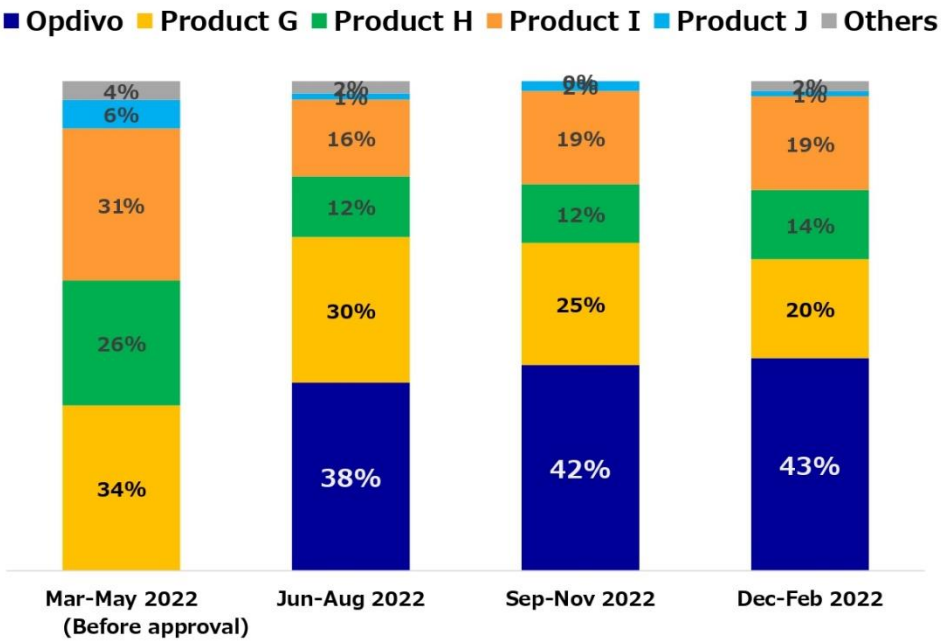
The market is very large, with 22,000 patients, and we would like to capture this area of gastric cancer.



Esophageal cancer area. In the first-line treatment of unresectable advanced or recurrent esophageal cancer, the number of patients eligible for such treatment is 10,000 for squamous cell carcinoma, which is also very large.

We are working on two regimens for this, Opdivo plus Yervoy and Opdivo plus chemotherapy.

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~Nov 2022: n=150~155)

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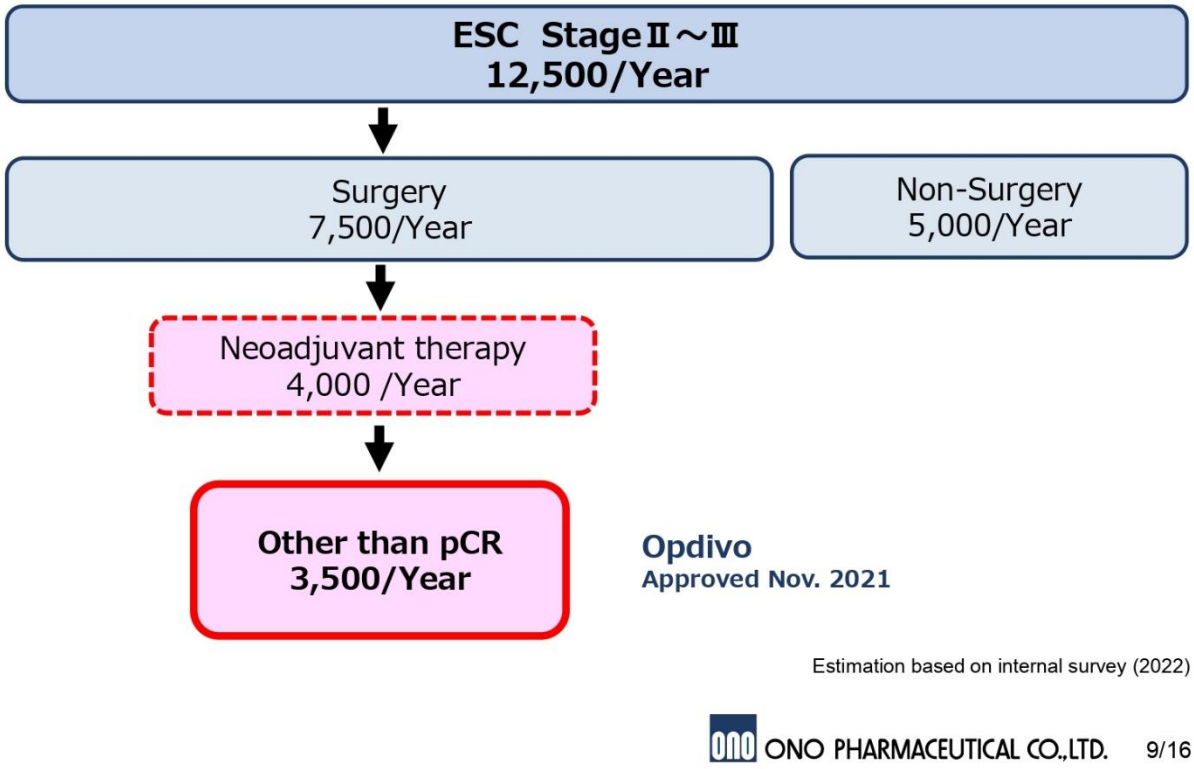
This is the share of new patient prescriptions for first-line treatment of esophageal cancer. With the entry of Opdivo regimen into first-line therapy, the share of new prescriptions for Opdivo regimen has risen to 43%.

In first-line treatment, including competitive products, the IO regimen itself has expanded to 60% in total, but 40% of patients are still on chemotherapy regimens. We believe that we can aim for a higher market share by capturing this 40% market, which is also very large, since there are still some segments left.

We believe that there is still a market for Opdivo plus Yervoy and Opdivo plus chemotherapy regimens to expand by about 15%, and we hope to capture this market in FY2023.

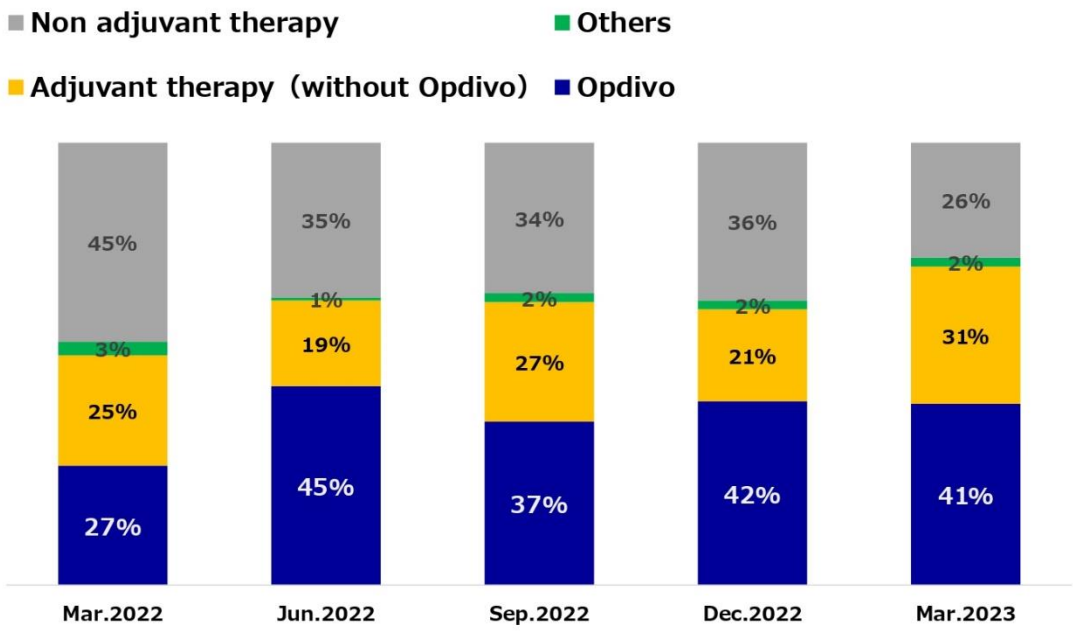
Number of ESC（Perioperative） Patients per year in Japan



The number of patients with perioperative esophageal cancer, which Opdivo was approved November in 2021.

It is estimated that there are about 12,000 patients per year with esophageal cancer at Stages II/III, of whom about 7,500 are eligible for surgery. Of these, we estimate that the number of patients who will receive preoperative adjuvant therapy is about 4,000, and that the number of patients eligible for Opdivo will be those with pathologic non-complete response, which is about 3,500.

Prescription Ratio in Patients Newly Treated for ESC (adjuvant therapy)



Source: External data（Mar 2022~Mar 2023: n=150~152)

※Patients starting treatment within the last 3 month

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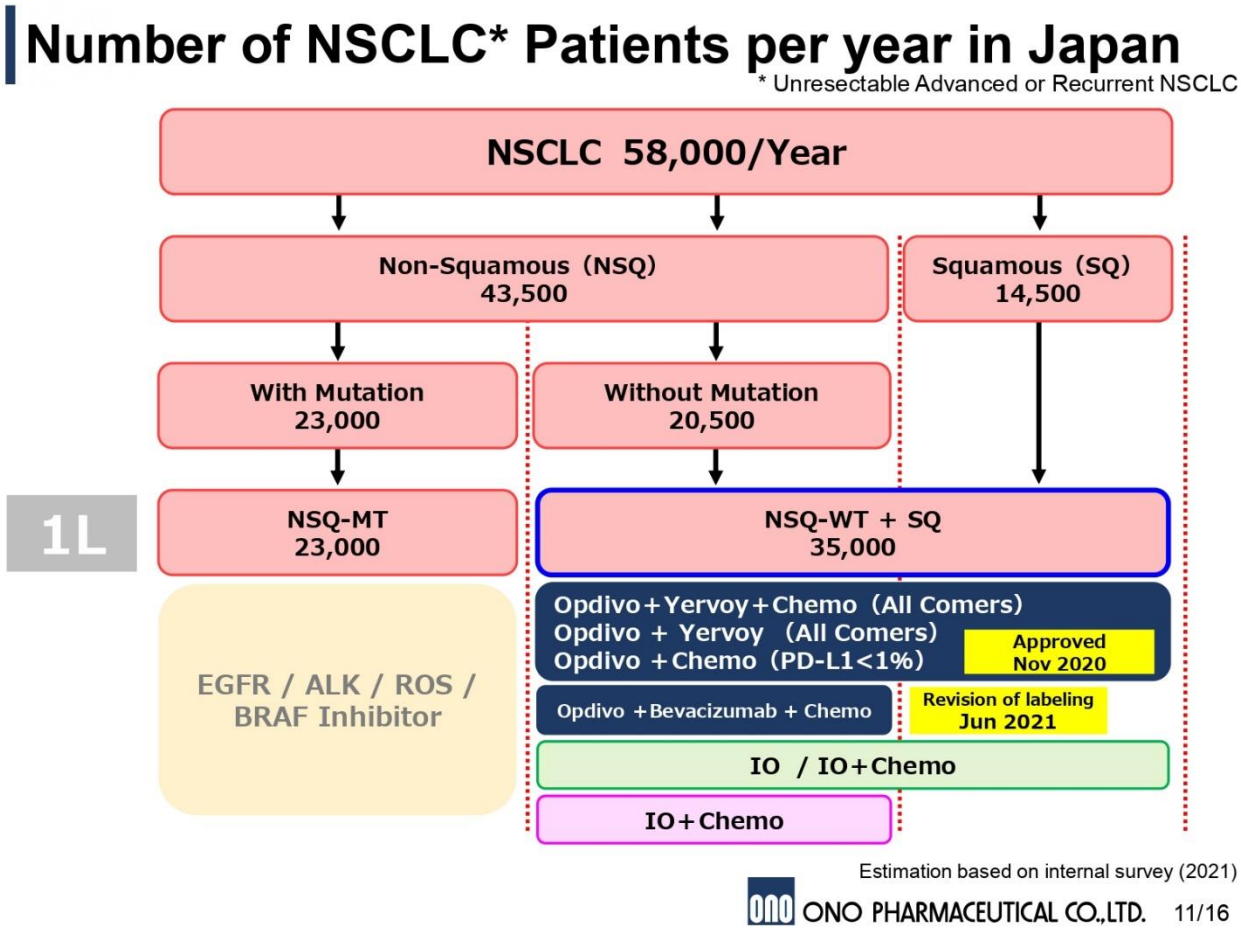
The share of new patient prescriptions for adjuvant treatment of esophageal cancer was 41% as of March.

The physicians who are using the product very frequently, as well as key opinion leaders, are increasingly recognizing that the product is a safe and useful treatment option for patients who have not had a pathologic complete response to preoperative CRT or postoperative therapy. Of course, we would like to encourage them for potential prescription by considering the risks and benefits, to continue to expand the prescriptions.

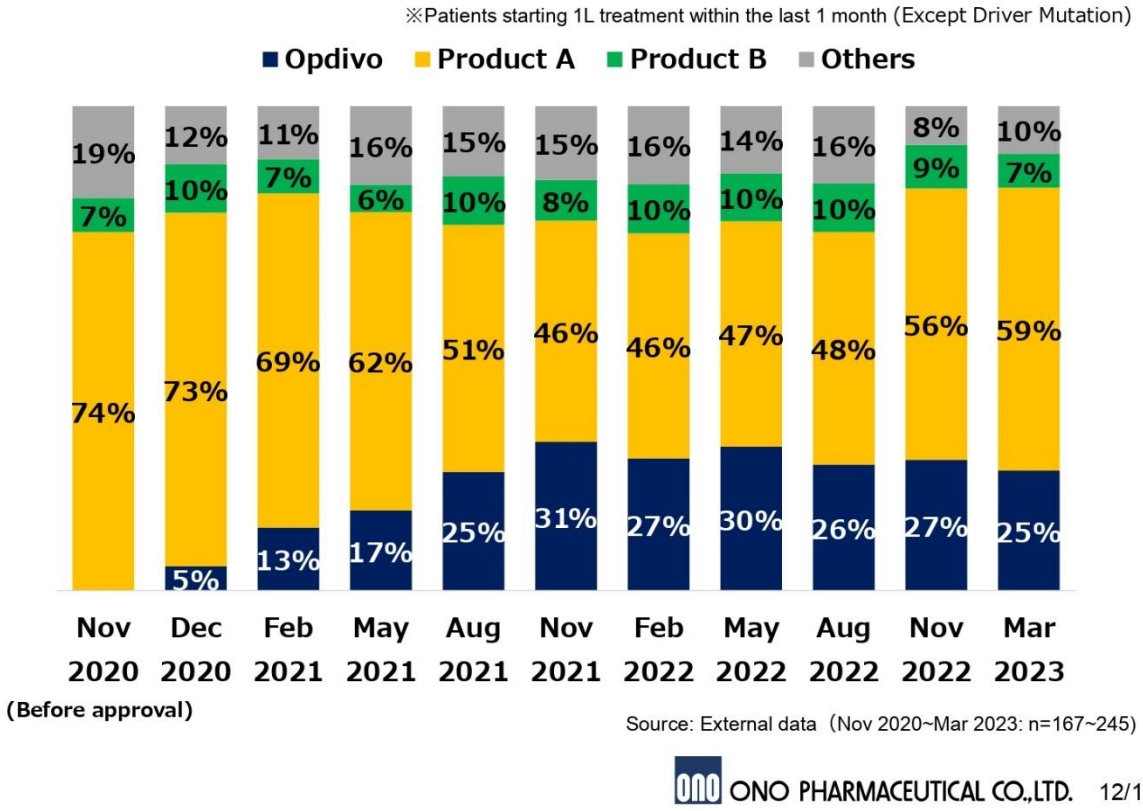
However, there are still 60% of cases where only chemotherapy or no chemotherapy is being administered, even for adjuvant treatment of esophageal cancer. There are still many rooms where Opdivo regimen can be evaluated and entered the market, and we believe that we can expect further expansion by working on this area this year.



Non-small cell lung cancer. The annual number of patients here is also very high, especially in the area where IO is indicated for non-squamous cancers without genetic mutations and squamous cell cancers, and the annual number of patients is about 35,000.

As you can see, this is a highly competitive area.

Prescription Ratio in Patients Newly Treated for 1L NSCLC



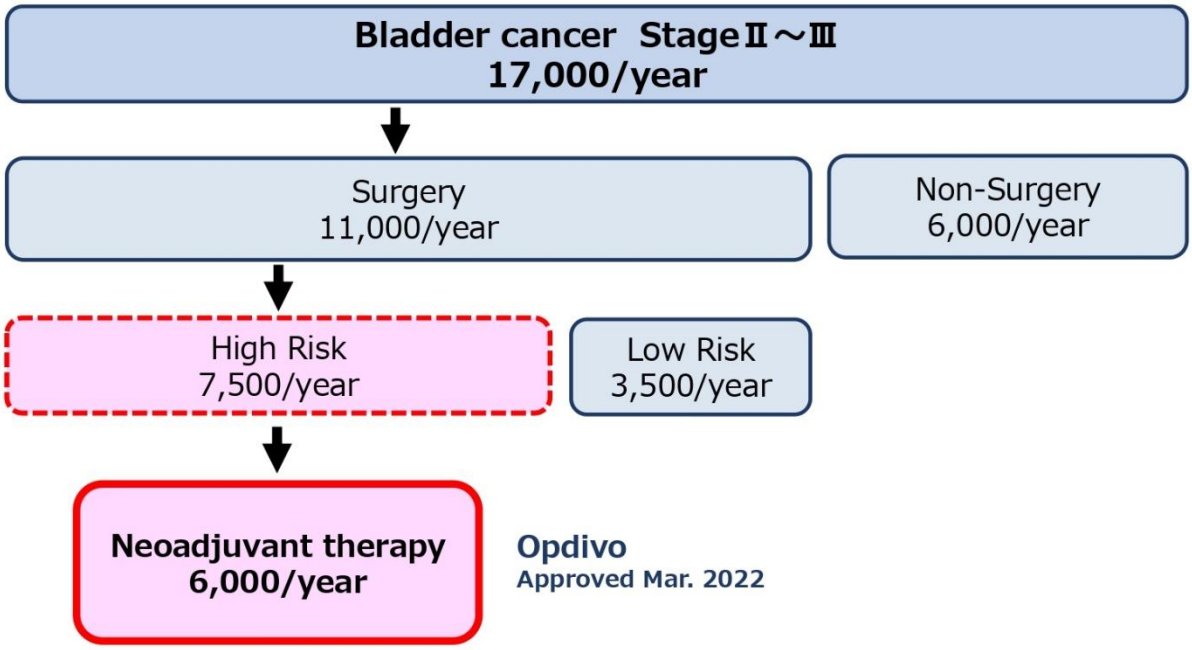
This table shows the prescription ratio in newly treated for the first-line treatment of lung cancer. The share of new patient prescriptions has just stagnated at 25% as of March.

Lung cancer was a major factor for our failure to reach our FY2022 plan. In particular, we have not been able to get rid of the negative aspects with regard to safety, and this caused the negative impact.

We are currently working to provide information on adverse drug reactions that we have collected up to this point, and with the advice of the Proper Use Committee and medical specialists, we have prepared a pamphlet on the subjects.

In addition, data suggesting long-term survival in PD-L1 negative patients have been obtained, especially in the area of lung cancer, so we would like to work in this area of lung cancer by firmly promoting the safety and efficacy of the drug. This will be our priority.

Number of Bladder Cancer（Perioperative） Patients per year in Japan



Estimation based on internal survey (2022)

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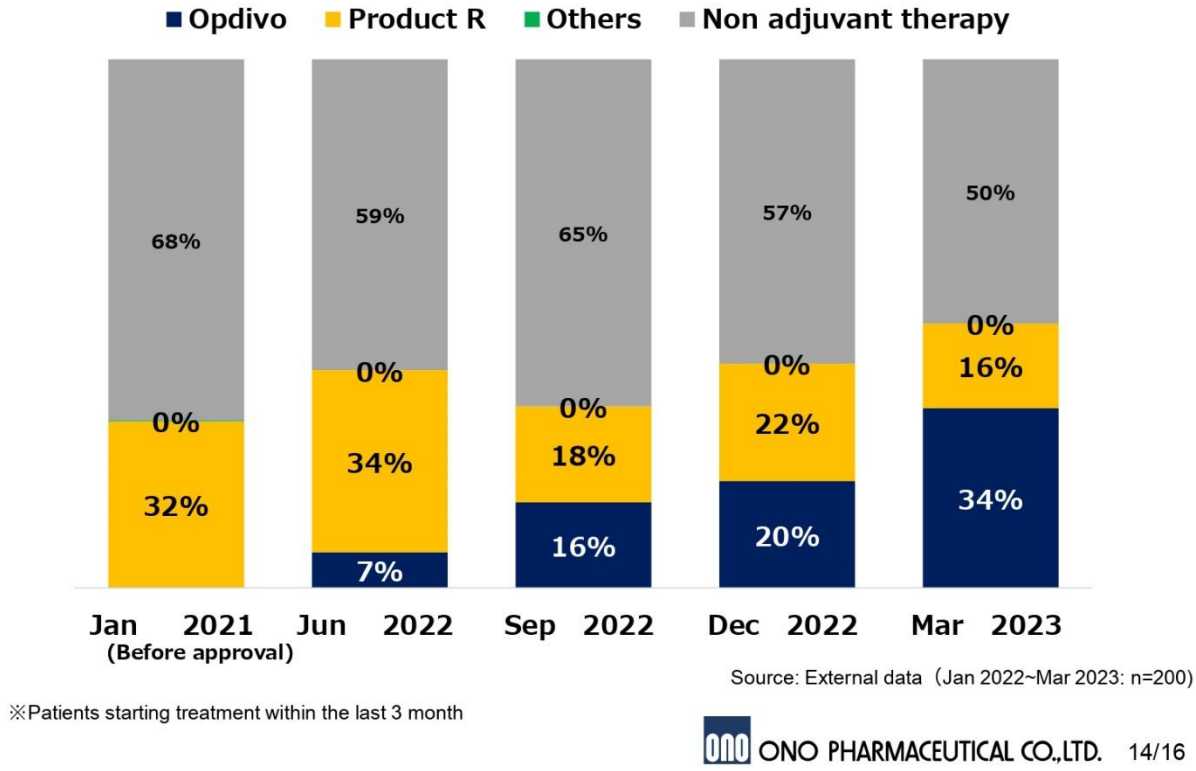
This shows the area of bladder cancer. As you know, bladder cancer is included in urothelial carcinoma. Bladder cancer is 80% of urothelial carcinomas in Japan, so I will only show the figures for bladder cancer.

In bladder cancer, there are 17,000 Stage III/IV patients per year, 11,000 of whom are eligible for surgery and 7,500 of whom are high risk. Of these, 6,000 patients per year receive an adjuvant therapy, which is the target of Opdivo.

Prescription Ratio in Patients Newly Treated for Bladder Cancer（adjuvant therapy）



Source: External data（Jan 2022~Mar 2023: n=200)

※Patients starting treatment within the last 3 month

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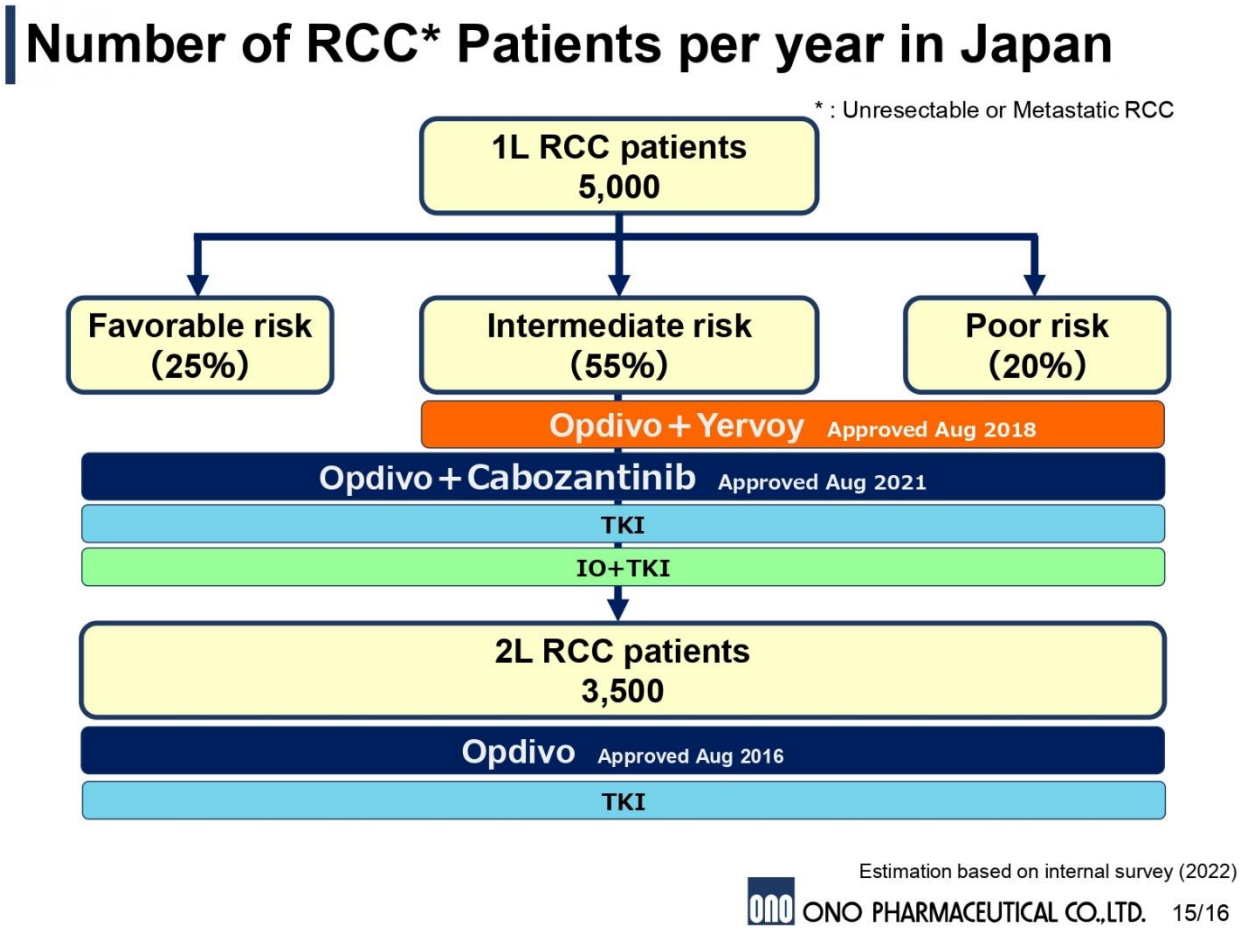
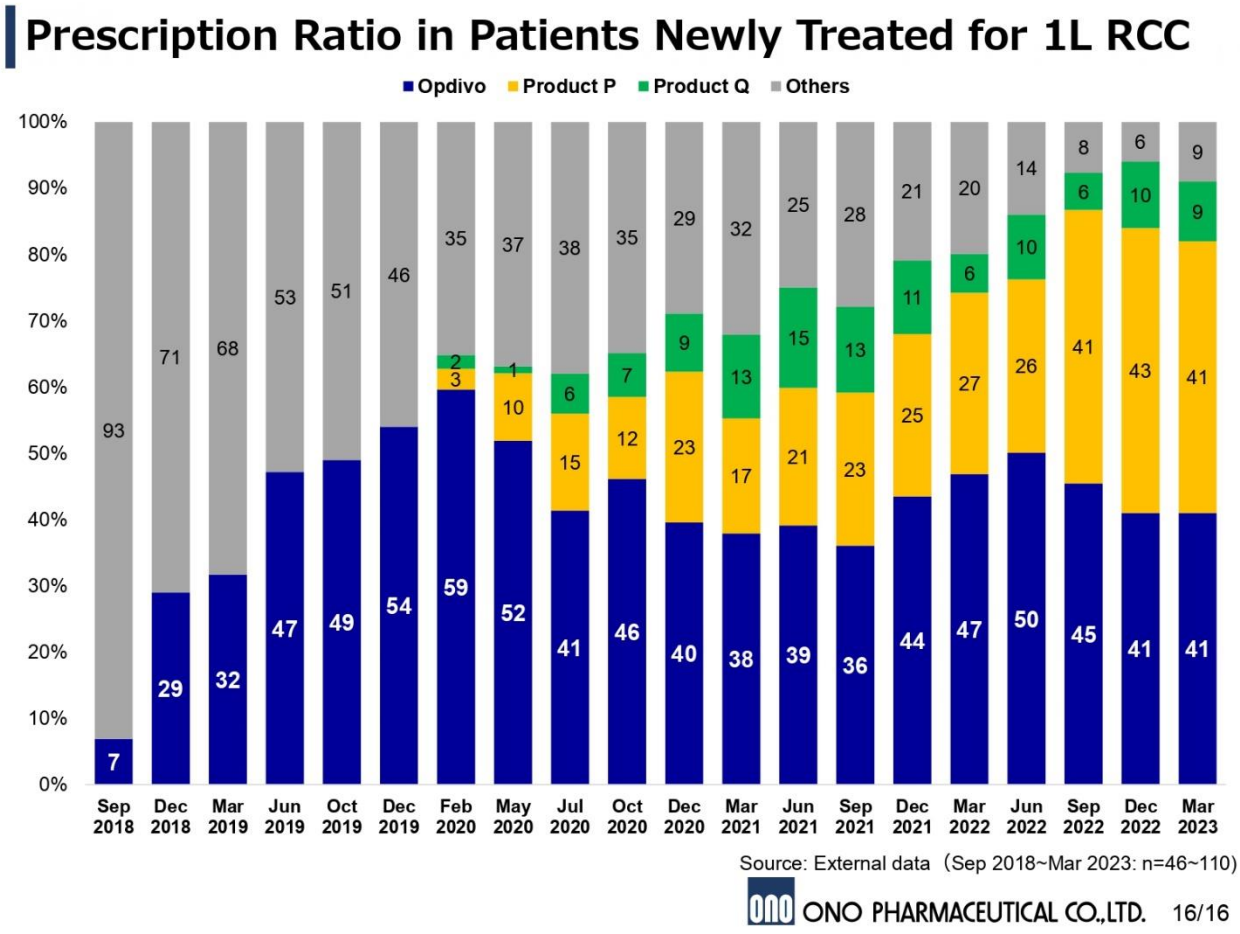
This is the share of new patient prescriptions as of March of this year. As of March, the number of patients has grown to 34%, and we expect further expansion in this fiscal year. Gradually, the Opdivo regimen is being evaluated more.

However, as you can see, 60% of the patients are still not receiving adjuvant therapy or are receiving other chemotherapy. Considering these points, there is a great deal of room for further entry and expansion of the Opdivo regimen. We will work hard to achieve this in this fiscal year.



Finally, I would like to report on the area of renal cell carcinoma.

As you are aware, Opdivo has all the evidence in first-line and second-line treatment, and we are working on sales activities for all line treatments.



This is the share of new patient prescriptions for first-line treatment of renal cell carcinoma. In first-line treatment, the expansion of IO prescriptions is progressing, as you can see, most recently at 90%.

We have two regimens of Opdivo, Opdivo plus Yervoy and Opdivo plus EGFR-TKI. Combined, the two regimens currently account for 41% of the market share of Opdivo.

Looking at the market share by risk of renal cell carcinoma, the number is 16% for low-risk, 41% for medium-risk, and 58% for high-risk. In particular, as you are aware, we have obtained a five-year follow-up data on Opdivo plus Yervoy regimen when we can expect a very good long-term survival. We would like to steadily expand prescriptions in patients with medium- to high-risks.

This was the explanation for the Opdivo trend. In FY2022, the acquisition of new prescriptions for first-line treatment of lung cancer was lower than expected, and the negative impact of this was not covered by other cancer types, resulting in the amount of JPY142.3 billion, which was below the revised plan.

The competitive environment is intensifying, but the market potential for Opdivo is very large, as shown in this slide. There are still many segments and patients to deliver, so we would like to challenge ourselves here and achieve our plan for this fiscal year.

Question & Answer

Questioner 1: I have a question about the forecast for Opdivo for this fiscal year. First, for gastric and esophageal cancer, I believe you expect double-digit sales growth this fiscal year. Are both of these necessary to achieve the plan, i.e., an increase in the proportion of patients in the early treatment line, which you explained earlier, and an increase in the treatment period per patient, as well as an increase in the market share in the first line?

I get the impression that the first-line market share remains high or rather stagnant at the moment. Could you tell me the degree of certainty of this achievement and how much room for upside remains?

Takahagi: As a factor of achievement, I believe there is still room to increase the prescription share. The reason for this is that we have secured a 90% share of prescriptions for the first-line treatment of gastric cancer in patient with CPS 5 and above, as you all know. On the other hand, for CPS below 5 is about 50% of the prescriptions, and we believe that there is still room for growth in the rest of the 50% portion of the population. The market ratio is 50-50 for CPS 5 and above and below 5. So, from this point of view, we believe that we can still aim even higher.

To take this a bit further, the response rate in patients with below CPS 5 is also about 10% higher in the Opdivo regimen compared to the chemo group. In particular, gastric cancer patients with tumors are also expected to shrink the tumors with respect to improvement of symptoms such as impaired passing of food. This improves the patient's QOL. From this perspective, we believe that we will be able to develop this part of our business.

In a sub-analysis of CheckMate -649, patients with particularly high response rates also showed longer survival. The data shows that the same trend has been observed even among those with CPS of less than 5, so we believe that we can continue to grow if we can gain a clear understanding of this trend.

Questioner 1: So am I correct to say that your plan for this fiscal year is based on the premise of further increasing market share in the first line.

Takahagi: Yes. We assume that.

Questioner 1: You explained mainly based on gastric cancer, but I understand that the same concept applies to esophageal cancer, am I correct?

Takahagi: Yes. Although there are competing products for esophageal cancer, we have two regimens as our strengths**:** Opdivo plus Yervoy and Opdivo plus chemotherapy.

Since the competing product has only the regimen plus chemo, we have heard from healthcare professionals and physicians that showing two of our regimens to patients when they make a choice is sufficient and easy to explain to them. We have also heard that long-term survival can be expected for Opdivo plus Yervoy regimen, and that the Opdivo plus chemotherapy regimen can be expected to reduce tumor size from the early stage. We believe that we can still aim higher if we can present those points out there. We can expect strongly.

Questioner 1: Another point is how you see the impact of the JCOG2007 trial results on your forecast for lung cancer this fiscal year? I would also like to know how much of the current Opdivo sales for lung cancer are made by the combination of Opdivo and Yervoy.

Takahagi: First, speaking in the framework of safety, including the JCOG2007 study, there were concerns about safety, especially in FY2022, and as I indicated earlier, new prescriptions have been stagnant throughout the year. Therefore, we do not have the accumulation of the portion of new patients that we were unable to take in FY2022, and we expect that portion to continue to tail off a bit in FY2023.

However, we will continue to provide safety information data, and as I mentioned earlier, we have strong data for PD-L1 negative cases, so we will continue to push both sides and stay the course. The current year's plan is a little smaller than the FY2022 plan, but I think you can rather say that the current year's plan is a little lower than the FY2022 plan because we did not gain many new patients in FY2022.

Questioner 1: What is the percentage of use in combination with Yervoy?

Takahagi: It is difficult to say in terms of sales, so if we look at the previous year of new patient acquisition, FY2022, 60% of new patients were on the Opdivo and Yervoy combination regimen and 40% on the CheckMate -9LA trial and the Opdivo plus Yervoy plus chemo regimen, so the current ratio is 60 to 40.

Questioner 1: Just to confirm, the safety concerns have already been raised in FY2022 and the number of new patients has already decreased, so is it correct to say that your plan assumes that the number of new patients will not decrease any further?

Takahagi: We want to hold our ground here to avoid further reduction.

Questioner 2: At this time, at the guidance, the R&D expenditures were strengthened to JPY109 billion. In the medium- to long-term growth that you previously indicated, you said JPY600 billion for the five-year cumulative total from FY2022, and I wonder if this sense of level is linear or if it will increase a bit more exponential in the future, how should we look at this?

Also, you mentioned another JPY250 billion for strategic investment, and I would like to know how much you expect to spend this year and the possibility of M&A in the future, and so on.

Sagara: Are you asking if the projected R&D investment of JPY600 billion is as scheduled?

Questioner 2: Yes. I am wondering if it is on schedule, and how it will increase in the next fiscal year and beyond.

Sagara: The JPY600 billion R&D cost over five years means an average of JPY120 billion per year. The first year was JPY95 billion. The second year is scheduled for JPY109 billion, and I am not sure if it is appropriate to say that we are on track so far, but I believe that we are on schedule. Considering that sales will increase in H2 as well as R&D expenses, we are looking on this as being on schedule.

Whether or not our non-R&D plans are on track may depend on whether they are going extremely well or not, but so far, they are proceeding as planned. It's what we do that matters, and while we appreciate your assessment, we ourselves would like to aim for effective and efficient investments qualitatively.

Questioner 2: How do you proceed with the strategic investment part?

Sagara: We are making progress on the strategic investment, but we do not disclose this. In various places, investment in venture capital is progressing. This is also generally progressing as planned.

Questioner 2: You also included investments in ventures in your R&D expenses, and although you don't disclose strategic investments, you say that they are expenses there as well.

Sagara: That's right. We are also pursuing other strategic ventures, including those related to pharmaceuticals, as well as new businesses. We are starting from a place of pure investment. We see it differently from investments in various collaborations.

Questioner 2: I see. Just to confirm, the data for the overseas development of Velexbru in the US will be available in June 2024 based on ClinicalTrials.gov, but will the timing of the market launch remain the same in FY2026 as you mentioned before?

Also, you are already in the process of increasing your staffing, but the increase in personnel expenses was not that much this year, and I would like to know how much it was and what kind of people you are mainly hiring.

Sagara: The target year of the market launch remains unchanged for now and is scheduled to go on the market in FY2026.

As for personnel, we will eventually have more than 150 people by then. Currently, the number of personnel is a little over 100, and we envision that the number will increase in stages by 2026.

Questioner 2: I see. With Velexbru coming out first, then Itolizumab, I believe there are several other pipelines and global products that you are focusing on. I would appreciate it if you could mention some products in the area of expectations.

Idemitsu: There are a number of products that we are focusing on, so it's difficult to say which one in particular, but fortunately products from the laboratory are under clinical trials and in-licensed products are coming in, so we are now focusing to quickly establish a PoC and get approval, especially in the United States.

Among them, in oncology, ONO-4578, an EP4 antagonist, is being investigated in combination with Opdivo to add to Opdivo's ineffectiveness or weak efficacy in, for example, colorectal cancer, and to further increase Opdivo's efficacy in gastric cancer and non-small cell lung cancer. Once that is confirmed, we would like to start verification trial. In addition, ONO-7018, an inhibitor of MALT1, which is an in-licensed product, is under clinical trials in the United States. We are currently focusing on these oncology projects.

Outside of oncology, we expect Itolizumab, which you mentioned earlier, will be approved next to Velexbru. We are developing ONO-4685 for the target indication of both lymphoma and autoimmune diseases, and if we can confirm its efficacy, we would like to conduct verification trials at once.

In addition, ONO-2910, which promotes Schwann cell differentiation, and ONO-2808, an S1P5 receptor agonist, for the treatment of neurodegenerative disease, as well as ONO-2020, having epigenetics regulation properties, have entered the clinical trials. Our current focus is to quickly confirm the safety and efficacy of these drugs, and as soon as their efficacy and safety are confirmed, we hope to begin late-stage clinical trials.

Questioner 3: First question is on Opdivo. I compared the second page of the chart you gave us with the same one for Q3, and I am concerned about the forecast for the current period. I understand stomach and esophageal cancer very well. This is a picture, so I can't say anything, but I was wondering if you do not have much expectation on renal cancer area, as you explained earlier. On the other hand, can we consider bladder cancer as the most potential area for expansion, like esophageal cancer, from what you have explained?

Takahagi: Yes. We would like to expand largely in the area of bladder cancer, and we believe it will grow.

Questioner 3: Is the reason for that as you explained earlier?

Takahagi: Yes.

Questioner 3: I see. Then, EPS is important to us, and as you explained in the financial statements, the tax rate has been reduced by 1.9 percentage points, hasn't it? So, the final profit has increased by 40%. This was partly due to deductible expenses, such as donations and research expenses that have risen significantly. What was the biggest cause?

Ito: Since we are a pharmaceutical manufacturer, the benefit of the non-deductible expenses for testing and research is the most significant. There is also a discrepancy between tax and accounting, and there are complex factors such as the portion of profit and R&D expenses and the timing of the completion of the trial.

It is difficult to estimate the portion that can be deducted from corporate income tax, because there are many conditions, such as the completion of research and development and the ability to apply for approval, complete data, various global development conditions, and so on, depending on the year. However, the most significant factor was that the tax rate was lower this fiscal year, or rather, the ended fiscal year, due to the benefit of the tax rate being lower than expected.

Questioner 3: I understand very well. The actual results, or rather the forecast, the financial results that ended the previous fiscal year were down temporarily, and because of that, it's only a 2% growth forecast in net income for the current fiscal year. Conversely, is it correct to say that last fiscal year's benefit was significant, and that this fiscal year's growth is low because it is no longer the case, and the starting place is high?

Ito: Yes.

Questioner 3: Last question. On the numbers, research expenses have gone up a lot compared to Q3, haven't they? Is my understanding correct that that was simply because the clinical trial has advanced? That is reducing the rate of profit attainment, isn't it? It was about 93%, or so, in the original plan. The research expenses have gone up a lot in Q3, and is it just because of the clinical progress?

Ito: Some of this is due to clinical trial advances, and some of it is due to higher licensing-related costs. It is from both factors.

Tani: One thing is that we in-licensed itolizumab during the term, and we will bear the development costs of Itolizumab, so I think that caused a little increase.

Questioner 4: I would like to ask one question. This is about the administration duration for postoperative adjuvant therapy with Opdivo. I understand that the competition in the development of these immune checkpoint inhibitors is now shifting to postoperative adjuvants.

Is the administration period, in postoperative adjuvant, to basically keep administrating all the way until the event occurs? When I look at the approvals, I think it is basically supposed to stop at 12 months. I was thinking that it is something that is expected to have the effect of suppressing recurrence, or cancer development, for a long time, so it is something that is administered continuously, but how is that situation scientifically?

Idemitsu: Are you asking about the current clinical practice situation? Or development protocol?

Questioner 4: Both. First, I would like to ask how it is handled clinically.

Idemitsu: Generally, in the development, the efficacy has been judged in one-year treatment period.

Questioner 5: The first is regarding the Opdivo patent. I thought there was a lawsuit with AstraZeneca, and my understanding is that this is continuing because it has not been disclosed. Is this continuing and the timing of resolution, including impact, still unknown? Please let me know if you have any updates.

Sagara: As you pointed out, the situation is continuing. We would appreciate your patience for any further information. It is still in dispute.

Questioner 5: Secondly, you have quite a few more Opdivo themes to file in H2. You do not explain all of them individually, but I would be grateful if you could mention some of them that have relatively high expectations in terms of the number of patients and duration of administration.

Idemitsu: I do not have a definite answer at this time, as it is very difficult to say which has higher or lower expectations while the results are not yet available, and depending on the results, I think any of them could be good.

Questioner 5: I see. Finally, you gave us an update on ONO-4685, and on clinical, it is suspended for psoriasis. Any progress on that? Please let me know if you have any updates.

Idemitsu: ONO-4685 is being developed for autoimmune diseases. Specifically, Phase I is being conducted in Europe in patients with psoriasis. I cannot disclose details, but we are not stopping because of any major problem. We hope you understand that there is no major problem, as we will resume as soon as we confirm the situation.

Questioner 6: Regarding the Opdivo usage for lung cancer, maybe it's because I haven't been listening well in the past, but you mentioned this time that the decline in the lung cancer patient share is due to the safety issue, and I would like to know a little more detail on this.

From FY2022, there has been a safety issue to begin with, and as to some earlier question about JCOG, I think this is more of a recent development rather than FY2022. If there was already a safety issue in FY2022, I wonder if the JCOG would have even more impact in the future, and the safety concerns would be more widespread, but am I wrong in that view?

You explained earlier that you would be going to regain new patients this fiscal year, but I was rather wondering if there is a risk of further decline in new patients, so please explain further about this.

Takahagi: JCOG was announced at the end of April this time, but I understand that the trial itself was started long ago. In this context, last year, when there was a bit of discussion within JCOG regarding this safety issue, especially regarding deaths, the safety information was provided to us. We have been regularly updating the safety information we can provide to medical institutions accordingly.

Therefore, we are aware that the JCOG had some influence on safety issue in the last fiscal year, although there was more than JCOG matter.

Questioner 6: So, given that JCOG is not a story that just started, is it safe to assume that doctors' understanding of this safety issue is going in a rather positive direction?

Takahagi: It is heading in a positive direction. However, when various information is updated, it fluctuates, and we are taking this into account and updating and sharing safety information on a regular basis.

Questioner 7: Regarding Opdivo, there was a time when I was expecting to see JPY200 billion in domestic sales soon because the momentum of sales for gastric cancer was very good until a while ago. However, looking at the materials this time, I think there is upside, but I am a little less confident that JPY200 billion is possible in the next few years, maybe two or three years. I would appreciate any comments on this, even if it is just your intention.

Sagara: If we go by intentions, yes. However, if it is just a matter of intentions, I don't think we should talk about when it will be at this point in time, or how much by when, etc. However, it does not mean that we have given up or lost the possibility, so the answer is that we will work hard toward it. Is that okay?

Questioner 7: This may be slightly flip side of that story, but the CheckMate -9DX trial of the adjuvant for hepatocellular carcinoma has been delayed significantly. I am wondering if this also has a negative impact on long-term projections and sales. Can you give me some more background on this? It has been delayed for a long time, but I have the impression that it was delayed significantly this time.

Idemitsu: I am sorry, but we refrain from disclosing the details because they are related to the content of the trial. The progress of pipelines we announce is the fastest possible results, so we would very much appreciate your understanding that delays are possible for a variety of reasons.

Questioner 7: Are you changing the study design or expanding the patient size?

Idemitsu: I hope you understand that we need to refrain from disclosing that matter, since it relates to the contents of clinical trials.

Sagara: I would like to add a few words about Opdivo. I think I did not clearly answer the question from the Questioner 1 as to whether both an increase in prescription rate and extension of prescription duration for gastric cancer are minimum requirements for achieving the goal for this fiscal year. I am telling you that this can surely be accomplished if both are done as planned. It doesn't mean that if we can't do both, we won't get there.

Questioner 8: I would like to know more about JCOG2007. I was looking at this process, and I saw that death occurred in 7% of the patients in ipilimumab combination therapy. Many of the cases had already been reported, such as pneumonitis, cytokine release syndrome, and myocarditis, but they occurred above the expected range of 5%. After that, the doctors suspended the trial and resumed it one more time, thinking that it would probably be safe for such people based on high white blood cell counts, high neutrophil counts, and so on, but there were more deaths, so the trial was suspended.

I wonder if this trend will inevitably destroy the myth that Opdivo and Yervoy are safe in low-dose Yervoy. If so, I believe this could affect not only lung cancer, but also the Yervoy combination therapy that will come out in the future.

Since you mentioned that your company would like to do its best in lung cancer, please tell us how you are going to explain JCOG2007, such as the fact that there are patients who were more likely to develop the disease, or other such circumstances.

Takahagi: As you are aware, JCOG2007 is a physician-initiated clinical trial, and we are not involved in it. Therefore, we would like to refrain from commenting on the trial. However, we take the cautions regarding the JCOG announcement very seriously.

However, we originally conducted a development study, the CheckMate-9LA study, on the combination of Opdivo plus Yervoy and chemotherapy. Among them, the incidence of deaths for which a causal relationship with this combination therapy cannot be ruled out is 2%. We are also conducting a post-marketing sponsor-initiated clinical study and have confirmed the incidence of adverse drug reactions, and as of June 10 last year, the treatment-related mortality rate was 2.8%, or six of 212 cases.

In addition, post-marketing, chemotherapy, Opdivo plus Yervoy, or CheckMate-9LA regimen have been used for non-small cell lung cancer, and this is only an estimate, but estimates show that it has been used in 4,000

cases. Of these, we and Bristol-Myers Squibb have 93 deaths. So, it is 2.3%. Therefore, we currently believe that the post-marketing information is about the same as that obtained during clinical trials.

However, we are planning to conduct a detailed investigation of the 11 death cases in the JCOG study under the cooperation with the JCOG. We are taking this into consideration, but we have been and will continue to make efforts to collect and properly evaluate safety information, of course.

We have been and will continue to be constantly evaluating the safety of the combination therapy of Opdivo and Yervoy, as you pointed out earlier, including other cancer types. We are working to promote the proper use of these products, consulting with regulatory authorities as necessary, and we hope to continue to do so in the future.

Sagara: I would like to add something. As I mentioned earlier, the number of deaths from the clinical trials and the approximately 4,000 cases of post-marketing use of the drug are in the 2% range. The current result from JCOG trial was from 148 cases, a very small number. My inclination is to compare them, but we will not or should not do that, so we will provide the data we have and the facts about safety to the healthcare professionals in a scientific manner.

On that basis, we ourselves do not mean that the combination regimen of Opdivo, Yervoy, and chemotherapy should not be recommended because of significant safety issues. As in the past, we will continue to provide information. Please understand that it is difficult for me to answer you directly as I cannot and should not discuss this on the basis of a direct comparison.

Questioner 9: Thank you for explaining the impact of the settlement with Dana-Farber Cancer Institute on the potential short-term payment. I would like to better understand this medium- to long-term impact.

Specifically, will the settlement affect the status of the current licensing agreement with Bristol-Myers Squibb? I believe the patent in the US is for up to 2028, since the financial statement report at the end of last fiscal year states that Opdivo royalty receipt is for the duration of the patent or 13 years from launch, whichever is longer. I am thinking that perhaps the current situation is that the contract is for royalty receipt until 2028, but is this likely to change? Or is it better to understand it literally that there will be no change? Can you confirm this?

Sagara: It doesn't affect our royalty agreement with BMS at all. Did it answer your question?

Questioner 9: I see. If so, would it be correct to say that in the US, you would receive royalties up to FY2028?

Sagara: Yes.

[END]