ONO PHARMACEUTICAL CO., LTD.

Q3 Financial Results for the Fiscal Year Ending March 2023

January 31, 2023

[Number of Speakers]	5	
	Gyo Sagara	President, Representative Director, and Chief Executive Officer
	Kiyoaki Idemitsu	Executive Officer, Executive Director of Clinical Development
	Satoshi Takahagi	Corporate Officer, Executive Director of Sales and Marketing, Primary Care Business Division
	Kazuhiro Nagahama	Director of Finance and Accounting Department
	Yukio Tani	Corporate Executive Officer, Head of Corporate Communications, Sustainability Promotion Department

Presentation

Sagara: As we have established a new foundation, I would like to report and explain the matter.

In response to the Mie University issue, ONO has stopped contributing its scholarship donation. In addition, we have also been suspended contributions to endowed courses. However, we would like to continue our contribution to academia in some form by giving back a portion of our earnings, and have been considering the best way to do this.

We are pleased to announce that we have established a new foundation from which we will continue to provide research grants in a transparent and fair manner. The new foundation will provide research grants for basic research in the three areas of cancer, immunology, and neurology, targeting at young researchers.

We would like to start by selecting grant recipients from the next fiscal year 2023, with an annual grant amount of about JPY300 million.

The funds for the foundation would be contributed as a donation from our company. First of all, we would like to start with a donation of about JPY2 billion in the current fiscal year. This has not yet been finalized, but that way we can begin providing grants in the next fiscal year.

It is currently a general incorporated foundation, but we hope to change to a public interest incorporated foundation as soon as possible. Other details are as indicated in the information provided. This will allow us to resume our contribution to academia, which has been suspended for two or three years.

Revenue

Revenue	YoY Change
¥ 339.0 billion	+ 24.9 %

Breakdown of Revenue

(Billion yen)

	FY 2021 Q3	FY 2022 Q3	YoY Change
Revenue of Goods and Products	185.9	225.5	+ 21.3 %
Royalty & other revenue	85.5	113.5	+ 32.7 %
Total	271.4	339.0	+ 24.9 %

Nagahama: I will now give an overview of the financial results for Q3 of the current fiscal year.

Revenue for the period increased by JPY67.6 billion, or 24.9%, from the same period last year to JPY339 billion.

Revenue of goods and products increased by JPY39.6 billion, or 21.3%, to JPY225.5 billion, and royalties and other revenue increased by JPY27.9 billion, or 32.7%, to JPY113.5 billion, due to the impact of foreign exchange rates.

Royalty from Bristol-Myers Squibb related to Opdivo increased by JPY14.7 billion to JPY66.8 billion, and royalty income from Merck related to sales of Keytruda increased by JPY11.2 billion to JPY33.6 billion.

Of the JPY14.7 billion increase in royalty income from Bristol-Myers Squibb, JPY12.4 billion was due to the effect of foreign exchange rates. Of the JPY11.2 billion increase in royalty income from Merck, JPY6 billion is attributable to foreign exchange rates.

Sales of Major Products

(Billion yen)

	FY 2021 Q3	FY 2022 Q3	YoY Change
Opdivo	85.1	**109.1**	+ 28.3 %
Forxiga	26.5	**41.9**	+ 58.0 %
Orencia SC	17.5	**19.1**	+ 9.0 %
Glactiv	19.3	**17.7**	- 8.5 %
Kyprolis	6.5	**6.8**	+ 4.4 %
Parsabiv	6.9	**6.5**	- 5.6 %
Velexbru	4.7	**6.5**	+ 38.5 %
Ongentys	2.0	**3.8**	+ 91.8 %
Onoact	3.9	**3.6**	- 9.0 %
Braftovi	2.1	**2.5**	+ 20.7 %
Mektovi	1.7	**2.0**	+ 15.5 %

I will explain the status of our main products.

First, sales of Opdivo for intravenous infusion increased by JPY24.1 billion, or 28.3%, YoY to JPY109.1 billion, as its use expanded mainly in gastric and esophageal cancer, despite intensifying competition from competing products.

Sales of Forxiga tablets increased by JPY15.4 billion, or 58%, YoY to JPY41.9 billion, thanks to solid performance in the diabetes area, as well as use in chronic heart failure, which was approved in November 2020, and chronic kidney disease, which was approved in August 2021.

Sales of Orencia subcutaneous injection increased by JPY1.6 billion, or 9%, YoY to JPY19.1 billion.

Sales of Glactiv tablets decreased by JPY1.6 billion, or 8.5%, YoY to JPY17.7 billion, due to the impact of the NHI price revision as well as the growth of combined drugs amid the shrinking market share of DPP-4 inhibitors in the treatment of type 2 diabetes.

Kyprolis for intravenous infusion increased by JPY300 million YoY to JPY6.8 billion, in line with expectations.

Sales of Parsabiv for intravenous dialysis decreased by JPY400 million YoY to JPY6.5 billion, due to an increasingly competitive environment with competing products.

Sales of Velexbru tablets increased by JPY1.8 billion YoY to JPY6.5 billion, exceeding the initial projection.

Sales of Ongentys increased by JPY1.8 billion YoY to JPY3.8 billion, thanks to the convenience of once-daily dosing and steady sales since the start of long-term dosing in September 2021.

Sales of Onoact for intravenous infusion decreased by JPY400 million YoY to JPY3.6 billion, due to the NHI price revision.

Braftovi capsule and Mektovi tablets also performed well, with Braftovi up by JPY400 million to JPY2.5 billion and Mektovi up by JPY300 million to JPY2 billion.

Sales of Long-term Listed Products

(Billion yen)

	FY 2021 Q3	FY 2022 Q3	YoY Change
Opalmon	3.7	**3.4**	- 7.5 %
Onon capsule	2.7	**1.7**	- 34.9 %

As for long-term listed drugs, sales of Opalmon tablets decreased by JPY300 million YoY to JPY3.4 billion and sales of Onon capsules decreased by JPY1 billion YoY to JPY1.7 billion.

Operating Profit

Operating Profit	YoY Change
¥ 122.6 billion	+ 49.2 %

Costs, etc.

(Billion yen)

	FY 2022 Q3	YoY Change
・Cost of Sales	83.8	(+ 18.6%)
・R&D Expenses	66.0	(+ 33.4%) ①
・SG&A Expenses	66.1	(+ 15.1%) ②
①+② Total	132.1	(+ 23.5%)
・Other Income	0.5	(- 30.5%)
・Other Expenses	1.0	(- 91.6%)

Next, let us look at operating profit.

Operating profit increased by JPY40.4 billion, or 49.2%, YoY to JPY122.6 billion.

Cost of sales increased by JPY13.2 billion, or 18.6%, YoY to JPY83.8 billion, mainly due to an increase in revenue of goods and products. The cost of sales ratio improved by 1.3%, YoY to 24.7%.

R&D expenses increased by JPY16.5 billion, or 33.4%, YoY to JPY66 billion. This was mainly due to an increase in research-related expenses, expenses related to drug discovery alliances, development expenses related to early-stage clinical trials, and joint development expenses with partner companies.

SG&A expenses excluding R&D expenses, increased by JPY8.7 billion, or 15.1%, YoY to JPY66.1 billion. This was due to increases in copromotion fees associated with the sales expansion of Forxiga and expenses associated with the strengthening of IT and digital-related information infrastructure.

Next, other income and other expenses. Other income was JPY500 million. Other expenses decreased by JPY11.4 billion YoY to JPY1 billion, due to a rebound from the recording of expenses related to litigation concerning PD1 antibody-related patents in FY2022.

As a result of the above, operating income increased by JPY40.4 billion, or 49.2%, YoY to JPY122.6 billion.

Profit before Tax

Profit before Tax	YoY Change
¥ 124.4 billion	+ 47.5 %

Net financial income, etc.

+ ¥ 1.8 billion (YoY Change - ¥ 0.4 billion)

Finance income : (Dividend income received, etc.)	¥ 2.4 billion
Finance costs : (Exchange losses, etc.)	¥ 0.6 billion

Next is profit before tax.

Since net financial income and other income decreased by JPY400 million YoY to JPY1.8 billion, profit before tax increased by JPY40 billion, or 47.5%, YoY to JPY124.4 billion.

Profit for the Period (Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 95.7 billion	+ 48.0 %

Income tax expense

¥ 28.6 billion (YoY Change + 45.1 %)

(Major change factors)

Increase in profit before tax	¥ 40.0 billion
Increase in corporate tax	¥ 8.9 billion

Profit for the period attributable to owners of the parent company increased by JPY31 billion, or 48%, YoY to JPY95.7 billion, due to an increase in profit before tax.

Both sales and profits reach record highs for the third quarter.

Financial Forecast for FY 2022

Financial forecast is unchanged from those announced on October 31, 2022

(Billion yen)

	FY 2021 (Result)	FY 2022 (Forecast)	YoY Change
Revenue	361.4	**440.0**	+ 21.8 %
Operating profit	103.2	**149.0**	+ 44.4 %
Profit before tax	105.0	**150.0**	+ 42.8 %
Profit for the year (Owners of the Parent Company)	80.5	**114.0**	+ 41.6 %

Exchange rate
FY 2022 (Forecast (2nd Half)): 1USD = 130 yen

Next, I will explain our forecast for the fiscal year ending March 31, 2023.

There is no change in the full year forecast from that announced on October 31, 2022. The assumed exchange rate for H2 FY2022 remains unchanged at JPY130 to the US dollar.

Sales Forecast of Major Products

(Billion yen)

	FY 2021 (Result)	FY 2022 (Forecast)			YoY Change
		Previous Forecast	Change	Revised Forecast	
Opdivo	112.4	155.0	- 10.0	**145.0**	+ 28.9 %
Forxiga	36.7	47.0	+ 8.0	**55.0**	+ 50.1 %
Orencia SC	22.9	23.0	+ 1.5	**24.5**	+ 7.0 %
Glactiv	24.5	23.0		**23.0**	- 6.3 %
Kyprolis	8.4	9.0		**9.0**	+ 7.6 %
Parsabiv	8.9	8.0		**8.0**	- 9.9 %
Velexbru	6.3	7.0	+ 1.5	**8.5**	+ 35.6 %
Ongentys	2.9	5.0		**5.0**	+ 73.6 %
Onoact	4.9	4.5		**4.5**	- 7.6 %
Braftovi	2.7	3.5		**3.5**	+ 27.4 %
Mektovi	2.2	2.5		**2.5**	+ 11.7 %

With regard to the sales forecasts for each main product, the sales forecasts for some products have been changed. Specifically, sales forecasts have been changed for five products.

First, the forecast for Opdivo has been revised downward by JPY10 billion. The revised full-year forecast is JPY145 billion, up JPY32.6 billion or 28.9% YoY.

Next, we revised our forecast for Forxiga upward by JPY8 billion. Our revised full-year forecast is JPY55 billion, up JPY18.3 billion or 50.1% YoY.

The full year forecast for Orencia has been revised upward by JPY1.5 billion to JPY24.5 billion, an increase of JPY1.6 billion, or 7%, YoY.

The forecast for Velexbru has been revised upward by JPY1.5 billion, and the revised full-year forecast is JPY8.5 billion, up JPY2.2 billion or 35.6% from the previous year.

Sales Forecast of Long-term listed products

(Billion yen)

	FY 2021 (Result)	FY 2022 (Forecast)			YoY Change
		Previous Forecast	Change	Revised Forecast	
Opalmon	4.7	3.5	+ 1.0	**4.5**	- 4.9 %
Onon capsule	3.6	2.5		**2.5**	- 29.7 %

Finally, we have revised our forecast for Opalmon upward by JPY1 billion, and our revised full-year forecast is JPY4.5 billion, a decrease of JPY200 million or 4.9% YoY.

These are the changes in sales forecasts for major products.

We plan to pay a year-end dividend of JPY33 per share, which remains unchanged at present.

4. Supplementary Information

(1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product Name	Nine months ended December 31, 2022 (April 1, 2022 to December 31, 2022)						FY 2022 Forecast (April 1, 2022 to March 31, 2023)				
	Cumulative				YoY		Previous Forecast	Change from Previous Forecast	Revised Forecast	YoY	
	Apr ~ Jun	Jul ~ Sep	Oct ~ Dec		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	34.1	35.8	39.3	**109.1**	24.1	28.3%	155.0	(10.0)	**145.0**	32.6	28.9%
Forxiga Tablets	13.1	13.3	15.5	**41.9**	15.4	58.0%	47.0	8.0	**55.0**	18.3	50.1%
Orencia for Subcutaneous Injection	6.2	6.2	6.7	**19.1**	1.6	9.0%	23.0	1.5	**24.5**	1.6	7.0%
Glactiv Tablets	6.0	5.7	5.9	**17.7**	(1.6)	(8.5%)	23.0		**23.0**	(1.5)	(6.3%)
Kyprolis for Intravenous Infusion	2.2	2.2	2.4	**6.8**	0.3	4.4%	9.0		**9.0**	0.6	7.6%
Parsabiv Intravenous Injection	2.1	2.1	2.3	**6.5**	(0.4)	(5.6%)	8.0		**8.0**	(0.9)	(9.9%)
Velexbru Tablets	2.1	2.0	2.4	**6.5**	1.8	38.5%	7.0	1.5	**8.5**	2.2	35.6%
Ongentys Tablets	1.2	1.2	1.4	**3.8**	1.8	91.8%	5.0		**5.0**	2.1	73.6%
Onoact for Intravenous Infusion	1.1	1.0	1.4	**3.6**	(0.4)	(9.0%)	4.5		**4.5**	(0.4)	(7.6%)
Opalmon Tablets	1.1	1.1	1.2	**3.4**	(0.3)	(7.5%)	3.5	1.0	**4.5**	(0.2)	(4.9%)
Braftovi Capsules	0.9	0.8	0.9	**2.5**	0.4	20.7%	3.5		**3.5**	0.8	27.4%
Mektovi Tablets	0.7	0.6	0.7	**2.0**	0.3	15.5%	2.5		**2.5**	0.3	11.7%
Onon Capsules	0.7	0.5	0.6	**1.7**	(0.9)	(34.9%)	2.5		**2.5**	(1.1)	(29.7%)

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecasts for the FY 2022, only currently approved indications are covered.

Takahagi: I would like to add something regarding the sales situation of each indication of Forxiga. We estimate it to be about JPY25 billion for the diabetes, about JPY7 billion for chronic heart failure, and about JPY10 billion for chronic kidney disease.

I would like to continue by adding a few words about the products for which we have revised our full-year sales forecast.

First, the sales forecast for Opdivo has been revised downward by JPY10 billion. This is due to the fact that the negative impact in non-small cell lung cancer could not be covered by other cancer types, although sales in first-line treatment of gastric cancer, and esophageal cancer are growing steadily. The revised full-year forecast is JPY145 billion, up JPY32.6 billion or 28.9% YoY.

The use of Forxiga has expanded with its approval for chronic heart failure in November 2020 and for chronic kidney disease in August 2021. The sales forecast has been revised upward by JPY8 billion due to the increasing trend. The revised full-year forecast is JPY55 billion, up JPY18.3 billion or 50.1% YoY.

The sales forecast for Orencia has been revised upward by JPY1.5 billion due to the continued progress in safety and efficacy evaluations and the expansion of prescriptions to patients under 65 years old, in addition to elderly patients over 65 years old previously evaluated well. The revised full-year forecast is JPY24.5 billion, up JPY1.6 billion, or 7%, YoY.

The sales forecast for Velexbru has been revised upward by JPY1.5 billion due to an increase in the number of cases of continuous administration. The revised full-year forecast is JPY8.5 billion, up JPY2.2 billion or 35.6% YoY.

Lastly, the sales forecast for Opalmon has been revised upward by JPY1 billion due to the switch from the concurrently sold product to Opalmon progressing more than expected following the discontinuation of co-marketed products. The revised full-year forecast is JPY4.5 billion, down JPY200 million or 4.9% YoY.

Development pipeline

Idemitsu: I will explain the updated portion of the financial results for Q2 FY2022 and beyond.

(4) Main Status of Development Pipelines (Oncology)

As of January 23, 2023

<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	Esophageal cancer	Injection	S. Korea	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 Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)

<I-O Related> *) : "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-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578 ★	New chemical entities	Colorectal cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor・Gastric cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 ★ /Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 ★ /Atamparib	New chemical entities	Solid tumor / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)
ONO-7122 ★	New chemical entities	Solid tumor / TGF-β inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 ★	New chemical entities	Solid tumor / STING agonist	Injection	Japan	I	In-house

First, in the oncology area, there is no update from Q2.

<Others> ***) :** "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-7913 / Magrolimab	New chemical entities	TP53-mutant acute myeloid leukemia / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 /Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Myelodysplastic syndromes (MDS) / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-4578	New chemical entities	Hormone receptor-positive, HER2-negative breast cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma / PD-1 x CD3 bispecific antibody	Injection	USA	I	In-house
ONO-7018	New chemical entities	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia / MALT1 inhibitor	Tablet	USA	I	In-license (Chordia Therapeutics Inc.)

★: Combination with Opdivo.

In the case of clinical development of the oncology drugs in the same indication, the most advanced clinical phase is described.

(5) Main Status of Development Pipelines (Areas other than Oncology)

As of January 23, 2023

<Clinical Trial Stage> ***) :** "In-house" compounds include a compound generated from collaborative research.

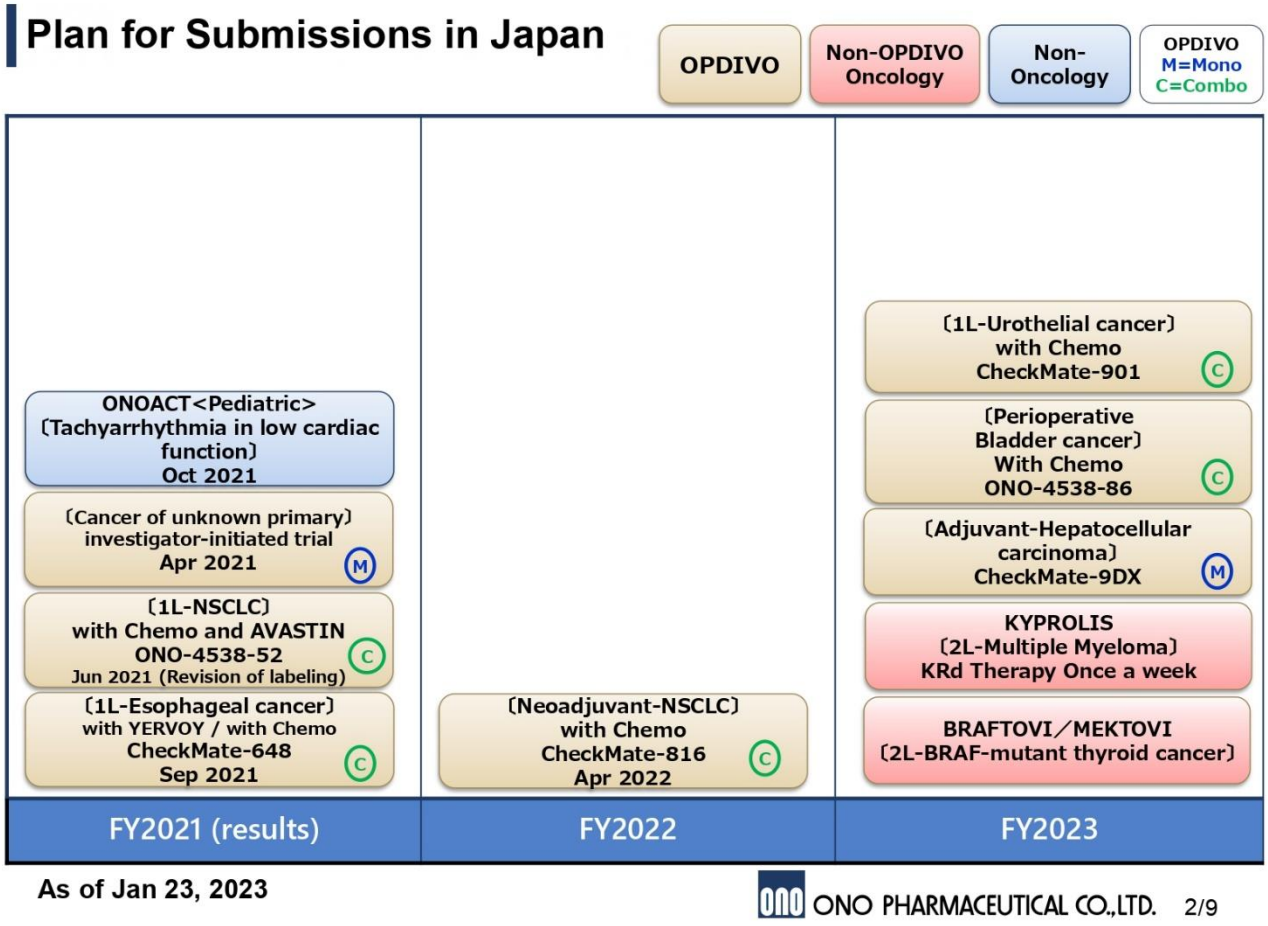
Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-2017 / Cenobamate	New chemical entities	Primary generalized tonic-clonic seizures / Inhibition of voltage-gated sodium currents/positive allosteric 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*1	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
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house
ONO-2020	New chemical entities	Neurodegenerative disease / Epigenetic regulation	Tablet	USA	I	In-house
ONO-1110*2	New chemical entities	Pain / Endocannabinoid regulation	Oral	Japan	I	In-house

The change from the announcement of financial results for the second quarter of the fiscal year ending March 2023 is as follows:
*1: Phase I of ONO-7684, FXIa inhibitor, was initiated in Japan for healthy adult subjects.
*2: Phase I of ONO-1110, Endocannabinoid regulation, was initiated in Japan for healthy adult subjects.

This is the main progress status of development products (other than oncology).

ONO-7684, a FXIa inhibitor, has entered Phase I trial in Japan.

ONO-1110, a regulator of endogenous cannabinoids, has likewise entered Phase I trial in Japan.



Next, I will explain the progress of the development pipeline.

Please note that the timing of the application is based on the fastest possible schedule if things proceed as planned, and the situation is subject to change.

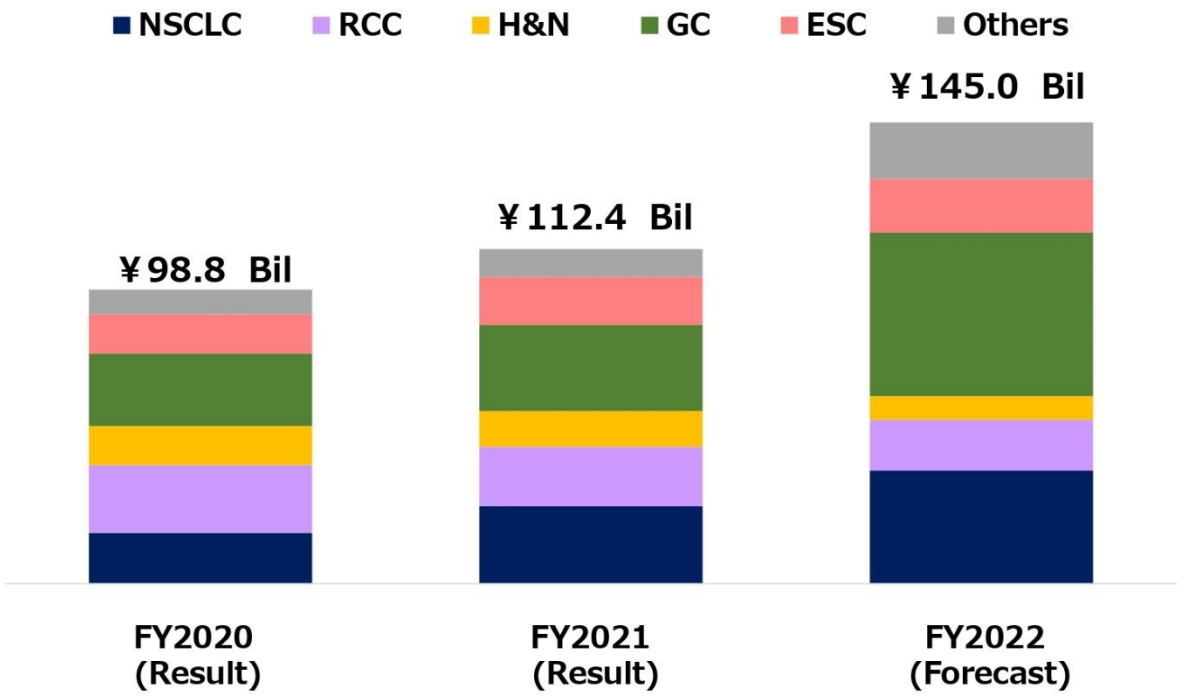
I will explain by focusing on changes from November 1. In the previous document, we had planned to submit an application for a postoperative adjuvant treatment of gastric cancer in FY2022, but unfortunately, the expected efficacy was not achieved, and the application was abandoned.

We had planned to submit applications for the combination of Opdivo and Yervoy for first-line treatment of urothelial carcinoma and for first line treatment of MSI-High colorectal cancer in FY2023 and FY2024, respectively. However, the timing for obtaining the results is expected to be later than originally planned, so we have changed the application timing to FY2024.

Trend of Opdivo

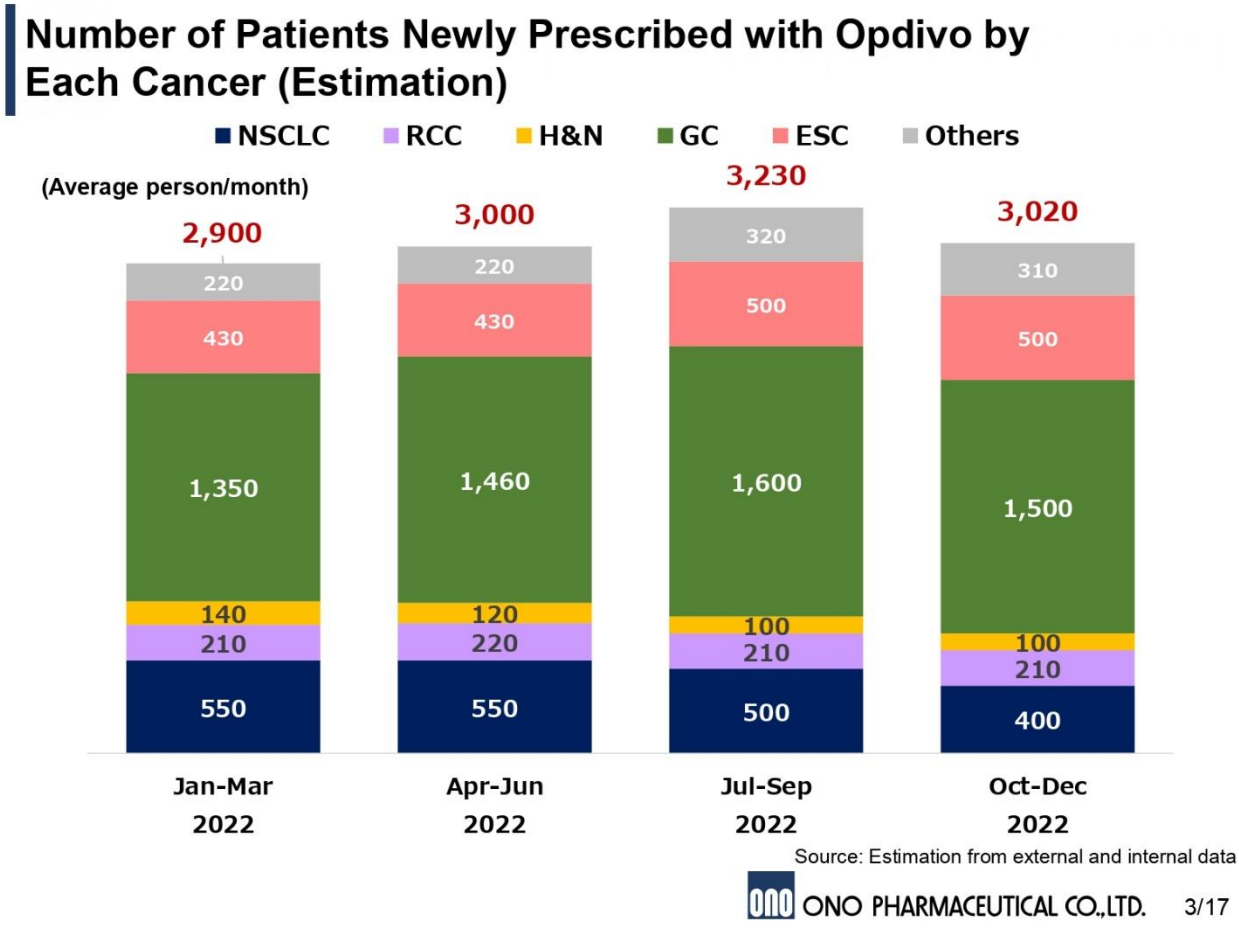
Takahagi: I will introduce the status of the Opdivo trend.

Sales Trend of Opdivo by Each Cancer



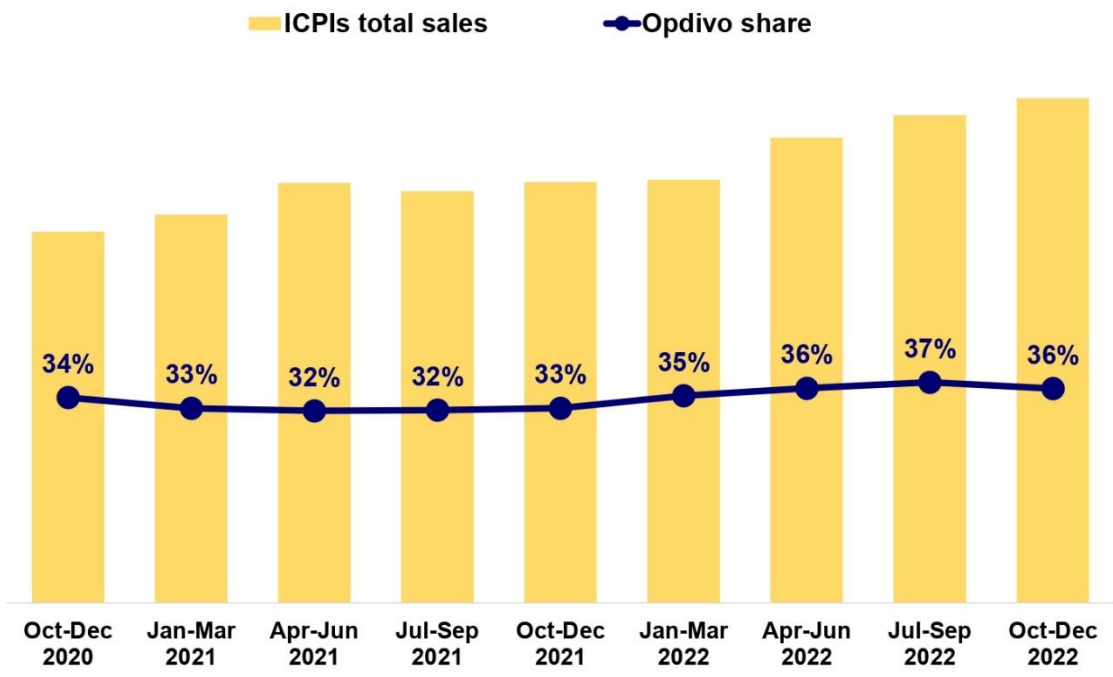
Source: Estimation from external and internal data

Takahagi: First, Opdivo sales. As I mentioned earlier, the number of new Opdivo prescriptions is not progressing as planned, especially in lung cancer, and the projection for this fiscal year is JPY145 billion.



In estimation of October to December 2022, 1,500 new prescriptions were initiated for stomach cancer, 500 for esophageal cancer, and 400 for lung cancer, for an overall average of 3,020 new prescriptions per month.

Trend of total sales of ICPIs and Opdivo share

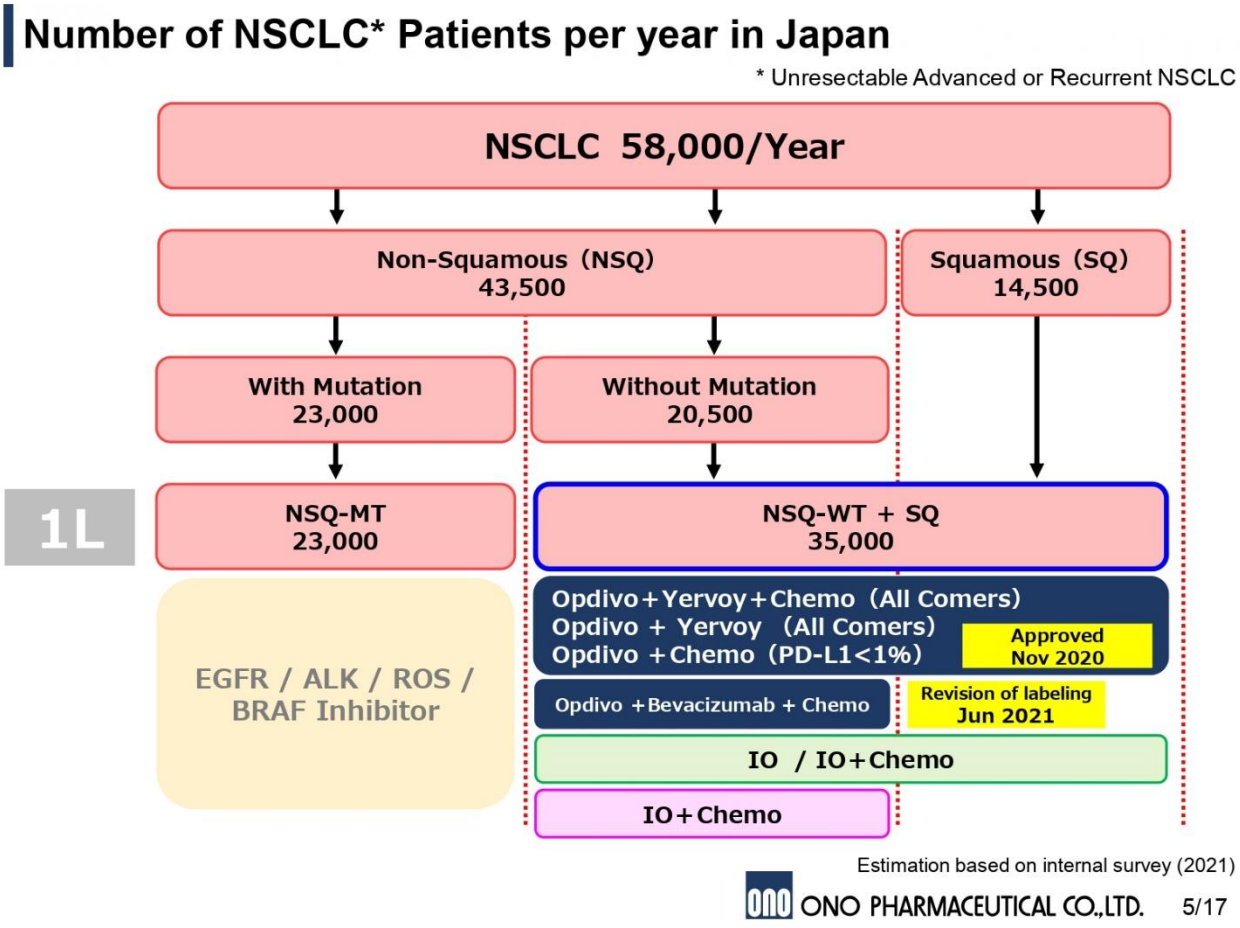


Source: External data

ONO PHARMACEUTICAL CO.,LTD. 4/17

This shows sales trends of all immune checkpoint inhibitors launched in Japan and Opdivo's market share.

Overall sales of immune checkpoint inhibitors have been increasing steadily, and despite the NHI price revision in FY2021, sales of all products have been growing. Opdivo's share of this market remains steady at 35%.



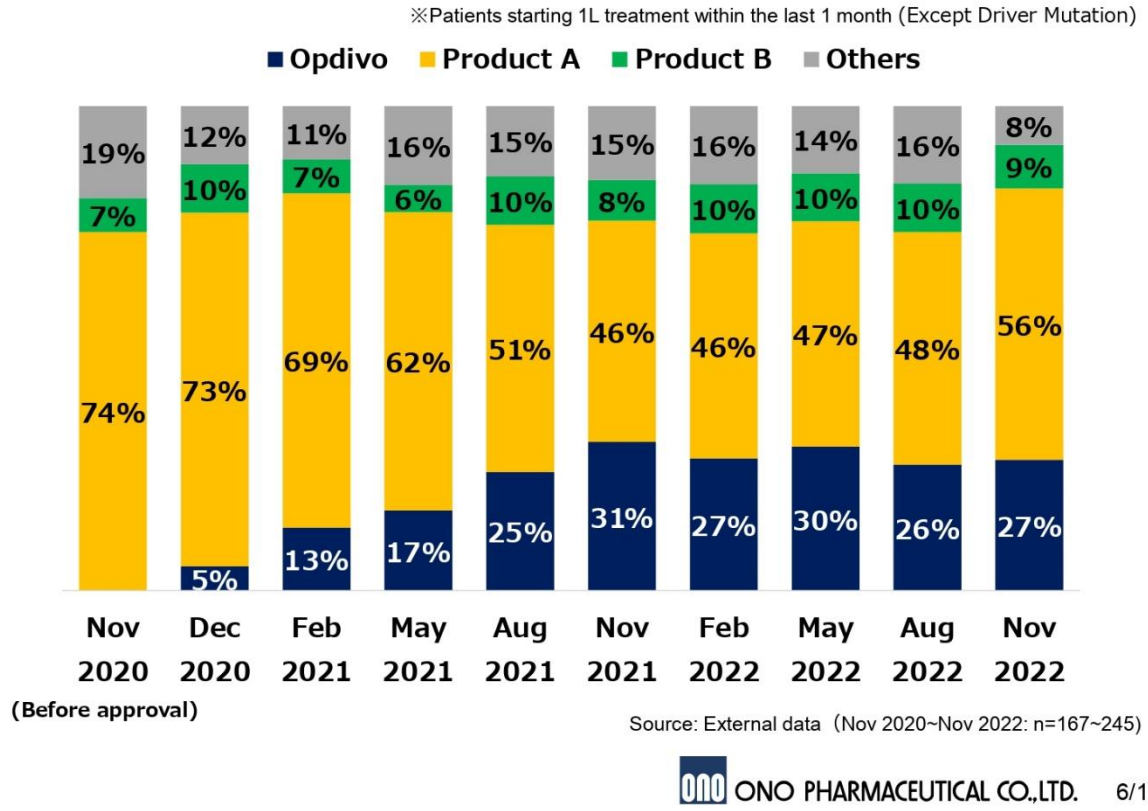
I will introduce you to the area of lung cancer. This shows the annual number of patients with non-small cell lung cancer.

The annual number of patients with unresectable advanced or recurrent non-small cell lung cancer is estimated at 58,000, according to our own in-house estimate.

Non-small cell lung cancer is divided into non-squamous and squamous cell carcinoma by histological subtypes, and non-squamous carcinoma is further divided by diagnosis with or without genetic mutation.

The therapeutic targets for immune checkpoint inhibitors such as Opdivo in the first-line treatment of lung cancer is very large, with an estimated 35,000 patients per year being treated for squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation. We are developing activities with the Opdivo regimen, although the current competitive environment is very tough.

Prescription Ratio in Patients Newly Treated for 1L NSCLC



Source: External data（Nov 2020~Nov 2022: n=167~245)

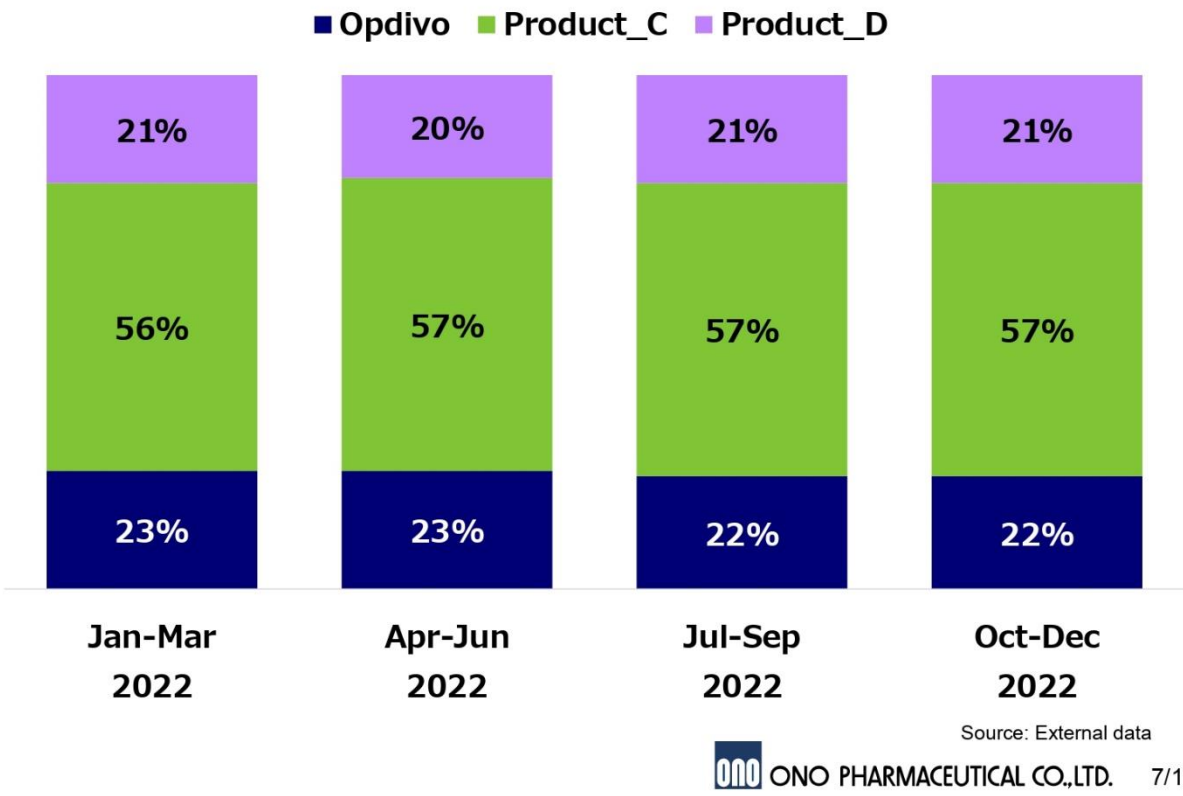
ONO PHARMACEUTICAL CO.,LTD. 6/17

This chart shows the share of new prescriptions in the first-line treatment of non-small cell lung cancer.

Opdivo's share of new prescriptions has stagnated at 27% as of November. New prescription acquisition of Opdivo has not been achieved as planned.

We are continuing to work on the need to further promote the efficacy and safety of the combination therapy of Opdivo with Yervoy (IO-IO), which are of a level not seen in competing products.

Sales Ratio of ICPIs in NSCLC (Estimation)

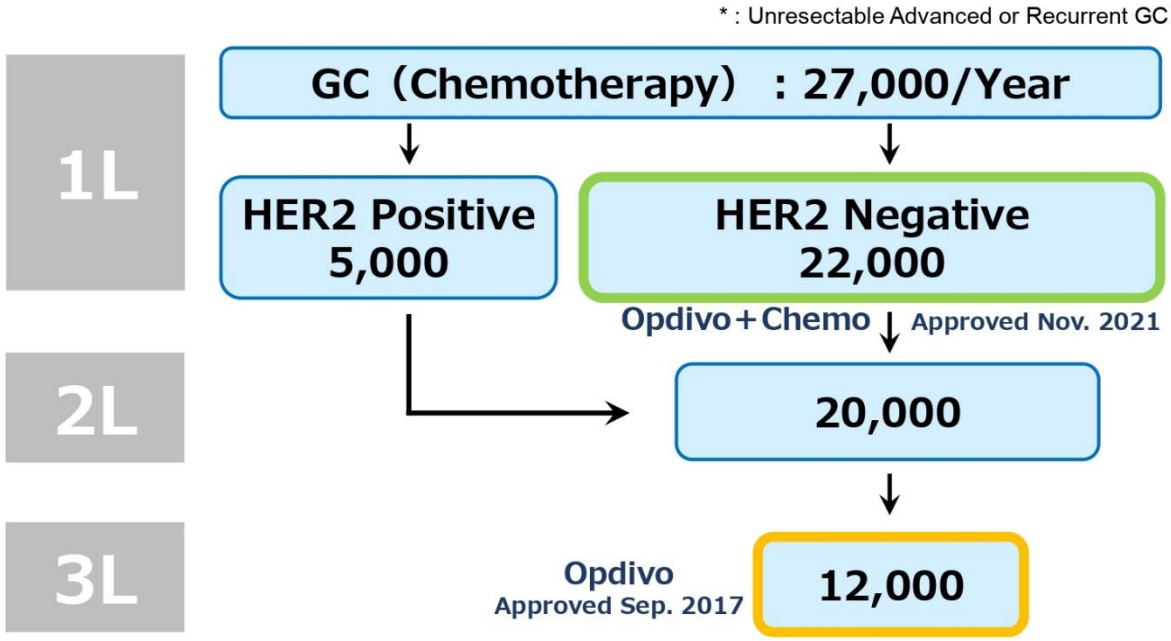


Source: External data

This table shows the sales ratio of immune checkpoint inhibitors in non-small cell lung cancer, including all treatment lines of first-line, second-line and beyond.

Opdivo is at 22%, and we consider that further growth will be needed in the first-line treatment of lung cancer.

Number of GC* Patients per year in Japan



Estimation based on internal survey (2020)

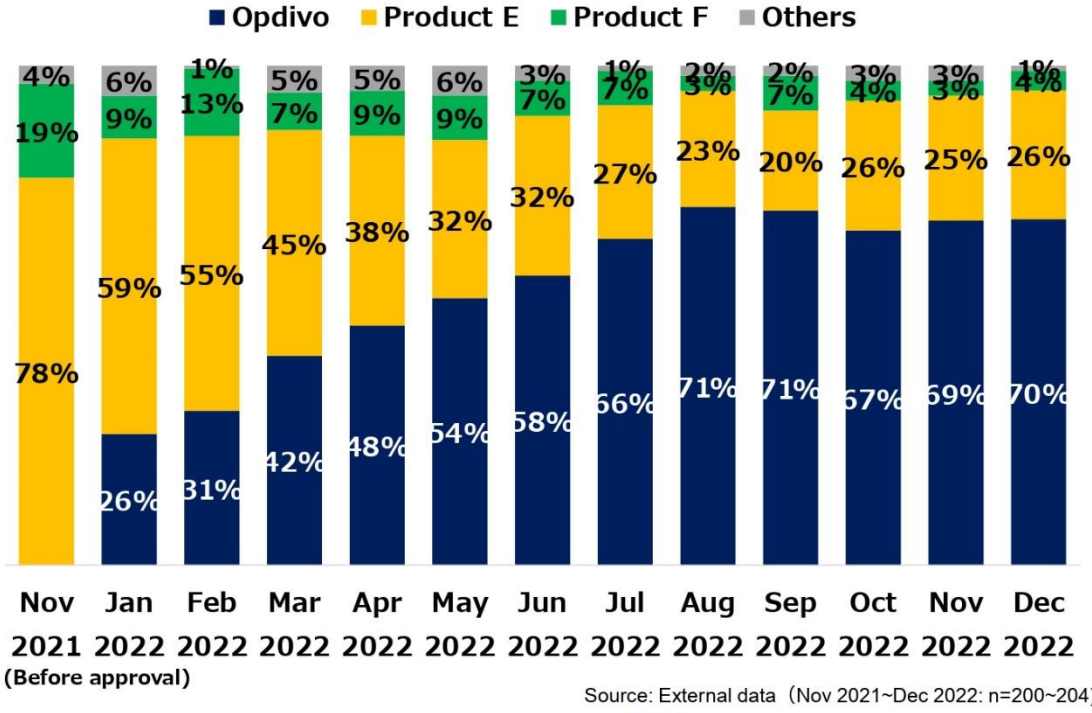
I will explain the field of gastric cancer. The table shows the annual number of patients with gastric cancer.

The annual number of patients with unresectable, advanced or recurrent gastric cancer is estimated at 27,000, according to our own estimate.

In November 2021, Opdivo was approved in combination with chemotherapy for the first-line treatment in HER2-negative gastric cancer.

Prescription Ratio in Patients Newly Treated for 1L GC

※Patients starting 1L treatment within the last 3 month



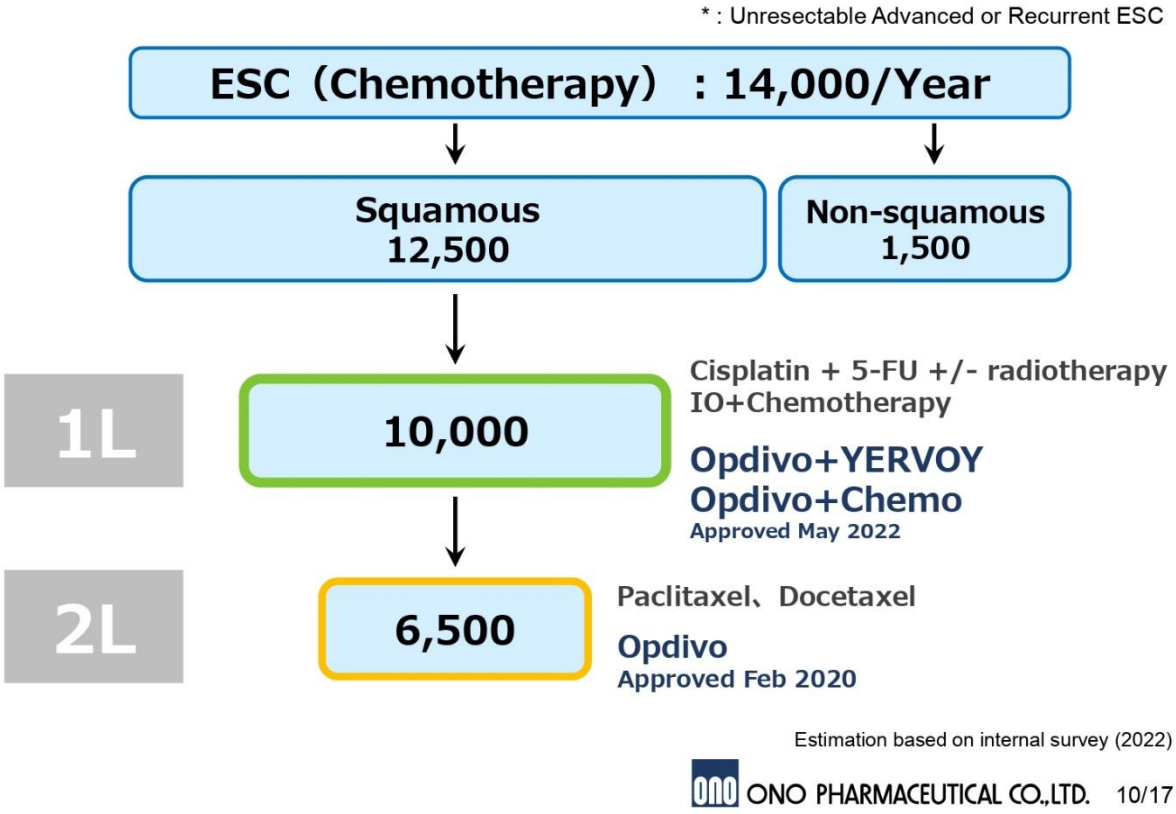
Source: External data（Nov 2021~Dec 2022: n=200~204)

ONO PHARMACEUTICAL CO.,LTD. 9/17

The table shows the share of new patient prescriptions for the first-line treatment of gastric cancer.

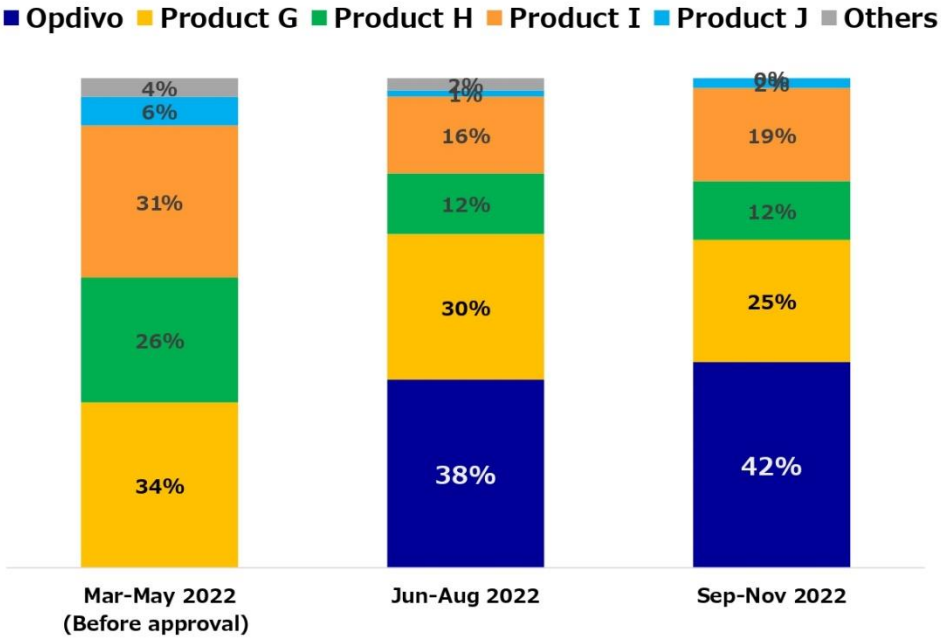
Opdivo's share of new patient prescriptions for the first-line treatment is currently 70%. The share of the market for the current fiscal year was planned to be 60%, but it has progressed beyond that.

Number of ESC* Patients per year in Japan



In May 2022, we received an approval for the combination treatment of Opdivo and Yervoy, as well as Opdivo and chemotherapy regimens, for the first-line treatment of unresectable advanced or recurrent esophageal cancer. The first line treatment target is squamous cell carcinoma, and the number of eligible patients is estimated to be 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~Nov 2022: n=150~155）

ONO PHARMACEUTICAL CO.,LTD. 11/17

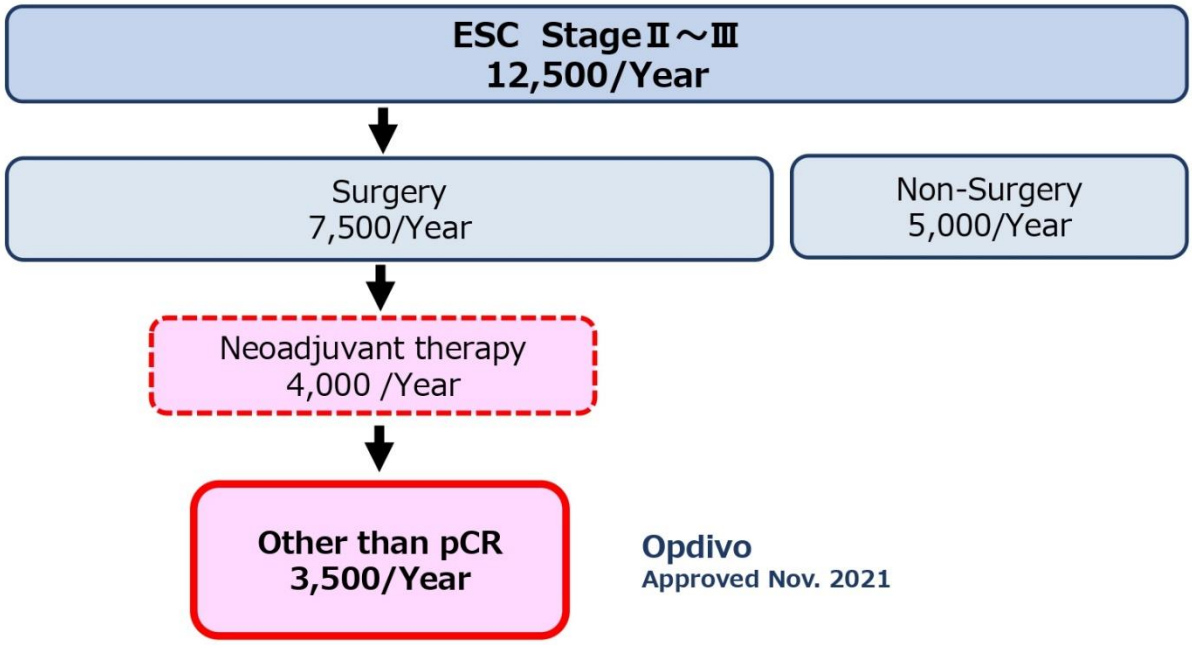
The table shows the share of new patient prescriptions in the first-line treatment of esophageal cancer.

A competing I-O and chemotherapy combination regimen entered the market in November 2021, and as of May 2022, I-O was in use about 30%.

With the entry of Opdivo regimen into first-line treatment, I-O market share has grown to nearly 70%, and Opdivo regimen's share of new patient prescriptions is currently 42%, which is higher than the competitor's I-O, and we consider that prescriptions are expanding steadily.

We hope to build up the number of cases in use in the future, which will lead to large sales.

Number of ESC（Perioperative） Patients per year in Japan



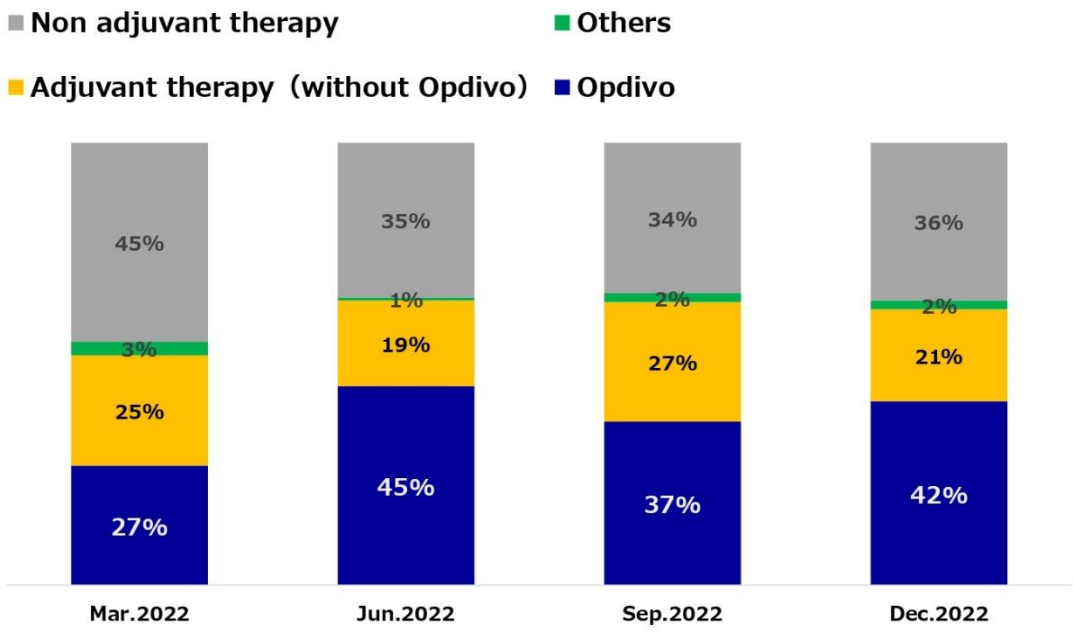
Estimation based on internal survey (2022)

ONO PHARMACEUTICAL CO.,LTD. 12/17

I would like to present the number of patients with surgically treated esophageal cancer, for which we received approval in November 2021.

The number of patients with stage II to III esophageal cancer is estimated to be 12,500 per year, of which 7,500 are eligible for surgery. We consider that 4,000 of these patients will receive preoperative adjuvant therapy, and 3,500 patients will be eligible for postoperative adjuvant therapy with Opdivo and have a pathologic non-complete response.

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



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

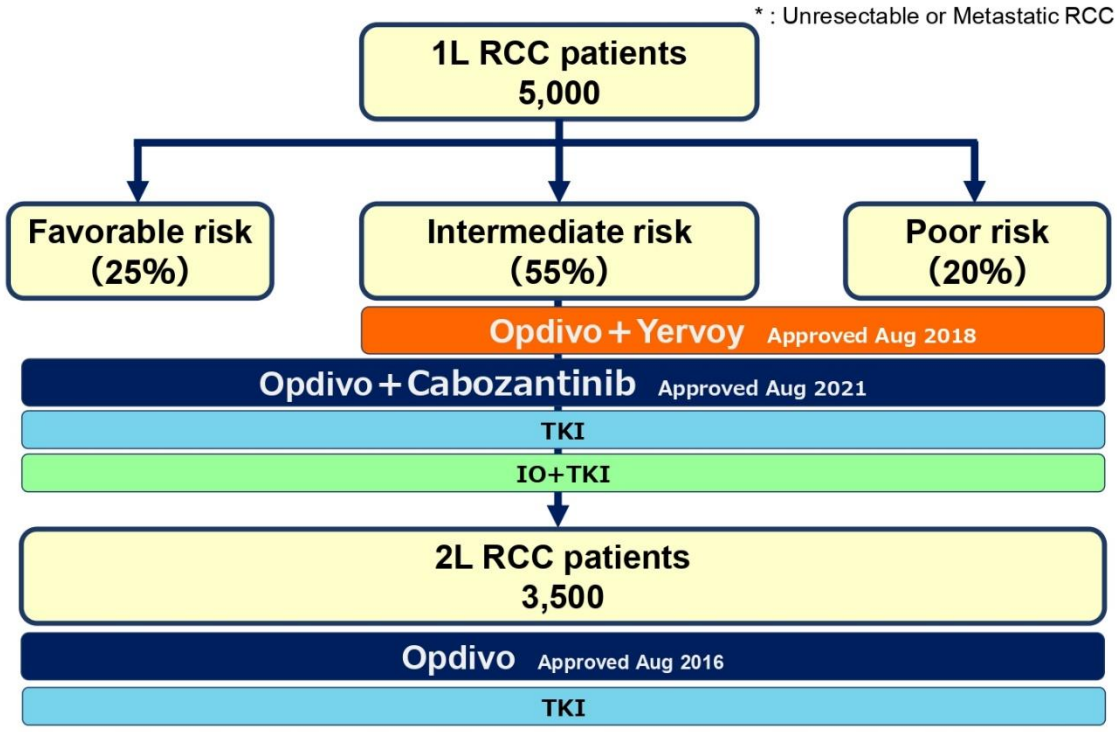
※Patients starting treatment within the last 3 month

ONO PHARMACEUTICAL CO.,LTD. 13/17

The share of new prescriptions for adjuvant therapy of esophageal cancer, for which approval was granted in November 2021, was 42% as of last December. The Japanese Top-KOLs who have prescribed this product have evaluated Opdivo as a useful treatment option without safety issues for patients who have failed to achieve a pathological complete response after surgery, considering the risk and benefit.

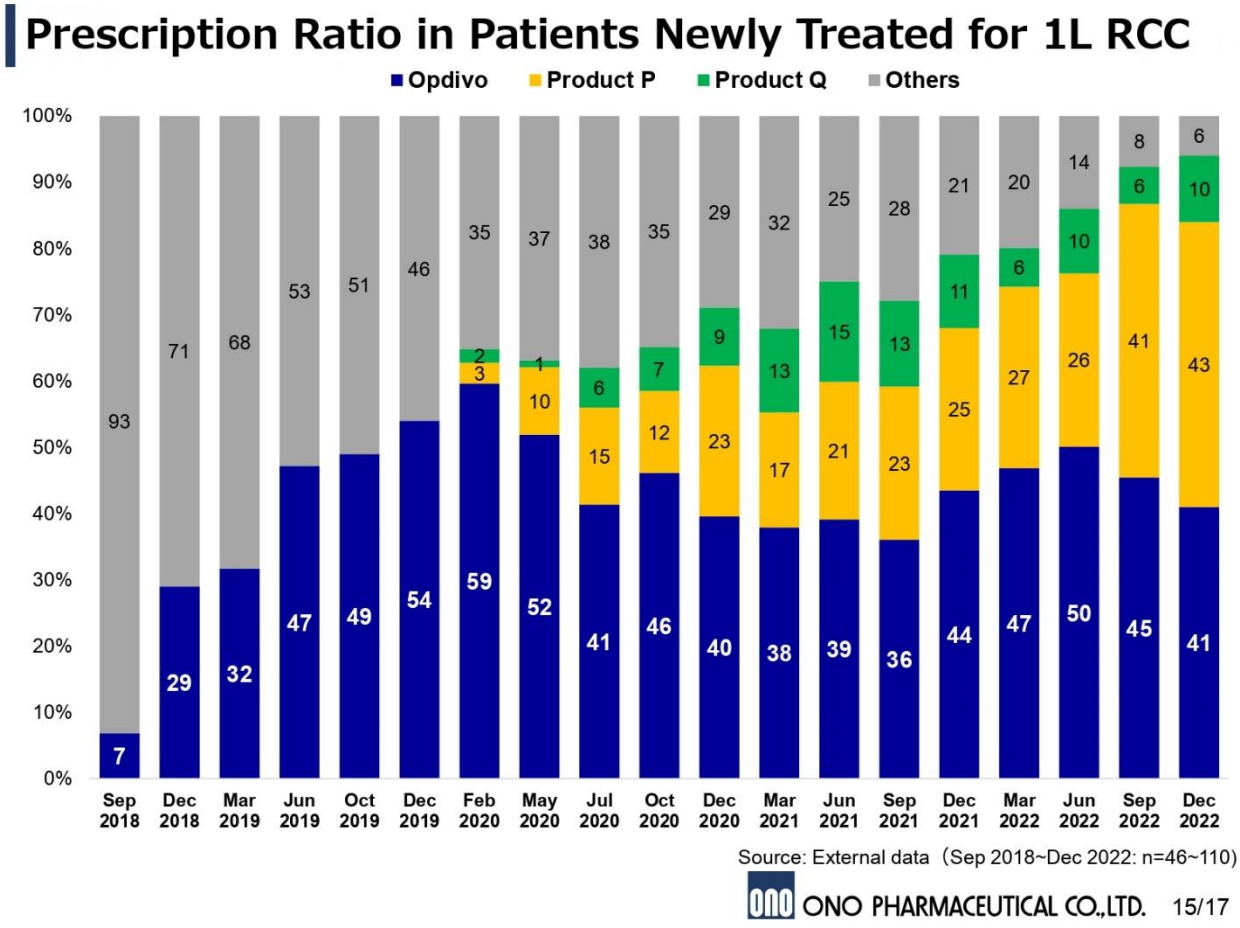
However, as nearly 40% of patients are still not receiving postoperative adjuvant chemotherapy, we will continue our efforts to raise awareness of the usefulness of Opdivo.

Number of RCC* Patients per year in Japan



Estimation based on internal survey (2022)

Finally, regarding the urology area, Opdivo has been approved for all treatment lines of the first-line, second-line and beyond in renal cell carcinoma.

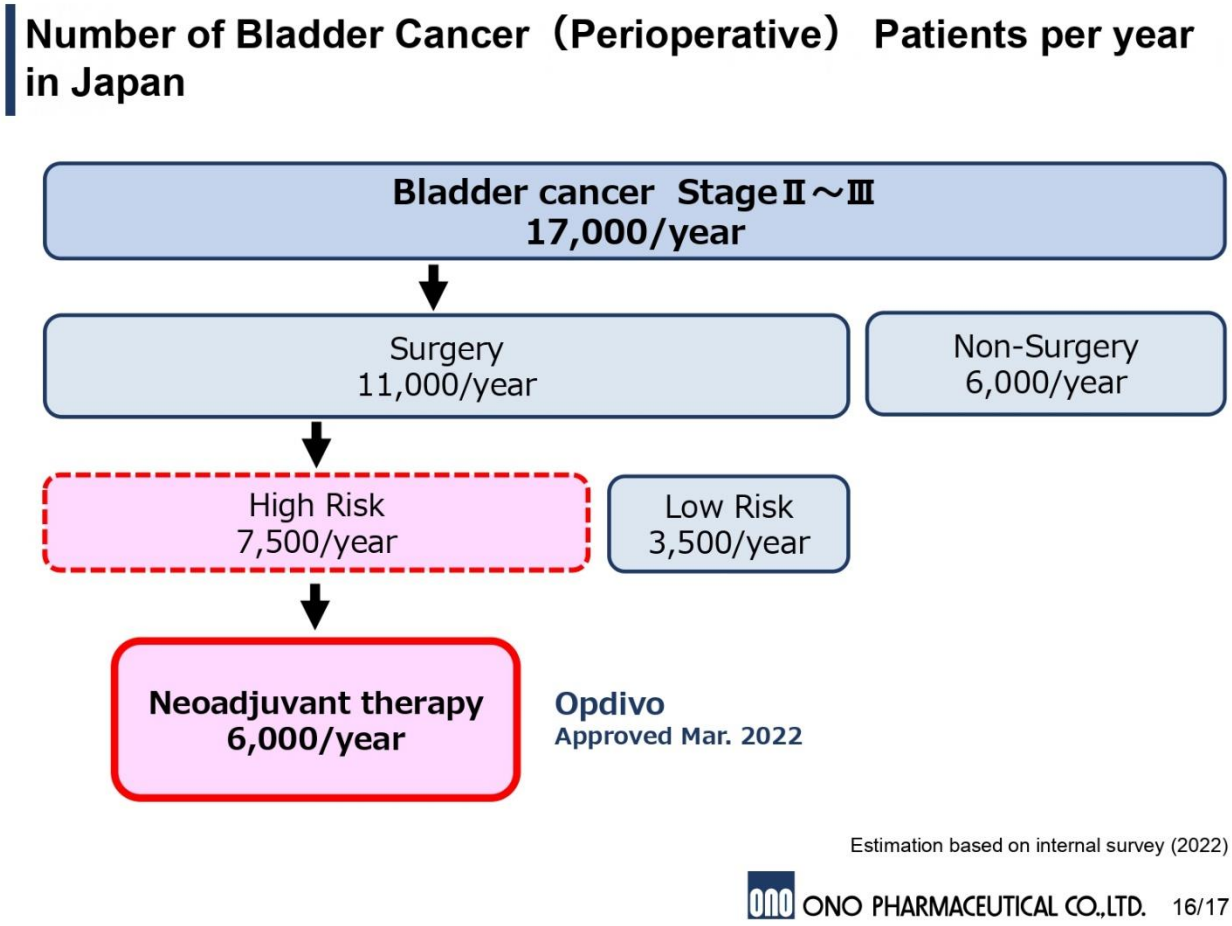


The table shows the new patient prescription share in the first-line treatment of renal cell carcinoma.

Prescription of I-O combination therapy has been expanding in first-line treatment, currently with more than 90% of patients receiving I-O combination therapy.

The current share of new prescriptions for the combination therapy of Opdivo, Yervoy, and TKI is 41%.

We intend to make a strong commitment to activities here in the future as well.

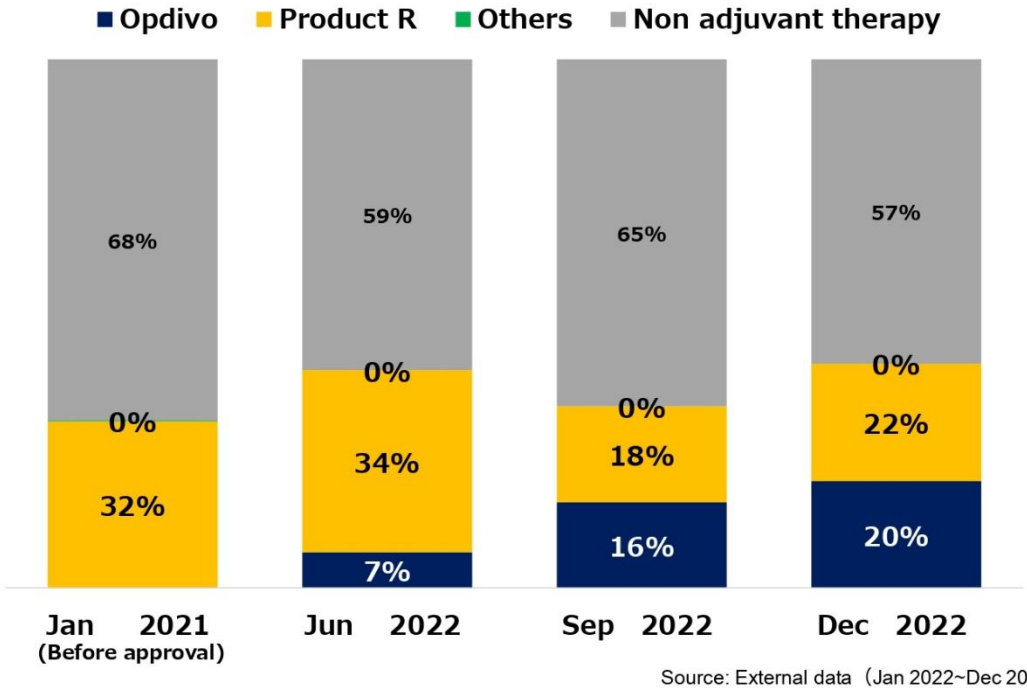


I will explain the situation of urothelial carcinoma.

Urothelial carcinoma that develops from the renal pelvis, ureter, bladder, and urothelial mucosa inside urethra. Bladder cancer accounts for 80% of all urothelial carcinomas in Japan. For this reason, I would like to present the number of patients in the perioperative period for with bladder cancer which has a large number of patients.

The number of patients with stage II to III bladder cancer is estimated to be 17,000 per year, of which 11,000 are eligible for surgery. Among these patients, we estimate that the number of high-risk patients with a high recurrence rate is 7,500, and the number of patients who are eligible for postoperative adjuvant therapy with Opdivo is estimated to be 6,000.

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



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

※Patients starting treatment within the last 3 month

The share of new prescriptions for postoperative adjuvant treatment of urothelial carcinoma, which was approved in March 2022, was 20% as of last December. We consider it is important to further strengthen our activities.

As for the Opdivo regimen, we are currently expanding to 23 regimens for 11 cancer types, and working on, targeting at such a very large market.

We will continue to strive to fulfill the unmet needs of cancer patients.

Question & Answer

Questioner 1: I understand that lung cancer is the reason for the downward revision of the Opdivo full year sales forecast, and the third slide certainly shows that prescriptions for lung cancer and the number of patients prescribed for lung cancer are also decreasing. On the other hand, the number of gastric cancer cases also appears to have decreased from 1,600 cases in July to September to 1,500 cases in October to December. Am I correct in understanding that the number of patients receiving it as second-line therapy is decreasing?

Takahagi: The number of patients in the third line is decreasing, while the first line is steadily expanding and now has about 1,000 cases. Opdivo regimen has been used for about more than one year in first-line treatment, and this is the reason why fewer I-O-naive patients are reaching the third-line treatment stage. This is within our expectation.

If the content of new prescriptions is changing in the future, as you pointed out, for example, for third-line treatment of stomach cancer and second-line treatment of esophageal cancer, we expect that the number of newly prescribed patients will continue to decrease.

On the other hand, first-line treatment has become more central in gastric and esophageal cancer, rather than the later line treatment. In particular, it is clear that the earlier lines treatment is longer in terms of administration period, so we believe that by using the product earlier, sales will be an increasing trend in the future.

Questioner 1: I would like to know briefly about the domestic sales forecast of Opdivo for the next fiscal year. This is because I think you have been able to maintain market share with respect to first-line treatment of gastric cancer, while the competitive environment has been a little tougher. I think that the duration of prescriptions will be extended in the future, but the number of patients will not grow much anymore.

I think it is difficult to see the factors for the increase in domestic sales and revenue of Opdivo for the next fiscal year because the adjuvant did not work out as well as planned.

Takahagi: We are considering gastrointestinal cancers as a growth driver for the next fiscal year, especially here in East Asia, where the number is high in Japan. As you say, we still have to aim at a higher prescription share in the future, but once we consider this to be the peak, the number of patients will increase from here on, and we will probably reach peak sales in about one, 1.5, or two years. As this is a sales increase pattern so far in cancer drugs, sales have not yet peaked here.

Since the number of patients using the product is increasing, we expect sales to increase steadily in the next fiscal year, especially in the treatment of gastric and esophageal cancer. However, we will share detailed sales figure when we report here in May.

Questioner 1: Finally, regarding the CD6 antibody, itolizumab which was announced in December, I don't think it is in the pipeline yet because your company has only obtained the option rights and have not actually decided to in-license it. Assuming that the results of the first Phase III for GVHD were good, is it safe to assume that your company could in-license it and it could perhaps be the first item that your company will launch in the US?

I see from the Clinical Trial that its primary endpoint of the GVHD Phase III will be available at the end of this year. If all goes well, I was wondering if there is a possibility of a sale around the next fiscal year.

Tani: It depends on the results of Phase III. We are currently considering Velexbru as the first drug for a US rollout. This is because it has already been approved in Japan, and we believe that this will be a stepping stone. However, I think that the next compound would be the one you asked about. We will wait for the results of the clinical trial.

Questioner 2: I would like to ask one thing about the Opdivo forecast revision. Looking at sales alone, we see YoY growth in Q1, Q2, and Q3, but I think the assumption is that sales will fall in Q4. On the other hand, with IQVIA and others checking wholesale data, Q3 has not grown that much either, but I wonder if there was a slight discrepancy between your company's shipments to wholesalers and digestion in Q3. I am wondering if there might be a year-end factor here.

Takahagi: It's tough to say, but I doubt there is much of a gap there. However, as you said, we have to check the inventory of medical institutions and that of wholesalers every month, so there may be some fluctuation, but we do not see this as having a major impact.

Questioner 2: I understand. As I have mentioned many times before in the area of lung cancer, you need to work hard on PD-L1 1-49%, but I think it is not easy. I think that your company is going to promote with the data you have had so far, but is there any new way to strike out?

Takahagi: We have been getting long-term data from Phase III trial every year, which will be up to five years. In that context, I would like to convey the tail plateau and long-term survival of both regimens, as well as the expectations of the PD-L1 1-49% and PD-L1 negative cases you mentioned.

The data that has just been released shows that the tail plateau has been reached, especially for PD-L1 negative patients, so we will continue to communicate this to clinicians. As you can see from the prescription share mentioned earlier, the market has stagnated, and we are hoping to somehow revive the situation.

Questioner 2: Finally, I would like to ask the progress of research and development expenses. In the past, Q4 is often associated with a flurry of activity, but this time, I have the impression that the work has been steadily digested from Q3. Is the JPY91 billion, a full-year forecast to be spent properly? What about the progress of R&D expenses.

Nagahama: We expect to spend JPY91 billion sharply on R&D expenses. We currently believe that we will be able to get roughly there, including the development cost of itolizumab in-licensed from Equillium.

Questioner 3: Regarding gastric cancer, I would like to know what you think of Opdivo's competitiveness. I think I heard that Keytruda has achieved the first line treatment at the end of last year, and it will probably come in around this time next year. One more thing, for the claudin drug by Astellas Pharma, zolbetuximab, the hazard ratio was 0.75, and I think they will be not too far away, at about the same timing. Please tell us where you envision your company being at that time and how it differs from the current situation.

Takahagi: First of all, the press release only states that OS, CSS, and ORR were met in clinical trial of Keytruda, but no actual figures or results have been published, we are not sure of the detailed result. However, I believe that it will be made public in the future, and we need to review the results.

On the other hand, with regard to zolbetuximab, the difference between that compound and Opdivo is that the results of the 649-trial show that Opdivo has occupied with 90% prescription share in patients with CPS of 5 or higher.

On the other hand, as for CPS less than 5, the evaluation has not yet been established, so I am wondering if there is a possibility that zolbetuximab could be used there. The market ratio is roughly 1:1 between CPS 5 and above and below 5. So, if we assume a marketability of 50% of patients with CPS less than 5, and if we

assume that the percentage of those patients positive for anti-claudin is 40%, then 5 x 4 is 20%, but it is very unlikely that it will be used in all cases, so we estimate that it could be used in between 10% and 20% cases.

However, we are still ahead of the competition, and we have data useful in demonstrating the efficacy of the Opdivo regimen, as well as on the response rate and shrinkage effect for patients with CPS less than 5. However, we still believe that we should conduct market research, and we would like to continue to carefully examine this area in the future.

Questioner 3: I know that zolbetuximab is also doing combination trials with PD-1 inhibitors Keytruda and Opdivo, and that results will start coming in about 2024. Isn't your company expecting too much there.

Takahagi: I think that ultimately it depends on the results. Based just on the design of the clinical trial, we are not able to say much, I think. Compared to looking at all the data. In the future, for example, we are still not sure how much CPS has been identified now, for example, it has been more than a year, but in some places, it has only grown to about 60%. In addition, both doctors and patients consider various factors such as concomitant regimens, administration intervals, and so on, so we cannot make a precise estimate without taking these factors into consideration. Therefore, we would like to scrutinize it and consider the degree of influence by looking at the results.

Questioner 3: Finally, I would like to ask about the 9DX for adjuvant treatment of liver cancer. I did not see much about 9DX in the data readouts for 2023, 2024, or 2025 in the IR materials that Bristol put out earlier this month, but your company's schedule has not changed. Am I correct in assuming that the timing is okay here?

Takahagi: Regarding the schedule for CheckMate-9DX for postoperative adjuvant for hepatocellular carcinoma, we believe that the results will be available at the earliest for application in FY2023 at this time.

Questioner 4: On the current point, including CheckMate-901, I believe that you mentioned at the end of Q2 that the application would be delayed to FY2023. I would like to check if there have been any further delays here.

Idemitsu: Which one are you referring to?

Questioner 4: I seem to recall that you mentioned that the CheckMate-901 and -9DX would be delayed, at the interim financial results briefing. However, if we follow your explanation this time, CheckMate-901 were further delayed from FY2023 and has been removed from the materials this time. Am I misunderstanding you?

Idemitsu: In CheckMate-901, the application timeframe for the combination therapy of Opdivo with Yervoy will be FY2024for the first line treatment of urothelial carcinoma. The CheckMate-901 consists of multiple cohorts, and we are currently planning to submit the application in FY2023 for the combination therapy of Opdivo and chemotherapy for the first-line treatment of urothelial carcinoma.

Questioner 4: Do you mention about the first line urothelial carcinoma?

Idemitsu: CheckMate-901 trial consists of multiple cohorts for urothelial carcinoma, and the result from a cohort of Opdivo and chemotherapy combination regimens for cisplatin-eligible patients is expected, at present, in the timing when the application can be submitted in FY2023.

On the other hand, the application plan will be delayed from FY2023 to 2024 for the combination therapy of Opdivo and Yervoy for cisplatin-ineligible patients.

Questioner 4: So, the combination with Yervoy will be delayed?

Idemitsu: Yes.

Questioner 4: What you are saying now is that the most advanced indications will be in FY2023, but the original Yervoy combination was delayed, is that your explanation?

Idemitsu: Yes.

Questioner 4: As for CheckMate-9DX, is it correct that there is no change in schedule, with a plan to file an application in FY2023?

Idemitsu: Yes. At this time, we have planned to get the results in time for the FY2023 application.

Questioner 4: I think you mentioned that the development schedule for Velexbru in the US is still the same, and that you are aiming to file for approval in FY2024 if things continue as planned. Is that correct?

Idemitsu: We have not yet officially announced our plan to apply for approval of Velexbru in the US. We are currently conducting clinical trials for approval. I believe that we are working on a schedule to launch the market by FY2026.

Questioner 4: I think you mentioned that Phase II will be completed by May of FY2024. Is that correct?

Idemitsu: Phase II will be completed by May 2024. I don't think we have made any changes in that schedule at this time.

Questioner 5: Let me confirm one overall point and two minor points about performance. First of all, the overall results are very good, with a 25% increase in sales and a 49% increase in operating profit. Since the progress rate toward the full-year is 82.3%, I think there is a high possibility of an upward swing. Last time the progress rate was 53% against the full year plan, and you revised it by JPY4 billion. This time, you did not revise the full-year forecast, and I was wondering why you didn't do that this time, especially as the use of research expenses is progressing at a high rate. Or, is this because of foreign exchange or many uncertain factors? Or is it Opdivo-related issues?

Tani: For individual products, as I indicated, if we do the arithmetic with the downward and upward revisions, we have an increase of about JPY2 billion. However, for the profit portion, since progress in both R&D and SG&A expenses has been delayed, we have not revised the overall plan at this time. We have judged that if these expenses are used as planned, there is no need to make major changes in the plan.

Questioner 5: In terms of individual areas, it is Opdivo. I am comparing the transition by carcinoma as of Q2 with this time, and it was very clear qualitatively. However, looking at this figure, it is true that lung cancer has fallen off when we expected it to grow. Conversely, can we assume that head and neck cancer and esophageal cancer will swing much higher?

Takahagi: It is mostly as planned. There is some upside, but no major upside. I would say that it is about as close as what we expected.

Questioner 5: So that 100 is already almost explained by non-small cell lung cancer?

Takahagi: Indeed.

Questioner 6: Two quick questions about the pipeline. First, regarding ONO-1110. I remember that many of the conventional cannabinoid receptor-related drugs have been discontinued due to CNS side effects. Please tell us about 1110, in terms of its blood-brain barrier permeability, selectivity for CD1 and CD2, CNS side effects, and what kind of profile it has. This is the first question.

Idemitsu: Regarding ONO-1110, I am very sorry that we are not able to disclose details, including the mechanism of action. This compound is being developed based on the concept of increasing endogenous cannabinoids levels and not causing side effects such as dependence or amnesia due to over-activation of endogenous cannabinoid receptors, as you just mentioned. The compound has been adjusted based on the concept that it will be a drug that avoids these problems, and we are now at the stage of trying to confirm this in humans. We are very sorry that we cannot disclose the details.

Questioner 6: The other question is about ONO-2020. As for the applicable diseases here, have you disclosed what you are targeting first among the neurodegenerative diseases? Is it Parkinson's, for example?

Idemitsu: This is still in Phase I, and the indications are as yet undisclosed. I am very sorry.

Questioner 7: In the gastric cancer area, you mentioned that the market share is 90% for CPS 5 and above, but can you tell me again what exactly is the market share for the rest of the areas? Also, as for the breakdown of patients, I was wondering if you could tell me what it would be like if you divide them into more than 1 and less than 5 and less than 1.

Takahagi: First, by CPS, 90% are above 5 and about 60% are below 5. Sorry, could you repeat the second part?

Questioner 7: Breaking down closely of CPS less than 5, such as less than 1, more than 1 and less than 5, and if we look at closely the zolbetuximab data, it could appear to be quite a threat. Looking at the details, the percentage of patients with zero in PS was 54% in Attraction 4, compared to 41% and 45% there. GEJ cancer has a poor prognosis, it's 8-9% in Attraction 4. Spotlight is 23% and 26%, quite a difference in PFS and OS for many severe patients.

Moreover, Japanese doctors always do this, don't they? If you look at Asians in the subgroup analysis, PFS has a much larger hazard ratio. About 80 people, as I recall, have risk reduction as per PFS, about 44%. I was wondering if this might be a threat, and that's why I was asking for a breakdown for patients by CPS.

Takahagi: We agree in the sense that we do not feel that there is zero threat. I do not have the detailed breakdown data for the CPS of less than 5 group at hand, so I sincerely apologize that I am unable to answer you now.

However, we are now at the leading edge, so we will continue to do our current activities. As indicated earlier, only 60% of the patients under CPS 5 are still using it, so we will firmly obtain the evaluation of Opdivo before they enter the market.

I can tell you that we will continue to conduct market research and make revisions to our strategies and tactics, as well as to correct any issues that need to be corrected. Sorry I can't give more detail in my answer.

Questioner 7: Finally, ONO-4538-86 is a clinical trial for preoperative and postoperative adjuvant for bladder cancer. Is my understanding correct that this is in combination with an IDO1 inhibitor?

Idemitsu: ONO-4538-86 was a combination study with an IDO inhibitor, but the development of the IDO inhibitor itself has been discontinued. Within the study, a group is set up for Opdivo in combination with chemotherapy, and we plan to file an application using the results of that study.

Questioner 7: In short, you mean preoperatively and postoperatively for the combination of nivolumab, gemcitabine and cisplatin.

Idemitsu: Yes.