ONO PHARMACEUTICAL CO., LTD.

Q1 Financial Results for the Fiscal Year Ending March 2024

July 31, 2023

[Number of Speakers]	5	
	Satoshi Takahagi	Corporate Executive Officer, Executive Director, Sales and Marketing
	Masaki Ito	Corporate Officer, Division Director, Corporate Strategy & Planning, Business Management Division
	Tatsuya Okamoto	Corporate Officer, Deputy Executive Director, Clinical Development
	Yukio Tani	Supervisor of Corporate Communications
	Ryuta Imura	Senior Director of Corporate Communications

Presentation

Revenue

Revenue	YoY Change
¥ 120.0 billion	+ 12.5 %

Breakdown of Revenue

(Billion yen)

	FY 2022 Q1	FY 2023 Q1	YoY Change
Revenue of Goods and Products	72.2	80.5	+ 11.6 %
Royalty & other revenue	34.6	39.5	+ 14.2 %
Total	106.7	120.0	+ 12.5 %

Ito: I will now explain our financial results for Q1 of the fiscal year ending March 2024.

First, let's look at revenue.

Revenue for Q1 increased JPY13.3 billion, or 12.5%, from the same period last year to JPY120 billion.

As for the breakdown of revenue, revenue of goods and products increased by JPY8.4 billion, or 11.6%, YoY to JPY80.5 billion due to the strong sales of Opdivo intravenous infusion, Forxiga tablets, and Velexbru tablets, despite a decline in sales of long-term listed products.

Royalty and other revenue increased JPY4.9 billion, or 14.2%, to JPY39.5 billion. Royalty and other revenue include royalty income of JPY22.6 billion from the Bristol-Myers Squibb Company related to Opdivo, up JPY1.8 billion from the same period last year, and royalty income of JPY12.2 billion from Merck & Co., Inc. related to Keytruda, up JPY2.4 billion.

Of the JPY1.8 billion increase in royalty income from BMS, JPY1 billion was the result of foreign exchange, and of the JPY2.4 billion increase in royalty income from Merck, JPY0.4 billion was the result of foreign exchange.

Other revenue of JPY4.7 billion includes royalty income from Roche, profit sharing from the sales of Yervoy, and co-promotion fees for the Orencia IV formulation.

Revenue

Sales of Major Products

(Billion yen)

	FY 2022 Q1	FY 2023 Q1	YoY Change
Opdivo	34.1	**37.8**	+ 10.9 %
Forxiga	13.1	**17.5**	+ 34.0 %
Orencia SC	6.2	**6.6**	+ 5.6 %
Glactiv	6.0	**5.6**	- 7.2 %
Velexbru	2.1	**2.6**	+ 23.7 %
Kyprolis	2.2	**2.2**	- 0.1 %
Parsabiv	2.1	**2.1**	- 3.0 %
Ongentys	1.2	**1.6**	+ 28.8 %
Onoact	1.1	**1.0**	- 7.5 %
Braftovi	0.9	**0.9**	+ 1.7 %
Mektovi	0.7	**0.7**	+ 0.5 %

Here is an overview by product.

Revenue from sales of the anti-cancer agent Opdivo for intravenous infusion increased JPY3.7 billion, or 10.9%, to JPY37.8 billion, mainly due to increased use in gastric cancer, esophageal cancer, and urothelial carcinoma, despite intensifying competition from competitor's products.

Among other major new products, revenue from sales of Forxiga, a treatment for diabetes, chronic heart failure, and chronic kidney disease, increased by JPY4.4 billion, or 34%, to JPY17.5 billion.

Revenue from sales of Orencia SC, a drug for rheumatoid arthritis treatment, increased JPY0.4 billion, or 5.6%, to JPY6.6 billion.

Revenue from sales of the anti-cancer agent Velexbru increased JPY0.5 billion, or 23.7%, to JPY2.6 billion.

Revenue from sales of Ongentys tablets, a Parkinson's disease treatment, increased JPY0.4 billion, or 28.8%, to JPY1.6 billion.

On the other hand, revenue from sales of Glactiv tablets, a drug for type 2 diabetes, decreased JPY0.4 billion, or 7.2%, to JPY5.6 billion from the same period last year.

Revenue from sales of Kyprolis for intravenous infusion, a treatment for multiple myeloma, was flat at JPY2.2 billion.

Revenue from sales of Parsabiv for intravenous dialysis, a treatment for secondary hyperparathyroidism under hemodialysis, was almost flat at JPY2.1 billion.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2022 Q1	FY 2023 Q1	YoY Change
Opalmon	1.1	**1.0**	**- 13.5 %**

In the area of long-term listed drugs, revenue from sales of Opalmon tablets, a drug for treatment and amelioration of peripheral circulatory disturbance, decreased JPY200 million, or 13.5%, from the previous year to JPY1 billion, mainly due to the effect of the NHI price revisions.

Operating Profit

Operating Profit	YoY Change
¥ 41.3 billion	+ 8.3 %

Costs, etc.

(Billion yen)

	FY 2023 Q1	YoY Change
・Cost of Sales	30.2	(+ 12.0%)
・R&D Expenses	24.6	(+ 26.6%) ①
・SG&A Expenses	23.5	(+ 8.1%) ②
①+② Total	48.1	(+ 16.8%)
・Other Income	0.1	(+ 11.8%)
・Other Expenses	0.6	(- 6.2%)

Operating profit increased JPY3.2 billion, or 8.3%, to JPY41.3 billion.

On the expense side, cost of sales increased JPY3.2 billion, or 12%, from the same period last year to JPY30.2 billion, mainly due to an increase in sales of goods and products.

R&D expenses increased JPY5.2 billion, or 26.6%, from the same period last year to JPY24.6 billion, mainly due to an increase in expenses for research, drug discovery collaboration, clinical trials, and joint development with partner companies.

Selling, general, and administrative expenses excluding R&D expenses, increased by JPY1.8 billion, or 8.1%, YoY to JPY23.5 billion, mainly due to an increase in co-promotion expenses associated with the sales increase of Forxiga and expenses related to IT digital-related information infrastructure enhancement.

As a result of the above, operating profit increased JPY3.2 billion, or 8.3%, YoY to JPY41.3 billion.

Profit before Tax

Profit before Tax	YoY Change
¥ 42.4 billion	+ 8.5 %

Net financial income, etc.

+ ¥ 1.0 billion (YoY Change + ¥ 0.2 billion)

Finance income : (Dividend income received, etc.)	¥ 1.3 billion
Finance costs : (Exchange losses, etc.)	¥ 0.2 billion

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As for quarterly profit before tax, financial income was JPY1.3 billion and financial expenses were JPY0.2 billion, resulting in a financial income of JPY1.0 billion, an increase of JPY0.2 billion from the same period last year. As a result, quarterly profit before tax increased JPY3.3 billion or 8.5% from the same period last year to JPY42.4 billion.

Profit for the Period
(Owners of the Company)

Profit for the Period (Owners of the Company)	YoY Change
¥ 31.8 billion	+ 7.9 %

Income tax expense

¥ 10.6 billion (YoY Change + 11.0 %)

(Major change factors)

Increase in profit before tax	¥ 3.3 billion
Increase in corporate tax	¥ 1.0 billion

Profit for the period attributable to owners of the parent company amounted to JPY31.8 billion, up JPY2.3 billion, or 7.9%, from the same period last year, due to an increase in profit before tax.

Both revenue and profit at each stage reached record highs for Q1.

Financial Forecast for FY 2023

Financial forecast is unchanged from that announced on May 10, 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

The full-year forecast remains unchanged from the full-year forecast announced on May 10, 2023.

4. Supplementary Information

(1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product name	**Three months ended June 30, 2023 (April 1, 2023 to June 30, 2023)**			**FY 2023 Forecast (April 1, 2023 to March 31, 2024)**		
	Result	YoY		**Forecast**	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	**37.8**	3.7	10.9%	**155.0**	12.7	8.9%
Forxiga Tablets	**17.5**	4.4	34.0%	**65.0**	8.5	15.0%
Orencia for Subcutaneous Injection	**6.6**	0.4	5.6%	**25.5**	0.7	3.0%
Glactiv Tablets	**5.6**	(0.4)	(7.2%)	**21.0**	(1.5)	(6.7%)
Velexbru Tablets	**2.6**	0.5	23.7%	**9.5**	1.0	11.3%
Kyprolis for Intravenous Infusion	**2.2**	(0.0)	(0.1%)	**8.5**	(0.2)	(2.3%)
Parsabiv Intravenous Injection	**2.1**	(0.1)	(3.0%)	**8.0**	(0.4)	(4.8%)
Ongentys Tablets	**1.6**	0.3	28.8%	**6.5**	1.5	30.5%
Onoact for Intravenous Infusion	**1.0**	(0.1)	(7.5%)	**4.5**	0.0	0.4%
Braftovi Capsules	**0.9**	0.0	1.7%	**4.0**	0.8	23.2%
Opalmon Tablets	**1.0**	(0.2)	(13.5%)	**3.5**	(0.9)	(19.9%)
Mektovi Tablets	**0.7**	0.0	0.5%	**3.0**	0.5	18.1%

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecasts for the fiscal year ending March 31, 2024, only currently approved indications are covered.

(2) Details of Sales Revenue

(Billions of yen)

	Three months ended June 30, 2022	**Three months ended June 30, 2023**
Revenue of goods and products	72.2	**80.5**
Royalty and others	34.6	**39.5**
Total	106.7	**120.0**

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥20.8 billion for the first quarter (three months) ended June 30, 2022, and ¥22.6 billion for the first quarter (three months) ended June 30, 2023. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥9.8 billion for the first quarter (three months) ended June 30, 2022, and ¥12.2 billion for the first quarter (three months) ended June 30, 2023.

(3) Revenue by Geographic Area

(Billions of yen)

	Three months ended June 30, 2022	**Three months ended June 30, 2023**
Japan	70.8	**78.2**
Americas	32.3	**37.1**
Asia	2.7	**3.5**
Europe	1.0	**1.1**
Total	106.7	**120.0**

Notes: 1. Revenue by geographic area is presented on the basis of the place of customers.
2. Due to the change in the place of a customer, we revised the classification of revenue by geographic area. Therefore, revenue by geographic area is reclassified for the three months ended June 30, 2022.

There is no change in the revenue forecast for each major product shown on page 12 of the financial results from the figures announced at the beginning of the fiscal year.

(5) Notes to Condensed Interim Consolidated Financial Statements

(Note Regarding Assumption of Going Concern)

Not Applicable

(Changes in Accounting Policies)

Our Group has applied the following standard from the first quarter of the fiscal year ending March 31, 2024.

IFRS		Overview of establishment and amendments
IAS 12	Income Taxes	Clarification of accounting treatment for deferred taxes on lease and decommissioning obligations

Application of this standard does not have a material impact on the our group's condensed interim consolidated financial statements.

(Segment Information)

Segment information is omitted herein because our group's business is a single segment of the pharmaceutical business.

(Significant Subsequent Events)

<Settlement of Significant Lawsuits and Disputes>

The Company and Bristol Myers Squibb (USA: hereinafter referred to as "BMS") signed an agreement with AstraZeneca UK Limited and MedImmune Ltd. (UK) and certain of their affiliates to completely and globally settle the infringement lawsuits and disputes over the PD-L1 and CTLA-4 antibody patents owned by the Company and BMS on July 24, 2023.
The Company will receive approximately 140 Million US dollars in total as a result of this settlement.
The impact on the consolidated financial results for the fiscal year ending March 31, 2024, will be disclosed at the announcement of the financial results for the second quarter of the fiscal year ending March 31, 2024.

<Acquisition and Retirement of Treasury Shares>

On July 25, 2023, in accordance with Article 370 (resolution by documents instead of resolution by board meetings) of the Companies Act, the Company resolved to acquire treasury shares under the provisions of Article 156 of the Companies Act, applied by the replacing terms pursuant to the provisions of Paragraph 3, Article 165 of the Companies Act, and retire treasury shares pursuant to the provisions of Article 178 of the Companies Act.

1. Reasons for the Acquisition and Retirement of Treasury Shares

The Company will acquire treasury shares for the purpose of shareholder return, future financial condition, common stock price and etc.

2. Contents of the Acquisition

(1) Class of shares to be acquired : Common stock of the Company
(2) Total number of shares to be acquired: 19 million shares (maximum)
(3.89% of the total outstanding shares excluding treasury shares)
(3) Aggregate amount of acquisition cost: ¥50.0 billion (maximum)
(4) Period of acquisition : August 1, 2023 to March 22, 2024
(5) Method for acquisition : Purchase on the Tokyo Stock Exchange
(6) Schedule after acquisition : All the common stock acquired will be retired.

3. Contents of the Retirement

(1) Class of shares to be retired : Common stock of the Company
(2) Total number of shares to be retired : All the common stock acquired in accordance with Section 2 above
(3) Scheduled date of retirement : March 29, 2024 (planned)

(Reference) Number of treasury shares held by the Company as of June 30, 2023
Total number of shares issued (excluding treasury shares): 488,399,226 shares
Total number of treasury shares : 29,025,974 shares

The impact of the full settlement with AstraZeneca announced last Tuesday, July 25, regarding the infringement lawsuits over patents related to anti-PD-L1 and anti-CTLA-4 antibodies will be announced at the time of the Q2 earnings announcement.

The settlement of the patent dispute with AstraZeneca and the share buyback announced on the same day are described as subsequent events on page 11 of the financial results.

The Company plans to pay an annual dividend of JPY80 per share, JPY40 for both the interim and year-end as announced, with no change. The annual dividend of JPY80 will be increased by JPY10.

These are the results for Q1.

Imura: Thank you very much.

Mr. Okamoto, Deputy Executive Officer of Clinical Development, will explain the progress of the main development pipeline.

Okamoto: I am Okamoto from the Clinical Development Division. I will explain based on the slide.

I will explain the progress of the developed compound, focusing on the changes since May 10. The explanation will be based on the material on the development pipeline progress status, which is available on our website.

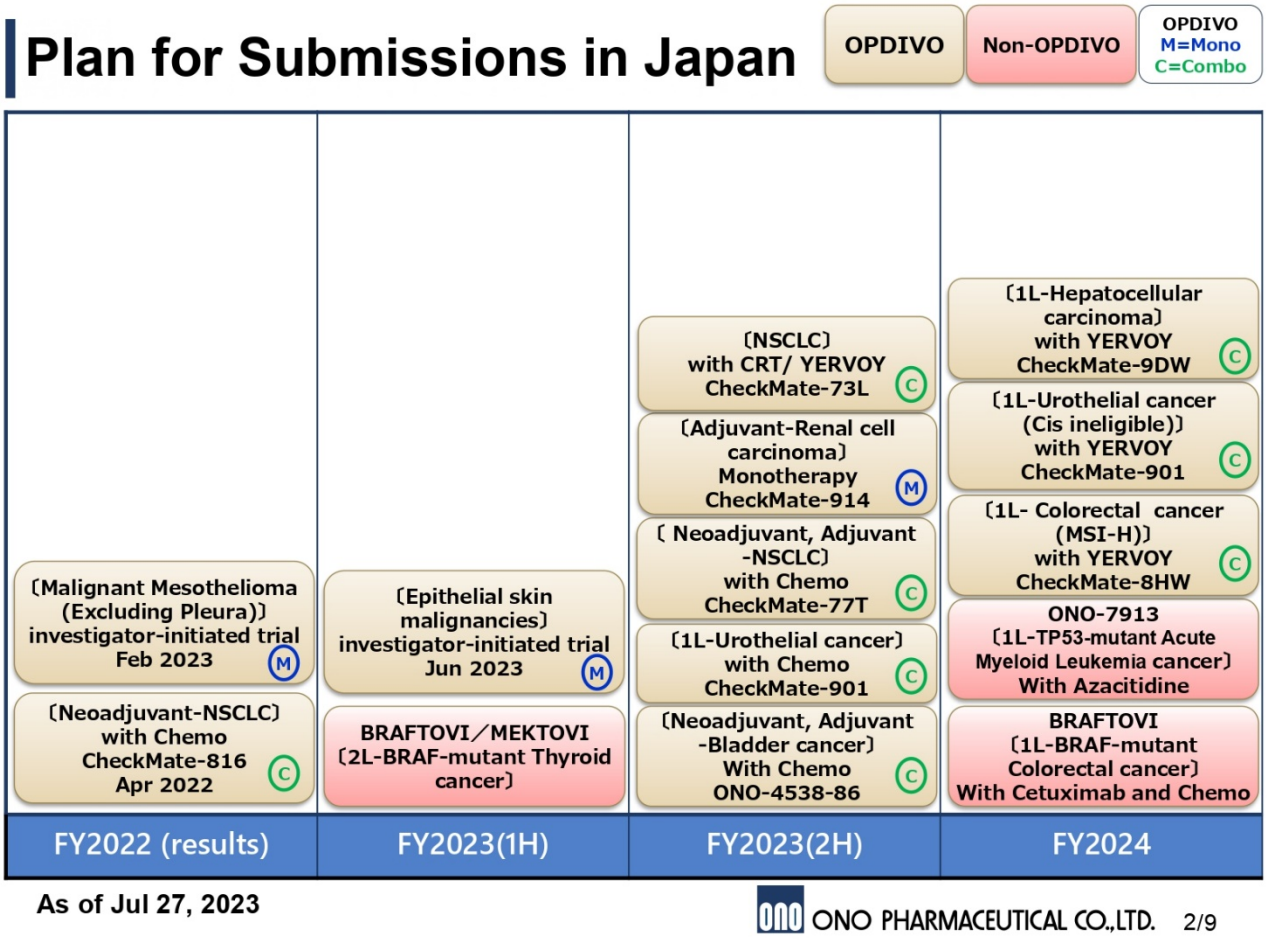
Cautionary Notes

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.

Here are some general notes.



First of all, I would like to explain the status of the planned application and the status of the application.

It is color-coded for Opdivo and non-Opdivo. For Opdivo, those marked M are monotherapy, and those marked Care combination therapy.

First, please look at H1 of FY2023.

At the end of May, we filed an application for an additional indication for the combination therapy of BRAFTOVI and MEKTOVI for the treatment of BRAF-mutant thyroid cancer in the second line and beyond.

In June, we filed an application for an additional indication of Opdivo for the treatment of epithelial skin malignancies. This application is based on the results of investigator-initiated clinical trials led by Keio University.

Next, look at H2 of FY2023.

First, we had planned to submit an application for once-weekly Kyprolis regimen, but unfortunately, it did not show the expected efficacy, and we have decided to abandon the application and have removed it from the application schedule.

In addition, as BMS mentioned in its earnings announcement last week, due to the disappointing lack of efficacy in the CheckMate-7DX trial, a Phase III study in castration-resistant prostate cancer, BMS has decided to discontinue the study based on the recommendation of an external data monitoring committee. Therefore, this has been removed from the application schedule.

As we have already announced, the CheckMate-901 study, a global Phase III study of the agent in combination with standard therapy for the first-line treatment of urothelial carcinoma, met its primary endpoints of overall survival (OS) and progression-free survival (PFS), and we are now preparing for submission of the application by the end of this year as shown in the table.

We are the first success story in the development of this first-line treatment for urothelial carcinoma, where competitors have failed to develop PD-1 or PD-L1 antibody drugs. We expect about 5,500 patients per year to be administered with the drug in Japan.

These are the changes in FY2023. There will be no change for FY2024. This is all about the domestic application schedule.

Development status of OPDIVO (1)

As of Jul 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant・1st・2nd	Monotherapy, with Ipi（1st line only）	Approved	Approved	Approved	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant ・Adjuvant	with Chemo	III	III	III	III	III
	Chemoradiotherapy	with CRT/Ipi	III	III	III	III	III
	1st	with Ipi	Approved	Approved	Approved	Approved	–
		with Ipi + Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	–	–	–	–
		with Chemo（NSQ）	Revision of labeling	Approved	Approved	–	–
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Hodgkin's lymphoma	Relapsed /Refractory	with Brentuximab	III	–	–	III	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	SOC refractory	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Filed				

Red: Update after May 2023

I will now move on to the main development status of Opdivo.

Changes and updates since May 10 are shown in red.

As added to the application schedule earlier, we have filed an application for an additional indication for the treatment of epithelial skin malignancies.

In addition, we have received a new approval in Europe for neoadjuvant therapy and adjuvant therapy for non-small cell lung cancer, which has already been approved in Japan.

Development status of OPDIVO (2)

As of Jul 27, 2023

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

* 2nd line

Red: Update after May 2023

There are no updates to this page.

Development status of OPDIVO (3)

As of Jul 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	Adjuvant	Monotherapy	III	–	–	III	III
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		with Ipi/TKI	–	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant ・Adjuvant	with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Malignant Mesothelioma (Excluding Pleural)〕	1st or 2nd	Monotherapy	Filed	–	–	–	–
Dosage and Administration	240 mg（every 2 weeks）		Approved	Approved	Approved	Approved	Approved
	360 mg（every 3 weeks）		Approved	Approved	Approved	Approved	Approved
	480 mg（every 4 weeks）		Approved	Approved	Approved	Approved	Approved

Red: Update after May 2023

There is no update here either.

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

As of Jul 27, 2023

Development code (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
ONO-4686 Anti-TIGIT antibody	Solid tumor	I ／II	I ／II	-
ONO-4482 (Relatlimab) Anti-LAG-3 antibody	Melanoma	I ／II	Approved★	-
ONO-4578 PG receptor (EP4) antagonist	Solid tumor, Gastric cancer	I	-	-
	Colorectal cancer	I	-	-
	Pancreatic cancer	I	-	-
	Non-small cell lung cancer	I	-	-
ONO-7475 (Tamnorzatinib) Axl/Mer inhibitor	Solid tumor	I	-	-
ONO-7913 (Magrolimab) Anti-CD47 antibody	Pancreatic cancer	I	-	-
	Colorectal cancer	I	-	-
ONO-7119 (Atamparib) PARP7 inhibitor	Solid tumor	I	-	-
ONO-7122 TGF-β inhibitor	Solid tumor	I	-	-
ONO-7914 STING agonist	Solid tumor	I	-	-
ONO-7226 Anti-ILT4 antibody	Solid tumor	I	I	-

★ fixed-dose combination of nivolumab and relatlimab

Red: Update after May 2023

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Here is a summary of the status of development for Opdivo in combination with other compounds.

ONO-7475 is an Axl/Mer inhibitor discovered by our company. Its generic name INN has been included in the WHO list and therefore has been added to the table. It is called Tamnorzatinib.

As listed in the bottom line, we have initiated a Phase I study of ONO-7226, an anti-ILT4 antibody for the treatment of solid tumors in Japan. ILT4 is a molecule expressed on monocytes, or macrophages and dendritic cells, and is known to negatively regulate tumor immunity. ONO-7226 is its antibody. In Europe and the US, BMS is conducting Phase I trials.

Development pipeline in Japan (Oncology area other than OPDIVO)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filed】		
BRAFTOVI (Encorafenib)	BRAF-mutant thyroid cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant thyroid cancer	MEK inhibitor
【Phase III】		
ONO-7913 (Magrolimab)	TP53-mutant Acute myeloid leukemia	Anti-CD47 antibody
【Phase I】		
ONO-4578	Solid tumor, Gastric cancer *	PG receptor (EP4) antagonist
	Colorectal cancer *	
	Pancreatic cancer *	
	Non-small cell lung cancer *	
	Hormone receptor-positive, HER2-negative breast cancer	
ONO-7475 (Tamnorzatinib)	Solid tumor *	Axl / Mer inhibitor
	EGFR mutation-positive non-small cell lung cancer	
ONO-7913 (Magrolimab)	Solid tumor	Anti-CD47 antibody
	Myelodysplastic syndrome	
	Pancreatic cancer *	
	Colorectal cancer *	

* Combination with Opdivo
Red: Update after May 2023

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See upper row. We have filed an additional application for the combination therapy of BRAFTOVI and MEKTOVI, which I mentioned earlier, for BRAF-mutant thyroid cancer.

I would like to add one additional point regarding Phase III of ONO-7913, Magrolimab. Gilead Sciences, Inc. recently issued a press release announcing the discontinuation of the ENHANCE study, an overseas Phase III study in untreated high-risk myelodysplastic syndromes (MDS), which was being conducted by Gilead. Please note that this is a different trial than the one you are now seeing for TP53-mutant acute myeloid leukemia.

In light of Gilead's decision, we will consider whether to continue the development of ONO-7913 for myelodysplastic syndromes, for which we are conducting a Phase I study.

Development pipeline in Japan (Non-oncology)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【PhaseⅢ】		
ONO-2017（Cenobamate）	Primary generalized tonic-clonic seizures	Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel
	Partial-onset seizures	
VELEXBRU (ONO-4059 : Tirabrutinib)	Pemphigus	BTK inhibitor
【Phase Ⅱ】		
ONO-2910	Diabetic polyneuropathy	Schwann cell differentiation promoter
	Chemotherapy-Induced Peripheral Neuropathy	
【Phase Ⅰ】		
ONO-4685	Autoimmune disease	PD-1×CD3 bispecific antibody
ONO-7684	Thrombosis	FXIa inhibitor
ONO-1110	Pain	Endocannabinoid regulation

Red: Update after May 2023

A new Phase II study of ONO-2910, Schwann cell differentiation promoter, for chemotherapy-induced peripheral neuropathy was initiated in Japan.

In addition, based on the results of the Phase I study in Japan, we have initiated a Phase II study of ONO-2808, an S1P5 receptor agonist, for multiple system atrophy in the US. Therefore, it has been removed from the domestic development pipeline.

Development pipeline in Japan (Non-oncology)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【PhaseⅢ】		
ONO-2017（Cenobamate）	Primary generalized tonic-clonic seizures	Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel
	Partial-onset seizures	
VELEXBRU (ONO-4059 : Tirabrutinib)	Pemphigus	BTK inhibitor
【Phase Ⅱ】		
ONO-2910	Diabetic polyneuropathy	Schwann cell differentiation promoter
	Chemotherapy-Induced Peripheral Neuropathy	
【Phase Ⅰ】		
ONO-4685	Autoimmune disease	PD-1×CD3 bispecific antibody
ONO-7684	Thrombosis	FXIa inhibitor
ONO-1110	Pain	Endocannabinoid regulation

Red: Update after May 2023

ONO PHARMACEUTICAL CO.,LTD. 8/9

This table shows the development pipeline outside Japan other than Opdivo.

As I mentioned earlier, ONO-2808 has been advanced to Phase II based on the results of the Phase I study conducted in Japan and Europe. We have initiated a new Phase II study in the US for multiple system atrophy.

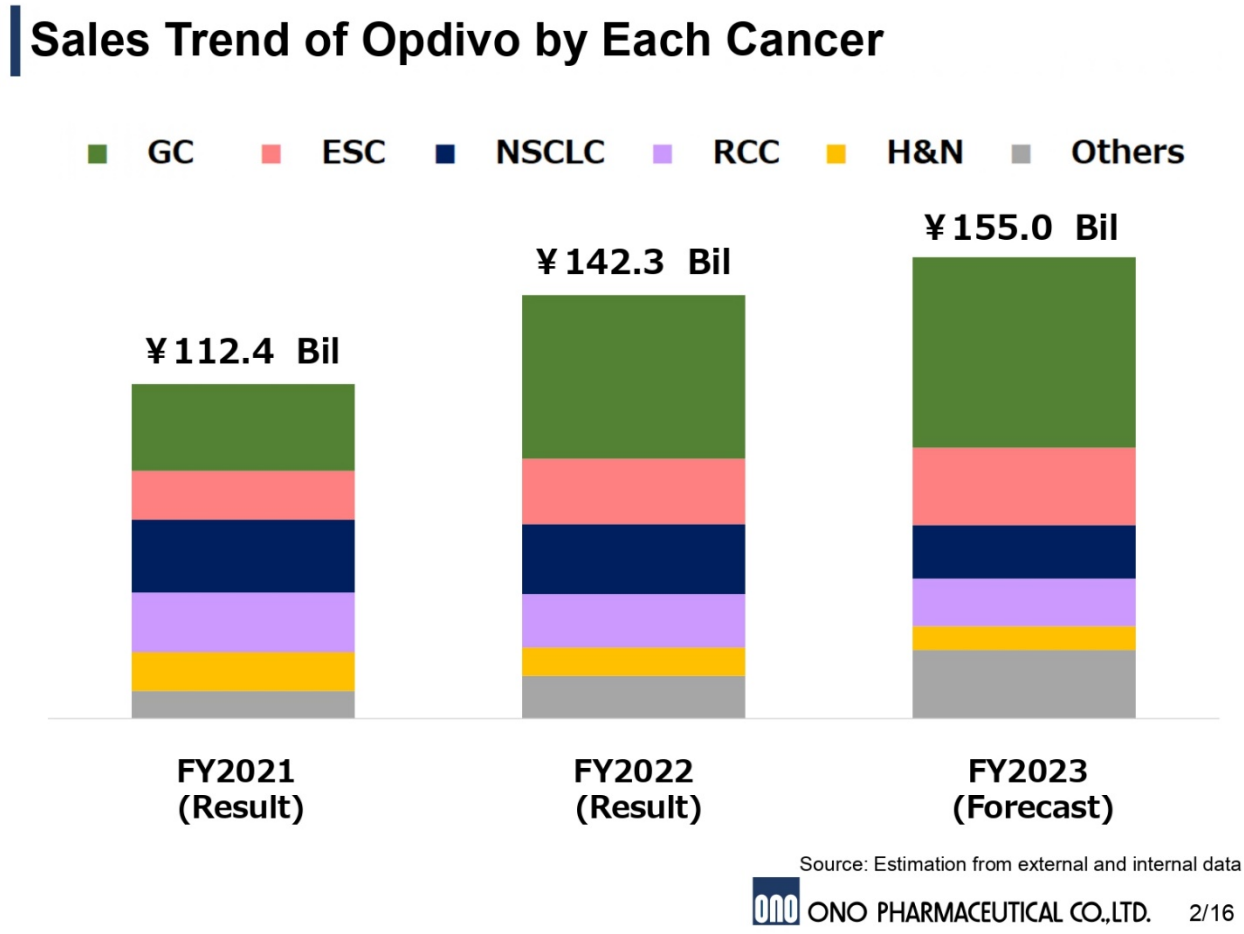
I have explained the progress of the developed compounds above. Thank you very much.

Imura: Thank you very much.

Mr. Takahagi, Executive Director of the Sales and Marketing Division, will explain the Opdivo trend.

Takahagi: I am Takahagi from the Sales and Marketing Division. I would like to introduce the trend of Opdivo.

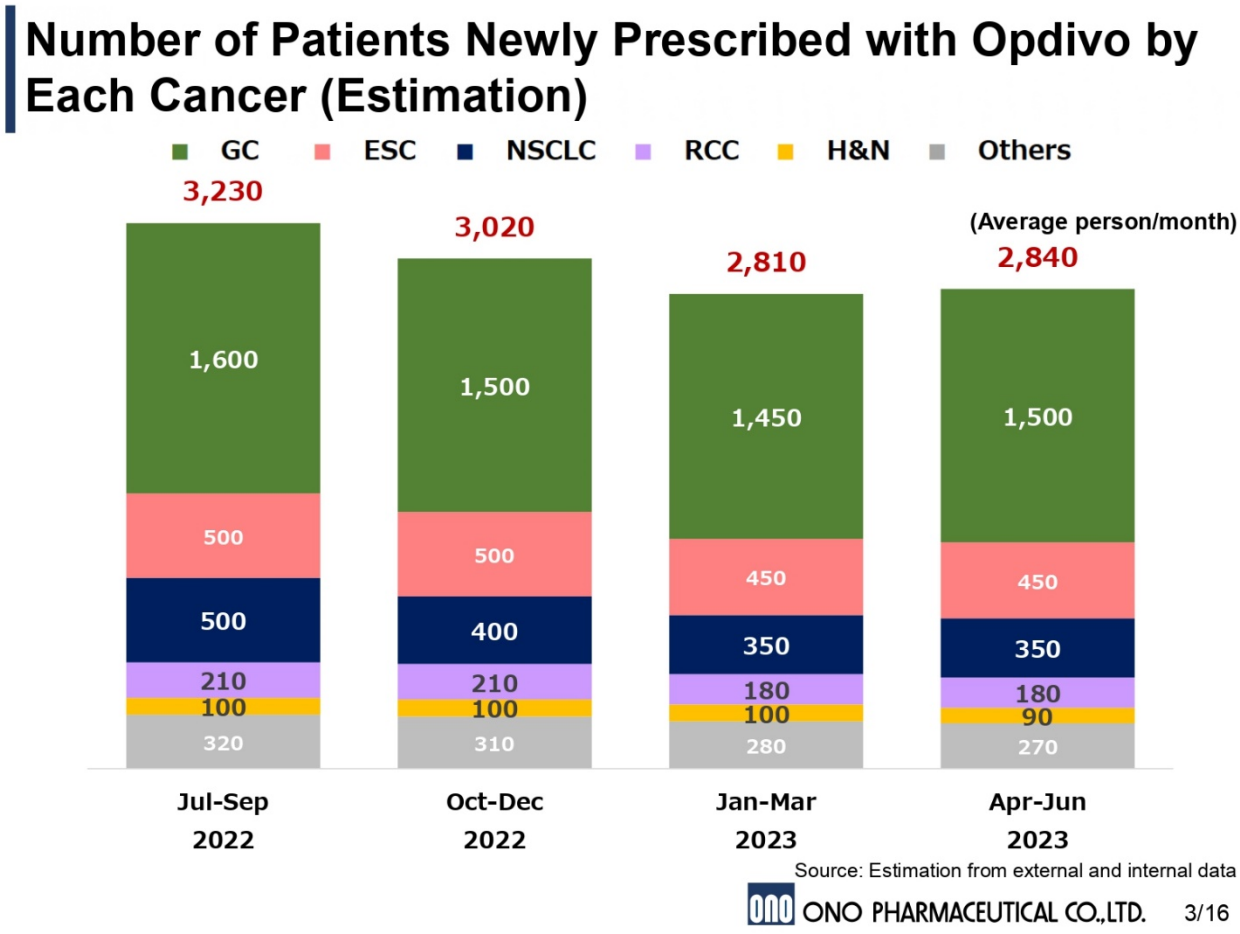
This slide deck is posted on the Company's website under IR information, financial results.



First is Opdivo sales.

From left to right: FY2021 results, FY2022 results, and FY2023 estimates.

For the current fiscal year, we forecast an increase of JPY12.7 billion, or 9%, over the previous year to JPY155 billion.

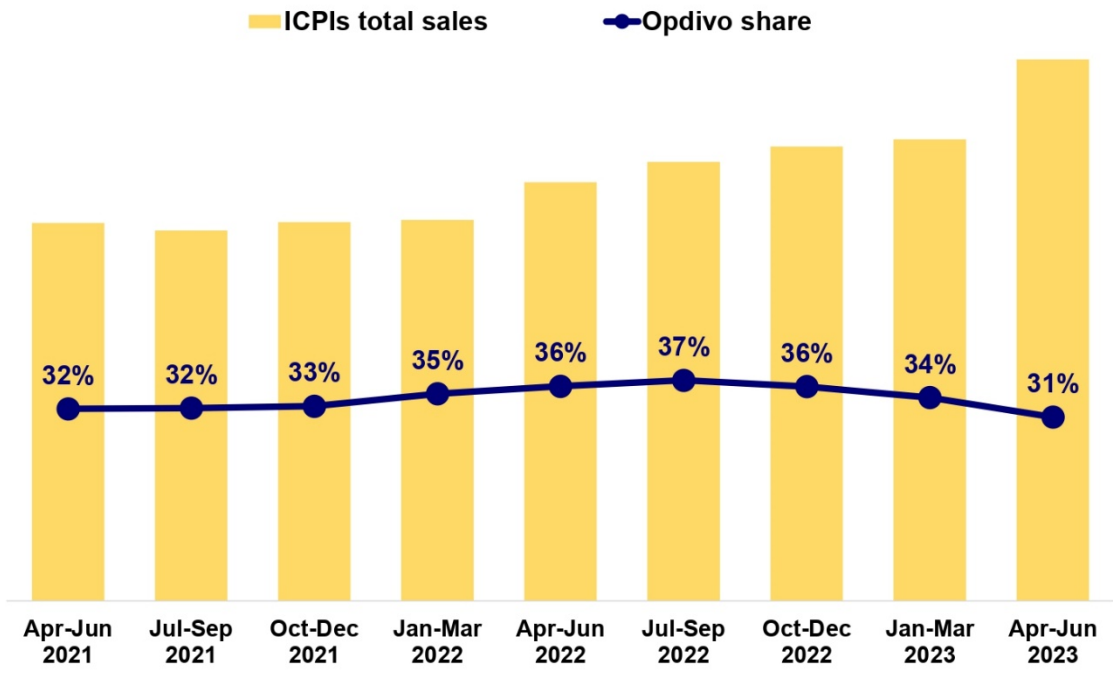


This table shows the average number of new prescriptions of Opdivo by cancer type per month for each quarter from July to September 2022 to April to June 2023.

Although this is only an estimate, from April to June 2023, 1,500 cases of stomach cancer, 450 cases of esophageal cancer, and 350 cases of lung cancer have begun to be prescribed. On average, 2,840 new prescriptions are initiated per month overall.

While the number of new prescriptions for the first-line treatment for gastric and esophageal cancer, has increased, the number of new prescriptions for the second-line treatment and beyond has decreased, resulting in a flat overall trend. However, it is increasingly being used for the first-line treatment patients for whom longer durations of administration can be expected.

Trend of total sales of ICPIs and Opdivo share



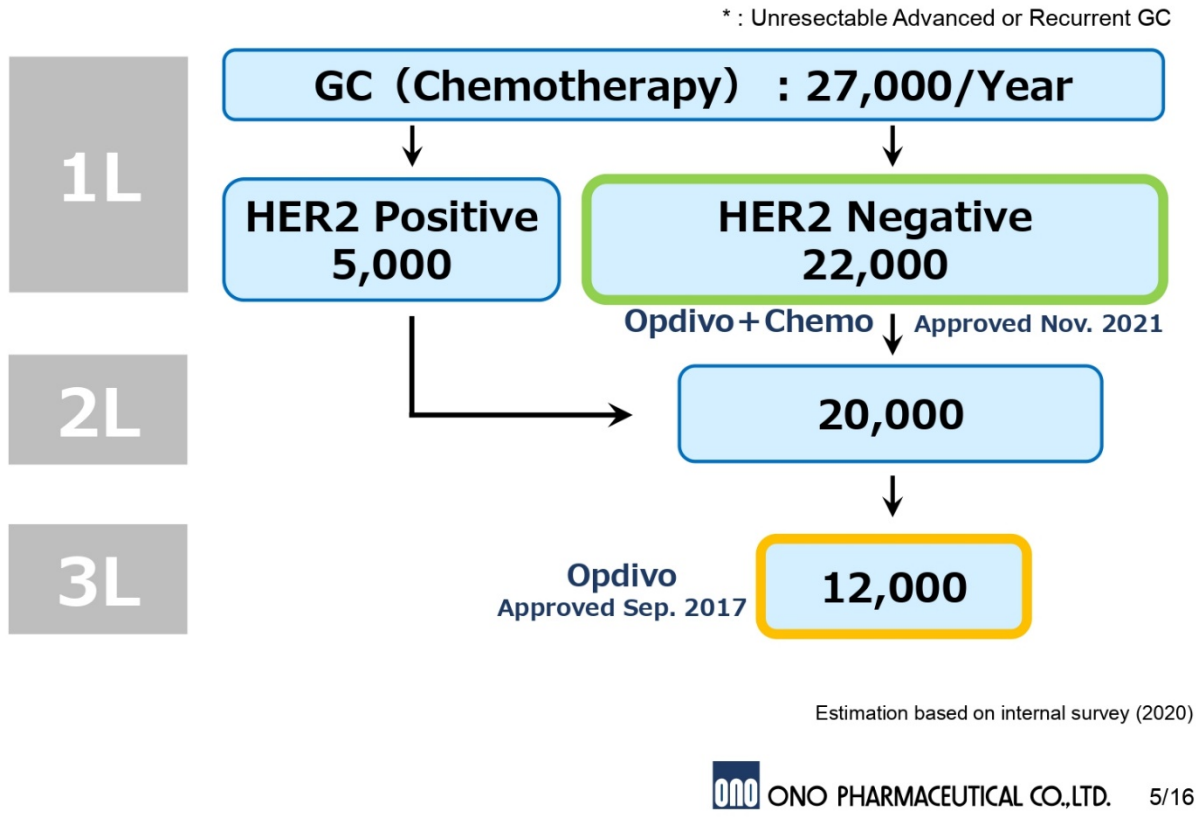
Source: External data

ONO PHARMACEUTICAL CO.,LTD. 4/16

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

The yellow bar graph shows the total sales of all immune checkpoint inhibitors, and the dark blue line graph shows the share of Opdivo.

Overall sales of immune checkpoint inhibitors are increasing steadily. Of these, it seems that the share of Opdivo decreased to 31% in April to June 2023, but the sales of Opdivo in April to June 2023 increased by 11% when compared to April to June 2022.

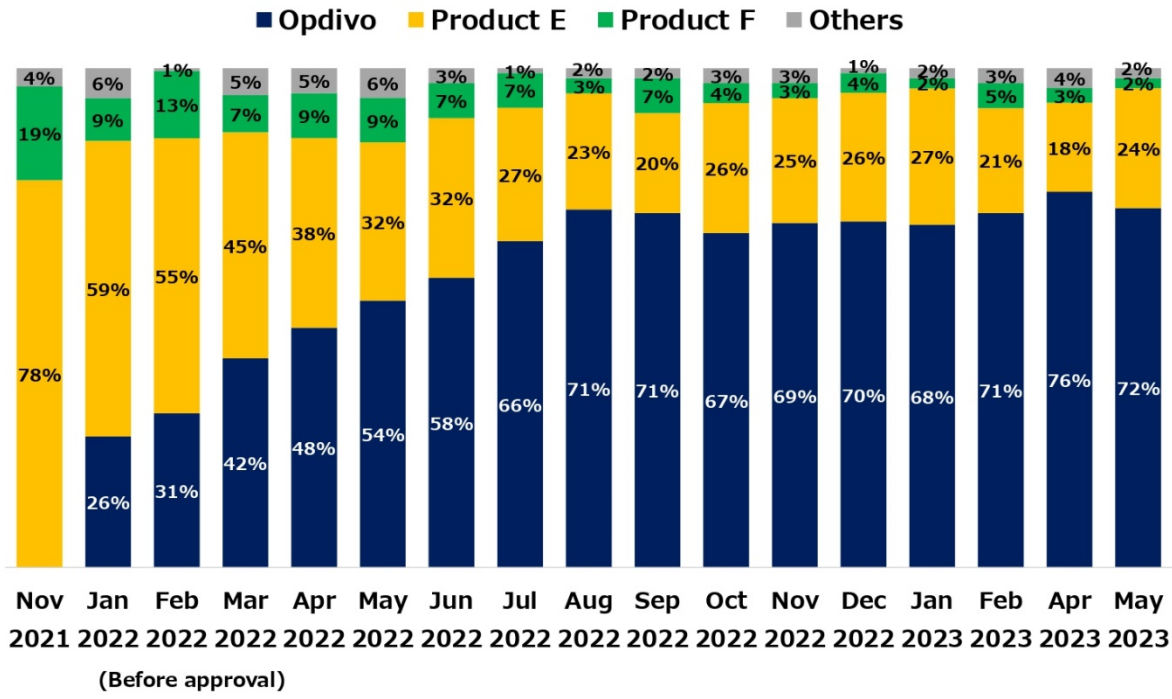


From the next slide, I will explain by cancer type.

First, let's look at the area 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 27,000, according to our own estimate. Among them, Opdivo is used in combination with chemotherapy in the first-line HER2-negative setting, and the number of patients is estimated at 22,000 per year.

Prescription Ratio in Patients Newly Treated※ for 1L GC



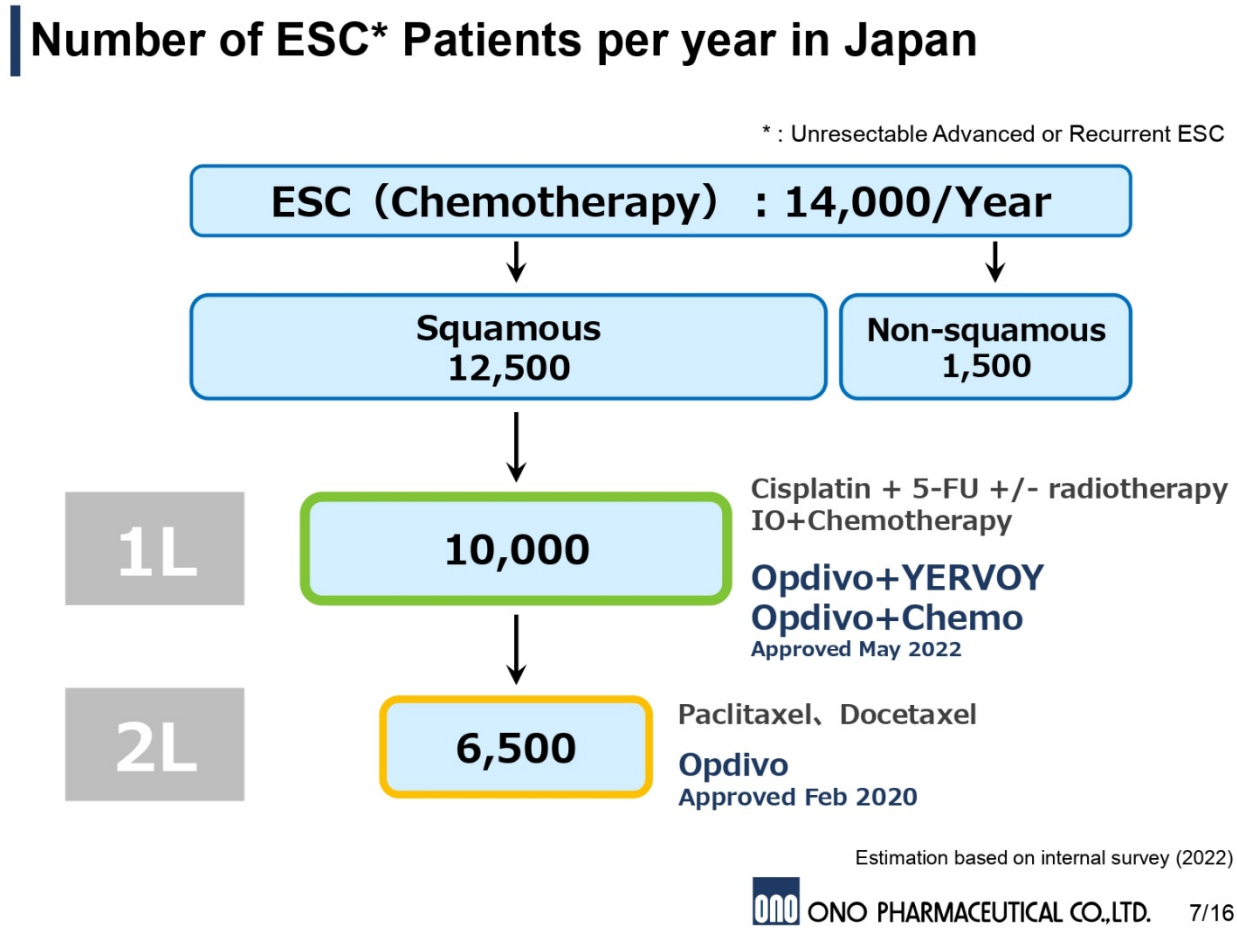
※Patients starting 1L treatment within the last 3 month

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

ONO PHARMACEUTICAL CO.,LTD. 6/16

The next slide shows the share of new prescriptions in first-line gastric cancer treatment.

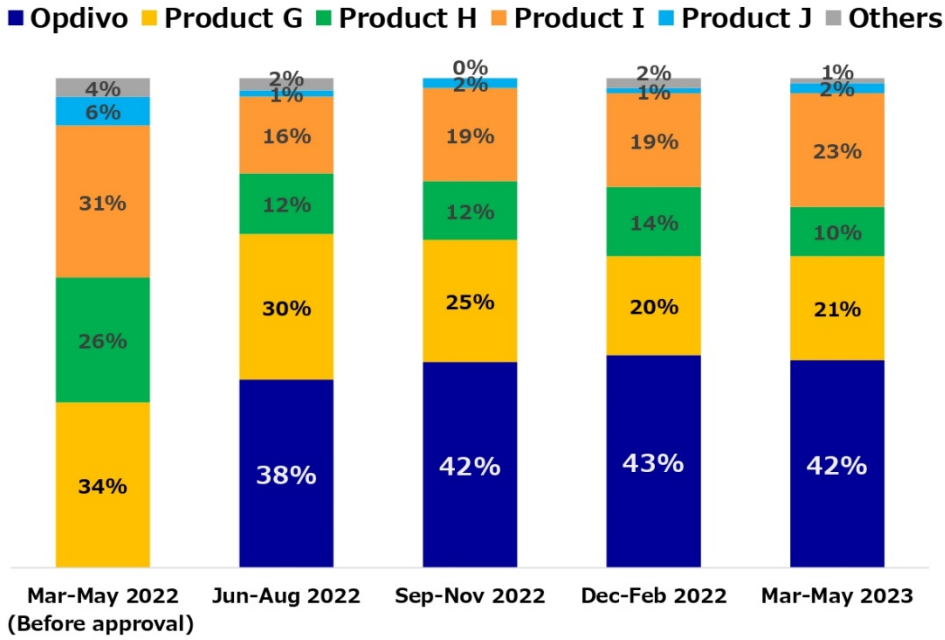
Opdivo's share of new prescriptions for first-line therapy is 72%.



In the next slide, I will explain the area of esophageal cancer.

Regimens of Opdivo in combination with Yervoy and Opdivo in combination with chemotherapy have been approved and are being used for the first-line treatment of unresectable advanced or recurrent esophageal cancer. The first-line treatment target is squamous cell carcinoma, and we believe the number of eligible patients is 10,000.

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



※Patients starting treatment within the last 3 month

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

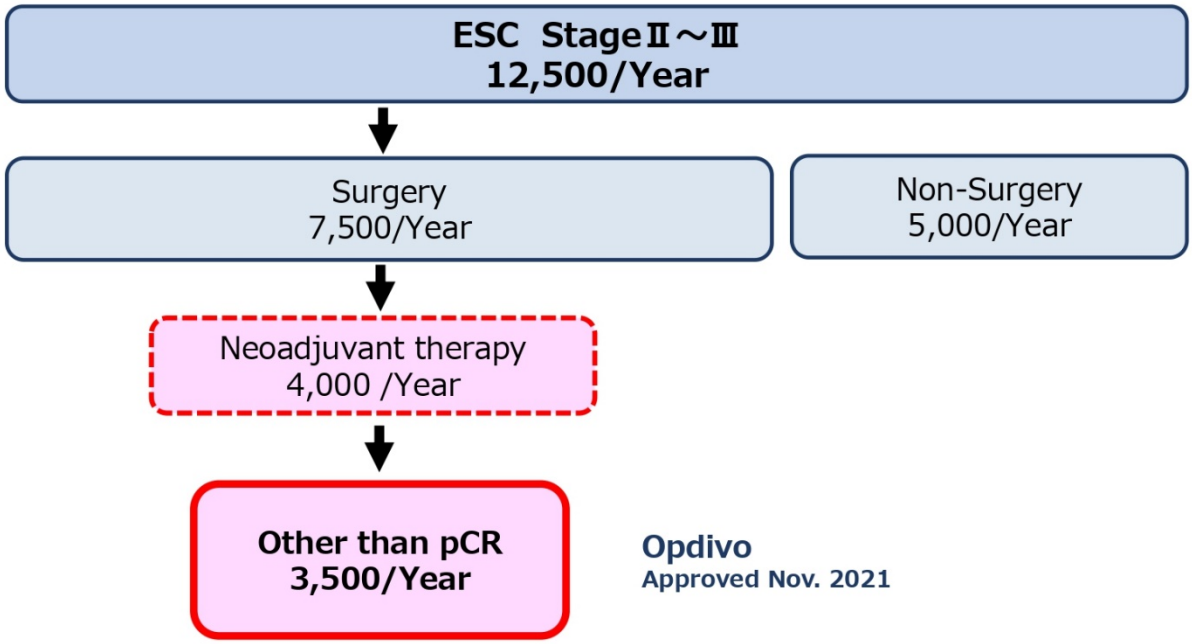
ONO PHARMACEUTICAL CO.,LTD. 8/16

The next slide shows the share of new prescriptions in first-line esophageal cancer treatment.

The Company entered first-line treatment with the Opdivo regimen and has a 42% share of new prescriptions for the Opdivo regimen. The IO regimen has expanded to 60% in first-line treatment, including competitor's products.

However, since chemotherapy regimens are used for 40%, there still remains a segment where the Opdivo regimen can expand. We will aim to further expand the Opdivo regimen.

Number of ESC(Perioperative)Patients per year in Japan



Estimation based on internal survey (2022)

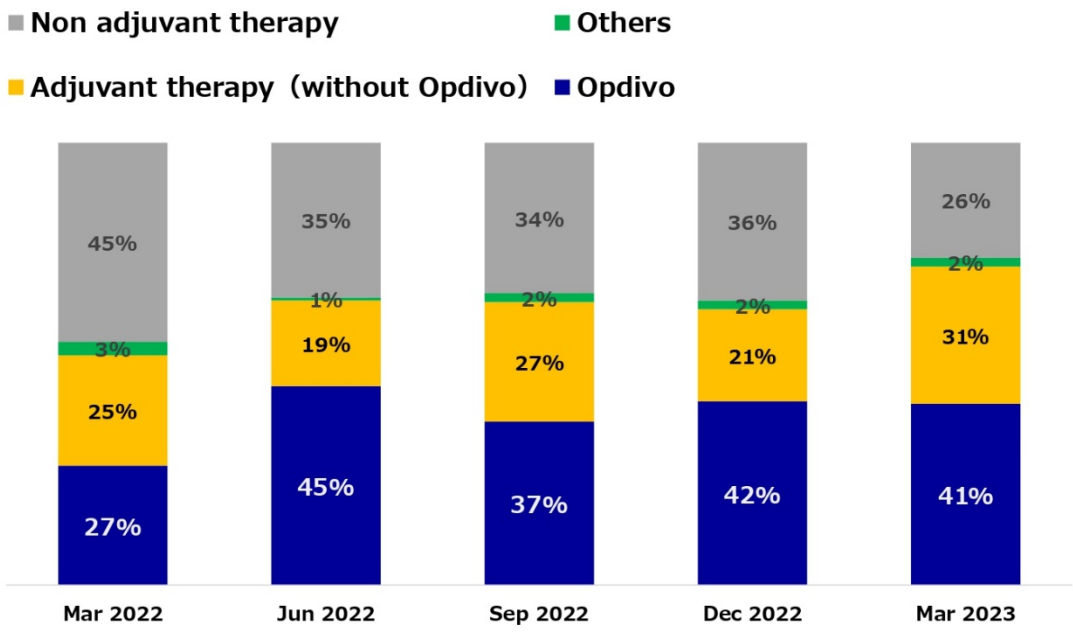
ONO PHARMACEUTICAL CO.,LTD. 9/16

On the next slide, we will explain the number of patients with esophageal cancer (perioperative).

The number of patients with Stage II to Stage III esophageal cancer is said to be 12,500 per year, of which 7,500 are eligible for surgery.

Among these patients, we believe that the number of patients who will receive neoadjuvant therapy is 4,000, and the number of patients with pathologic non-complete response who are eligible for neoadjuvant therapy with Opdivo is estimated to be 3,500.

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



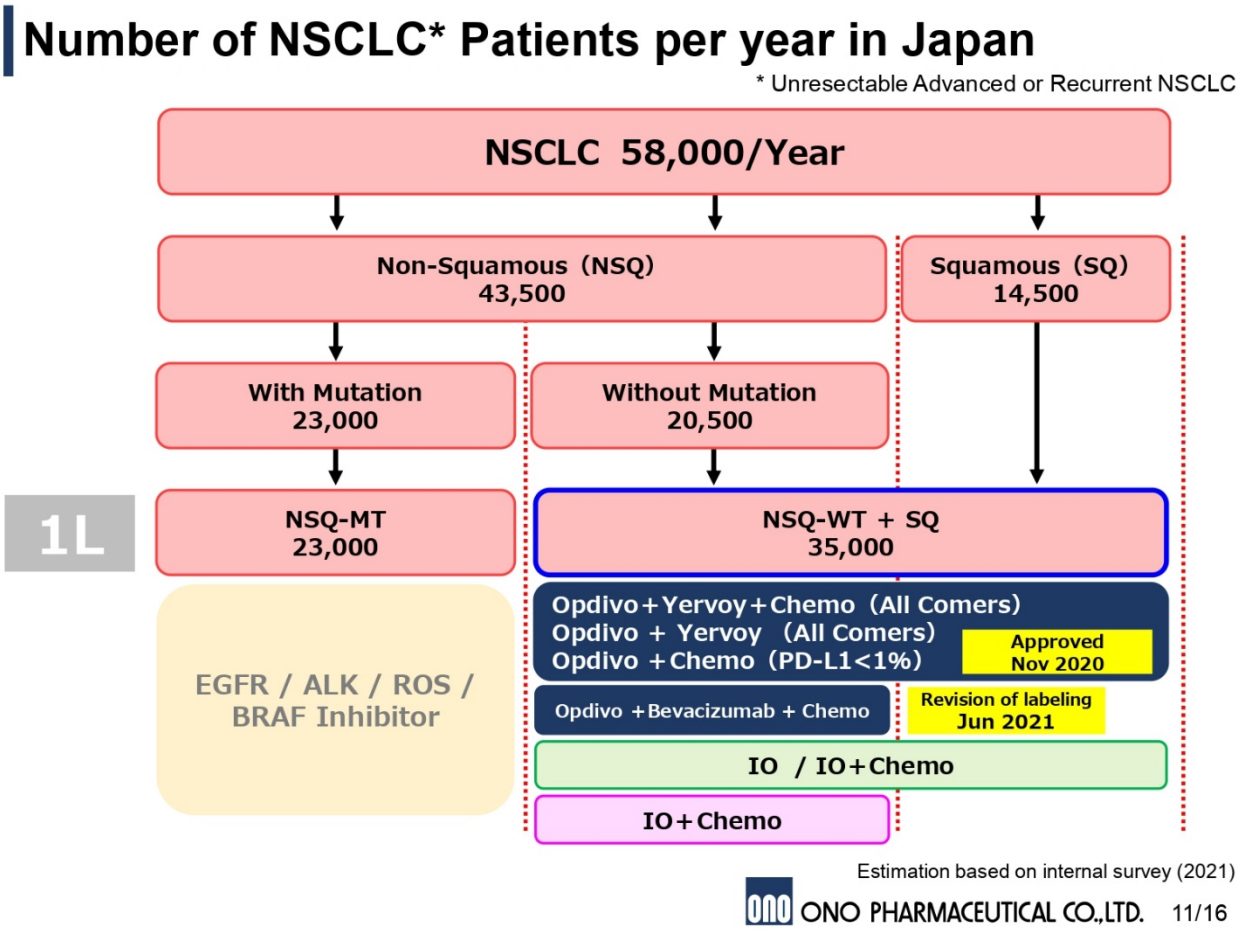
※Patients starting treatment within the last 3 month

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

ONO PHARMACEUTICAL CO.,LTD. 10/16

The share of new prescriptions in adjuvant esophageal cancer has not been updated from the Opdivo trend posted in May. As of March, the rate was 41%.

We will continue to educate about the benefits of Opdivo, as there remain many patients who receive only adjuvant chemotherapy or who have not received any adjuvant chemotherapy.



In the next slide, we will explain the area of lung cancer.

The table shows the annual number of patients with non-small cell lung cancer.

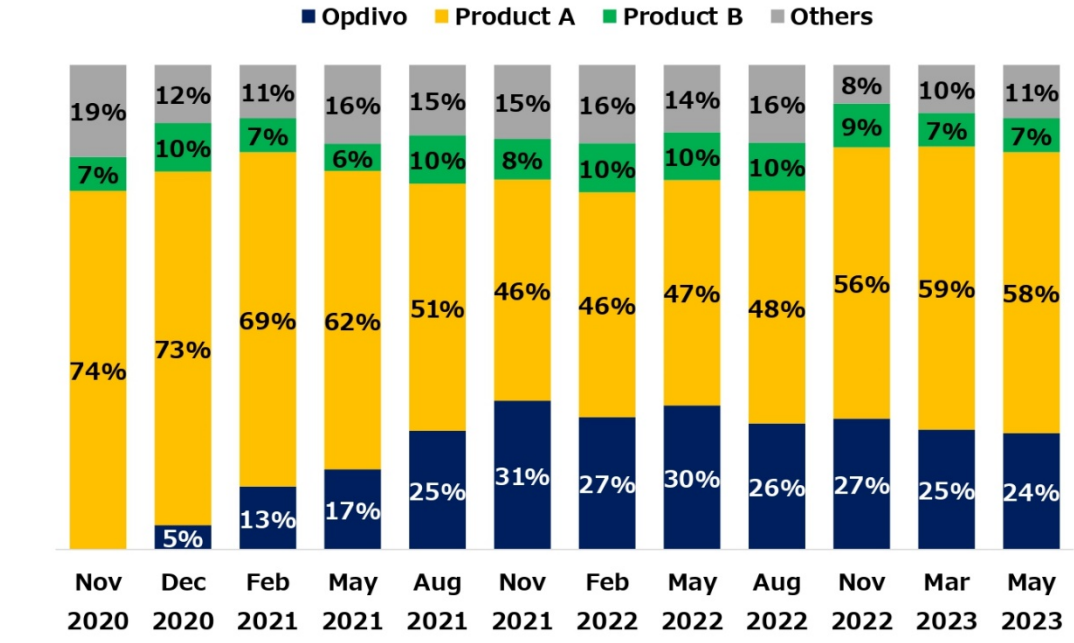
The annual number of patients with unresectable advanced or recurrent non-small cell lung cancer is estimated at 58,000, according to our own estimate.

Non-small cell lung cancer is divided into non-squamous and squamous cell carcinoma according to histologic type, and non-squamous carcinoma is further divided into diagnoses with and without genetic mutations.

The market for immune checkpoint inhibitors such as Opdivo in the first-line treatment of lung cancer includes squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation, a market estimated at 35,000 patients per year.

We are currently active in the Opdivo regimen, although the competitive environment is very intense.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



(Before approval)

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

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

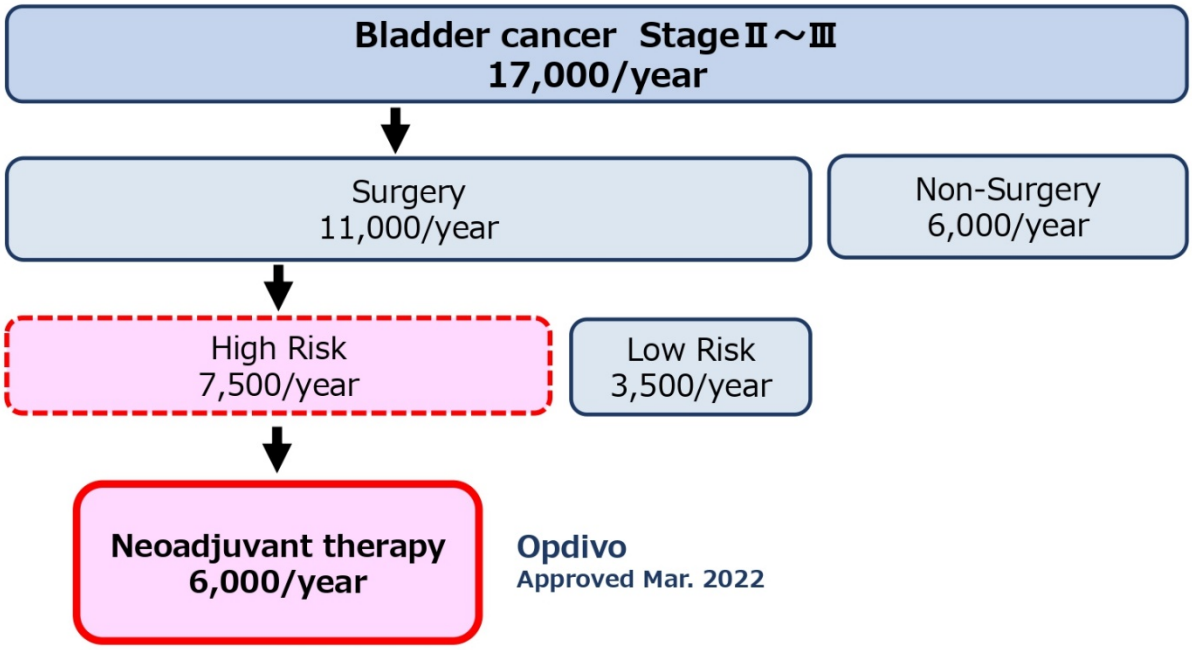
ONO PHARMACEUTICAL CO.,LTD. 12/16

The next slide shows the share of new prescriptions in first-line lung cancer treatment.

Opdivo's share of new prescriptions has stagnated at 24% as of May. The stagnation is due to an increasingly competitive environment and the time it has taken to dispel safety concerns.

We will continue our efforts.

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



Estimation based on internal survey (2022)

ONO PHARMACEUTICAL CO.,LTD. 13/16

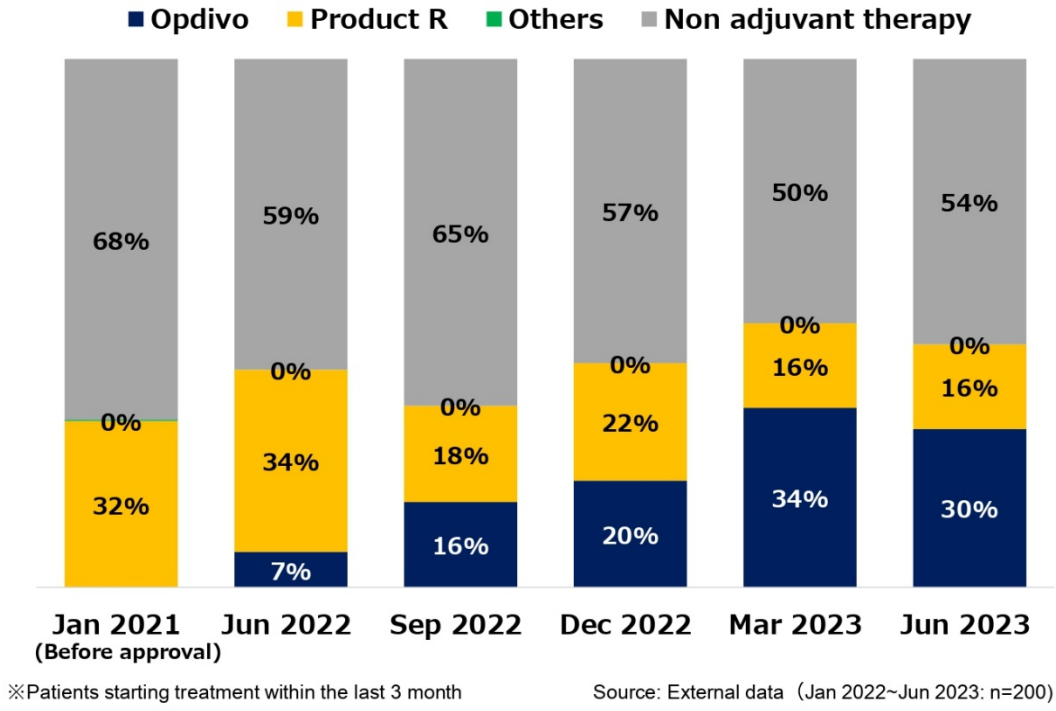
On the next slide, we will explain the bladder cancer situation.

Urothelial carcinoma is a cancer that develops in the mucosa of the inner urothelium of the renal pelvis, ureter, bladder, and urethra. In Japan, bladder cancer represents 80% of all urothelial carcinomas. For this reason, we present the following information regarding the perioperative number of patients with bladder cancer, which is the most common type of cancer.

The number of patients with Stage II to Stage III bladder cancer is estimated to be 17,000 per year, of which 11,000 are eligible for surgery.

Among these patients, we believe that the number of high-risk patients with high recurrence rates is 7,500, and the number of patients who will be eligible for neoadjuvant therapy with Opdivo is estimated to be 6,000.

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



※Patients starting treatment within the last 3 month

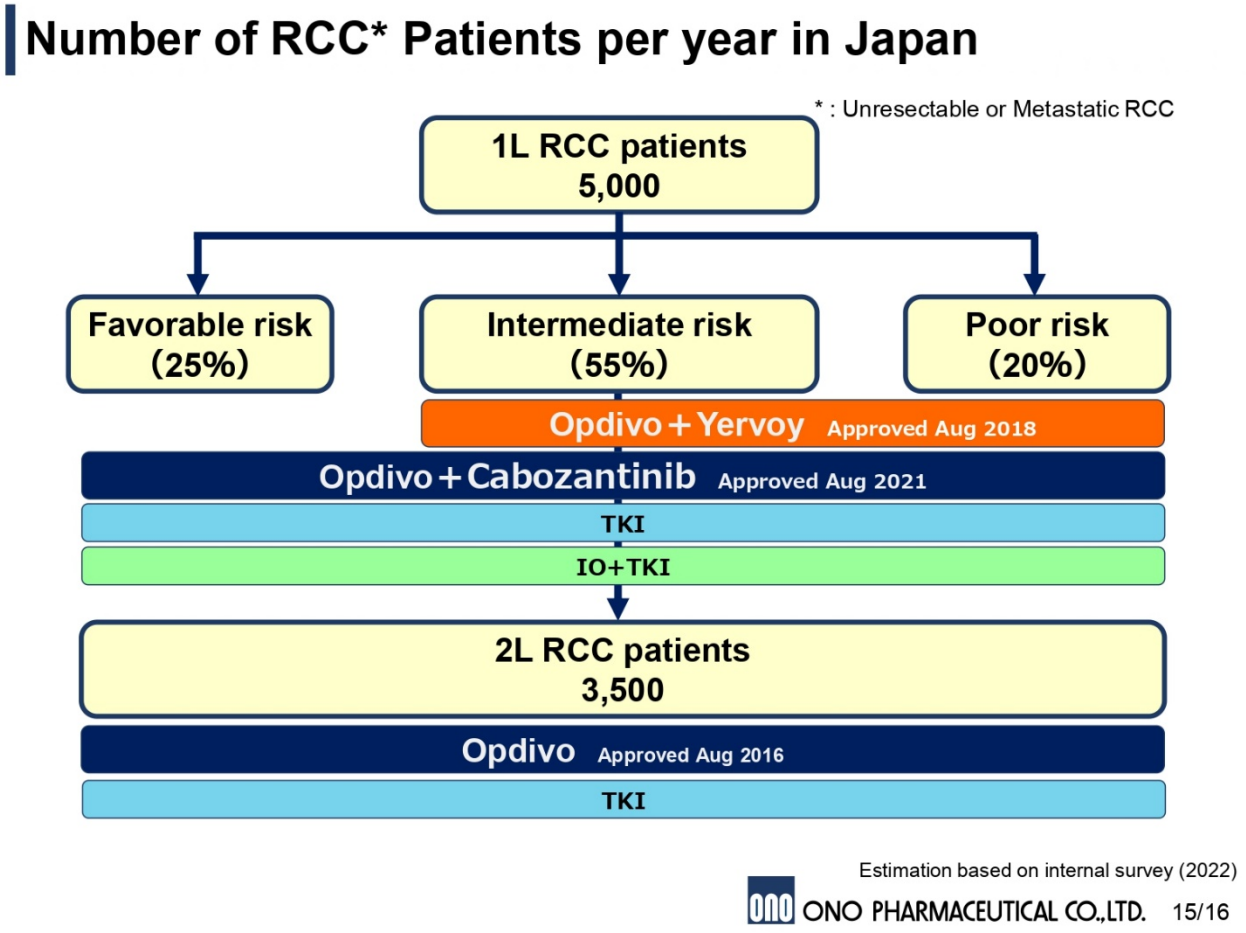
Source: External data（Jan 2022~Jun 2023: n=200)

ONO PHARMACEUTICAL CO.,LTD. 14/16

Next slide, please.

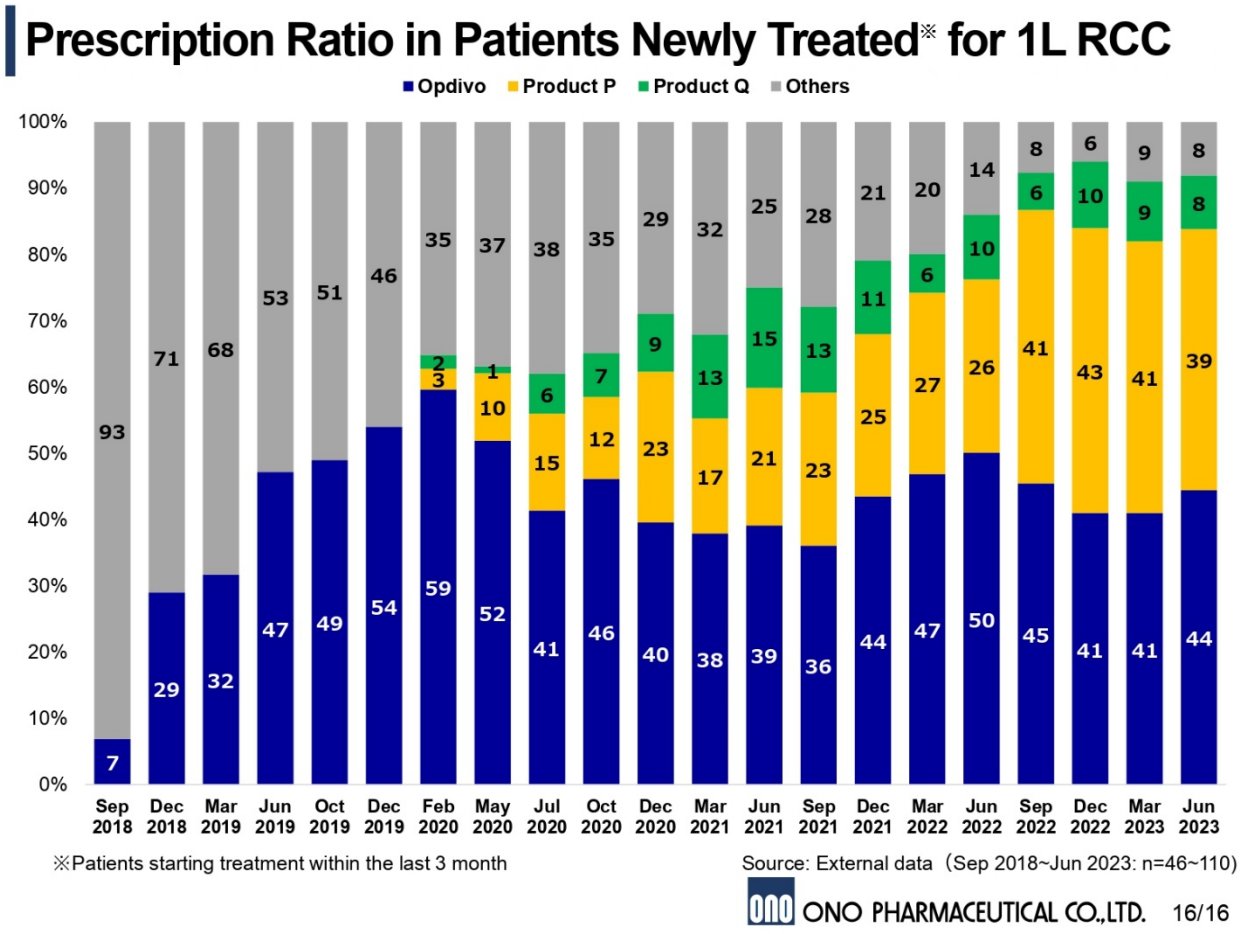
The share of new prescriptions for adjuvant bladder cancer surgery is 30% as of June.

Since 60% of patients do not receive adjuvant therapy, we will continue to raise awareness of the usefulness of Opdivo so that it can be evaluated as a necessary option.



Finally, I will explain renal cell carcinoma on the next slide.

The annual number of patients for first-line treatment of renal cell carcinoma is 5,000, and we are active in these two regimens for first-line treatment: Opdivo + Cabozantinib and Opdivo + Yervoy.



The next slide shows the share of new prescriptions acquired in the first-line treatment of renal cell carcinoma.

In first-line treatment, combination therapy with IO is used in over 90% of cases. The share of new patient prescriptions for Opdivo + Yervoy and Opdivo + TKI therapy is 44%, with 21% of prescriptions being obtained at low risk, 47% at intermediate risk, and 55% at high risk.

These are the explanations by cancer type. I have explained the trends of Opdivo in general and by cancer type.

Although the competitive environment is currently intensifying, we will further build up new prescriptions this fiscal year, mainly for gastric cancer, esophageal cancer, and urothelial cancer. We will continue to strive to meet the unmet needs of cancer patients.

Thank you very much.

Question & Answer

Questioner 1: First, let me confirm. In the announcement about AstraZeneca's USD140 million, I believe you mentioned that there would be a cash-in over multiple periods but that it would be recorded once this fiscal year in the P&L. I know there are a lot of unsettled issues regarding this, but can you tell me if this is recorded as sales or as other income?

Also, if the future portion is considered, it seems too little, compared to the case with Roche, for example. Any suggestions on how to think about this would be helpful.

Ito: Regarding the approximate USD140 million, as you have heard, the cash flow is multi-year. However, since it has already been confirmed that we will receive it, we are currently in discussion with the auditing firm to account for this almost as a lump sum. It will be a little while before the auditor's conclusion is reached, so we can't say for sure, but we would like to record it as sales as a lump sum.

Since the contract was concluded on July 24, the exchange rate is roughly JPY140, and everyone is saying it is close to JPY20 billion. However, since the cash inflow exceeds one year, it needs to be discounted by NPV (Net Present Value) with respect to the cash flow, and we expect that the cash flow will be reduced a little by interest rate. As for how to account for the difference between the total amount coming in over multiple years, the accounting treatment for that portion is that the interest equivalent is divided over several years. The difference between the current year's lump-sum appropriation and the 20 billion yen amount will be divided into several years as an interest portion.

As for accounting treatment, I have just mentioned.

Questioner 1: Don't you believe the amount of USD140 million is too small? Do you have any comments regarding the future portion?

Tani: This is what our company, AstraZeneca, and BMS have agreed to by contract. It is up to you how you feel that. Please understand that we are unable to comment.

Questioner 1: I would like to ask about Opdivo's share of new prescriptions in first-line gastric cancer on page six. Maybe I missed it earlier, but Opdivo's market share has dropped from 76% to 72%, and competitor E's market share has increased significantly. Is this maybe Enhertu, for example, Keytruda? Could you please explain a little about your relationship with product E in terms of market share?

Takahagi: Are you asking about first-line gastric cancer?

Questioner 1: Yes. I am asking about your share in the first-line of gastric cancer on page six.

Takahagi: This is based on confirming the share of prescriptions to about 200 physicians each month. Since the physicians are not fixed, there is likely to be some variability in the results, and we believe the change is minor.

Also, this is only chemotherapy, so the product E, which appears to have slightly increased in prescription share, is not Keytruda.

Questioner 2: The first is not related to financial results, but to the recently announced share buyback. The release stated that the decision was made based on the financial situation and the level of the stock price. In this regard, I would like to know again the reason why this was implemented at this time. I also thought that

your company would rather allocate money to growth investments. I would like to know how you think about the combination of growth investment and share buybacks.

Will share buybacks continue to be implemented based on the level of the stock price?

Ito: Of course, our policy of investing in growth remains unchanged, but one of the main reasons for the share buyback is the approximately JPY20 billion in cash inflow.

Our financial assets increased considerably last fiscal year; so, although we increased the dividend this time, we still believe there is room to return profits to shareholders. Therefore, we have decided to buy back our own shares.

We have always said that we would implement share buybacks in a flexible manner. We have given you certain guidelines for future growth investment, but if we were to increase our investments, we would have to make decisions on share buybacks while keeping a close eye on cash flow to some extent. We will consider share buybacks in the future as we monitor the situation.

Questioner 2: Understood. Since you are considering the balance between investment in growth and shareholder returns, is it correct to assume that the announcement of the share buyback means that there is not likely to be a major investment in growth this fiscal year?

Ito: To be honest, we do not have any major investment plans at this time, but we still have eight months left, so we would like to invest aggressively if there is an opportunity.

Questioner 2: The second is about the progress of royalties. Opdivo royalties, in particular, seemed to be somewhat low. Can you tell us about the progress of royalties in terms of BMS, Merck, and Roche?

Ito: We have heard about BMS's global sales forecasts for North America, Europe, etc., and Merck's sales.

Questioner 2: Can you tell us about each product?

Ito: I'm sorry. Okay, Opdivo and Keytruda.

As for Opdivo sales, I do not think we are far behind. As for Keytruda, at this point, we believe that royalty income is almost as planned.

Questioner 2: Lastly, regarding Opdivo prescriptions for lung cancer, I believe the impact of 9LA was already factored into the initial plan for this fiscal year. Are you saying that the number of prescriptions in Q1 was lower than the negative impact with 9LA factored in? Was it as low as expected or lower than expected?

Takahagi: As expected.

Questioner 2: I understand very well. Thank you very much.

Questioner 3: I am looking at Opdivo on page two of the document and at bladder cancer on page 14. Sales were very good, up 10.9%, while some market share is declining.

However, as you explained on page 14 regarding bladder cancer, the apparent share has decreased. If the number of patients with non-adjuvant therapy is increasing, that doesn't mean that competitors are taking market share, but that Opdivo's market share will increase in the future. Is that correct?

Takahagi: Yes, in this fiscal year, other than gastrointestinal cancers, we hope to firmly increase our market share in adjuvant bladder cancer treatment.

As you mentioned, there are still many patients who have not yet received adjuvant therapy in this area, and I think the key to expansion in this area this fiscal year is to obtain evaluations in this area. Different doctors have slightly different criteria for judging high risk. The current issue is that we must educate in this area in a MR-to-doctor or doctor-to-doctor format.

Questioner 3: Understood. Opdivo has grown 11% in one quarter. Prescriptions for new patients with gastric cancer are strong, and the market share in renal cancer is very high. It's hard to tell from the information you gave us, but which of these contributed the most to this 11%, and which were better than expected? I guess it depends on the number of patients.

Takahagi: The growth rate of urothelial carcinoma, which I talked about a little earlier, is positive. This is because the April to June period of the last fiscal year was just after the approval of additional indications, and therefore almost no results were available. The first-line treatment for gastric cancer has also increased from about 780 newly prescribed patients in the April to June period of last fiscal year to over 1,000 in the April to June period of this year.

The first-line treatment for esophageal cancer also did not make a positive contribution during the April to June period last year, but during the April to June period of this fiscal year, there was an increase of about 150 cases. I think those are the reasons for this 11% increase.

Questioner 3: Finally, I am very sorry to ask this question as a layman, but there was an announcement about the USD140 million settlement from AstraZeneca. Imfinzi is growing at a tremendous rate in Japan. You mentioned earlier that there will be some differences in interest rates. Unlike the Merck case, what is the decision to receive a lump sum as a settlement? Is it difficult to get some kind of fee based on sales?

Tani: As I mentioned earlier, this is the contract with AstraZeneca and BMS. I hope you could understand that a full settlement including various items was made, and the associated lump sum will be paid.

Questioner 4: My question is about the impact of Opdivo's first-line, CheckMate-901 trial for urothelial carcinoma. Earlier, you mentioned that there are about 5,500 patients per year who are eligible for Opdivo administration. What is your opinion of the competitiveness against the combination of Padcev and Keytruda? Based on that, I would like to know your current view on how many of the 5,500 patients it will penetrate.

Okamoto: I will answer your question about the combination of Padcev and Keytruda and our current perception.

First of all, of the 5,500 patients with urothelial carcinoma, most of them have bladder cancer. The population that met the primary endpoint in Study 901 was patients eligible for cisplatin-containing chemotherapy. We believe that the combination of cisplatin and gemcitabine is the current standard of care for the first-line treatment of urothelial carcinoma, and that the study design to add Opdivo to this standard of care will include 5,500 eligible patients.

On the other hand, in terms of the competitiveness against the combination of Padcev and Keytruda, we do not know the status of approval of the competitors, so we are not able to analyze the detailed figures at present.

Questioner 4: I understand. At which medical association would you be willing to share the data from the 901 study with us?

Okamoto: BMS is the implementing entity for global, and BMS would like to make a presentation at the earliest possible conference timing. Sorry, we have not determined which conference specifically at this time.

Questioner 5: First, since this is Q1, there was no particular change in numbers this time. Forxiga seems to be doing particularly well. If possible, what products were particularly good or bad in Q1?

Takahagi: In Q1, Opdivo was in line with the plan, and Forxiga was slightly above plan. Orencia also went according to plan. Glactiv is in a slightly tougher situation. That's all for the main products.

Questioner 5: I believe there was a discussion about lung cancer safety at the previous meeting. I think it started with the physician-initiated clinical trial. I understand that it is difficult for your company to deal with this issue, but what is the current situation? Is it still going to take a long time or is the information getting out soon? I think the lung cancer area has been particularly impacted.

Takahagi: First of all, compared to the plan, as you asked, the situation is as severe as expected. We are now in the process of delivering the information we have to medical professionals, focusing on safety information.

However, as you say, not all doctors understand this, so we must continue to educate them. It is difficult to read when we will be able to fully recover, but we hope to get out of this situation as soon as possible.

Questioner 5: I have heard that it would stop developing Magrolimab, CD47 for MDS. Is there any possibility of an impairment movement within your company's assets, or does it seem unlikely?

Okamoto: First, Gilead, the company that originated the drug, is discontinuing the program for MDS because it meets the pre-defined criteria for futility discontinuation.

On the other hand, at the same time, we are also conducting development for other indications, including trials for AML, some solid tumors, etc., which will continue. We are also developing the drug for solid tumors in Japan and do not believe that the results of the MDS will affect that.

Questioner 5: So, there is no impact?

Okamoto: No.

Questioner 5: Finally, I understand that your company has an option right for Itolizumab. Has this been exercised yet?

Okamoto: No, it has not been exercised yet.

Questioner 5: It appears that the other party's development is quite advanced, and data is beginning to emerge. Are you close to exercising, or do you not know?

Okamoto: We don't know yet.

Questioner 6: I would like to ask about the so-called housekeeping. First, I believe you have been in discussions with BMS for about a year regarding plans to introduce Opdivo SC in Japan. I would like to ask about the current situation.

Okamoto: We believe the point you have asked is very important. I cannot give you a specific date for development, but we are discussing the development of Opdivo subcutaneous injection in Japan so that it will be available to the medical community soon.

Questioner 6: I guess you are saying that you cannot disclose a specific date yet?

Okamoto: Thank you. Please allow us to refrain from discussing the specific timing of the start of development today, as it is related to our development strategy.

Questioner 6: Finally, the future of gastric cancer will considerably determine the growth of Opdivo. I know that has been a factor in the past, but I would like to see a clearer picture of the current competitive situation.

I understand that the so-called Opdivo IO combination is taking the market by storm. How does your company see the situation now, including the situation of competitors? I understand the disclosed number of patients, but please tell me how your company perceives the competitive environment.

Takahagi: First, we believe that IO in the same area is the Keytruda regimen. However, at present, we do not believe that there appears to be much difference in the clinical trial results between the Opdivo and Keytruda regimens. Opdivo is well ahead of other drugs, and because we are ahead of other drugs, we can provide long-term dosing data and long-term survival rates before other drugs, so we believe that we have an advantage in this area.

On the other hand, we believe that Zolbetuximab has become a very hot topic recently. We estimate that about 40% of patients with HER2-negative gastric cancer are anti-Claudin antibody-positive.

However, on the other hand, regarding the current status of Opdivo, almost 90% of patients with CPS 5 or higher are on Opdivo regimens. On the other hand, only for about 60% of patients with a CPS of less than five, the Opdivo regimen is used. So, if we take it into account the maximum impact of Zolbetuximab, I expect that Zolbetuximab is likely to penetrate to the area below CPS 5.

As for patients with CPS of less than five, half of the HER2-negative patients with gastric cancer are considered to be the market. We estimate that the impact is at most 20%.

However, the high response rate of Opdivo for CPS of less than five has been well demonstrated, especially in combination regimens. So, our current thinking is that we would like to build a solid wall based on such things and long-term dosing results.

I hope you got the message.

Questioner 6: Yes, thank you.

From what you, Mr. Takahagi, just said, I get the impression that you show little interest in Enhertu, which enters the market for all comers. In the future, probably Imfinzi will also come in, but do you think that this can be blocked?

Takahagi: In the end, we cannot make a judgment without seeing the test results of competing products. We would also like to see what the conditions of approval would be and to have a good understanding of the level of impact. I have answered only those questions for which we currently have solid data.

Questioner 6: Understood. Thank you.

Imura: Thank you all very much for taking time out of your busy schedules to join us today. This will be the end of the meeting.

[END]