ONO PHARMACEUTICAL CO., LTD.

Q2 Financial Results for the Fiscal Year Ending March 2024

November 2, 2023

[Number of Speakers]	6	
	Gyo Sagara	President, Representative Director, and Chief Executive Officer
	Toichi Takino	Member of the Board of Directors, Senior Executive Officer, Executive Director of Discovery & Research
	Satoshi Takahagi	Corporate Officer, Executive Director of Sales and Marketing
	Masaki Ito	Corporate Officer, Division Director, Corporate Strategy & Planning, Business Management Division
	Tatsuya Okamoto	Corporate Officer, Deputy Executive Director, Clinical Development
	Ryuta Imura	Senior Director, Corporate Communications

Presentation

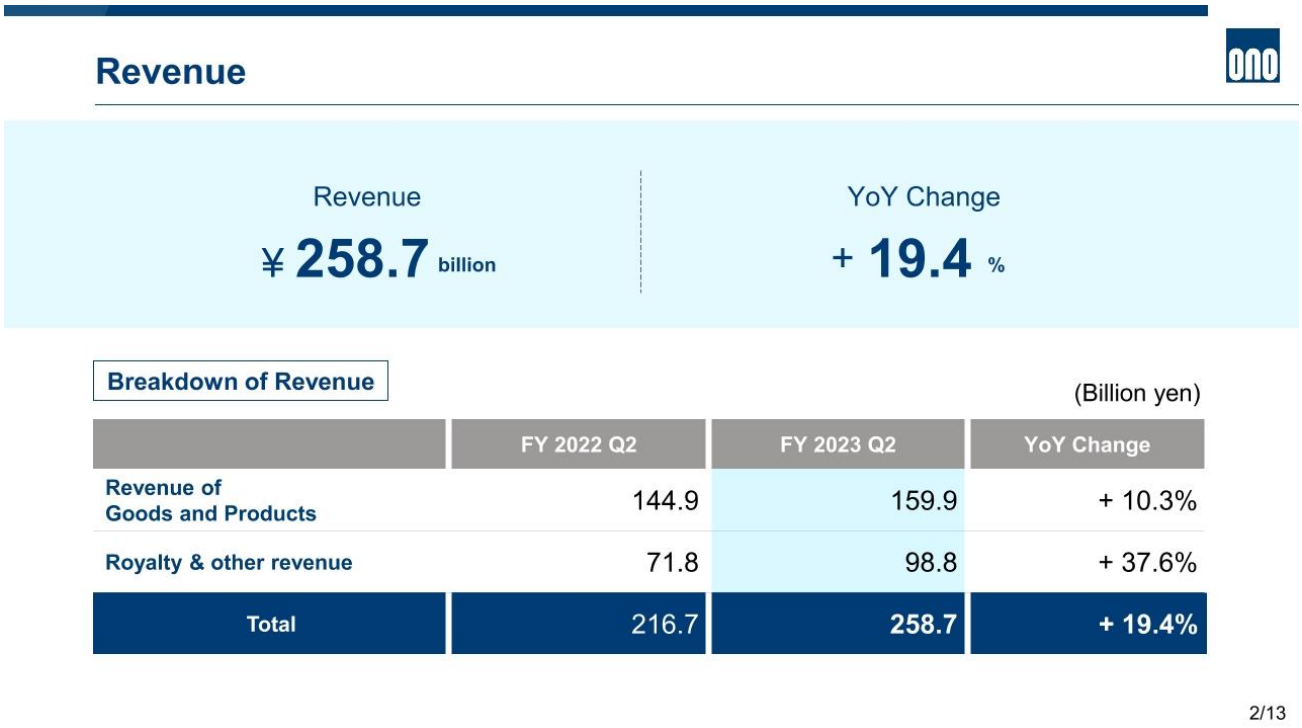
Imura: Here are today's contents. First, Mr. Ito, Division Director of the Business Management Division, will present an overview of the financial results for Q2 of the fiscal year ending March 31, 2024, as well as the full-year results, followed by a reduction plan of cross-shareholdings. President Sagara will then introduce the Company's future growth strategy.

Next, Mr. Okamoto, Deputy Executive Director of the Development Division, will give an update on the progress of development products, and finally, Mr. Takahagi, Executive Director of Sales and Marketing Division, will give an update on Opdivo.

The documents, including the summary of financial results, the status of cross-shareholdings, the progress of development products, and the trends of Opdivo, have already been posted on our website, so please refer to them.

First, Mr. Ito, Division Director of the Business Management Division, will give an overview of the financial results.

Ito: First, I would like to explain the results of H1 of the fiscal year ending March 31, 2024.



Now, let me explain our business performance.

As you have already seen, sales revenue increased JPY42 billion, or 19.4%, YoY to JPY258.7 billion in Q2 of the current fiscal year.

Sales of products such as Opdivo for intravenous infusion and Forxiga tablets increased by JPY15 billion, or 10.3%, YoY to JPY159.9 billion.

Royalties and others increased by JPY27 billion, or 37.6%, YoY to JPY98.8 billion.

This is a breakdown of royalties. Royalties from BMS on Opdivo rose 12.6%, or JPY5.3 billion, to JPY47.4 billion, and royalties from Merck on sales of Keytruda rose 19.6%, or JPY4.2 billion, to JPY25.6 billion. Other sales include a JPY17 billion upfront payment from the settlement of a patent-related lawsuit with AstraZeneca, and other sales of JPY8.8 billion include royalties from Roche, profit sharing from the sales of Yervoy, and co-promotion fee for Orencia IV.

Revenue

Sales of Major Products

(Billion yen)

	FY 2022 Q2	FY 2023 Q2	YoY Change
Opdivo	69.9	75.0	+7.3%
Forxiga	26.4	35.9	+36.1%
Orencia SC	12.5	13.0	+4.5%
Glactiv	11.7	10.8	-7.5%
Velexbru	4.1	5.0	+22.0%
Kyprolis	4.4	4.6	+3.9%
Parsabiv	4.3	4.1	-2.9%
Ongentys	2.4	3.1	+27.9%
Onoact	2.1	2.1	-3.5%
Braftovi	1.6	1.7	+5.5%
Mektovi	1.3	1.3	+4.1%

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The following is a brief overview of the status of our main products.

Except for Forxiga tablets, which continues to outperform the plan, sales of Opdivo and other products have been favorable as planned at the beginning of the fiscal year.

Sales of Opdivo increased JPY5.1 billion, or 7.3%, to JPY75 billion from the same period of the previous year, due to the growing prescriptions of Opdivo in gastric cancer, esophageal cancer, and urothelial cancer, despite intensifying competition from other competing products.

Sales of Forxiga tablets increased JPY9.5 billion, or 36.1%, from the same period of the previous year to JPY35.9 billion, due to steady sales increase in the diabetes field and expanded prescriptions in chronic heart failure and chronic kidney disease.

As for other products, the antineoplastic agent Velexbru Tablets and the Parkinson's disease treatment Ongentys Tablets contributed to sales growth, while the type 2 diabetes treatment Glactiv Tablets, the secondary hyperparathyroidism treatment Parsabiv Intravenous Injection for intravenous dialysis, and Onoact for Intravenous Infusion experienced a slight sales decline.

Operating Profit

Operating Profit	YoY Change
¥ 97.0 billion	+ 20.9 %

Costs, etc.

(Billion yen)

	FY 2023 Q2	YoY Change	
Cost of Sales	64.8	+20.6%	
R&D Expenses	49.4	+24.6%	①
SG&A Expenses	47.6	+10.8%	②
① + ② Total	97.0	+17.4%	
Other Income	0.9	+95.8%	
Other Expenses	0.8	+39.8%	

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Next is operating profit.

Operating profit increased JPY16.8 billion, or 20.9% YoY to JPY97 billion.

And now for costs. Cost of sales increased 20.6%, or JPY11.1 billion, to JPY64.8 billion, due to an increase in product sales and a JPY5.4 billion impairment loss on sales rights related to the osteoarthritis treatment Joyclu Intra-articular Injection and the cancer cachexia treatment Adlumiz Tablets. The cost of sales ratio was 25.0%, up 0.2 percentage points from the same period of the previous year.

R&D expenses increased by JPY9.7 billion, or 24.6%, YoY to JPY49.4 billion, due to an increase in research-related expenses, expenses related to drug discovery alliances, and development expenses related to clinical trials, as well as joint development expenses for in-licensing and other activities. Progress toward the full-year management plan of JPY109 billion at the beginning of the fiscal year is approximately 45%.

SG&A expenses, excluding R&D expenses, increased 10.8%, or JPY4.7 billion, YoY to JPY47.6 billion, mainly due to co-promotion fee for sales expansion of Forxiga tablets, etc. and costs associated with IT digital-related information infrastructure enhancement efforts.

Other income totaled JPY0.9 billion and other expenses totaled JPY0.8 billion, resulting in operating profit of JPY97 billion, up JPY16.8 billion, or 20.9%, YoY.

Profit before Tax

Profit before Tax	YoY Change
¥ 99.3 billion	+ 22.6 %

Net financial income, etc.

+ ¥ 2.3 billion	(YoY Change + ¥ 1.5 Billion)
Finance income :	¥ 2.3 billion
(Dividend income received, Exchange gain, etc.)	
Finance costs :	¥ 0.1 billion
(Interest expenses, etc.)	

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Profit before taxes increased JPY18.3 billion, or 22.6% YoY to JPY99.3 billion, as the financial account balance increased JPY1.5 billion, or about 3 times, to JPY2.3 billion.

Profit for the Period (Owners of the Company)

Profit for the Period (Owners of the Company)	YoY Change
¥ 74.5 billion	+ 19.5 %

Income tax expense

¥ 24.8 billion	(YoY Change + 33.4 %)
(Major change factors)	
Increase in profit before tax	¥ 18.3 billion
Increase in corporate tax	¥ 6.2 billion

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Quarterly net income attributable to owners of the parent increased JPY12.2 billion, or 19.5% YoY to JPY74.5 billion, due to an increase in profit before taxes.

The results from the interim period have continued to be a record high.

Financial Forecast for FY 2023

Financial forecast is changed from that announced on May 10, 2023

(Billion yen)

	FY 2022 (Result)	FY 2023 (Previous Forecast)	FY 2023 (Revised Forecast)	YoY Change
Revenue	447.2	**475.0**	**500.0**	**+ 11.8 %**
Operating profit	142.0	**153.0**	**167.0**	**+ 17.6 %**
Profit before tax	143.5	**154.0**	**169.0**	**+ 17.7 %**
Profit for the year (Owners of the Company)	112.7	**115.0**	**126.0**	**+ 11.8 %**

Exchange rate
FY 2023 (Previous Forecast): 1USD = 130 yen
FY 2023 (Revised Forecast (2nd Half)): 1USD = 140 yen

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We have revised our full-year forecast for this fiscal year during this Q2 period.

The sales forecast for Forxiga tablets has been revised to take into account the lump sum payment received in Q2 as a result of the settlement of a patent-related litigation with AstraZeneca. As you can see, this is our consolidated earnings forecast for the full year.

The assumed exchange rate, which was set at JPY130 at the beginning of the fiscal year, has been revised to JPY140 from H2 of the fiscal year.

Let me explain each item.

Revenue (Forecast)

Revenue	YoY Change
¥ 500.0 billion	+ 11.8 %

Breakdown of Revenue

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Revenue of Goods and Products	295.0	315.0	+ 6.8%
Royalty & other revenue	152.1	185.0	+ 21.6%
Total	447.2	**500.0**	**+ 11.8%**

8/13

First, let us look at revenue.

As mentioned at the beginning of this report, we recorded JPY17 billion in one-time income from the settlement of patent-related litigation with AstraZeneca and revised our sales forecast for Forxiga tablets. This is an upward revision of JPY25 billion, or 5.3%, from the previously announced forecast. The forecast is JPY500 billion. This represents an increase of JPY52.8 billion, or 11.8%, YoY.

This is the breakdown. Forxiga's sales forecast, previously estimated at JPY65 billion, has been revised upward by JPY5 billion to JPY70 billion. Revenue of products have been revised from JPY310 billion to JPY315 billion to reflect this change.

In addition, we have revised our overall royalties and others forecast from JPY165 billion to JPY185 billion, reflecting the rump sum payment received from the settlement of the patent-related litigation with AstraZeneca.

Revenue (Forecast)

Sales Forecasts of Major Products

(Billion yen)

	FY 2022 (Result)	FY 2023 (Forecast)	YoY Change
Opdivo	142.3	155.0	+8.9%
Forxiga	56.5	70.0	+23.8%
Orencia SC	24.8	25.5	+3.0%
Glactiv	22.5	21.0	-6.7%
Velexbru	8.5	9.5	+11.3%
Kyprolis	8.7	8.5	-2.3%
Parsabiv	8.4	8.0	-4.8%
Ongentys	5.0	6.5	+30.5%
Onoact	4.5	4.5	+0.4%
Braftovi	3.2	4.0	+23.2%
Mektovi	2.5	3.0	+18.1%

※The sales revenue forecast of Forxiga Tablets was revised from 65 billion yen to 70 billion yen.

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With regard to individual products, as you can see, there are products that are trending up, products that are trending slightly down, etc. Only Forxiga tablets have been revised forecast upward.

Operating Profit (Forecast)

Operating Profit	YoY Change
¥ 167.0 billion	+ 17.6 %

Costs, etc.

(Billion yen)

	FY 2023 (Forecast)	YoY Change	
Cost of Sales	122.0	+ 10.8%	
R&D Expenses	109.0	+ 14.3%	①
SG&A Expenses	98.0	+ 9.5%	②
① + ② Total	207.0	+ 12.0%	
Other Income	1.0	+ 36.3%	
Other Expenses	5.0	- 54.8%	

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Next is operating profit.

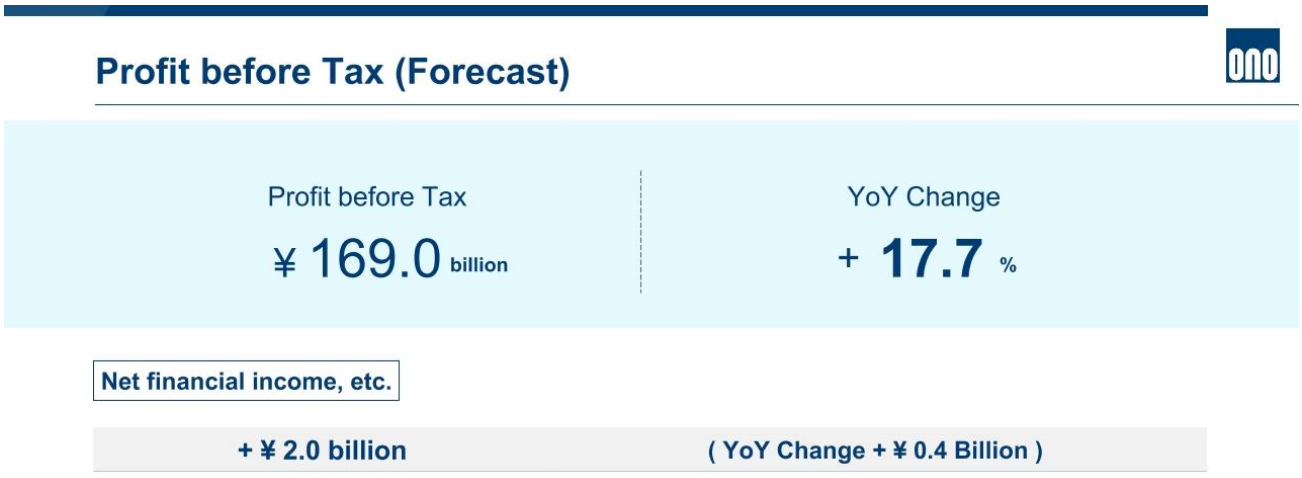
Operating profit was JPY153 billion in the previous forecast but has been revised upward by JPY14 billion, or 9.2%, to JPY167 billion. The increase is JPY25 billion, or 17.6%, YoY.

Cost of sales increased due to the revision of the product sales forecast, and the impairment loss of JPY5.4 billion on sales rights for Joyclu intra-articular injection and Adlumiz tablets, as mentioned in H1 of the fiscal year. The cost of sales is expected to increase JPY9 billion from the previous forecast of JPY113 billion to JPY122 billion, an increase of 1JPY1.9 billion, or 10.8%, YoY.

R&D expenses, annual forecast of JPY109 billion, remain unchanged.

SG&A expenses, excluding R&D expenses, are expected to increase by JPY2 billion from the previous forecast of JPY96 billion to JPY98 billion, an increase of JPY8.5 billion, or 9.5%, YoY, due to an increase in co-promotion fees in line with sales expansion of Forxiga tablets and expenses associated with strengthening information infrastructure related to digital IT.

In addition, we expect other income of JPY1 billion and other expenses of JPY5 billion.



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Profit before tax.

Profit before tax has been revised upward by JPY15 billion, or 9.7%, from the previously announced forecast of JPY154 billion to JPY169 billion. Compared to the previous year, this represents an increase of JPY25.5 billion, or 17.7%.

The financial account balance is expected to increase JPY0.4 billion YoY to JPY2 billion.

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

Profit for the Year (Owners of the Company)	YoY Change
¥ 126.0 billion	+ 11.8 %

Income tax expense

¥ 42.8 billion	(YoY Change + 39.8 %)
(Major change factors)	
Increase in profit before tax	¥ 25.5 billion
Increase in corporate tax	¥ 12.2 billion

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Net income attributable to owners of the parent has been revised to JPY126 billion, up JPY11 billion, or 9.6%, from the previously announced forecast of JPY115 billion. Compared to the previous year, this represents an increase of JPY13.3 billion, or 11.8%.

Income tax expenses is expected to increase JPY12.1 billion, or 39.8%, YoY to JPY42.8 billion.

The annual dividend forecast for FY2023 remains unchanged at JPY80 per share of common stock.

This is all about the business results for the current term and the revision of the full-year business forecast.

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

➢ **Reduction plan**

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

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

➢ **Medium-to long-term plan**

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

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I would like to continue by explaining the status of reduction plan of cross-shareholdings to date.

At the November 2021 financial results meeting 2 years ago, we announced a plan to reduce our reduction plan of cross-shareholdings.

I would like to talk about three things about the reduction plan. First, we have announced that we will reduce the amount by 30% from the JPY141.8 billion based on the market value as of the end of September 2021 by the end of March 2025, over a period of three and a half years from October 2021.

In addition, by the end of March 31, 2022, the ratio of cross-shareholdings to net assets must be reduced to less than 20%, which ultimately stands at 17.2%.

In the medium to long term, we aim to achieve a ratio of cross-shareholdings in the balance sheet of less than 10% of net assets.

Status of reduction of Cross-shareholdings

	End of September 2021	End of September 2023	Reduction*	Reduction rate
Market price at the end of September 2021	**¥ 141.8 bil**	**¥ 110.3 bil**	**¥ 31.5 bil**	**22.2%**

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of September 2023	Reduction	Reduction rate
Balance sheet accounting amount	**¥ 141.8 bil**	**¥ 114.3 bil**	**¥ 27.5 bil**	**19.4%**

※End of September 2023
Ratio of Cross-shareholdings to net assets：14.6%

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As of the end of September 2023, we have achieved a reduction of JPY31.5 billion in the market value base as of the end of September 2021, for a reduction rate of 22.2%, which is on track to meet the planned 30% reduction rate.

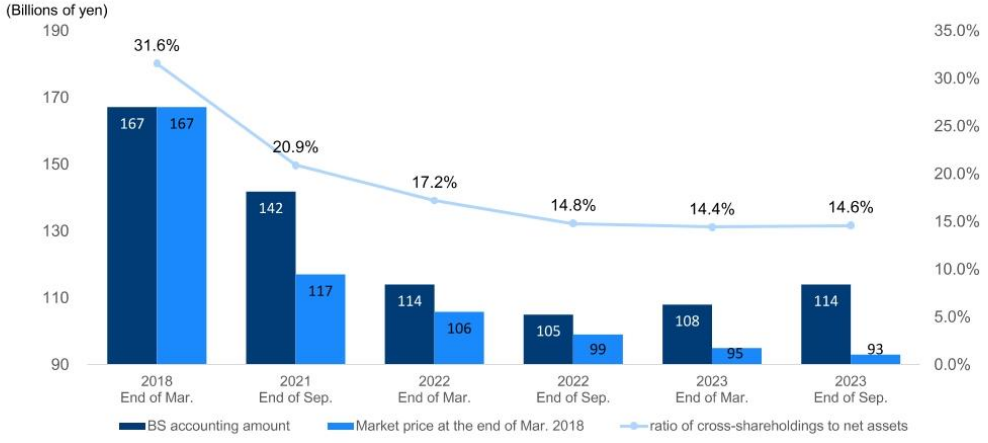
On the basis of the balance sheet amount as of the end of September 2023, the balance sheet amount was reduced by JPY27.5 billion, or 19.4% of the total.

Status of reduction of Cross-shareholdings

➢ **Reduction plan**

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

➢ **Changes of reduction**



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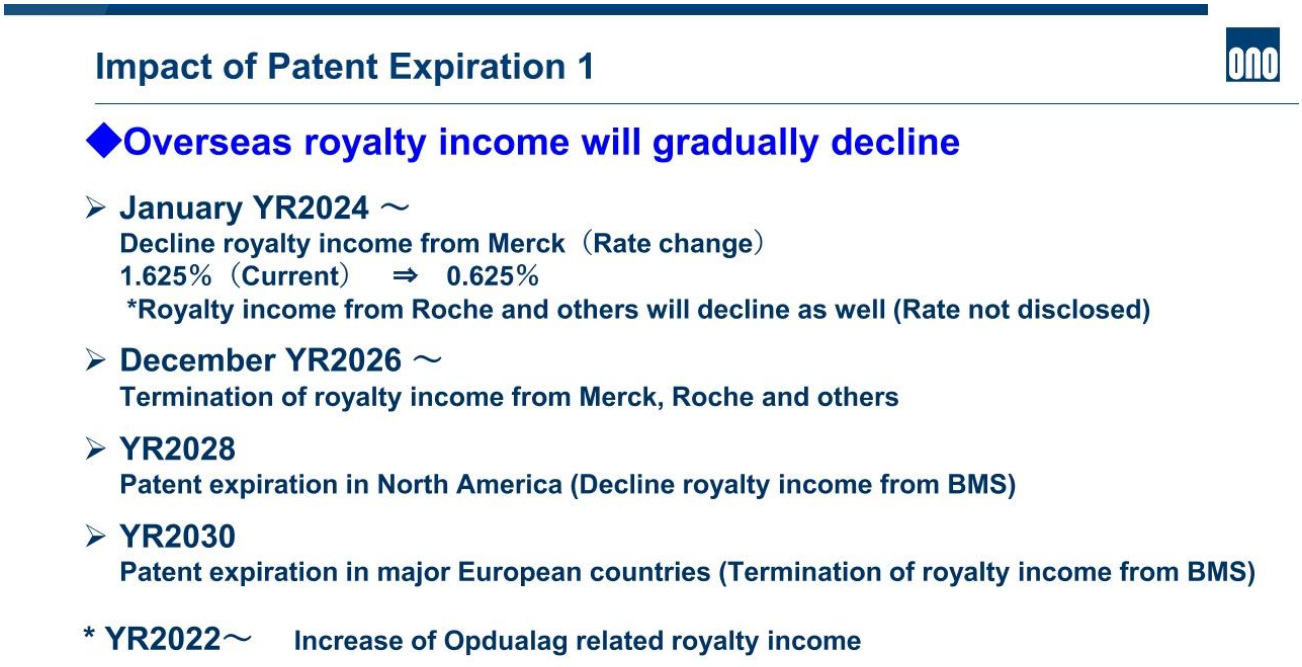
The ratio of cross-shareholdings to consolidated net assets has been steadily increasing from 20.9% at the end of September 2021 to 14.6% despite the rise in the Nikkei Stock Average and other factors.

This is the status of reduction of cross-shareholdings.

Imura: Mr. Sagara, President, will now explain our future growth strategy.

Sagara: Thank you for joining us today out of your busy schedule. As you are already aware, the Opdivo patent will expire in 2028, starting in the US. I would like to talk about our basic policy today, such as how it will impact on our business performance, how we plan to cover and overcome this issue, and grow further.

First, I will explain the impact of Opdivo's patent expiration on our business performance. Then, I will explain that we will overcome the problem by developing own sales system in the US and Europe. I will also explain what kind of candidate products are available for this purpose. The fourth is to introduce the status of joint research and other activities being conducted by the research division to generate new drug candidates.



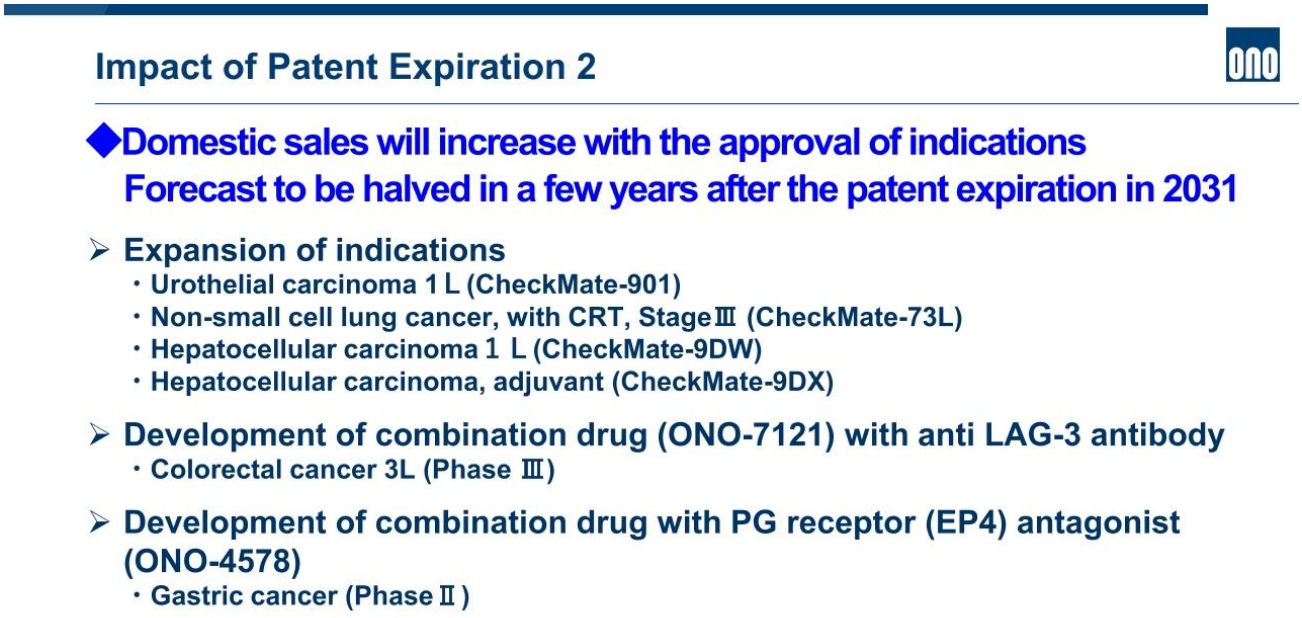
Royalties will decrease first, and then domestic sales will decrease.

First of all, regarding the decrease in royalties, it will be as you are almost all already aware. In 2026, royalties from Merck and Roche will cease. The rate will decrease from 2024 and end in 2026, which means that after 2027, the only royalties will be from BMS.

And since the patent expires in North America in 2028, royalties from North American sales will end in 2028 and go to zero starting in 2029.

Then in 2030, the patents will expire in European countries, so the last year of receiving royalties is 2030, and all royalties will cease in 2031. Royalties currently received from BMS, Merck, and Roche will be zero in FY2031. That means that it will be gone 8 years from now.

In terms of the monetary amount, the current royalties of JPY150 to 160 billion from the three companies will be zero.



This is written mainly for domestic sales, but since the Japanese patent will expire in 2031, domestic sales will start to decline in stages from 2032 with the arrival of biosimilars.

Until then, until 2030, we still expect to expand the range of indications, such as urothelial carcinoma, combined chemoradiotherapy for lung cancer, first line hepatocellular carcinoma, and postoperative adjuvant therapy. Also, we are developing a combination drug with anti-LAG-3 antibody. We are also developing combination therapy with ONO-4578, etc.

Our sales forecast for this year is JPY155 billion, but we believe that this is not the peak and that there is room for further expansion. It is a little difficult to say when the peak will be, but it is expected to continue to increase until 2031.

As for the subsequent decrease, looking at the current decrease in the sales of antibody drugs for which biosimilars have been introduced, I think it will take 3 to 4 years, or even 4 to 5 years, for the decrease to be reduced to about half. I am not sure if that will be the case in 10 years, but that is the image I have at this stage.

This is a rough image of what we are forecasting, but the dark blue color at the bottom represents domestic sales, and the light blue color represents royalties. Beginning in FY2027, only royalties from BMS will be available. So, royalties from Merck, Roche, etc., will be gone. The US patent will expire in 2028, so from 2029 there will be only European royalties. As I explained earlier, the European patents will expire in FY2030.

Assuming that the domestic sales are JPY150 billion now, I am not sure what sales will be at the peak, but I roughly estimate that sales will be between JPY200 billion and 150 billion. The patent expires in FY2031, and sales will be reduced beginning in FY2032.

We are also developing a combination drug with anti-LAG-3 and a subcutaneous injection, so we will launch them on the market at some point. That will contribute a little to Opdivo sales, and new royalties will come in from the combination drug with anti-LAG-3 and the subcutaneous injection, which are selling well overseas, so I guess that will replace the current royalties from intravenous injection. There are some overlapping periods of time, but that is what is coming in.

Roughly speaking, if we assume that current domestic sales are JPY150 billion and royalties are JPY150 billion, and a total of JPY300 billion, we are now looking at a loss of JPY200 billion, which means that in 12 years, it will be around JPY100 billion.

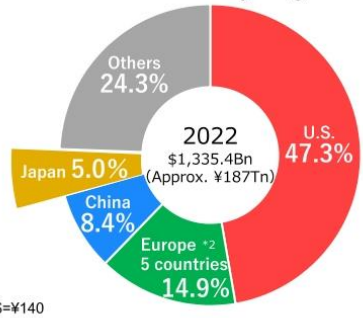
Growth strategy through direct sales in the U.S. and Europe

Comparison of sales composition with other pharma
(FY2022 : Billion yen)

	Domestic sales	Overseas sales	Total
Company A	2,848	12,338	15,186
Company B	2,503	4,941	7,444
ONO	**2,882**	**1,590**	**4,472**

* Based on each financial announcement materials

Sales Share by Region *1



*1. $=¥140
*2. Germany, France, UK, Italy, Spain

- **Approximately 50% of pharmaceutical market sales in FY2022 were in the U.S. (Approx.5% in Japan)**
- **ONO will overcome Opdivo patent expiration toward further growth by launching multiple products in the U.S. and Europe with large markets**

*1.Calculated in-house based on「IQVIA Analytics Link（2022）」

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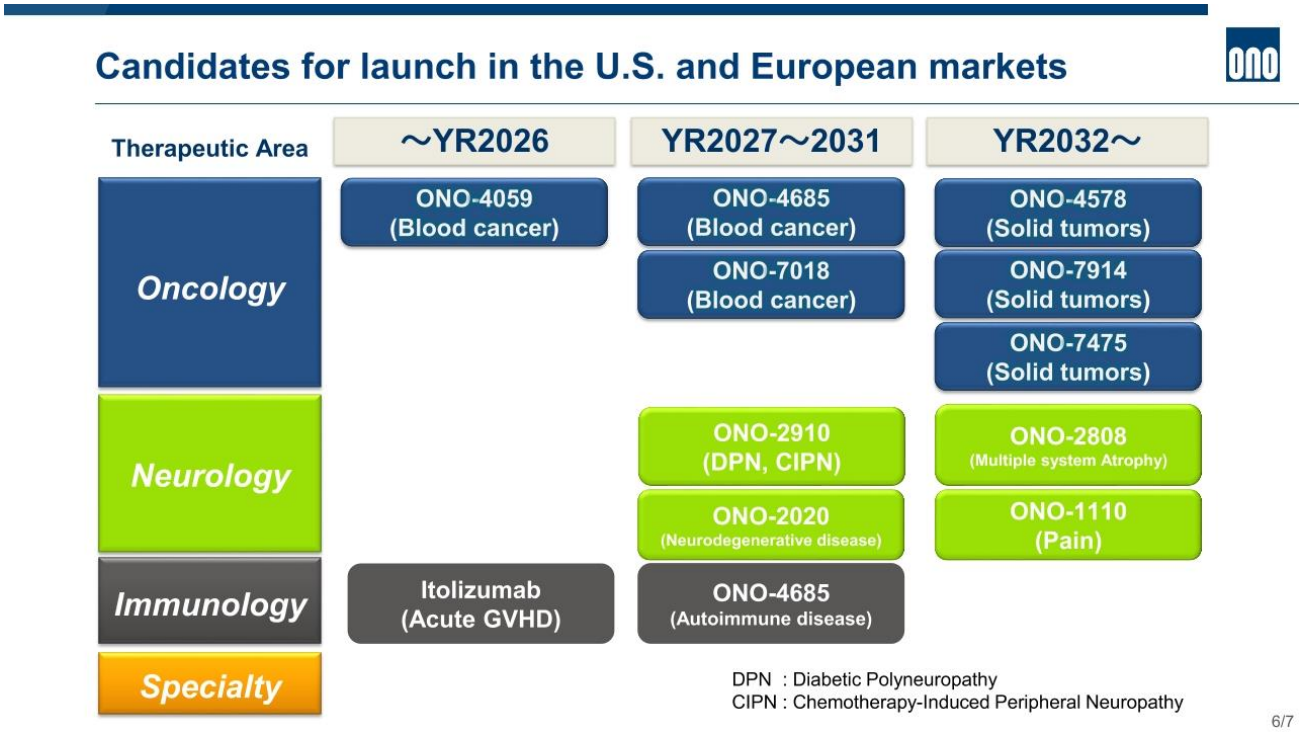
The pie chart on the right shows Japan's sales share of the global market, which is now 5%. There was a time when it was 17 to 18%, but it is now down to 5%. This is the only place ONO has been competing. We have been out-licensed in the other regions.

As you can see in the table, these are domestic manufacturers. Company A, Company B, and our company currently have about the same level of domestic sales, but Company A's overseas sales are JPY1.2 trillion and Company B's are JPY500 billion. ONO sees room for growth here, as our JPY150 billion almost comes all from royalties.

This is a completely unreliable estimate, but Opdivo is now selling JPY1.1 trillion overseas. In reality, this was not possible, but if ONO had handled global sales in-house when development began in 2007 or 2008, Opdivo's overseas sales would have been JPY1.1 trillion, for a total of JPY1.4 trillion.

To develop Opdivo, BMS had spent over JPY1 trillion on clinical trials alone. And the reality was that ONO had never done cancer, never had it approved overseas, never marketed it, and could not have done it very well on our own. If Opdivo were new to ONO right now, it would be difficult to do, but looking at the compounds in ONO's pipeline right now, there are many compounds that are being introduced into niche markets to start, so I think we may be able to handle that.

For example, Velexbru, is already at a pace of JPY10 billion sales per year in Japan. If we could sell JPY10 billion in 5% of the market, we would sell JPY200 billion globally, but it would never work out that way, so we decided to do it right only in the US and Europe. It will be 13 times as much, but as a practical matter, we are looking at the possibility that if things go well, we can expect about 10 times as much, and Japan's could be considered, so maybe we can expect tens of billions of yen, or 5 to 6 times, 5 to 10 times, and I think we have no choice but to expand there.



This is the current pipeline, phase 1 and beyond.

We are hoping to launch Velexbru, which is expected to be on the market by 2026, ONO-4059, and in-licensed itolizumab.

Velexbru also sees that launching in the US can be covered by about 20 medical representatives. There is a concentration of patients in about 100 facilities, and if there are 20 medical representatives, each of them can be in charge of about 5 facilities. It seems like a possibility, and we can start if in a niche market.

It is time to make a decision on whether we get the marketing rights for Itolizumab in the near future, but this could be launched by around 2026. We are presenting compounds that we expect to be on the market by 2031, or even later. We are still at the stage where we will not know how many of these products we can successfully launch until we try them, so we would like to make every effort to launch one or two products globally.

At the same time, this alone is not reassuring, and there are many compounds for which evidence has not yet been established, so we would like to move forward by steadily acquiring in-licensed product candidates as well.

If one product sells, let's say, JPY100 billion globally, two or three products would cover the negative impact on Opdivo's performance that I mentioned earlier, and if we can generate additional sales, we can grow further.

If we were to lose JPY200 billion all at once, it would be extremely difficult to do anything about it, but if we were to lose JPY200 billion over the next 12 years, there is a possibility that we can grow to compensate for it.

We believe that the next step is to see if we can really launch these developed drug candidates and plus more.

Promoting Open Innovation

Research collaborations and discovery partnerships with world-leading researchers and biopharma in the U.S. and Europe

Acquisition original drug discovery seeds
Discovery of new drug candidates

Research collaborations

Area	Number
Domestic	195
Overseas	167
Total	362

Number of drug discovery collaborations

YR2020	YR2021	**YR2022**
1	4	**11**

Initiated 110 research collaborations and 11 drug discovery collaborations in 2022

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This is the work we are currently doing in the research department called Open Innovation.

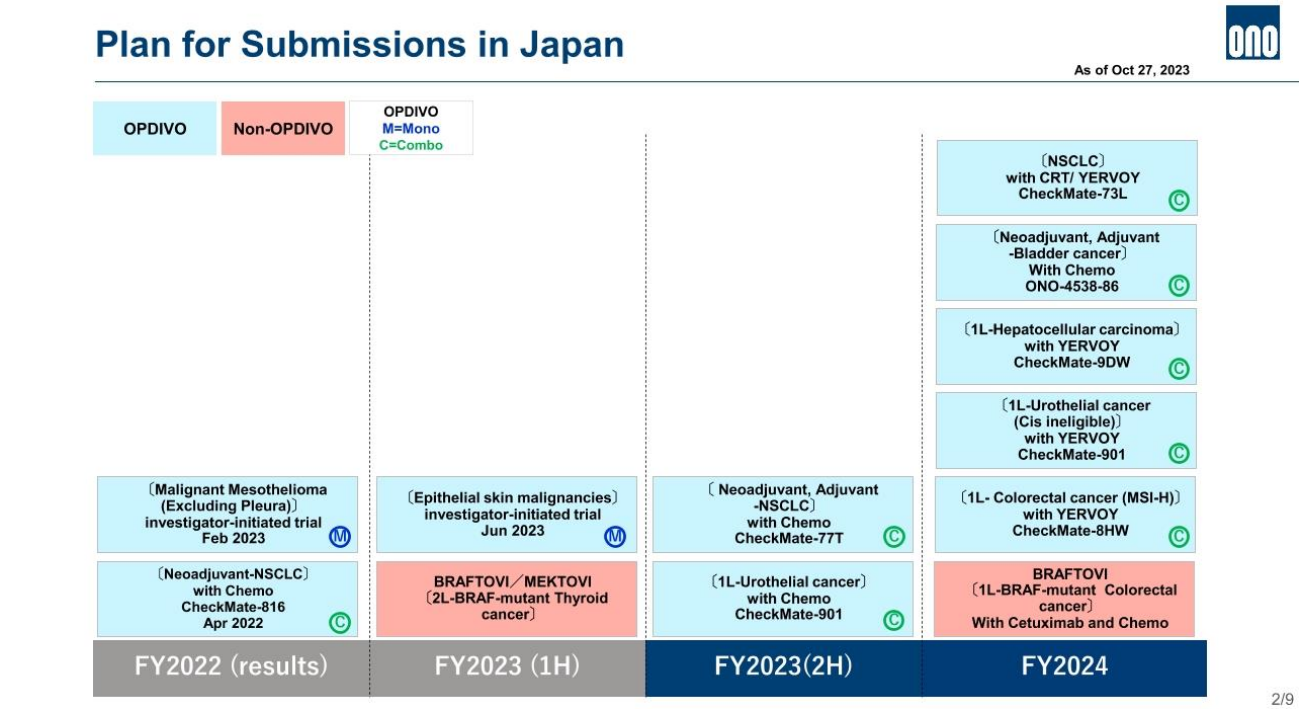
The one on the right is called drug discovery alliances, which is already the final stage in the research division, and this number has increased to 11 in 2022. We are adding one case, then four, then eleven, and so on.

On the left, we are conducting about 200 domestic and 160 overseas joint research projects including the early-stage ones, ranging from large to small projects. Most of the time we fail, but I hope that we can generate one, two, or three from here.

I explained the basic measures, or policy for future growth. That's all.

Imura: Next, Mr. Okamoto, Deputy Executive Director, Clinical Development, will explain the progress of development of drug candidates.

Okamoto: I will use this tabular document, which is available on our website, to explain the changes and updates since July 31st.



First of all, we have shown the schedule for future applications in Japan.

For H1 of FY2023, there were no changes from the previous presentation.

In H2 of FY2023, the current fiscal term, as you know, we have already achieved the primary endpoints for the adjuvant chemotherapy combination for non-small cell lung cancer and the first line chemotherapy combination for urothelial carcinoma, both of which are in combination with chemotherapy. We are currently preparing for application for approval. As planned, the Company plans to apply for approval in H2 of the current fiscal year.

On the other hand, the top two studies in FY2024, the CheckMate-73L study for patients with non-small cell lung cancer who are eligible for chemoradiation therapy, and the 4538-86 study for preoperative and postoperative adjuvant for bladder cancer, will be delayed in the timing of obtaining the results. As a result, the schedule for the application has been changed from H2 of FY2023 to FY2024.

As you are aware, the CheckMate-914 study, which was being conducted for the adjuvant treatment of renal cell carcinoma, unfortunately did not show the expected efficacy, and has been removed from our plans for application.

As for the application schedule for FY2024, the ENHANCE2 study, a global phase 3 study led by Gilead for patients with TP53 mutation-positive acute myeloid leukemia (AML), was already announced, but unfortunately the efficacy of the study was not confirmed, and Gilead has decided to terminate the study. Therefore, we have removed it from our application schedule.

This was the explanation of the schedule for domestic applications.

Development status of OPDIVO (1)

As of Oct 27, 2023

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

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)　※Red: Update after May 2023　※Red: Update after 1Q 2023

3/9

I will now explain the main development status of Opdivo.

First of all, on the bottom left, we have an anti-LAG-3 antibody, coded ONO-4482. This is a so-called combination drug that combines this and Opdivo in the same vial, coded ONO-7121. We have also decided to include this in the development status of the project.

Please note that changes and updates since this year's closing are indicated in red, and changes and updates since July 31 are highlighted in yellow.

There are no changes to this page.

Development status of OPDIVO (2)

As of Oct 27, 2023

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

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)　★★ 2nd line　※Red: Update after May 2023　※Red: Update after 1Q 2023

4/9

The second one from the bottom is for colorectal cancer, and we have added a note about ONO-7121, the anti-LAG-3 antibody combination drug that I mentioned earlier, because we are conducting a global phase 3 study for the third-line treatment or later stage of colorectal cancer.

On the other hand, we had conducted a global Phase 2/3 study of Opdivo in combination with standard therapy for first-line colorectal cancer, but unfortunately, we could not confirm the efficacy to advance from Phase 2 to Phase 3, so the study was removed from the table.

This is all for my explanation of this page.

Development status of OPDIVO (3)

As of Oct 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		with Ipi/TKI	–	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with 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	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Filed	–	–	–	–
Dosage and Administration	240 mg（every 2 weeks）		Approved	Approved	Approved	Approved	Approved
	360 mg（every 3 weeks）		Approved	Approved	Approved	Approved	Approved
	480 mg（every 4 weeks）		Approved	Approved	Approved	Approved	Approved

※Red: Update after May 2023 ※Red: Update after 1Q 2023

5/9

I mentioned earlier in terms of the application regarding renal cell carcinoma, top of the list. This study has been removed due to the failure and lack of efficacy in the CheckMate-914 trial, which was conducted as an adjuvant treatment for renal cell carcinoma.

This is all for the status of Opdivo development and the planned application for approval.

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

As of Oct 27, 2023

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

※Red: Update after May 2023 ※Red: Update after 1Q 2023

6/9

I will now explain the main developments in the combination of Opdivo and cancer immunizing compounds.

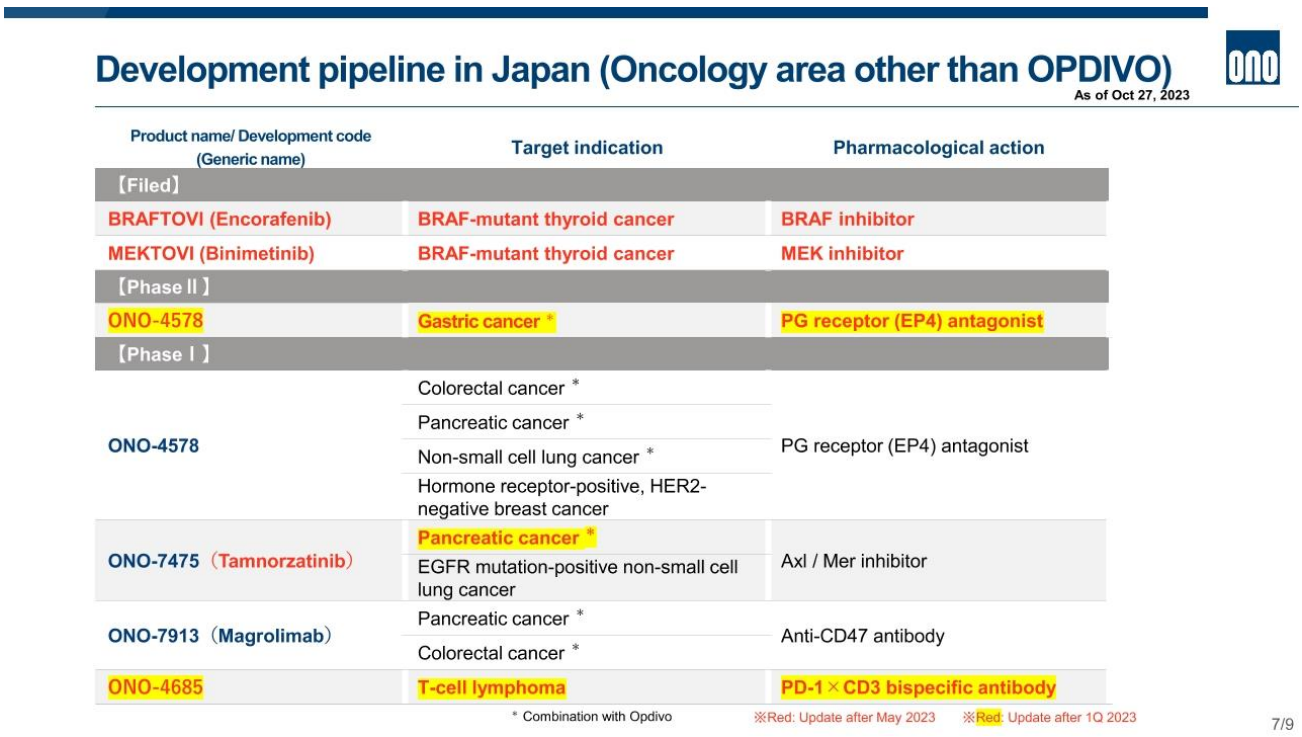
I am afraid it is a bit complicated, but at the top, this is ONO-4482, a vial formulation containing only relatlimab, an anti-LAG-3 antibody, and we are conducting a global phase 2 study in hepatocellular carcinoma in combination with Opdivo, so we have added this information.

Next, ONO-4578 is a drug that has an antagonistic effect on EP4, which is one of the prostaglandin receptors. Based on the results of the Phase 1 trial, we have decided to move up the stage. We have added a note that we have initiated a global phase 2 study for the first-line treatment of gastric cancer in combination with standard therapy and Opdivo.

Below that, ONO-7475, this is an Axl/Mer inhibitor. We have added a note that, based on the results of the Phase 1 trial, which was also conducted in Japan, we are conducting a Phase 1 trial in Japan in which it is used in combination with Opdivo as the standard treatment for first-line treatment of pancreatic cancer.

The development of ONO-4686, an anti-TIGIT antibody, has been removed from the table. We had participated from Japan in the global Phase 1/2 study led by BMS, but the development has been terminated for strategic reasons.

The above is the main development status of Opdivo in combination with I-O compounds.



Development pipeline in Japan (Oncology area other than OPDIVO)

As of Oct 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 II】		
ONO-4578	Gastric cancer *	PG receptor (EP4) antagonist
【Phase I】		
ONO-4578	Colorectal cancer *	PG receptor (EP4) antagonist
	Pancreatic cancer *	
	Non-small cell lung cancer *	
	Hormone receptor-positive, HER2-negative breast cancer	
ONO-7475（Tamnorzatinib）	Pancreatic cancer *	Axl / Mer inhibitor
	EGFR mutation-positive non-small cell lung cancer	
ONO-7913（Magrolimab）	Pancreatic cancer *	Anti-CD47 antibody
	Colorectal cancer *	
ONO-4685	T-cell lymphoma	PD-1 × CD3 bispecific antibody

* Combination with Opdivo ※Red: Update after May 2023 ※Red: Update after 1Q 2023

7/9

This page summarizes the development status of oncology drugs other than Opdivo in Japan.

The highlighted ONO-4578 and ONO-7475 for pancreatic cancer are as I mentioned earlier.

On the other hand, there is ONO-7913. Previously, the MDS (Myelodysplastic Syndrome) was listed here, but due to the results of the global Phase 3 ENHANCE trial being conducted by Gilead and the discontinuation of that trial, the MDS was removed from this list.

The bottom is ONO-4685. This is a bispecific antibody against PD-1 and CD3, and a Phase 1 study for T-cell lymphoma was conducted in the US prior to Japan, and now a Phase 1 study for the same disease has been started in Japan. So we have added it in the table.

Development pipeline in Japan (Non-oncology)

As of Oct 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	Enhancement of Schwann cell differentiation
	Chemotherapy-Induced Peripheral Neuropathy	
【Phase Ⅰ】		
ONO-4685	Autoimmune disease	PD-1 × CD3 bispecific antibody
ONO-1110	Pain	Endocannabinoid regulation

※Red: Update after May 2023 ※Red: Update after 1Q 2023

8/9

This page shows the development pipeline in Japan other than the oncology field.

ONO-7684, an inhibitor of activated coagulation factor XI, which was previously listed here, has been removed from the table as we have discontinued its development for strategic reasons.

Global development projects (Other than OPDIVO)

As of Oct 27, 2023

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

※Red: Update after May 2023 ※Red: Update after 1Q 2023

9/9

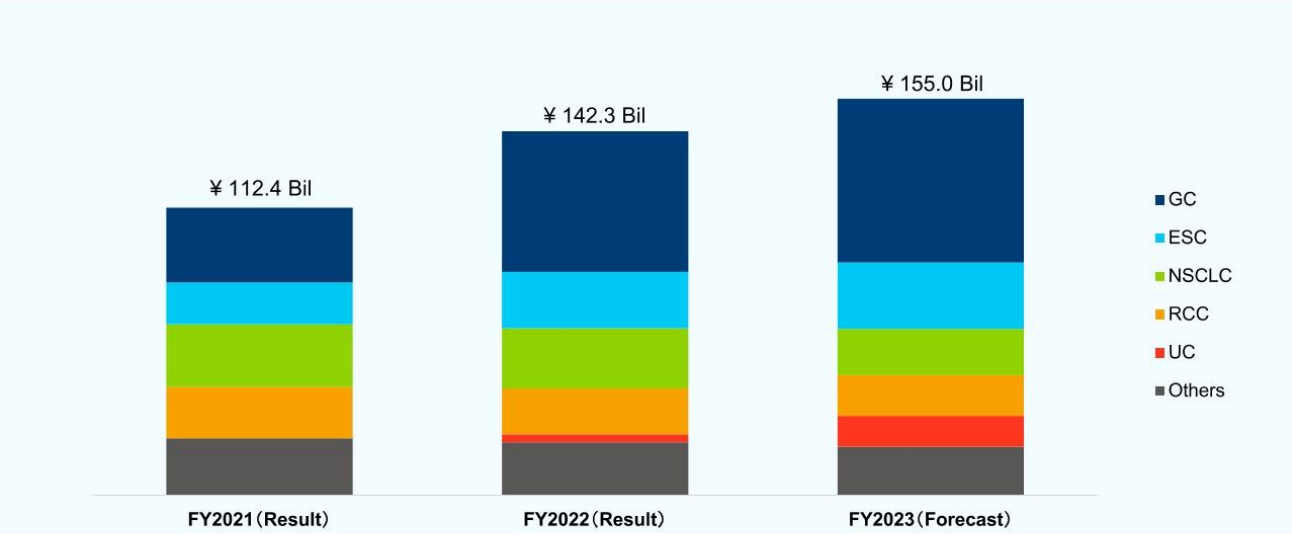
This is the last one. This section summarizes the global pipeline other than Opdivo.

As for the ONO-4578 highlighted above, as I mentioned earlier, we include Korea and Taiwan, so it is listed in the global pipeline.

Above, I have explained the progress of the developed drug candidates, focusing on changes and updates since the last time.

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

Sales Trend of Opdivo by Each Cancer



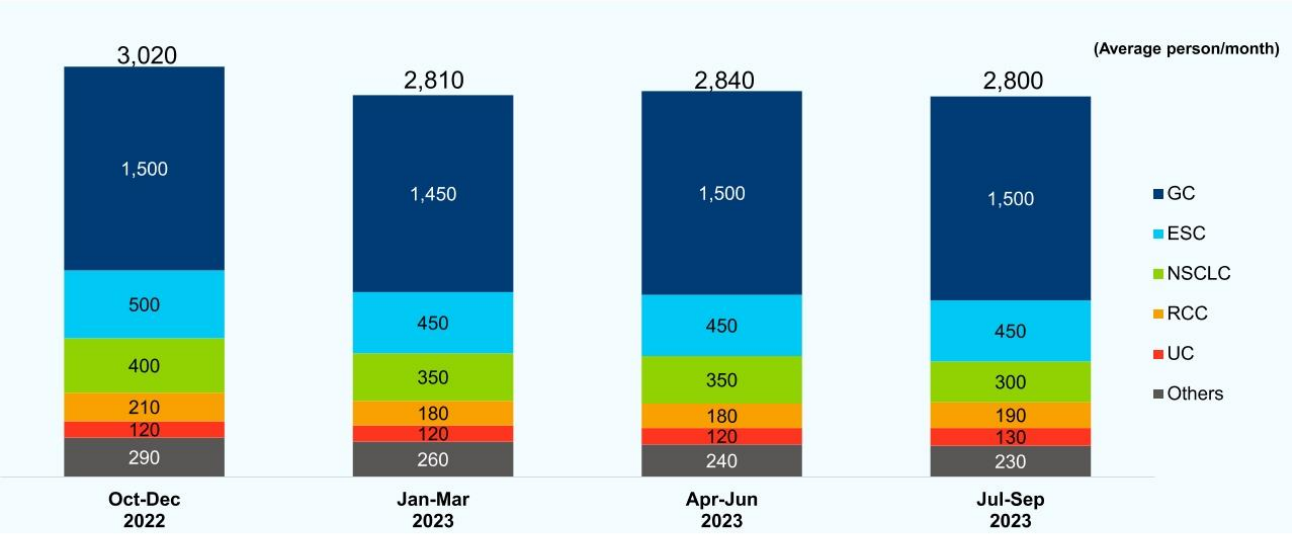
Source: Estimation from external and internal data

2/16

Takahagi: First, Opdivo sales.

From the bar graph on the left, this shows results for FY2021 and FY2022, and FY2023 forecast. For the current fiscal year, we are projecting an increase of JPY12.7 billion, or 9% YoY to JPY155 billion.

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



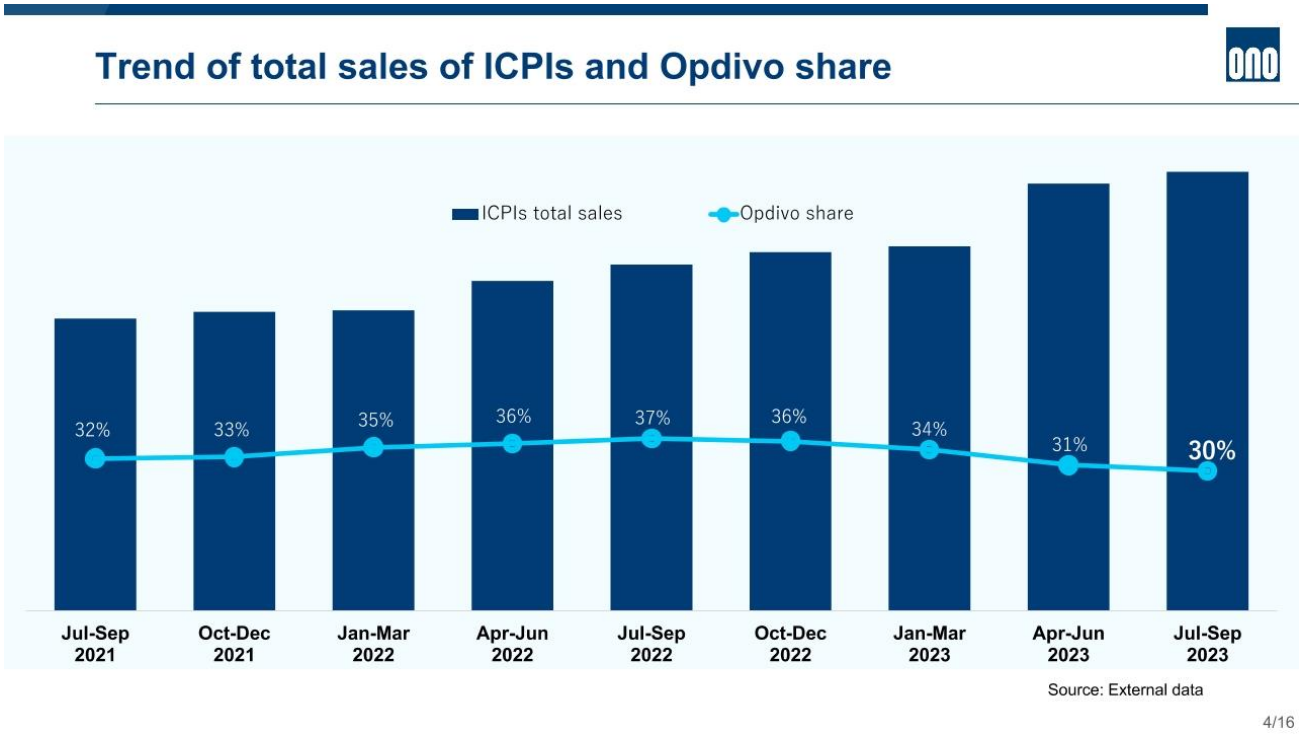
Source: Estimation from external and internal data

3/16

This chart shows the estimated number of new prescriptions of Opdivo by carcinoma.

In the bar graph on the left, we show the average number of patients per month per quarters from October to December 2022 to July to September 2023.

It is estimated that 1,500 cases of stomach cancer, 450 cases of esophageal cancer, and 300 cases of lung cancer will be newly prescribed in July to September, 2023, which is a monthly average of 2,800 new prescriptions.

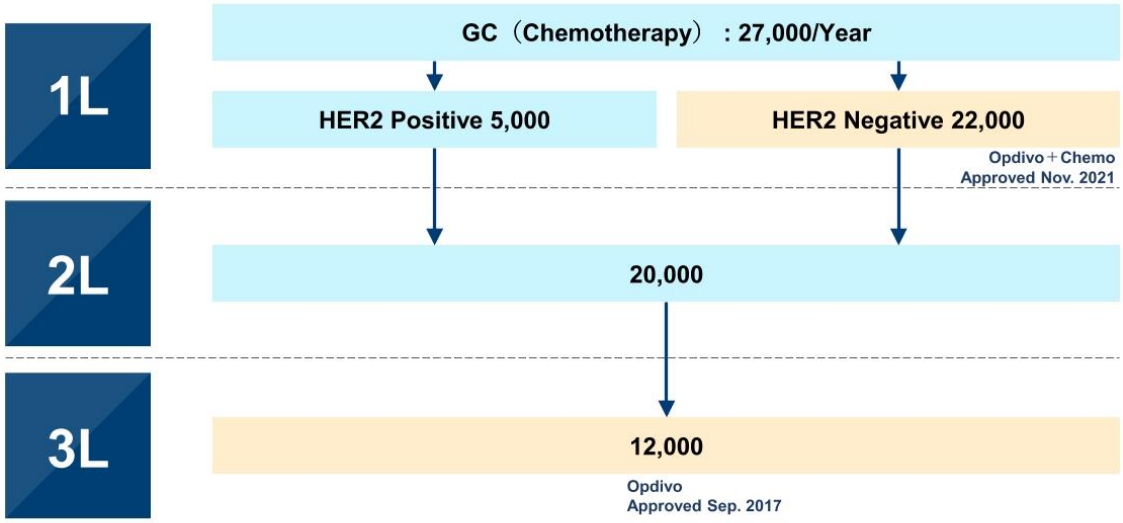


Here is trend of total sales of immune checkpoint inhibitors launched in Japan and Opdivo's market share.

The bar graph shows the total sales of immune checkpoints inhibitors, and the line graph shows the Opdivo's share. Overall sales of immune checkpoint inhibitors are increasing steadily, with Opdivo's market share of 30% in the July -September period of 2023.

Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC



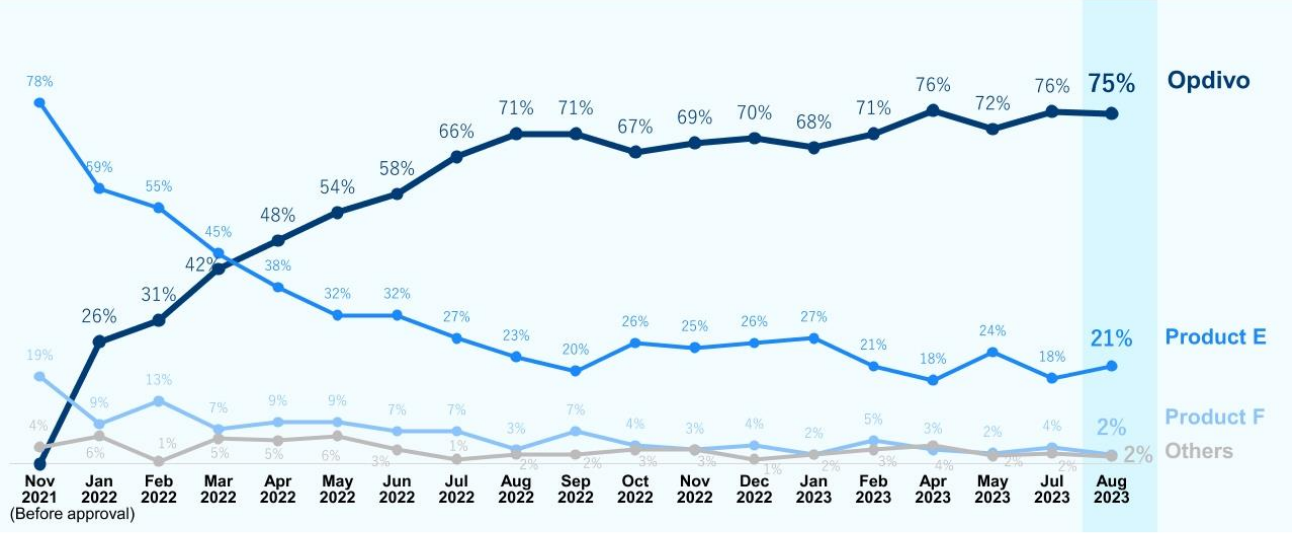
Estimation based on internal survey (2020)

5/16

From here, I will report by cancer type.

First is gastric cancer. The annual number of gastric cancer patients is 27,000, of which 22,000 are HER2-negative patients who are eligible to receive Opdivo as first-line treatment.

Prescription Ratio in Patients Newly Treated※ for 1L GC



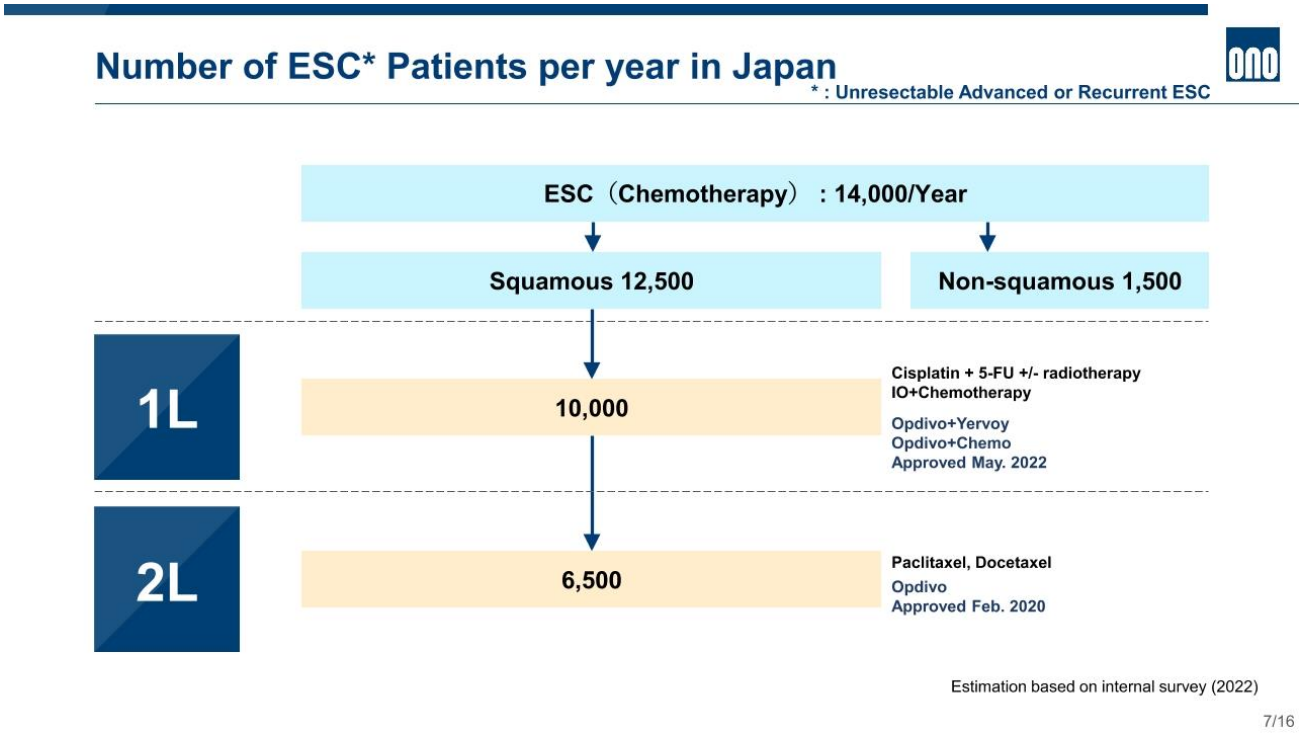
※Patients starting 1L treatment within the last 3 month

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

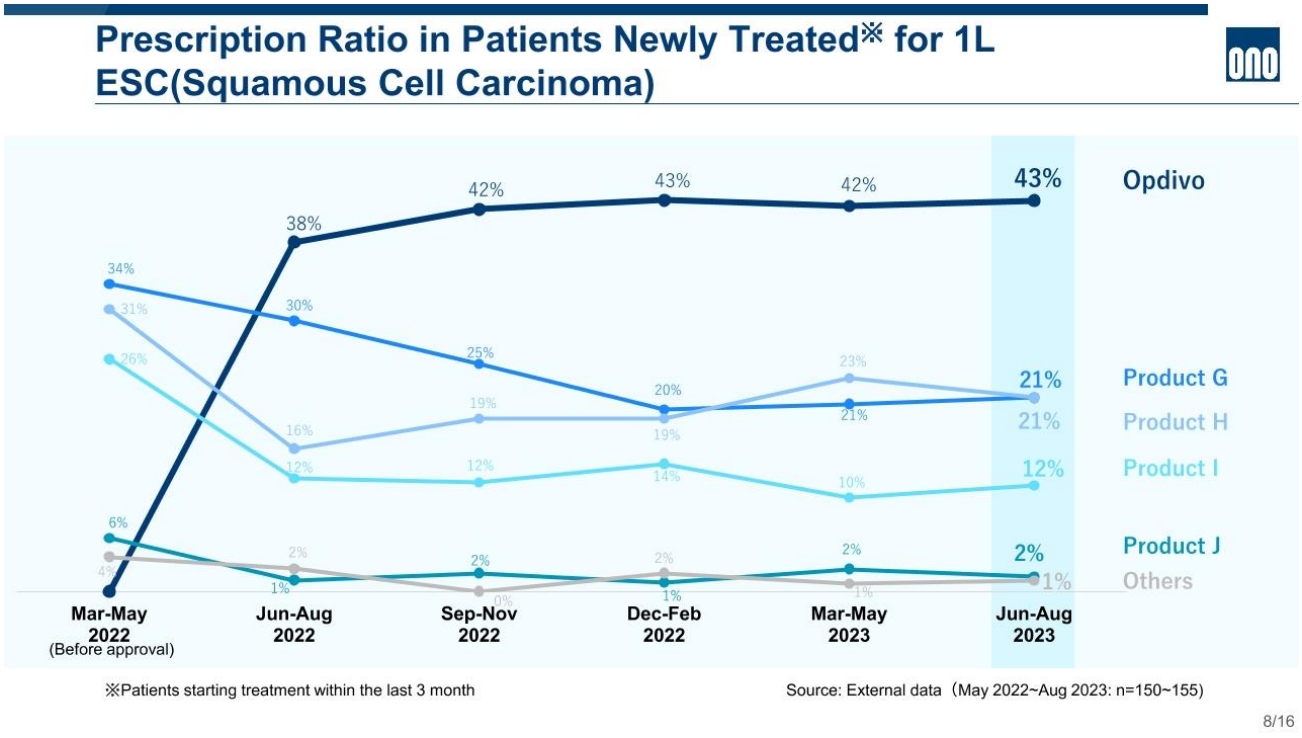
6/16

We have made some changes to the graphs this time. Please note that we have used the line graph regarding the share of new prescriptions.

The share of new patient prescriptions for first-line treatment of gastric cancer, which accounts for the highest percentage of the sales target for this fiscal year, had been hovering around 70%, but in the beginning of this fiscal year, especially in the most recent period, it has already risen to 75%.



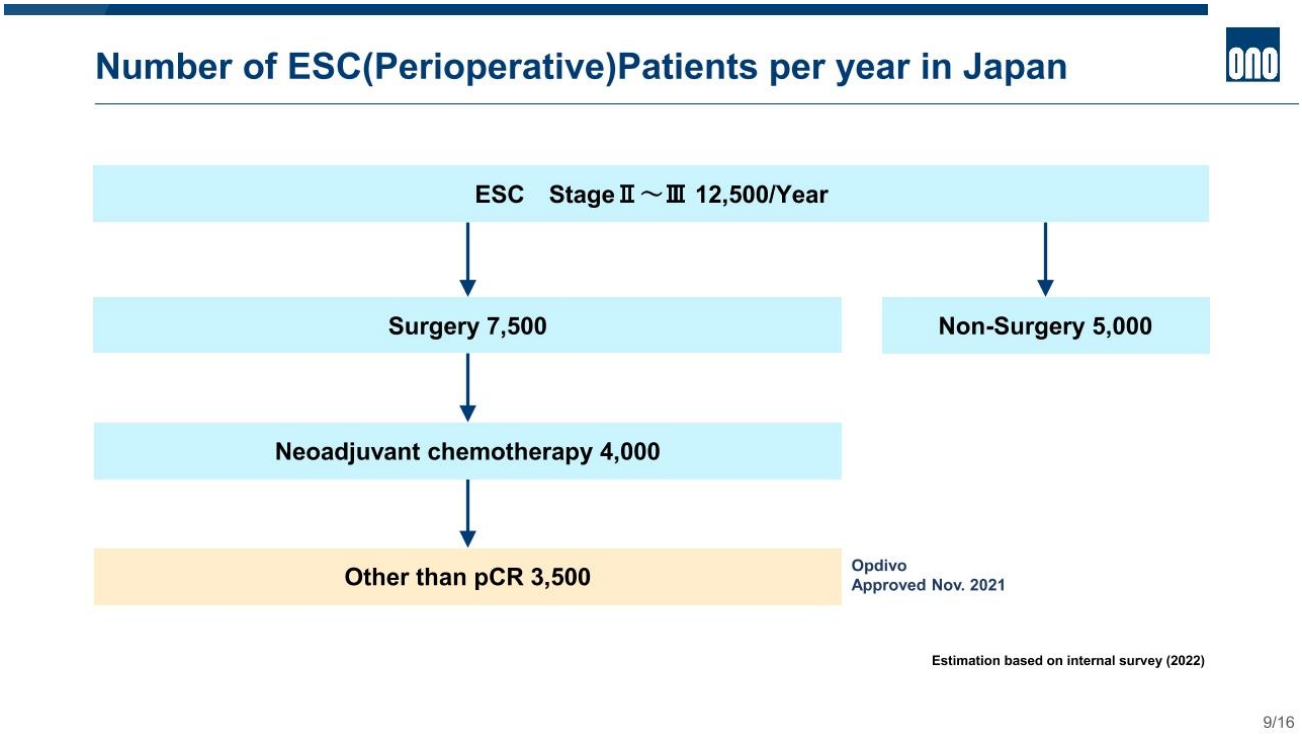
Esophageal cancer. The target population for Opdivo for the first-line treatment of esophageal cancer is squamous cell carcinoma, and we believe the number of eligible patients is 10,000.



This is the trend in the share of prescriptions for new patients in the first-line treatment of esophageal cancer.

The Opdivo regimen has been introduced in the first-line treatment, and there are two Opdivo regimens, both of which have a 43% share of new patient prescriptions. In first-line treatment, including competing products, I-O regimens account for about 60%, which is currently a little stagnant.

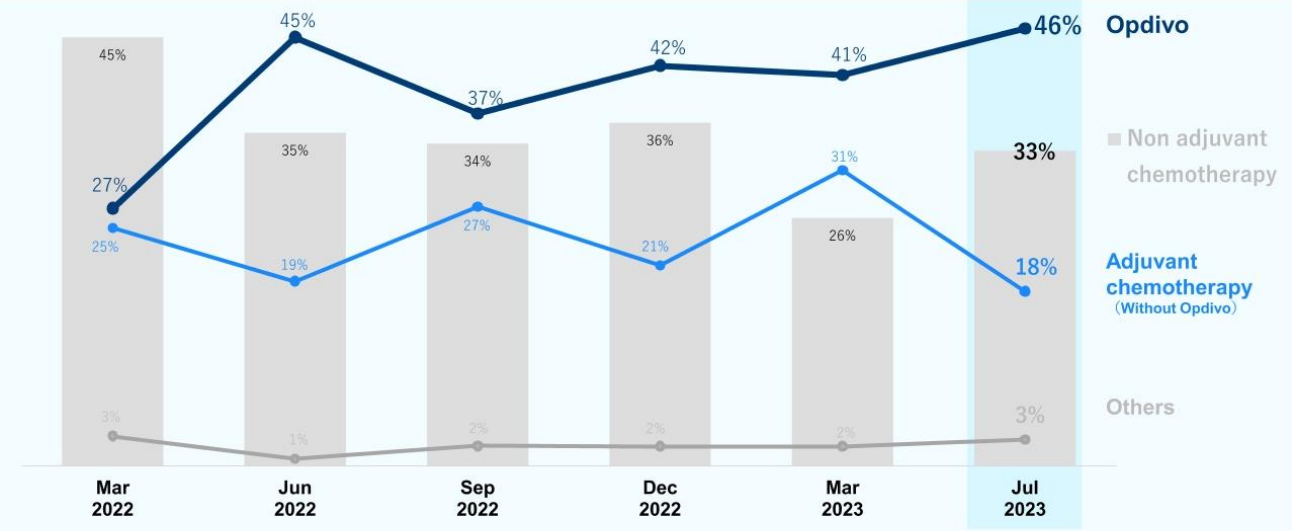
Since 40% of treatment still prescribe chemotherapy regimens, there is still a sufficient segment to expand the Opdivo regimen, and we are currently working to further expand this segment.



This is the number of patients in the perioperative period of esophageal cancer.

The number of patients eligible for postoperative adjuvant therapy with Opdivo is currently estimated at 3,500 patients with pathologic non-complete response.

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



※Patients starting treatment within the last 3 month

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

10/16

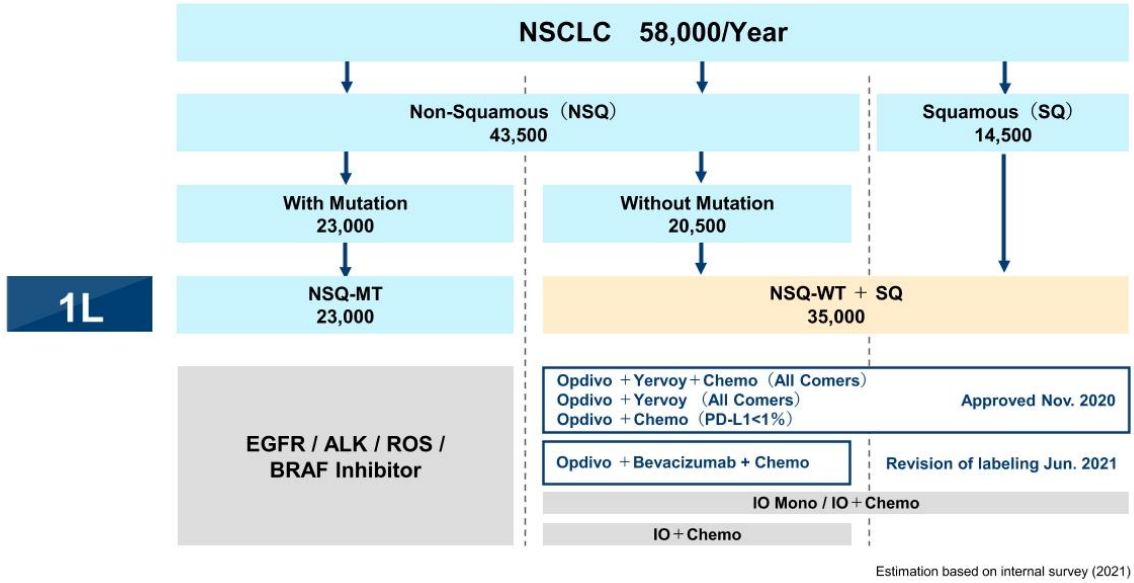
The share of new patient prescriptions for postoperative adjuvant therapy for esophageal cancer is 46% and is gradually growing.

However, there are still enough patients who have received only postoperative chemotherapy and have not yet received chemotherapy, so we are continuing to educate the effectiveness of Opdivo. Sales for first-line treatment and postoperative adjuvant for esophageal cancer are expected to continue to grow in the future, and in Q2, we focused our activities on this esophageal cancer field.

Especially in the area of postoperative adjuvant therapy, we have seen an increase in the number of new patients receiving this therapy since September, even though it is based on in-house data. We believe that we can fully expect to see results in H2.

Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC



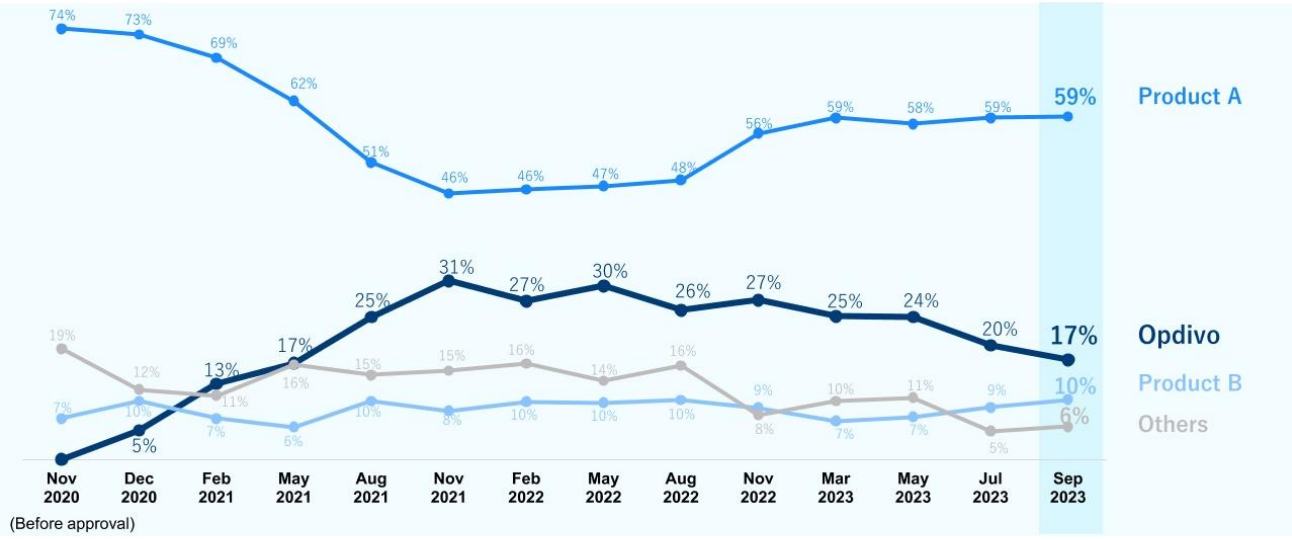
Estimation based on internal survey (2021)

11/16

The next is about non-small cell lung cancer.

The annual number of patients with non-small cell lung cancer is shown in the table. The target patients for the first-line treatment of lung cancer with immune checkpoint inhibitors such as Opdivo are squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation, and we estimate that the number of patients per year is 35,000.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



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

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

12/16

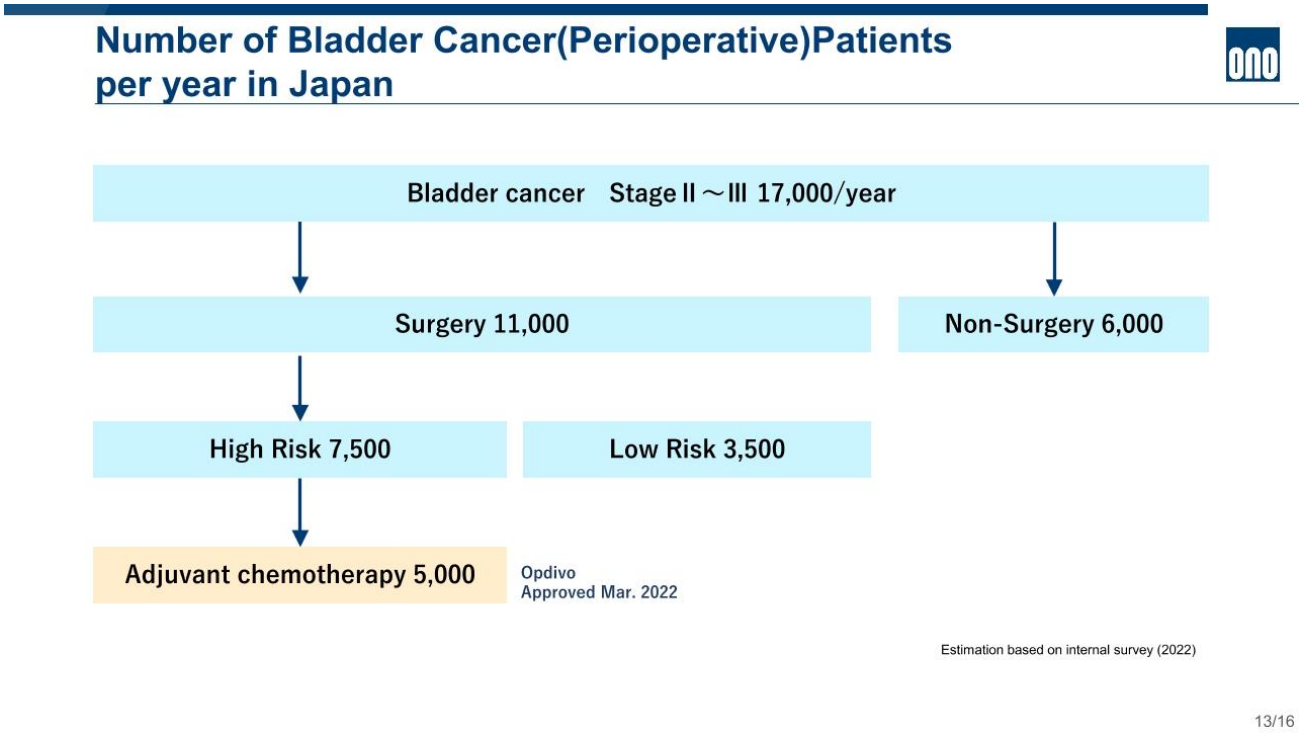
This table shows the prescription share in new patients for the first-line treatment of gastric cancer.

The most recent Opdivo new patient share was 17%. This is also in-house medical representatives' reports, but the confirmed number of new patient prescriptions bottomed out around July to August of this year, and since then, the Opdivo lung cancer situation has been on a gradual recovery trend.

The four-year follow-up data of the CheckMate-9LA trial was presented at the ASCO international meeting in June of this year, and it was reported that the four-year survival rate for patients with PD-L1 expression levels below 1% was 23% for the 9LA regimen while it was 13% for the control regimen.

In addition, at the World Lung Cancer Congress in September of this year, six-year follow-up data for the CheckMate-227 regimen were presented, showing that the six-year survival rate for patients with PD-L1 expression levels below 1% was 16% for the 227 regimen and 5% for the control group, a more than three-fold difference. The benefits of both regimens are more pronounced in patients with high unmet need who have negative PD-L1 expression levels of less than 1%.

That alone is not enough, so we are also working to support the irAE management system, which is safety. We believe that this drug can contribute to the long-term survival of many lung cancer patients in the future, and as I mentioned earlier, we believe that we can firmly recover using both regimens since the prescription of the drug is gradually recovering.

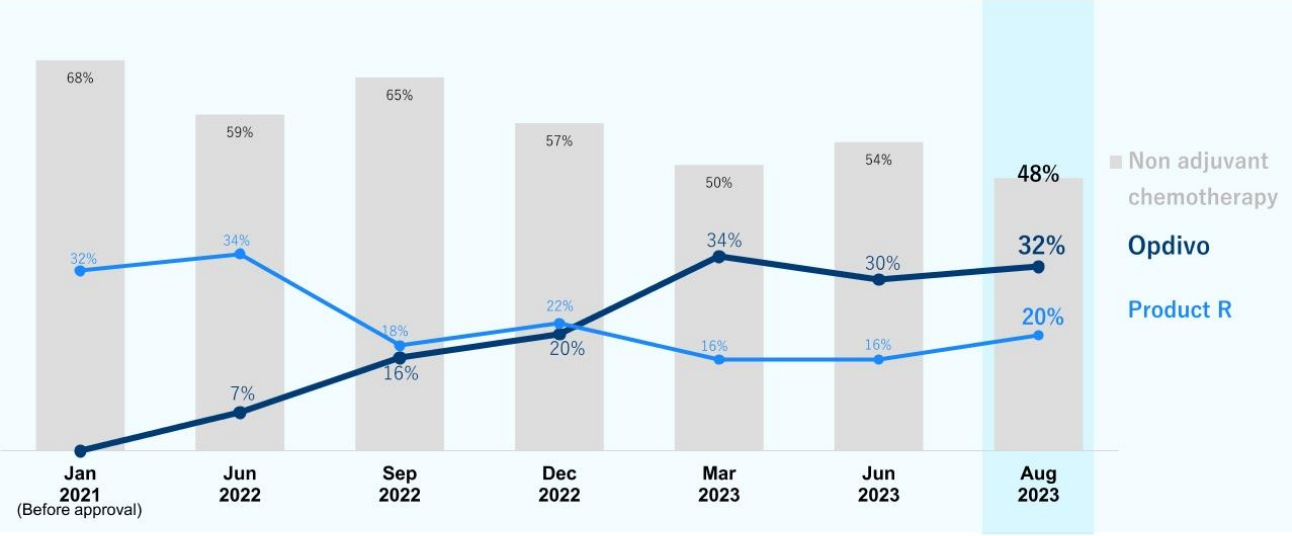


I would like to explain urothelial carcinoma.

In Japan, bladder cancer accounts for 80% of all urothelial cancers. For this reason, we are showing you the number of patients with bladder cancer in the perioperative period, which is the most common type of cancer in the patient population.

We believe that 5,000 patients receiving postoperative adjuvant chemotherapy will be eligible for Opdivo adjuvant treatment.

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



※Patients starting treatment within the last 3 month

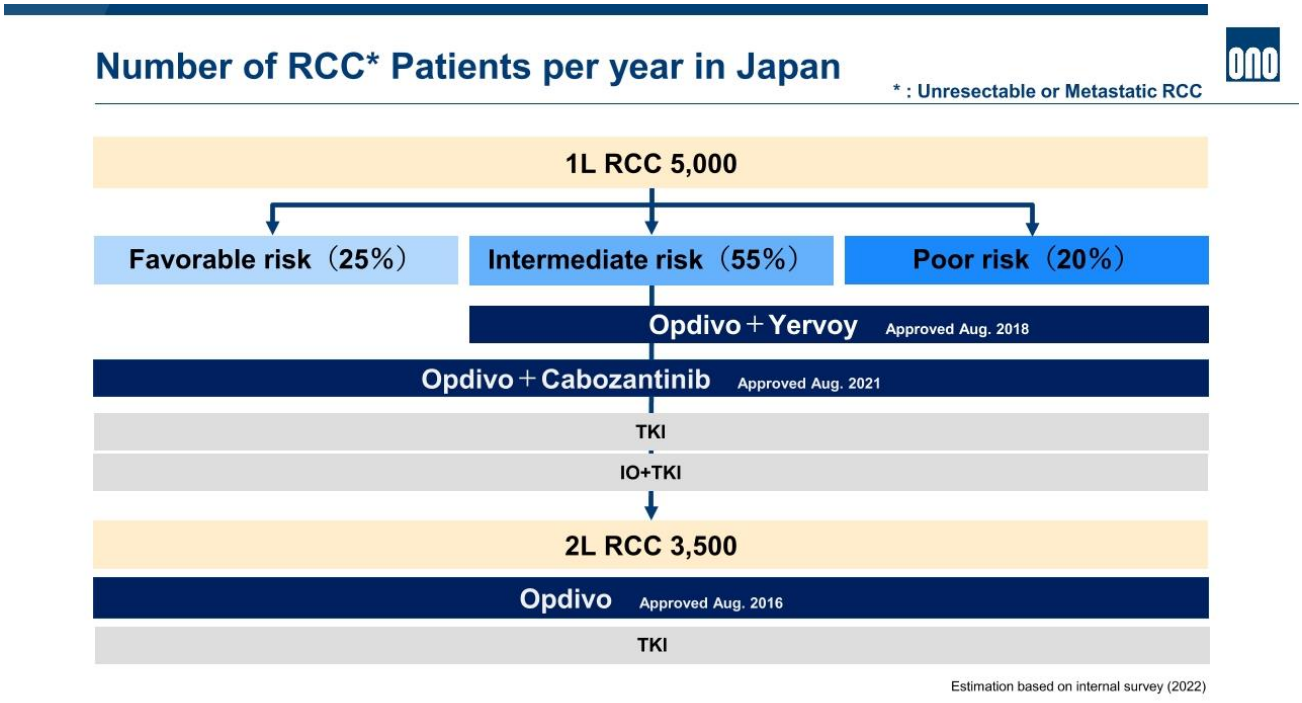
Source: External data (Jan 2022~Aug 2023: n=200)

14/16

The share of new prescriptions for adjuvant bladder cancer treatment is 32%, but 50% of patients have not yet received postoperative adjuvant chemotherapy, so we are continuing to promote the effectiveness of this treatment so that it will be evaluated as an essential treatment option.

Like esophageal cancer, which I mentioned earlier, this is another carcinoma for which sales growth is very promising. Thus, although the share of new patient prescriptions has been stagnant for a little while, we have been intensively working on the urothelial cancer area, as well as the esophageal cancer area, in Q2.

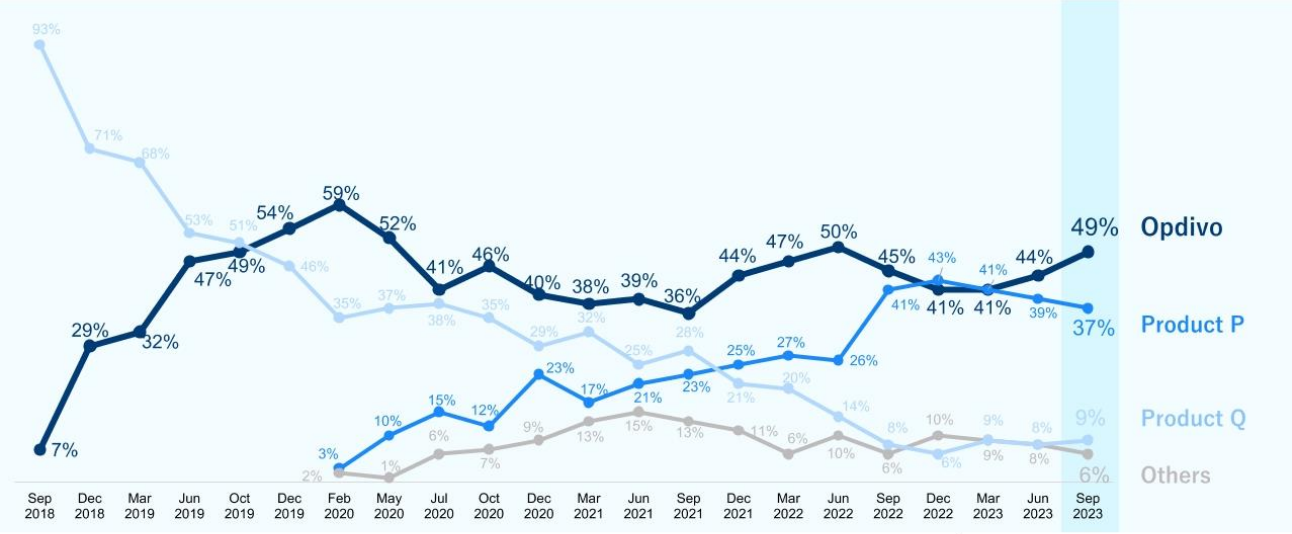
Although this data is also based on in-house data, the number of new prescriptions acquired has been increasing since September. We expect to see results in H2.



Finally, I would like to explain renal cell carcinoma.

This is the share of new acquisitions in the first-line treatment of renal cell carcinoma. Currently, the use of I-O as the first-line treatment has become the standard of care in this field. In this context, we had expected the current fiscal year to be difficult, but in the renal cell carcinoma field, we have been able to recover more than expected.

Prescription Ratio in Patients Newly Treated※ for 1L RCC



※Patients starting treatment within the last 3 month

Source: External data（Sep 2018~Sep 2023: n=46~110)

16/16

The share of new patient prescriptions for Opdivo, Yervoy, and the Opdivo/TKI combination regimen has recovered to 49%. We intend to continue to expand this area while working to maximize the value of Opdivo products.

This was the explanation for the Opdivo trend. Although competition is intensifying, we believe that we are achieving our plans by further new prescriptions, particularly for gastric cancer, esophageal cancer, and urothelial carcinoma field, which I have explained to you today.

It may sound like the same story over and over again, but in gastric cancer, which accounts for a particularly high percentage of Opdivo's sales target, the share of new prescriptions acquired was around 70%, but has risen to 75% as of the beginning as of this fiscal year.

In Q2, we also focused on esophageal cancer and urothelial carcinoma, where sales are expected to grow, and although it is at the reporting level from our medial representatives, the number of newly acquired cases is also increasing.

Furthermore, renal cell carcinoma, which I explained last, is also recovering more than expected. As a result of the above, we expect to achieve the fiscal year target of JPY155 billion.

We will continue our efforts to maximize product value to meet unmet needs of cancer patients. That is all.

Question & Answer

Imura: The participants at the venue, if you have any questions, please raise your hand.

Yamaguchi: This is Yamaguchi from Citigroup Global Markets Japan Inc. The first is the part about Opdivo, which you explained in detail at the end. I believe that you have given us your interim results for H1 of the fiscal year and your outlook for the full fiscal year. Maybe the renal carcinoma area seemed to be on the upswing, but what about the rest? Were they very subtle? Can you tell us how well you have done up to H1 and what you plan to do in H2? I would appreciate it if you could tell us a little more about the difference between your company's performance up to H1 and your expectations. This was my first question.

Takahagi: Overall, H1 of the fiscal year is almost in line with the plan.

However, I think the gastric cancer got off to a bit of a slow start. Esophageal cancer as well. Also, where the performance with urothelial carcinoma did not do well, we were able to cover that with renal cell carcinoma and other cancers. As for lung cancer, we believe that it is in line with the plan.

The first half of the fiscal year was just a little behind plan, but the positive results for gastric cancer, esophageal cancer, and urothelial carcinoma began to emerge around September, so we believe we will be able to achieve the fiscal year's plan.

Yamaguchi: I see. Also, Padcev, I think, showed very good data on urothelial carcinoma, and your company's data was also shown, but do you think there will be an impact on the urothelial in the future? Especially Cisplatin, I think the data showed that there are not many differences in outcome with or without Cisplatin. Please comment on that.

Takahagi: Yes, the results of the ESMO trial have just been published, but the safety profile of both regimens is different. Also, until now, the standard therapy in Japan has been using Cisplatin. Urologists are already familiar with the Cisplatin and Opdivo combination regimen.

I think it is also a very clinical question as to how we should think about sequencing, including Padcev, in the future.

We believe that there will always be optimal patients for this combination regimen of Opdivo and Cisplatin, and we also believe that the addition of the drug will make it easier to use, and that it could be used as a second-line treatment. We would like to discuss these issues with doctors.

However, I am sorry to say that various data have just been released and we have not yet been able to analyze them in detail.

Yamaguchi: Secondly, you explained the items for the expansion of the indications for Opdivo, which were mentioned in the mid-term plan, but I remember that in the past, you also mentioned something like "this is about this much". I would like to know how much can be put on these four items, especially since the biggest one is probably the top one, ChekMate-901, but I would like to know how much can be put on them in relation to the overall image, if you have any figures.

Sagara: This is a very troubling question. I've never said it at this stage. I have high hopes, but of course there will be competitions out there. So, in this case, please forgive me to say that we have to wait to see the data that are not yet available, since prescribing intentions vary greatly depending on the resulting data.

So urothelial carcinoma data has yet to be scrutinized, so please just give us some time. However, I do have high expectations. We are especially interested in first line and adjuvant for hepatocellular carcinoma, and we are hoping to get some good data here. Sorry, but that's all.

Yamaguchi: Lastly, regarding the bispecific, ONO-4685. You are also working on T-cell lymphoma in Japan. Also, in the area of autoimmunity, I believe there was a halt in trials in Europe due to psoriasis, and I wonder if there will be an update on this area of autoimmunity. This is an agonist, so it should work in the direction of lowering immunity, but I'm a little confused as to why it would work for T-cell lymphoma, so just those two things, please.

Okamoto: Let me start with the latter question. In the literature, there is a report that when a similar drug, an anti-PD-1 antibody, was administered to PTCL, a type of T-cell lymphoma, it was rapidly reversed and worsened.

At the basic level, it has been reported that PD-1 signals expressed on T cells are suppressively activated when the T cells become cancerous. The analogy from this is that in some cases, by administering an agonist, it may be possible to suppress the differentiation and proliferation of T cells that originally became cancerous, when the signal is put into the agonistic.

The other is what we called trans-engagement, in which healthy normal T cells are on this side and cancerous T cells are on the other side, and by linking them together as T cell engagers, we believe that it will exert a cell-killing effect on T-cell lymphomas. This is the reason why we believe that T-cell lymphoma is effective against T-cell lymphoma.

Regarding your first question, the temporary interruption of trials due to psoriasis was originally stipulated in the protocol, and there was nothing particularly wrong with that.

As for the update, I am afraid I will refrain, as I have in the past, from discussing the contents of the ongoing trials.

Yamaguchi: How many indications are you working on, regarding autoimmunity?

Okamoto: What we are doing for now is working on psoriasis. We are still in Phase 1.

Imura: Next questioner, please go ahead.

Muraoka: This is Muraoka from Morgan Stanley MUFG Securities Co., Ltd. This is about the chart on page 6 in the president's presentation material, which shows the planned launch of the product in the United States and Europe. I'm sorry that this is a very rough question, but especially in H1, around 26 to 27, what would be the order in which you expect to see the sales?

Sagara: I'm sorry, about 26, 27, do you mean FY2026, FY2027?

Muraoka: That's right, in 27 to 31.

Sagara: I am expecting ONO-4059 Velexbru and then, and this is still one step away from a final decision, Itolizumab. Regarding compounds to be sold between 2027 and 2031, I don't think we will be able to launch it in time for 2027, so for now, I would like to say these two.

Muraoka: Okay, among these five or so in 2027 to 2031, which are the ones that seem to have the highest potentials, especially after taking into account the probability of success?

Sagara: we have high hopes with all of these. Since 2910 has a strong market in Japan, we have to think about what we will do if it is successful in the US I mean, we need to think about whether to go it alone, not to do it, or to collaborate. I hope something like that will work.

Muraoka: Thank you. I think the president was talking today about a rough calculation around this ONO-4059 and Itolizumab, and I think president was talking about something like JPY100 billion.

Sagara: I did not say that much.

Muraoka: That's right. That is a bit of an exaggeration.

Sagara: If the same efficacy were to be achieved, if JPY10 billion units were sold in Japan, there is a possibility that 10 times as many could be sold in the US and Europe, based on the size of the market.

Muraoka: I see. I understand. Also, I think there was a slide that said that sales towards patent expiration, which was only on the slide, would be like this. Looking at the dark bar at the bottom of the Opdivo domestic sales chart, I would have guessed from the current sales that it would not reach the JPY200 billion mark.

Sagara: The size of the sales data in the slide is really rough and it's not a precise length, so it doesn't mean it won't exceed JPY200 billion.

Muraoka: I see. Of course, the possibility of exceeding this is if things go well with hepatocellular carcinoma, I guess.

Sagara: Yes, I think there is a possibility if various factors, as mentioned in slide number four earlier, can be successfully brought together.

Muraoka: I see. Lastly, regarding the development of ONO-4059 overseas, PCNSL, I think, I just looked at the development status in ClinicalTrials.gov now. Primary Completion is scheduled in 2027, and a while ago, I think that was scheduled for completion in 2024 and was scheduled for the launch in 2026. Please explain this.

Okamoto: Regarding the ONO-4059 trials for PCNSL, which is undergoing in the US, actually has two parts, A and B. Part A is for so-called relapsed and refractory PCNSL, which has already been approved in Japan. We would like to apply for approval with these results.

Part B, on the other hand, is for untreated PCNSL, and this is the trial of combination with existing standard of care and multidrug therapy. After first confirming the tolerability of the combination therapy, an exploratory or preliminary efficacy study will be conducted. This is Part B, and part A and part B comprise one study. We have updated the new timeframe for the expected end of the trial of the endpoint for untreated patients Part B.

We believe that the progress of the already-approved target population Part A in Japan is as expected, we have no intention of changing the timing of the application for approval.

Muraoka: Then, originally, it was scheduled to end in about 2024, and as for Part A trial, do you expect to see results by next summer or so? I don't expect that you will fail it.

Okamoto: I would like to refrain from answering this question, as the situation is a bit related to the endpoints of the ongoing study. I would like to reiterate that it has been decided as a company-wide policy that the first step in expanding our business to the United States will be Velexbru. We, as the development department, are working toward that goal, and we are moving forward in the direction of achieving it.

Imura: Next questioner, please.

Haruta: This is Haruta form UBS Securities Japan Co., Ltd. First question. What is your thinking on Opdivo in Japan for the next fiscal year? The earlier explanation also suggested the possibility that the lung cancer area bottomed out in Q2 and will recover a bit. For gastric cancers, I think that Keytruda or Astellas' zolbetuximab could enter the market.

Also, speaking of prices, I think there is a risk of tailgating due to the expansion of the Bavencio market and re-pricing, so I would like to know a little bit about the cancer type and price, and your thoughts on next year.

Takahagi: Yes, first of all, by carcinoma type, I believe gastric cancer comes first. As you said, next year, perhaps, I do not know when, but I still believe that Keytruda, then Zolbetuximab, will definitely come in.

Among them, regarding Keytruda, the data for Opdivo regimen is almost the same with CheckMate-649. We have already released three-year follow-up data, so we will not only release three-year follow-up data, but we will also conduct CPS-specific results and landmark analysis to see how the OS of patients with high response rate develops afterwards.

When we introduce these products to doctors, they are highly evaluated as a great reference for selecting drugs, so with regard to Keytruda, we firmly believe that we have a first-mover advantage.

Another point is that zolbetuximab is an anti-claudin antibody, which has a slightly different mechanism of action, but there may be some sequencing issues, such as that I explained with urothelial carcinoma. Also, looking at the data of Opdivo CheckMate-649, the efficacy is very high in the segment of CPS 5 or higher.

In particular, if we look at the current prescription intentions, the number of prescription intentions has never fallen below 90%. However, on the other hand, less than 60% of doctors have prescription intensions for patients with a CPS of less than 5, so our current challenge is to provide information on patients with a CPS of less than 5 as our priority in our strategy.

The data show that the response rate is high for Opdivo regimens for patients with a CPS of less than 5.

In the landmark analysis I mentioned earlier, OS data is also emerging showing that patients with high response rates can expect long-term survival, so we are hoping to somehow build a wall by using both data. We believe that our largest focus in the coming year will be gastric cancer.

Haruta: How do you see the risk in terms of the impact of tailgating?

Sagara: Yes, I believe that there will be a risk of Bavencio's tailgating, but I am hoping that we can somehow avoid this as a result.

Haruta: Do you mean there is something, as you said, "as a result"?

Sagara: No, lately, discussions about tailgating have finally begun, so I hope that the rules will be relaxed or even eliminated. I am not sure if this applies at the moment, but I think the risk will be, as you say, there.

Haruta: The second question. You mentioned subcutaneous injections, which I think are important from the perspective of life cycle management. What are your views on the timing of market introduction in the US and Japan, market needs, what percent are expected to switch from IV to subcutaneous injection, or you will try to acquire new prescriptions? Also, if it were to be launched fairly early in the US, could you tell me a little bit about your perspective on that, including the upside in terms of royalties?

Sagara: Nothing has been decided yet. As for how to consider the timing of the launch, competing products are also doing subcutaneous injections. Therefore, we need to consider what the status of the subcutaneous injection launch of that competing product is. Also, what is the status of Opdivo launch in the US and Europe and what is the response? Based on these various considerations, we will decide on whether going domestic or not.

If we introduce the product early, we can take advantage of subcutaneous injections, but considering the term of the patent, it will expire soon, and so on. We will make a decision in the not-too-distant future while considering the things I have just mentioned.

Haruta: You said that it has not been decided, but I thought it had been decided that it would be introduced in Japan.

Sagara: It has almost been decided that we will launch it.

Imura: Next questioner, please go ahead.

Hashiguchi: My name is Hashiguchi from Daiwa Securities Co., Ltd. I may have just missed it, but regarding Opdivo royalties, did you clearly say earlier that you get royalties from subcutaneous injections as well?

Sagara: Yes, that is correct.

Hashiguchi: Despite that, you used the expression that Opdivo royalties will run out at some point in time.

Sagara: There will no longer be royalties related to the current intravenous Opdivo.

Hashiguchi: Also, I don't think CHeckMate-77T was included in the list of expected expansion of indications in Japan. Regarding the current sales situation, its sales for the perioperative treatment of lung cancer were not mentioned in Mr. Takahagi's presentation.

Of course, I'm sure it's small as far as sales go, since the number of doses is low right now. I think the situation may change once this 77T comes in, but could you please comment on your expectations regarding this?

Takahagi: We have a high expectation for that, too. First of all, we are now working on preoperative adjuvant therapy, CheckMate-816, and we are assuming that its marketability will reach about 5,500 patients per year. We have been providing information for about 6 months now, and the share of new prescriptions has risen to about 10%, which we believe is almost in line with our plan.

Sales are certainly not large, as they are administered only three times before the surgery. However, there has been no standard treatment for preoperative adjuvant therapy, and the hazard rate of 0.68 in EFS from the three-year follow-up was released recently. The current situation is that doctors' evaluation for this is gradually growing.

However, on the other hand, the CheckMate-77T also recently came out with a result of 0.58, which we are very excited about. However, on the other hand, two competing products will probably enter the market first, so we need to make sure to gain the market share.

However, even now, looking at the results of this 77T and 816, it showed that the efficacy of Opdivo is very reproducible. We are hoping to capture about 50% of the market share through solid activities of the current 816 regimen by the time the competitive products enter the market, and if we can reach that point by then, we believe that the 77T will do great after that as well.

Hashiguchi: You just mentioned 10%, but do you know how much of the postoperative market share you are getting? Another competitor, for postoperative.

Takahagi: There is no competing products for postoperative that are indicated for I-O.

Hashiguchi: Atezolizumab?

Takahagi: I'm sorry that we haven't had a chance to take a good look at the postoperative products.

Hashiguchi: When the new preoperative and postoperative drugs are introduced, there will be three major types of usage: preoperative, postoperative, and perioperative, and I would like to know how you will differentiate the usage. Is there anything you can tell me now about how to differentiate this product since there are two already available drugs?

Takahagi: First, I believe that the discussion with doctors will become more intense from now on, whether it will be used only preoperative or both pre- and postoperative. As of now, some say it is fine to use it just preoperatively, since the PCRs are almost similar. We will continue to research and make decisions considering such opinions as well.

As for the other products, we have not yet conducted a thorough research on them, so we are not yet clear on what kind of strategy we should adopt. But at least, as I said before, we will first get a good evaluation on the 816, and then bring it to the 77T.

However, at that time, we believe that if we do not win at 816, we will not be able to win afterwards, so we are currently working to maximize 816 as much as possible.

Imura: Next questioner, please go ahead.

Akahane: I have one question on Opdivo, one on the performance standings, and one on the business structure.

First of all, regarding Opdivo, thank you for the data on urothelial carcinoma this time. Compared to the last one, the total sales is the same amount, though. With the indication for urothelial carcinoma and others, have you not the changed sales forecast? You mentioned earlier that the sales on gastric cancer, esophageal cancer, and lung cancer will drop slightly, and you are saying that these figures have not been revised at all since the last time?

Takahagi: We have not changed it at all.

Akahane: If there were to be an upside movement, would it be gastric cancer and, this quarter, esophageal cancer?

Takahagi: Yes, we would like to increase those.

Akahane: Regarding the performance standings. On page 7 of the revised report, the sales forecast is JPY25 billion, but only Forxiga's sales have been revised to JPY5 billion, making it JPY17 billion royalties. This will make JPY15 billion in profit before taxes and JPY11 billion in final profit. Is this because you are assuming that the final profit will be quite inflated in terms of taxation with royalties? Also, the revision is not very large considering the royalties. How do you estimate that?

Ito: You are right that royalties are not included fully in the final profit, but we have included an impairment of JPY5.4 billion in the cost of goods in the revision of our business performance. This has an impact on the

profit and loss. In addition, there was a slight increase in expenses, which had an impact on the final operating profit margin.

Akahane: I would like to ask the last question to the president. You have to think about the future, including Opdivo's patent expiration, of course, but looking at the current situation, when royalties are excluded, operating income is JPY97 billion at this point, so if you exclude everything else, you're in the red JPY1.8 billion.

The plan is a deficit of JPY18 billion, but even though this is a deficit when royalties are excluded, this is probably because you can afford it with the very ample royalties, so I think this is why you are spending a lot on R&D. Looking ahead, I don't mean to say something insignificant that earnings other than royalties will swing upward in the future, including this fiscal year, but how do you see the future?

Other than royalties, I think there would be quite a bit of profit. That's because it's already profitable. Since the Tokyo Building has been built and does not require much capital, how do you expect to generate revenue other than royalties in the future? This was my last question.

Sagara: Yes, you are basically pointing out that if royalties are excluded, there is a deficit. The reality is as you say, though.

One is that even earning royalties has cost past R&D investments.

Also, as you mentioned earlier, we are currently receiving ample royalties, so we can invest more and more in R&D for the future, which I think we should do. Especially in the near future in ONO, because of that situation that I mentioned earlier, I would like to invest more in R&D.

On the other hand, I have always had in my mind that if there were no royalties, we would be in the red. However, I think that is okay, for now.

In the future, as we see it now, we will expand from a business that earns royalties to a business that sells by ourselves, so royalties will decrease. And I believe that the profit margin, in total, may decrease a little.

However, as I said earlier, our thinking is that we want to ensure a 25% operating profit margin even in such a situation.

Akahane: I understand very well. Thank you.

Imura: Now, I would like to close. Thank you all for taking time out of your busy schedules to attend and participate in today's meeting.