ONO PHARMACEUTICAL CO., LTD.

Presentation of FY2024 Q3 Business Results to Institutional Investors and Business Analysts

February 3, 2025

[Number of Speakers] 4

Satoshi Takahagi	Corporate Executive Officer, Executive Director of Sales and Marketing
Masaki Itoh	Corporate Officer, Division Director, Corporate Strategy & Planning, Business Management Division
Tatsuya Okamoto	Corporate Officer, Executive Director, Clinical Development
Ryuta Imura	Senior Director of Public Relations

Presentation

Imura: Thank you very much for joining us today for ONO PHARMACEUTICAL's financial results briefing for the Q3 of the fiscal year ending March 31, 2025.

First, Mr. Itoh will give an overview of the Q3 financial results. Next, Mr. Okamoto will give an update on the progress of the development pipeline. Finally, Mr. Takahagi will talk about OPDIVO trends. Please refer to the materials posted on the Company's website.

Highlights of Financial Results for FY2024 Q3

- **In the third quarter of the current fiscal year, the purchase price allocation (PPA) for the acquisition of Deciphera Pharmaceuticals, Inc., was completed, and "intangible assets", "revaluation of inventories (step-up)" and "goodwill" at the time of acquisition were recorded in the consolidated statement of financial position.**
- **In the third quarter of the current fiscal year, amortization expense (for the six months from July to December) associated with "intangible assets" and "inventory step-up" recognized in the PPA was recorded in the consolidated statement of income.**
- **In October 2024, we entered into a license agreement with LigaChem Biosciences of South Korea for LCB97, an antibody-drug conjugate (ADC) for the treatment of solid tumors, and a drug discovery collaboration agreement for the discovery of new ADCs using their ADC platform. The upfront payment and research milestone payments were recorded as R&D expenses in the consolidated statements of income in the third quarter of the current fiscal year.**

5/45

Itoh: I am pleased to present a summary of the financial results for Q3 of the fiscal year ending March 31, 2025.

First, I will summarize the topics in these financial results. In Q3, the allocation of the acquisition consideration for Deciphera Pharmaceuticals, the so-called purchase price allocation, or PPA, was completed.

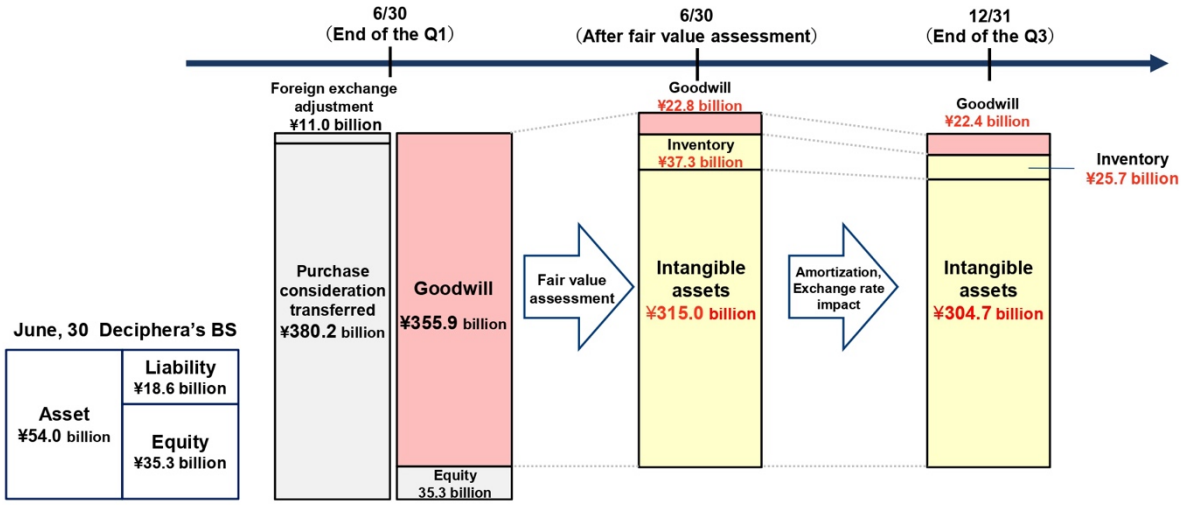
Until Q2, the difference between the acquisition consideration and net assets was accounted for in full as goodwill as a provisional accounting treatment. With the completion of this PPA, as of the acquisition date, the amount of the step-up in revaluation of intangible assets and inventories related to QINLOCK and vimseltinib as well as goodwill have been recorded in the consolidated statement of our financial position.

For the step-up of intangible assets and inventories recognized in the PPA, an amortization expense was recorded in the consolidated statement of income for the six-month period from July to December, retroactive to the date of acquisition.

Lastly, in October 2024, we entered into a licensing agreement with LigaChem Biosciences of South Korea for antibody-drug conjugates (ADC) and LCB97 for the treatment of solid tumors and a drug discovery collaboration agreement for the discovery of new ADCs using their ADC platform. The upfront payment and research milestone expenses are included in R&D expenses in the consolidated statements of income.

Fair value of assets acquired, liabilities assumed and purchase consideration transferred at the acquisition date

- In the first and second quarters, the entire difference between the acquisition price and net assets was recorded as "goodwill" (provisional accounting treatment).
- In the third quarter, the company identifies intangible assets and other assets as of the acquisition date through a fair value assessment (PPA).



6/45

This slide is an overview of the PPA. As a result of the PPA, the Company recorded JPY315 billion in intangible assets retroactive to June 30, the date of acquisition, of which approximately JPY150 billion was related to QINLOCK and JPY160 billion was related to vimseltinib.

Each will be amortized on a straight-line basis over the patent term from the time of sale. The corresponding period is expected to be approximately 16 years for QINLOCK and approximately 14 years for vimseltinib.

In addition, inventory valuation increased by JPY37.3 billion as a result of inventory revaluation. In Q3, six months of QINLOCK amortization and step-up amortization related to inventory that has been cleared by sales are recorded in the income statement, with a corresponding decrease in assets.

FY2024 Q3 : Sales Revenue

Revenue
¥374.6 billion
YoY -15.3 billion (-3.9%)

Goods and Products Sales
¥256.9 billion
YoY +9.9 billion (+4.0%)

Royalty and Others
¥117.7 billion
YoY -25.3 billion (-17.7%)

7/45

I will now give an overview of our business performance.

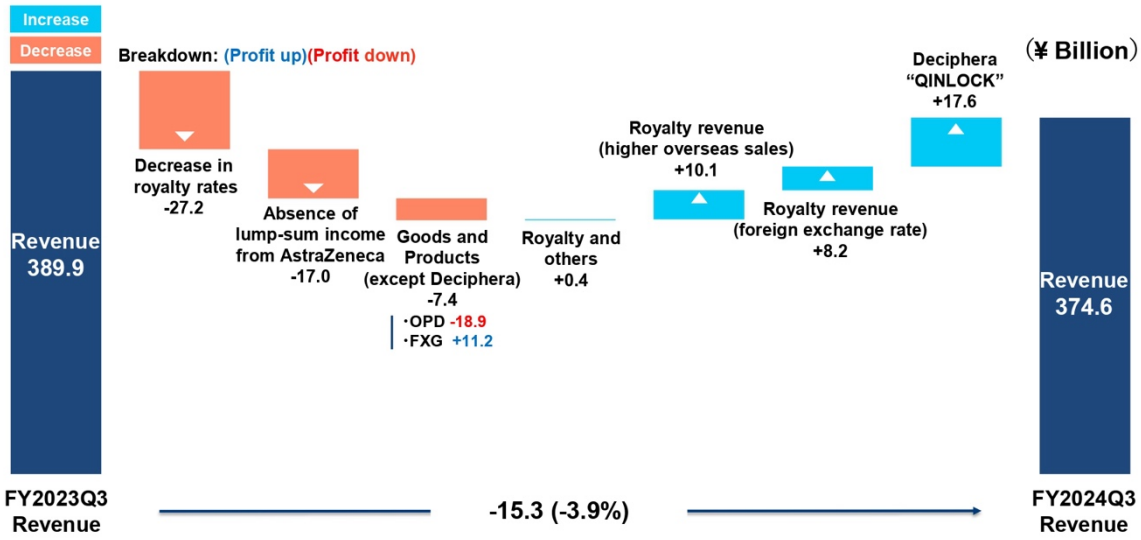
Revenue for Q3 decreased by JPY15.3 billion or 3.9% YoY to JPY374.6 billion.

This comprises product sales of JPY256.9 billion, up JPY9.9 billion or 4% YoY. While a decrease in domestic sales was recorded, the figure increased due to the addition of Deciphera's sales since July as a result of the acquisition.

Royalties and others decreased by JPY25.3 billion or 17.7% YoY to JPY117.7 billion. This is due to lower royalty rates at Merck and elsewhere.

FY2024 Q3 : Sales Revenue (Breakdown)

- Revenue was decreased mainly due to the revision of drug price of Opdivo, despite an increase in sales of Forxiga Tablets.
- Royalty revenue was decreased mainly due to a decrease in royalty rates from Merck, despite an increase in royalty revenue from Bristol-Myers Squibb.



8/45

Next, the breakdown of change in revenue.

There were several factors that contributed to the decrease in sales in H2 compared to the previous year, including a decrease in revenues due to lower royalty rates received from Merck and other companies, a decrease due to the absence of revenue from the settlement of patent-related litigation with AstraZeneca in the previous year, and a decrease in sales due to the OPDIVO NHI drug price reductions.

On the other hand, compared to the steady sales of Forxiga due to its expanded use in chronic renal failure, royalty income from overseas increased due to an increase in royalty income from an increase in local sales and also due to the positive currency impact from the weaker yen. The addition of JPY17.6 billion in sales of QINLOCK, a gastrointestinal stromal tumor treatment acquired through the acquisition of Deciphera, mostly offset multiple negative factors and limited the decline of JPY15.3 billion YoY, to JPY374.6 billion.

FY2024 Q3 : Sales Revenue by Product (Domestic)

¥ in Billion

	FY2023Q3	FY2024Q3	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	389.9	374.6	(15.3)	(3.9%)	485.0
Goods and products	246.9	256.9	9.9	4.0%	333.0
Royalty and others	143.0	117.7	(25.3)	(17.7%)	152.0

Goods and Products (Domestic)	FY2023Q3	FY2024Q3	YoY		FY2024 Forecast*
			Change	Change (%)	
Opdivo Intravenous Infusion	114.9	96.0	(18.9)	(16.5%)	125.0
Forxiga Tablets	57.5	68.7	11.2	19.5%	89.0
Orencia for Subcutaneous Injection	20.0	20.8	0.7	3.7%	27.0
Glactiv Tablets	16.7	14.7	(2.0)	(12.2%)	18.5
Velexbru Tablets	8.0	8.2	0.3	3.1%	10.0
Kyprolis for Intravenous Infusion	7.1	6.9	(0.2)	(2.6%)	9.5
Parsabiv Intravenous Injection	6.4	6.6	0.2	2.8%	8.5
Ongentys Tablets	4.9	6.0	1.1	22.5%	7.5

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price).
・Sales revenue of overseas products is shown in a net sales basis.

9/45

Next, here are the domestic sales by product.

Sales of OPDIVO decreased by JPY18.9 billion or 16.5% YoY to JPY96 billion for OPDIVO. Sales of Forxiga increased JPY11.2 billion or 19.5% to JPY68.7 billion.

Among other major products, sales of ORENCIA subcutaneous injection, a drug for rheumatoid arthritis treatment, increased JPY700 million or 3.7% YoY to JPY20.8 billion. Sales of the anti-cancer drug VELEXBRU increased by JPY300 million or 3.1% YoY to JPY8.2 billion. Sales of PARSABIV, a treatment for secondary hyperparathyroidism in hemodialysis, increased by JPY200 million or 2.8% YoY to JPY6.6 billion. Sales of ONGENTYS tablets, a drug for Parkinson's disease, increased JPY1.1 billion or 22.5% YoY to JPY6 billion.

On the other hand, sales of GLACTIV, a drug for type 2 diabetes, decreased by JPY2 billion or 12.2% to JPY14.7 billion. Sales of KYPROLIS, a treatment for multiple myeloma, decreased JPY200 million or 2.6% to JPY6.9 billion.

FY2024 Q3 : Sales Revenue by Product (Overseas) / Royalty

¥ in Billion

	FY2023Q3	FY2024Q3	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	389.9	374.6	(15.3)	(3.9%)	485.0
Goods and products	246.9	256.9	9.9	4.0%	333.0
Royalty and others	143.0	117.7	(25.3)	(17.7%)	152.0

Goods and Product（Overseas）	FY2023Q3	FY2024Q3	YoY	
			Change	Change (%)
OPDIVO	9.1	10.0	0.9	10.2%
QINLOCK	–	17.3	–	–

Royalty and others	FY2023Q3	FY2024Q3	YoY	
			Change	Change (%)
OPDIVO	73.9	86.3	12.4	16.8%
KEYTRUDA®	38.9	19.4	(19.5)	(50.1%)

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price).
・Sales revenue of overseas products is shown in a net sales basis.

10/45

The following are the sales of our main products overseas.

For OPDIVO in Korea and Taiwan, total sales increased by JPY900 million YoY to JPY10 billion. Sales of QINLOCK, which was acquired through the acquisition of Deciphera, totaled JPY17.3 billion for the past six months.

As for royalties and others, royalty income from Bristol-Myers Squibb Company related to OPDIVO increased by JPY12.8 billion YoY to JPY86.3 billion. Royalties from Merck related to KEYTRUDA decreased by JPY19.5 billion to JPY19.4 billion due to lower rates.

FY2024 Q3 : Core Operating Profit

Core Operating Profit
¥ 97.7 billion
YoY -56.9 billion
(-36.8%)

Revenue ¥ 374.6 billion
YoY -15.3 billion (-3.9%)

R&D Expense ¥103.4 billion
YoY +26.9 billion (+35.1%)

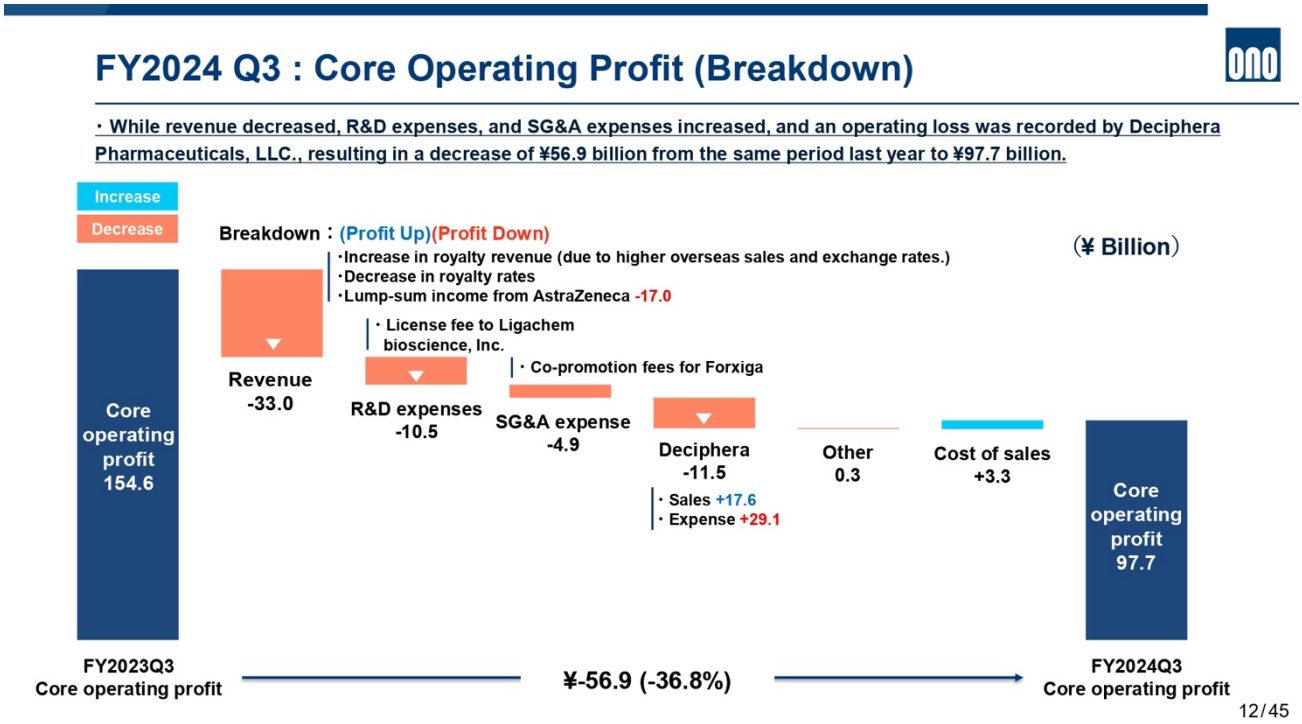
SG&A Expense ¥90.2 billion
YoY +16.9 billion (+23.0%)

11/45

Next is operating profit.

I will present the Q3 results on a core basis. Core operating profit decreased JPY56.9 billion or JPY36.8% YoY to JPY97.7 billion.

Revenue decreased by JPY15.3 billion YoY. Furthermore, R&D expenses increased by JPY26.9 billion YoY, and selling, general and administrative expenses increased by JPY16.9 billion YoY.



This is a breakdown of the change in core operating income.

The main reasons for the decline were a decrease in sales revenue, an increase in R&D expenses, and an increase in SG&A expenses. Another factor was the operating loss of JPY11.5 billion at Deciphera, which recorded sales of JPY17.6 billion and expenses of JPY29.1 billion.

FY2024 Q3 : Financial Overview (Core)

¥ in Billion

	FY2023 Q3	FY2024 Q3	YoY		FY2024 Forecast*
			Change	Change(%)	
Revenue	389.9	374.6	(15.3)	(3.9%)	485.0
Cost of sales	85.3	83.1	(2.2)	(2.6%)	109.0
R&D expenses	76.5	103.4	26.9	35.1%	143.0
SG&A expenses	73.3	90.2	16.9	23.0%	120.0
Other income	0.5	0.8	0.3	47.9%	0.5
Other expenses	0.7	1.1	0.4	50.8%	3.5
Core operating profit	154.6	97.7	(56.9)	(36.8%)	110.0
Core profit before tax	157.3	100.0	(57.3)	(36.4%)	110.5
Core profit for the period (attributable to owners of the Company)	123.6	76.5	(47.1)	(38.1%)	81.0

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

YoY Breakdown

R&D expenses +¥26.9 billion (+35.1%)

R&D ratio：27.6%

Main reasons

- Development costs for clinical trials
- R&D expenses from Deciphera +¥16.4 billion
- Upfront & Milestone payment to Ligachem Bioscience, Inc.

SG&A expenses +¥16.9 billion (+23.0%)

Main reasons

- Co-promotion fees for Forxiga Tablets
- SG&A expenses from Deciphera +¥12.0 billion

13/45

This is a breakdown of core operating income.

Cost of sales decreased JPY2.2 billion or 2.6% from the same period last year to JPY83.1 billion. R&D expenses increased by JPY26.9 billion or 35.1% YoY to JPY103.4 billion. This is due to an increase in expenses related to clinical trials, expenses related to the drug discovery alliance with LigaChem Biosciences, and expenses related to R&D at Deciphera.

Selling, general and administrative expenses increased by JPY16.9 billion or 23% YoY to JPY90.2 billion. This was due to increased promotional expenses associated with the sales expansion of FORXIGA, as well as expenses related to business operations of Deciphera.

As a result, core operating profit decreased by JYP56.9 billion or 36.8% YoY.

(Ref) FY2024 Q3 : Financial Overview

¥ in Billion

	FY2023 Q3	FY2024 Q3	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	389.9	374.6	(15.3)	(3.9%)	485.0
Cost of sales	95.5	102.7	7.3	7.6%	130.0
R&D expenses	76.5	107.1	30.6	40.0%	147.0
SG&A expenses	73.3	93.7	20.4	27.9%	123.0
Operating profit	144.6	70.8	(73.9)	(51.1%)	82.0
Adjustment	10.0	26.9			
Core operating profit	154.6	97.7	(56.9)	(36.8%)	110.0
Profit before tax	147.3	72.0	(75.3)	(51.1%)	81.5
Profit for the period (attributable to owners of the Company)	110.5	56.6	(54.0)	(48.8%)	58.0
Core Profit for the period	123.6	76.5	(47.1)	(38.1%)	81.0

* The consolidated financial forecast for the fiscal year ending March 2025, announced on October 31, 2024, is provided.

YoY Breakdown

Cost of sales ¥7.3 billion

Main reasons
- Amortization expenses associated with QINLOCK, etc. ¥15.1 billion
- Absence of impairment losses on sales licenses recorded in the previous fiscal year ¥-5.4 billion

R&D expenses +¥30.6 billion R&D ratio：28.6%

Main reasons
- Development costs for clinical trials
- R&D expenses from Deciphera ¥16.4 billion
- Impairment loss for itolizumab ¥3.5 billion
- Upfront & Milestone payment to Ligachem Bioscience, Inc.

SG&A expenses +¥19.3 billion

Main reasons
- Co-promotion fees for Forxiga Tablets
- R&D expenses from Deciphera ¥12.0 billion
- Expenses associated with the acquisition of Deciphera

Adjustment

Main adjustment
- Amortization expenses associated with Intangible assets and inventory (step-up) ¥15.1 billion
- Impairment loss for itolizumab ¥3.5 billion
- Acquisition costs for the acquisition of Deciphera

14/45

Next, the consolidated results, which are the actual results on a full basis.

Factors affecting performance include amortization associated with the PPA and the impact of inventory step-up.

FY2024 : Financial Forecast

There are no change from the financial forecast for the fiscal year ending March 2025, announced on October 31, 2024.

¥ in Billion

	FY2023 Actual	FY2024 Forecast	Change	Change (%)
Revenue	502.7	485.0	(17.7)	(3.5%)
Cost of sales	109.6	109.0	(0.6)	(0.5%)
R&D expenses	108.5	143.0	+34.5	+31.8%
SG&A expenses	100.3	120.0	+19.7	+19.7%
Core operating profit	180.9	110.0	(70.9)	(39.2%)
Core profit before tax	184.7	110.5	(74.2)	(40.1%)
Income tax expense	42.1	29.4	(12.7)	(30.2%)
Core profit for the year	142.5	81.0	(61.5)	(43.2%)

* The exchange rate assumed for the second half of the fiscal year in the financial forecast is ¥145 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥0.4 billion in revenue and a decrease of ¥0.2 billion in operating profit for every ¥1 depreciation of the yen.

15/45

Next, the full-year forecast.

There is no change from the earnings forecast announced on October 31, 2024. We forecast that revenue will decrease by JPY17.7 billion or 3.5% YoY to JPY485 billion. Core operating profit is forecast to decrease by

JPY70.9 billion or 39.2% YoY to JPY110 billion, and core profit for the year is forecast to decrease by JPY61.5 billion or 43.2% YoY to JPY81 billion.

FY2024 : Financial Forecast (Sales by Product)

¥ in Billion

Goods and Products (Domestic)	FY2023	FY2024 Forecast	YoY	
			Change	Change (%)
Opdivo Intravenous Infusion	145.5	125.0	(20.5)	(14.1%)
Forxiga Tablets	76.1	89.0	12.9	16.9%
Orencia for Subcutaneous Injection	25.8	27.0	1.2	4.5%
Glactiv Tablets	21.2	18.5	(2.7)	(12.7%)
Velexbru Tablets	10.2	10.0	(0.2)	(2.1%)
Kyprolis for Intravenous Infusion	9.1	9.5	0.4	3.9%
Parsabiv Intravenous Injection	8.2	8.5	0.3	3.3%
Ongentys Tablets	6.3	7.5	1.2	18.8%

Goods and Product (Overseas)	FY2023	FY2024 Forecast	YoY	
			Change	Change (%)
OPDIVO	12.0	13.5	1.5	12.5%
QINLOCK*	–	25.0	–	–

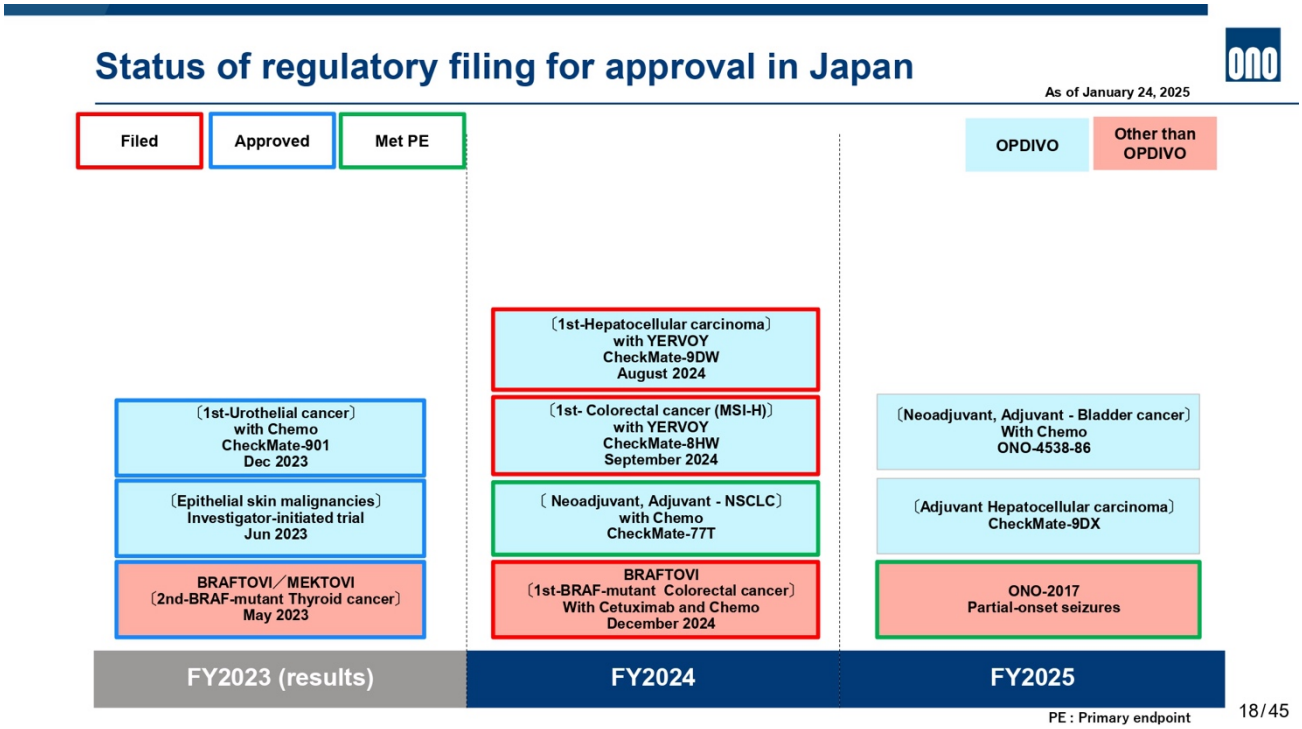
* Sales of QINLOCK are forecasted to be ¥25.0 billion, an upward revision of ¥1.5 billion from the previous forecast announced on October 31st, 2024.
* Sales revenue of domestic products is shown in a gross sales basis (shipment price).
* Sales revenue of overseas products is shown in a net sales basis.

16/45

While the domestic sales forecast remains unchanged, overseas product sales of QINLOCK, a gastrointestinal stromal tumor treatment acquired through the Deciphera acquisition, are forecast to increase by JPY1.5 billion from the previous forecast to JPY25 billion. This new forecast takes into account the sales situation to date.

This concludes my summary of the financial results for Q3. Thank you very much.

Imura: Mr. Okamoto of the development division will continue with an update on the progress of the main development pipeline.



Okamoto: I would like to present the progress of our development products.

I will present the progress of our development pipeline, which is posted on our website. I will focus on changes that have occurred since the last meeting on October 31 last year.

First, applications for approval, actual and planned. This slide shows the situation domestically. First, on the left side, the additional indication of OPDIVO in combination with chemotherapy for the first-line treatment of urothelial carcinoma, which was submitted in FY2023, was approved in Japan on December 27, 2024.

Next is FY2024 the middle column. As a change from the previous application status, we filed an application for BRAF inhibitor Braftovi for first-line treatment of BRAF-mutant colorectal cancer on December 12, 2024. The application is shown in red. The BRAF-positive rate in colorectal cancer is reported to be about 7%, and there are about 32,000 patients in Japan.

As announced by BMS on October 31, 2024, the CheckMate-901 study, a global Phase III study for first-line urothelial cancer, is a combination therapy with YERVOY that was conducted with patients who were not eligible for cisplatin. Unfortunately, the expected efficacy was not confirmed, so it has been deleted from the table.

On the other hand, the bottom right-hand corner shows ONO-2017, generic name cenobamate, which was in-licensed from SK Biopharmaceuticals of South Korea. It is highlighted in green here because the Phase III study for patients in South Korea, China, and Japan was successful.

This concludes the update on the results and plans regarding the application for approvals in Japan.

Development status of OPDIVO (1)

As of January 24, 2025

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant・1st・2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug★ (relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Approved	Filed
	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	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
	Standard of care refractory	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

19/45

I will continue with an explanation of the major changes in the development status of OPDIVO.

As in the past, changes from previous years are shown in red and highlighted in yellow, but there are no updates in this table.

Development status of OPDIVO (2)

As of January 24, 2025

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

★★2nd Line

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

20/45

This table has been updated to reflect the European approval of ipilimumab combination therapy for MSI-High colorectal cancer in first-line treatment.

The results of the CheckMate-8HW study, on which this approval was based, were presented at the recent ASCO GI meeting held in the United States. The hazard ratio for PFS versus OPDIVO monotherapy in the overall treatment line patient population was a very good 0.62.

Currently, pembrolizumab monotherapy is the standard of care for first-line treatment of MSI-High colorectal cancer. We are looking forward to the availability of this excellent treatment option for patients in Japan in the future.

For your information, the number of patients in Japan is estimated to be about 7% of all colorectal cancer patients or 34,000 people, which is almost the same percentage as that of the BRAF-positive type I mentioned earlier.

In addition, as announced in the press release this morning, while ipilimumab combination therapy for first-line hepatocellular carcinoma treatment is still under regulatory review in the EU, BMS has received a positive opinion from the European regulatory authority. Next slide.

Development status of OPDIVO (3)

As of January 24, 2025

Target disease	Treatment Line	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
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant ・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Ⅱ	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	–	–	–	–
Richter transformation	2nd	Monotherapy	Ⅱ	–	–	–	–
Flat dose	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved
Solid tumor	–	ONO-4538HSC (Comibination with vorhyaluronidase alfa)	Ⅰ	–	–	Approved	Filed

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

21/45

As I mentioned earlier, we are updating this page as we received approval in Japan on December 27 for the first-line treatment of urothelial cancer based on the results of the international Phase III CheckMate-901 study.

On the other hand, as I mentioned earlier in the application, the ipilimumab combination part of the same 901 study in a different population was unfortunately not confirmed to have the expected efficacy, so it has been removed from the table.

We have also added a note about Richter transformation, as we have started a domestic Phase II study for patients affected by this condition. Richter transformation is defined as a transformation from chronic lymphocytic leukemia to diffuse large B-cell lymphoma or Hodgkin's lymphoma.

The prognosis after the onset of Richter transformation is poor and there are no drugs approved by the pharmaceutical industry, making it a rare disease with an extremely high unmet need. Although the disease is very rare with only about 10 patients in Japan, we have decided to develop nivolumab to meet this unmet

need in Japan. Since this is a rare disease, we would like to submit an application for approval in Japan if the results of the Phase II trial are favorable.

As previously announced, nivolumab subcutaneous injection was approved by the US FDA on January 6, 2025. I will explain the indications for which subcutaneous injection can be used on another slide.

Status of approval of OPDIVO (i.v. and s.c.) in the US

As of January 24, 2025

Indication	Line	TREATMENTS ADMINISTERED	i.v.	s.c.
Melanoma	Adjuvant	Monotherapy	Approval	Approval
	1L	Monotherapy	Approval	Approval
		With YERVOY	Approval	(monotherapy after combination therapy)
	2L	Monotherapy	Approval	Approval
Non-small cell lung cancer	Neoadjuvant	With chemotherapy	Approval	Approval
	Neo-adjuvant /Adjuvant	With chemotherapy	Approval	Approval
	1L	With YERVOY	Approval	
		With YERVOY or with chemotherapy	Approval	
	2L	Monotherapy	Approval	Approval
Hodgkin's lymphoma	Relapsed/refractory	Monotherapy	Approval	
Head and neck cancer	2L	Monotherapy	Approval	Approval
Malignant pleural mesothelioma	1L	With YERVOY	Approval	
Gastric cancer	1L	With chemotherapy	Approval	Approval

Indication	Line	TREATMENTS ADMINISTERED	i.v.	s.c.
Esophageal cancer	Adjuvant	Monotherapy	Approval	Approval
	1L	With YERVOY	Approval	
		With chemotherapy	Approval	Approval
	2L	Monotherapy	Approval	Approval
Colorectal cancer	MSI-H/dMMR (3rd line)	Monotherapy	Approval	Approval
		With YERVOY	Approval	(Following combination therapy monotherapy)
Hepatocellular carcinoma	2L	With YERVOY	Approval	(Following combination therapy monotherapy)
Renal cell carcinoma	1L	With YERVOY	Approval	(Following combination therapy monotherapy)
		With TKI	Approval	Approval
	2L	Monotherapy	Approval	Approval
Urothelial carcinoma/ Bladder cancer	Adjuvant	Monotherapy	Approval	Approval
	1L	With chemotherapy	Approval	Approval
	2L	Monotherapy	Approval	Approval

OPDIVO Qvantig
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION

22/45

This is a list of the approval status of intravenous and subcutaneous formulations of OPDIVO in the US.

The approval of the subcutaneous formulation of OPDIVO means that all indications for which the intravenous formulation of OPDIVO has been approved, so far have been approved except for Hodgkin's lymphoma and indications that require continuous concomitant administration with ipilimumab.

To add a little more to the continuous part, for example, in the first-line treatment of renal cell carcinoma, the combination with ipilimumab is required up to the first four times of treatment, but after that, treatment with OPDIVO alone is continued.

Thus, even if the combination with ipilimumab is necessary in the initial stage of treatment, OPDIVO can be switched after that to the newly approved subcutaneous formulation for the monotherapy portion of OPDIVO for indications that allow the switch to monotherapy.

As you can see in the table below, the approval of this product will cover many indications that were already covered by the intravenous formulation for subcutaneous injection.

BMS estimates that about 30-40% of intravenous formulations will be switched to subcutaneous formulations.

In Japan, as we have been saying for some time, a Phase I study is underway, and the study is progressing extremely well, including patient enrollment.

Development pipeline (Oncology) ①

As of January 24, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer			FY2024.5 Approval			
MEKTOVI Tablet (Binimetinib) MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer			FY2024.5 Approval			
QINLOCK (ripretinib) KIT inhibitor	NCT05734105/NA, SA, EU, AU, KR, TW	Gastrointestinal Stromal Tumor 2nd KIT Exon 11+17/18			FY2025 Primary Completion			
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma			FY2025 Primary Completion (Part A)			
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT01968109/JP, US, EU	Melanoma*			FY2024 Primary Completion (Actual)			
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*			FY2025 Primary Completion			
	NCT06547385/JP	Colorectal cancer*			FY2027 Primary Completion			
	NCT06542731/JP	Non-small cell lung cancer*			FY2026 Primary Completion			
	NCT06570031/JP	Hormone receptor-positive, HER2-negative breast cancer			FY2025 Primary Completion			
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*			FY2025 Primary Completion			
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor (with sotorasib)			FY2027 Primary completion			
	NCT05957367/US	Advanced Malignancies (with ripretinib)			FY2026 Primary completion			
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Advanced Malignancies			FY2026 Primary completion			
DCC-3009 Pan-KIT inhibitor	NCT06630234/US	Gastrointestinal Stromal Tumor			FY2028 Primary completion			

NA : North America, SA : South America, AU : Australia, EU : European countries
* : Combination with OPDIVO
Estimated study completion date shown in jRCT or ClinicaiTrials.gov

※Red: Update after announcement of FY 2023 financial result in May 2024
※Red: Update after Q1 FY2024 in July
MOA : Mode of Action

23/45

This section shows the progress of the development pipeline in the field of oncology, excluding OPDIVO.

Please note that from this time onwards, we are also presenting Deciphera's pipeline in the same table.

The first is ONO-4482, an anti-LAG-3 antibody, relatlimab, which is being tested in combination with OPDIVO in a Phase II study for hepatocellular carcinoma under the leadership of BMS. However, the expected effectiveness could not be confirmed, so it has been removed from the table.

The EP4 antagonist ONO-4578, which was in Phase I trials for pancreatic cancer in combination with OPDIVO in Japan, has been removed from the table as its development has been discontinued for strategic reasons.

DCC-3009, an inhibitor of pan-KIT, has been newly tested in the US for gastrointestinal stromal tumors, GIST.

In addition, there is ONO-4059, VELEXBRU, which is in Phase II trials for PCNSL in the US. As I have already mentioned, we are making good progress in the trials, and we plan to file for approval this year.

Development pipeline (Oncology) ②

As of January 24, 2025

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	NCT06532331/JP	Pancreatic cancer*	FY2027 Primary Completion					
	NCT06525246/JP	EGFR-mutated non-small cell lung cancer	FY2025 Primary Completion					
ONO-7913 (magrolimab) Anti CD47 antibody	NCT06532344/JP	Pancreatic cancer*	FY2026 Primary Completion					
	NCT06540261/JP	Colorectal cancer*	FY2027 Primary Completion					
ONO-7914 STING agonist	NCT06535009/JP	Solid tumor	FY2026 Primary Completion					
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma	FY2025 Primary Completion					
	NCT06547528/JP		FY2028 Primary Completion					
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	FY2027 Primary Completion					
	NCT06622226/JP		FY2027 Primary Completion					
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor	FY2029 Primary Completion					
ONO-7428 Anti-ONCOKINE-1 antibody	Enrolling/JP	Solid tumor	FY2029 Primary Completion					

* : Combination with OPDIVO, Estimated study completion date shown in jRCT or ClinicaiTrials.gov

MOA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

This slide also covers the oncology area.

Here is ONO-7428. We have added an entry for anti-ONCOKINE-1 antibody, as Phase I trials for this antibody for solid tumors have been newly initiated in Japan.

ONO-7428 has been newly transferred to the clinical stage, and we will provide an overview of it later.

Development pipeline (Non-oncology)

As of January 24, 2025

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU	Tenosynovial Giant Cell Tumor			FY2024 FDA: Filing accepted EMA: Filing accepted			
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	NCT06579573/JP	Primary generalized tonic-clonic seizures			FY2026 Primary Completion			
	NCT04557085/JP	Partial-onset seizures			FY2024 Primary Completion(Actual)			
VELEXBRU Tablet (ONO-4059：tirabrutinib) BTK inhibitor	NCT06696716/JP	Pemphigus			FY2027 Primary Completion			
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy		FY2025 Primary Completion				
DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT06619561/US	chronic Graft Versus Host Disease		FY2029 Primary Completion				
ONO-1110 Endocannabinoid regulation	NCT06708416/JP	Postherpetic Neuralgia		FY2026 Primary Completion				
	NCT06752590/JP	Fibromyalgia		FY2026 Primary Completion				
	NCT06752603/JP	Hunner Type Interstitial Cystitis		FY2026 Primary Completion				
	NCT06792136/JP	Major Depressive Disorder		FY2026 Primary Completion				
	jRCT2031240578/JP	Social Anxiety Disorder		FY2026 Completion (jRCT)				
ONO-2020 Epigenetic Regulation	Enrolling/JP, US	Alzheimer's Disease		FY2026 Primary Completion				
	Enrolling/JP	Agitation Associated with Dementia Due to Alzheimer's Disease		FY2026 Completion (jRCT)				
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease	FY2024 Completion (jRCT)					
	NCT05332704/EU		FY2024 Primary Completion(Actual)					
ONO-4915 PD-1 x CD19 bispecific antibody	jRCT2071240056/JP	Autoimmune disease	FY2026 Completion (jRCT)					

NA : North America,
EU : European countries

Estimated study completion date shown in jRCT or ClinicaiTrials.gov. Dashed lines indicate studies on healthy adults.

MOA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

The following section summarizes the status of development in the non-oncology area.

ONO-4059 is also being developed in the non-oncology field. A domestic Phase III study for pemphigus is underway, and we have recently updated the timing of the acquisition of the primary data in the public database. We believe that we will be able to make a decision on the achievement of key evaluation items by the end of FY2027.

We have started a new Phase II study for DCC-3014, vimseltinib, in the US for cGVHD, chronic graft-versus-host-disease. As you know, we have submitted an application to the FDA and the EMA for approval of vimseltinib for the treatment of tenosynovial giant cell tumor, which is a non-malignant tumor. Applications for approval have been received in each of these areas and are currently under review.

Next, based on the results of Phase I studies conducted to date, we have initiated a new Phase II PoC study in Japan for ONO-1110, a drug candidate that regulates endogenous cannabinoids, targeting five candidate diseases.

The Phase II trials were initiated around the same time for the following five diseases: postherpetic neuralgia, fibromyalgia, Hunner type interstitial cystitis, major depressive disorder, and social anxiety disorder.

The word cannabinoid may remind some people of cannabis, which is one of the exogenous cannabinoid receptor agonists.

In contrast, ONO-1110 is a drug that aims to control endogenous cannabinoids. Medical marijuana has been reported to be effective to some extent for pain relief and depression, but on the other hand, central side effects such as euphoria and somnolence are problematic.

Since the mechanism of action of ONO-1110 is different from that of marijuana, we believe that ONO-1110 is a particularly promising new drug candidate. It is expected to demonstrate the positive pharmacological effects of cannabinoids while limiting these side effects. Accordingly, PoC trials were initiated for five diseases at approximately the same time.

In addition, we have initiated Phase I trials of ONO-2020, a drug candidate with a mechanism of action relating to epigenetics, for Alzheimer's disease and agitation associated with Alzheimer's disease, respectively.

On the other hand, ONO-2910, a drug candidate with Schwann cell differentiation promoting activity, was in Phase II trials in Japan for chemotherapy-induced neuropathy, but unfortunately, the expected efficacy was not confirmed, so development was discontinued and the drug has been removed from the table.

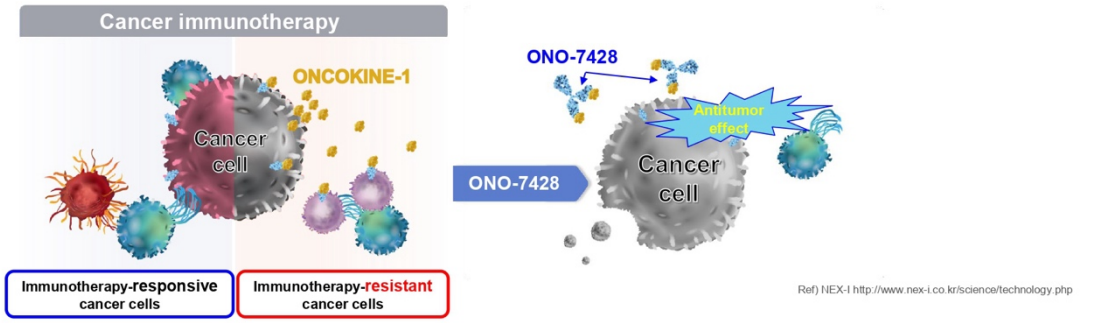
As I mentioned earlier, I would like to give an overview of ONO-7428, which has recently entered the clinical stage.

ONO-7428

- **First-in-class antibody drug candidate[2] targeting ONCOKINE-1[1]**
- **P1 study in solid tumors initiated in FY2024 2H**

【 Hypothetical Mechanism of Action】

- ONCOKINE-1 is a tumor-derived protein involved in the acquisition of resistance to cancer immunotherapy.
- ONCOKINE-1 acts on cancer cells and immune cells, contributing to cancer progression and exacerbation.
- ONO-7428 is a monoclonal antibody targeting ONCOKINE-1, inhibiting its function and exerting antitumor effects.



Ref) NEX-I http://www.nex-i.co.kr/science/technology.php

1) A novel target protein identified by South Korean company NEX-I as a factor leading to cancer immunotherapy resistance.
2) ONO entered into an exclusive global license agreement with NEX-I for the development and commercialization in March 2024.

26/45

ONO-7428 is a first-in-class antibody-drug candidate targeting ONCOKINE-1. We acquired the exclusive worldwide rights to develop and commercialize the product from NEX-I of Korea in March 2024.

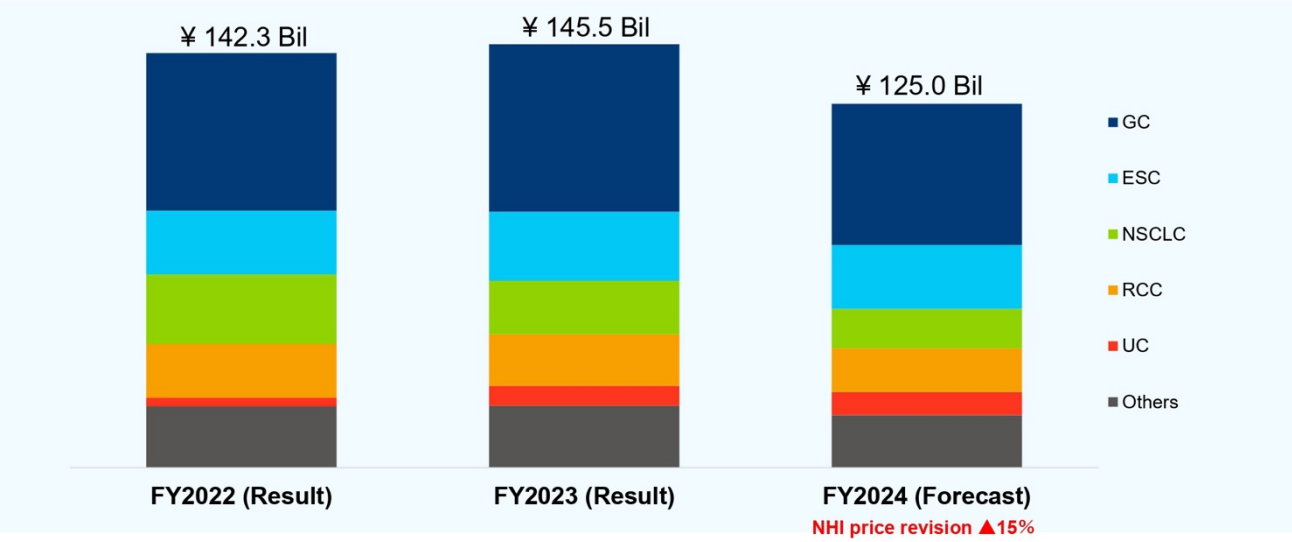
As shown in the picture on the left, ONCOKINE-1 is a protein secreted by cancer cells. The results of basic research suggest that its secretion is increased in cancer cells that have become resistant to cancer immunotherapy. ONCOKINE-1 is thought to be involved in tumor progression and exacerbation by acting on both cancer cells and immune cells.

We believe that ONO-7428 exerts its anti-tumor effect by inhibiting the action of ONCOKINE-1, and we have high expectations for ONO-7428 because of its very unique mechanism and its first-in-class status. We have just started Phase I trials in Japan.

This concludes my presentation. Thank you very much.

Imura: Now, Mr. Takahagi will continue with a presentation on OPDIVO trends.

Sales Trend of OPDIVO by Each Cancer

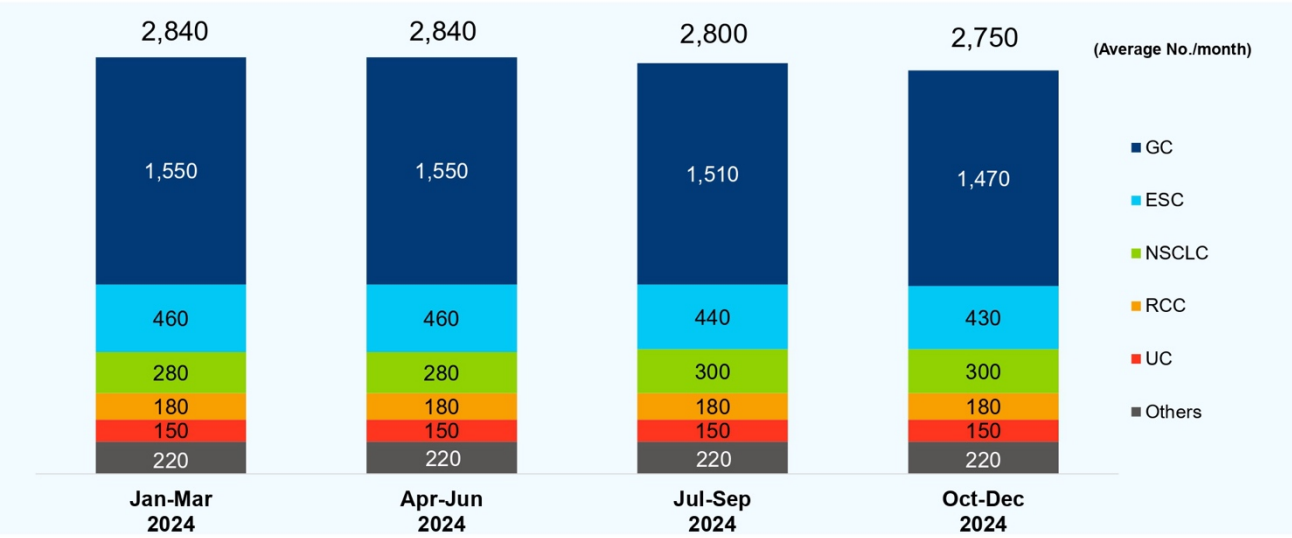


Source: Estimation from external and internal data 31/45

Takahagi: We expect to achieve our full-year forecast of JPY125 billion in the January-March period, even though we are a little behind schedule at JPY96 billion for April-December.

In the most recent external survey, we saw a recovery in the market share of new prescriptions in lung cancer, which is a large market. In gastric cancer, the use of competitive products is almost in line with expectations, and we will continue to take measures with competitive products in mind.

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



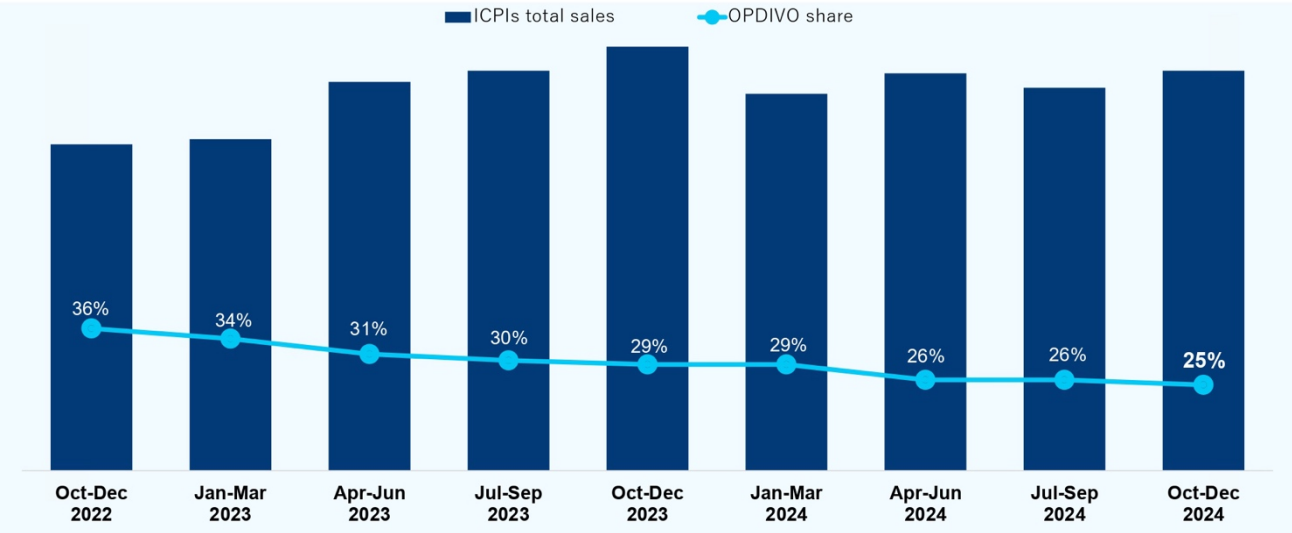
Source: Estimation from external and internal data
32/45

The following table shows the estimated number of new prescriptions of OPDIVO by cancer type, broken down by quarter and monthly averages.

In the most recent October to December period, 1,470 prescriptions were initiated for stomach cancer, 430 for esophageal cancer, and 300 for lung cancer.

Due to the impact of competing products, there were 40 cases of gastric cancer in first-line treatment and nearly 80% of esophageal cancer patients were treated with immune checkpoint inhibitors in first-line treatment. This resulted in a decrease in the number of naïve patients treated with immune checkpoint inhibitors in second-line treatment. As a result, the average number of cases per month was 2,750.

Trend of total sales of ICPIs and OPDIVO share

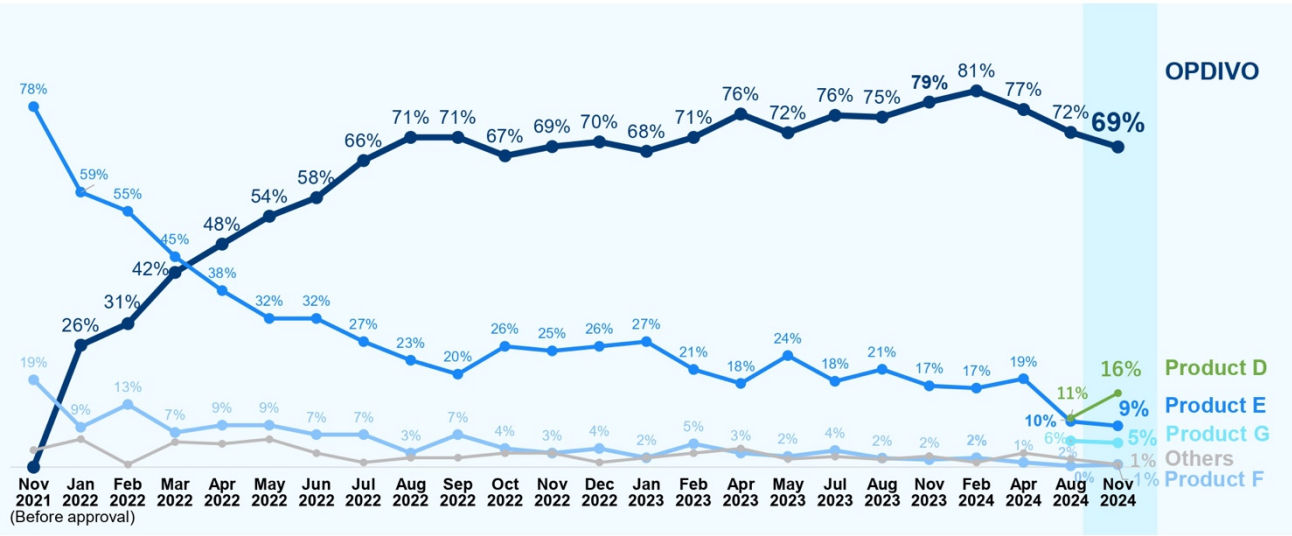


Source: External data

33/45

From October to December, OPDIVO's share of the immune checkpoint inhibitor market in Japan was 25%.

Prescription Ratio in Patients Newly Treated※ for 1L GC



※Patients starting 1L treatment within the last 3 month

Source: External data（Nov 2021~Nov 2024: n=200~204）

35/45

Next, I will focus on gastric cancer.

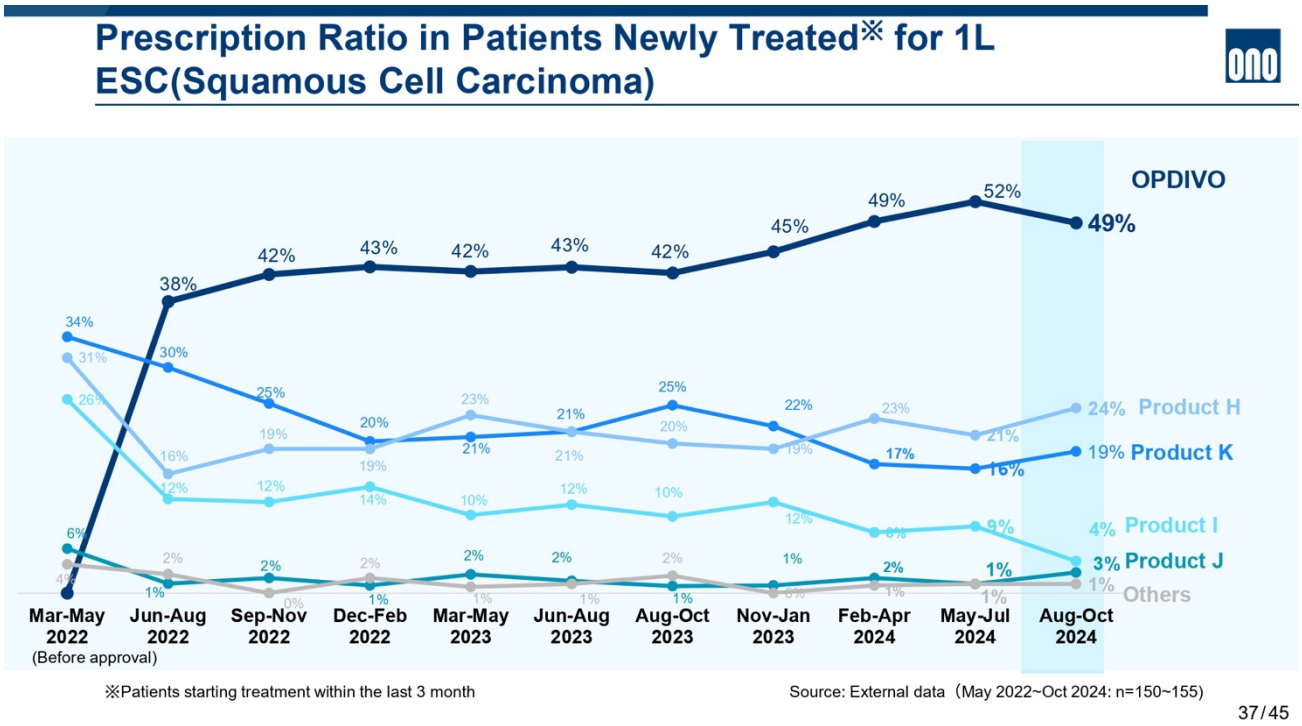
The share of new prescriptions for first-line treatment of gastric cancer is at 69%. The impact of competing products is largely in line with our expectations. Since the entry of competing products, OPDIVO's share of new prescriptions has dropped about 10% from its peak of 80%.

On the other hand, while chemotherapy was used in 20% of cases in the past, that figure is now at 10%. That 20% has been a target population for all competitors.

In particular, among competing products, we still see the addition to chemotherapy as a positive factor. We are currently conducting a thorough external and internal survey of the prescribing intentions of physicians, gastroenterologists and gastroenterological surgeons. We are currently in the process of examining the usefulness of competing products in actual clinical practice, and there have been cases in which the usefulness of OPDIVO has been re-evaluated.

In addition, an increasing number of physicians are selecting therapeutic agents based on the patient's age, tumor size, presence or absence of metastases, and subjective symptoms, among other factors. Therefore, we do not believe that it is currently possible for clinicians to prescribe a competing product simply because it is positive for some marker like claudin.

With OPDIVO, we have a two-and-a-half-year advantage in first-line treatment activities, and we would like to continue to secure 70% of the new prescription share by providing solid information on long-term follow-up data and real-world data in Japan. I will show you this data later.

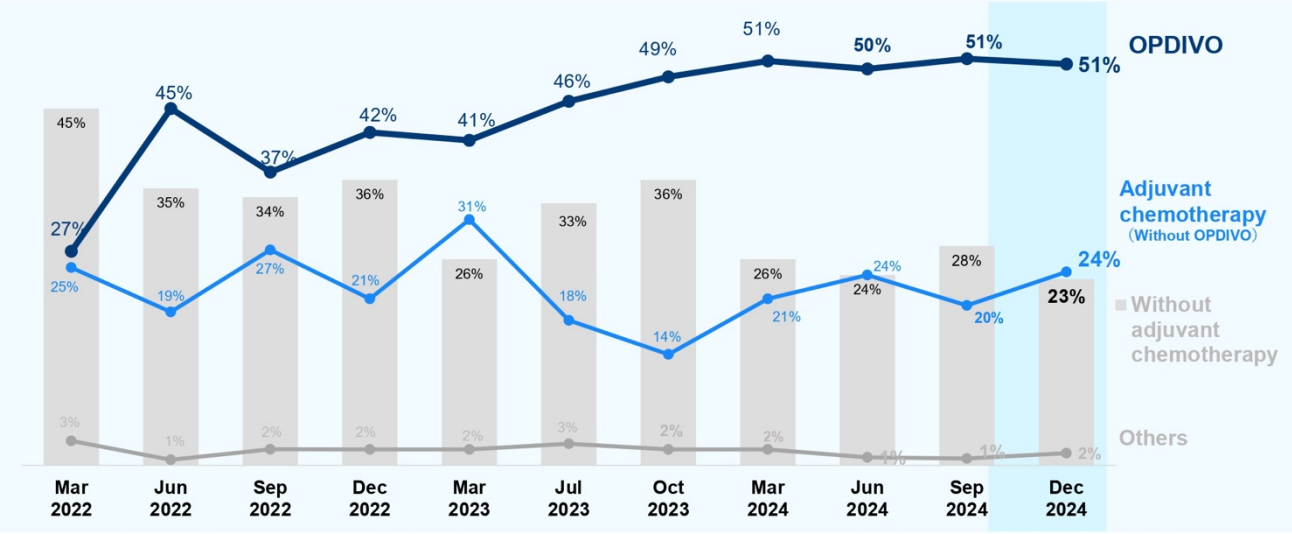


37/45

Next, the share of new prescriptions for primary treatment of esophageal cancer is 49%.

The issue is how to distinguish the use of the combination of OPDIVO and YERVOY and IO chemotherapy including OPDIVO, and we are working on this issue.

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



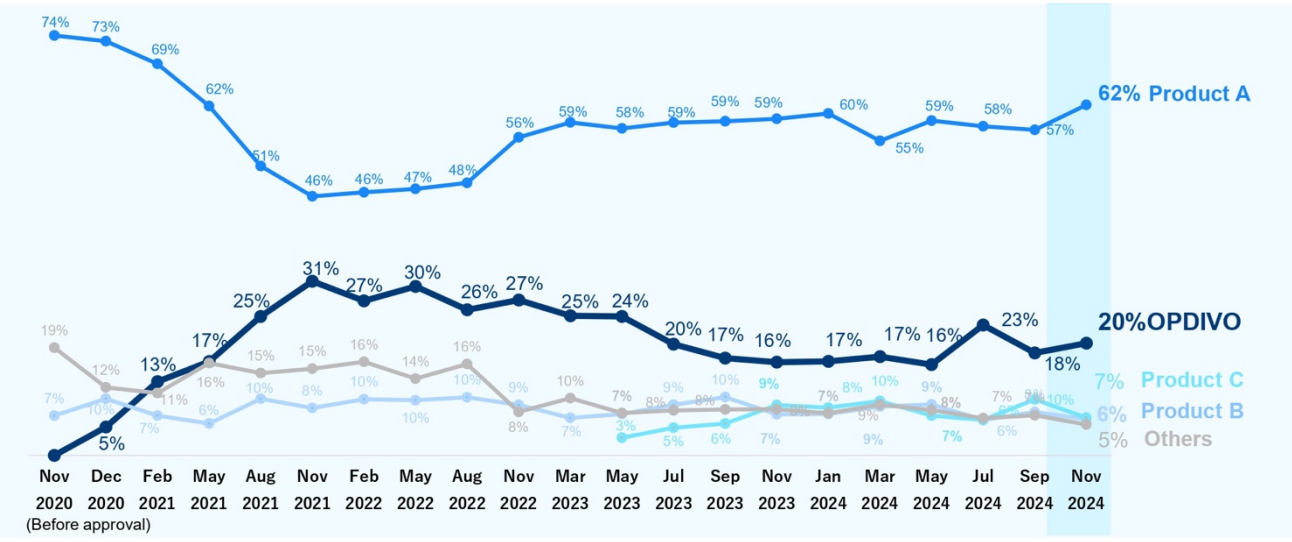
※Patients starting treatment within the last 3 months

Source: External data（Mar 2022~Sep 2024 n=130~152)

Next, the share of new prescriptions for postoperative adjuvant esophageal cancer is now 51%.

There are a certain number of physicians who are challenged by the prolonged DFS effect of OPDIVO and the management of side effects, leaving some patients with chemotherapy only or no chemotherapy. We would like to continue to firmly educate the public about the usefulness of OPDIVO and speed up the process here.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC

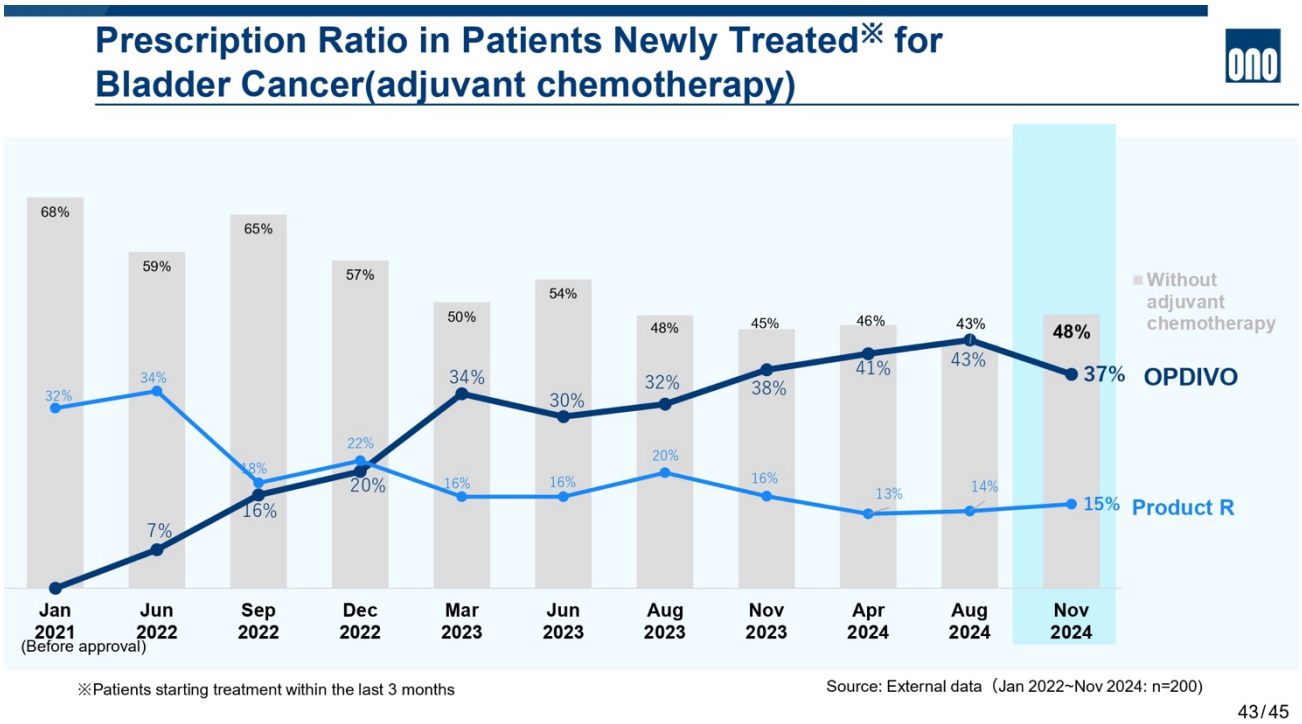


※Patients starting 1L treatment within the last 1 month (Except Driver Mutation)

Source: External data（Nov 2020~Nov 2024: n=167~245)

The share of new prescriptions for first-line treatment in non-small cell lung cancer is 20%.

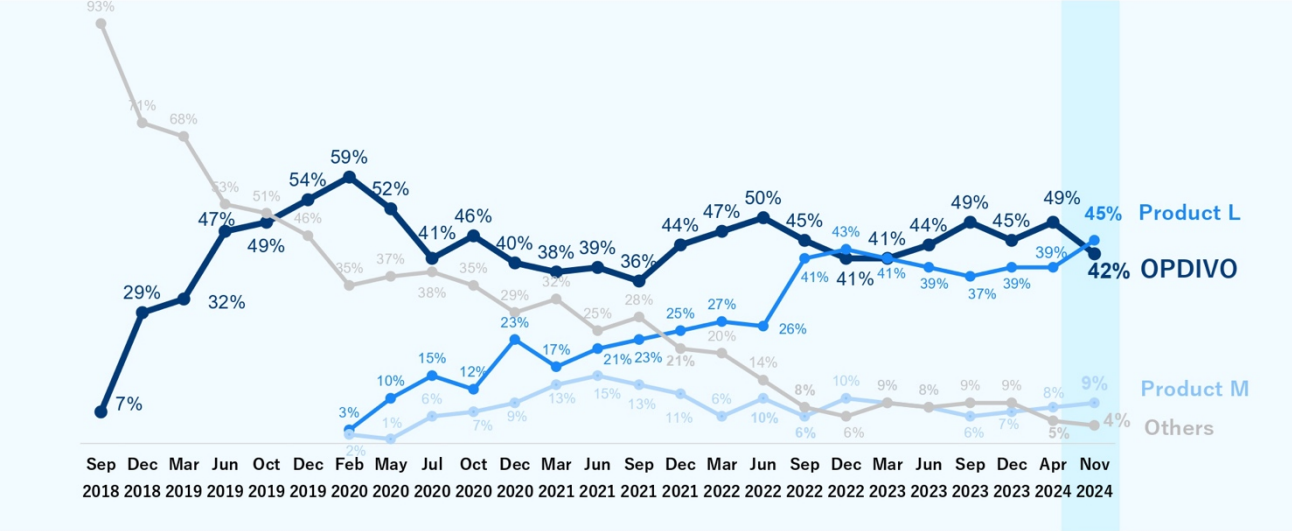
The efficacy and safety demonstrated in CheckMate-227 and CheckMate-9LA are becoming more widely recognized through follow-up data, and safety concerns have been shrinking since the JCOG press release. We are in the process of regaining ground here.



The share of new prescriptions for postoperative adjuvant therapy for urothelial carcinoma was 37%.

Although there is a slight downward trend from the previous survey, we consider this to be within the margin of error. The percentage of physicians who recognize the image of patients at high risk of recurrence has risen to about 50% in external data. However, on the other hand, half of physicians are still unable to match this perception of the patient's risk of recurrence. We are firmly strengthening our information activities to dispel this.

Prescription Ratio in Patients Newly Treated※ for 1L RCC



※Patients starting treatment within the last 3 months

Source: External data（Sep 2018~Nov 2024: n=46~150）

45/45

The share of new prescriptions for renal cell carcinoma is currently at 42%.

We believe that there is a slight decline in the perception of the value of YERVOY among urologists. The eight-year follow-up data for CheckMate-214 was comprehensively presented last November and December. The follow-up data were very positive and have highlighted the value of YERVOY, particularly for the 75% of the market that is intermediate- and high-risk renal cell patients.

We are currently discussing the use of OPDIVO, YERVOY, IO, and TKI in combination, and we are getting a good response. According to MR reports, there are no signs of a reduction. We will continue to focus on this area. Along with the information on urothelial carcinoma I just presented, we will continue to work on this too as a set.

With an eye to the large lung cancer market in particular, we are looking forward to entering a growth phase as new indications may soon be added. With the current fiscal year as the low point, we are confident of the coming growth phase as our products are used in first-line treatment of gastric cancer and lung cancer.

We will continue to firmly engage in activities to meet the unmet needs of cancer patients. Thank you. Thank you very much.

Question & Answer

Imura : First of all, Mr. Yamaguchi of Citigroup Securities, please go ahead.

Yamaguchi : I think that the first part of Q3 of the financial results shows that there were various intangible expenses on a full basis, or rather on a normal basis, not core. On a normal basis, there was the incorporation of such expenses.

Just to confirm, this is in Q3 in the year-to-date, but it was not in Q1 or Q2, so it is only in Q3 for convenience, numerically speaking.

Itoh : Please refer to page 15 of the reference material. The cost of sales, for example, is shown here as JPY15.1 billion, and this amount includes the amortization of six-months of QINLOCK.

Yamaguchi : Yes, that's right. So, if we take out only Q3, not including Q1 and Q2, just Q3, it looks like gross profit has dropped considerably. Are you saying that's a significant effect?

Itoh : Yes. That's right.

Yamaguchi : Is it correct to say that this will not be the case in the future, and that only Q3 includes it for six months, and after that, the costs will be handled and priority periods will be handled?

Itoh : Yes, that's right. In Q4, the period to be announced this coming May, it will be a nine-month cumulative total, with the remaining three months to be multiplied. Reference: For the Q2 of the fiscal year 2024, the results will be revised to reflect the depreciation for 3 months under PPA when the results for the Q2 of the fiscal year 2025 are disclosed.

Yamaguchi : I see. I understand. I don't mind if it's core or operating income, though the progress rate is quite high, especially when you look at core. There are some areas externally that are slightly harder to see because the core and full have been separated. The rate of progress against the full-year forecast is quite high. Is your company's view that the progress is quite good, or rather better than expected? Or is it an assumed trend? How do you see the rate of progress in this area?

Itoh : We get that question in Q3 every year. The issue is that some of the other expenses are not evenly distributed. The plan is not to prorate the profit and loss evenly quarterly, so the profit and loss is in line with the original plan. From the outside, the progress will appear very strong, but we expect to be roughly on schedule as expenses come in during Q4.

Yamaguchi : I see. So internally, things are steady.

Itoh : Yes.

Yamaguchi : I understand. Also, just one more thing, sorry, QINLOCK has been revised upward, but have you not amended the full-year forecast. Is there some latent potential upside there? Or are there other things that are driving down sales? Only QINLOCK is up, but only a little bit.

Itoh : There is a positive factor of JPY1.5 billion, but there is also the impact of generics in Japan. Although we have not changed the overall product sales forecast, I think there is a risk goes up and down, so we will keep the total unchanged.

Yamaguchi : I understand. Lastly, ONO-1110 is being developed for an increased number of indications at once. It seems to me that this compound is getting a lot of attention from the Company. I'm wondering what areas it will be competing in. Of course, the Company is trying to develop the drug as quickly as possible. I just think that you must be getting a good feel by now as to what areas it will be strongest in. Could you comment on that?

Okamoto : First of all, we are aware that there are no competing products in the same class. As for the expectations, as I explained in my presentation earlier, we believe that the mechanism is very -- it is a little difficult to describe -- promising. Therefore, we have just started a Phase II study to establish PoC for three pain-related diseases and two psychiatric-related diseases at the same time.

To add a little more about the word promising for example, ONCOKINE-1, 7428, which I mentioned earlier, is thought to act on both cancer cells and tumor immunity at the basic level, but there is no evidence in humans at this time.

Regarding ONO-1110, it regulates cannabinoid at least. We already know that medical marijuana has a certain degree of clinical efficacy with regard to pain and psychiatric disorders, as I mentioned earlier. We have taken all of these factors into consideration and have started looking at these five areas.

Yamaguchi : I understand. Pharmacologically, it is probably possible to separate them, but if it is somehow associated with the image of marijuana, it will be difficult to do so.

Okamoto : Yes. You're right. Of course, the pharmacological action is different from medical marijuana in that it controls endogenous cannabinoids.

Yamaguchi : I understand. That's all from me. Thank you very much.

Imura : Next, Mr. Wakao of JPMorgan Securities.

Wakao : Thank you very much. I understand from Mr. Yamaguchi's previous question about the outlook for this fiscal year. Could you please share your thoughts on the next fiscal year?

If we consider the next fiscal year from a core perspective, I think we can expect sales and profit growth since new drugs will be added to the product lineup. On the other hand, it is difficult to see the full contribution of amortization expenses and other such areas in the case of reporting.

Itoh : As for the next fiscal year, the impact of the PPA will be nine months for this fiscal year and 12 months for the next fiscal year, and the burden of amortization for three months will be heavy, as you mentioned. You are correct in pointing out that the full IFRS basis would increase the cost of that.

On the other hand, there is no way to clearly say at this point how much of that can be covered by new drug sales, so I will be able to provide more detailed explanations once we have sales figures.

Wakao : I understand. What about in the core figures? I think what you just said is more of a reported story, but how about in the core?

Itoh : For the core, we have not yet identified any factors that would cause a large increase or decrease, so it is still a bit unclear, but we will be able to explain the positive and negative factors in this financial statement while looking at the control of expenses.

Wakao : I understand. About vimseltinib, I think the PDUFA date is close on Feb 17. I am not sure if there is any problem with the approval, but I would like to know if there are any changes in the status of the screening

process or any other areas. Also, what is your company's current position regarding market penetration after the product is launched?

There are existing drugs, and if you can differentiate from them in terms of safety, can we expect a reasonable speed of market penetration? Or do you envision a gradual market penetration? To sum up, what is your company's position on the current approval and on subsequent market penetration?

Okamoto : Regarding the status of the review, as you indicated earlier, the FDA review is well under way with a February 17 deadline. As for the details, I am afraid that we do not disclose the contents of review by authorities in the US.

And regarding speedy market penetration, I can't speak to that point because we are still in the process of getting approval. As you mentioned earlier, due to hepatotoxicity of the preceding product, we were unable to achieve the market penetration that we had originally planned.

Vimseltinib has a superior safety profile, at least in clinical trials, compared to its competitors and predecessors. From this point of view, we expect it to penetrate the market relatively quickly in terms of filling an unmet need.

Wakao : Understood. I think the earlier products were covered by REMS, but you are basically assuming that your company's products are not covered by REMS.

Okamoto : I'm sorry. At this time, with the application under review, I would like to refrain from discussing the details of the review.

Wakao : I understand. The other thing is the situation in the US, as you mentioned earlier, with Velexbru. Is the application due this year, or could you be a little more specific about the timing of the data readout, for example, is it July to September or October to December?

Okamoto : In the non-oncology pipeline Slide, I have not written here what month or when, but I hope you understand that the results will be available in the not-too-distant future. I cannot be more precise than that.

Wakao : Okay. Yes, the information is not on the clinical trials site. As I recall, the primary is completion is listed, and I think it's the timing of Part B. So, I asked the question because I don't know when Part A ends. When you say you don't have anything to report, is it correct to think of it as a time frame in the next two or three months or something like that?

Okamoto : I think you can take it that way, that it is not in a distant future.

Wakao : I understand. Thank you very much. That is all.

Imura : Next, Mr. Muraoka from Morgan Stanley, please go ahead.

Muraoka : Morgan Stanley, Muraoka. About Deciphera, I just want to ask sure about QINLOCK, for confirmation.

I do think that sales are strong, you have made upward revisions, and the exchange rate assumption has not changed from JPY145, so I think it is genuinely strong. Suppose at the end of the year, at the end of December, for example, the inventory swelled and there was a risk of a rebound in January to March, or there is this risk in terms of insurance reimbursement.

Likewise, the Deciphera costs are much higher in the October to December period than in the July to September period, although I don't know since I subtracted the cost in yen terms. Would you be able to give us some more information on whether the cost will be more in January to March as well?

Itoh : You are right that QINLOCK sales are increasing not only in yen terms but also in dollar terms. I am not sure if the increase in the dollar base has been preempted in the January to March period or not, but I think there is some risk of it. In terms of the full-year forecast, we do not anticipate any deviations in this area.

In terms of costs, it is not just QINLOCK. In Q3, we also had to pay for various preparations prior to the sale of vimseltinib, which is the reason for the increase in costs.

Muraoka : If you spent pre-launch expenses from October to December, is it possible that you will spend a little more from January to March, and that the Deciphera portion of the cost will be a little higher than planned?

Itoh : The impact on the overall amount is minor, but there will be some portion of that cost.

Muraoka : I understand. Earlier, I think Mr. Wakao asked what the core operating profit will be for the next fiscal year. I think the loss of Deciphera will decrease no matter how you look at it, so I think the next fiscal year will to some extent be more profitable on a core basis. What, if anything, am I overlooking about the risks to increased profit here?

Itoh : Even on a core basis, the Deciphera loss, operating loss will be incurred for 3 months in the next term..

Muraoka : Yes, that's right. So, nine months will become 12 months. Does that mean it still won't change much?

Itoh : That amount will have an operating loss impact. How much of that can be covered by sales revenue and vimseltinib sales is still too early to say at this point.

Muraoka : I see. I understand. Lastly, ONO-1110, endogenous cannabinoid. This is something I saw in the development of a new drug for another company, so I am not sure if it applies to your company. Pain medications, antidepressants and psychotropics have a placebo effect, or an ambiguous evaluation system, and it is sometimes disappointing when something that is supposed to work doesn't work. Of course, I understand that it is a cannabinoid, so it should work, but should we not worry too much about that, at least in the Phase II stage?

It seems that safety is an important factor. Is there anything you can tell me at this stage to reassure me about this area? I would like to know about the safety of this compound, as well as the potential for addiction.

Okamoto : Thank you. Generally speaking, for those of us involved in clinical development in this industry, the placebo effect is very large in the development process for indications such as pain, depression, and social anxiety. It is difficult to find clinical significance in these diseases.

This is not purely from the viewpoint of whether the drug was effective or not but also from the viewpoint of whether the clinical trial was executed according to the protocol. Regarding the execution of the trial, we take the points you have just pointed out very seriously.

As far as I can tell, three of the five candidate diseases will be monitored in-house, manufactured in-house, and tested under our direct supervision. I can't think of anything that would eliminate the clinical and placebo effects more than that.

Regarding safety, other than the fact that there were no problems in Phase I, there is no other information that I can provide at this time. In Phase II, we will naturally evaluate not only efficacy but also safety, which we expect will become clear in the future. Thank you.

Muraoka : Thank you very much. Are you saying that in preclinical and other areas, the addictiveness is separable?

Okamoto : Based on the data we have obtained so far, as I mentioned earlier, we believe that there are no side effects like those seen when exogenous cannabinoids are administered.

Muraoka : I understand. Thank you very much. That is all.

Imura : Mr. Sakai of UBS Securities, please go ahead.

Sakai : You disclosed the breakdown of intangible assets this time, and you said that QINLOCK and vimseltinib amounted to JPY150 billion and JPY160 billion, respectively. I believe you once mentioned that QINLOCK's peak sales were approximately JPY40 billion to JPY50 billion. One thing to confirm is whether this breakdown of intangible assets was done on that basis.

And one more thing, your company does not provide core EPS, is there any reason for this? Thank you.

Itoh : Regarding sales, QINLOCK is evaluated also based on additional indications.

Sakai : So, you are talking about the JPY40 billion to JPY50 billion? Or are you saying that there is a further addition to this?

Itoh : In terms of money, we are talking about JPY40 billion to JPY50 billion.

Sakai : I understand. Is it my understanding that vimseltinib has also allocated intangible assets based on that expected amount?

Itoh : The time period is different between vimseltinib and QINLOCK, so I am not sure if the numbers are completely accurate, but I hope you understand that the scale is similar.

Sakai : I understand.

Itoh : You also asked about why there is no core EPS. In Q3, the actual results of core EPS are shown at the top of the brief, but the actual results are not shown at the bottom of the brief. The forecast below that is also stated as basic core net income EPS, JPY172.46, starting from Q3.

Sakai : I'm sorry. I missed that. So now, in a nutshell, the core will continue to be disclosed, including the forecast for the next fiscal year?

Itoh : Yes.

Sakai : One last point, about the subcutaneous OPDIVO, is it my understanding that the decision has been made that SC cannot be used for the combination part with YERVOY?

Okamoto : As you understand, at this time, it is not possible to administer it in combination with YERVOY or at the same time as YERVOY.

Sakai : You mentioned about maintenance, or rather, switching to SC after the YERVOY is finished. Would that still be the main focus, and would it be a bit difficult to use SC in combination with YERVOY? What are your thoughts there?

Okamoto : Yes, that's right. At this point, I'm afraid I'm repeating myself, but it's an indication that was originally obtained in the dosage and administration of YERVOY up to how many times and in combination with OPDIVO up to how many times. After YERVOY administration is completed, patients will be treated with OPDIVO monotherapy, so it can be used for those indications that require it.

So, for example, the first-line treatment for MSI-High, as I mentioned earlier. Here too, the first few times will be in combination with ipilimumab, and after that, OPDIVO monotherapy can be used, and that can be by subcutaneous injection.

Sakai : I understand. So that is what Bristol is saying about coexistence with IV OPDIVO and ipilimumab.

Okamoto : Yes. I am not sure in detail what specifically BMS have said on this, but I think we are basically talking about switching about 30% to 40% of the intravenous drugs to subcutaneous injection.

Sakai : I understand. Thank you very much.

Imura : Thank you very much. This concludes our meeting.

[END]