ONO PHARMACEUTICAL CO., LTD.

Q1 Financial Results Meeting for the Fiscal Year Ending March 2025

July 31, 2024

[Number of Speakers]	5	
	Satoshi Takahagi	Corporate Executive Officer, Executive Director, Sales and Marketing
	Masaki Itoh	Corporate Officer, Division Director, Corporate Strategy & Planning
	Tatsuya Okamoto	Corporate Officer, Executive Director, Clinical Development
	Masayuki Tanigawa	Corporate Officer, Executive Director, Corporate Development & Strategy
	Ryuta Imura	Senior Director, Corporate Communications

Presentation

Imura: Thank you very much for attending ONO PHARMACEUTICAL CO., LTD.'s Financial Results Meeting for the Q1 of the fiscal year ending March 2025 today. We will be holding a presentation session in online format from now on.

Agenda

2025年3月期第1四半期決算概要 (14:00-14:15)
Material for Financial Announcement FY 2024 Q1

執行役員　経営戦略本部　経営管理統括部長
Corporate Officer / Division Director, Corporate Strategy & Planning
伊藤　雅樹
Masaki Ito

開発品の進捗状況 (14:15-14:30)
Development Pipeline Progress Status

執行役員　開発本部長
Corporate Officer / Executive Director, Clinical Development
岡本　達也
Tatsuya Okamoto

オプジーボの動向 (14:30-14:45)
Trend of Opdivo

常務執行役員　営業本部長
Corporate Executive Officer /
Executive Director, Sales and Marketing
髙萩　聰
Satoshi Takahagi

質疑応答
Q&A Session (14:45-15:00)

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Itoh will provide an overview of the financial results.

FY2024 Q1 : Financial Overview

Operating profit was ¥30.7 billion, a decrease of ¥10.7 billion (25.8%), mainly due to the revision of the National Health Insurance(NHI) drug price, a decrease in royalty rates from Merck and others, and an increase in expenses associated with the acquisition of Deciphera, despite increases in sales of Forxiga Tablet and royalty revenue from Bristol-Myers Squibb.

¥ Billion	FY2023Q1	FY2024Q1	YoY		FY2024 (Forecast)
			Change	Change (%)	
Revenue	120.0	117.7	(2.3)	(1.9%)	450.0
Cost of sales	30.2	29.7	0.5	(1.7%)	113.0
R&D expenses	24.6	28.9	4.3	17.4%	112.0
SG&A expenses	23.5	27.9	4.4	18.8%	100.0
Other income	0.1	0.0	(0.1)	(68.5%)	0.5
Other expenses	0.6	0.6	0.1	10.1%	3.5
Operating profit	41.3	30.7	(10.7)	(25.8%)	122.0
Net financial income	1.0	2.6	1.6	153.7%	1.0
Profit before tax	42.4	33.3	(9.1)	(21.4%)	123.0
Profit for the period (attributable to owners of the Company)	31.8	24.8	(7.0)	(22.1%)	91.0

YoY Breakdown (Profit up)(Profit down)

Sales revenue ¥-2.3 billion
- Sales of OPD: ¥-5.7 billion (37.8→32.1)
- Sales of FXG: ¥4.6 billion (17.5→22.2)
- Royalty revenue from BMS: ¥5.9 billion (22.6→28.5)
- Royalty revenue from Merck: ¥-5.9 billion (122→63)

R&D Expenses ¥+4.3 billion (R&D ratio : 24.5%)

Main reasons
- Increases in research costs
- Increases in development costs for clinical trials

SG&A Expenses ¥+4.4 billion yen

Main reasons
- Expenses associated with the acquisition of Deciphera
- Co-promotion fees for Forxiga Tablets

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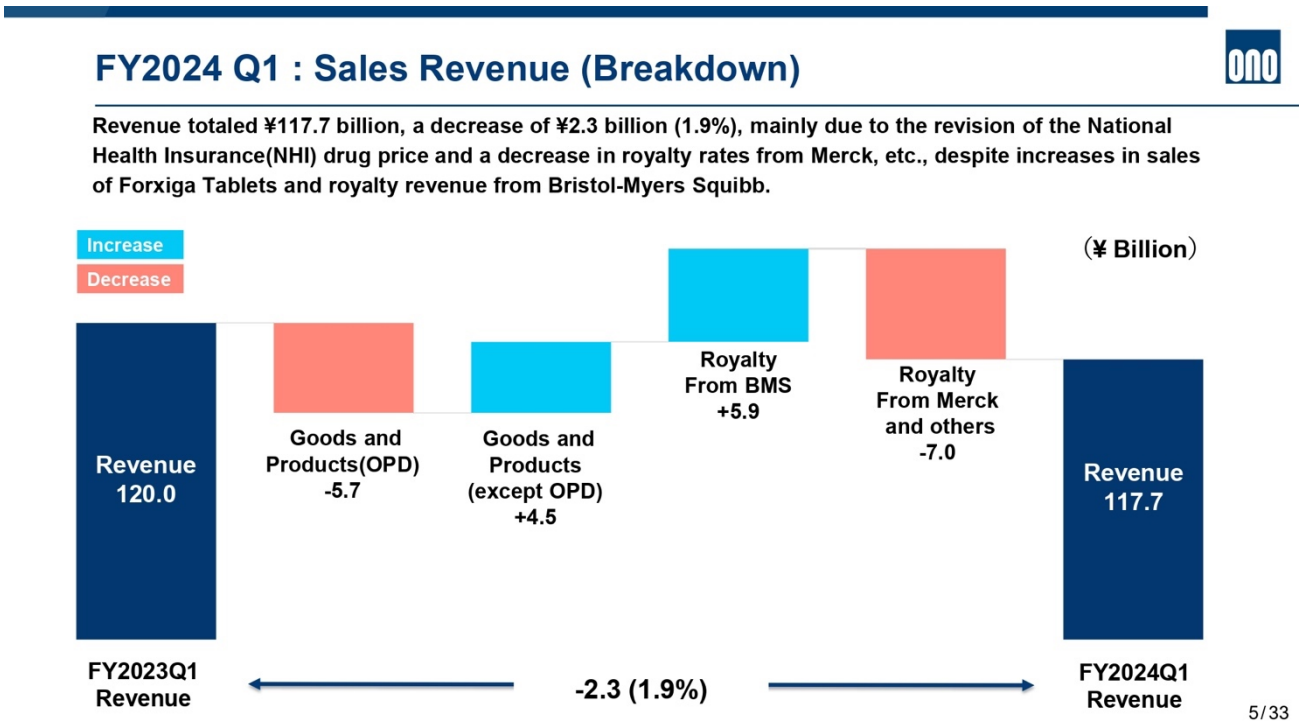
Itoh: I will now report an overview of our financial results for Q1.

This is a summary of our business results for Q1 of the fiscal year ending March 31, 2025. Revenue decreased by JPY2.3 billion, or 1.9%, to JPY117.7 billion, operating profit decreased by JPY10.7 billion, or 25.8%, to JPY30.7 billion, and profit for the period attributable to owners of the Company decreased by JPY7 billion, or 22.1%, to JPY24.8 billion.



Here is a detailed explanation of each item. First is revenue. On the one hand, Q1 revenue decreased due to OPDIVO NHI price reductions, royalty income from Merck and others, and lower royalty rates.

On the other hand, sale of FORXIGA tablet with expanded use for chronic kidney disease and royalty revenue from Bristol-Myers Squibb increased, as a result, revenue decreased by JPY2.3 billion, or 1.9%, to JPY117.7 billion from JPY120 billion in Q1 of the previous year The progress rate against the full-year plan is 26.2%.

FY2024 Q1 : Sales Revenue

¥ Billion	FY2023Q1	FY2024Q1	YoY		FY2024 Forecast
			Change	Change (%)	
Revenue	120.0	117.7	(2.3)	(1.9%)	450.0
Goods and products	80.5	79.3	(1.2)	(1.5%)	304.0
Royalty and others	39.5	38.3	(1.1)	(2.9%)	146.0
OPDIVO	22.6	28.5	5.9	25.9%	
KEYTRUDA®	12.2	6.3	(5.9)	(48.5%)	

Sales of Main Products (Gross Sales Basis)	FY2023Q1	FY2024Q1	YoY		FY2024 Forecast
			Change	Change (%)	
Opdivo Intravenous Infusion	37.8	32.1	(5.7)	(15.1%)	125.0
Forxiga Tablets	17.5	22.2	4.6	26.4%	83.0
Orencia for Subcutaneous Injection	6.6	6.9	0.3	4.5%	27.0
Glactiv Tablets	5.6	5.0	(0.6)	(10.7%)	18.5
Velexbru Tablets	2.6	2.7	0.1	3.9%	10.0
Kyprolis for Intravenous Infusion	2.2	2.3	0.1	3.0%	9.5
Parsabiv Intravenous Injection	2.1	2.1	(0.0)	(0.3%)	8.5
Ongentys Tablets	1.6	1.9	0.4	23.2%	7.5

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Goods and products decreased by JPY1.2 billion, or 1.5%, from the same period last year to JPY79.3 billion.

Overview by product. Sales of anti-cancer agent OPDIVO for intravenous infusion decreased by JPY5.7 billion, or 15.1%, to JPY32 billion due to the NHI price reduction.

FORXIGA tablets, a drug for diabetes, chronic heart failure and chronic kidney disease, increased by JPY4.6 billion, or 26.4%, to JPY22.2 billion due to expanded use in chronic kidney disease.

Among other major products, sales of Orencia for Subcutaneous Injection, a treatment for rheumatoid arthritis, increased by JPY300 million, or 4.5%, to JPY6.9 billion, and sales of VELEXBRU Tablets, an anti-cancer agent, rose by JPY100 million, or 3.9%, to JPY2.7 billion, despite a 15% reduction in the NHI price.

Sales of KYPROLIS for Intravenous Infusion, a treatment for multiple myeloma, increased by JPY100 million, or 3%, to JPY2.3 billion, and sales of ONGENTYS Tablets, a treatment for Parkinson's disease, increased by JPY400 million, or 23.2%, to JPY1.9 billion.

On the other hand, sales of GLACTIVE Tablets, a treatment for type II diabetes, decreased by JPY0.6 billion, or 10.7%, to JPY5 billion, and sales of PARSABIV Intravenous Injection, a treatment for secondary hyperparathyroidism under hemodialysis, remained almost unchanged at JPY2.1 billion.

In Royalty and others, royalty income from Bristol-Myers Squibb increased, but royalty income from Merck and other companies decreased due to a decline in royalty rates, resulting in a YoY decrease by JPY1.1 billion, or 2.9%, to JPY38.3 billion.

Royalty income from Bristol-Myers Squibb related to OPDIVO Intravenous Infusion increased by JPY5.9 billion to JPY28.5 billion YoY, while royalty income from Merck related to KEYTRUDA decreased by JPY5.9 billion to JPY6.3 billion.

Next is operating profit. Operating profit decreased by JPY10.7 billion, or 25.8%, from the same period last year to JPY30.7 billion. Revenue decreased by JPY2.3 billion to JPY117.7 billion, while cost of sales decreased by JPY0.5 billion, or 1.7%, to JPY29.7 billion.

R&D expenses increased by JPY4.3 billion or 17.4% from the same period last year to JPY28.9 billion due to an increase in expenses related to research and clinical trials. The full-year plan is 25.8% ahead of the JPY112 billion target, which is almost in line with the plan.

SG&A Expenses increased by JPY4.4 billion, or 18.8%, to JPY27.9 billion, mainly due to an increase in co-promotion expenses in line with higher sales of FORXIGA Tablets, as well as expenses related to the acquisition of Deciphera.

As a result, operating profit decreased by JPY10.7 billion, or 25.8%, from the same period last year to JPY30.7 billion.

Next is Profit before tax. Profit before tax decreased by JPY9.1 billion, or 21.4%, YoY to JPY33.3 billion, as a result of financial income of JPY2.7 billion and financial expenses of JPY0.1 billion, resulting in a net outflow of JPY2.6 billion, an increase of JPY1.6 billion from the same period last year.

Finally, Profit for the period attributable to owners of the Company decreased by JPY7 billion, or 22.1%, from the previous year to JPY24.8 billion, due to lower Profit before tax.

FY2024 : Financial Forecasts

No changes from the consolidated financial forecasts, announced on May 9, 2024. The impact of the acquisition of Deciphera on the consolidated financial results is currently being reviewed.

¥ Billion	FY2023 (Actual)	FY2024 (Forecast)	Change	Change (%)
Revenue	502.7	450.0	(52.7)	(10.5%)
Cost of sales	127.1	113.0	(14.1)	(11.1%)
R&D expenses	112.2	112.0	(0.2)	(0.2%)
Ratio of R&D to revenue	22.3%	24.9%		
SG&A expenses	100.3	100.0	(0.3)	(0.3%)
Other income	1.2	0.5	(0.7)	(57.5%)
Other expenses	4.3	3.5	(0.8)	(19.4%)
Operating profit	159.9	122.0	(37.9)	(23.7%)
Net financial income	3.8	1.0	(2.8)	(73.7%)
Profit before tax	163.7	123.0	(40.7)	(24.9%)
Profit for the period (attributable to owners of the Company)	128.0	91.0	(37.0)	(28.9%)

- The annual exchange rate assumed in this forecast is 1 USD＝145 yen. Foreign exchange sensitivity in case of a depreciation of 1 yen may increase revenue and operating profit by ¥0.6 billion and ¥ 0.2 billion, respectively.

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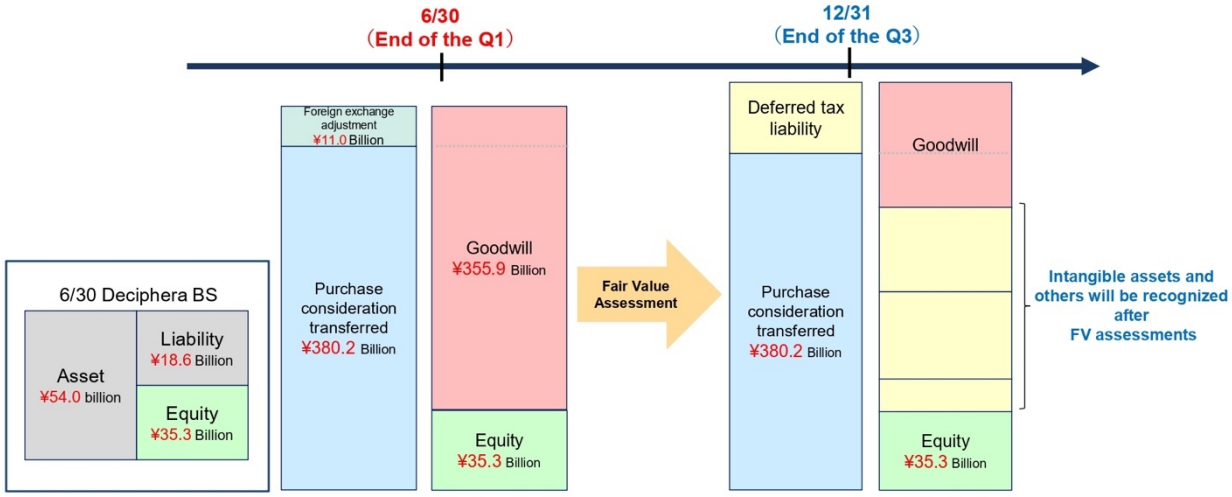
Next is the financial forecasts. The financial forecast for the fiscal year ending March 31, 2025 remains unchanged from the forecast announced on May 9.

In addition, there is no change in the sales forecast for each of the major products shown on page 13 of the Financial Statements from the figures announced at the beginning of the fiscal year.

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

- During the first quarter, the difference between the purchase consideration transferred and the equity was recorded as goodwill（Provisional accounting treatment）.
- Intangible assets and others as of the acquisition date will be recognized through fair value assessments by the end of third quarter.



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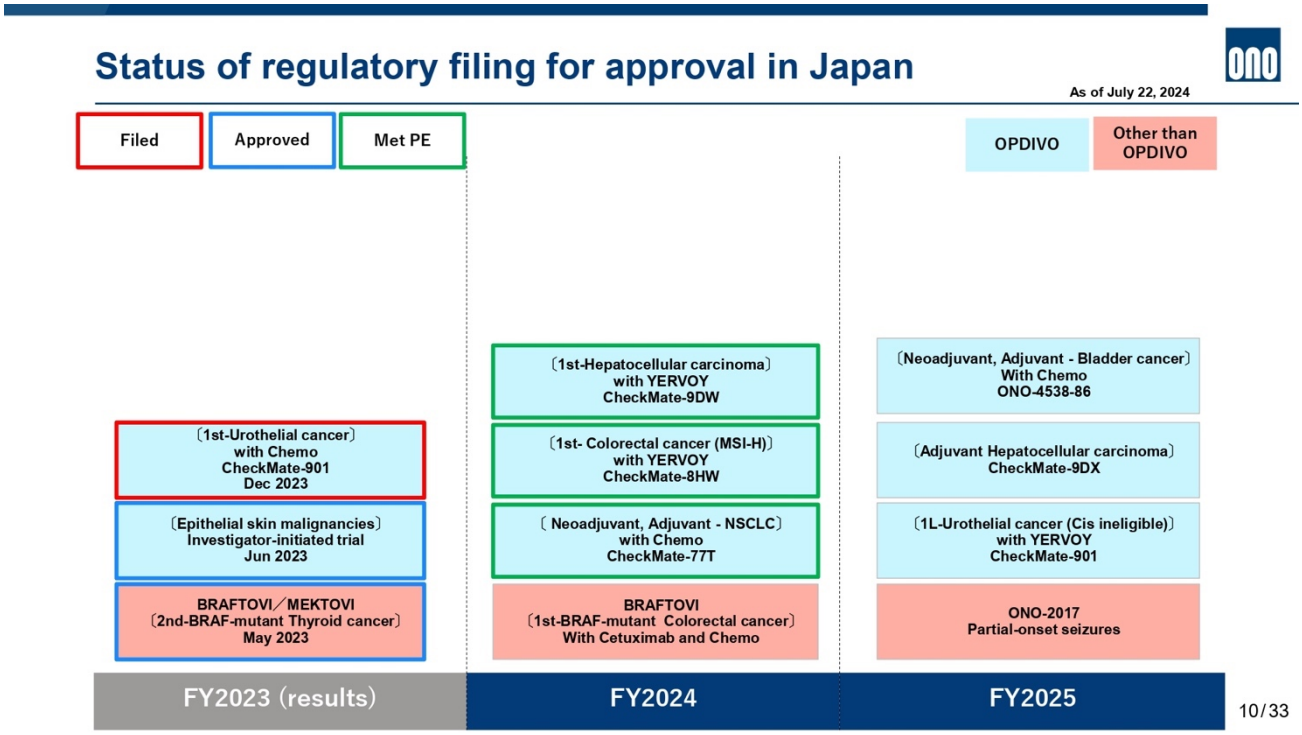
Although the impact of the acquisition of Deciphera on the Group's results is still under scrutiny, the consolidated financial statements for Q1 of the current fiscal year have been prepared using June 30 as the deemed acquisition date for Deciphera, rather than June 11, the actual acquisition date.

Therefore, the performance results are not incorporated into the consolidated statements of income, but are reflected only in the consolidated balance sheets. In addition, in incorporating the information into the balance sheet, the difference between the purchase transferred consideration and Deciphera's net assets is accounted for as goodwill on a provisional basis.

The fair value assessment of the difference between the acquisition consideration and Deciphera's net assets is expected to be completed by the end of Q3, at which time a portion of the goodwill will be identified in the respective intangible assets.

This is all about business performance.

Imura: Next, Okamoto, Executive Director, Clinical Development, will continue with an update on the progress of the main development pipeline.



Okamoto: I would like to mainly explain the changes since May 9 of this year, using the development pipeline progress materials posted on our website.

First, this shows the schedule for application in FY2024. There have been two changes since the last time. The first is that the CheckMate-73L study for curatively irradiable non-small cell lung cancer unfortunately did not yield the expected results, as we have already announced in the press release, and therefore, it has been removed from the planned application schedule.

Another point, the ONO-4538-86 study for preoperative and adjuvant therapy of bladder cancer, is expected to be filed in FY2025, as the timing of obtaining the results is expected to be delayed.

As explained previously, the results of the study have already been obtained for the Japanese regulatory application based on the global multi-center Phase III CheckMate-77T study for preoperative and adjuvant therapy of non-small cell lung cancer.

However, there are still some differences of opinion with the authorities, and to date, these differences have not been resolved. We would like to apply as soon as we reach a resolution to this issue, and at this time we are planning to apply in FY2024.

Regarding FY2025, one change from the previous fiscal year is that we plan to file for approval of the ONO-4538-86 study for preoperative and adjuvant therapy for bladder cancer, as I mentioned earlier. No other changes have been made since the last meeting.

Finally, here is an update on the projects already applied for in FY2023. The combination therapy with BRAFTOVI and MEKTOVI is indicated for the treatment of unresectable thyroid cancer with BRAF mutation that has progressed after cancer chemotherapy, and for the treatment of unresectable undifferentiated thyroid cancer with BRAF mutation.

This was the explanation of the schedule for domestic applications.

Development status of OPDIVO (1)

As of July 22, 2024

Target disease	Line of Therapy	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	Approved
	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	Approved				

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

※Red: Update after May 2024

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I would like to explain the major changes in the development status of OPDIVO.

First, here are the changes since the last time on this page. As I mentioned earlier, the CheckMate-73L study in curatively irradiable non-small cell lung cancer unfortunately did not show the expected results, so it has been removed from the table.

Development status of OPDIVO (2)

As of July 22, 2024

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

★★2nd Line

※Red: Update after May 2024

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There are no changes here.

Development status of OPDIVO (3)

As of July 22, 2024

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 Chemo	Filed	Approved	Ⅲ	Approved	Approved
		with Ipi	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	Monotherapy	Ⅱ	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
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
Solid tumor	–	ONO-4538HSC（Comibination with vorhyaluronidase alfa）	Ⅰ	–	–	Filed	Filed

※Red: Update after May 2024

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This is an update as the product was approved in South Korea on July 17, based on the results of the global multi-center Phase III CheckMate-901 study in first-line urothelial carcinoma. In addition, BMS has received approval in Europe, and we are updating it as well.

As BMS announced in a press release on June 21 (US time), the application for nivolumab subcutaneous injection has been accepted by the European regulatory authorities. This application covers all efficacies for which the intravenous formulation of nivolumab has been approved as a single agent or in combination with chemotherapy or cabozantinib.

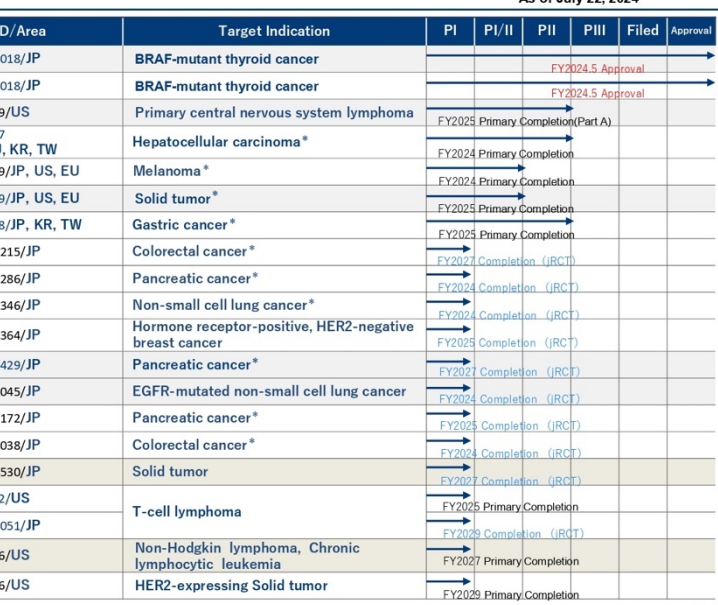
Regarding ipilimumab combination therapy, the approval application is based on the approved efficacy of nivolumab as a single agent administered for maintenance therapy. Please note that this approval application is only for adults.

Global multi-center Phase III study in combination with rucaparib, a PARP inhibitor, for first-line ovarian cancer was conducted by the rucaparib development company under a development alliance, but unfortunately, this study did not yield the expected results and has been removed from the table.

Development pipeline (Oncology)

As of July 22, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
Braftovi Capsules (Encorafenib) BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
Mektovi Tablets (Binimetinib) MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer						
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma						
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*						
	NCT01968109/JP, US, EU	Melanoma*						
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*						
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*						
	jRCT2031200215/JP	Colorectal cancer*						
	jRCT2031200286/JP	Pancreatic cancer*						
	jRCT2031200346/JP	Non-small cell lung cancer*						
	jRCT2031210364/JP	Hormone receptor-positive, HER2-negative breast cancer						
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	jRCT2031230429/JP	Pancreatic cancer*						
	jRCT2051210045/JP	EGFR-mutated non-small cell lung cancer						
ONO-7913 (magrolimab) Anti-CD47 antibody	jRCT2031210172/JP	Pancreatic cancer*						
	jRCT2051210038/JP	Colorectal cancer*						
ONO-7914 STING agonist	jRCT2031210530/JP	Solid tumor						
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma						
	jRCT2011230051/JP							
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia						
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor						



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

※Red: Update after May 2024

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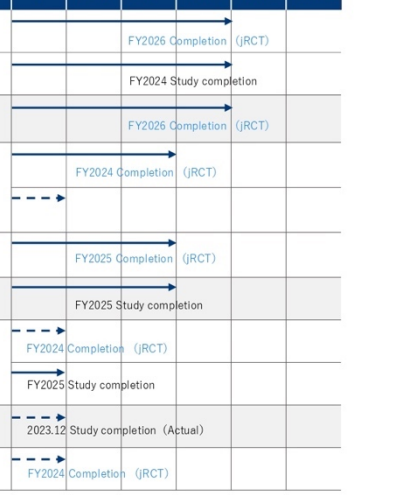
Next is the oncology pipeline, excluding OPDIVO. At the top, as I mentioned at the beginning, BRAFTOVI and MEKTOVI were approved for BRAF mutation-positive thyroid cancer.

Development pipeline (Non-oncology)

As of July 22, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-2017 (cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	jRCT2031210624/JP	Primary generalized tonic-clonic seizures						
	NCT04557085/JP	Partial-onset seizures						
Velexbru Tablets (ONO-4059 : tirabrutinib) BTK inhibitor	jRCT2031220043/JP	Pemphigus						
ONO-2910 Enhancement of Schwann cell differentiation	jRCT2061210008/JP	Diabetic polyneuropathy						
	·····/US							
	jRCT2031230173/JP	Chemotherapy-Induced Peripheral Neuropathy						
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy						
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease						
	NCT05332704/EU							
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease						
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain						



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

※Red: Update after May 2024

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Next, here is a summary of the development status of the non-oncology field. There will be no updates here at this time.

Development pipeline - Deciphera

As of July 22, 2024

Code （Generic name） MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
QINLOCK（ripretinib） KIT inhibitor	NCT03353753/NA, EU, AU, SG	GIST ≧4th	→	→	→	→	FY2020 Approval	→
	NCT05734105/NA, SA, EU, AU, KR, TW	GIST 2nd KIT Exon 11+17/18	→	→	→	FY2025 Primary Completion		
DCC-3014（vimseltinib） CSF-1R inhibitor	NCT05059262/NA, EU, AU, HK	TGCT	→	→	→	→	FY2024 FDA: Planned regulatory filing EMA: Filing accepted	
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor（with sotorasib）	→	FY2027 Study completion				
	NCT05957367/US	Solid tumor（with ripretinib）	→	FY2026 Study completion				
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Solid tumor	→	FY2026 Study completion				

NA : North America, SA : South America, AU : Australia, SG : Singapore, HK : Hong Kong, KR : Korea, TW : Taiwan, JP : Japan

Estimated study completion date shown in jRCT or ClinicaiTrials.gov. Dashed lines indicate studies on healthy adults. ※Red: Update after May 2024

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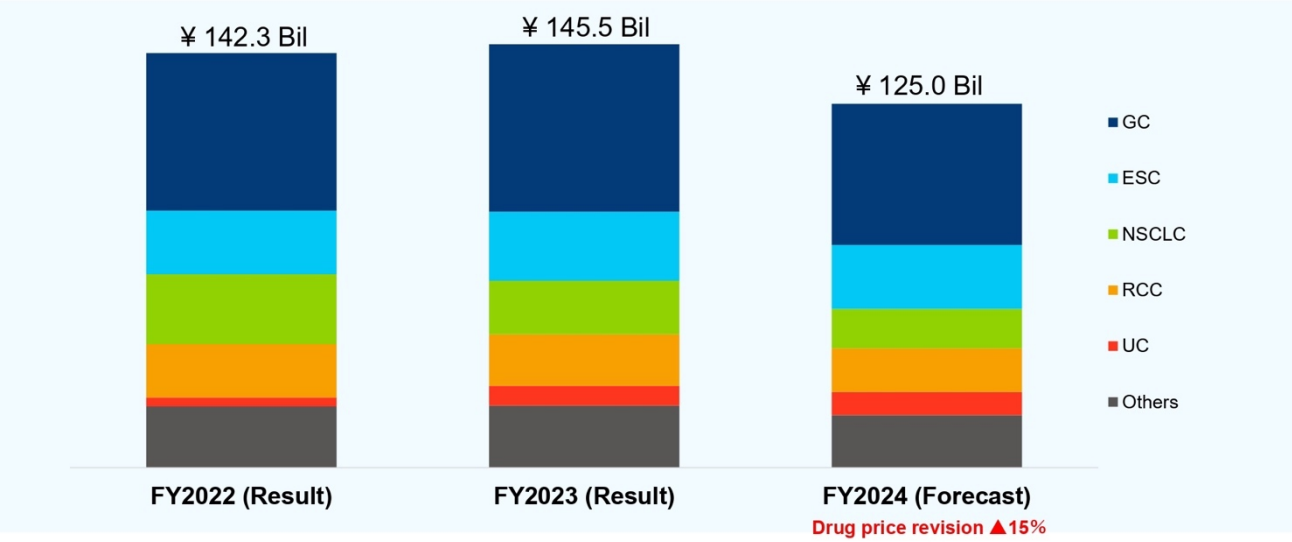
Deciphera's pipeline. From this meeting, we will also present the development pipeline by Deciphera.

The top row, QINLOCK, a KIT inhibitor, as you know, has already been approved in North America, Europe, Australia, and Singapore for the treatment of gastrointestinal stromal tumor GIST after fourth-line therapy.

In addition, as previously announced in the press release, an application for vimseltinib, an inhibitor of CSF-1R, has been accepted by the European regulatory authorities for the treatment of tenosynovial giant cell tumor, a benign tumor, based on the results of a Phase III study. The status of the application with the US FDA is expected to be submitted.

Imura: Next, Takahagi, Executive Director of Sales and Marketing, will give an overview of the OPDIVO trend.

Sales Trend of OPDIVO by Each Cancer

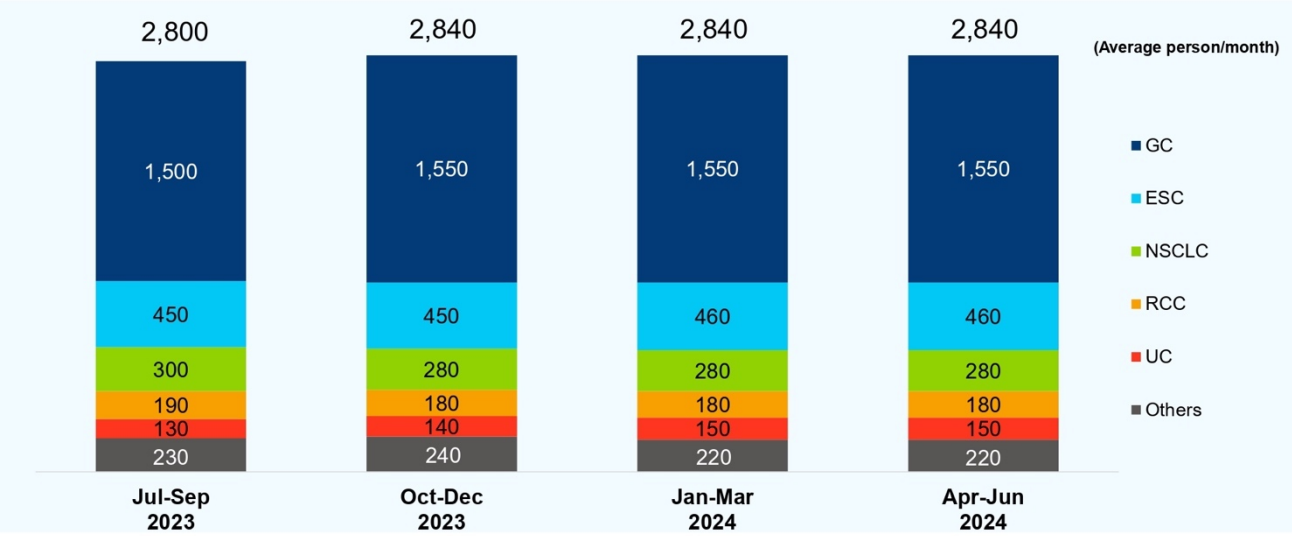


Source: Estimation from external and internal data 19/33

Takahagi: In FY2024, there is a negative factor of entry of competitors into the NHI price area, but we are now building a foundation for a turnaround by focusing on the gastric cancer and lung cancer areas. In the areas of gastric cancer and lung cancer, there are positive factors such as long-term follow-up data, and we are in the process of re-evaluating and recovering prescriptions in lung cancer.

Esophageal cancer and urothelial carcinoma remain growth areas and are expected to grow and reach 125 billion in FY2024, up 1.1% on a volume basis compared to FY2023.

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

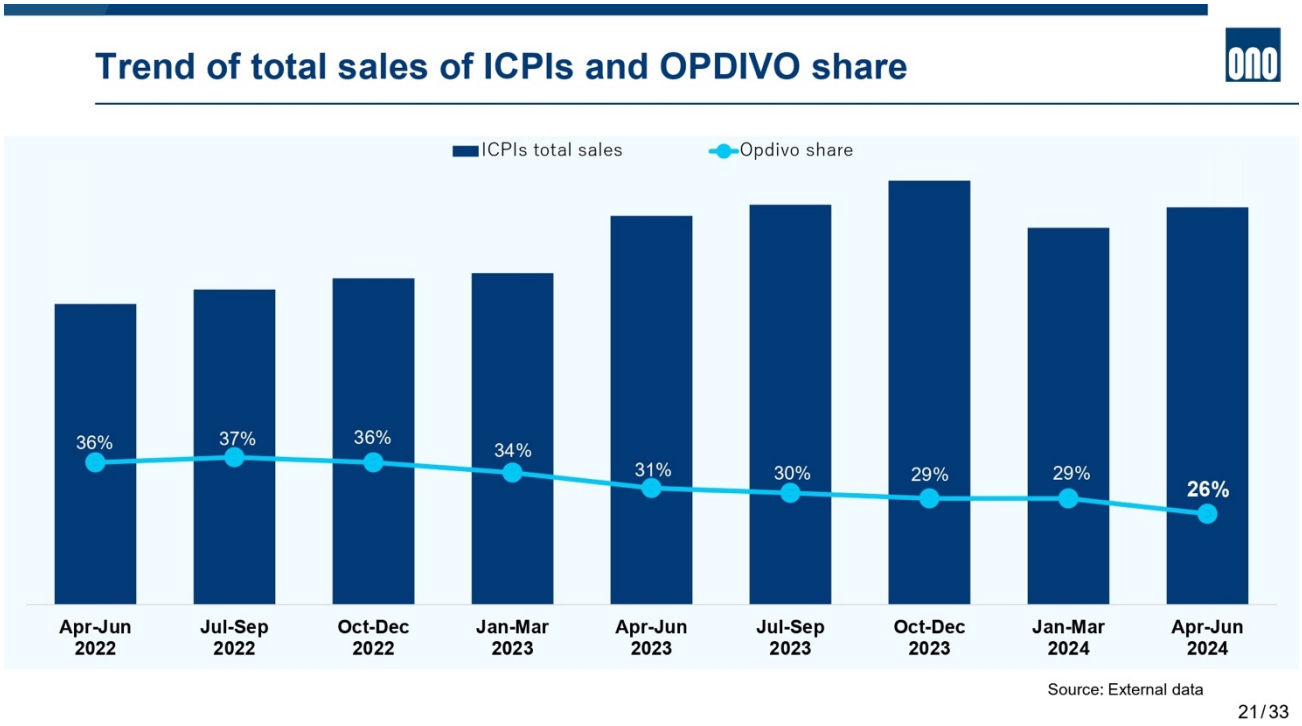


Source: Estimation from external and internal data
20/33

The bar graph on the left shows the estimated number of new prescriptions of OPDIVO by cancer type from July to September 2023 to the end of April 2024, broken down by quarter and the average number of patients per month.

Although it is an estimate, prescriptions were initiated for 1,550 cases of gastric cancer, 460 cases of esophageal cancer, and 280 cases of lung cancer in the April to June period. Prescriptions for gastric cancer and esophageal cancer have expanded to include primary treatment, while prescriptions for esophageal cancer and urothelial cancer have expanded to include adjuvant therapy.

As a monthly average, the total number of cases is about 2,840.

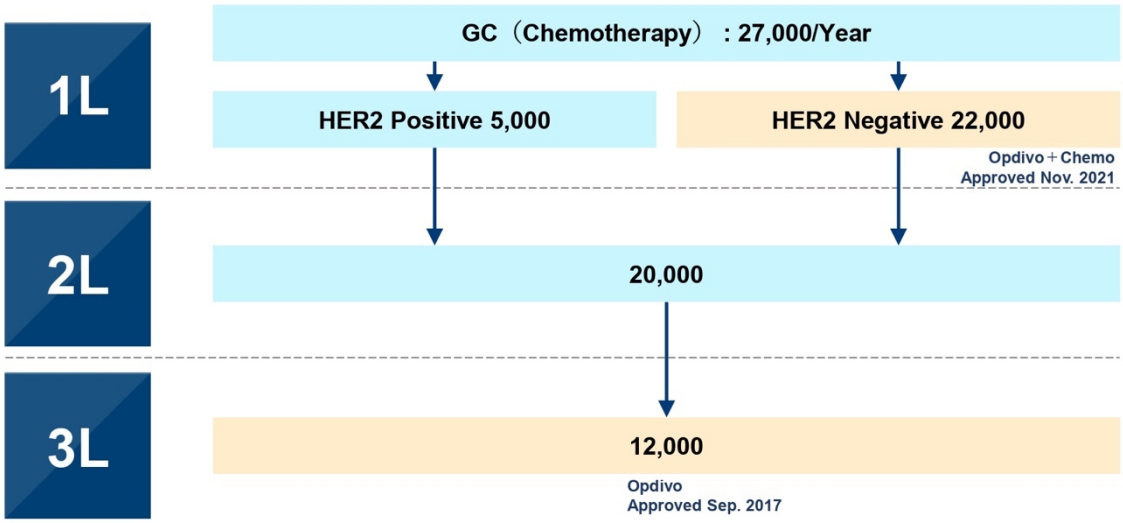


This shows the trend of total sales of all immune checkpoint inhibitors launched in Japan and OPDIVO's market share. The bar graph shows the total sales of immune checkpoints inhibitors and the line graph shows the OPDIVO’s share.

OPDIVO had a share of 26% at April to June, due in part to the NHI price reductions.

Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC

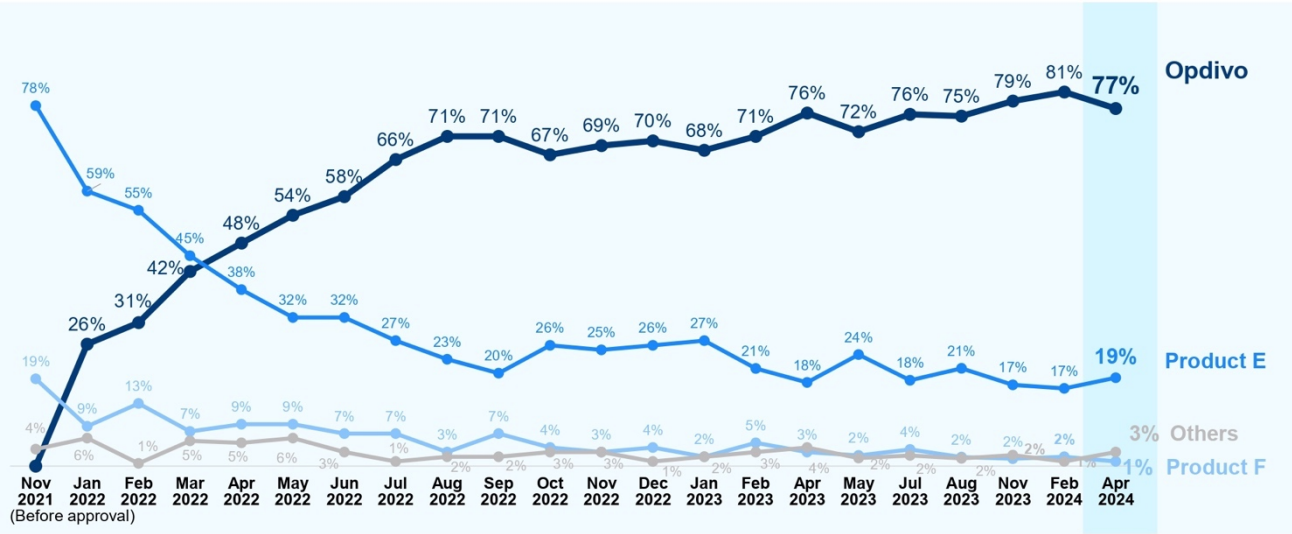


Estimation based on internal survey (2020)

22/33

I would like to introduce the gastric cancer area. The annual number of HER2-negative patients eligible for first-line treatment with OPDIVO is estimated at 22,000.

Prescription Ratio in Patients Newly Treated※ for 1L GC



※Patients starting treatment within the last 3 month

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

23/33

The share of new prescriptions for the primary treatment of gastric cancer is 77%, where we are maintaining 80% of the market.

In the treatment of gastric cancer, doctors place great importance on the improvement of symptoms such as impaired transit due to tumor shrinkage as well as long-term survival. Four-year follow-up data are available

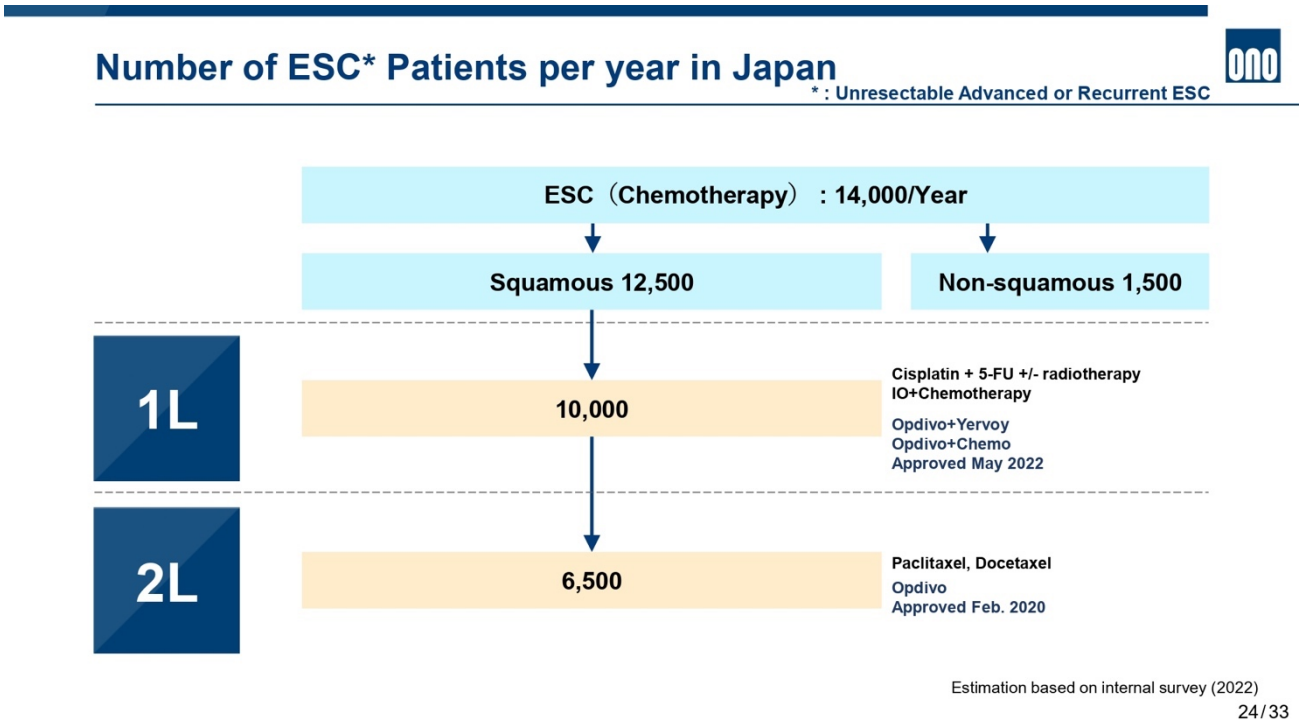
for the CheckMate-649 study, and overall survival in the overall population is shown at the time of approval, followed by two-year, three-year, and four-year follow-up results.

At four years, there is still a difference from the control group, with a 13% survival rate for OPDIVO chemotherapy. Gastric cancer is a cancer with a poor prognosis, but OPDIVO chemotherapy has shown that one in eight patients survives at the fourth year. In addition, a tail plateau is visible in the Kaplan-Meier curve after four years, which is a promising result for long-term survival.

The hazard ratio for OS at the time of approval was 0.8, but it was still 0.79 at the fourth year. The fact that the hazard ratio has been maintained is another strength of OPDIVO and is highly regarded by physicians.

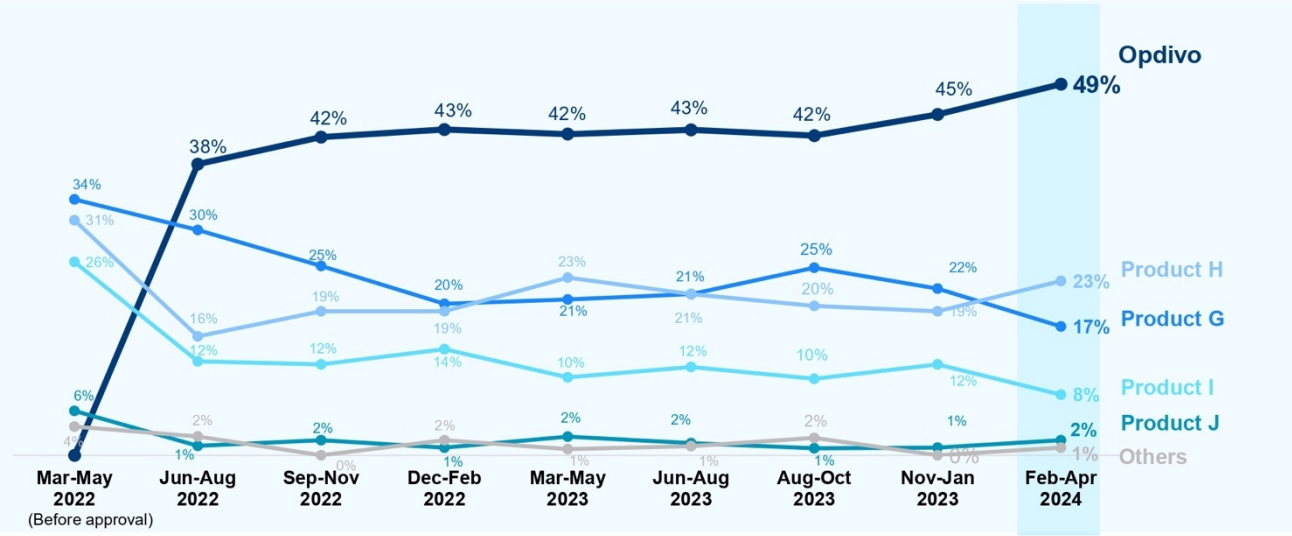
In the guidelines for the treatment of gastric cancer, improvement of clinical symptoms associated with cancer progression as well as prolongation of survival are defined as treatment goals, and improvement of impaired transit due to tumor shrinkage is very important for cancer patients.

OPDIVO chemotherapy has been shown to have a higher response, or tumor shrinkage, which is plus 12%, than chemotherapy. In the future, we believe that in the OPDIVO chemotherapy combination therapy, we have a lot of data to promote the usefulness of OPDIVO, and we believe that we can keep the impact of competition to within 10%.



The following is an introduction to the primary treatment of esophageal cancer. The number of patients indicated for OPDIVO is estimated at 10,000 per year.

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



※Patients starting treatment within the last 3 month

Source: External data（May 2022~Apr 2024: n=150~155)

25/33

Our share of new patients in the primary treatment of esophageal cancer is 49%, and has risen above the competition since our entry into the market, which we believe this demonstrates our strong presence in the gastrointestinal field.

The 45-month follow-up data for CheckMate-648 was presented at ASCO in June of this year. The left and right figures show the overall survival results for the overall population at 29 and 45 months of follow-up data, respectively, comparing the OPDIVO chemotherapy group to the control group.

At 45 months of follow-up, the 3- and 4-year survival rates for the nivolumab-OPDIVO chemotherapy groups are 18% and 14%, respectively.

The hazard ratio at 29 months was 0.78, and at 45 months, the hazard ratio remained at 0.77. At the 29-month follow-up, the difference between the long-term results and chemotherapy was not clear, but at the 45-month follow-up, the difference was clear.

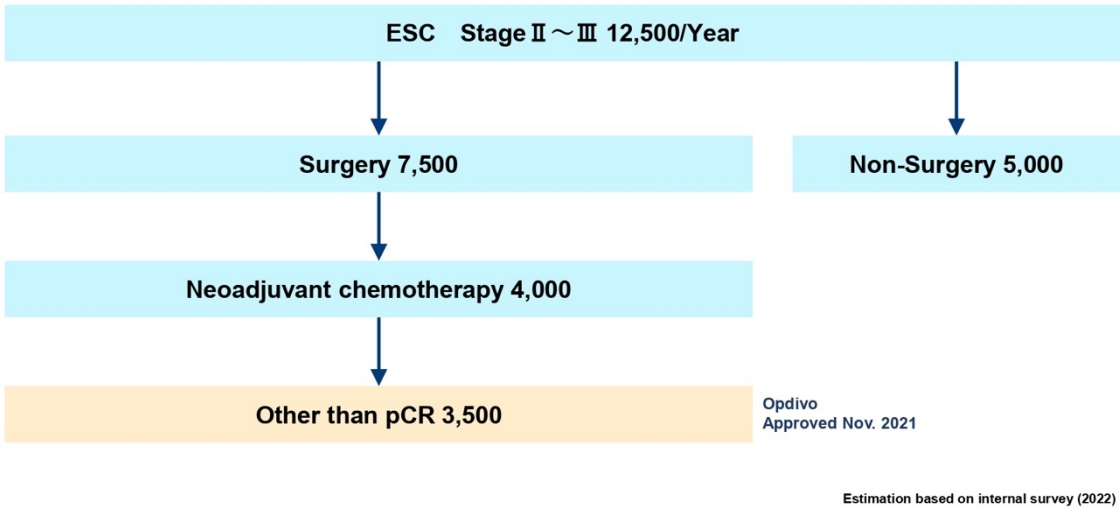
The figures show the OS results for the OPDIVO/YERVOY group compared to the control group at 29 and 45 months of follow-up data for the overall population, respectively.

At 45 months of follow-up, the 3- and 4-year survival rates for OPDIVO/YERVOY were 21 and 17%, respectively, with a hazard of 0.77 at 29 months, but the hazard ratio remained at 0.78 at 45 months. At the 45-month follow-up, the results showed that a clear difference was maintained.

This is highly evaluated by physicians as a characteristic of OPDIVO in those two results.

However, considering that about 30% of the chemotherapy regimen remains, we would like to expand the prescription share by proposing two regimens, the combination of chemotherapy and YERVOY, in addition to the OPDIVO regimen, since the ability to choose between these two regimens is also a strength of OPDIVO.

Number of ESC(Perioperative)Patients per year in Japan

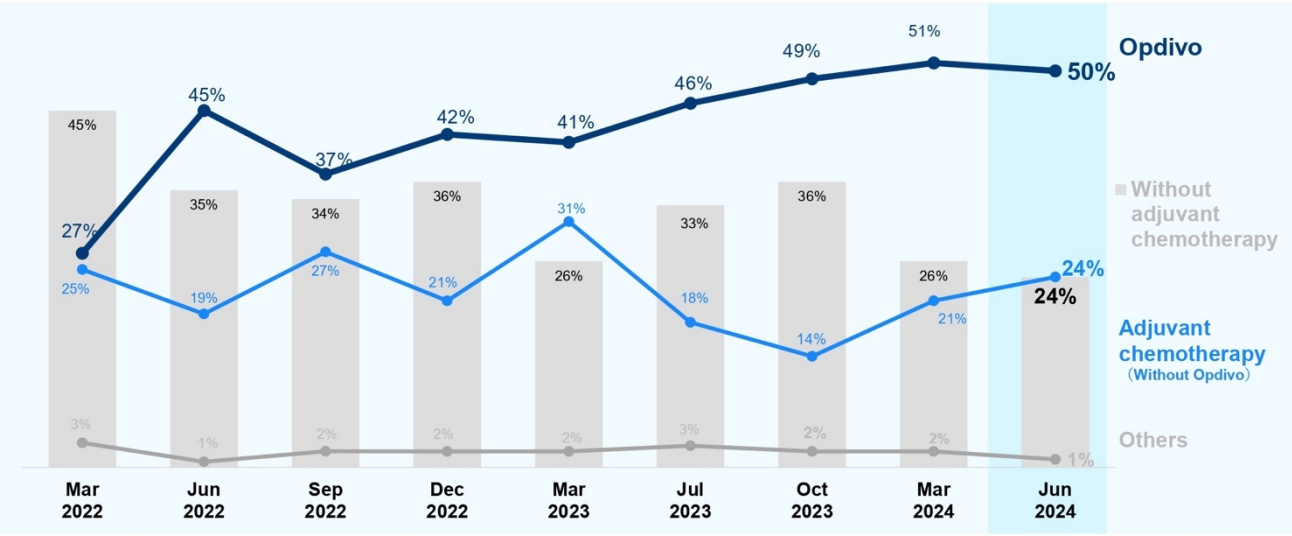


Estimation based on internal survey (2022)

26/33

I would like to introduce adjuvant therapy for esophageal cancer. We estimate that the annual number of patients with pathologic non-complete response indicated for adjuvant therapy with OPDIVO is 3,500.

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



※Patients starting treatment within the last 3 months

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

27/33

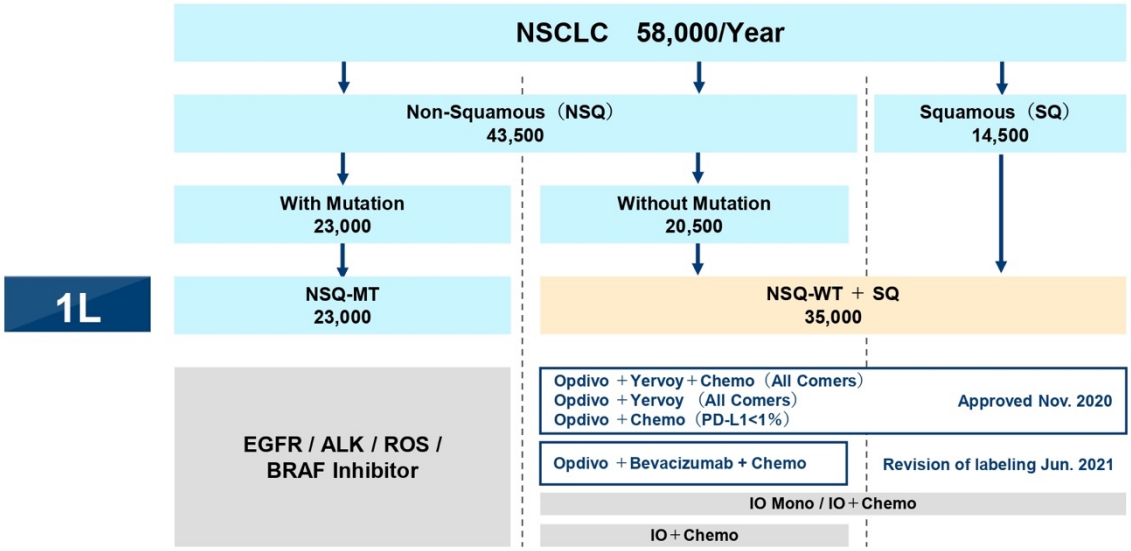
The share of adjuvant therapy for esophageal cancer is 50%.

We are currently expanding prescriptions by introducing clinical data accumulated in actual clinical practice on a doctor to doctor basis, but there are still many patients who have only received adjuvant chemotherapy or have not yet tried adjuvant chemotherapy, leaving ample room for expansion. We would like to further expand it by firmly educating the physicians about the efficiency of OPDIVO.

We have introduced gastric cancer and esophageal cancer. We have a presence in the gastrointestinal field, and we will continue to focus on this area.

Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC

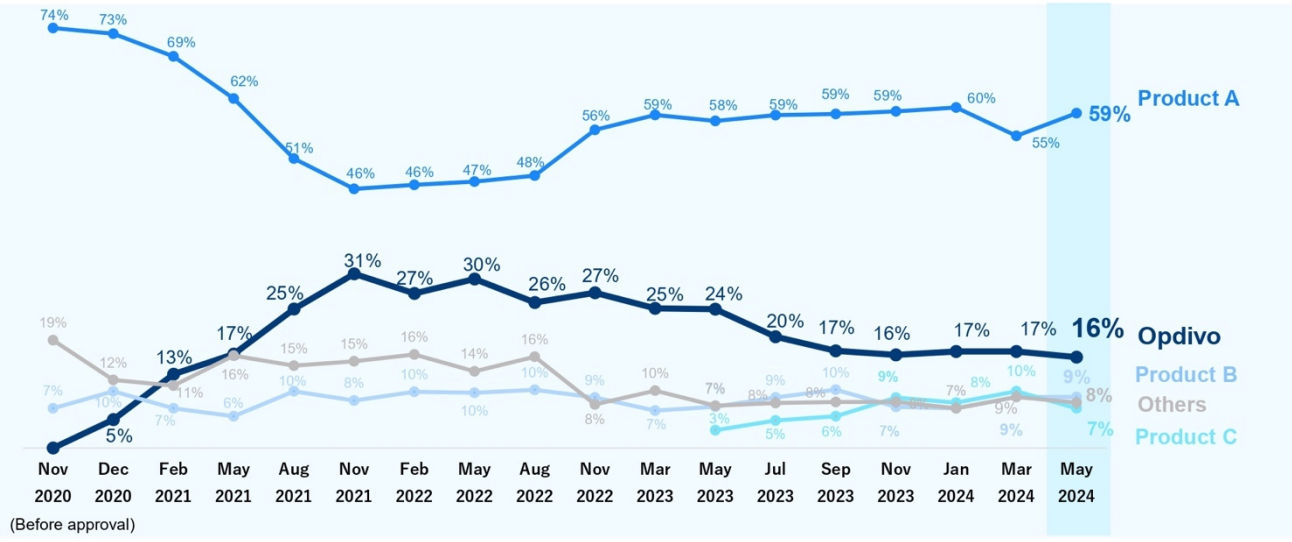


Estimation based on internal survey (2021)

28/33

Now I would like to introduce the lung cancer area. The annual number of patients indicated for OPDIVO in the treatment of lung cancer is estimated at 35,000.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



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

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

29/33

The share of new patients in the first-line treatment of non-small cell lung cancer is 16%, which is at the bottom with respect to the decline in new prescriptions, but the current result is that we have not been able to break away from it.

Five-year follow-up data from the CheckMate-9LA study was also presented at ASCO in June of this year.

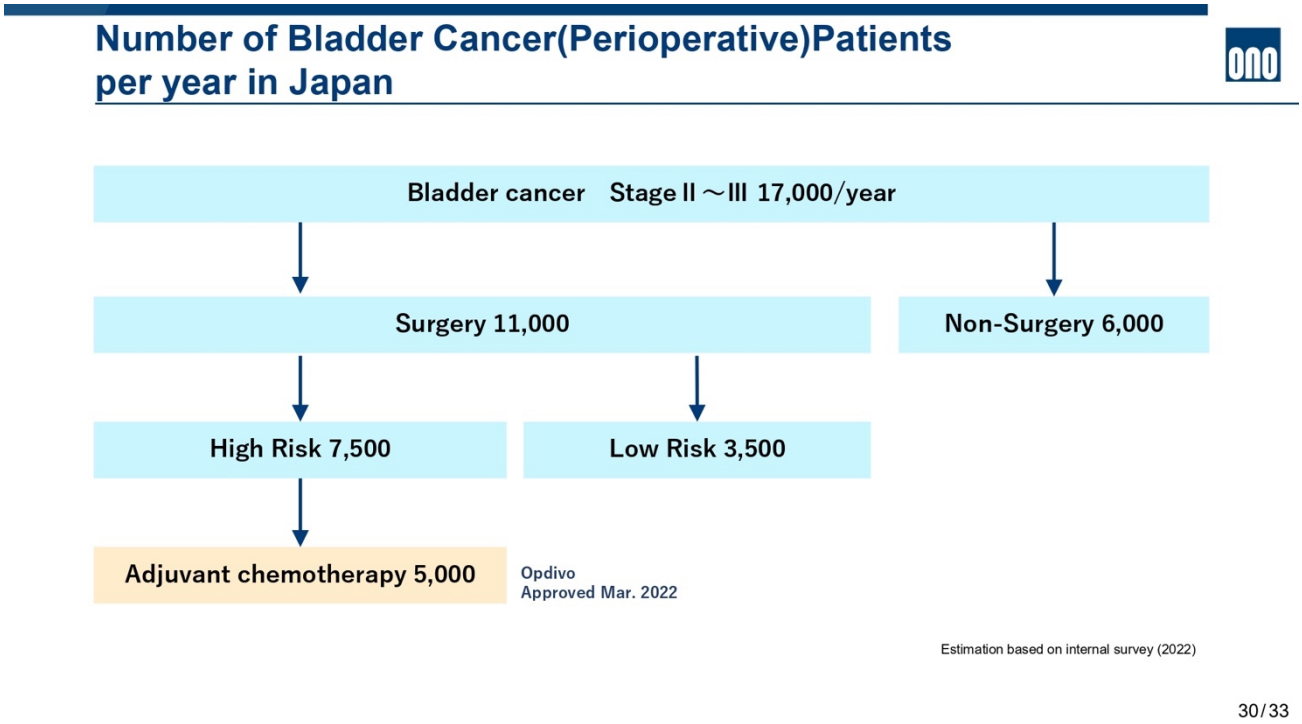
The five-year follow-up data comparing the OPDIVO/YERVOY chemotherapy group with the control group also showed significant and sustained overall survival in the overall population in the OPDIVO/YERVOY chemotherapy arm, particularly in the PD-L <15%, with an overall survival of 22% at five years. The hazard ratio at the time of approval was 0.62, and at five years, it was still 0.633, indicating that the hazard ratio has been maintained.

While the use of the CheckMate-9LA regimen in one investigator-initiated clinical trial has stalled due to safety concerns, the CheckMate-9LA study, which is the clinical developmental study, has demonstrated a consistent safety profile with no trend toward an increase in serious immune-related adverse events at four and five years of long-term follow-up.

In patients who do not express PD-L1, the combination of OPDIVO and YERVOY, a CTLA-4 inhibitor, is expected to increase the percentage of patients who achieve long-term survival.

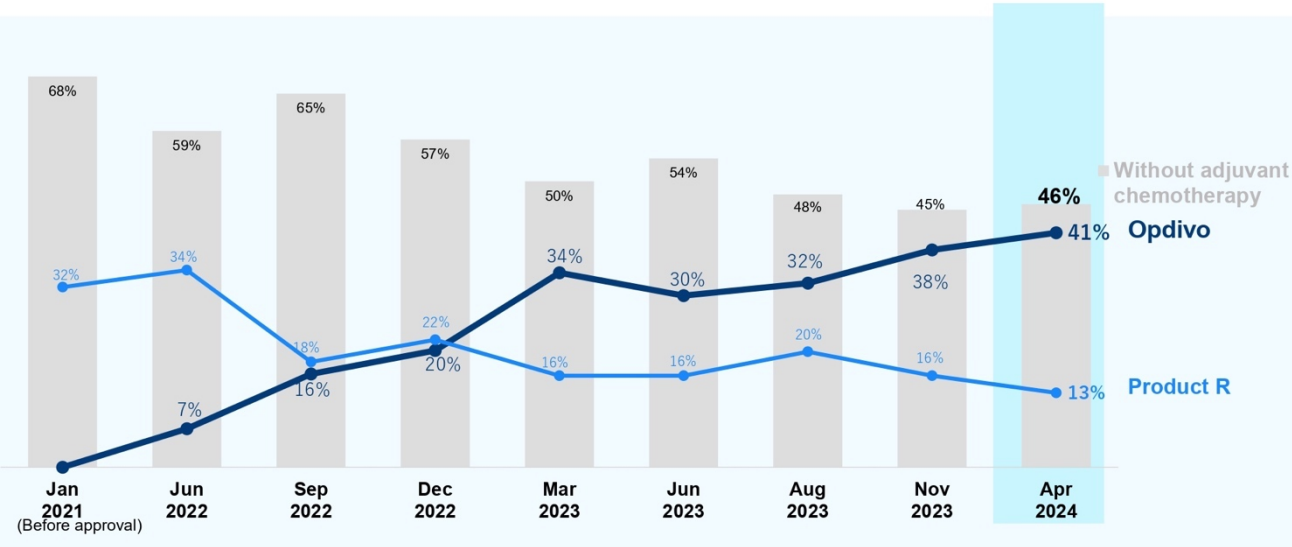
We believe that the CheckMate-9LA and CheckMate-227 regimens are a benefit where the unmet need is high for patients with this PD-L1 expression level of less than 1%.

By working hard to support the management and safety systems of irAE, we will continue to work to contribute to the long-term survival of many patients.



I also would like to introduce urothelial carcinoma. In Japan, bladder cancer accounts for 80% of all urothelial carcinomas, and I would like to introduce the case. The number of patients indicated for OPDIVO adjuvant therapy is estimated at 5,000.

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



※Patients starting treatment within the last 3 months

Source: External data（Jan 2022~Apr 2024: n=200)

31/33

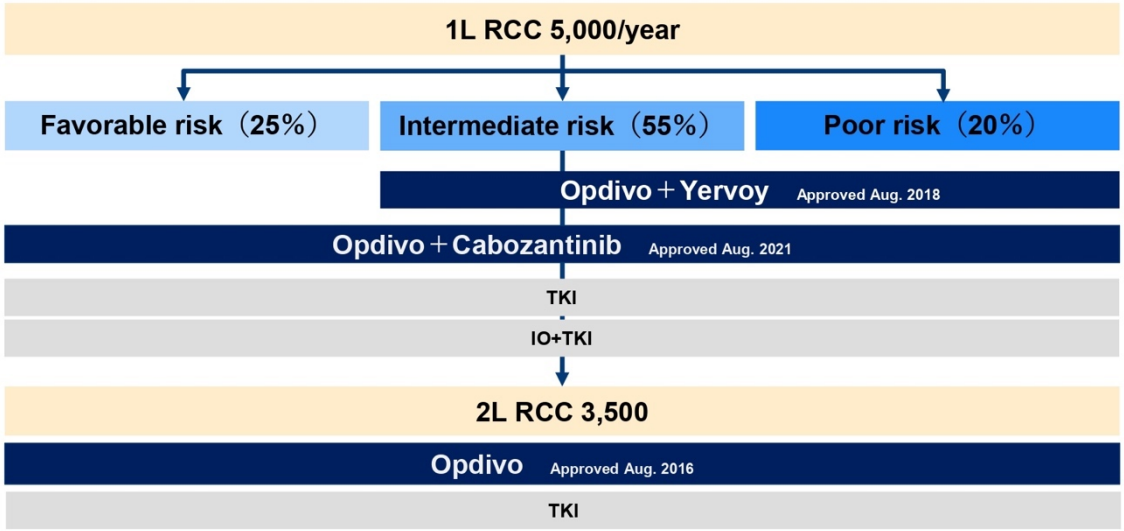
For patients who are considered by doctors to be at risk of recurrence, we are strengthening information provision activities such as doctor to doctor to dispel differences in perception, and the number of confirmed prescriptions is gradually increasing, with the current new prescription share at 41%.

At this year's European Urology Congress, this CheckMate-274, disease-free survival and overall follow-up data from the approved trial have been presented, showing continued benefit.

By firmly share these new data, physicians have increased their willingness to prescribe the drug, and we intend to further enhance the awareness.

Number of RCC* Patients per year in Japan

* : Unresectable or Metastatic RCC

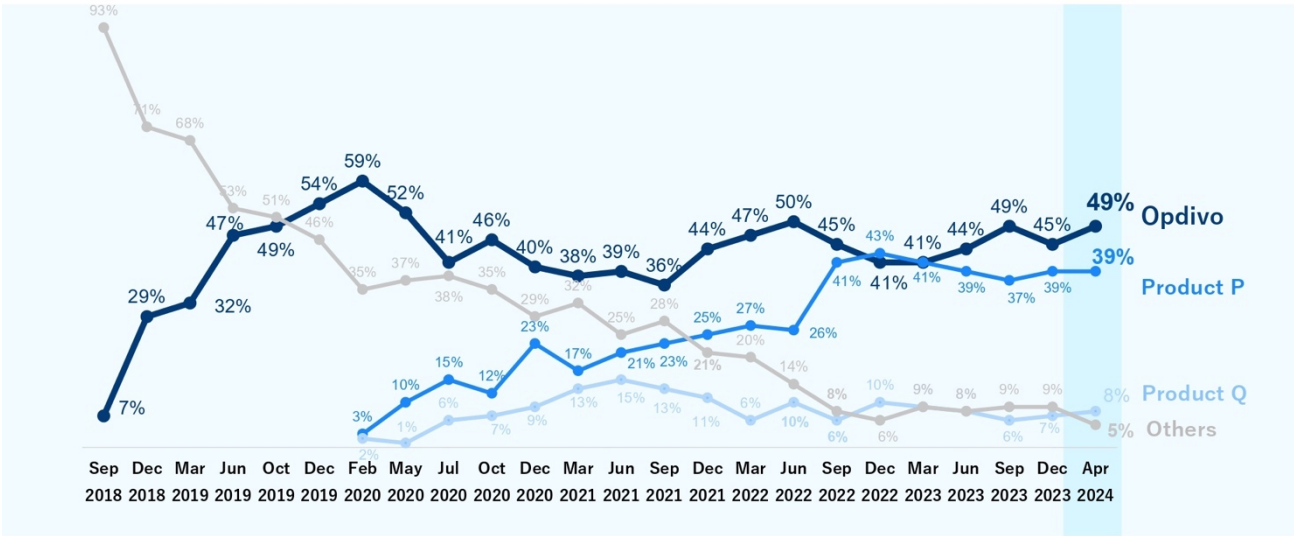


Estimation based on internal survey (2022)

32/33

Finally, I introduce renal cell carcinoma. The number of patients indicated for first-line OPDIVO regimen treatment is estimated at 5,000.

Prescription Ratio in Patients Newly Treated※ for 1L RCC



※Patients starting treatment within the last 3 months

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

33/33

The share of new patients in the first-line treatment of renal cell carcinoma is 49% and outperforms competing products. By continuing to provide information and appealing for follow-up data, we hope to firmly establish a presence in the field of urology and maintain our number one position in this field.

Here is the last slide. In FY2024, we have positive factors in the gastric cancer and lung cancer fields, and positive factors in esophageal cancer, so we are currently strengthening sales activities to eliminate negative factors and create a foundation for a turnaround.

Especially in the area of gastric cancer, physicians are focusing on the improvement of impaired transit symptom due to tumor shrinkage as well as long-term survival. OPDIVO is a drug with high expectations for long-term survival and tumor shrinkage, and we hope to keep new prescriptions by competing products within 10% and maintain a firm volume base.

In addition, we are now promoting the symptomatic therapy for cytokine release syndrome, etc., which has become a safety concern in non-small cell lung cancer, through medical specialists. In addition, we intend to firmly promote the efficacy and safety of the OPDIVO regimen using the ASCO data and other data, in an effort to reel in the market.

In addition, esophageal cancer and urothelial carcinoma continue to be growth areas, and we intend to expand in these areas.

We believe that if we enter new areas in the future, such as hepatocellular carcinoma, and acquire new regimens in lung cancer, colorectal cancer, and urothelial carcinoma, we can fully expect sales expansion, and we would like to move toward the growth phase there in the current fiscal year and after FY2025. We will continue to work to meet the unmet needs of cancer patients.

That is all from me. Thank you.

Question & Answer

Imura : First, Mr. Yamaguchi from Citigroup Global Markets, please go ahead.

Yamaguchi : I have two questions.

First of all, at OPDIVO, you are aiming for a 1% increase overall. And so far, the volume appears to be flat, so the full year comparison seems a bit slow, but is that due to the lung cancer area or due to being bullish? You explained a lot of things, but is the overall picture still a bit weak or are you in the range of assumption?

Also, of course the gastric cancer KEYTRUDA, and VYLOY, which just came in. So whatever it is, is it affected by KEYTRUDA and VYLOY? Please explain this point.

Takahagi : First of all, we believe that the overall sales plan for OPDIVO is already on track. As for the slightly weak part where you thought, we were not able to obtain enough new prescriptions for lung cancer last year, and the accumulation of new prescriptions for this part has resulted in a slight negative impact. But looking at only April to June, we believe that we are making progress as planned.

With regard to July to September, we are focusing on the recovery of lung cancer. And with regard to gastric cancer, the impact of competing products on April to June has been almost zero, with no negative impact. However, we are sure that in the July to September period the competitors will come in, so we are now promoting using the data I have just shown you. To do so, we believe that we will be able to achieve a positive volume pace for the fiscal year.

Yamaguchi : Secondly, in your opening comment regarding the inclusion timing of Deciphera's performance, I think you mentioned Q3. I think there was some talk about Q2, but at present, do you expect to incorporate it into the overall results after the announcement of Q3, i.e., the October-December financial results?

Itoh : As of the end of June, once we take in Deciphera's balance sheet, we will incorporate their results into our P/L from Q2. And the goodwill is put as the difference between the acquisition costs and net assets, as the total amount. But the PPA（Purchase Price Allocation）, what is the difference between the so-called purchase price and the net assets, is now being calculated for the pipeline, which is off-balance sheet, how much it cost. It will be finalized at the end of Q3.

That calculation would take about six months to calculate and discuss with the accounting firm and the auditing firm. How much of the goodwill, which is about 356 billion at the end of June, will eventually be allocated, for example, to QINLOCK, which has already been in the market, or to vimseltinib? How much can the pipeline under development be accounted for as in-process R&D?

The remaining balance after allocating 356 billion in this way will be the final goodwill, so we will include amortization, etc. retroactive to the end of June, so there may be some adjustments at the end of December. But basically, the P/L will be affected from Q2, and the top line and expenses will both be included. That is something we expect.

Yamaguchi : Just to confirm, amortization of intangible assets will not be determined in Q2, but will be included separately in Q3 onward, correct?

Itoh : I think that would also depend on the importance of the amount and would be discussed with the auditing firm. However, if the amortization expense of nine months is naturally taken on board for the year, we will try to factor that into the earnings forecast as of Q2, if possible.

Yamaguchi : Is it for six months or nine months that you factor into your forecast?

Itoh : For the full year, we will give a forecast as the finish of this performance, so nine months.

Imura : Sakai from UBS Securities Japan Co., Ltd., please go ahead.

Sakai : There is the number of patients newly prescribed with OPDIVO by each cancer If you look at the top, it's almost 2,800, and this is 2023, or roughly 2,840 in April as well, almost unchanged, and the breakdown of cancer types has changed very little at all.

Mr. Takahagi, you have said a lot about rewinding, but do you mean to say that those numbers will be reflected here in the future? Can you tell us a little about its credibility?

Takahagi : Thank you. In particular, speaking of gastric cancer, in the past, for example, July to September in 2023, July to September had 1,500 cases, and this year April to June, says 1,550, but the content has changed a lot.

In the past, there were many cases of tertiary treatment, to be more specific, there were about 1,025 cases of first-line gastric cancer in the July to September period in 2023. We estimate that there are about 475 cases of tertiary treatment, in the April to June period this year, the number of primary gastric cancer cases is 1,100, while the number of tertiary treatment is 450. In other words, the ratio of first-line treatment has already increased considerably.

As you are already aware, the administration period is longer for first-line treatment, so when we consider the accumulation of this part, we can see that first-line treatment contributes positively to sales in such areas as gastric cancer and esophageal cancer, for example.

Sakai : So, I believe you have introduced the breakdown of sales for various primary and cancer types. It is currently this primary. The primary on the last slide was that this is about in place, and that the adjuvant is also in place. Does this mean that the yellow area will increase by another 30,000 from 90,000 in the future?

Takahagi : That’s right. We have a very large market with an additional 30,000 patients who are expected to be indicated, but we also have a large market of 90,000 existing patients, and we need to expand that as well. We also talked about the 30,000 people here that will be increasing in the future, and that we need to do our job well once we get approval.

Sakai : I think you are saying that the overall OPDIVO sales forecast of JPY125 billion for the current fiscal year is negative because of the 15% NHI price revision, and that volume growth will be possible to some extent.

If we assume that there will be no recalculation in the future as long as the patents are maintained in Japan, do you have an estimate of how much your company can extend to the expected peak? Do you have any kind of estimate?

Takahagi : It is difficult to estimate how much in general because the peaks of each type of cancer are different. I think it will also be related to how the new trials will meet the endpoints, and we would like to introduce the new indications when they are added, or in the new year, etc.

However, since we are operating in such a large market, we would like to aim higher in terms of sales. If possible, we would like to recover the amount that was down before the NHI price was lowered. And we believe that this is the first passing point, but we would like to aim for more than that.

Sakai : I would like to ask one more question, Mr. Itoh. You have just explained the inclusion of Deciphera, but Deciphera alone had a deficit of almost JPY30 billion, I believe, before your company acquired it.

There are some numbers that need to be made, but will this go directly to your company's deficit? Or are you going to make some treatment in advance, say some kind of cost reduction? Since this is about Q2, I don't think you have that much time, but I would be very grateful if you could explain a little more about the impact on accounting at the current stage, including the inclusion of these figures, which I think will have quite a large impact.

Also, you mentioned earlier that it was for nine months of inclusion. But I thought that Deciphera's fiscal year ends in December. So this time, nine months will hit your P/L until the end of March next year. Is my understanding correct? And, is it my understanding correct that the December portion will have an impact next year?

Itoh : Yes. Regarding your first question, I think you are asking if we should look at the P/L of Deciphera, the actual results of the last fiscal year as it is, and look at it for nine months.

It is difficult to say exactly how much cost reduction can be achieved. And since the timing of expenses is also a factor, it is difficult to say at this point whether it is enough to just click on the calculator and put in three-quarters of the cost.

Deciphera settles its accounts in December. But the settlement of accounts from July to December will be handled as is, and the quarter from January to March will be handled either as a provisional settlement of accounts or a change in the settlement period. We are currently discussing this with Deciphera and our accountant. The image of the inclusion is that the profit and loss will be included from July to March next year, in line with our fiscal year end.

Sakai : So, you mean that Deciphera will cease to exist once the corporate consolidation takes place, is that correct? In other words, you mean that it is no longer disclosed as a stand-alone entity there?

Itoh : Yes. There will be no more disclosures as a stand-alone entity.

Sakai : That is why I am asking for a detailed explanation of when to include it in advance. Thank you for your understanding.

Itoh : Yes.

Imura : Next, Mr. Wakao from JPMorgan Securities, please go ahead.

Wakao : I have three questions.

The first is about FORXIGA. From this Q1, I thought you have been doing very well against your full-year plan. Please let us know the status of the current Q1.

Please also tell us about the status of the competition, as I believe an indication was added for Jardiance for chronic kidney disease.

Takahagi : As for FORXIGA, progress is being made at a slightly faster pace than planned. It is true that the number of competing products in the chronic kidney disease segment is increasing, but we are also increasing our products. In the first place, the concept of chronic kidney disease did not exist until now, but we have pried it open. Furthermore, the number of potential patients is still increasing, and both companies are working to increase this number.

However, we will have to outpace their growth in the future to achieve our sales plan, and we will do our best to keep up with our competitors.

Wakao : The original 83 billion for the full year incorporates the impact of competition.

Takahagi : It was factored in.

Wakao : I see. Then, it's like Q1 is strong and gradually some quarters are weaker than others, that kind of thing.

Takahagi : I have an image of it, but we are hoping that this July to September will help us to see that again to some extent.

Wakao : The second question is about fixed costs. As for SG&A expenses, I think there is an increase due to the sales of FORXIGA. But on the other hand, I think R&D expenses have progressed at a high rate from Q1. Is this one as planned? Is it just something temporarily looking a bit stronger due to exchange rate effects, etc.?

Itoh : Yes, there is surely an increase due to the exchange rate. However, the plan itself, Q1, has traditionally had a lower track record than the rest of the year. But this time, Q1 was originally planned to be relatively high, and we landed on the line.

Wakao : Lastly, on the balance sheet and cash flow. It is a balance sheet, I would like to know. I believe you borrowed some for the acquisition of Deciphera. I think it is JPY150 billion on a stand-alone basis.

I am wondering how much of it will be refinanced into long term loans. Can you give us an outlook on the refinancing of this JPY150 billion loan and the timing of future repayments?

Itoh : We are borrowing 150 billion now, but it is just a bridge. And from here, we plan to refinance into a mix of long-term and short-term bank loans. Repayment will begin in the next fiscal year, and this 150 billion will remain until the end of the current fiscal year.

Wakao : I understand that repayment is a mix of long and short term loans. But can you tell us about the long and short term loans, the ratio of these loans, and how long they will be?

Itoh : I misunderstood short term and long term. I'm sorry. We plan to take out a long-term loan of about five years. At that time, we will have a mix of variableand short-term fixed interest rates. I was talking a little bit about that image. The loan will be refinanced in five years, the bridge loan is usually (maximum) one year. But we are now negotiating with the bank with a plan to refinance it into a five-year loan and pay it back in five years, one year from now.

Wakao : Finally, if you do that, you have about JPY130 billion in cash, and I think you still have a reasonable amount of cash, including working capital. Can you tell us what you think about capital allocation at this point in time, or business investment and shareholder returns, based on this current balance sheet?

Itoh : With regard to shareholder returns, including capital allocation, we also have JPY 130 billion in short-term cash as you see. And we still have some policy investment shares remaining(as a financial asset), which we plan to withdraw. It will be difficult to reach the point of drastically reducing this to zero in the current fiscal year, but we are making progress in eliminating it little by little.

In terms of investment in this context, it may be difficult to make large strategic investments with the cash we have now, and it may be difficult to make investments on par with Deciphera right away. But we will just continue to make strategic investments.

With regard to shareholder returns, we have already announced our dividend policy. And as to whether we can buy back our own shares right now, there is nothing that we cannot do given our current cash position.

But we would like to consider it while keeping an eye on the situation and considering our cash position not in the short term but in the medium to long term.

Wakao : Thank you. I understand very well.

Imura : Now, Mr. Akahane with Tokai Tokyo Intelligence Laboratory, please ask your questions.

Akahane : First of all, I would like to check Q1. I understand that the sales were down 1.9%, OPDIVO was okay, almost as much as the NHI price reduction, and I understand FORXIGA very well. The progress rate for Q1 was 27%, which is very good, and the progress rate for ONGENTYS is also good, so it is about in line with expectations.

Royalties are down 26% from Bristol-Myers and 1 point down from Merck since January, so I have the impression that this is not bad considering that. I guess this is almost all as you expected, right?

Itoh : As far as sales are concerned, they are about as strong as expected, maybe a little stronger.

Akahane : Profit is at 25% of progress, so it seems that there are some advance research expenses to go along with that, but is this also almost as expected?

Itoh : Yes. We are on schedule to plan for Q1, in part because the expenses will not be incurred evenly.

Akahane : And Bristol is doing well, but Merck is down 1 point since January, right? It is almost halved, but if we take into account that it just dropped one point, it is growing. But is this 0.6 for the time being? Or should we assume that this level can be maintained since it will continue to be 0.6?

Itoh : Regarding the royalties from Merck and other companies, the rates have dropped considerably from the January 2024 sales, although our inclusion was delayed by three months and started in Q1 of this year. The timing of that was from this Q1, but I see that we are slightly above where we planned to be in terms of royalties, slightly above on a local sales basis. For now, we are confident that this kind of performance will continue in the future.

Akahane : From 1.625 to 0.625, which is a little better than expected, I think, given that level.

Itoh : Yes, it is my understanding.

Akahane : There have been a lot of questions about OPDIVO, but the overall picture is that it hasn't changed much. Since the NHI price is reduced by 15%, I am simply estimating based on market share alone. But is it correct to say that renal cancer, esophageal cancer, and bladder cancer, or rather urothelial carcinoma, are growing by double digits in volume terms in these areas?

Akahane : Can we see double-digit growth around urothelial carcinoma, renal cancer, and esophageal cancer?

Takahagi : We cannot say clearly about the number of digits, but it is growing for these cancer types.

Akahane : But regarding the concern, the issue of gastric cancer and lung cancer is a little weaker than expected?.

Takahagi : Gastric cancer and esophageal cancer are also progressing as planned. But on the contrary, lung cancer has not yet returned just as we assumed, as the market share was not originally taken.

Akahane : Last question. Including all of that, including M&A, I'm not sure because there are a lot of uncertainties, but Q1 was as expected. Q2 will have the lowered NHI prices issue, lower royalty rates. Q2 and Q3 and beyond will be okay. Do you not think there is much to be concerned about at this point?

Itoh : With regard to this fiscal year's performance, I believe that it will be necessary to revise the current forecast because it will include the performance related to M&A and the performance of Deciphera, which was mentioned by the previous questioners. That is what we hope to present in our Q2 earnings announcement.

One more thing, sorry, on Mr. Yamaguchi's question about amortization and whether it can be started from Q2, it may be a little difficult to determine whether it can be amortized in a deemed manner while the actual amount of goodwill and then each item of intangible assets is not clear. So please include the possibility that the amortization may not be recorded in Q2, but may be recorded in Q3 as a six-month amount.

Akahane : Since that is unclear, it is safer to see the status quo in the Q2, right?

Itoh : Yes. The full picture may not yet be seen in the results of the two-quarter earnings announcement. We would like you to review the information based on the earnings forecast including that point.

Imura : Then, Mr. Tsuzuki from Mizuho Securities, please go ahead.

Tsuzuki : My question is about the development of products. As for ONO-2910, I think the clinical study has been completed in Japan, so I am wondering about the timing of the results here. Also, regarding itolizumab, the decision to exercise the option right is in 2024, so I was wondering if you could give us an update on this area, if any.

Okamoto : Regarding the Phase II study of ONO-2910 in diabetic polyneuropathy, I mentioned at the last time of this opportunity that the results of the PoC study would be available this year, during the year 2024. But at this point, the results are not yet available.

Regarding itolizumab, as you pointed out, we expect to exercise the option during this fiscal year, but it depends on the status of events in the ongoing trials. We do not yet have all the information necessary to make such a decision at this time, and this is the current situation.

Tsuzuki : One more point is ONO-4578. This is also the part of pancreatic cancer and lung cancer, Phase I will end, will there be a publication of the results including conferences later this year? What is your perspective on this?

Okamoto : For the Phase I oncology trials, we have written that multiple trials are scheduled to be completed in FY2024. But there are patients who are still being treated, so it depends on the status of each trial as to when the data will be compiled and published. At this time, we are unable to say which conference we can focus on to release the results.

Imura : Next will be Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka : I know it is difficult to say quantitatively, since I think that in the Deciphera situation, the April to June results are not available anywhere. But qualitatively, was there any irregularity from past trends in QINLOCK's sales, use of costs, etc., and the resulting level of operating losses? Or was it as smooth as ever? It would be helpful if you could tell us as much as possible.

Tanigawa : Based on past history, there has been no major change, or rather, no major change, QINLOCK had sales of 163 million last year. And now, with market expansion plus the increasing number of new patients, sales are growing as planned.

Muraoka : So the deficit is steadily decreasing, on a three-month basis.

Tanigawa : I can't say yes to the steady decrease in the deficit because of the growth in QINLOCK sales and the development and multiple products.

Muraoka : One more thing, also about Deciphera, there was a press release the other day saying that vimseltinib has been accepted for filing in Europe. But if I recall, I think Deciphera had said that the US application is scheduled for April to June. In looking at your company's materials today, there is a subtle change in the wording of the application within FY2024, please tell me if I am misremembering here or if there has been any change.

Tanigawa : We are in the process of applying within the year, and there has not been any problem. We are in the process of submitting the application as planned.

Muraoka : Are you saying that my memory is wrong when Deciphera said April to June application?

Tanigawa : With regard to Deciphera, they said that the application would be filed during the April to June period.

Okamoto : I would like to add some information.

Regarding the pipeline applications in Europe and the US, as you pointed out, first of all, we have now issued a press release for Europe that the application has been accepted. On the other hand, as you are aware, unlike in Japan, there is uncertainty in the regulatory authorities in Europe and the US as to whether the review process will actually begin even if the application itself is accepted.

Our policy is to make a press release when an application is accepted by the regulatory authorities. In Japan, a press release is issued when an application is filed. But in the US and Europe, we would like to issue a press release upon the acceptance of the application by the regulatory authorities.

From that perspective, I am sorry that I cannot give you a clear answer to your question. But I hope you will understand that we are describing the FDA as a prospective application.

Muraoka : I see. Am I correct in my understanding that the schedule has not changed in any particular way, just that the method of disclosure has been adapted to your company's side?

Okamoto : As you understand.

Imura : Mr. Mamegano from BofA Securities, please go ahead.

Mamegano : Let me just confirm one point. I would like to confirm the upside of OPDIVO. CheckMate-9DW, I think it was a very good result. There was a comparison between the competing regimen and what you just mentioned about response and DOR, and I feel like combination of atezolizumab and bevacizumab is better when we look at it in terms of hazard, but could you comment on that? That Combination of nivolumab and ipilimumab seems longer when viewed in terms of median, but a little worse when viewed in terms of hazard, so any comments on that would be appreciated.

Okamoto : It is difficult to compare OS and PFS, so-called time-to-event (time-dependent events), between different trials, so I have refrained from mentioning them.

The point you are asking about cannot be directly compared. But in our trial, we have not only sorafenib but also lenvatinib in the control group. As for this, the fact is that lenvatinib, which is as effective as or more effective than sorafenib, is used as a control, and as a result, the median OS in the control group has also been

considerably prolonged. Therefore, we interpret that it is quite difficult to compare the hazard ratios with previous competitive trials, atezolizumab or durvalumab.

On the other hand, in general, a high response rate and a long DOR, duration of response, mean that patients who start treatment in the first-line treatment and respond well can continue treatment for a long period without progression. Therefore, we believe that our regimen may be superior to those two existing competing products.

Imura : Thank you. This concludes the Financial Results Meeting for Q1 of the fiscal year ending March 2025. Thank you all for joining us today.