ONO PHARMACEUTICAL CO., LTD.

Financial Results Briefing for FY2025 Q2

October 30, 2025

[Number of Speakers] 6

Toichi Takino	Representative Director, President and Chief Operating Officer
Masaki Itoh	Corporate Executive Officer / Division Director, Corporate Strategy & Planning, Business Management Division
Tatsuya Okamoto	Corporate Officer, Executive Director, Clinical Development
Hirokazu Kitada	Corporate Officer, Executive Director, Sales and Marketing
Hiroyuki Takahashi	Director of Oncology Business Division, Sales and Marketing
Ryuta Imura	Senior Director of Corporate Communications

Presentation

Imura: Thank you very much for attending ONO PHARMACEUTICAL CO., LTD.'s, financial results meeting for Q2 of the fiscal year ending March 31, 2026, today.

To begin, I would like to introduce the attendees. Takino, Representative Director, President and COO. Okamoto, Corporate Officer, Executive Director, Clinical Development. Kitada, Corporate Officer, Executive Director, Sales and Marketing. Itoh, Corporate Executive Officer, Division Director, Corporate Strategy & Planning, Business Management Division. Takahashi, Director of Oncology Business Division, Sales and Marketing.

Agenda

2026年3月期第2四半期 決算概要について
Financial Results FY2025 Q2 （14:00-14:20）

代表取締役 社長 COO
Representative Director, President and Chief Operating Officer
滝野　十一
Toichi Takino

開発品の進捗状況
Development Pipeline Progress Status（14:20-14:40）

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
Trend of OPDIVO（14:40-14:55）

執行役員 営業本部長
Corporate Officer / Executive Director, Sales and Marketing
北田　浩一
Hirokazu Kitada

質疑応答
Q&A Session（14:55-15:15）

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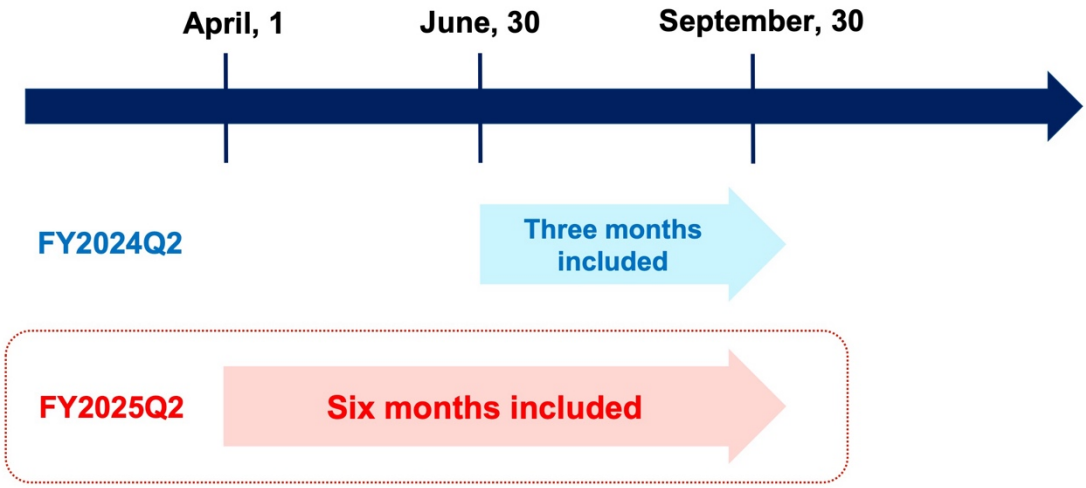
Imura: First, Takino, President, will present an overview of the financial results for Q2 of the fiscal year ending March 31, 2026. Next, Okamoto, Executive Director of Clinical Development, will explain the progress status of our development pipeline. Finally, Kitada, Executive Director of Sales and Marketing, will give an overview of the trend of OPDIVO.

I would now like to begin with an explanation by President Takino of an overview of the financial results for Q2 of the fiscal year ending March 31, 2026.

Profit and Loss Recognition Period for Deciphera

Regarding the profit and loss recognition for Deciphera Pharmaceuticals, Inc., three months were recorded in the same period last year, while six months have been recorded this year.



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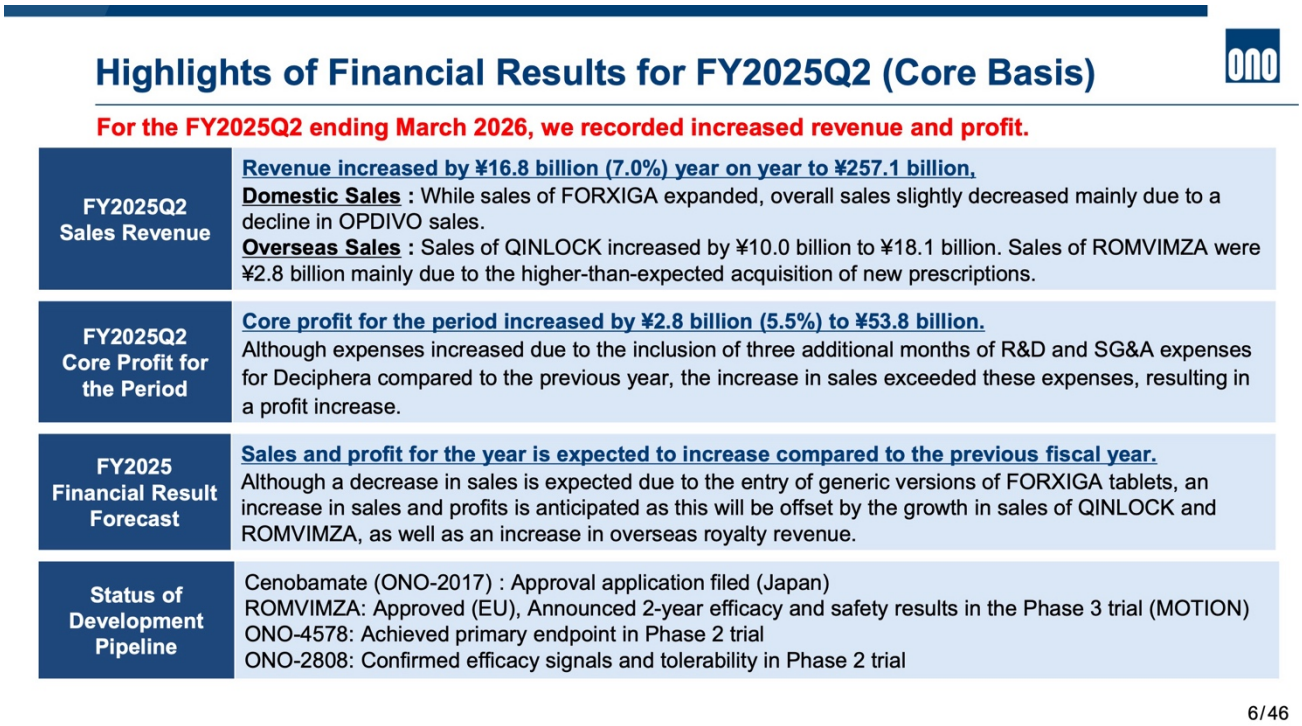
Takino: First, I would like to share some points to keep in mind.

As you may know, the acquisition of Deciphera was completed in June of last year, so the Q2 financial results of last year include Deciphera's profit and loss for three months from July to September, while the current year's results are for six months from April to September. Therefore, please keep in mind that there is a three-month difference when comparing the same period of the previous year.

In addition, since last fiscal year, we have been disclosing core financial indicators with the aim of presenting our performance in our core business, and today I will again report mainly on a core basis.



Let me introduce the first point of today's meeting.

Our interim financial results for the current fiscal year showed an increase in both sales and profit.

First of all, revenue increased by 7% YoY steadily to JPY257.1 billion.

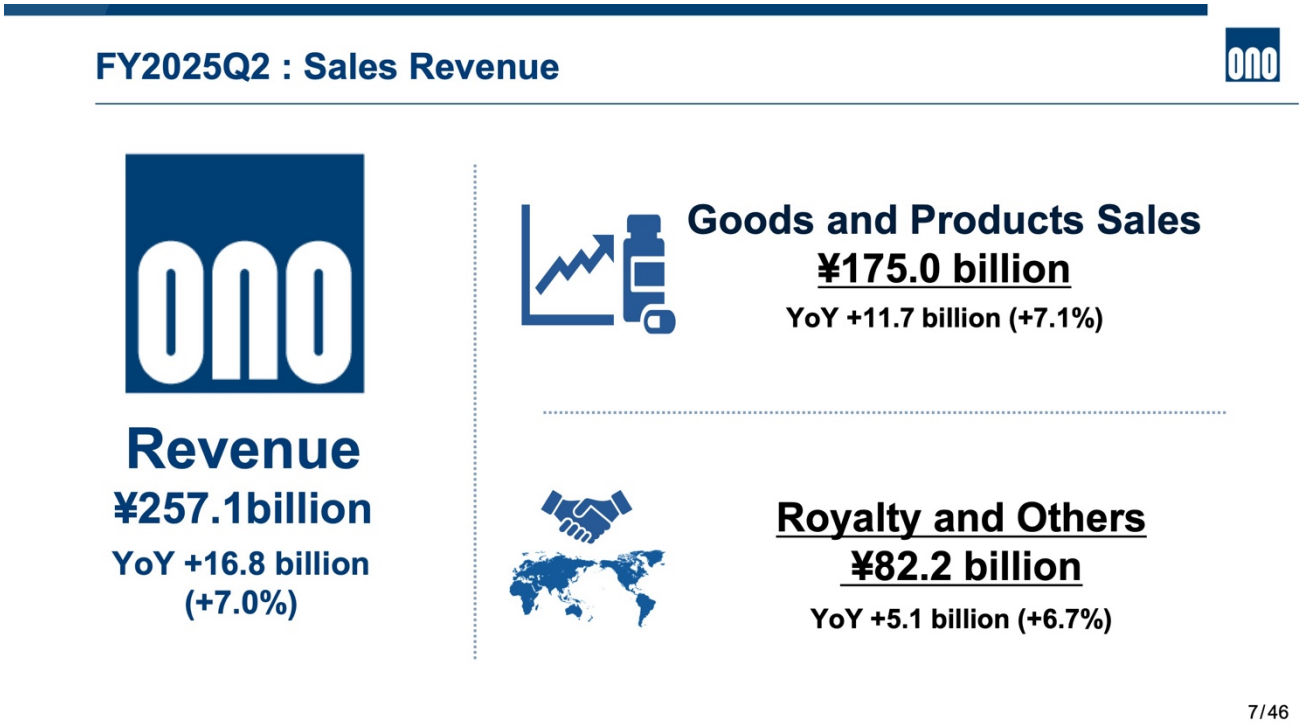
As for domestic sales, while sales of FORXIGA expanded, overall sales slightly decreased because the sales of OPDIVO declined to intensified competition.

However, sales increased due to QINLOCK, a treatment for gastrointestinal stromal tumors (GIST) acquired through the Deciphera acquisition, which saw a JPY10 billion increase compared to the same period last year, and ROMVIMZA, a treatment for tenosynovial giant cell tumor (TGCT) newly launched in the US this year, which generated JPY2.8 billion in sales.

Next, regarding profitability, while R&D expenses and SG&A expenses increased YoY due to the inclusion of Deciphera's figures, core net profit rose by 5.5% YoY to JPY53.8 billion, driven by sales growth that exceeded these increases.

Regarding our full-year earnings forecast for the fiscal year ending March 2026, we have only made adjustments to certain product-specific sales figures from the revenue and profit growth forecast announced on May 8. There are no revisions to the overall profit and loss outlook.

Lastly, I would like to discuss the status of development pipelines. As previously announced in our press release, we have submitted a domestic application for approval of the antiepileptic drug, Cenobamate (ONO-2017), obtained approval for ROMVIMZA in Europe, and presented two-year data at the European Society for Medical Oncology (ESMO). In addition, we have made several positive developments that will provide future growth opportunities, including Phase II data for ONO-4578, a novel anticancer drug candidate, and ONO-2808, a candidate for the treatment of multiple systemic atrophy, both in the clinical development phase. I will introduce a few of them later, at the end of my presentation and in an update from the development.



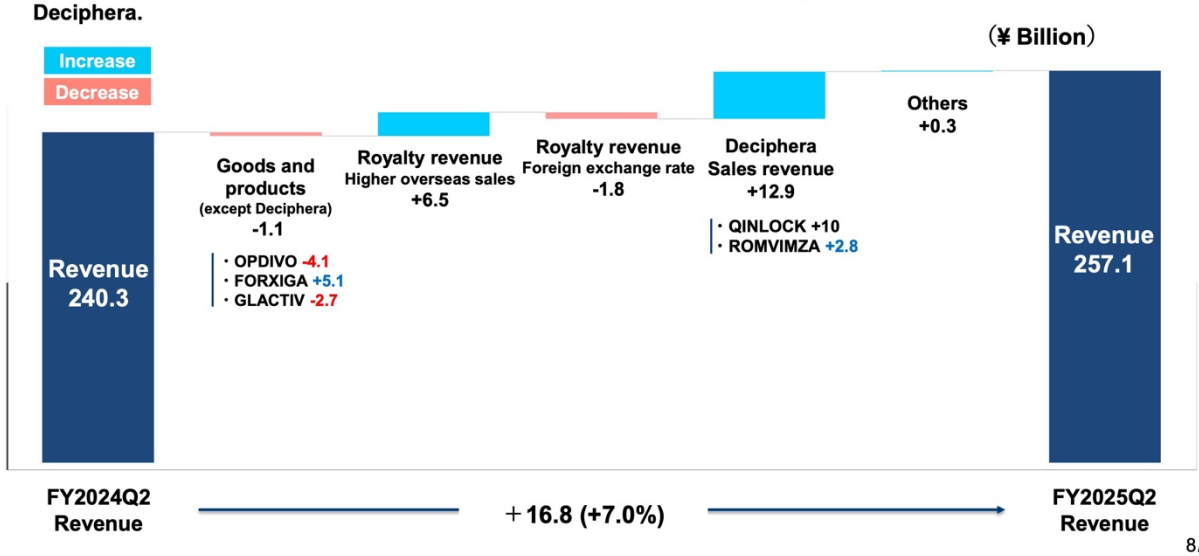
First, let's start with sales revenue.

In Q2, goods and products sales increased by JPY11.7 billion from the same period last year to JPY175 billion, and royalties and others increased by JPY5.1 billion from the same period last year to JPY82.2 billion.

Total revenue increased by JPY16.8 billion, or 7%, from the same period last year to JPY257.1 billion.

FY2025Q2 : Sales Revenue (Breakdown)

Domestic sales decreased due to intensified competition affecting OPDIVO, despite the increase in sales of FORXIGA Tablet. However, overall sales increased by ¥16.8 billion year on year, driven by the revenue from Deciphera.



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The details of the increase or decrease are shown below.

The increase in overseas sales contributed to the JPY16.8 billion increase in sales revenue during Q2 of this fiscal year.

Overall sales of domestic product lines decreased by JPY1.1 billion due to a decrease in sales of OPDIVO, GLACTIV, and other products, while sales of FORXIGA continued to increase.

Overseas sales, on the other hand, increased due to a JPY4.7 billion increase in royalty income related to OPDIVO and KEYTRUDA, including foreign exchange gains, and a combined JPY12.9 billion increase in sales of Deciphera's QINLOCK and ROMVIMZA.

FY2025Q2 : Sales Revenue by Product (Domestic)

¥ in Billion	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	240.3	257.1	16.8	7.0%	490.0
Goods and products	163.3	175.0	11.7	7.1%	330.0
Royalty and others	77.0	82.2	5.1	6.7%	160.0

Goods and Products (Domestic)	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	62.6	58.5	-4.1	-6.5%	125.0
FORXIGA Tablets	43.7	48.8	5.1	11.6%	80.0
ORENCIA for Subcutaneous Injection	13.5	13.8	0.3	2.1%	28.0
GLACTIV Tablets	9.6	6.9	-2.7	-28.2%	12.0
VELEXBRU Tablets	5.2	6.0	0.8	15.8%	11.0
ONGENTYS Tablets	3.8	4.5	0.7	18.6%	9.0
PARSABIV Intravenous Injection	4.2	4.5	0.3	7.4%	9.0
KYPROLIS for Intravenous Infusion	4.6	4.0	-0.5	-12.1%	9.0

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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The next slide shows an overview of the products by category.

OPDIVO sales decreased by JPY4.1 billion or 6.5% YoY to JPY58.5 billion due to an increasingly competitive environment. FORXIGA continued to perform well, increasing by JPY5.1 billion, or 11.6%, from the same period last year to JPY48.8 billion.

Among other major products, ORENCIA for subcutaneous injection increased by JPY0.3 billion or 2.1% to JPY13.8 billion, VELEXBRU increased by JPY0.8 billion or 15.8% to JPY6 billion, ONGENTYS increased by JPY0.7 billion or 18.6% to JPY4.5 billion, and PARSABIV increased by JPY0.3 billion or 7.4% to JPY4.5 billion.

On the other hand, sales of GLACTIV decreased by JPY2.7 billion, or 28.2%, to JPY6.9 billion and KYPROLIS decreased by JPY0.5 billion, or 12.1%, to JPY4 billion, both YoY, due largely to NHI price reductions.

FY2025Q2 : Sales Revenue by Product (Overseas) / Royalty

¥ in Billion	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	240.3	257.1	16.8	7.0%	490.0
Goods and products	163.3	175.0	11.7	7.1%	330.0
Royalty and others	77.0	82.2	5.1	6.7%	160.0

Goods and Products (Overseas)	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO	6.5	7.2	0.7	11.5%	13.5
QINLOCK®	8.1	18.1	10.0	123.3%	34.0
ROMVIMZA™	–	2.8	–	–	5.0

Royalty and others	FY2024Q2	FY2025Q2	YoY		
			Change	Change(%)	
OPDIVO	56.4	59.4	3.0	5.3%	
KEYTRUDA®	12.8	13.8	1.0	7.5%	

* The consolidated financial forecast for the fiscal year ending March 2026, announced on May 8, 2025, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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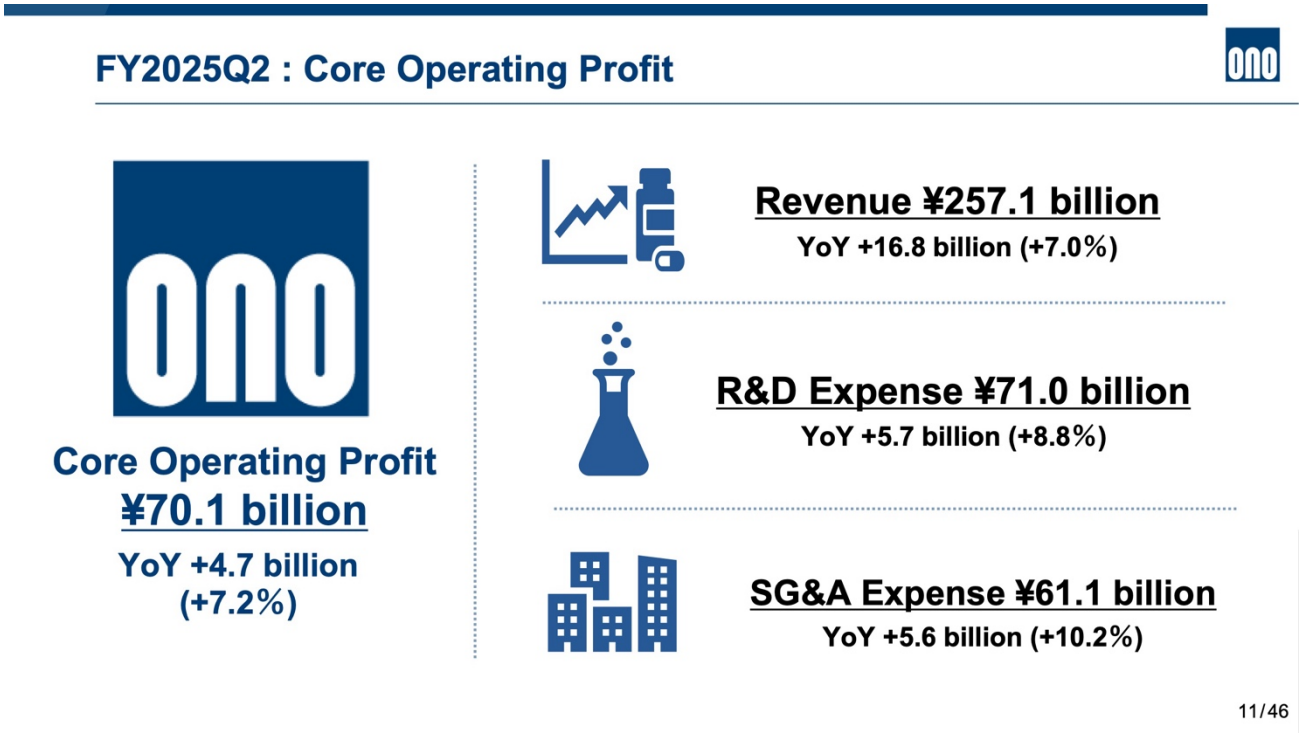
Next, we will look at overseas sales by product.

OPDIVO sales, which are the sum of those in South Korea and Taiwan, increased by JPY0.7 billion YoY to JPY7.2 billion. Deciphera's QINLOCK sales reached JPY18.1 billion, an increase of JPY10 billion compared to the same period last year. This represents steady progress toward the initial forecast of JPY34 billion. Sales of ROMVIMZA totaled JPY2.8 billion, which is also on track to meet the JPY5 billion yen forecast announced at the beginning of the fiscal year.

Royalties from Bristol Myers for OPDIVO increased by JPY3 billion, or 5.3%, to JPY59.4 billion, and those from MSD for KEYTRUDA increased by JPY1 billion, or 7.5%, to JPY13.8 billion.



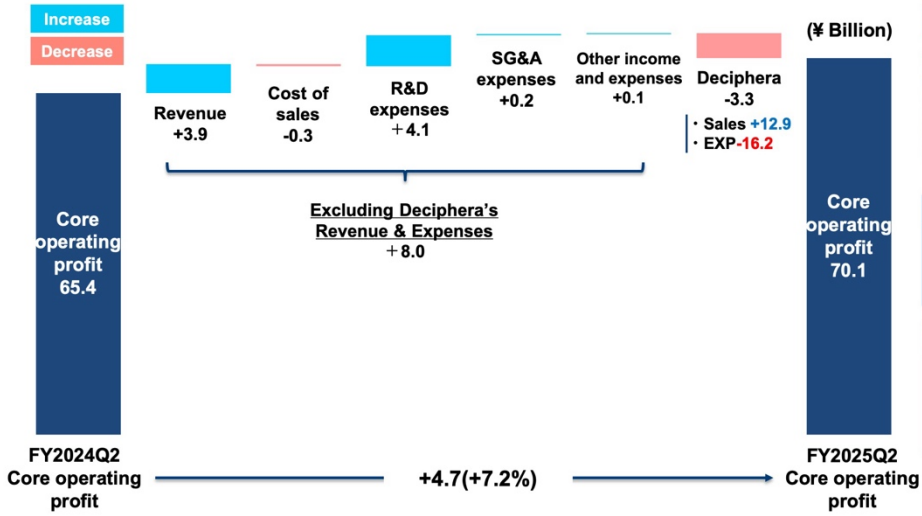
Next, the total amount of core operating profit was JPY70.1 billion, an increase of JPY4.7 billion, or 7.2% from the same period of the previous year.

The increase was driven by Deciphera expenses being recognized for three additional months in the current fiscal year, resulting in a JPY5.7 billion YoY increase in R&D expenses and a JPY5.6 billion YoY increase in SG&A expenses. However, this was more than offset by a JPY16.8 billion YoY increase in revenue, leading to higher profits.

The details of the increase or decrease are shown here. We will explain separately for Deciphera and others.

FY2025Q2 : Core Operating Profit (Breakdown)

While R&D and SG&A expenses have been recorded by Deciphera, which were not recorded in the first quarter of the previous fiscal year, core operating profit increased by ¥4.7 billion year on year to ¥70.1 billion due to an increase in royalty revenue and a promotion of cost efficiency.



YoY Breakdown

Sales revenue (excluding Deciphera)

Main reason
Royalty and others : +4.9
Goods and product : -1.1

R&D expenses (excluding Deciphera)

Main reason
- Decrease in research costs and clinical trial costs

SG&A expenses (excluding Deciphera)

Main reason
- Increase in co-promotion fee for FORXIGA tablet
- Promotion of cost efficiency

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Excluding Deciphera, increased sales including higher OPDIVO royalty income from overseas and reduced R&D expenses contributed to a JPY8 billion increase in profit compared to the previous period.

On the other hand, for Deciphera, the current fiscal year includes three additional months of profit and loss recognition, resulting in a JPY3.3 billion increase in losses; however, overall core operating profit increased by JPY4.7 billion compared to the same period last year.

FY2025Q2 : Financial Overview (Core)

¥ in Billion	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	240.3	257.1	16.8	7.0%	490.0
Cost of sales	53.9	54.8	0.9	1.7%	103.5
R&D expenses	65.3	71.0	5.7	8.8%	150.0
SG&A expenses	55.4	61.1	5.6	10.2%	120.0
Other income	0.6	0.6	-0.0	-2.6%	0.5
Other expenses	0.9	0.8	-0.1	-15.8%	3.0
Core operating profit	65.4	70.1	4.7	7.2%	114.0
Core profit before tax	65.2	70.7	5.5	8.4%	114.0
Core profit for the period (attributable to owners of the Company)	51.0	53.8	2.8	5.5%	91.0

* The consolidated financial forecast for the fiscal year ending March 2026, announced on March 8, 2025, is provided.

YoY Breakdown

Cost of sales +¥0.9 billion (+1.7%)

COGS ratio : 21.3%
Main reason
- Increase in cost of goods sold

R&D expenses +¥5.7 billion (+8.8%)

R&D ratio : 27.6%
Main reason
- R&D expenses from Deciphera
- Milestone payment to LigaChem Bioscience, Inc.

SG&A expenses +¥5.6 billion (+10.2%)

Main reason
- SG&A expenses from Deciphera
- Increase in co-promotion fee for FORXIGA tablet

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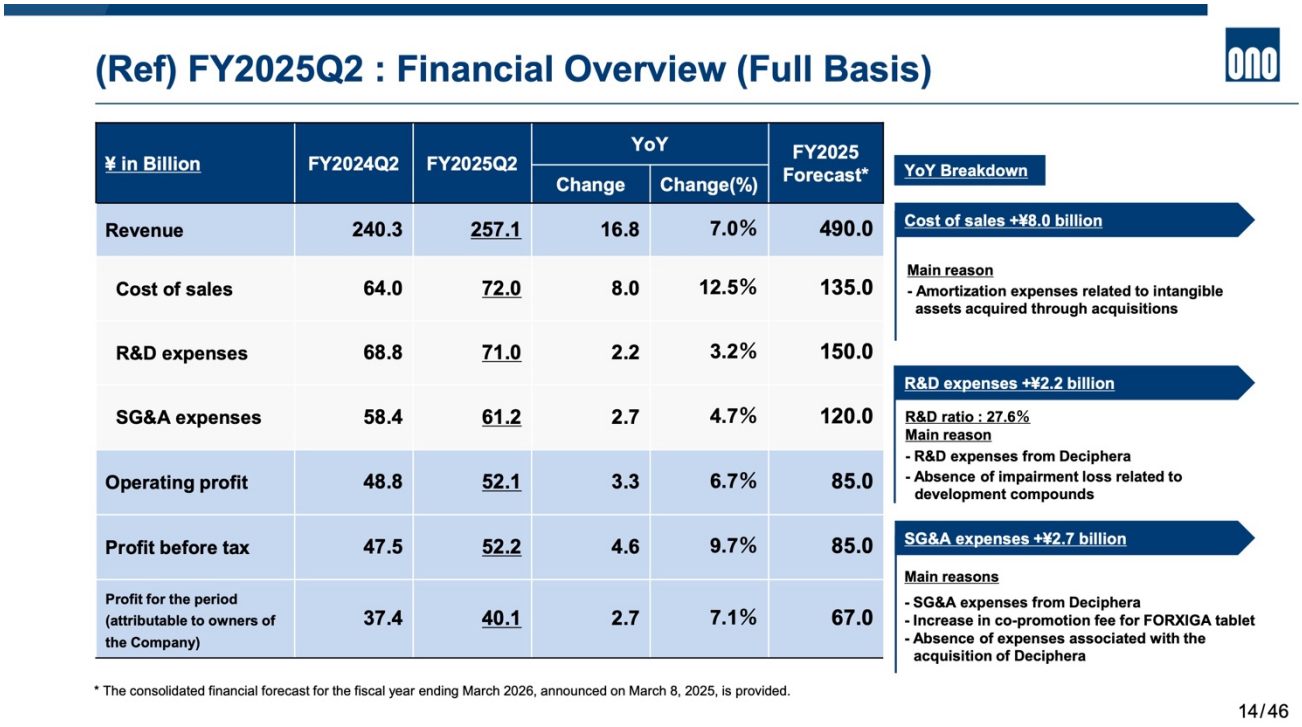
This is the overall income statement on a core basis.

Revenue increased by JPY16.8 billion, or 7%, YoY to JPY257.1 billion. Core operating profit increased by JPY4.7 billion, or 7.2%, YoY to JPY70.1 billion. Core profit for the period increased by JPY2.8 billion, or 5.5%, YoY to JPY53.8 billion. The Q2 results showed both revenue and profit growth.



(Ref) FY2025Q2 : Financial Overview (Full Basis)

¥ in Billion	FY2024Q2	FY2025Q2	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	240.3	257.1	16.8	7.0%	490.0
Cost of sales	64.0	72.0	8.0	12.5%	135.0
R&D expenses	68.8	71.0	2.2	3.2%	150.0
SG&A expenses	58.4	61.2	2.7	4.7%	120.0
Operating profit	48.8	52.1	3.3	6.7%	85.0
Profit before tax	47.5	52.2	4.6	9.7%	85.0
Profit for the period (attributable to owners of the Company)	37.4	40.1	2.7	7.1%	67.0

YoY Breakdown

Cost of sales +¥8.0 billion

Main reason
- Amortization expenses related to intangible assets acquired through acquisitions

R&D expenses +¥2.2 billion

R&D ratio : 27.6%
Main reason
- R&D expenses from Deciphera
- Absence of impairment loss related to development compounds

SG&A expenses +¥2.7 billion

Main reasons
- SG&A expenses from Deciphera
- Increase in co-promotion fee for FORXIGA tablet
- Absence of expenses associated with the acquisition of Deciphera

* The consolidated financial forecast for the fiscal year ending March 2026, announced on March 8, 2025, is provided.

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This is for reference only, but it is consolidated results on a full basis.

Please note the following points regarding the figures for Q2 of the previous fiscal year ending March 2025.

As of the previous Q2, we had applied provisional accounting treatment related to the business combination. In Q3 of the fiscal year ended March 2025, we completed the definitive accounting treatment related to the business combination. Therefore, please note that the figures for Q2 of the previous fiscal year ended March 2025 have been restated to reflect the finalized results of the provisional accounting treatment.

Revenue remained unchanged on a core basis, but operating profit increased by JPY3.3 billion, or 6.7%, YoY to JPY52.1 billion. The profit for the period rose by JPY2.7 billion, or 7.1%, YoY to JPY40.1 billion. This represents growth in both revenue and profit on a full-year basis.

(Ref) FY2025Q2 : Reconciliation from Full to Core Basis

¥ in Billion	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Sales revenue	257.1				–	257.1
Cost of sales	72.0	-12.5		-4.7	-17.2	54.8
Gross profit	185.2	+12.5	–	+4.7	+17.2	202.4
R&D expenses	71.0				–	71.0
SG&A expenses	61.2			-0.1	-0.1	61.1
Other income /expenses	-0.9			-0.7	-0.7	-0.2
Operating profit	52.1	+12.5	–	+5.5	+18.0	70.1
Operating profit ratio	20.2%				–	27.2%
Finance income / Finance cost	0.1			-0.5	-0.5	0.6
Profit before tax	52.2	+12.5	–	+6.0	+18.5	70.7
Income tax expense	12.2	+3.3		+1.5	+4.8	17.0
Profit for the year	40.1	+9.2	–	+4.5	+13.7	53.8

Breakdown

Cost of sales -¥17.2 billion

Main reasons

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- Amortization expenses related to inventories from PPA

R&D expenses

No Adjustment

SG&A expenses and Other income&expense

Main reason

- Termination Fee for lease contract cancellation

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Here is a table of reconciliation from full base to core base.

Reconciliation items are mainly cost of sales items, such as JPY12.5 billion of amortization expense on intangible assets related to acquisitions and in-licensing, and JPY4.7 billion of expensing of inventories evaluated at fair value. In addition, a one-time charge of JPY0.7 billion for lease contract cancellation was adjusted in other expenses, and a gain and loss on valuation of investment securities of JPY0.5 billion was adjusted in financial income and expenses.

FY2025 : Financial Forecast (Core/Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	106.9	103.5	-3.4	-3.1%
R&D expenses	143.3	150.0	6.7	4.7%
SG&A expenses	122.2	120.0	-2.2	-1.8%
Core operating profit	112.7	114.0	1.3	1.2%
Core profit before tax	113.9	114.0	0.1	0.1%
Income tax expense	23.4	23.0	-0.4	-1.8%
Core profit for the year	90.4	91.0	0.6	0.7%

* The exchange rate assumed for the second half of the fiscal year is ¥145 per US dollar.

Breakdown

Cost of sales -¥3.4 billion

Main reason

- Decrease in sales related to FORXIGA tablets and long-term listed products

R&D expenses +¥6.7 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Costs associated with sapablursen in-licensed from Ionis Pharmaceuticals, Inc.
- Promotion of cost efficiency measures

SG&A expenses -¥2.2 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Promotion of cost efficiency measures

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The following is the forecast for the full year.

For the fiscal year ending March 31, 2026, there is no change to the full-year core-based earnings forecast announced on May 8.

Although sales are expected to decline due to the entry of generic versions of FORXIGA, we anticipate increased revenue and profits as this will be offset by growth in QINLOCK, ROMVIMZA, and overseas royalty income.

We forecast that sales revenue will increase by JPY3.1 billion, or 0.6%, from the previous year to JPY490 billion, core operating profit will increase by JPY1.3 billion, or 1.2%, to JPY114 billion, and core profit for the year will increase by JPY0.6 billion, or 0.7%, to JPY91 billion.

FY2025 : Financial Forecast (Sales Revenue by Product)

Goods and Products (Domestic)	FY2024 Actual	FY2025 Previous forecast	Revision from previous forecast	FY2025 Revised forecast	YoY	
					Change	Change(%)
OPDIVO Intravenous Infusion	120.3	125.0	-5.0	120.0	-0.3	-0.3%
FORXIGA Tablets	89.6	80.0		80.0	-9.6	-10.7%
ORENCIA for Subcutaneous Injection	26.6	28.0		28.0	1.4	5.2%
GLACTIV Tablets	18.3	12.0		12.0	-6.3	-34.6%
VELEXBRU Tablets	10.5	11.0		11.0	0.5	4.4%
ONGENTYS Tablets	7.6	9.0		9.0	1.4	17.8%
KYPROLIS for Intravenous Infusion	8.6	9.0		9.0	0.4	4.6%
PARSABIV Intravenous Injection	8.4	9.0		9.0	0.6	6.7%
Goods and Products (Overseas)	**FY2024 Actual**	**FY2025 Previous forecast**	**Revision from previous forecast**	**FY2025 Revised forecast**	**YoY**	
					Change	**Change(%)**
OPDIVO	13.1	13.5		13.5	0.4	2.9%
QINLOCK®	25.5	34.0	2.0	36.0	10.5	41.2%
ROMVIMZA™	–	5.0	3.0	8.0	–	

・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

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There are some revisions in the sales forecast by product.

The forecast for OPDIVO has been revised downward by JPY5 billion to JPY120 billion from the previously announced forecast of JPY125 billion. Meanwhile, QINLOCK expects JPY360 billion, an upward revision of JPY2 billion from its previous forecast of JPY34 billion, while ROMVIMZA expects JPY8 billion, an upward revision of JPY3 billion from its previous forecast of JPY5 billion.

As a result, as indicated earlier, there is no revision to the overall full-year forecast for sales revenue, which is expected to be JPY490 billion.

FY2025 : Financial Forecast (Full / Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2025.

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	147.9	135.0	-12.9	-8.8%
R&D expenses	149.9	150.0	0.1	0.1%
SG&A expenses	125.7	120.0	-5.7	-4.5%
Operating profit	59.7	85.0	25.3	42.3%
Profit before tax	59.3	85.0	25.7	43.3%
Income tax expense	9.2	18.0	8.8	96.5%
Profit for the year	50.0	67.0	16.9	33.8%

* The exchange rate assumed for the second half of the fiscal year is ¥145 per US dollar.
For the second half of the fiscal year, the sensitivity to exchange rates is assumed to be an increase of ¥0.7 billion in revenue and an increase of ¥0.2 billion in operating profit for every ¥1 depreciation of the yen.

Breakdown

Cost of sales -¥12.9 billion

Main reasons

- Decrease in sales related to FORXIGA tablets and long-term listed products
- Absence of sales milestone on FORXIGA recorded in the previous fiscal year

R&D expenses +¥0.1 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Costs associated with sapablursen in-licensed from Ionis Pharmaceuticals, Inc.
- Absence of impairment losses on development compounds in the previous fiscal year

SG&A expenses -¥5.7 billion

Main reasons

- Costs related to Deciphera Pharmaceuticals (from 9 months to 12 months)
- Promotion of cost efficiency measures

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This is for reference only, but the full-year forecast on a full basis is also unchanged from the full-year forecast announced on May 8.

From here, I would like to give a brief update on Cenobamate (ONO-2017) and ROMVIMZA in a few slides.

Cenobamate (ONO-2017)

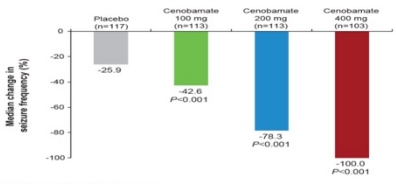
- **An antiepileptic drug with two action**
  - Inhibition voltage-dependent sodium currents and positive modulation of γ-aminobutyric acid type A ($GABA_A$) ion channels[1] -
- **Application for approval was submitted at the end of September based on the results of the Phase 3 clinical trial in patients with partial-onset seizures in Japan, South Korea, and China.**

【Cenobamate】

- U.S. approved: 2020 / Europe approved : 2021
- The cumulative number of prescriptions worldwide is approximately 220,000 (June 2025 data).
- In Phase 3 clinical trial, patients with uncontrolled partial-onset seizures despite treatment with 1 to 3 ASMs, once-daily cenobamate therapy for 12 weeks at all dose levels resulted in a significant reduction in the median percent change in seizure frequency.
- Compared to existing treatments, the combination therapy showed a favorable safety profile and was well tolerated.

【Primary Endpoint of Phase 3 Clinical trial】

Median percentage change in 28-day focal seizure frequency (MITT-M population)

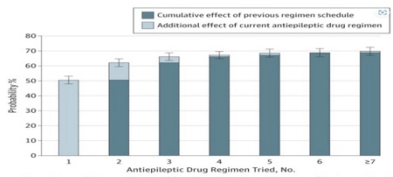


Source : Sunita N Misra, Louis Ferrari, Zhen Hong, et.al.,
A Randomized, Double – Blind, Placebo – Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Adjunctive CENOBAMATE in Asian Patients with Focal Seizures. AES 2024

【Epilepsy】

- Epilepsy is a chronic brain disorder occurring at any age in which seizures are triggered by abnormal excitability of nerve cells in the brain.
- In Japan, approximately 1 million people with epilepsy, and approximately 86,000 new cases are diagnosed each year. [2]
- Approximately 30% of patients with epilepsy are drug-resistant, meaning that even with combination therapy using existent anti-seizure medications, they are unable to achieve seizure freedom. [3]

Number of Concomitant Antiepileptic Drugs and Rate of Seizure Freedom



Seizure freedom is achieved in 50% of patients with the first antiepileptic drug, after adding more drugs, the maximum rate reaches approximately 70%.

Source : Chen Z et al : JAMA Neurol. 2018 Mar 1;75(3):279-286

1) Ono pharmaceutical press release in Oct., 2020
2) Japanese Society of Epilepsy. Guidebook for Board-Certified Epileptologists, Revised 2nd Edition. Shindan to Chiryo Sha; 2020.
3) Chen Z et al : JAMA Neurol. 2018 Mar 1;75(3):279-286

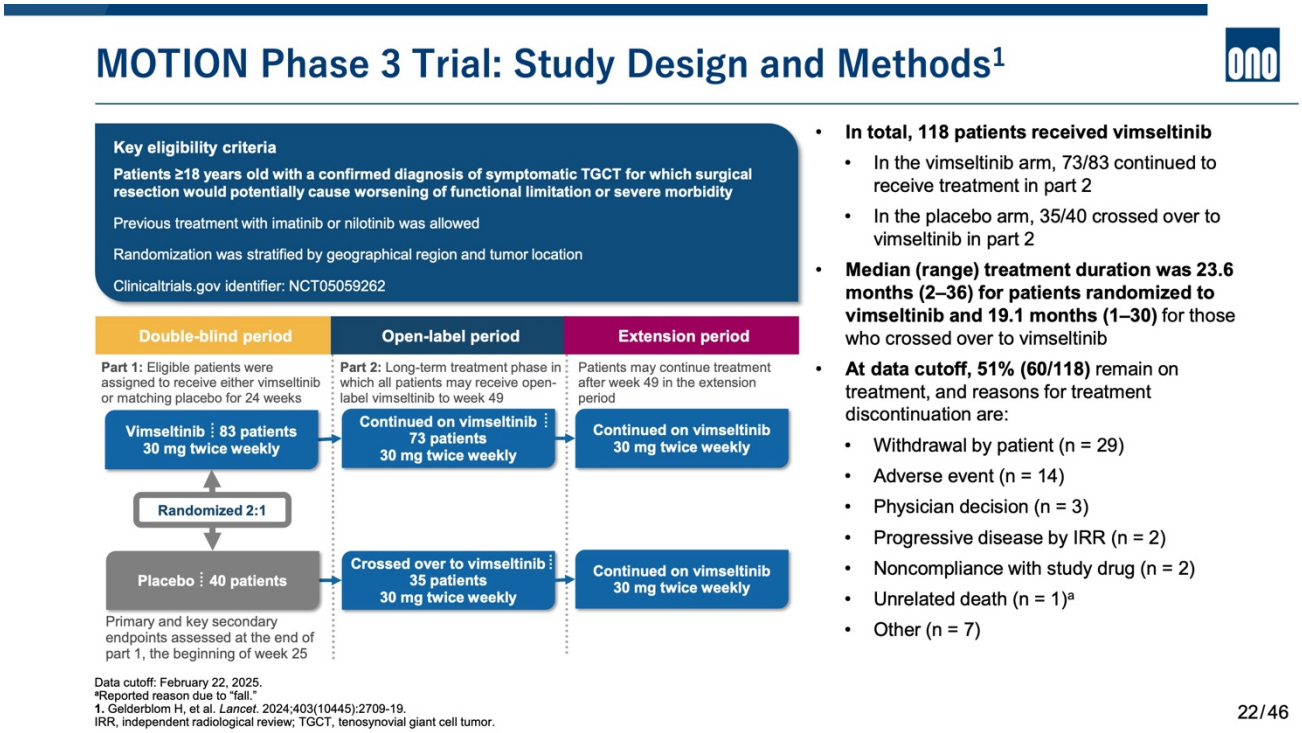
20/46

First, we filed for approval of Cenobamate (ONO-2017) in Japan last month, in September. The indication is partial-onset seizures.

It is estimated that approximately one million people in Japan have epilepsy. Currently, about 30% of these patients still experience uncontrolled seizures, forcing them to live their daily lives with lingering anxiety.

The results of the study have already been announced in academic conferences, and the results report a favorable efficacy and safety profile, with both Inhibition voltage-dependent sodium currents and positive modulation of γ-aminobutyric acid type A ($GABA_A$) ion channels actions.

Although the product is usually expected to be on the market in approximately one year, we are hopeful that Cenobamate will contribute to patients who are still suffering from seizures in the future.



I would like to talk about the two-year data from the Phase III study of ROMVIMZA. This was presented at the recent European Society for Medical Oncology (ESMO) 2025.

To begin with, here is an overview of the trial.

This trial was conducted mainly at facilities in Europe and the US Based on the Part 1 data from this trial, the yellow part, the efficacy and safety data at 25 weeks, the drug was approved in the US in February and in Europe in September.

The results of this study will evaluate the efficacy and safety of the product over a two-year period, including Part 2 and beyond. In addition to patients who received ROMVIMZA from the start, patients who initially received placebo in Part 1 also received ROMVIMZA in Part 2, resulting in a total of 118 patients in the data.

MOTION Phase 3 Trial: Efficacy

Response assessed by IRR per RECIST v1.1 and TVS

	Week 25		≥2 years on study[b]	
	Vimseltinib n = 83	Placebo n = 40	Vimseltinib n = 83	Crossover n = 35
RECIST v1.1				
ORR, n (%) (95% CI)	33 (40)[a] (29 to 51)	0 (0 to 9)	40 (48) (37 to 59)	19 (54) (37 to 71)
Complete response	4 (5)	0	19 (23)	4 (11)
Partial response	29 (35)	0	21 (25)	15 (43)
DOR, median (range), months	NR[b] (2.5+ to 30.9+)	N/A	NR (0.03+ to 30.9+)	NR (0.03+ to 25.4+)
TVS[c]				
ORR, n (%) (95% CI)	56 (67)[a] (56 to 77)	0 (0 to 9)	67 (81) (71 to 89)	25 (71) (54 to 85)
Complete response	4 (5)	0	20 (24)	4 (11)
Partial response	52 (63)	0	47 (57)	21 (60)
DOR, median (range), months	NR[b] (2.5+ to 33.1+)	N/A	NR (2.4+ to 33.1+)	NR (1.9+ to 25.4+)

- **2-Year Results: Vimseltinib Shows Robust and Durable Antitumor Efficacy.**
- **ORR by RECIST v1.1**
  - 48% (40/83) in the randomized vimseltinib group (where patients continued to receive vimseltinib in part 2)
  - 54% (19/35) in the crossover group (where patients randomized to placebo crossed over to vimseltinib in part 2)
- **ORR by Tumor Volume Score (TVS)**
  - 81% (67/83) in the randomized vimseltinib group (where patients continued to receive vimseltinib in part 2)
  - 71% (25/35) in the crossover group (where patients randomized to placebo crossed over to vimseltinib in part 2)
- The median DOR per RECIST v1.1 and TVS was still not reached for both groups after ≥2 years on study

\+ denotes response was ongoing at the last assessment. Dark blue and patterned shading represents the DOR. Baseline for all patients (including those who crossed over from placebo to vimseltinib) was defined as the last assessment prior to treatment with vimseltinib.
[a]Data cutoff: August 22, 2023, from Gelderblom H, et al. *Lancet*. 2024;403(10445):2709-19.
[b]Data cutoff: February 22, 2025.
[c]TVS response corresponds to ≥50% reduction in estimated tumor volume.[1]
1. Peterfy C, et al. *Future Oncol*. 2022;18(12):1449-59.
CI, confidence interval; CR, complete response; DOR, duration of response; IRR, independent radiological review; N/A, not applicable; NE, not evaluable; NR, not reached; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease; TVS, Tumor Volume Score.

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First, regarding efficacy, the results at Week 25 at the time of approval were robust, demonstrating durable antitumor effects.

The response rate, or ORR, as determined by RECIST, which evaluates tumor size in a planar fashion, is 48% for the ROMVIMZA group in Part 1 and 54% for the group starting in Part 2, demonstrating robust and durable anti-tumor efficacy.

Furthermore, the response rate, or ORR as determined by TVS, which evaluate with tumor volume score, showed that the ROMVIMZA group achieved 81% in Part 1 and 71% in Part 2. Compared to the 67% observed at the end of Part 1, Week 25, these results indicate a deeper and more sustained response, representing favorable outcomes.

MOTION Phase 3 Trial: Safety

Preferred term, n (%)	Vimseltinib n = 83		Crossover n = 35		Vimseltinib total n = 118	
	All Grades	Grade 3/4	All Grades	Grade 3/4	All Grades	Grade 3/4
Periorbital edema[a]	40 (48)	4 (5)	17 (49)	1 (3)	57 (48)	5 (4)
Pruritus[a]	31 (37)	3 (4)	11 (31)	2 (6)	42 (36)	5 (4)
Face edema[a]	28 (34)	1 (1)	9 (26)	0	37 (31)	1 (1)
Arthralgia	27 (33)	0	9 (26)	0	36 (31)	0
Blood CPK increased	26 (31)	12 (14)	10 (29)	7 (20)	36 (31)	19 (16)
Asthenia[a]	27 (33)	1 (1)	8 (23)	1 (3)	35 (30)	2 (2)
Fatigue	30 (36)	1 (1)	5 (14)	0	35 (30)	1 (1)
AST increased	23 (28)	1 (1)	11 (31)	0	34 (29)	1 (1)
Headache[a]	25 (30)	1 (1)	9 (26)	1 (3)	34 (29)	2 (2)
Rash	27 (33)	0	6 (17)	0	33 (28)	0
Hypertension	18 (22)	6 (7)	11 (31)	4 (11)	29 (25)	10 (8)
Edema peripheral	21 (25)	0	8 (23)	0	29 (25)	0
Nausea	22 (27)	0	6 (17)	0	28 (24)	0
Rash maculopapular[a]	20 (24)	2 (2)	6 (17)	0	26 (22)	2 (2)
Diarrhea	15 (18)	1 (1)	8 (23)	0	23 (19)	1 (1)
ALT increased	13 (16)	0	8 (23)	0	21 (18)	0
COVID-19	16 (19)	1 (1)	3 (9)	0	19 (16)	1 (1)
Generalized edema	15 (18)	1 (1)	4 (11)	0	19 (16)	1 (1)

- **Most TEAEs were grade 1/2, and grade 3/4 TEAEs were similar between randomized vimseltinib and crossover groups**
- There were no new TEAEs (preferred terms) in ≥15% of patients receiving vimseltinib and no new SAEs in >1 patient
- There was no evidence of cholestatic hepatotoxicity or drug-induced liver injury
- TEAEs led to dose interruption in 63% (74/118) and dose reduction in 58% (68/118) of patients, and 12% (14/118) of patients discontinued due to TEAEs
  - TEAEs that led to treatment discontinuation in >1 patient were periorbital edema (n = 3), pruritus (n = 3), and rash (n = 2)

Data cutoff: February 22, 2025.
[a]Denotes AEs without grade 4 criteria per Common Terminology Criteria for AEs version 5.0.
AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; COVID-19, coronavirus disease-2019; CPK, creatine phosphokinase; SAE, serious AE; TEAE, treatment-emergent AE.

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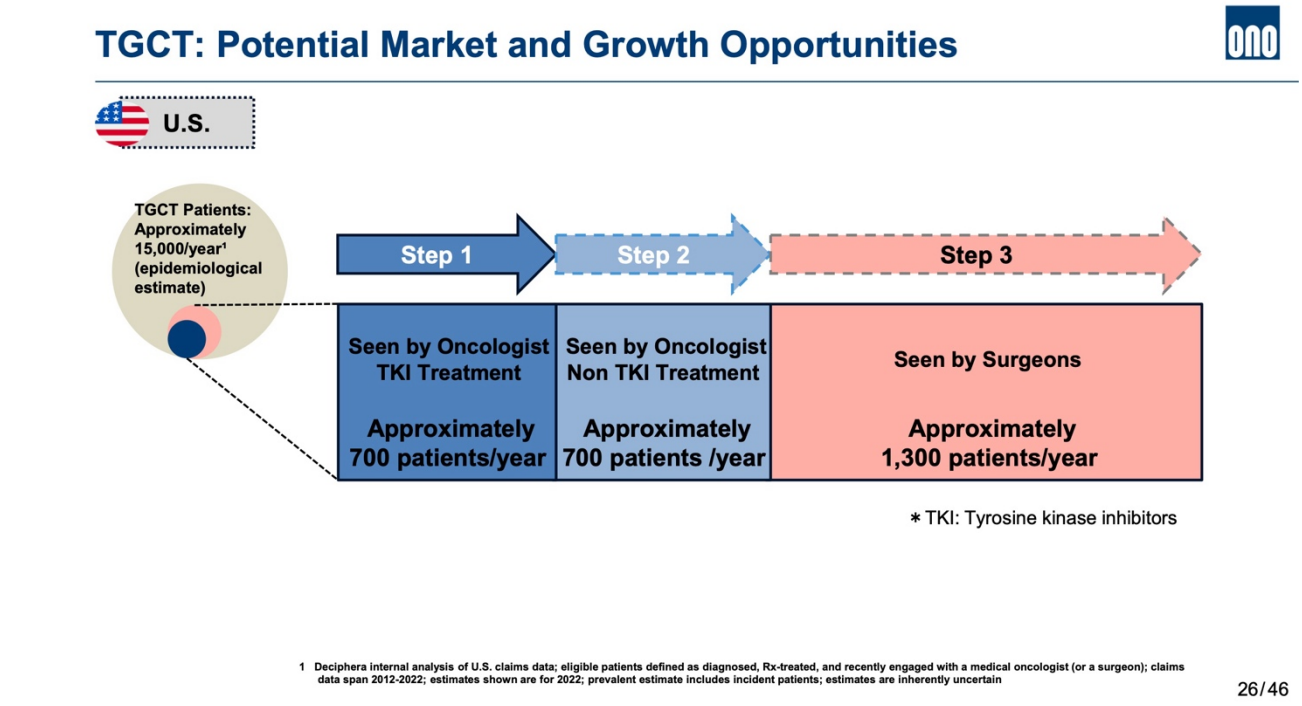
On the other hand, the slide here shows safety, and there were no noteworthy adverse events in the two-year study results, and no new events of hepatotoxicity or liver injury were observed.

Therefore, having obtained results demonstrating the efficacy and safety of ROMVIMZA over a relatively long period of two years, we intend to continue our efforts in the US and Europe to make ROMVIMZA available to more TGCT patients.



Finally, I would like to explain a little about the current status of ROMVIMZA prescriptions and the market in the US.

As we have already reported, market penetration of ROMVIMZA has been greater than initially expected, and we have revised our sales forecast upward to JPY8 billion for the current fiscal year.

First, as for the status of TGCT patients in the US, epidemiological information indicates that about 15,000 people are reported to be affected annually. Within this context, we are considering three distinct patient groups that could be candidates for treatment with ROMVIMZA.

In other words, as indicated in dark blue, approximately 700 patients per year actually receive treatment from medical oncologists using anticancer drugs, TKIs, tyrosine kinase inhibitors. And, as shown in light blue, about 700 patients per year who are seen by medical oncologists but not treated with anticancer drugs or TKIs. In addition, approximately 1,300 patients, shown in red, who are seen by orthopedic surgeons. This is our current analysis.

ROMVIMZA, which was approved in the US in February of this year, has already penetrated the market very steadily, with more than half of the patients in Step 1, shown in dark blue, being prescribed by the end of this fiscal year.

Therefore, even at the current pace, if the administration period for each patient continues for one or two years, we expect that the number of patients treated will accumulate in the next fiscal year and the year after that, and sales will grow to double or triple the current year's forecast.

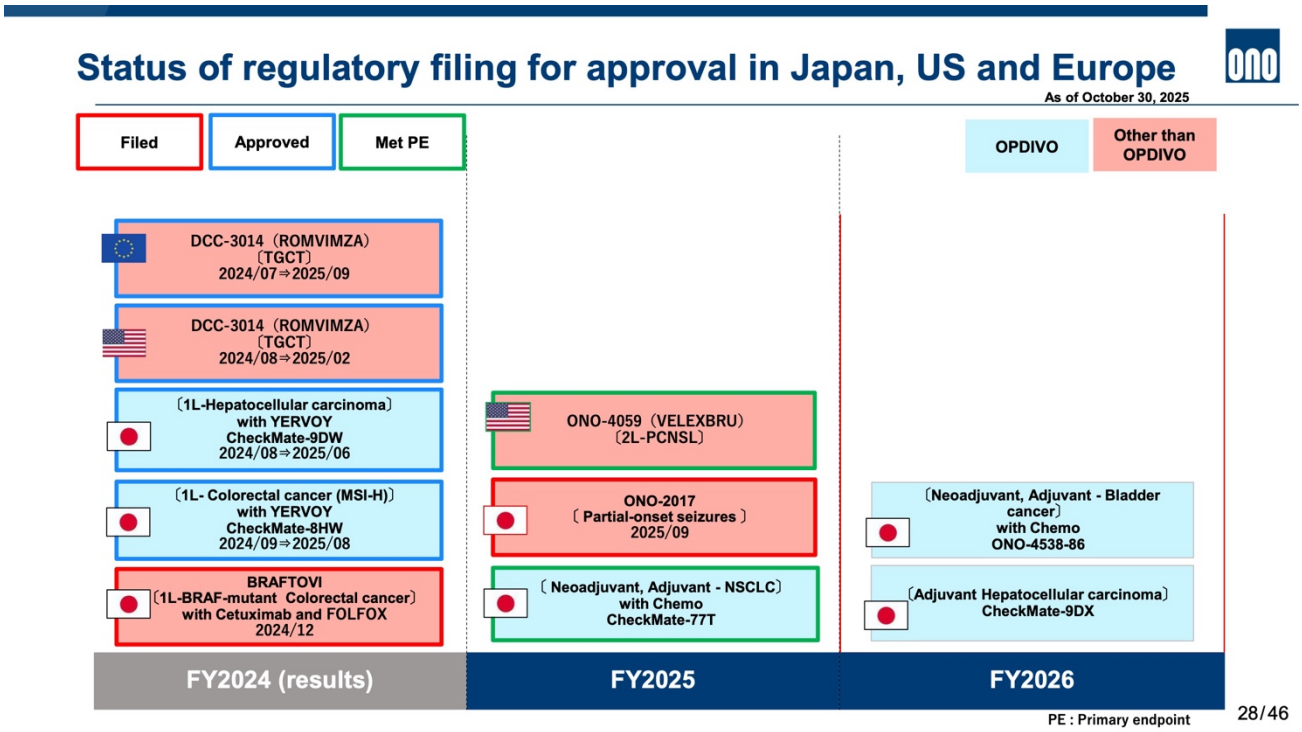
Furthermore, once ROMVIMZA's reputation for safety and rapid response is established, we believe that it will be expanded to patients who are seen by oncologists but have not yet been prescribed anticancer drugs or TKIs, as shown in Step 2, and further to TGCT patients who are not yet involved with an oncologist, as shown in Step 3.

The product was approved in Europe last month in September, and we plan to launch it successively in the future. We expect to be able to achieve peak sales of JPY50 billion to JPY60 billion, or even more, which we

expect from ROMVIMZA. In fact, we are feeling the market's appreciation and response to our products, and we hope that you will have high expectations for our products.

I would like to conclude my explanation with the comment that we are beginning to see a number of positive factors other than the financial results, and that we are beginning to see more and more things to look forward to. Thank you very much.

Imura: Next, Okamoto of Clinical Development will explain the progress status of development pipelines.



Okamoto: From me, as always, based on the materials posted on our website. I will use this document to explain the progress status of the development pipelines, focusing on the changes since the previous meeting on August 1 of this year.

First is the actual and planned application for approval. I will speak from the left column.

As you know, we are pleased to update you that the combination therapy of OPDIVO and YERVOY has been approved in Japan for the treatment of colorectal cancer with MSI-H in the first line of treatment, here. The area outlined in blue.

Also, as President Takino mentioned earlier, ROMVIMZA has been approved in Europe for the treatment of tenosynovial giant cell tumors, so we are also updating it.

In addition, the review by the authorities for BRAFTOVI, the first-line treatment for BRAF mutation-positive colorectal cancer, is currently in the final stage and is progressing well.

Then we move to the middle column, which is the row for applications scheduled for the current year.

As we recently announced in a press release, we have filed an application for Cenobamate, ONO-2017, for the expected indication of partial-onset seizures in epilepsy on September 30 and updated it.

Next is the schedule for future applications.

First, regarding the Phase III trial of OPDIVO and YERVOY, and combined with chemotherapy for first-line gastric cancer treatment, which was conducted in Japan, South Korea and Taiwan, the primary endpoint was unfortunately not met. Consequently, we have removed this from our planned application for FY2026.

The US application for ONO-4059, VELEXIBLE, is scheduled to be submitted by the end of this year.

This is all for the results and plans regarding the application for approval.

Development status of OPDIVO

As of October 30, 2025

- Approval or filed/awaiting approval in the past year
- Ongoing key clinical trials for approval

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Non-small cell lung cancer	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Approved	Approved
Colorectal cancer	MSI-H／dMMR (1st)	with Ipi	Approved	–	–	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant ・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	–	–	–	–
Richter transformation	2nd	Monotherapy	Ⅱ	–	–	–	–
Solid tumor	–	ONO-4538HSC (Comibination with vorhyaluronidase alfa)	Ⅰ	–	–	Approved	Approved

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after Q1 FY2025 in August

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This is an explanation of the major changes in the development status of OPDIVO.

As in the past, changes from the last time are indicated in red and yellow highlighting.

As mentioned earlier, we have obtained approval in Japan for the combination therapy with YERVOY for colorectal cancer with MSI-H as the first-line treatment and have updated this accordingly.

Additionally, the international Phase III trial evaluating the combination of YERVOY and chemotherapy for first-line gastric cancer treatment has been removed, as it failed to meet its primary endpoint.

These are the main updates of OPDIVO development status.

Development pipeline (Oncology) ①

As of October 30, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	BRAF-mutant thyroid cancer							FY2024.12 Filing accepted	JP, US, EU, KR, TW and others*	NCT04607421
QINLOCK (ripretinib) KIT inhibitor	Gastrointestinal Stromal Tumor 2L KIT Exon 11+17/18 (GIST)							FY2025 Primary Completion	US, EU, KR, TW and others	NCT05734105
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL) ≥2L							FY2027 Primary Completion	US	NCT07104032
	Primary central nervous system lymphoma (PCNSL) 1L, ≥2L							FY2025 Primary Completion (Part A) (Actual)	US	NCT04947319
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*							FY2025 Primary Completion (Actual)	JP, KR, TW	NCT06256328
	Colorectal cancer*							FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*							FY2026 Primary Completion	JP	NCT06542731
	Hormone receptor-positive, HER2-negative breast cancer							FY2026 Primary Completion	JP	NCT06570031
ONO-0530（sapablursen） Antisense oligonucleotide targeting TMPRSS6	Polycythemia Vera							FY2025 Primary Completion	US, EU and others	NCT05143957
ONO-4482 (relatlimab) Anti-LAG-3 antibody	Melanoma*							FY2024 Primary Completion (Actual)	JP, US, EU and others	NCT01968109
ONO-7427 Anti-CCR8 antibody	Solid tumor*							FY2025 Primary Completion	JP, US, EU and others	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced Malignancies (with ripretinib)							FY2026 Primary Completion	US	NCT05957367

MOA : Mode of Action

* : Combination with OPDIVO, * : Development rights countries: JP, KR
Estimated study completion date shown in jRCT or ClinicalTrials.gov

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after Q1 FY2025 in August

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The next is the progress status of the development pipelines in the oncology field excluding OPDIVO.

The third row from the top, ONO-4059, VELEXBRU, has been updated to reflect the initiation of a new randomized Phase III trial in the US targeting primary central nervous system lymphoma, PCNSL, in patients receiving second-line or later treatment.

As I mentioned earlier in the section on the schedule for submission for approval, we are planning to submit an expedited application for the target to the FDA this year based on the results of the Phase II study, as shown in the next column. The Phase III study I mentioned earlier is positioned as a confirmatory study. Preparations for the actual test are underway to launch the study not only in the US but also in Europe.

The EP4 antagonist, ONO-4578, as we recently announced in a press release, has shown positive results in a phase II study in first-line gastric cancer patients. We are unable to present the results here today, but we will provide an overview of the test and other information later.

Next, ONO-0530, sapablursen for which we have acquired global rights from Ionis, has completed Phase II trial results. We have received information from Ionis that these results are expected to be presented at an upcoming academic conference. In addition, sapablursen received Breakthrough Therapy designation from the FDA in May of this year.

Additionally, regarding the bottom row, the ULK inhibitor, DCC-3116, we have discontinued its development in combination with sotorasib, a KRAS G12C inhibitor, for strategic reasons, and removed it.

On the other hand, as mentioned on the slide, we continue development in combination with ripretinib, which is QINLOCK.

Development pipeline (Oncology) ②

As of October 30, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
DCC-3009 Pan-KIT inhibitor	Gastrointestinal Stromal Tumor							FY2028 Primary Completion	US	NCT06630234
ONO-7913 (magrolimab) Anti CD47 antibody	Pancreatic cancer*							FY2026 Primary Completion	JP	NCT06532344
	Colorectal cancer*							FY2027 Primary Completion	JP	NCT06540261
ONO-4685 PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2025 Primary Completion	US	NCT05079282
								FY2028 Primary Completion	JP	NCT06547528
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	HER2-expressing Solid tumor							FY2029 Primary Completion	US	NCT06241456
ONO-7428 Anti-ONCOKINE-1 antibody	Solid tumor							FY2029 Primary Completion	JP	NCT06816108
DCC-2812 GCN2 Activator	Renal Cell Carcinoma, Urothelial Cancer, Castration-Resistant Prostate Cancer							FY2028 Primary Completion	US	NCT06966024

MOA : Mode of Action

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

F : Filed, A : Approval

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after Q1 FY2025 in August

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We continue the area of oncology.

DCC-3084, a pan-RAF inhibitor, has been removed as we have discontinued its development for strategic reasons.

On the other hand, at the bottom, Phase I trial of DCC-2812, a drug candidate with GCN2 activating action, has started in the US, so we have added it.

Development pipeline (Non-oncology) ①

As of October 30, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial Giant Cell Tumor	■	■	■	■	■	■	FY2024 US: Approval FY2025 EU: Approval	US, EU and others	NCT05059262
	chronic Graft Versus Host Disease	■	■	■				FY2029 Primary Completion	US	NCT06619561
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	Partial-onset seizures	■	■	■	■	■		FY2025 JP : Filed	JP, KR and others*1	NCT04557085
	Primary generalized tonic-clonic seizures	■	■	■	■			FY2026 Primary Completion	JP	NCT06579573
VELEXBRU Tablet (ONO-4059：tirabrutinib) BTK inhibitor	Pemphigus	■	■	■	■			FY2027 Primary Completion	JP	NCT06696716
ONO-8531（povetacicept） BAFF/APRIL dual antagonist	IgA Nephropathy	■	■	■	■			FY2028 Primary Completion	JP, US, EU, KR, TW and others*2	NCT06564142
ONO-5532（Gel-One） Cross-linked hyaluronate	Knee osteoarthritis	■	■	■	■			FY2027 Completion	JP	jRCT2031240621
	Hip osteoarthritis	■	■	■	■			FY2027 Completion	JP	jRCT2061240110
ONO-2808 S1P5 receptor agonist	Multiple System Atrophy	■	■	■				FY2025 Primary Completion (Actual)	JP, US	NCT05923866

MOA : Mode of Action
*1 : Development rights country: JP, *2 : Development rights countries: JP, KR
Estimated study completion date shown in jRCT or ClinicalTrials.gov
F : Filed, A : Approval
EU : European countries
※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after Q1 FY2025 in August

The next slide summarizes the status of development pipelines in the non-oncology area.

Regarding the upper row, ROMVIMZA, as I mentioned earlier, it has been approved in Europe, so we updated it. Also, as for Cenobamate, it is just as I mentioned earlier.

We have acquired the development and commercialization rights in Japan and South Korea for povetacicept, a dual inhibitor of BAFF and APRIL, from Vertex Pharmaceuticals of the US. We have determined that the development code for this compound is ONO-8531 and added it here.

Next, regarding Gel-One, for which we have acquired exclusive rights for joint development and sales in Japan from Seikagaku, as noted in the middle column, we are currently conducting Phase III trials in Japan targeting osteoarthritis of the knee and osteoarthritis of the hip.

Finally, regarding the S1P5 receptor agonist ONO-2808, which is currently undergoing an international Phase II trial for multiple system atrophy, as President Takino mentioned earlier, I regret to inform you that we cannot present the results today; however, similar to ONO-4578, I will provide an overview of the trial.

Development pipeline (Non-oncology) ②

As of October 30, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-1110 Endocannabinoid regulation	Postherpetic Neuralgia							FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia							FY2026 Primary Completion	JP	NCT06752590
	Hunner Type Interstitial Cystitis							FY2026 Primary Completion	JP	NCT06752603
	Major Depressive Disorder							FY2026 Primary Completion	JP	NCT06792136
	Social Anxiety Disorder							FY2026 Primary Completion	JP	NCT06805565
ONO-2020 Epigenetic regulation	Alzheimer's Disease							FY2026 Primary Completion	JP, US	NCT06881836
	Agitation Associated with Dementia Due to Alzheimer's Disease							FY2026 Primary Completion	JP	NCT06803823
ONO-4685 PD-1 x CD3 bispecific antibody	Autoimmune disease							FY2024 Completion (jRCT)	JP	jRCT2071220081
								FY2024 Primary Completion(Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2026 Completion (jRCT)	JP	jRCT2071240056

MOA : Mode of Action

Estimated study completion date shown in jRCT or ClinicaiTrials.gov
Shaded boxes indicate studies on healthy volunteers.

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after Q1 FY2025 in August

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There are no updated sections here.

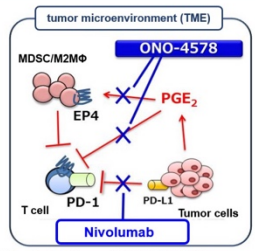
ONO-4578 overview

Compound information

Compound	ONO-4578
Originator	Ono Pharmaceutical Co., Ltd.
Mechanism	Prostaglandin receptor (EP4) antagonist
Formulation	Tablet
Target indication	Solid tumor
Development status	Phase II : gastric cancer 1L (JP, KR, TW) : colorectal cancer 1L (JP, US, EU, etc) Phase I : non-small cell lung cancer (JP) : hormone receptor-positive, HER2-negative breast cancer (JP)

Mechanism of Action

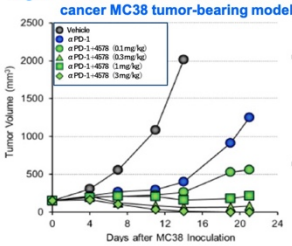
- Prostaglandin E_2 (PGE_2) is a bioactive lipid produced by the cyclooxygenase (COX) pathway and exerts various actions via its receptors (EP1-EP4).
- COX-2 is overexpressed in solid tumor[1], PGE_2 has been reported to induce myeloid-derived suppressor cells (MDSC) and M2 macrophages in the tumor microenvironment through one of its receptors, EP4, and suppress activation of cytotoxic T cells[2].
- ONO-4578, a novel selective EP4 antagonist, is expected to have an antitumor effect by abolishing the tumor immunosuppressive mechanism that PGE_2 constructs via EP4.



1) Bing L, et al. Cancer Cell Int; 2015:15:106
2) Yukinori T, et al. Front Immunol. 2020;11:324

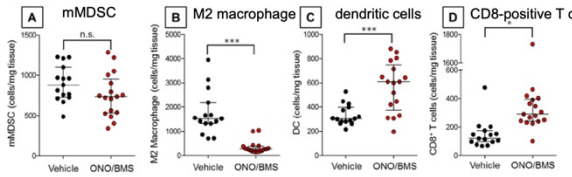
Non-clinical data

Fig 1. Time course of median tumor volume in syngeneic mouse colorectal cancer MC38 tumor-bearing model



- In syngeneic mouse tumor-bearing model, ONO-4578 improved immunosuppressive tumor microenvironment and showed antitumor effects (Figs. 1 and 2).
- Furthermore, ONO-4578 enhanced its antitumor effect by co-administration with anti-mouse PD-1 antibody (αPD-1) (Fig. 1).

Fig 2. Effect of ONO-4578 on intra-tumoral immune cells in syngeneic mouse colorectal cancer MC38 tumor-bearing model AACR 2020: Poster #4443



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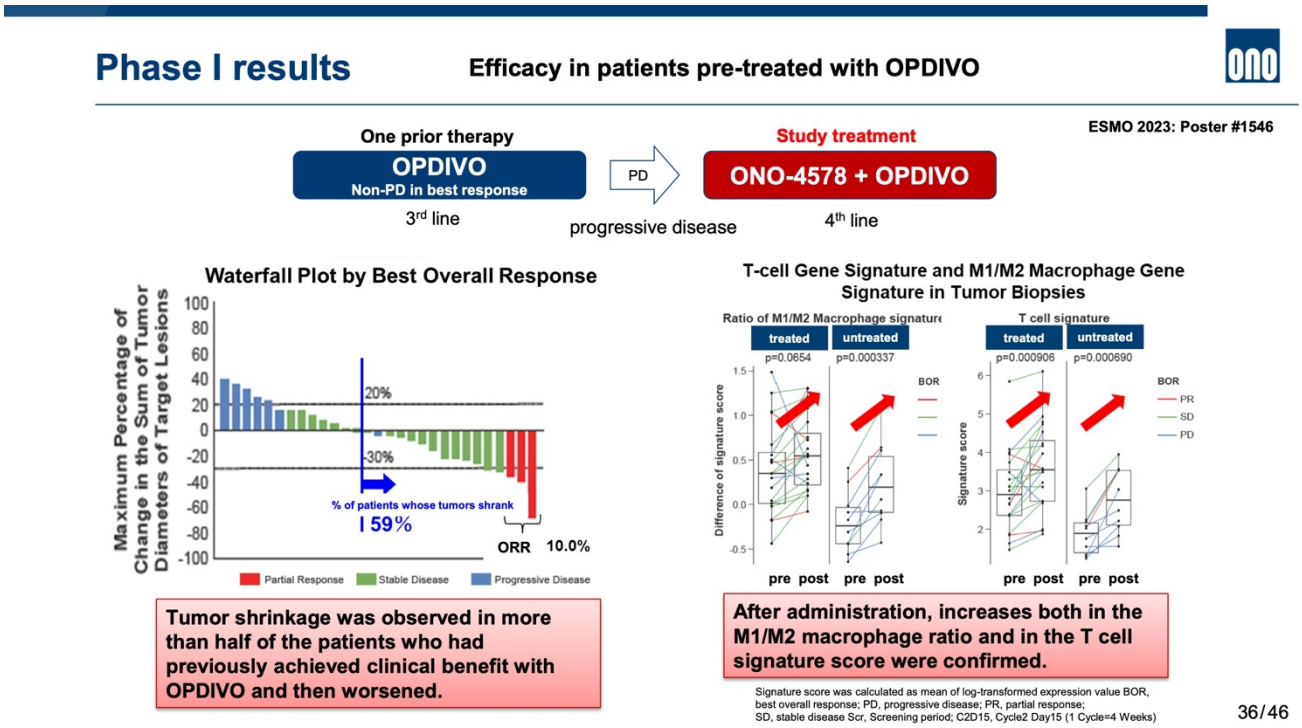
Let me start with ONO-4578 and briefly explain what the Phase II trial was about and the development process up to this point.

As we have previously introduced at R&D Meeting, ONO-4578 is an antagonist of EP4, one of the four receptors for prostaglandin E2, which was discovered by our company.

Regarding the mechanism of action, within the tumor microenvironment, it is thought to exert an antitumor effect by suppressing the activation and induction of cells such as MDSCs and M2 macrophages, which are believed to negatively regulate tumor immunity. This facilitates the activity of CD8-positive T cells, also known as killer T cells, which attack the tumor.

This mechanism suggests that combination therapy with OPDIVO, which activates T cells, can be expected to enhance efficacy. Indeed, as shown in the lower left, we have confirmed this synergistic effect in non-clinical studies. Additionally, regarding the mechanism mentioned earlier, we have confirmed this in the non-clinical phase.



This data was also introduced previously, but it shows the results of a Phase I trial conducted domestically combining ONO-4578 with OPDIVO.

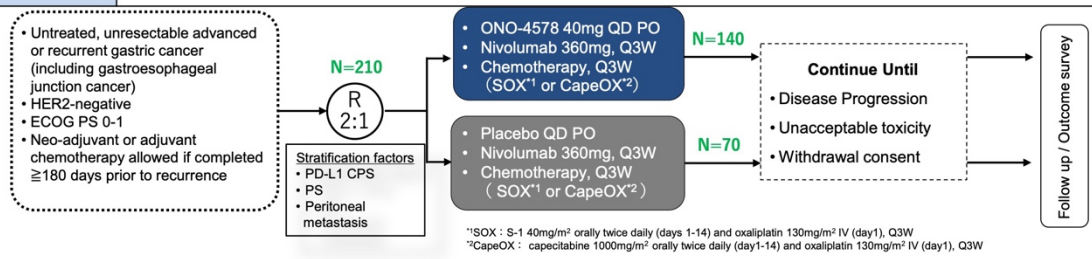
At that time, patients receiving OPDIVO monotherapy as standard third-line treatment demonstrated efficacy; however, in a cohort of patients who subsequently experienced disease progression, tumor shrinkage was observed again in more than half of the patients.

Also, in this study, we ask patients to cooperate with us before and after administration and collect tumor tissue from their specimens. Biomarker analysis here has confirmed behavior that supports the assumed mechanism of action.

Based on the above, we believe that our results support the hypothesis of the mechanism of action I mentioned earlier. In other words, one of the causes of reducing efficacy of OPDIVO treatment is the involvement of cells that negatively regulate tumor immunity, such as MDSCs and M2 macrophages, as has long been known. We believe we have obtained confirmation that ONO-4578 can reverse this.

ONO-4578-08 Study Design

Objective	This clinical trial was conducted in patients with previously untreated, HER2-negative unresectable advanced or recurrent gastric cancer or gastroesophageal junction cancer. ONO-4578 in combination with nivolumab and fluoropyrimidine-based and platinum-based chemotherapy which is one of the standard treatments in this setting was compared with placebo in combination with nivolumab and chemotherapy. The primary endpoint of this trial is progression-free survival (PFS).
Target population	Previously untreated, HER2-negative unresectable advanced or recurrent gastric cancer (including gastroesophageal junction cancer)
Study design	A multicenter, double-blind, randomized controlled Phase 2 clinical trial
Usage・Dosage	ONO-4578 group：ONO-4578 40mg QD／nivolumab 360mg Q3W／Chemotherapy (SOX*1 or CapeOX*2) Q3W Placebo group：Placebo QD／nivolumab 360mg Q3W／Chemotherapy (SOX*1 or CapeOX*2) Q3W
Endpoint	Primary endpoint：progression-free survival（PFS） Secondary endpoint：overall survival（OS）, objective response rate（ORR）, duration of response（DOR）, safety, etc
Target enrollment	210 patients［Japan, South Korea and Taiwan］



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Therefore, we designed a trial targeting gastric cancer in its first-line treatment, adding ONO-4578 to the combination therapy of OPDIVO and chemotherapy, which was already the standard treatment at that stage. This is the Phase II study that we recently released in a press release, ONO-4578-08.

This ONO-4578-08 trial is a multicenter, randomized, phase II trial in patients with HER2-negative gastric cancer in first-line treatment. At that time, and currently as well, we established a control group receiving the standard treatment of OPDIVO plus chemotherapy combined with a placebo. We then evaluated the efficacy and safety of a group receiving OPDIVO plus chemotherapy combined with the addition of ONO-4578 as the active drug group.

A total of 210 patients were randomized in a 2:1 ratio to the active drug group and the placebo group. For efficacy, PFS was the primary endpoint, and other efficacy endpoints evaluated included OS and ORR.

The results showed a statistically significant prolongation of PFS. We apologize that we cannot present specific data here today as the development lead. However, including the results for efficacy endpoints other than PFS, we believe we have obtained results that allow us to proceed confidently to Phase III trials, and that is our assessment.

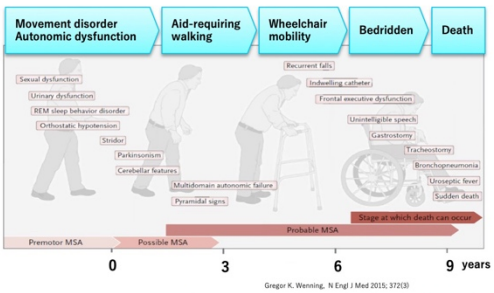
We expect to announce the results of this trial at the conference in the spring of next year or later. We are preparing to announce the results in the spring or later, with an eye on the most prominent cancer conferences in the world. That is all for ONO-4578.

ONO-2808 and MSA

Compound information

Compound	ONO-2808
Originator	ONO Pharmaceutical Co., Ltd.
Mechanism	S1P5 receptor agonist
Formulation	Oral
Target indication	MSA (Multiple System Atrophy)
Development status	Phase II (US, Japan)

Multiple System Atrophy

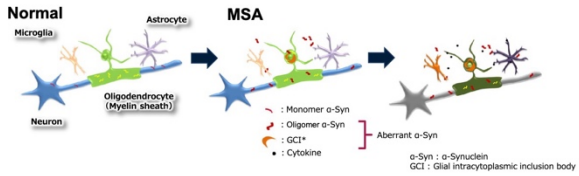


Gregor K. Wenning, N Engl J Med 2015; 372(3)

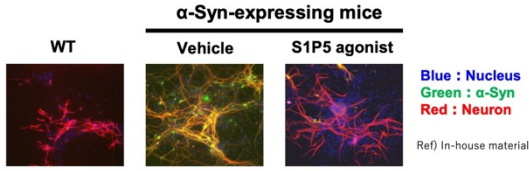
<Features>

- Progressive neurodegenerative disease with cerebellar atrophy
- Average onset age: 55–60 years
- Severe and rapidly progressive
- Currently symptomatic treatment with limited efficacy
- Estimated patients
  US [1), 2)]: 15,000～50,000, Japan [3)]：10,000

＊EU5：France, Germany, Italy, Spain, UK



Primary whole-brain cultures from oligodendrocyte-specific human α-Syn-expressing mice



S1P5 agonist suppressed α-Syn accumulation in neuronal axons

1) National Institutes of Health: https://www.ninds.nih.gov/health-information/disorders/multiple-system-atrophy, 2) Kaplan S, et al. Parkinsonism Relat Disord. 2023;117:105920. 3) https://www.nanbyou.or.jp/entry/59

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We will continue with the ONO-2808-03 study.

First, we would like to introduce the ONO-2808 itself. I believe that we have introduced this pipeline in the past at R&D meeting and other events.

The ONO-2808 is a selective agonist of the S1P5 receptor, discovered by our company. The dosage form is oral. We are currently developing this product for multiple system atrophy.

Multiple system atrophy is a progressive neurodegenerative disease in which the cerebellum and other parts of the brain atrophy. The diagram in the lower left shows the progression of the disease stage; however, this is a disease with rapid progression and a poor prognosis. In Japan, the disease is designated as a designated intractable disease, and it is estimated that there are approximately 10,000 patients with the disease, but we believe that there are nearly 50,000 patients worldwide, including those in Europe and the US. At present, there is no fundamental cure for this disease, and we believe that it is one of the diseases for which there is a particularly high unmet need.

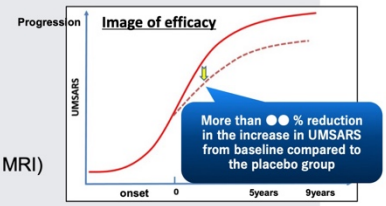
The pathogenesis of multiple system atrophy is believed to involve abnormal aggregation and accumulation of the protein α-Syn in oligodendrocytes and neurons. The diagram is in the upper right.

The lower right-hand side is in a non-clinical study. It was confirmed that an agonist of S1P5 inhibited the accumulation of α-Syn. If you compare this picture of the vehicle with the S1P5 agonist on the right, you can clearly see what I mean. We have confirmed that the accumulation of α-Syn, this green substance, is suppressed.

Therefore, we are developing ONO-2808, a selective S1P5 agonist, as a potential new treatment for multiple system atrophy.

Outline of the global phase II ONO-2808-03 study

ONO-2808-03 study	
Objective	To investigate the safety, tolerability, and pharmacokinetics of repeated-dose oral administration of ONO-2808 in patients with MSA.
Study design	Placebo-controlled, double-blind, randomized, parallel-group study
Target criteria	• Patients 30 to 80 years of age diagnosed with MSA • Patients defined as a maximum of 5 years since the onset of symptoms such as parkinsonism, ataxia, orthostatic hypotension and urinary dysfunction • Patients with an anticipated survival of at least 3 years
Endpoint	**Primary endpoint** • **Safety, tolerability** Secondary endpoint • PK、concentration in cerebrospinal fluid (CSF) Exploratory Endpoints • **UMSARS (Historical Review, Motor Examination)** • MSA-QoL、MoCA(Montreal Cognitive Assessment), COMPASS-31* • Brain volume(MRI：Brain stem, Cerebellum), White matter(Diffusion MRI) • Plasma BM(Neurofilament Light Chain, α-Syn, proteomics, etc.)
Dosage	**Double-blind phase：Placebo, low dose, medium dose, high dose** Extension phase：Maintain dose level(P group switches to low dose after completion of the transition period)
Duration	**Double-blind phase：6 months** Extension phase: 14months(Transition period for 2 months, extension phase for 12 months)
Enrollment	**20 patients per group, 80 in total**
Trial countries	US, Japan



COMPASS-31*： Autonomic Examination

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Here is a summary of the ONO-2808-03 study, Phase II.

ONO-2808-03 study is a multicenter, randomized, Phase II trial in Japan and the US in patients with multiple system atrophy within five years of symptom onset.

The study consists of a core part, which is a double-blind phase, and then an extended-dose part for longer-term evaluation. The results obtained this time are for the core part.

This trial comprised four groups: placebo, low-dose, medium-dose, and high-dose. While the primary endpoints were safety and tolerability, we also evaluated multiple exploratory efficacy measures. These included the UMSARS score, an indicator consisting of activities of daily living and motor function assessments, which is the primary endpoint in this Phase III trial for multiple system atrophy.

Results showed that, at each dose, ONO-2808 was first tolerated. Then, regarding the safety profile, we believe it was manageable.

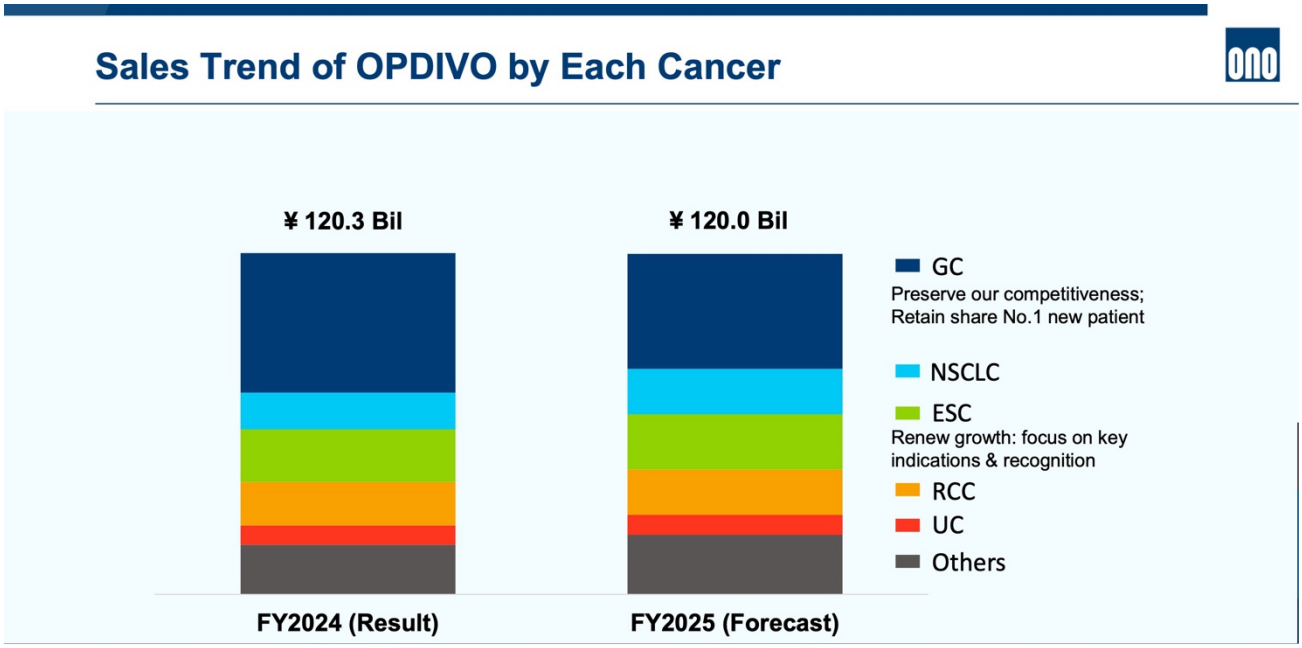
On the other hand, regarding efficacy, the trial design and settings positioned these as exploratory endpoints. Therefore, as mentioned earlier with ONO-4578, the trial was not designed to perform statistical testing; however, as stated previously, in multiple efficacy-related endpoints, including UMSARS, which will be the primary endpoint in the Phase III trial for this disease, numerically favorable results compared to placebo were obtained.

I am sorry that we cannot give you more details but based on the results of this study and our past efforts, we believe that we have obtained sufficient results to proceed to the next phase of the study.

We are now preparing to announce the results of this study at an academic conference in the spring of next year, which will be the largest academic conference in this field in the US.

That is all I have to say about the progress of the development pipelines and the most recent cases of ONO-4578 and ONO-2808. Thank you very much.

Imura: Lastly, Kitada of Sales and Marketing would like to introduce OPDIVO trends.



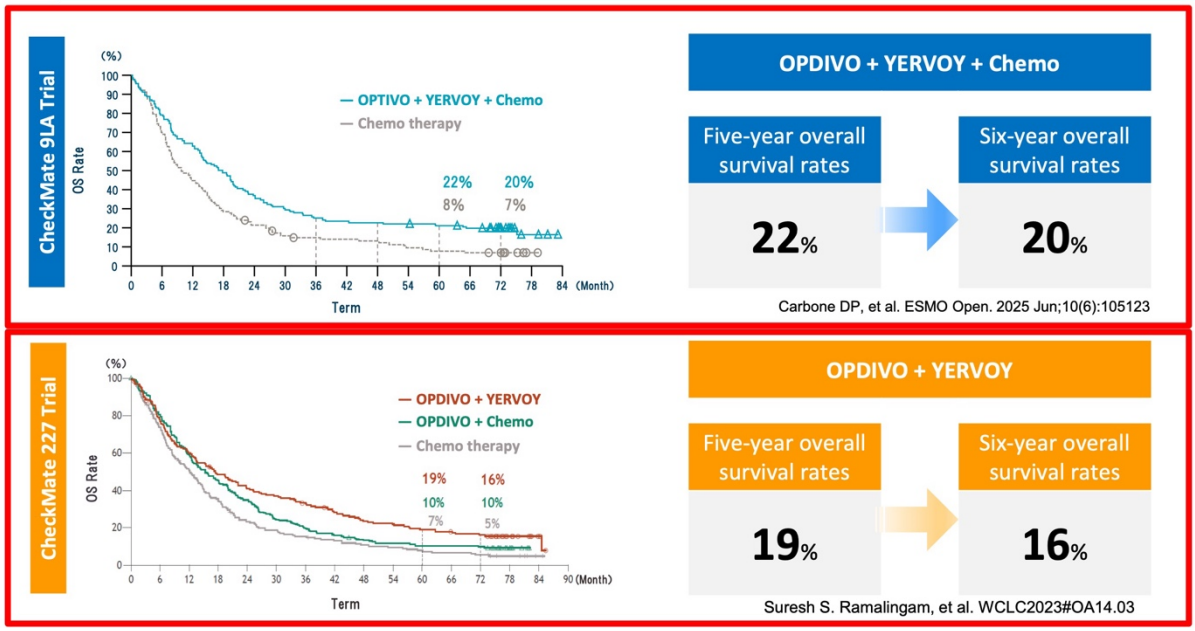
Kitada: I would now like to explain about the trend of our main product, OPDIVO.

This is an overview of the estimated sales of OPDIVO by cancer type.

In FY2024, the result was JPY120.3 billion. For the initial target of FY2025, we had projected JPY125 billion; however, as explained earlier, competition against OPDIVO continues to intensify. Particularly in gastric cancer, we are experiencing greater erosion from other agents than initially anticipated. Consequently, we have revised our annual forecast to JPY120 billion.

Moving forward, for gastric cancer, we will minimize competitive erosion while rapidly launching non-small cell lung cancer, hepatocellular carcinoma, which received an expanded indication in June, and colorectal cancer, which received an expanded indication in August, thereby building a foundation for OPDIVO's growth.

The result of Clinical Trial - NSCLC 1L（PD-L1 negative）-



I will now explain about non-small cell lung cancer, hepatocellular carcinoma, and colorectal cancer.

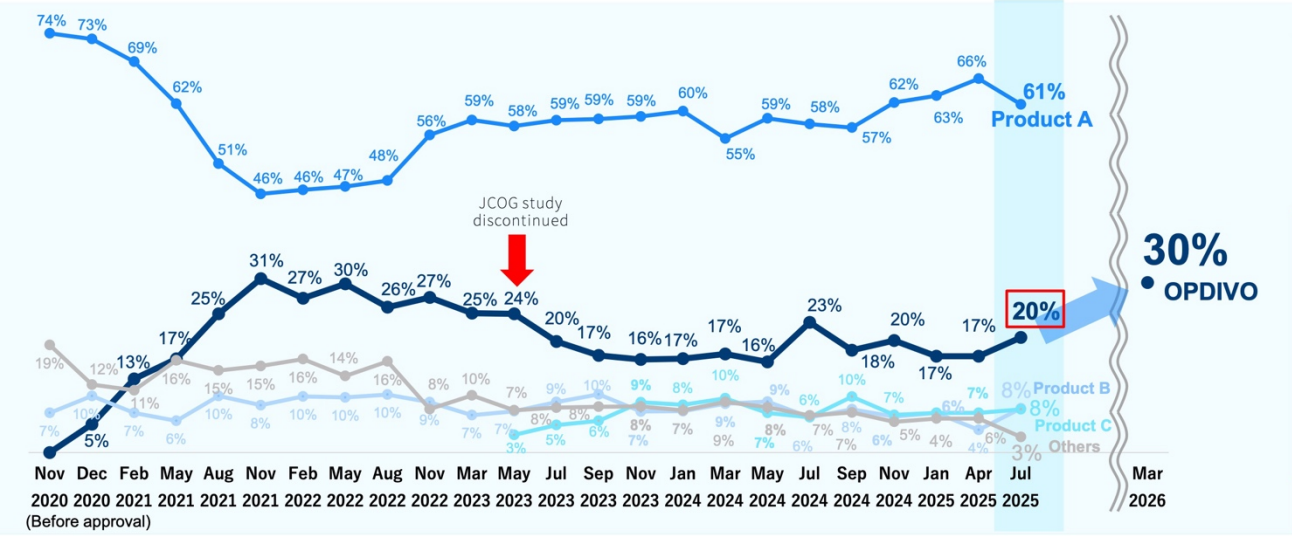
First, let me explain about non-small cell lung cancer.

The paper was published in June this year. In addition to the previous CheckMate-227 study, six-year follow-up data from the CheckMate-9LA study has been published in ESMO Open.

In this analysis, among PD-L1-negative patients with poor prognosis who had exhausted other treatment options, the combination therapy of OPDIVO and YERVOY demonstrated a six-year overall survival rate of 20%. The majority of patients who survived for five years were still alive at the six-year mark.

Note that the five-year survival rate obtained with other treatment options, as recommended by the guidelines for PD-L1-negative patients, is less than 10%. This demonstrates the renewed necessity of the OPDIVO plus YERVOY combination therapy for achieving long-term survival, and we have been advocating for this approach.

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



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

Source: Primary research results
(Nov 2020~Jul 2025: n=167~245)

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This chart shows the trend in new prescription share. As a result of the activities mentioned earlier, the new prescription share has recently recovered to 20%.

In FY2025, we will focus our activities on PD-L1-negative patients with solid evidence. We will strive to exceed the new prescription share achieved prior to the discontinuation of the JCOG trial within the current fiscal year and expect this to drive growth from the following fiscal year onward.

The Clinical Trial Result of HCC 1L

CheckMate 9DW Study

	OPDIVO＋YERVOY	Control Group (molecular-targeted drug)
OS	23.7 months	20.6 months
PFS	9.1 months	9.2 months
ORR	36%	13%
DOR	30.4 months	12.9 months
Three-years overall survival rates (follow-up data)	38%	24%
Steroid	29%*	-
Treatment-related death	3.6%	0.9%

* Percentage of high-dose steroid use

Lancet. 2025 May 24;405(10492):1851-1864.

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Next is hepatocellular carcinoma.

The results of the CheckMate-9DW study showed high efficacy in terms of response rate, duration of response, and three-year survival rate. Regarding the initial response to the activities, we have received feedback expressing high expectations for their effectiveness.

The share of new prescriptions for first-line treatment of hepatocellular carcinoma is steadily increasing, currently reaching 11%. As clinical experience continues to accumulate and awareness of its efficacy and safety measures spreads, we anticipate further significant growth. We expect immunotherapy to become the standard first-line treatment for hepatocellular carcinoma in the future.

Next is colorectal cancer.

In the CheckMate-8HW trial, the OPDIVO/YERVOY group demonstrated a hazard ratio of 0.21 for progression-free survival compared to the control group receiving chemotherapy, indicating a 79% reduction in the risk of death or disease progression. We will emphasize this data to promote the product.

We will continue to strengthen our activities in gastric cancer, hepatocellular carcinoma, colorectal cancer, and esophageal cancer in the gastrointestinal field in order to achieve growth for OPDIVO.

Question & Answer

Imura : I would now like to take your questions.

Thank you very much, Mr. Yamaguchi of Citigroup Securities.

Yamaguchi : I would like to ask a few questions briefly.

First of all, Q1 is not Apple to Apple, but when comparing Q2, it is Apple to Apple. If you compare Q2 with Deciphera on board, I think SG&A and R&D expenses are down YoY. There was a description of this area, and it was mentioned that you are keeping costs down a bit, but is this something that would continue throughout the year? I think the achievement rate for H1 of the fiscal year is quite high for that, and it looks as if the full year will also be on the upswing if things continue as is.

Itoh : Overall, we are managing expenses for R&D and SG&A separately. However, our fundamental policy is to fully utilize R&D expenses. Therefore, while there may be instances where unplanned expenses arise and cause costs to exceed projections, we expect the budget to proceed as planned.

By out of management, we are assuming that there will be some new licensing agreements and that R&D expenses will be included in the cost.

Yamaguchi : How is the overall progress? I think the rate of progress is pretty good, though. The company-wide profit progress rate, which I believe exceeded 60% in Q2, is also considered to be in line with your expectations.

Itoh : Yes, that's right. I know that Mr. Yamaguchi has been observing our company for many years, but basically, expenses tend to be biased toward H2.

We also have plans for H1 and H2 of the fiscal year in a non-half-and-half form, so we are not sure if profits will be overachieved or not, but they are almost in line with our projections for 1H. The increase in profit is due in part to the increase in sales, but in general, please understand that we are making good progress according to plan.

Yamaguchi : Can you tell us about one point in the pipelines? Regarding EP4, the domestic Phase II trial for gastric cancer went well, so I'm looking forward to seeing how things progress from here.

Will this asset be adapted and expanded, especially domestically? I understand that the asset originally came back from Bristol, but what are your current thoughts on domestic and international strategies, including global expansion, including whether you would choose candidates other than Bristol if you were to launch new markets?

Okamoto : As for your question, the first premise is that all of our in-house developed products are positioned as globally developed products. Naturally, our next plan for ONO-4578 in gastric cancer is to conduct our own international Phase III trials, including in Europe and the US, and to do so as the ONO Group.

ONO-4578 is already being tested for first-line treatment of colorectal cancer in Europe and the US, so I think you can understand that we have already begun to implement the so-called global expansion.

Yamaguchi : So you mean, since you also have Deciphera, you are expanding on the premise that you will do everything yourself.

Okamoto : Regarding Deciphera, I used the term ONO Group earlier, but I would appreciate it if you could understand it in that context.

Imura : Mr. Wakao from JP Morgan Securities, please.

Wakao : First of all, you are making very good progress in terms of ROMVIMZA. Can you give us some more details about the patient share and the outlook for H2? You mentioned earlier that you would administer the drug to more than half of the Step 1 patients during this fiscal year, right now. In that case, could you please provide more details about Step 1's market share and patient share, and whether the drug is currently not being administered outside of Step 1 to a limited extent?

Takino : As you are aware, Step 1 is currently being implemented at a pace where we anticipate that over half of the approximately 700 patients we expect annually will be prescribed the treatment throughout the year. We think it would be better if we could imagine half of that number in H1, say, a little over 200 patients.

Wakao : You say that progress is better than initially expected. What do you think is being evaluated? Also, in H2, maybe, as for the US, you can continue to take half the number, but please also tell us how Europe is factored in.

Takino : As of this half year, we have already reached the point where we hope we will be able to reach this level, and in fact, as we look at the movement of competitive product, we are imagining that the majority of cases are already using the ROMVIMZA formulation as the first choice.

While the US market did have some existing products that we entered into, one key point is that we have the impression that a well-profiled product like ROMVIMZA would be ideal to gain uptake from the very beginning.

In Europe, as you are well aware, systems differ from country to country, and I think that each country, starting with one country, will gradually launch its own system over a period of one, two, or three years, using the system of the respective country from where it can be developed. I do not have any comments on the figures, such as this is how the project will be launched.

Wakao : I would like to know two more things.

The first is about ONO-4578. As for the data, I think ASCO will provide it. Currently, gastric cancer development is very active, as seen at the recent ESMO, particularly targeting Claudin 18.2. We're also seeing the impact of VYLOY in the immediate term. However, regarding this ONO-4578, it targets a different population than Claudin.

So, is it your intention that Claudin will continue to target Claudin positive or low expression, and this ONO-4578 of yours will target areas where Claudin is not expressed? Based on the data we are seeing now, what is the situation going to be like in the future? Could you please tell us your company's current assumptions in this regard?

Okamoto : As I mentioned earlier in my introduction of the study outline, the development of ONO-4578 is an addition to the current standard of care, which is OPDIVO and chemotherapy, so I believe that the design of the Phase III study will not be significantly different from that of Phase II. I think that the design of Phase III will not differ greatly from that of Phase II.

On the other hand, next, as you pointed out, since OPDIVO entered the first-line therapy, the Claudin antibody has come in and entered the market. Currently, we are aware that the use of them is being differentiated based on guidelines and other factors. In some cases, as many as 50% of the patients are HER2-negative and Claudin-negative, so this is naturally a target for us.

On the other hand, this is true for the development of all drugs, anti-cancer drugs, such as PD-1/L1 antibodies, not only our OPDIVO but also KEYTRUDA. There are no head-to-head comparative studies of this combination therapy and chemotherapy, or of the combination therapy with Claudin antibody and chemotherapy, so at this point, we do not have an answer as to what makes this the first choice for the first line.

This will depend on the results and what choices are made based on them. Therefore, in response to your question, the trial design will first evaluate the added benefit for patients receiving OPDIVO plus chemotherapy. On the other hand, I believe it's impossible to say how the results will be applied in practice until the results are actually in.

Wakao : I understand that, but looking at the data now, do you have any sense as to whether it will be like Claudin is going to be separated, or whether you will be able to get it back again?

Okamoto : I am very sorry, but I would like to refrain from giving details about the data today.

Wakao : Lastly, ONO-2808. First of all, I think we will proceed with the current indications, but based on the mechanism, I would have expectations for multiple sclerosis. What is your company's current thinking regarding this area, and what can you tell us about your strategy for development?

Okamoto : Please understand that we have traditionally refrained from answering questions regarding specific development strategies.

Wakao : You don't have any human data, right now, for multiple sclerosis, nothing.

Okamoto : I hope you will forgive me for not being able to answer today about the non-clinical, non-disclosed items.

Imura : Mr. Hashiguchi of Daiwa Securities, please welcome.

Hashiguchi : As for ONO-4578, you mentioned that Phase III will be conducted on a global basis and by your own company. What are your thoughts on sales? Will it change or not depending on how magrolimab development goes? If a third party were to make an offer to develop a product together with you, would you decline the offer, saying, "No, we'll do it ourselves" or would you consider it a situation that is worth considering? Can you tell us what you are thinking now, looking a little further down the road?

Takino : For now, we, ourselves, are thinking along the lines of developing and marketing our own products on a global basis as well. Of course, there is a possibility that we may take a different option in the future, but for now, that is the way we are thinking.

Regarding magrolimab, the rights we currently hold are strictly limited to Japan and Asia. Therefore, I believe our approach will be based on considerations related to that scope.

Okamoto : We have not developed magrolimab for gastric cancer. Therefore, we would like to proceed with the global development of gastric cancer without having to think about internal cannibalism or this or that.

Hashiguchi : Another question about ONO-2808. Maybe I didn't hear it right, but I think the press release mentioned an interim analysis. Is it my understanding that this is the double-blind part, six months of data has been compiled? Also, you mentioned that the data was sufficient to enter the next phase, but I was wondering if you could tell us if the timing for entering the next phase is already somewhat clear.

Okamoto : To begin with, as you just asked, it is correct to understand that the double-blind phase has now concluded and the results from that phase have been obtained.

We are preparing for the next phase, which is ONO-4578, and since the results were obtained at the same time, we hope to consult with the regulatory authorities, specifically the FDA, by H1 of the next fiscal year regarding the study design, etc., for the next phase for both projects.

That is to say, based on the results, we would like to commence trials as early as possible. As a first step, we plan to initiate trial consultations with the FDA early in the next fiscal year.

Imura : Mr. Ueda of Goldman Sachs Securities, please welcome.

Ueda : I would like to ask you, first question, to tell us about your view of the future of R&D expenditure. As you introduced today, in places such as ONO-4578 and ONO-2808, as you are making steady progress, could you tell us about your approach to investment in this area, including whether there is a possibility that the ratio of R&D expenses to net sales will temporarily increase to some extent in the next fiscal year and beyond?

Takino : We cannot deny the possibility that this will have some impact, but we would like to control the situation so that it does not grow to the extent that you are concerned about.

Ueda : Second, I would like to know if the changes in the US business environment pose any risk to your company. Regarding US tariffs and MFN of NHI price, I imagine that for your company, since much of it involves royalty income, there are aspects where you aren't directly involved.

Through communication with Bristol Myers and others, if there are any areas of your company that you see as a risk, or if you have any ideas on how to deal with them, would you be willing to share them with us?

Itoh : Regarding the tariffs in the US, and the actual tariffs on pharmaceuticals, drug pricing policies, etc., are not yet clear in detail. The impact on royalties and the impact on the US business are still uncertain, and we will continue to monitor the situation closely.

At this point, we are not taking any concrete measures.

Imura : Next, Mr. Sakai from UBS Securities, please.

Sakai : I think the foreign exchange impact in this H1, with the addition of Deciphera, I think that part of three months is affected by that, and then royalties from Bristol and Merck. Basically, I think it is positive because of the weak yen, but the table on page eight shows the royalty foreign exchange impact, minus JPY1.8 billion. Could you please explain this, including the factors causing these fluctuations?

Itoh : Last year, , the exchange rate started in the JPY150 range at the beginning of the period, then rose to the JPY160 range in June. At the end of June, when we acquired Deciphera and included it in our financial results, the rate reached JPY161. After that, the yen suddenly increased by about JPY20, dropping to the low JPY140 range. On average, the exchange rate for the first half of last year was around JPY152.

In contrast, this fiscal year, overall, the average rate for the six-month period averaged JPY146, so although royalties on a sales basis and on a dollar basis increased compared to the previous fiscal year, this red 18 is negative because of that swing to a stronger yen. That is the way it is.

Sakai : Since this is a royalty, does that mean you are excluding the Deciphera portion?

Itoh : This portion does not have an impact by Deciphera.

Sakai : No impact. Do you mean because there are no figures in the previous term? You mean because there are so few of them?

Itoh : Yes.

Sakai : I have the impression that the yen is very strong at JPY146 for the current term. How much are you looking for assumptions, including H2?

Itoh : We are still looking at the assumption of JPY145 for H2.

Sakai : JPY145. So, this would mean an upward swing, at the current exchange rate level.

Itoh : As we go along now, yes.

Imura : Mr. Muraoka of Morgan Stanley Securities, please.

Muraoka : Briefly, about the R&D expenses in the next quarter and beyond. To minimize the impact, I believe you need to be much more decisive going forward, you have to ruthlessly cut out what doesn't work. Is that understanding, correct?

Takino : I am not sure if ruthlessly is the right word, but we will always prioritize and allocate resources appropriately.

Muraoka : As a result, you don't want to increase R&D expenses that much in the next fiscal year, is that right?

Takino : I might say there will be some expansion, but we will try to control it as much as possible.

Imura : We have reached the time. Thank you very much for long time.

[END]