FY2025 Q2 Financial Results

Oct 30, 2025

ONO PHARMA

Today's Attendees

代表取締役 社長 COO Representative Director, President and Chief Operating Officer	滝野　十一 Toichi Takino
常務執行役員 経営戦略本部 経営管理統括部長 Corporate Executive Officer / Division Director, Corporate Strategy & Planning, Business Management Division,	伊藤　雅樹 Masaki Itoh
執行役員 開発本部長 Corporate Officer / Executive Director, Clinical Development	岡本　達也 Tatsuya Okamoto
執行役員 営業本部長 Corporate Officer / Executive Director, Sales and Marketing	北田　浩一 Hirokazu Kitada
オンコロジー統括部長 Director of Oncology Business Division	高橋　宏幸 Hiroyuki Takahashi

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）

Forward-Looking Statements

Forecasts and other forward-looking statements included in this document are based on information currently available and certain assumptions that the Company deems reasonable.
Actual performance and other results may differ significantly due to various factors. Such factors include, but are not limited to:

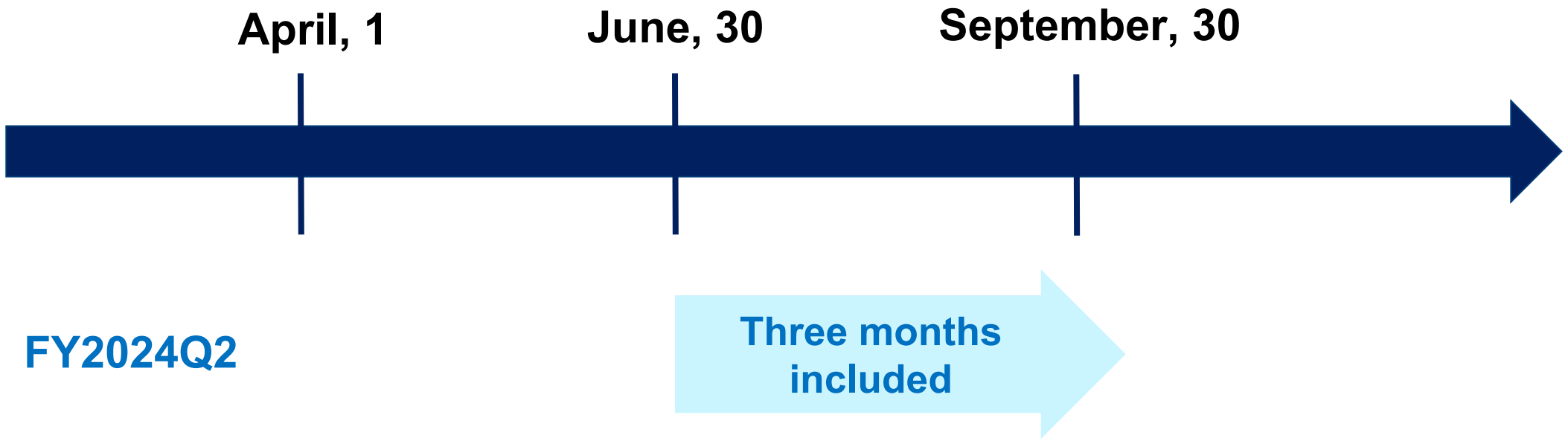
Forward-looking statements:	This presentation contains forward-looking statements regarding the Company's future plans, strategies, and performance.
Current assumptions:	These statements are based on current expectations, assumptions, and information available to management at this time.
Risks and uncertainties:	Forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially.
No guarantee of outcomes:	Forecasts, targets, and projections are not guarantees of future performance or achievement of stated goals.
Official guidance:	Official financial guidance should be referred to in accordance with relevant regulatory requirements and disclosures.
Product/market risks:	Risks include, but are not limited to, product development challenges, regulatory approvals, market acceptance, and competition.
Economic/industry risks:	Additional risks may arise from changes in economic conditions, currency fluctuations, and healthcare policy reforms.
No obligation to update:	The Company undertakes no obligation to update or revise any forward-looking statements as a result of new information or future events.
Prevailing language:	In the event of any inconsistency between language versions, the original Japanese language version shall prevail.

Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

FY2025 Q2 Financial Results

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.



Highlights of Financial Results for FY2025Q2 (Core Basis)

For the FY2025Q2 ending March 2026, we recorded increased revenue and profit.

FY2025Q2 Sales Revenue	**Revenue increased by ¥16.8 billion (7.0%) year on year to ¥257.1 billion,** **Domestic Sales :** While sales of FORXIGA expanded, overall sales slightly decreased mainly due to a decline in OPDIVO sales. **Overseas Sales :** Sales of QINLOCK increased by ¥10.0 billion to ¥18.1 billion. Sales of ROMVIMZA were ¥2.8 billion mainly due to the higher-than-expected acquisition of new prescriptions.
FY2025Q2 Core Profit for the Period	**Core profit for the period increased by ¥2.8 billion (5.5%) to ¥53.8 billion.** Although expenses increased due to the inclusion of three additional months of R&D and SG&A expenses for Deciphera compared to the previous year, the increase in sales exceeded these expenses, resulting in a profit increase.
FY2025 Financial Result Forecast	**Sales and profit for the year is expected to increase compared to the previous fiscal year.** Although a decrease in sales is expected due to the entry of generic versions of FORXIGA tablets, an increase in sales and profits is anticipated as this will be offset by the growth in sales of QINLOCK and ROMVIMZA, as well as an increase in overseas royalty revenue.
Status of Development Pipeline	Cenobamate (ONO-2017) : Approval application filed (Japan) ROMVIMZA: Approved (EU), Announced 2-year efficacy and safety results in the Phase 3 trial (MOTION) ONO-4578: Achieved primary endpoint in Phase 2 trial ONO-2808: Confirmed efficacy signals and tolerability in Phase 2 trial

FY2025Q2 : Sales Revenue

Revenue
¥257.1billion
YoY +16.8 billion
(+7.0%)

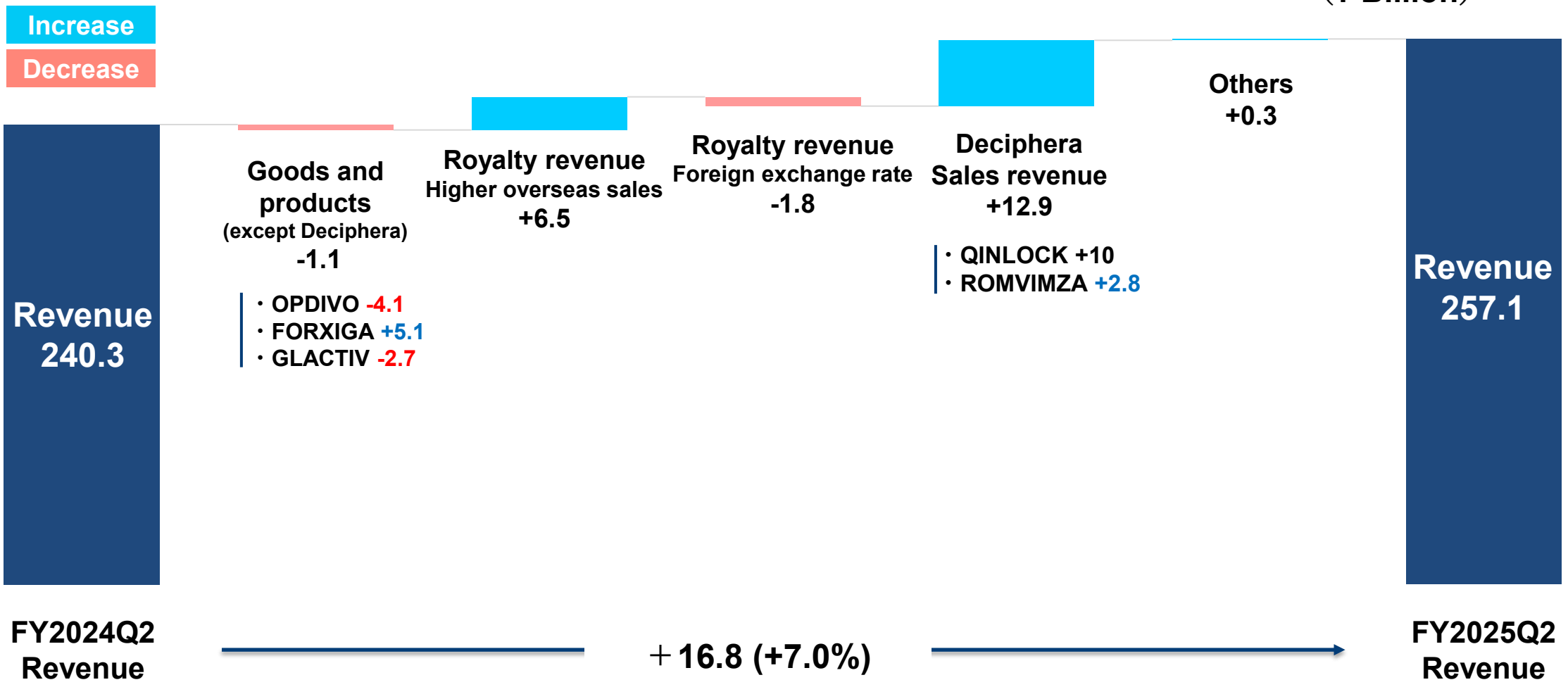
Goods and Products Sales
¥175.0 billion
YoY +11.7 billion (+7.1%)

Royalty and Others
¥82.2 billion
YoY +5.1 billion (+6.7%)

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.

(¥ Billion)



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.

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.

FY2025Q2 : Core Operating Profit

Core Operating Profit
¥70.1 billion

YoY +4.7 billion
(+7.2%)

Revenue ¥257.1 billion

YoY +16.8 billion (+7.0%)

R&D Expense ¥71.0 billion

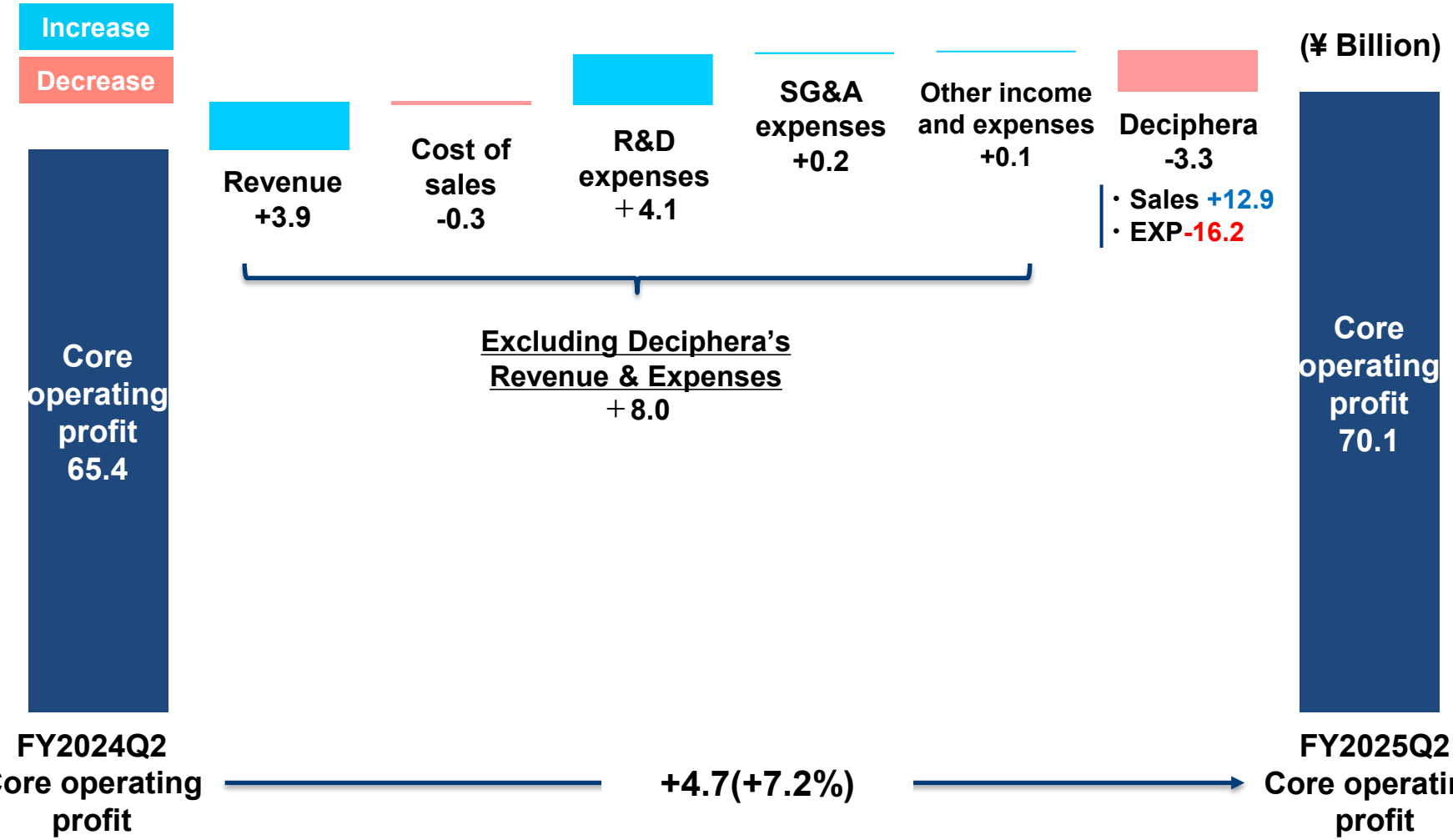
YoY +5.7 billion (+8.8%)

SG&A Expense ¥61.1 billion

YoY +5.6 billion (+10.2%)

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

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

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

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

(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.

(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

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

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.

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

Application for Approval of Cenobamate in Japan

Cenobamate（ONO-2017）

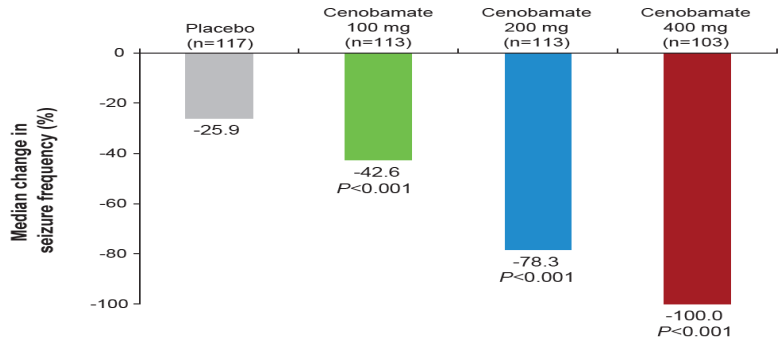
- **An antiepileptic drug with two action**
  - Inhibition voltage-dependent sodium currents and positive modulation of γ-aminobutyric acid type A ($GABA_A$) ion channels[1] -
- **Application for approval was submitted at the end of September based on the results of the Phase 3 clinical trial in patients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

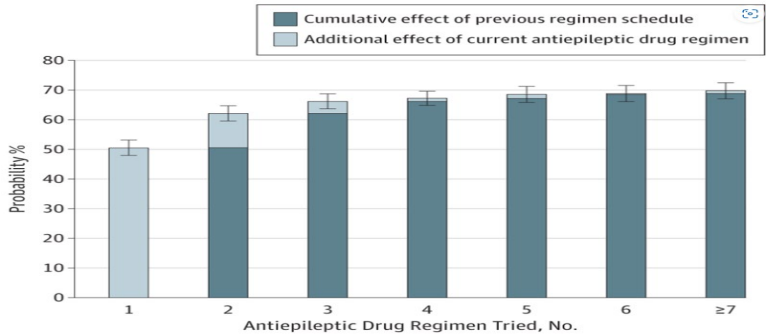


Source：Sunita N Misra, Louis Ferrari, Zhen Hong, et.al.,
A Randomized, Double－Blind, Placebo－Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Adjunctive CENOBAMATE in Asian Patients with Focal Seizures. AES 2024

【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

ROMVIMZA : Phase 3 Trial: 2-year data
- European Society For Medical Oncology 2025 presentation data -

MOTION Phase 3 Trial: Study Design and Methods[1]

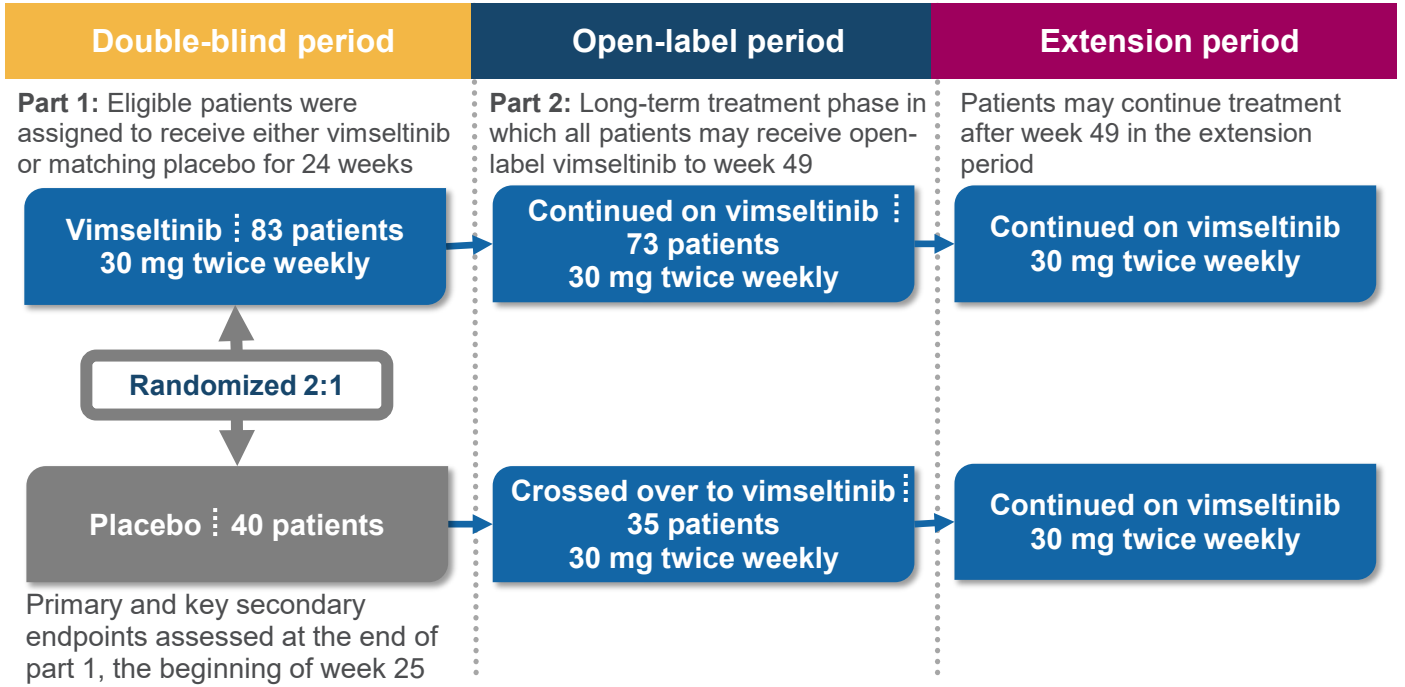
Key eligibility criteria

Patients ≥18 years old with a confirmed diagnosis of symptomatic TGCT for which surgical resection would potentially cause worsening of functional limitation or severe morbidity

Previous treatment with imatinib or nilotinib was allowed

Randomization was stratified by geographical region and tumor location

Clinicaltrials.gov identifier: NCT05059262



- **In total, 118 patients received vimseltinib**
  - In the vimseltinib arm, 73/83 continued to receive treatment in part 2
  - In the placebo arm, 35/40 crossed over to vimseltinib in part 2
- **Median (range) treatment duration was 23.6 months (2–36) for patients randomized to vimseltinib and 19.1 months (1–30)** for those who crossed over to vimseltinib
- **At data cutoff, 51% (60/118)** remain on treatment, and reasons for treatment discontinuation are:
  - Withdrawal by patient (n = 29)
  - Adverse event (n = 14)
  - Physician decision (n = 3)
  - Progressive disease by IRR (n = 2)
  - Noncompliance with study drug (n = 2)
  - Unrelated death (n = 1)[a]
  - Other (n = 7)

Data cutoff: February 22, 2025.
[a]Reported reason due to "fall."
1. Gelderblom H, et al. *Lancet*. 2024;403(10445):2709-19.
IRR, independent radiological review; TGCT, tenosynovial giant cell tumor.

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.

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)

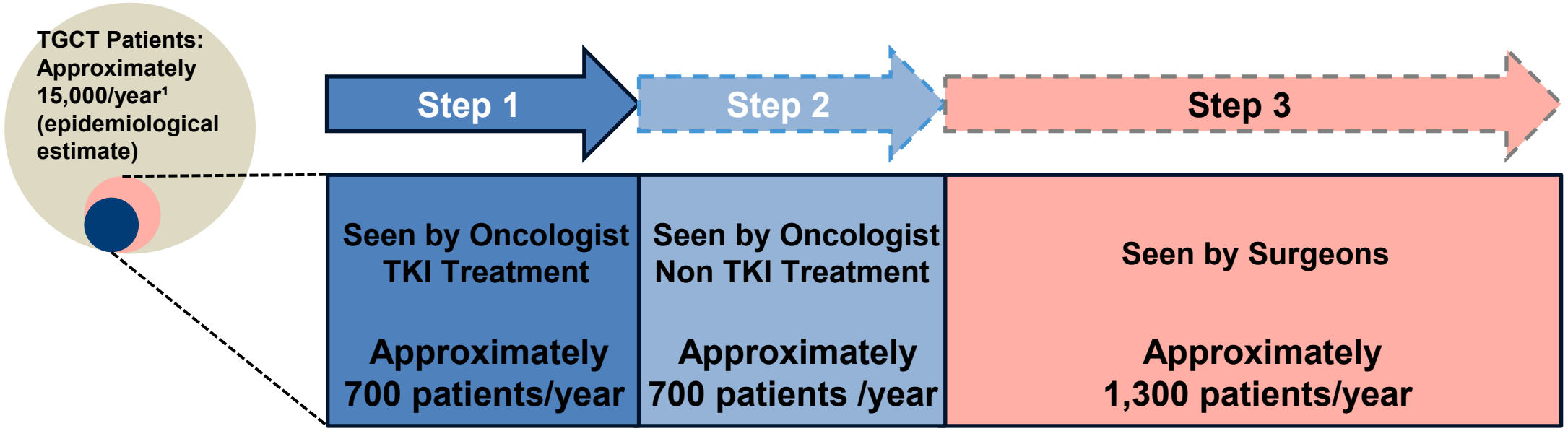
- **Most TEAEs were grade 1/2, and grade 3/4 TEAEs were similar between randomized vimseltinib and crossover groups**
- There were no new TEAEs (preferred terms) in ≥15% of patients receiving vimseltinib and no new SAEs in >1 patient
- There was no evidence of cholestatic hepatotoxicity or drug-induced 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.

Tenosynovial giant cell tumor(TGCT) Market Potential in the U.S.

TGCT: Potential Market and Growth Opportunities

U.S.



∗ TKI: Tyrosine kinase inhibitors

1 Deciphera internal analysis of U.S. claims data; eligible patients defined as diagnosed, Rx-treated, and recently engaged with a medical oncologist (or a surgeon); claims data span 2012-2022; estimates shown are for 2022; prevalent estimate includes incident patients; estimates are inherently uncertain

Development Pipeline Progress Status

Status of regulatory filing for approval in Japan, US and Europe

As of October 30, 2025

Filed | Approved | Met PE

OPDIVO | Other than OPDIVO

DCC-3014（ROMVIMZA）
〔TGCT〕
2024/07⇒2025/09

DCC-3014（ROMVIMZA）
〔TGCT〕
2024/08⇒2025/02

〔1L-Hepatocellular carcinoma〕
with YERVOY
CheckMate-9DW
2024/08⇒2025/06

〔1L- Colorectal cancer (MSI-H)〕
with YERVOY
CheckMate-8HW
2024/09⇒2025/08

BRAFTOVI
〔1L-BRAF-mutant Colorectal cancer〕
with Cetuximab and FOLFOX
2024/12

ONO-4059（VELEXBRU）
〔2L-PCNSL〕

ONO-2017
〔Partial-onset seizures〕
2025/09

〔Neoadjuvant, Adjuvant - NSCLC〕
with Chemo
CheckMate-77T

〔Neoadjuvant, Adjuvant - Bladder cancer〕
with Chemo
ONO-4538-86

〔Adjuvant Hepatocellular carcinoma〕
CheckMate-9DX

FY2024 (results) | FY2025 | FY2026

PE : Primary endpoint

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

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 ClinicaiTrials.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

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

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 ClinicaiTrials.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

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

ONO-4578-08 study

EP4 antagonist / Gastric Cancer, 1L

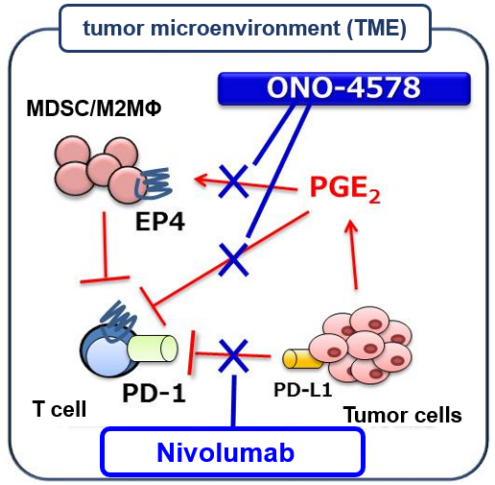
ONO-4578 overview

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

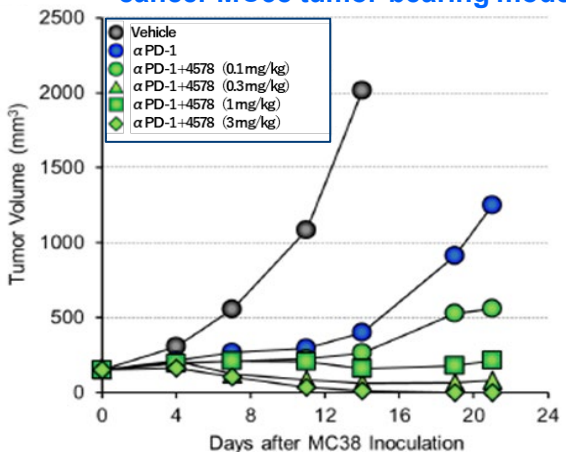
- Prostaglandin E_2 (PGE_2) is a bioactive lipid produced by the cyclooxygenase (COX) pathway and exerts various actions via its receptors (EP1-EP4).
- COX-2 is overexpressed in solid tumor[1]. PGE_2 has been reported to induce myeloid-derived suppressor cells (MDSC) and M2 macrophages in the tumor microenvironment 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

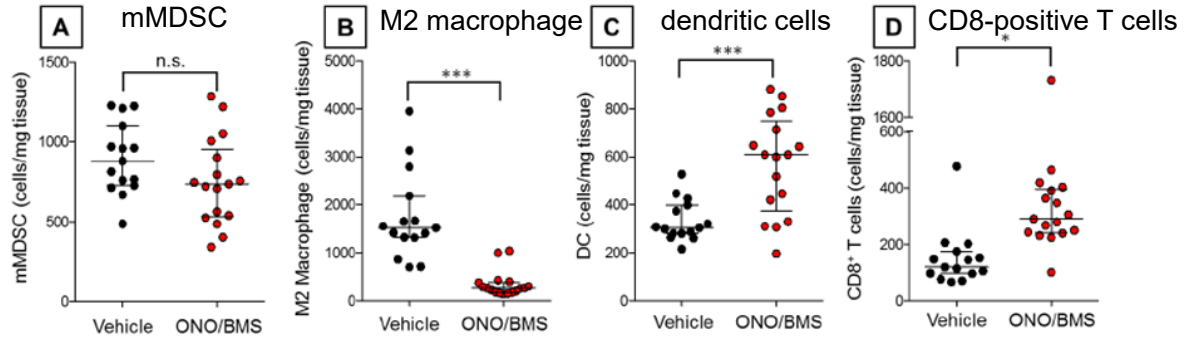
Fig 1. Time course of median tumor volume in syngeneic mouse colorectal cancer MC38 tumor-bearing model



- 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



Phase I results

Efficacy in patients pre-treated with OPDIVO

ESMO 2023: Poster #1546

One prior therapy

OPDIVO
Non-PD in best response

3rd line

PD

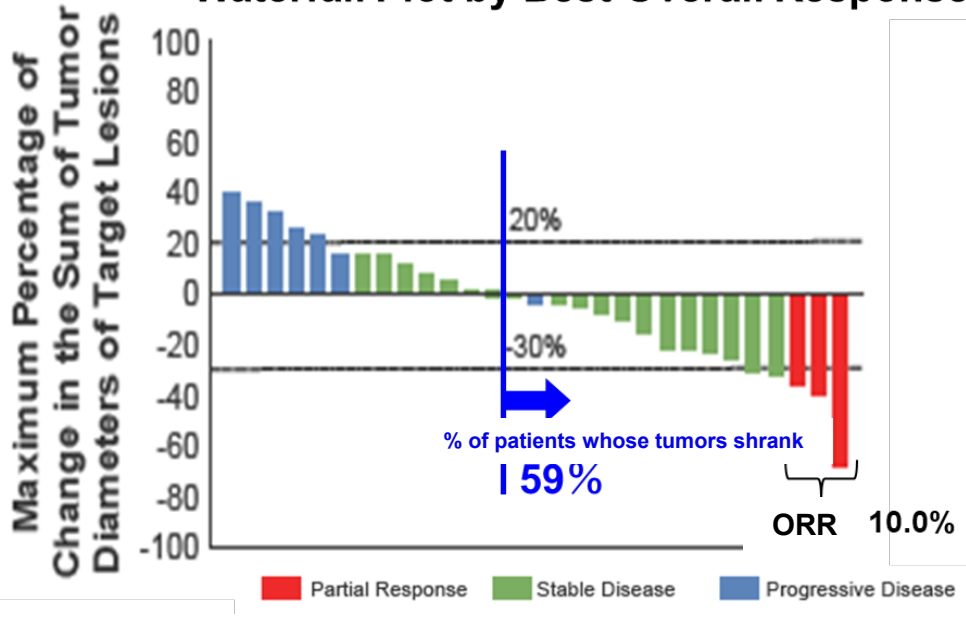
progressive disease

Study treatment

ONO-4578 + OPDIVO

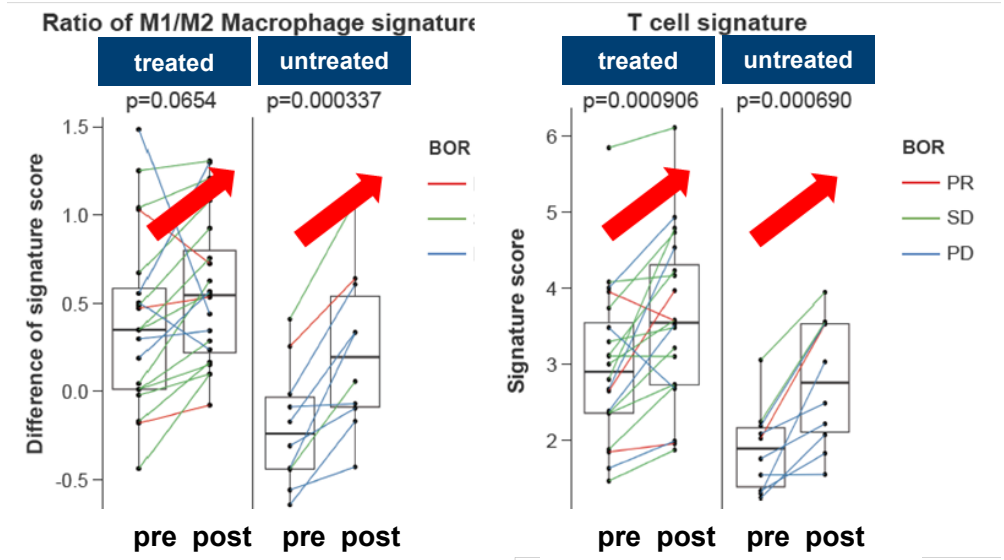
4th line

Waterfall Plot by Best Overall Response



Tumor shrinkage was observed in more than half of the patients who had previously achieved clinical benefit with OPDIVO and then worsened.

T-cell Gene Signature and M1/M2 Macrophage Gene Signature in Tumor Biopsies

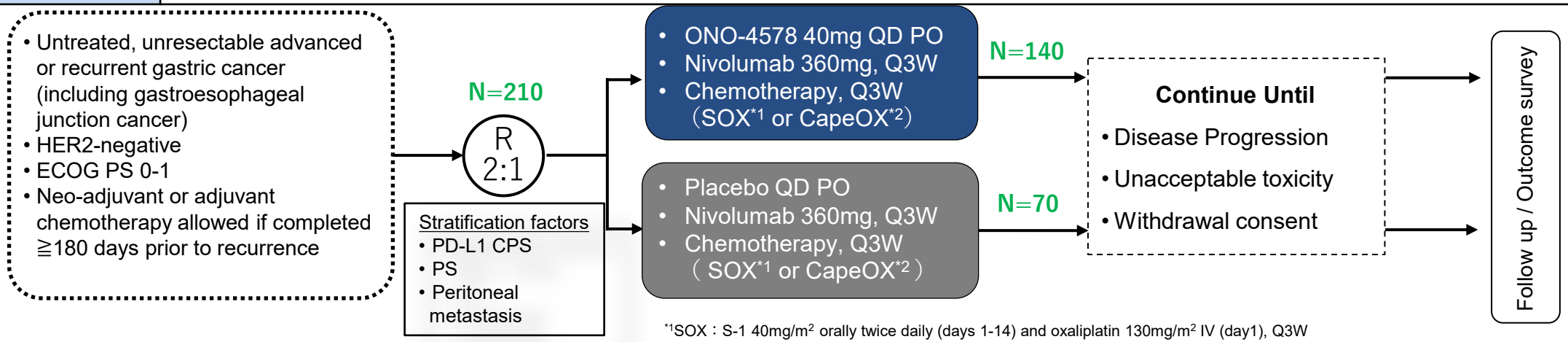


After administration, increases both in the M1/M2 macrophage ratio and in the T cell signature score were confirmed.

Signature score was calculated as mean of log-transformed expression value BOR, best overall response; PD, progressive disease; PR, partial response; SD, stable disease Scr, Screening period; C2D15, Cycle2 Day15 (1 Cycle=4 Weeks)

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］



*1SOX：S-1 40mg/m² orally twice daily (days 1-14) and oxaliplatin 130mg/m² IV (day1), Q3W
*2CapeOX： capecitabine 1000mg/m² orally twice daily (day1-14) and oxaliplatin 130mg/m² IV (day1), Q3W

Annual Number of Gastric Cancer Patients (Japan)

Gastric Cancer Prevalence

- Approximately 126,000 patients per year[1]

Unresectable, Advanced, or Recurrent Gastric Cancer (Eligible for Chemotherapy)

- Approximately 27,000 patients per year[2]
  - HER2-negative: Approximately 22,000 patients per year[2]

Reference[2]

- US : Estimated 11,000 patients (HER2-negative: 9,000)
- EU : Estimated 26,000 patients (HER2-negative: 22,000)
- anti-PD-1 antibody + chemotherapy (HER2-negative, Claudin-negative) : approx. 50%

1) Globocan 2022: Stomach Cancer, Japan, World Health Organization Available at: https://gco.iarc.who.int/media/globocan/factsheets/populations/392-japan-fact-sheet.pdf
2) Ono internal estimates

ONO-2808-03 study

S1P5 Receptor Agonist

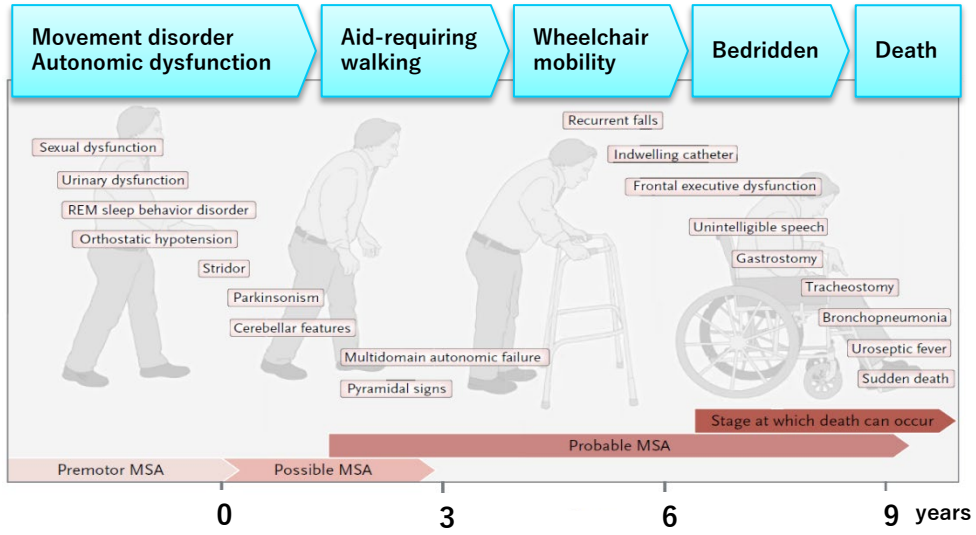
MSA；Multiple System Atrophy

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

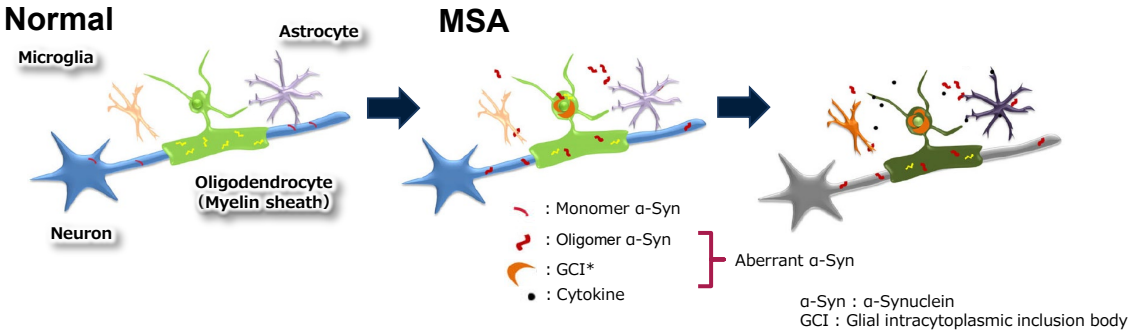


Gregor K. Wenning, N Engl J Med 2015; 372(3)

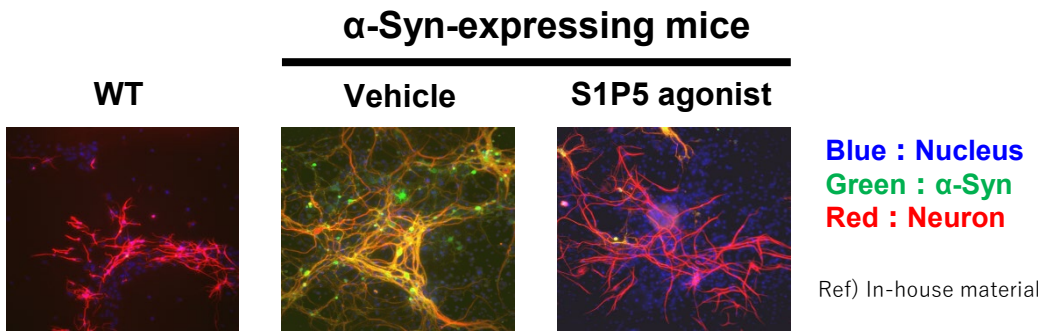
<Features>

- 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



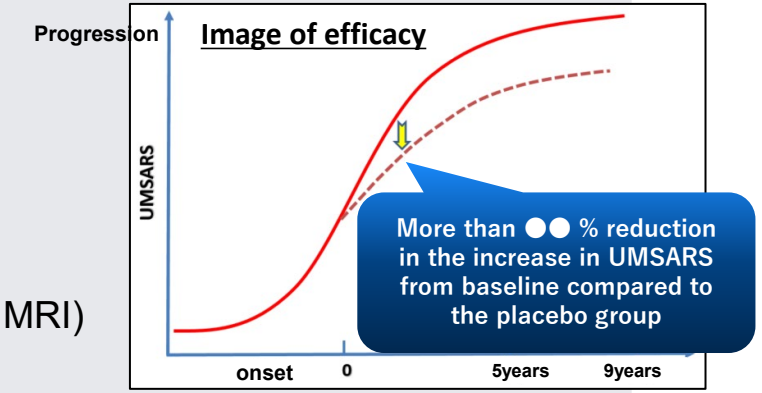
Ref) In-house material

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

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

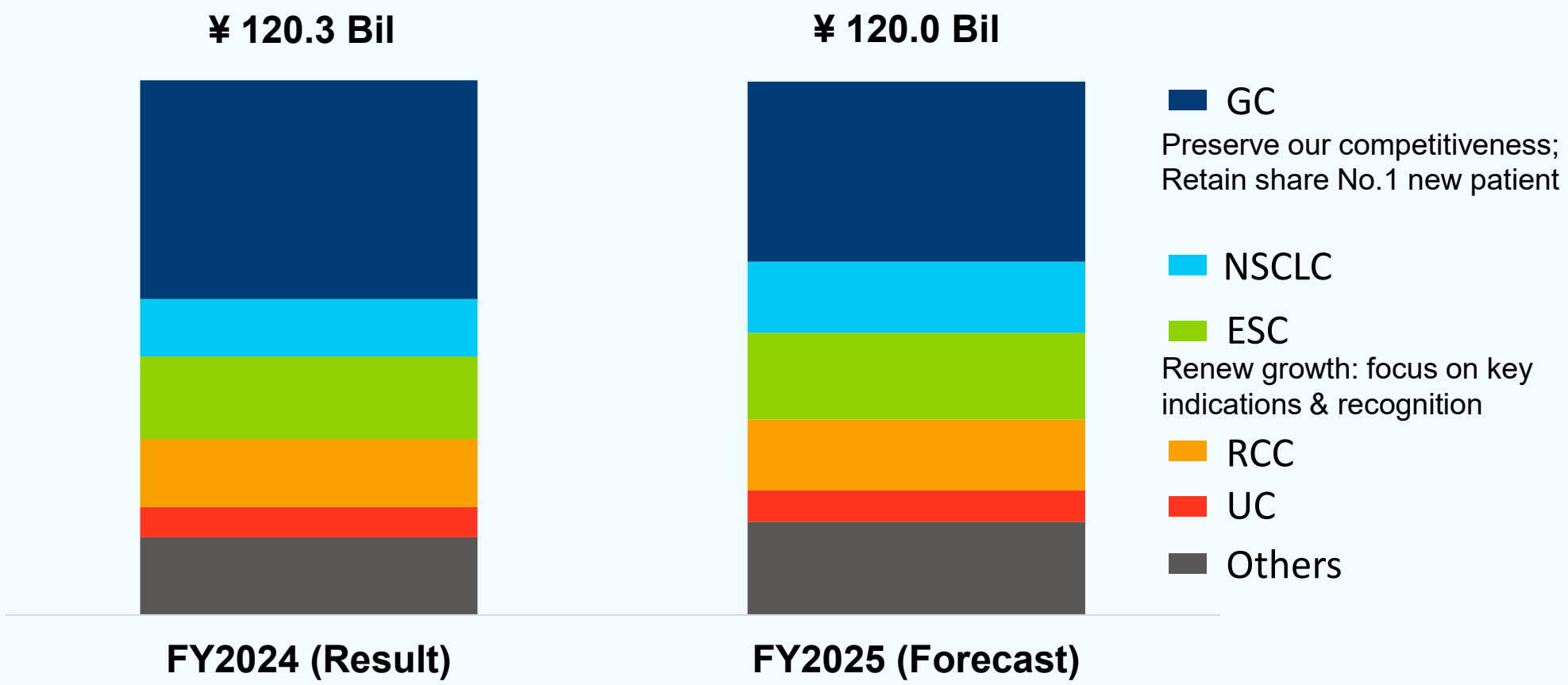
ONO-2808-03 study	
Objective	To investigate the safety, tolerability, and pharmacokinetics of repeated-dose oral administration of ONO-2808 in patients with MSA.
Study design	Placebo-controlled, double-blind, randomized, parallel-group study
Target criteria	• Patients 30 to 80 years of age diagnosed 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**

Trend of OPDIVO

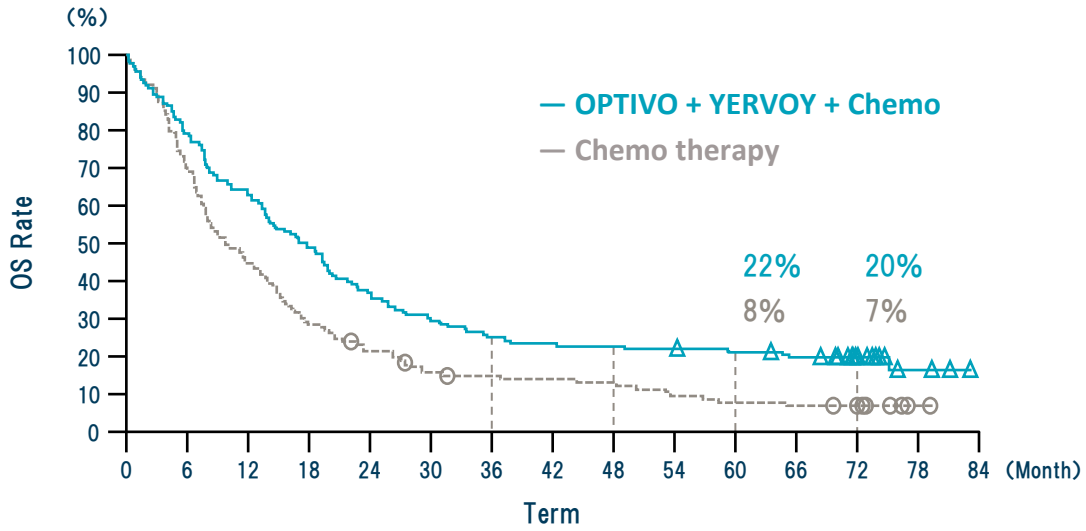
Sales Trend of OPDIVO by Each Cancer



Source: Estimation from external and internal data

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

CheckMate 9LA Trial

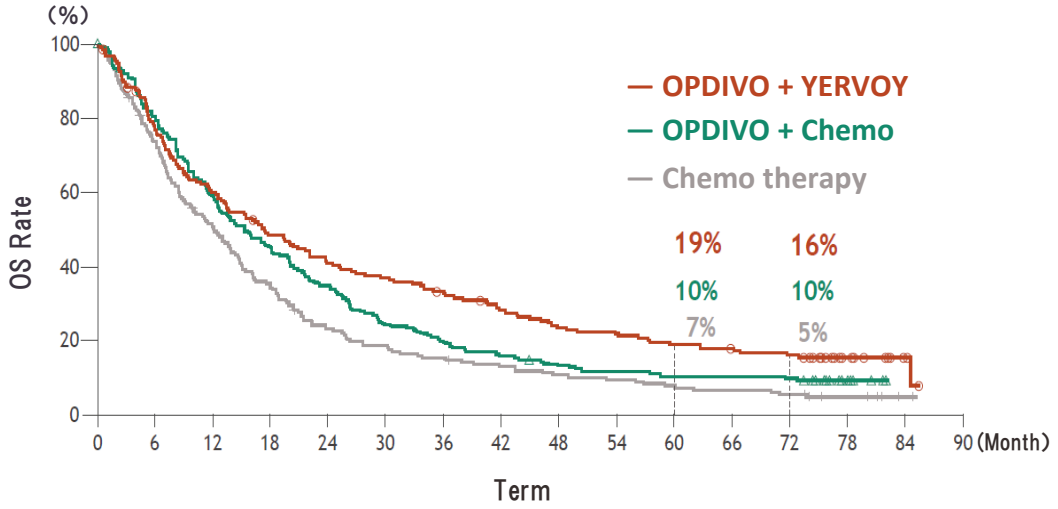


OPDIVO + YERVOY + Chemo

Five-year overall survival rates	Six-year overall survival rates
22%	20%

Carbone DP, et al. ESMO Open. 2025 Jun;10(6):105123

CheckMate 227 Trial

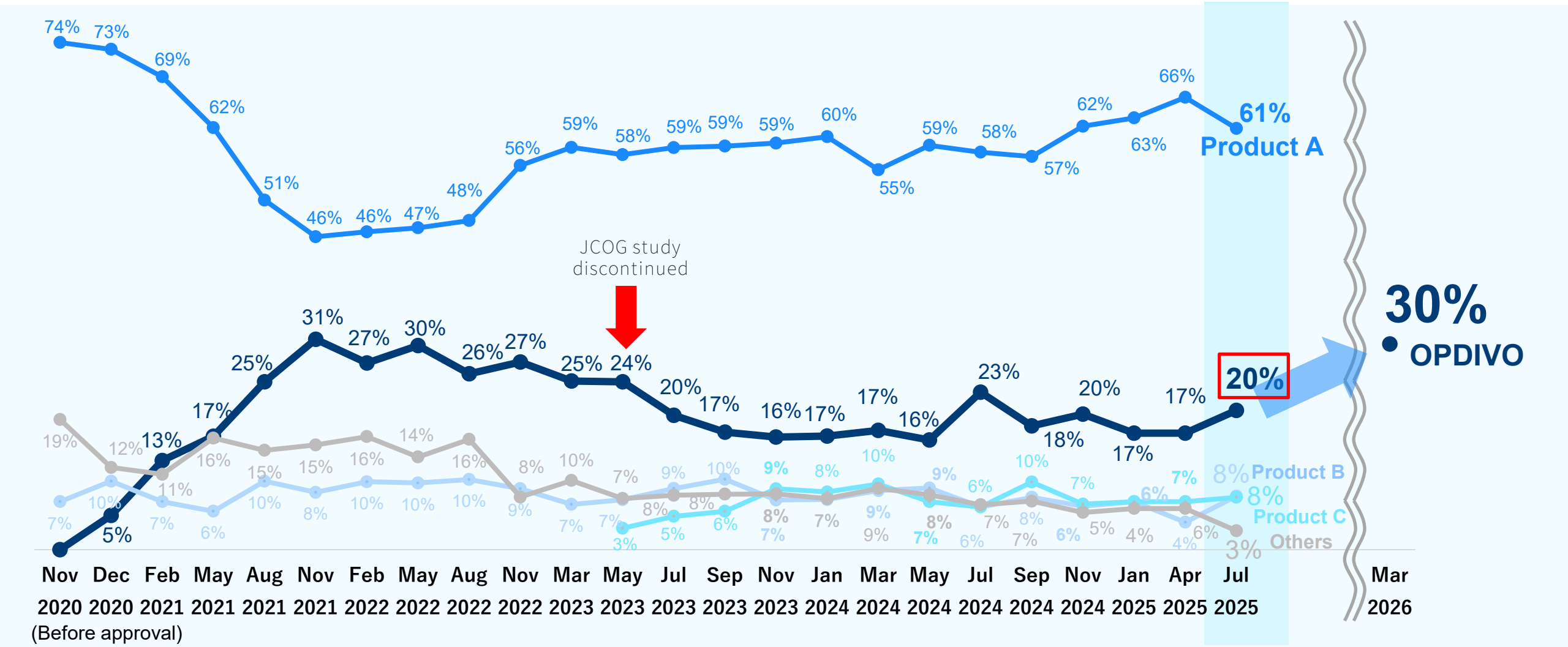


OPDIVO + YERVOY

Five-year overall survival rates	Six-year overall survival rates
19%	16%

Suresh S. Ramalingam, et al. WCLC2023#OA14.03

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)

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.

Appendix

OPDIVO Approval Track Record(1)

As of October 30, 2025

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant・1st・2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug† (relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi	Approved	Approved	Approved	Approved	–
		with Ipi/Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	–	–	–	–
		with Chemo (NSQ)	Revision of labeling	Approved	Approved	–	–
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Hodgkin's lymphoma	Relapsed /Refractory	Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st	Monotherapy	Approved	–	–	–	–

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

OPDIVO Approval Track Record(2)

As of October 30, 2025

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
	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 (3rd)	Monotherapy	Approved	–	Approved	Approved	–
		with Ipi	Approved	Approved	Approved	Approved	Approved★★
Hepatocellular carcinoma	2nd	with Ipi	–	–	Approved	Approved	–

★★2nd Line

OPDIVO Approval Track Record(3)

As of October 30, 2025

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	–	Approved	Approved	Approved	Approved
Cancer of unknown primary	1st	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Flat dose	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved

Key milestones in FY2025 Q1 (FY ending March 2026)

As of October 30, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	ROMVIMZA (vimseltinib)	Tenosynovial Giant Cell Tumor (TGCT)	Approved in EU (Sep.2025)
	OPDIVO	Hepatocellular carcinoma(1st with Ipi) / CheckMate-9DW	Approved in KR, TW (Jul.2025)
		MSI-high Colorectal cancer(1st with Ipi) / CheckMate-8HW	Approved in JP (Aug.2025)
		Gastric cancer (1st with Ipi, chemo) / ONO-4578-113	Discontinued (Oct.2025)
	ONO-2017(cenobamate)	Partial-onset seizures	Filed in JP (Sep.2025)
P3	ONO-4059(tirabrutinib)	Primary central nervous system lymphoma(PCNSL)	Started in US(Aug.2025)
P2	ONO-4578	Gastric cancer (with OPDIVO)	Met the primary endpoint in JP, KR, TW (Oct.2025)
	ONO-2808	Multiple System Atropy	Safety and efficacy signals were observed in JP, US (Oct.2025)

Key milestones in FY2025 Q1 (FY ending March 2026)

As of October 30, 2025

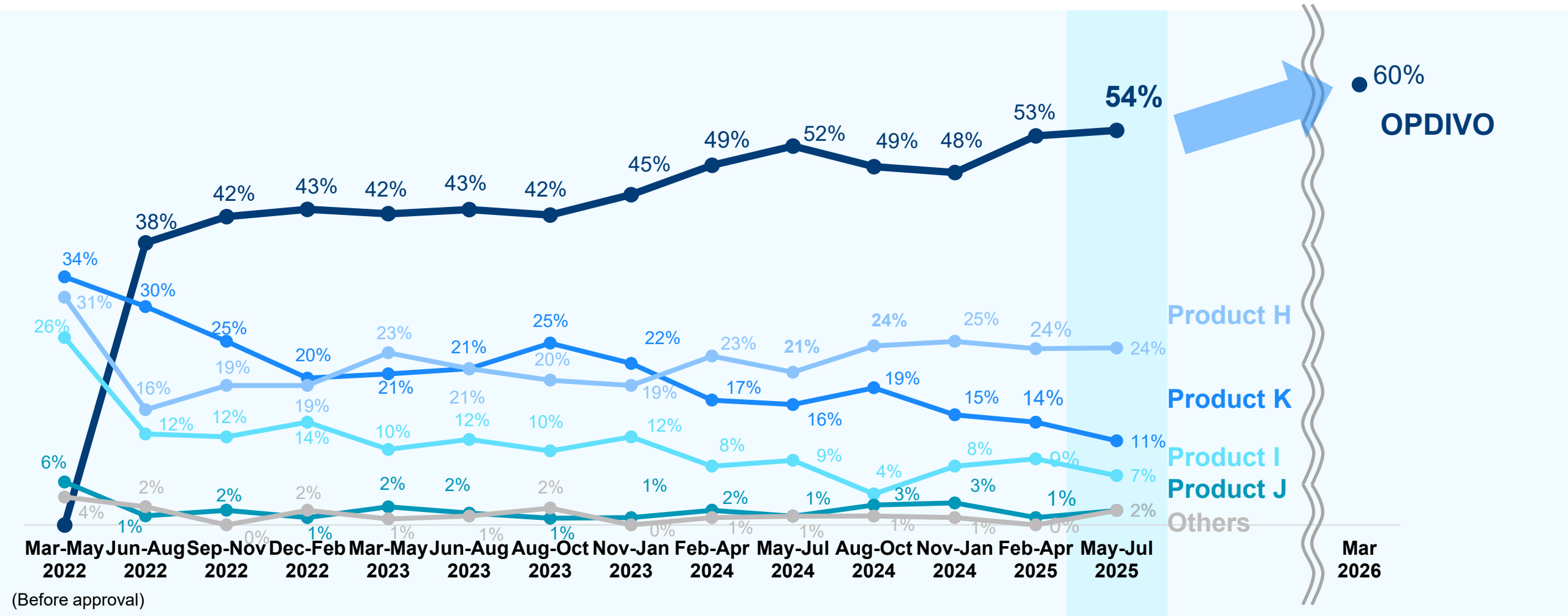
(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
P1/2	DCC-3116 (inlexisertib)	Solid tumor (with sotorasib)	Discontinued in US(Sep.2025)
	DCC-3084	Advanced Malignancies	Discontinued in US(Sep.2025)
P1	DCC-2812	Renal Cell Carcinoma, Urothelial Cancer, Castration-Resistant Prostate Cancer	Started in US(Aug.2025)
	ONO-7475 (tamnorzatinib)	EGFR-mutated non-small cell lung cancer	Discontinued in JP(Jul.2025)

(Drug discovery partnerships & Research collaborations/Licensing & Co-promotion)

Title	Progress
Ono Enters into a Basic Agreement with Seikagaku for Co-development and Marketing Collaboration on Gel-One for the treatment of Osteoarthritis in Japan	Definitive Agreement (Aug.2025) P3 ongoing in JP
ONO Enters into an Option and Collaboration Agreement with Numab to Develop Multi-specific Antibody NM49 (2024.2~)	Discontinued
Ono Expands Drug Discovery Collaboration with Neurimmune AG in the Field of Neurodegenerative Diseases (2022.1~)	Discontinued

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



※Patients starting treatment within the last 3 month

Source: Primary research results
(May 2022~Jul 2025: n=150~155)