2026年3月期第1四半期 決算説明会
Q1 FY2025 Financial Results Meeting

Aug 1, 2025

ONO PHARMA

Today’s Attendees

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1四半期 決算概要について
Financial Results Q1 FY 2025 （14:00-14:20）

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

開発品の進捗状況
Development Pipeline Progress Status（14:20-14:30）

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（14:30-14:40）

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（14:40-15:00）

Cautionary Notes

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:

- **(i) failures in new product development**
- **(ii) changes in general economic conditions due to reform of medical insurance system**
- **(iii) failures in obtaining the expected results due to effects of competing products or generic drugs**
- **(iv) infringements of the Company's intellectual property rights by third parties**
- **(v) stagnation of product supply from the delay in production due to natural disasters, fires and so on**
- **(vi) onset of new side effect of post-licensure medical product and,**
- **(vii) currency exchange rate fluctuations and interest rate trend.**

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

Material for Financial Announcement Q1 FY 2025

Highlights of Financial Results for FY2025Q1 (Core Basis)

FY2025Q1 Sales Revenue	**Revenue increased by ¥9.9 billion (8.4%) year on year to ¥127.5 billion, marking a new record high for the first quarter.** **Domestic Sales Results** While sales of FORXIGA expanded, overall sales slightly decreased mainly due to a decline in OPDIVO sales resulting from intensified competition. **Overseas Sales Results** Sales increased mainly due to the inclusion of the sales of QINLOCK(R) (ripretinib) and ROMVIMZA(TM) (vimseltinib), which were not recorded in the previous period (April-June). QINLOCK sales were ¥8.9 billion, and ROMVIMZA sales were ¥1.1 billion.
FY2025Q1 R&D, SG&A Expenses	**Inclusion of Deciphera's R&D and SG&A expenses resulted in an increase compared to the same period last year.** R&D：Expenses, excluding Deciphera's R&D expenses, decreased compared to the previous period. SG&A：The figures are roughly at the same level as the previous period, excluding the co-promotion costs for Forxiga and Deciphera's SG&A.
FY2025Q1 Core Operating Profit	**Core operating profit decreased by ¥3.5 billion (10.1%) year on year to ¥31.6 billion.** The inclusion of Deciphera's operating loss, which was not recorded in the previous period (April-June), led to a decrease in core operating profit .

FY2025Q1 : Sales Revenue

Revenue

¥127.5 billion

YoY +9.9 billion
(+8.4%)

Goods and Products Sales

¥87.8 billion

YoY +8.4 billion (+10.6%)

Royalty and Others

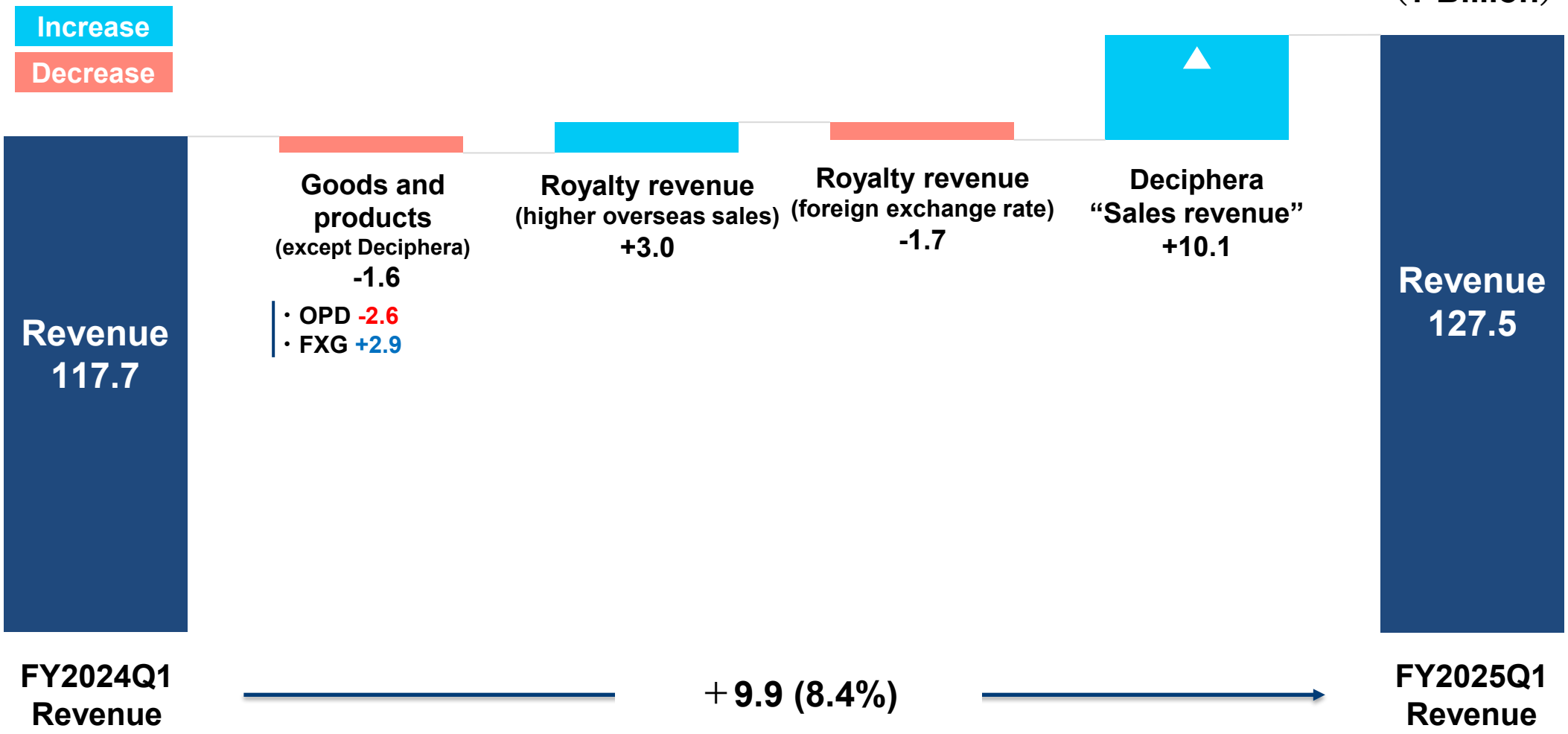
¥39.8 billion

YoY +1.4 billion (+3.7%)

FY2025Q1 : 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 ¥9.9 billion year on year, driven by the revenue from Deciphera.

(¥ Billion)



FY2025Q1 : Sales Revenue by Product (Domestic)

¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	127.5	9.9	8.4%	490.0
Goods and products	79.3	87.8	8.4	10.6%	330.0
Royalty and others	38.3	39.8	1.4	3.7%	160.0

Goods and Products (Domestic)	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	32.1	**29.4**	(2.6)	(8.2%)	125.0
FORXIGA Tablets	22.2	**25.1**	2.9	13.1%	80.0
ORENCIA for Subcutaneous Injection	6.9	**7.0**	0.1	1.8%	28.0
GLACTIV Tablets	5.0	**3.6**	(1.4)	(28.8%)	12.0
VELEXBRU Tablets	2.7	**3.0**	0.3	12.0%	11.0
ONGENTYS Tablets	1.9	**2.3**	0.3	17.2%	9.0
PARSABIV Intravenous Injection	2.1	**2.2**	0.1	5.9%	9.0
KYPROLIS for Intravenous Infusion	2.3	**2.0**	(0.3)	(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.

FY2025Q1 : Sales Revenue by Product (Overseas) / Royalty

¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	**127.5**	9.9	8.4%	490.0
Goods and products	79.3	**87.8**	8.4	10.6%	330.0
Royalty and others	38.3	**39.8**	1.4	3.7%	160.0

Goods and Products (Overseas)	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
OPDIVO	3.1	**3.3**	0.2	5.5%	13.5
QINLOCK	–	**8.9**	–	–	34.0
ROMVIMZA	–	**1.1**	–	–	5.0

Royalty and others	FY2024Q1	FY2025Q1	YoY		
			Change	Change(%)	
OPDIVO	28.5	**29.2**	0.7	2.6%	
KEYTRUDA®	6.3	**6.5**	0.2	3.9%	

* 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.

FY2025Q1 : Core Operating Profit

Core Operating Profit
¥31.6 billion

YoY -3.5 billion
(-10.1%)

Revenue ¥127.5 billion

YoY +9.9 billion (+8.4%)

R&D Expense ¥36.3 billion

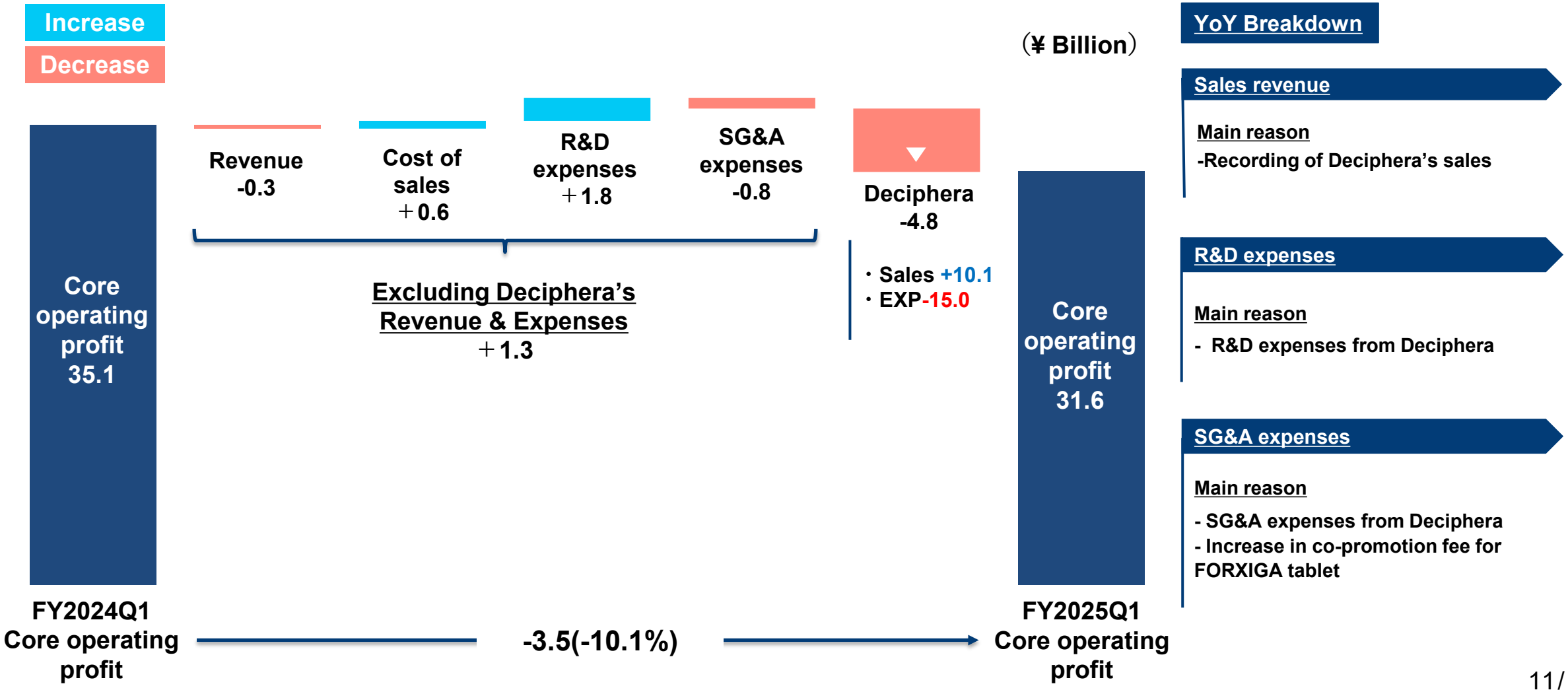
YoY +7.4 billion (+25.6%)

SG&A Expense ¥31.1 billion

YoY +6.1 billion (+24.4%)

FY2025Q1 : Core Operating Profit (Breakdown)

R&D and SG&A expenses have been recorded by Deciphera, which were not recorded in the first quarter of the previous fiscal year, resulting in a decrease of ¥3.5 billion from the same period last year to ¥31.6 billion.



YoY Breakdown

Sales revenue

Main reason

-Recording of Deciphera's sales

R&D expenses

Main reason

- R&D expenses from Deciphera

SG&A expenses

Main reason

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

FY2025Q1 : Financial Overview (Core)

¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	127.5	9.9	8.4%	490.0
Cost of sales	28.2	28.1	(0.1)	(0.2%)	103.5
R&D expenses	28.9	36.3	7.4	25.6%	150.0
SG&A expenses	25.0	31.1	6.1	24.4%	120.0
Other income	0.0	0.1	0.1	204.6%	0.5
Other expenses	0.6	0.6	0.0	4.2%	3.0
Core operating profit	35.1	31.6	(3.5)	(10.1%)	114.0
Core profit before tax	37.7	32.2	(5.5)	(14.6%)	114.0
Core profit for the period (attributable to owners of the Company)	28.7	24.8	(3.9)	(13.7%)	91.0

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

YoY Breakdown

R&D expenses +¥7.4 billion (+25.6%)

R&D ratio：28.4%

Main reason

- R&D expenses from Deciphera

SG&A expenses +¥6.1 billion (+24.4%)

Main reasons

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

(Ref) FY2025Q1 : Financial Overview (Full Basis)

¥ in Billion	FY2024Q1	FY2025Q1	YoY		FY2025 Forecast*
			Change	Change(%)	
Revenue	117.7	127.5	9.9	8.4%	490.0
Cost of sales	29.7	37.0	7.3	24.7%	135.0
R&D expenses	28.9	36.3	7.4	25.6%	150.0
SG&A expenses	27.9	31.1	3.2	11.5%	120.0
Operating profit	30.7	22.0	(8.7)	(28.3%)	85.0
Profit before tax	33.3	22.6	(10.7)	(32.0%)	85.0
Profit for the period (attributable to owners of the Company)	24.8	17.7	(7.1)	(28.7%)	67.0

Breakdown

Cost of sales +¥7.3 billion

Main reason
- Amortization expenses related to intangible assets acquired through acquisitions and inventory assets evaluated at fair value

R&D expenses +¥7.4 billion R&D ratio:28.4%

Main reason
- R&D expenses from Deciphera +¥9.1 billion

SG&A expenses +¥3.2 billion

Main reasons
- SG&A expenses from Deciphera +¥5.3billion
- 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 May 8, 2025, is provided.

(Ref) FY2025Q1 : Reconciliation from Full to Core Basis

¥ in Billion	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Sales revenue	127.5				–	127.5
Cost of sales	37.0	(6.2)		(2.7)	(8.9)	28.1
Gross profit	90.5	+6.2	–	+2.7	+8.9	99.4
R&D costs	36.3				–	36.3
SG&A expenses	31.1				–	31.1
Other income /expenses	(1.2)			(0.7)	(0.7)	(0.5)
Operating profit	22.0	+6.2	–	+3.4	+9.6	31.6
Operating profit ratio	17.2%				–	24.8%
Finance income / Finance cost	0.7				–	0.7
Profit before tax	22.6	+6.2	–	+3.4	+9.6	32.2
Income tax expense	5.0	+1.6		+0.8	+2.4	7.5
Profit for the year	17.7	+4.6	–	+2.5	+7.1	24.8

Breakdown

Cost of sales -¥8.9 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%

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

* The exchange rate assumed in the financial forecast is ¥145 per US dollar.

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 in the financial forecast is ¥145 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥1.3 billion in revenue and an increase of ¥0.3 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

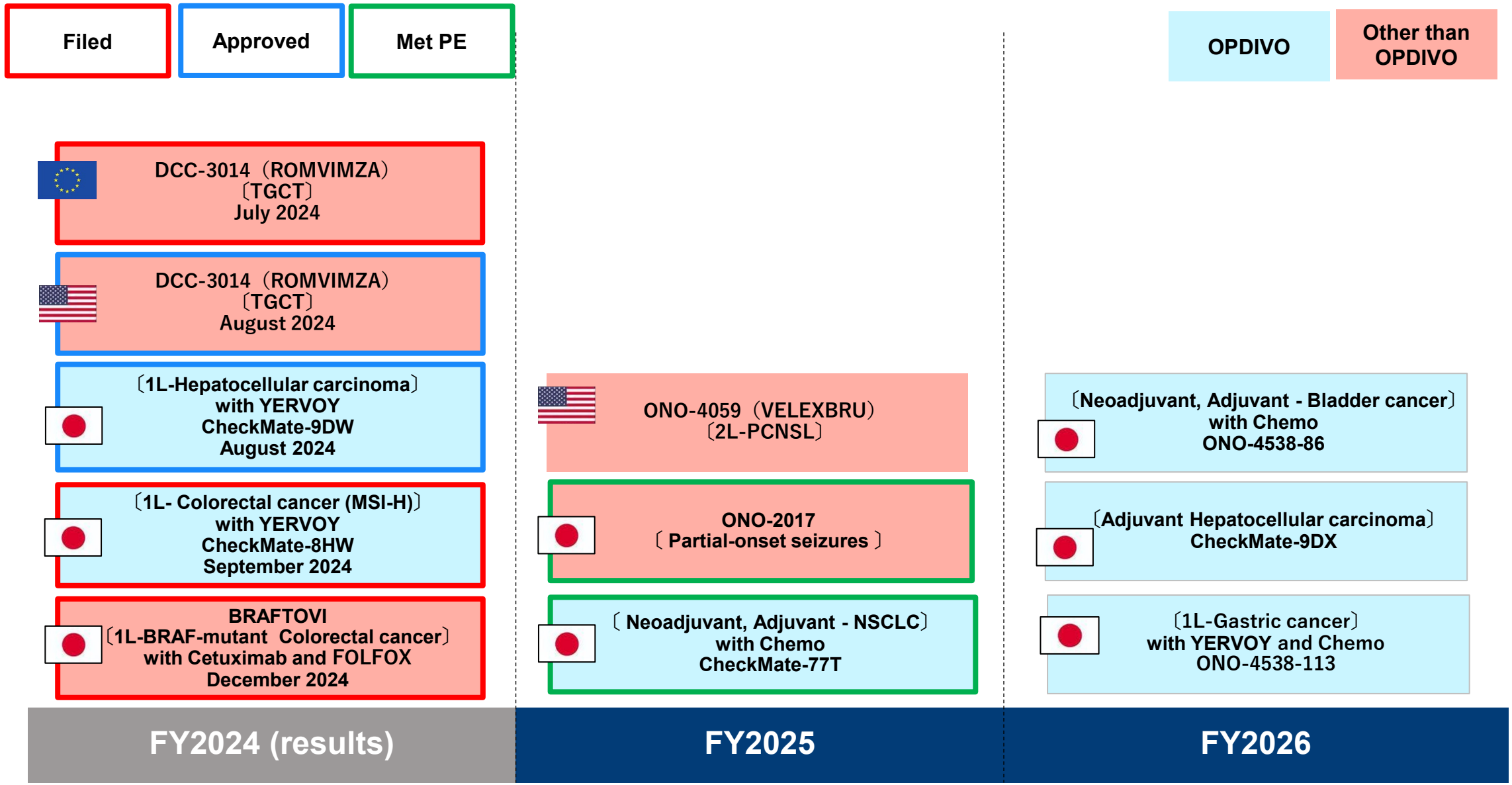
Main reasons

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

Development Pipeline Progress Status

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

As of August1, 2025



PE : Primary endpoint

Development status of OPDIVO

As of August1, 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
Gastric cancer	1st	with Ipi/Chemo	Ⅲ	Ⅲ	Ⅲ	–	–
Colorectal cancer	MSI-H／dMMR (1st)	with Ipi	Filed	–	–	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

Development pipeline (Oncology) ①

As of August1, 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)	■	■	■				FY2025 Primary Completion (Part A) (Actual)	US	NCT04947319
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*	■	■	■				FY2025 Primary Completion	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	Solid tumor (with sotorasib)	■	■					FY2027 Primary Completion	US	NCT04892017
	Advanced Malignancies (with ripretinib)	■	■					FY2026 Primary Completion	US	NCT05957367

MOA : Mode of Action

F : Filed, A : Approval

EU : European countries

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

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

Development pipeline (Oncology) ②

As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
DCC-3084　Pan-RAF inhibitor	Advanced Malignancies							FY2026 Primary Completion	US	NCT06287463
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

MOA : Mode of Action

F : Filed, A : Approval

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

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

Development pipeline (Non-oncology)

As of August1, 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 FDA: Approval EMA: Filing accepted	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	Primary generalized tonic-clonic seizures	■	■	■	■			FY2026 Primary Completion	JP	NCT06579573
	Partial-onset seizures	■	■	■	■			FY2024 Primary Completion(Actual)	JP, KR and others★1	NCT04557085
VELEXBRU Tablet (ONO-4059：tirabrutinib) BTK inhibitor	Pemphigus	■	■	■	■			FY2027 Primary Completion	JP	NCT06696716
Povetacicept BAFF/APRIL dual antagonist	IgA Nephropathy	■	■	■	■			FY2028 Primary Completion	JP, US, EU, KR, TW and others★2	NCT06564142
ONO-2808 S1P5 receptor agonist	Multiple System Atrophy	■	■	■				FY2025 Primary Completion	JP, US	NCT05923866
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

F : Filed, A : Approval

★1 : Development rights country: JP, ★2 : Development rights countries: JP, KR

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

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

Povetacicept

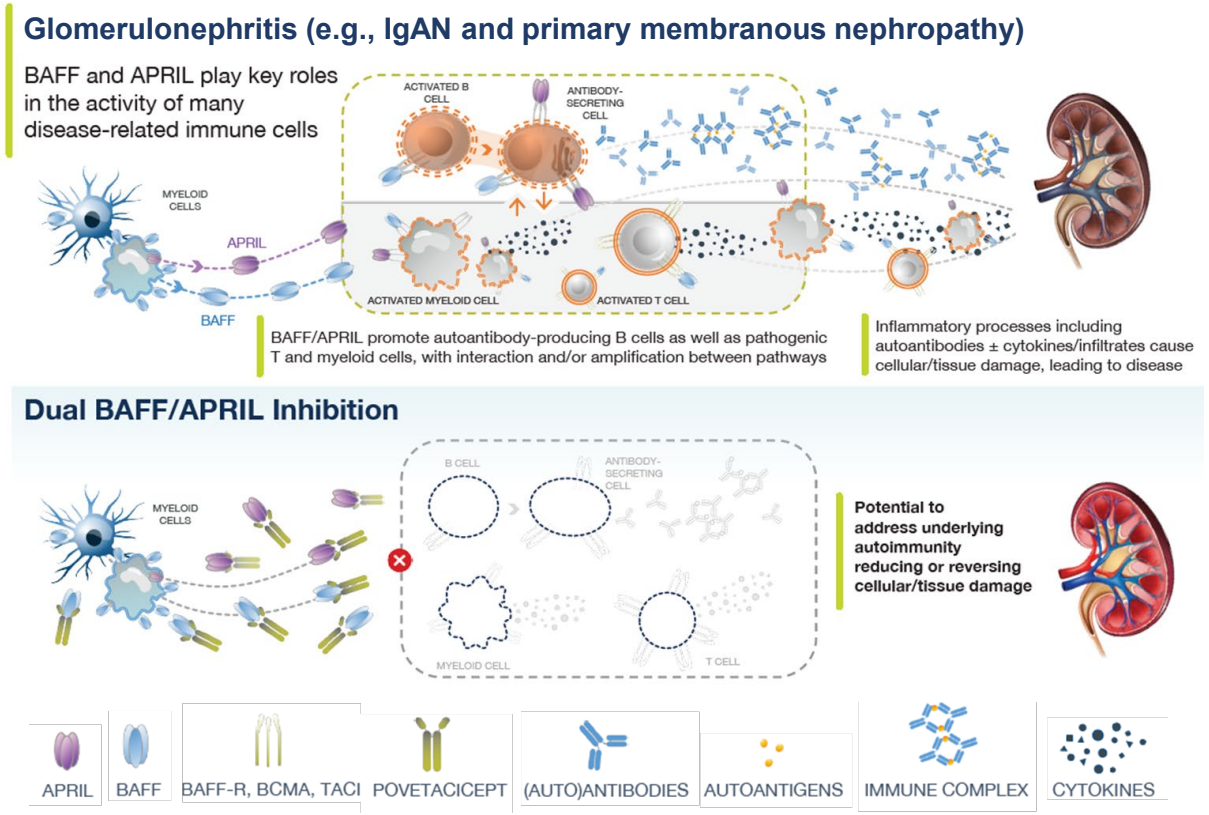
- Ono Pharmaceutical and Vertex enter into strategic agreement to develop and commercialize povetacicept in Japan and South Korea[1)]
- Povetacicept is a recombinant fusion protein and a dual antagonist of the BAFF[2)] and APRIL[3)] cytokines
- Povetacicept is in development for multiple serious B cell-mediated diseases, including IgA nephropathy, primary membranous nephropathy

【IgA Nephropathy (IgAN)】

- IgAN results from deposition of circulating immune complexes consisting of autoantibodies in the renal glomerular mesangium
- Up to 72% of adult IgAN patients progress to end-stage renal disease within 20 years
- There are no approved therapies that specifically target the underlying cause of IgAN

【Povetacicept】

- Povetacicept has higher binding affinity and greater potency in preclinical studies versus other inhibitors of BAFF and/or APRIL alone
- Treatment with povetacicept 80 mg every 4 weeks subcutaneously reduced mean UPCR[4)] by 66%[5)] at 48 weeks
- A global Phase 3 pivotal study (RAINIER study) is currently being conducted in patients with IgAN, including in Japan

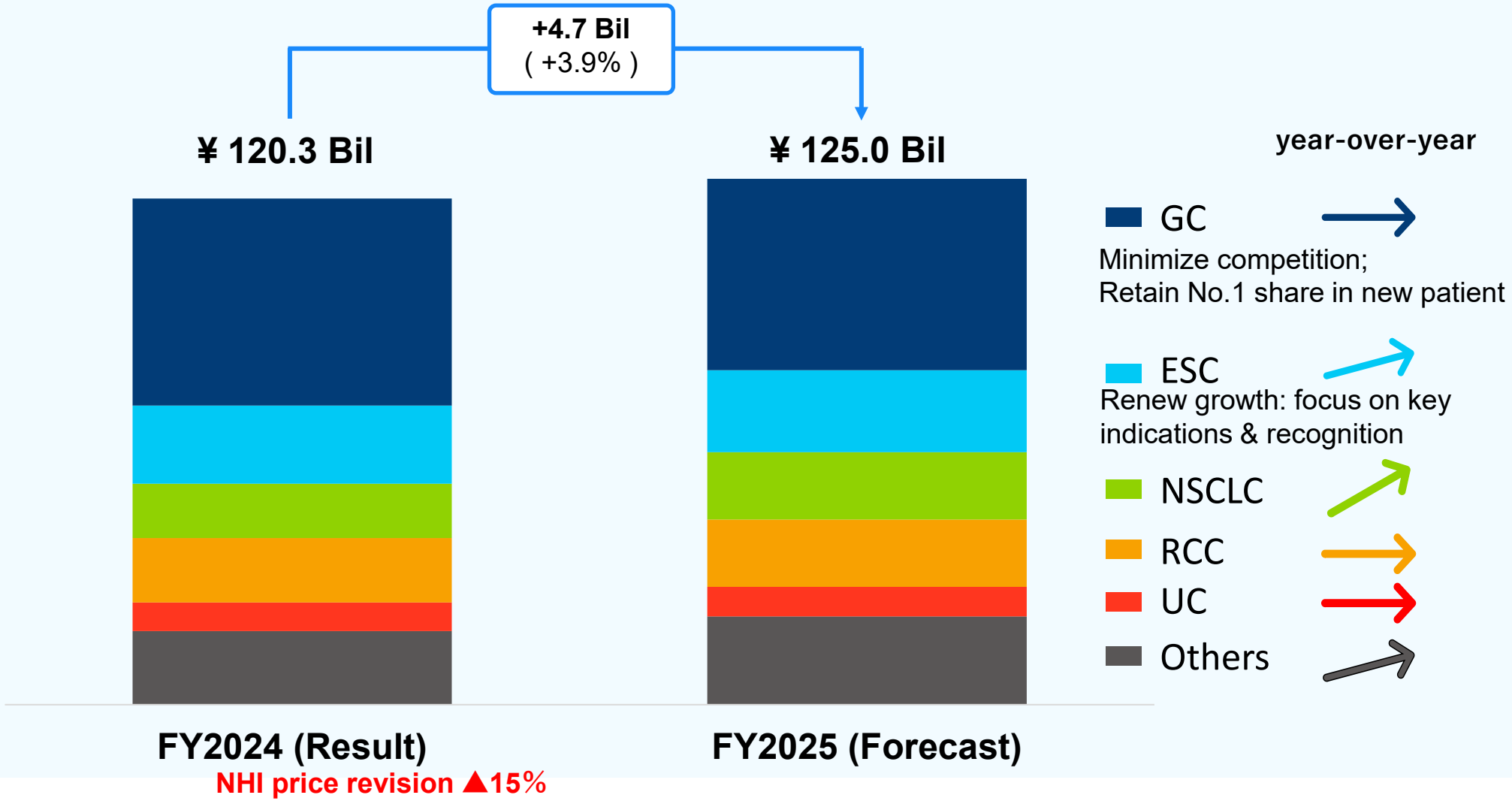


Adapted from Ju-Young Moon, et al. Presentation at the 45th Annual Meeting of the Korean Society of Nephrology (KSN), 20 June 2025, Seoul, Korea.

1）Ono Pharmaceutical press release（https://www.ono-pharma.com/en/news/20250623.html）
2）A Proliferation Inducing Ligand
3）B Cell Activating Factor
4）Urine protein/creatinine ratio
5）Ju-Young Moon, et al. Presentation at KSN 2025

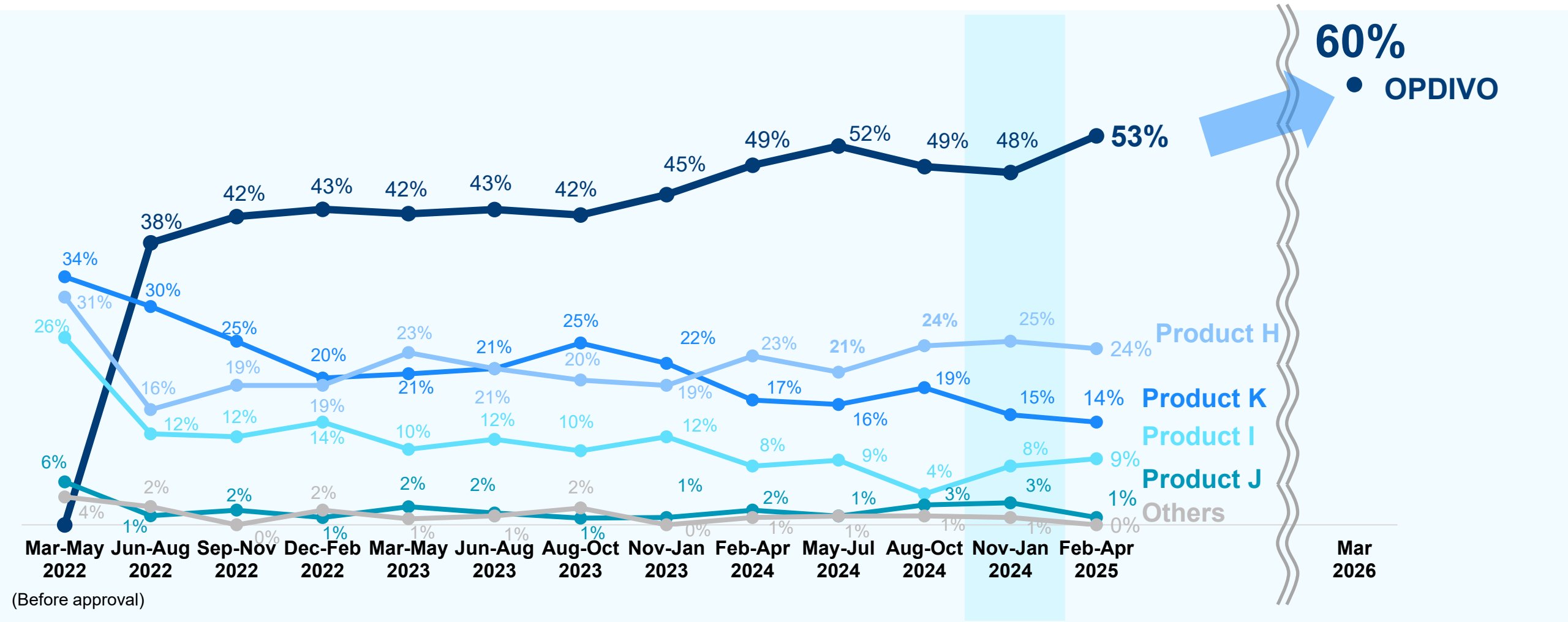
Trend of OPDIVO

Sales Trend of OPDIVO by Each Cancer



Source: Estimation from external and internal data

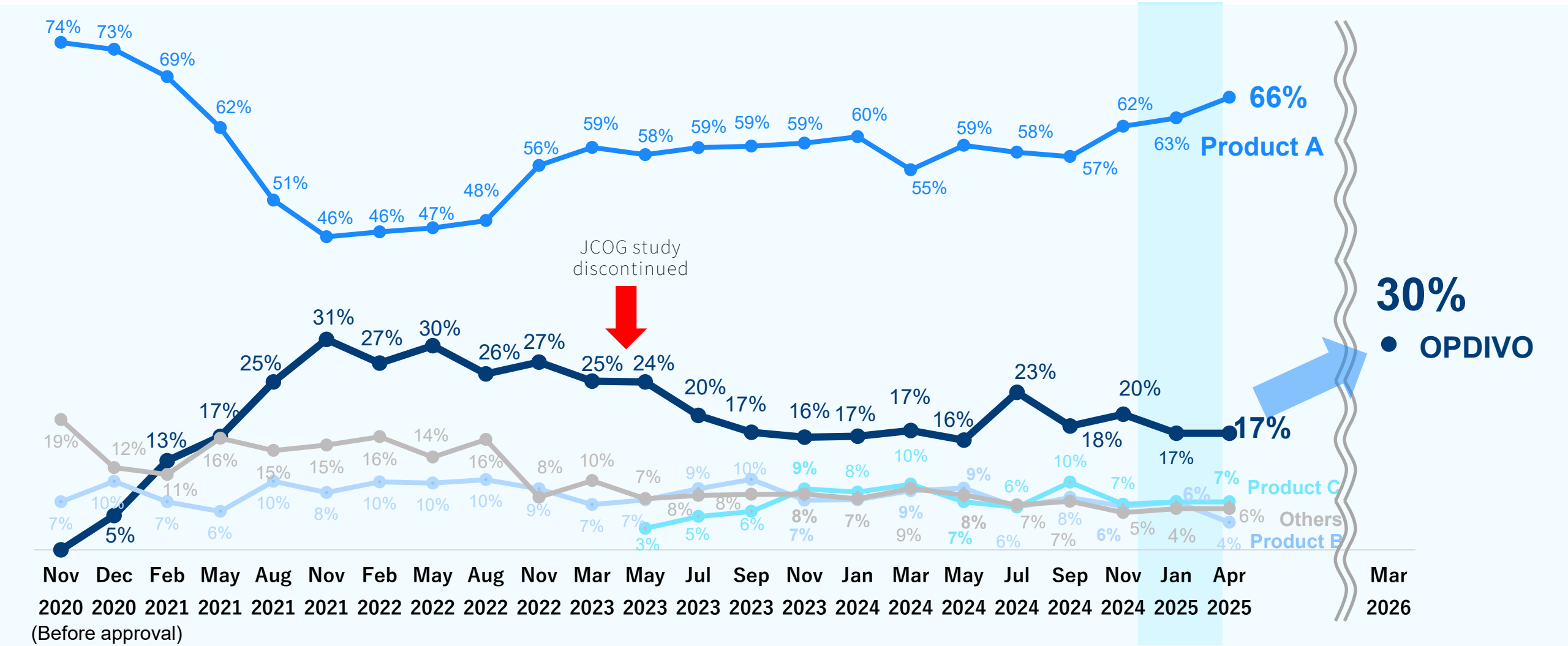
Prescription Ratio in Patients Newly Treated※ for 1L ESC(Squamous Cell Carcinoma)



※Patients starting treatment within the last 3 month

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

Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



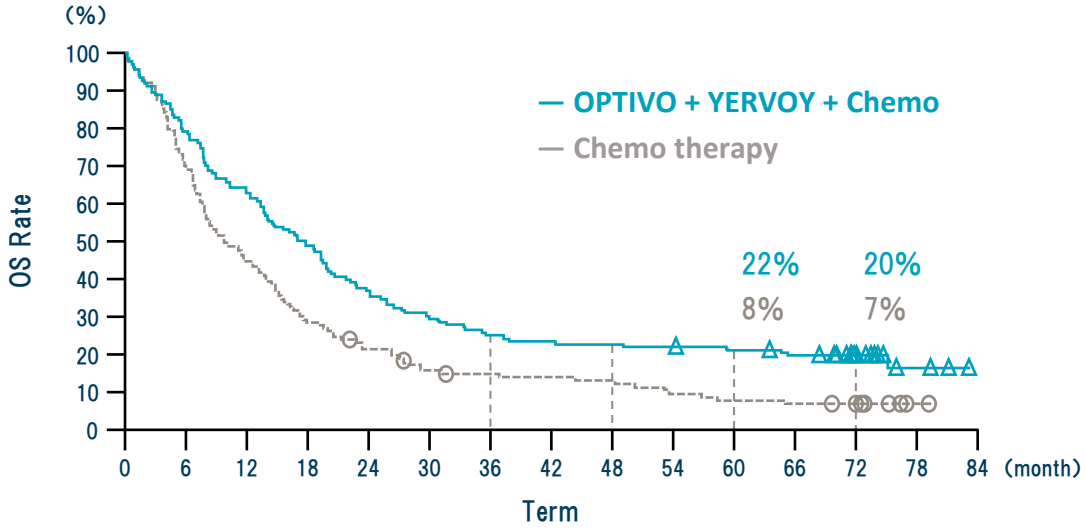
(Before approval)

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

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

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

CheckMate 9LA Trial

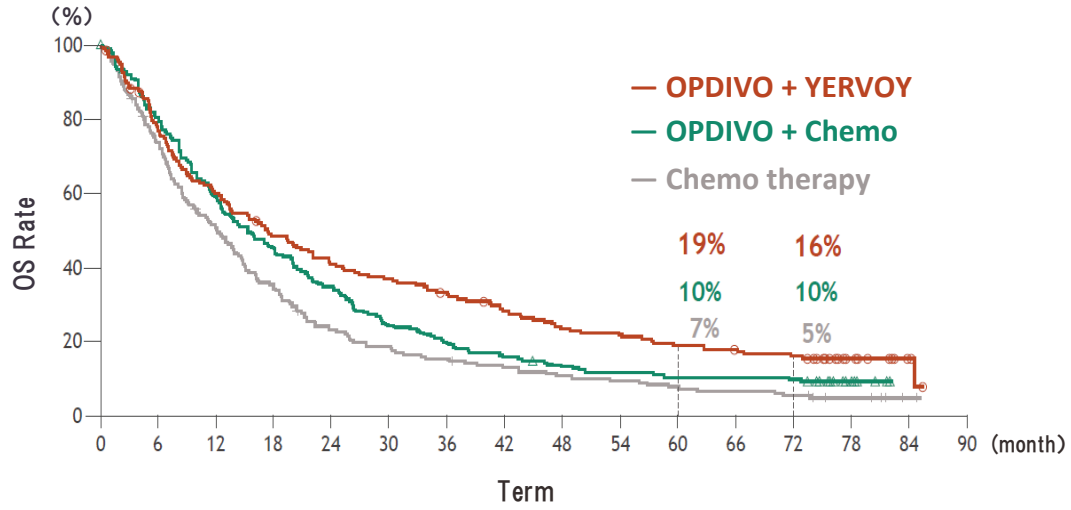


OPDIVO + YERVOY + Chemo

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%

The Clinical Trial Result of HCC 1L

CheckMate 9DW Trial

	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.


ONO PHARMACEUTICAL CO.,LTD.
Dedicated to the Fight against Disease and Pain

Appendix

OPDIVO Approval Track Record(1)

As of August1, 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)) ※Red: Update after announcement of FY 2024 financial result in May 2025

OPDIVO Approval Track Record(2)

As of August1, 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 ※Red: Update after announcement of FY 2024 financial result in May 2025

OPDIVO Approval Track Record(3)

As of August1, 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

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

Key milestones in FY2025 Q1 (FY ending March 2026)

As of August1, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	ROMVIMZA (vimseltinib)	Tenosynovial Giant Cell Tumor (TGCT)	Positive CHMP Opinion (Jul.2025)
	OPDIVO	Hepatocellular carcinoma(1st with Ipi) /CheckMate-9DW	Approved in JP (Jun.2025) Approved in KR, TW (Jul.2025)
		NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T	Approved in EU (May.2025)
	OPDIVO Qvantig	Solid tumor/CheckMate-67T	Approved in EU (May.2025)
P1	ONO-7475	EGFR-mutated non-small cell lung cancer (1L with osimertinib)	Discontinued (Jul.2025)

Events from April 2025 to August 1

Key milestones in FY2025 Q1 (FY ending March 2026)

As of August1, 2025

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

Title	Progress
Ono Pharmaceutical and Vertex Announce Strategic Agreement to Develop and Commercialize Povetacicept in Japan and South Korea	License-in (Jun.2025)
Ono Enters into a Basic Agreement with Seikagaku for Co-development and Marketing Collaboration on Gel-One for the treatment of Osteoarthritis in Japan	Basic Agreement (Apr.2025)
Ono Commences Research Collaboration with Jorna Therapeutics to Generate Novel RNA Editing Therapeutics	Started
Ono Enters a Drug Discovery Collaboration Agreement with Captor Therapeutics to Develop Small Molecule Protein Degraders for the Treatment of Neurodegenerative Diseases	Discontinued
ONO Enters into Exclusive License Agreement with Chordia Therapeutics on CTX-177, a MALT1 Inhibitor, and its Related Compounds	Discontinued

Events from April 2025 to August 1