FY2024 Q3 Financial Results Meeting

February 3, 2025

ONO PHARMA

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.

Today's Speaker

Corporate Executive Officer / Executive Director, Sales and Marketing	Satoshi Takahagi
Corporate Officer / Division Director, Corporate Strategy & Planning, Business Management Division,	Masaki Itoh
Corporate Officer / Executive Director, Clinical Development	Tatsuya Okamoto

Agenda

Material for Financial Announcement FY 2024 Q3 (14:00-14:15)

Corporate Officer /
Division Director, Corporate Strategy & Planning,
Business Management Division,
Masaki Itoh

Development Pipeline Progress Status (14:15-14:25)

Corporate Officer /
Executive Director, Clinical Development
Tatsuya Okamoto

Trend of OPDIVO (14:25-14:35)

Corporate Executive Officer /
Executive Director, Sales and Marketing
Satoshi Takahagi

Q&A Session (14:35-15:00)

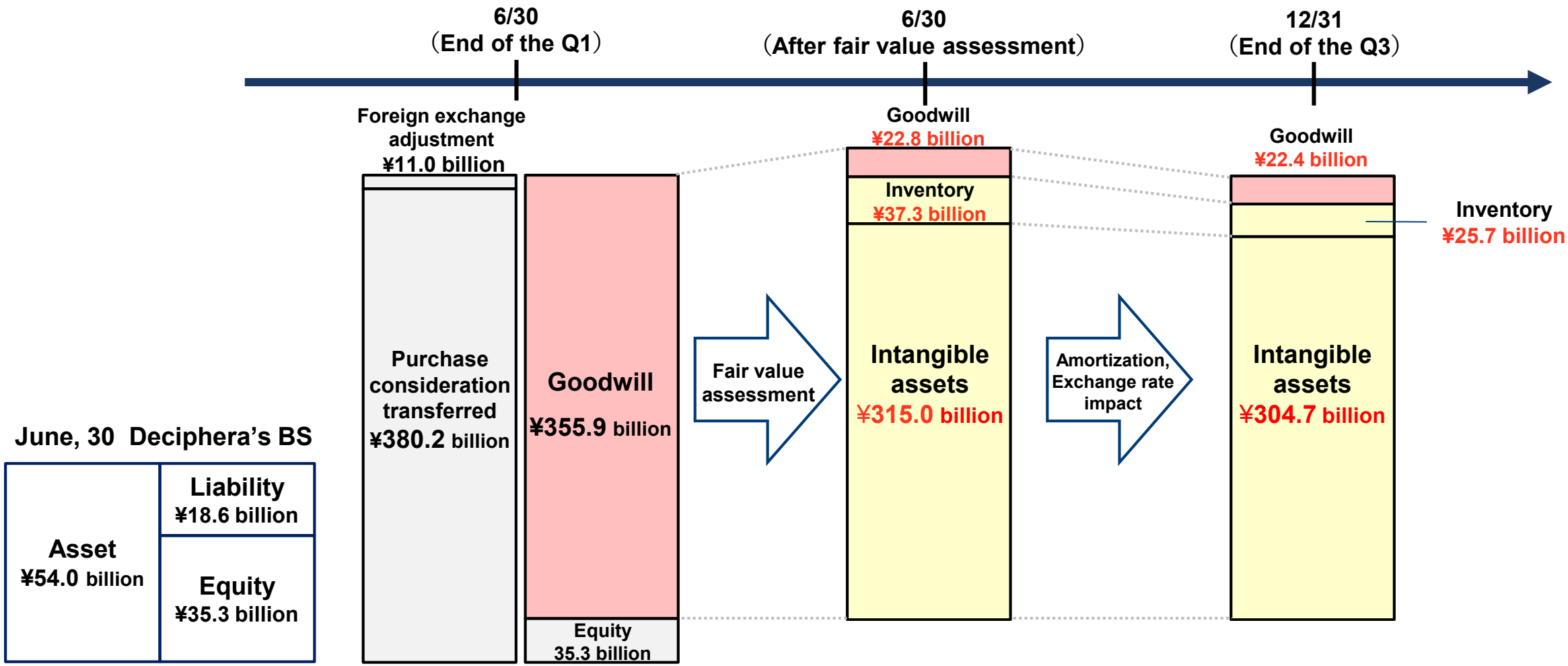
Material for Financial Announcement Q3 FY 2024

Highlights of Financial Results for FY2024 Q3

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

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

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



FY2024 Q3 : Sales Revenue

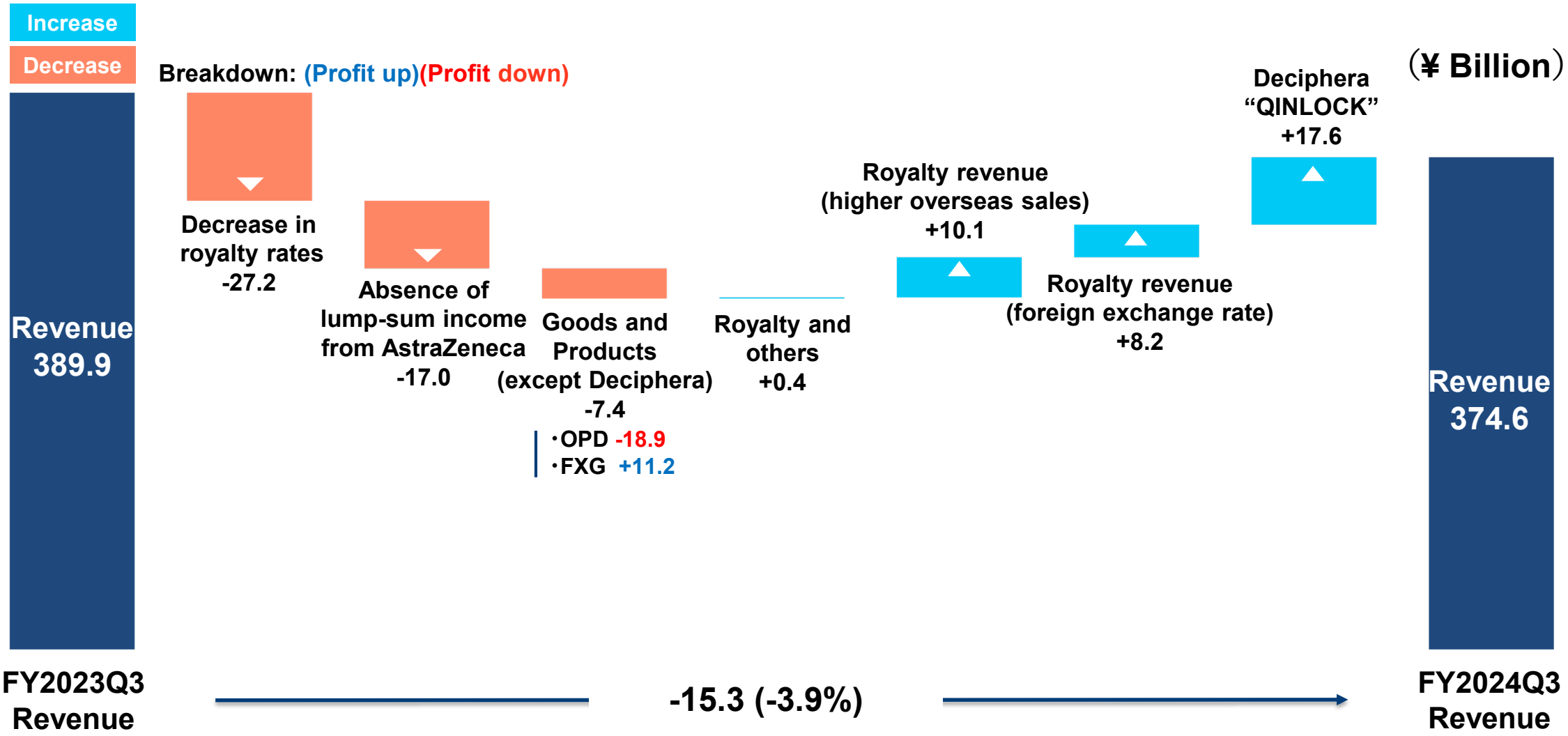
Revenue
¥374.6 billion
YoY -15.3 billion (-3.9%)

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

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

FY2024 Q3 : Sales Revenue (Breakdown)

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



FY2024 Q3 : Sales Revenue by Product (Domestic)

¥ in Billion

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

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

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

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

・Sales revenue of overseas products is shown in a net sales basis.

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

¥ in Billion

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

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

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

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

FY2024 Q3 : Core Operating Profit

Core Operating Profit

¥ 97.7 billion

YoY -56.9 billion
(-36.8%)

Revenue ¥ 374.6 billion

YoY -15.3 billion (-3.9%)

R&D Expense ¥103.4 billion

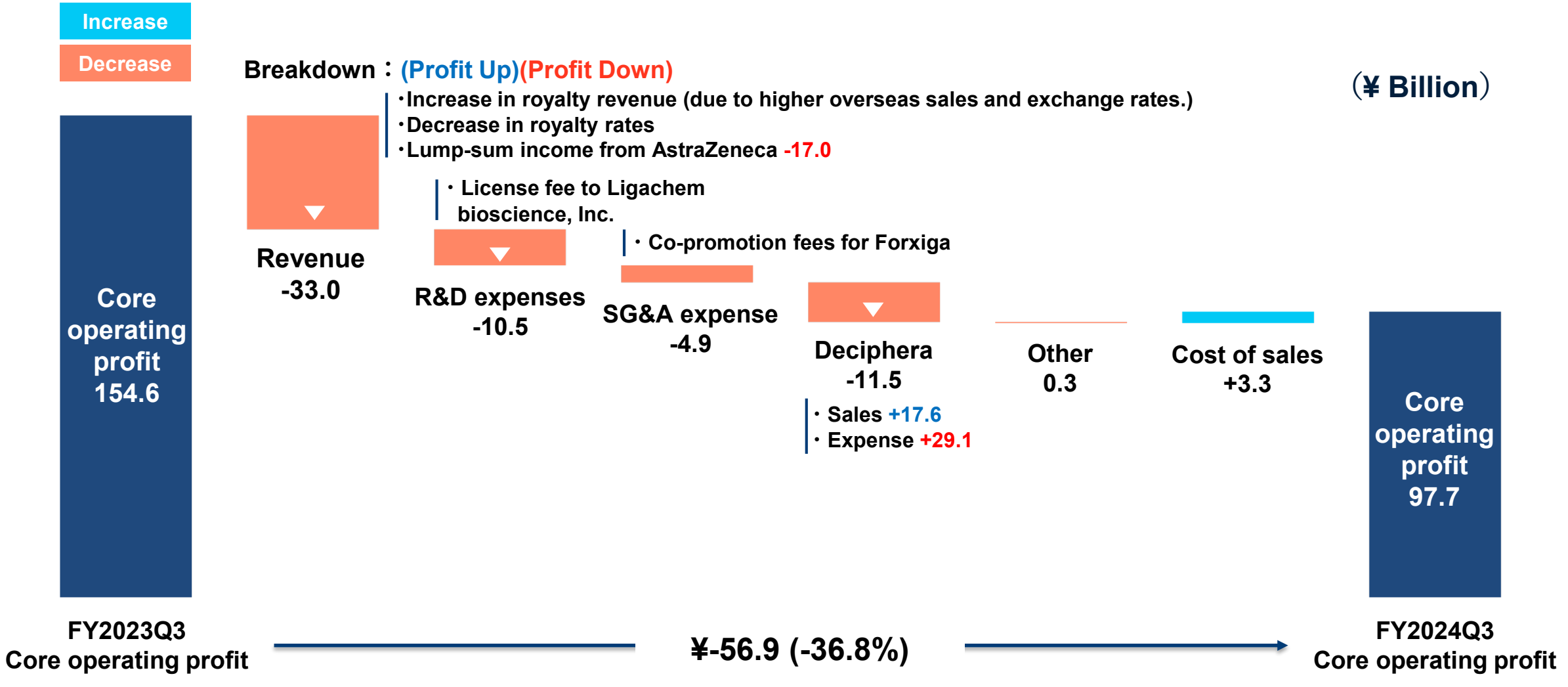
YoY +26.9 billion (+35.1%)

SG&A Expense ¥90.2 billion

YoY +16.9 billion (+23.0%)

FY2024 Q3 : Core Operating Profit (Breakdown)

・While revenue decreased, R&D expenses, and SG&A expenses increased, and an operating loss was recorded by Deciphera Pharmaceuticals, LLC., resulting in a decrease of ¥56.9 billion from the same period last year to ¥97.7 billion.



FY2024 Q3 : Financial Overview (Core)

¥ in Billion

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

YoY Breakdown

R&D expenses +¥26.9 billion (+35.1%)

R&D ratio：27.6%

Main reasons

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

SG&A expenses +¥16.9 billion (+23.0%)

Main reasons

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

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

(Ref) FY2024 Q3 : Financial Overview

¥ in Billion

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

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

YoY Breakdown

Cost of sales ¥7.3 billion

Main reasons

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

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

Main reasons

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

SG&A expenses +¥19.3 billion

Main reasons

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

Adjustment

Main adjustment

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

FY2024 : Financial Forecast

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

¥ in Billion

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

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

FY2024 : Financial Forecast (Sales by Product)

¥ in Billion

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

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

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

Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of January 24, 2025

Filed | Approved | Met PE

OPDIVO | Other than OPDIVO

FY2023 (results)

〔1st-Urothelial cancer〕
with Chemo
CheckMate-901
Dec 2023

〔Epithelial skin malignancies〕
Investigator-initiated trial
Jun 2023

BRAFTOVI／MEKTOVI
〔2nd-BRAF-mutant Thyroid cancer〕
May 2023

FY2024

〔1st-Hepatocellular carcinoma〕
with YERVOY
CheckMate-9DW
August 2024

〔1st- Colorectal cancer (MSI-H)〕
with YERVOY
CheckMate-8HW
September 2024

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

BRAFTOVI
〔1st-BRAF-mutant Colorectal cancer〕
With Cetuximab and Chemo
December 2024

FY2025

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

〔Adjuvant Hepatocellular carcinoma〕
CheckMate-9DX

ONO-2017
Partial-onset seizures

PE : Primary endpoint

Development status of OPDIVO (1)

As of January 24, 2025

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

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

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

Development status of OPDIVO (2)

As of January 24, 2025

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

★★2nd Line

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

Development status of OPDIVO (3)

As of January 24, 2025

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

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

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

As of January 24, 2025

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

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

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Development pipeline (Oncology) ①

As of January 24, 2025

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

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

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

Development pipeline (Oncology) ②

As of January 24, 2025

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

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

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

Development pipeline (Non-oncology)

As of January 24, 2025

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

NA : North America,
EU : European countries

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

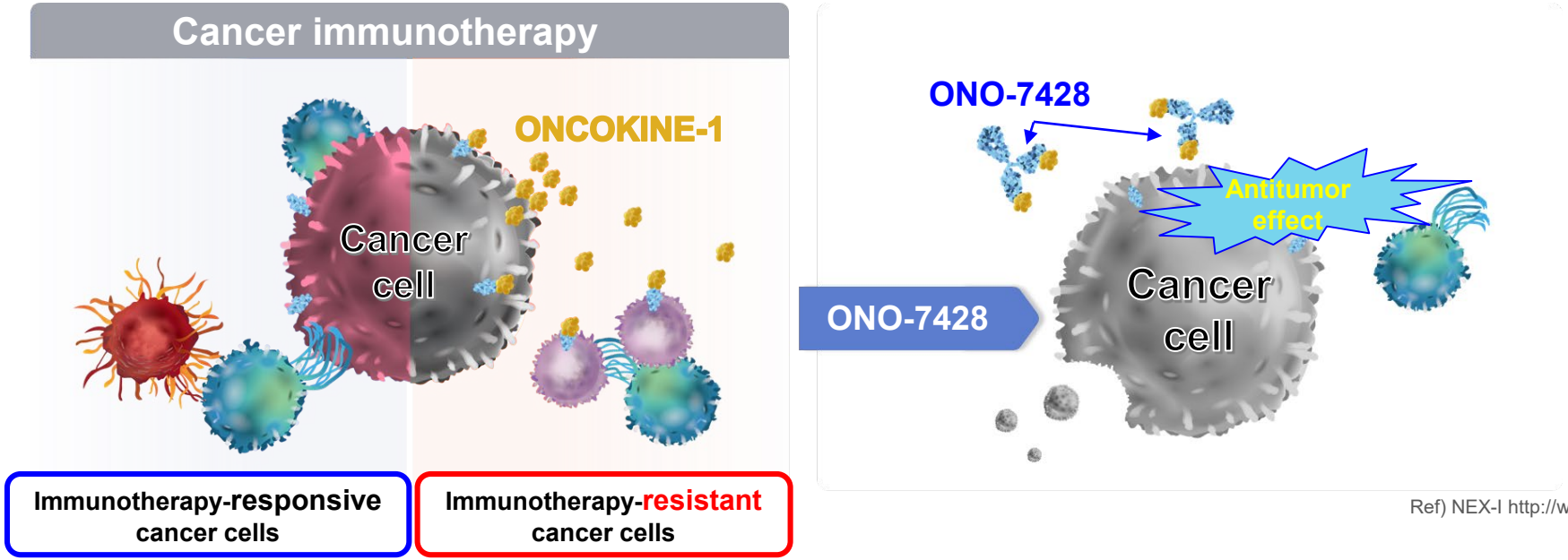
MOA : Mode of Action　※Red: Update after announcement of FY 2023 financial result in May 2024　※Red: Update after Q1 FY2024 in July

ONO-7428

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

【Hypothetical Mechanism of Action】

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



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

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

Key milestones in FY2024 Q3 (FY ending March 2025)

As of January 24, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO Qvantig	Solid cancer /CheckMate-67T	Approved in US (Dec.2024)
	OPDIVO	Urothelial cancer (1L with Chemo) /CheckMate-901	Approved in JP (Dec.2024)
		MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Approved in EU (Dec.2024)
	BRAFTOVI	$BRAF^{V600E}$ - Mutant Metastatic Colorectal Cancer	Approved in US (Dec.2024)
		BRAF - Mutant Colorectal Cancer (with Cetuximab and chemo)	Filed in JP (Dec.2024)
P3	OPDIVO	Cis ineligible Urothelial cancer (1L with Ipi) /CheckMate-901	Discontinued (Nov.2024)
P2	OPDIVO	Richter transformation	Started in JP (Jan.2025)
	ONO-2020	Alzheimer's disease	Started in JP/US (Jan.2025)
		Agitation Associated with Dementia Due to Alzheimer's Disease	Started in JP (Nov.2024)
	ONO-1110	Postherpetic Neuralgia, Major Depressive Disorder	Started in JP (Oct.2024)
		Fibromyalgia, Hunner Type Interstitial Cystitis, Social Anxiety Disorder	Started in JP (Nov.2024)
	DCC-3014 (vimseltinib)	chronic Graft Versus Host Disease	Started in US (Nov.2024)
	ONO-2910	Chemotherapy-Induced Peripheral Neuropathy	Discontinued (Dec.2024)
P1	ONO-4578	Pancreatic cancer	Discontinued (Jan.2025)
	ONO-7428	Solid tumor	Started in JP (Nov.2024)
	DCC-3009	GastroIntestinal Stromal Tumor	Started in US (Dec.2024)

Key milestones in FY2024 Q3 (FY ending March 2025)

As of January 24, 2025

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

Title	Progress
Ono Enters into Drug Discovery Collaboration Agreement with Congruence Therapeutics to Generate Novel Small Molecule Correctors in the Oncology Area	Started (Dec.2024)
Ono Enters into Collaboration Agreement with EVQLV to Generate Novel Antibodies against Multiple Targets Utilizing EVQLV's AI-powered Antibody Design Engine for Development of Innovative Antibody Drugs	Discontinued
Ono Enters into a Multi Target R&D Collaboration Agreement with PrecisionLife	
ONO and Knowledge Palette Enter into an Agreement to Expand Research Collaboration on Building a Data-driven New Drug Discovery Platform	
ONO Enters into Collaboration Agreement with Iktos	

Trend of OPDIVO

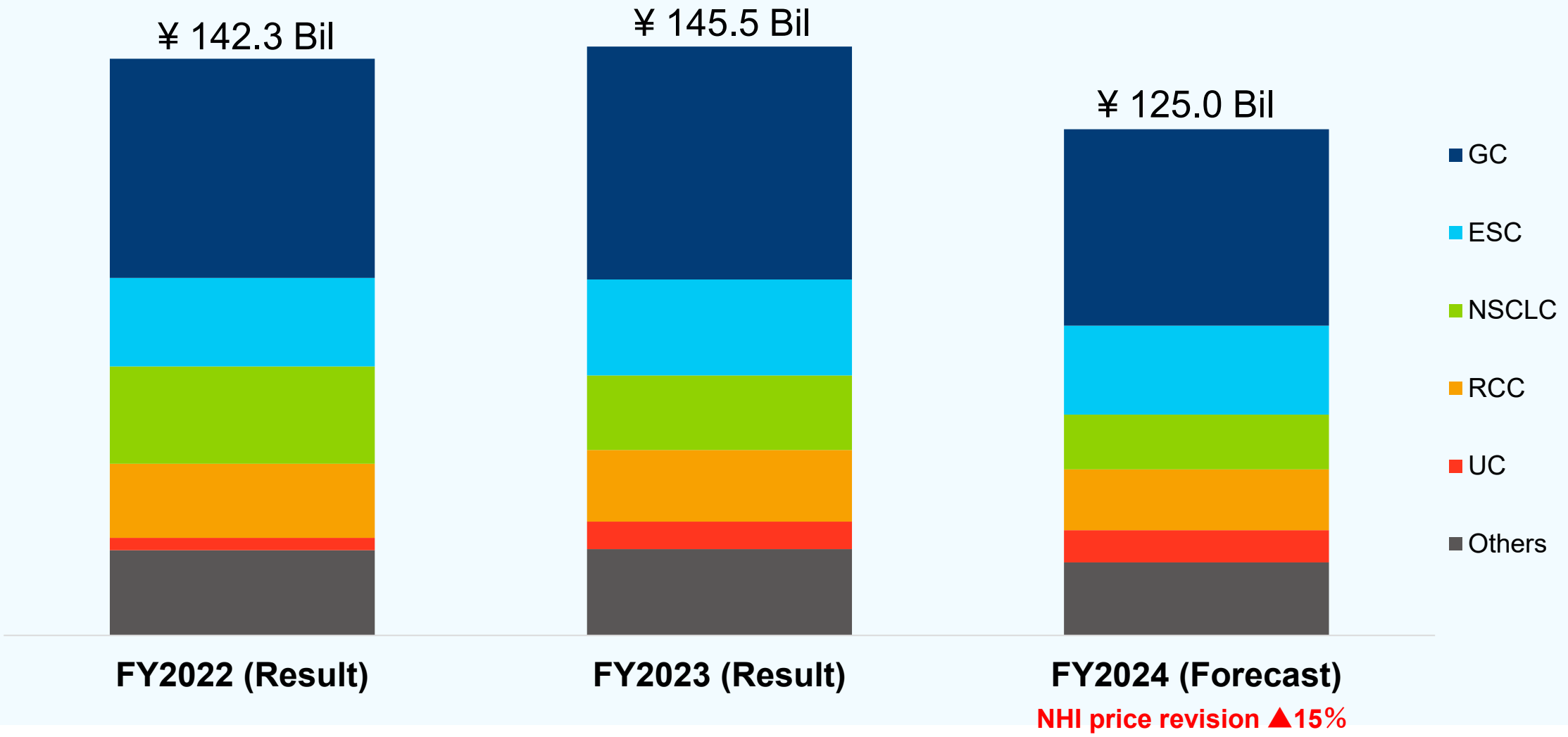
Cautionary Notes

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.**

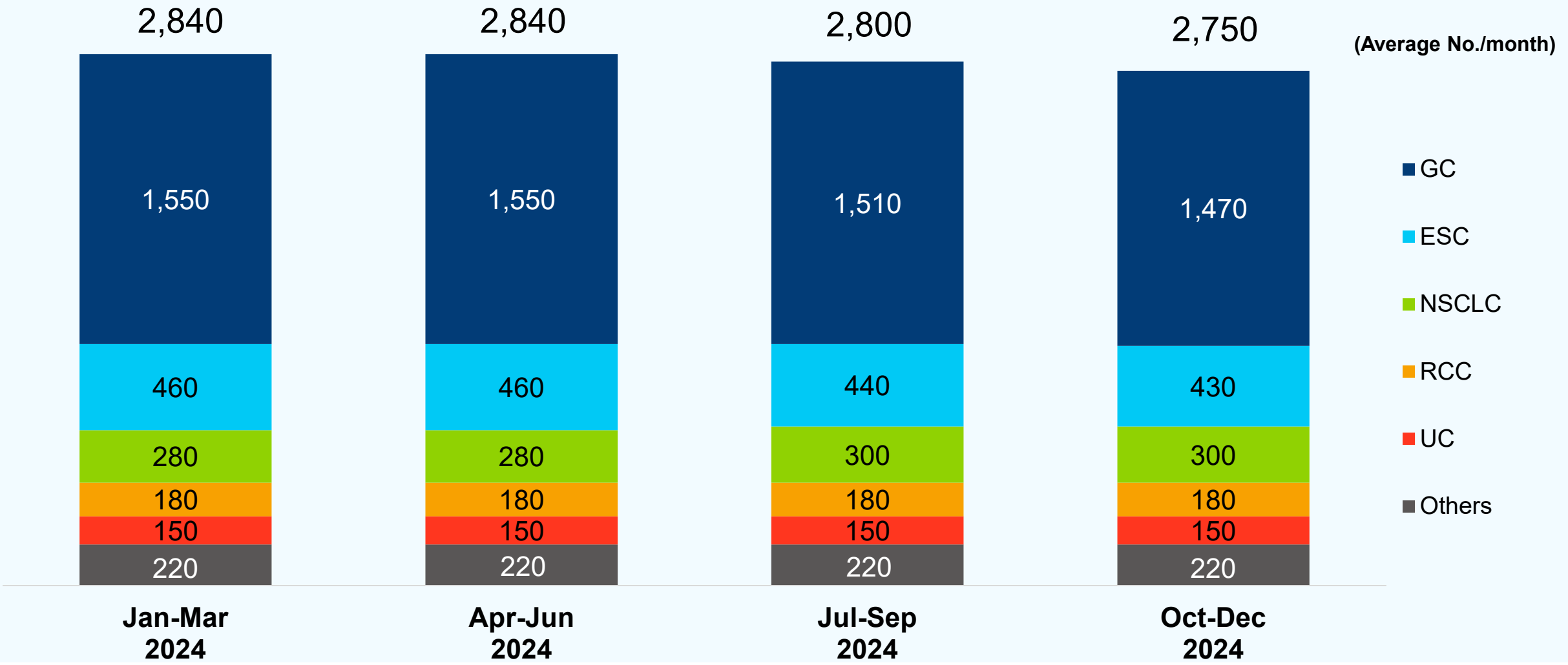
Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

Sales Trend of OPDIVO by Each Cancer



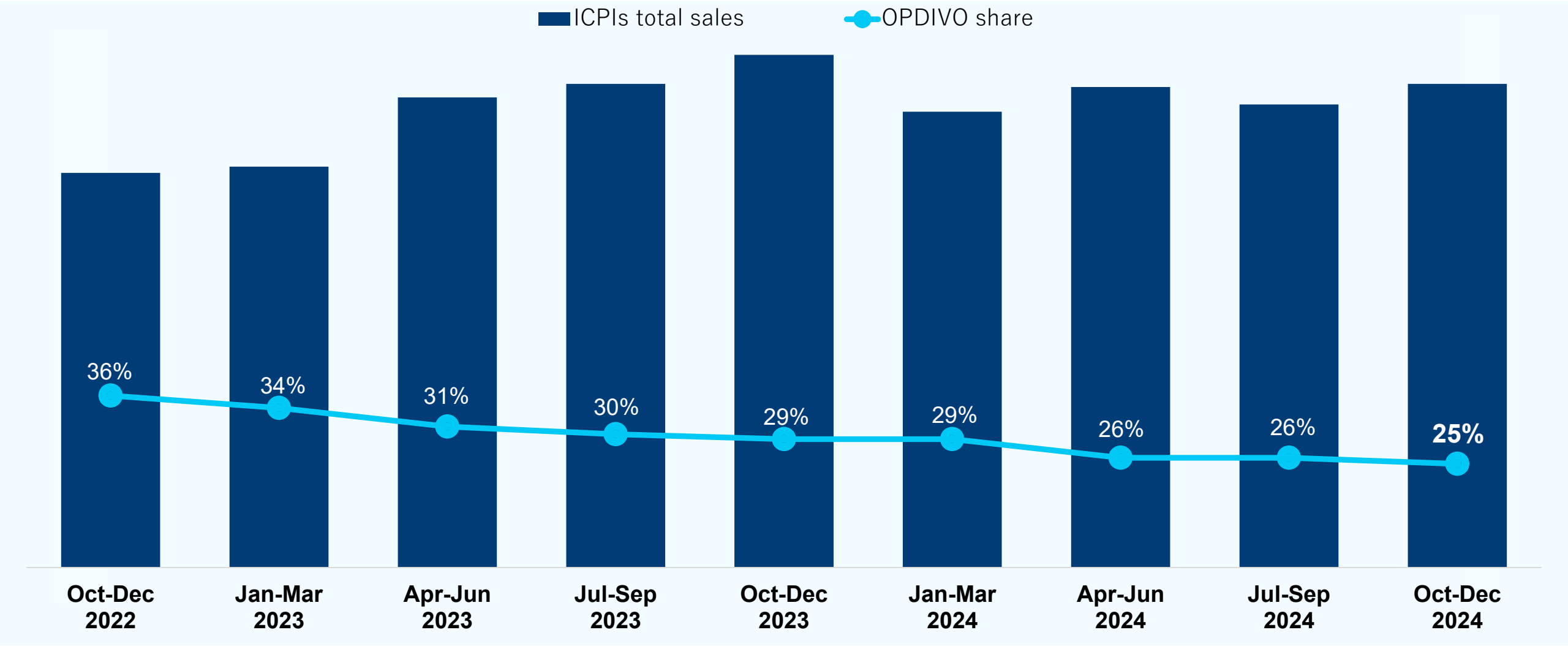
Source: Estimation from external and internal data

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



Source: Estimation from external and internal data

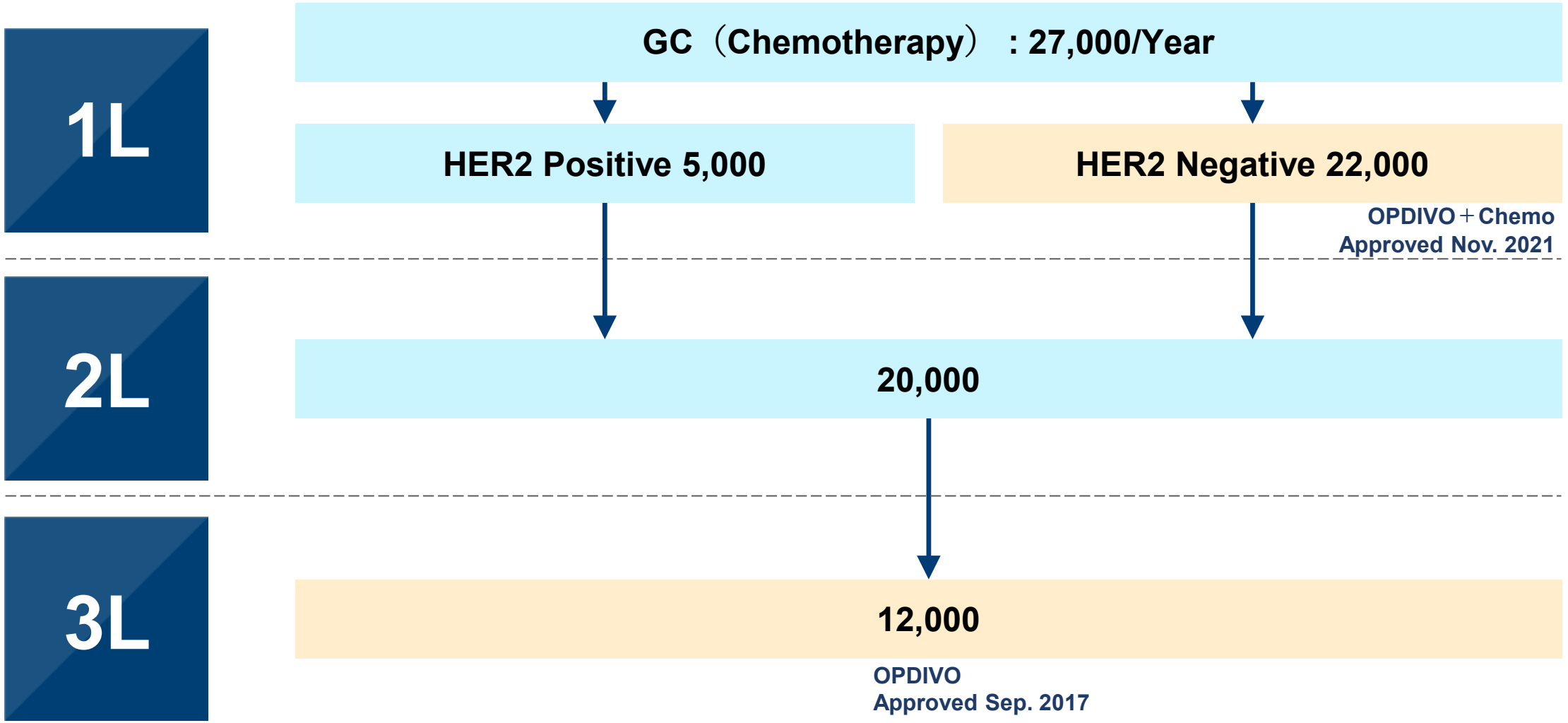
Trend of total sales of ICPIs and OPDIVO share



Source: External data

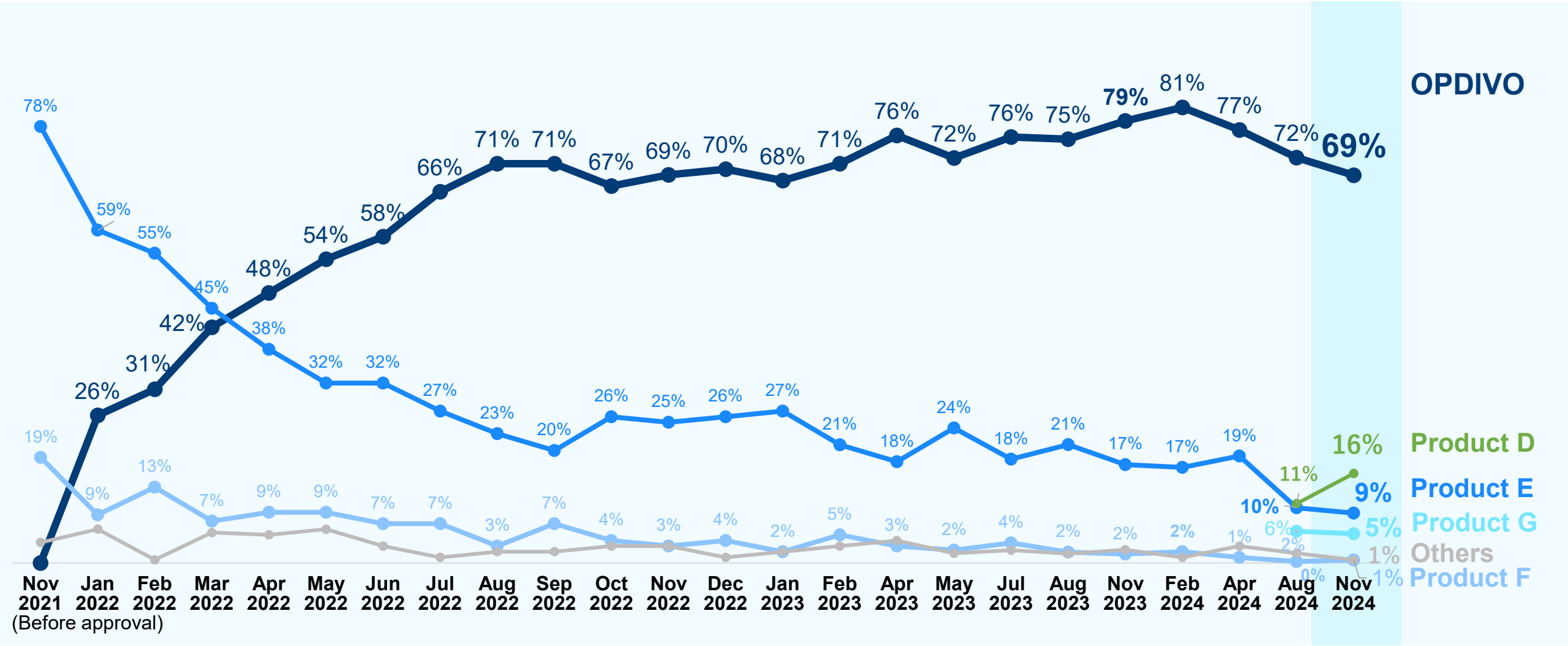
Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC



Estimation based on internal survey (2020)

Prescription Ratio in Patients Newly Treated※ for 1L GC

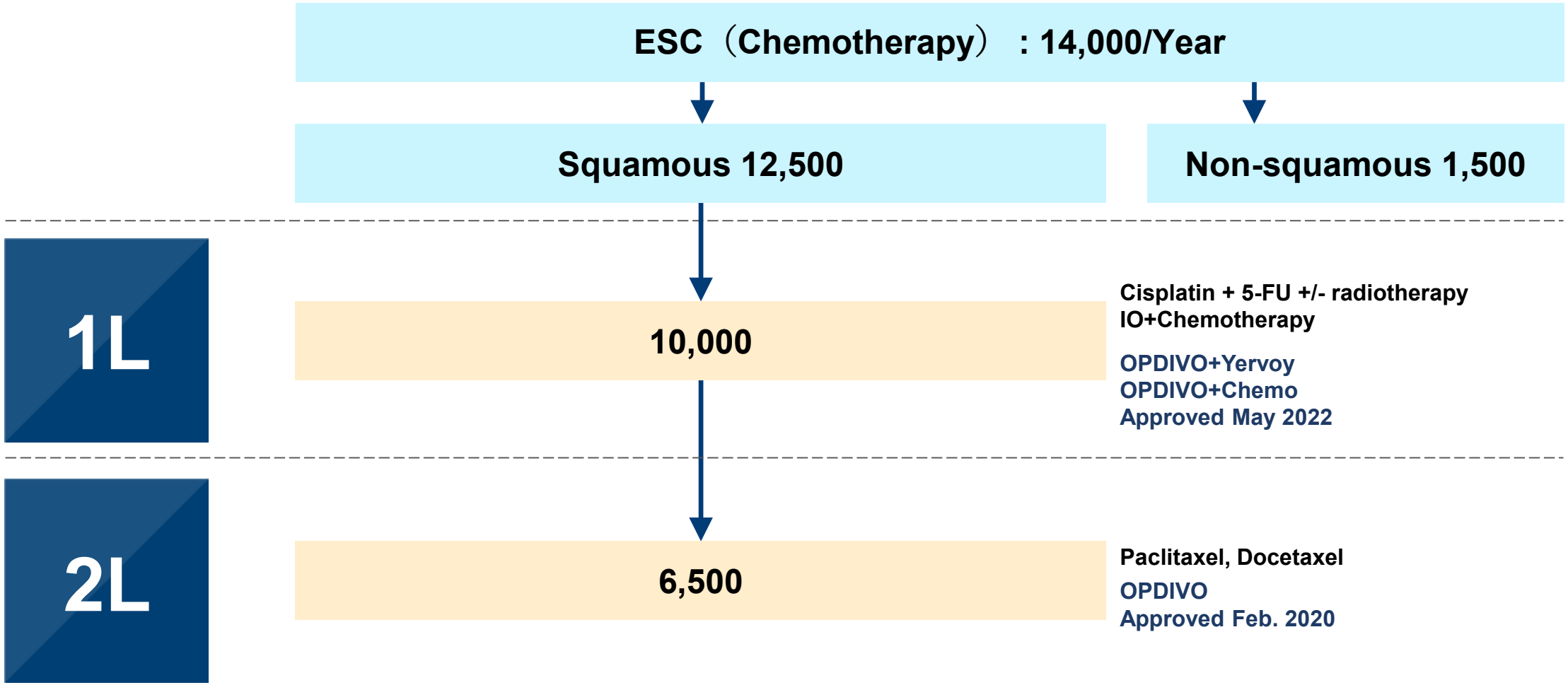


※Patients starting 1L treatment within the last 3 month

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

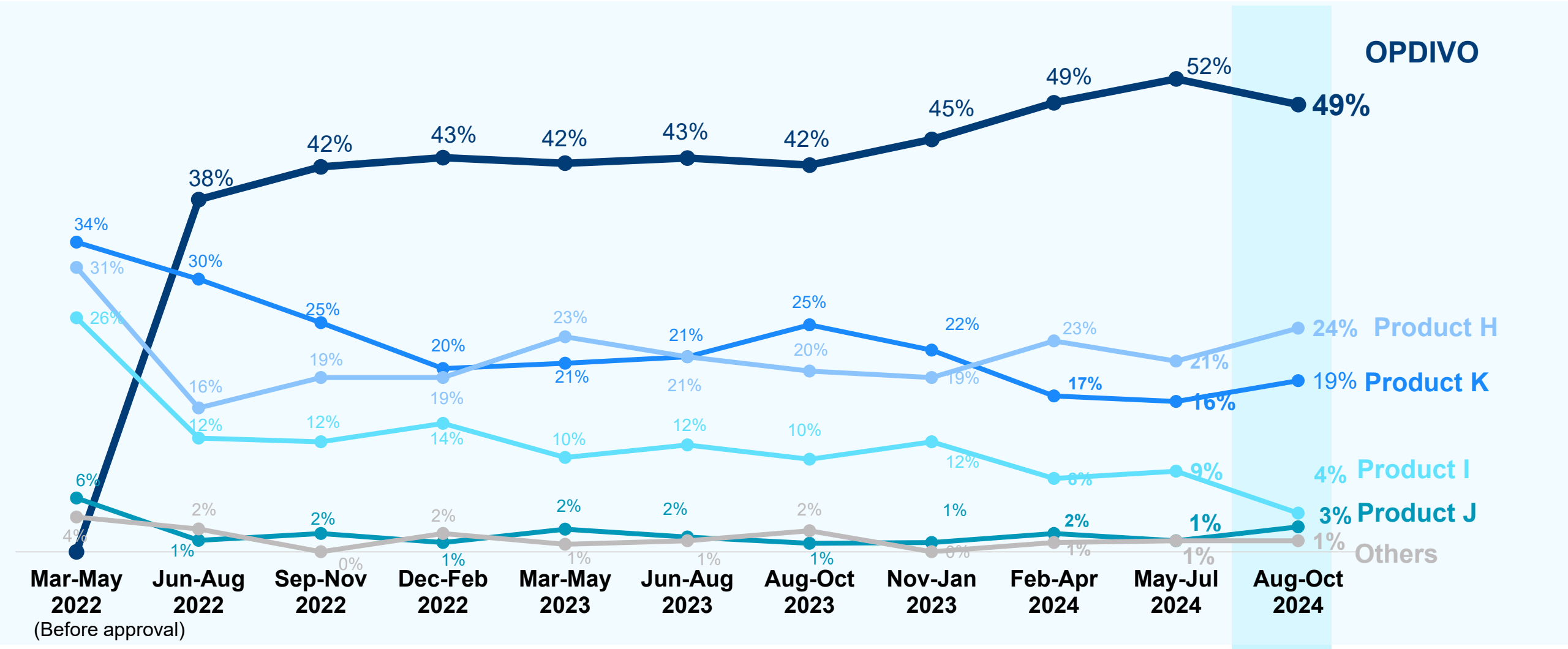
Number of ESC* Patients per year in Japan

* : Unresectable Advanced or Recurrent ESC



Estimation based on internal survey (2022)

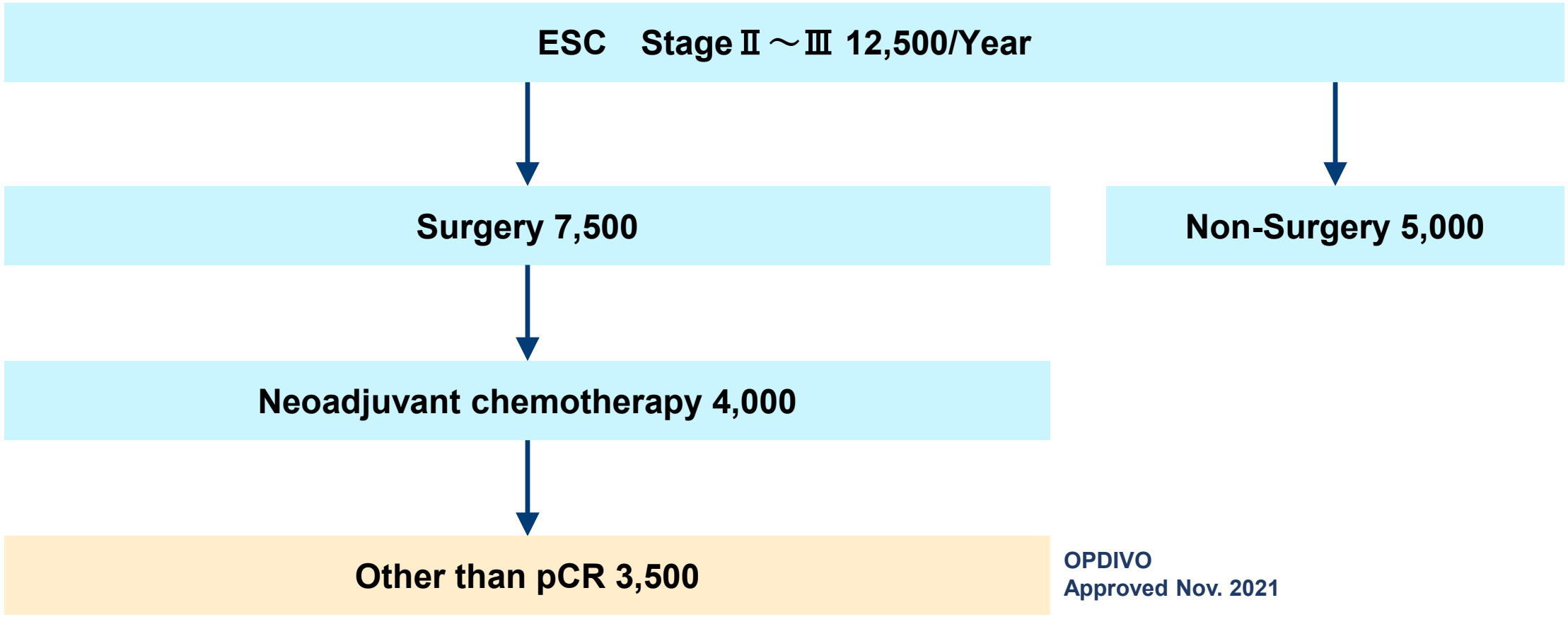
Prescription Ratio in Patients Newly Treated※ for 1L ESC(Squamous Cell Carcinoma)



※Patients starting treatment within the last 3 month

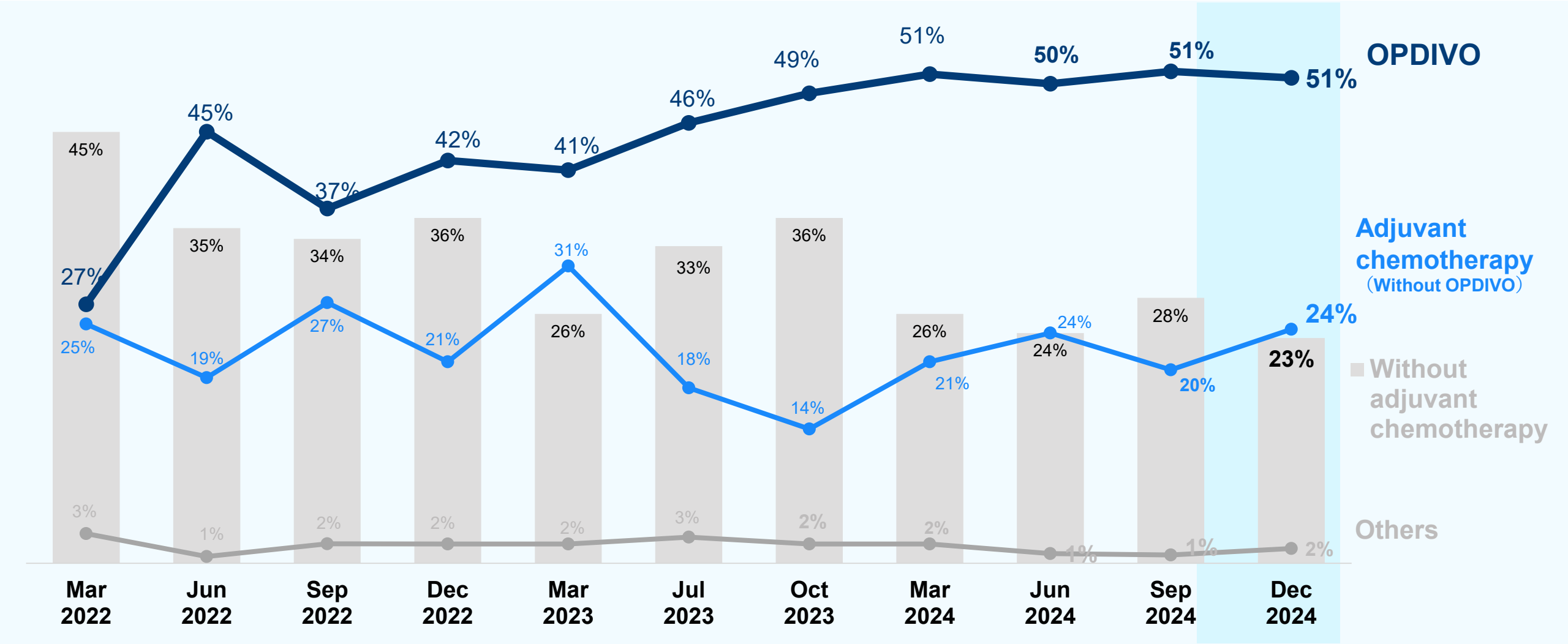
Source: External data（May 2022~Oct 2024: n=150~155）

Number of ESC(Perioperative)Patients per year in Japan



Estimation based on internal survey (2022)

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

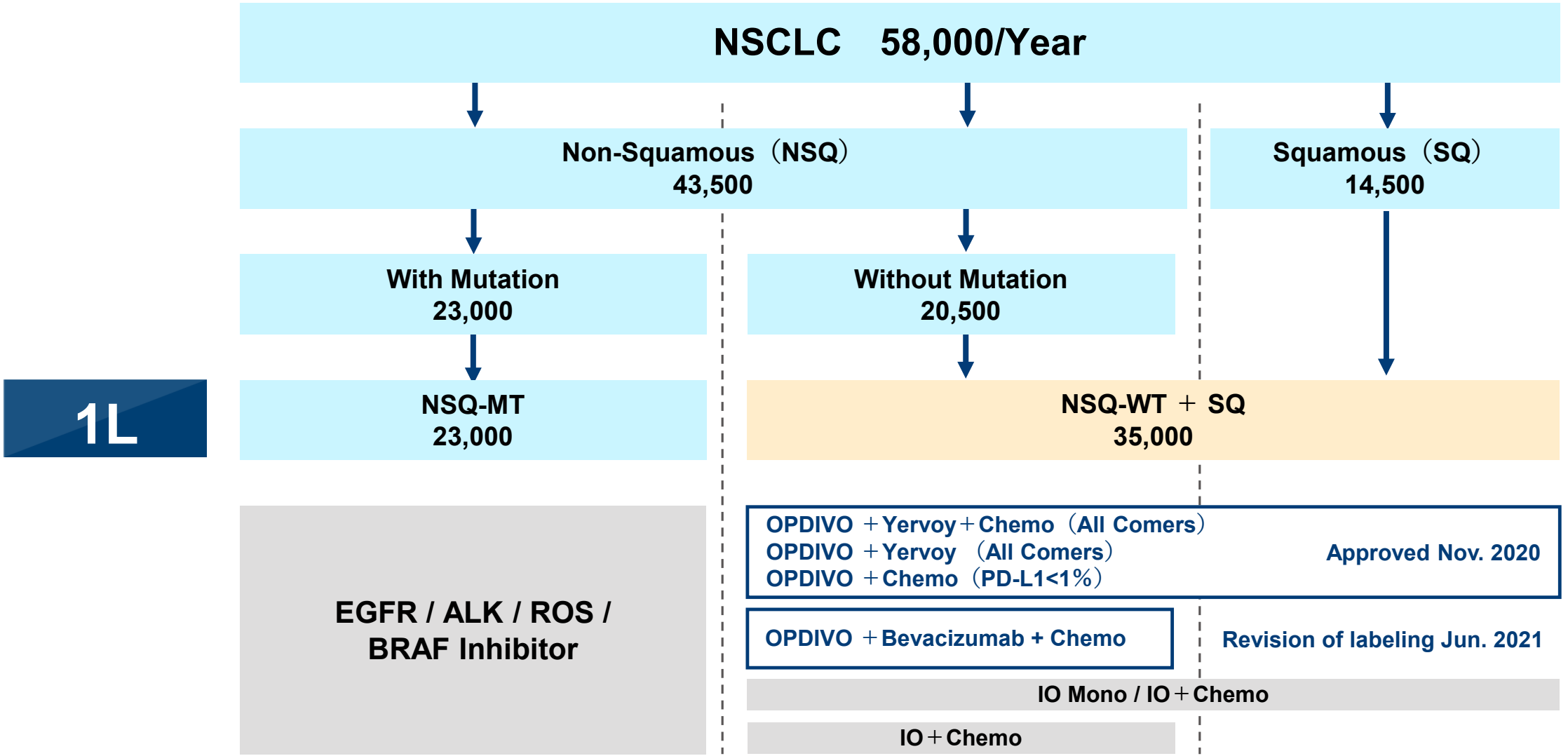


※Patients starting treatment within the last 3 months

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

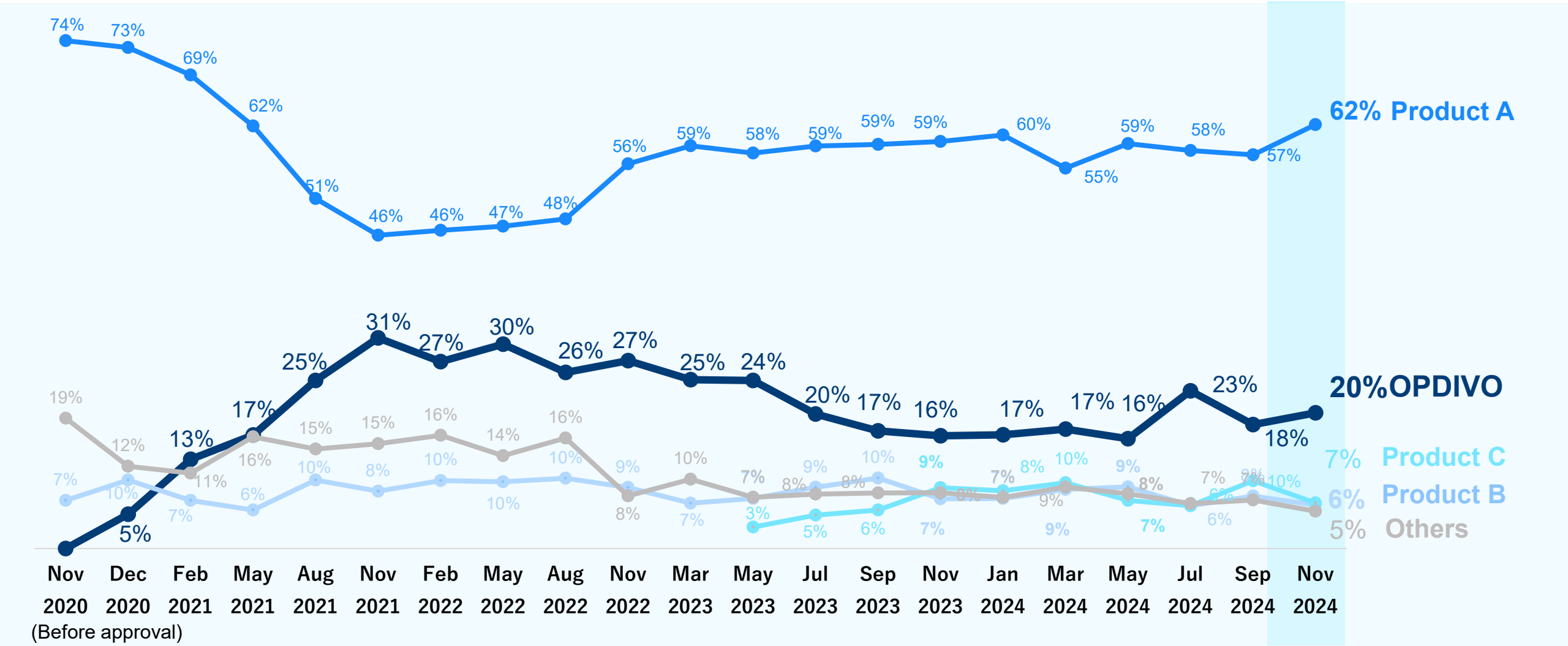
Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC



Estimation based on internal survey (2021)

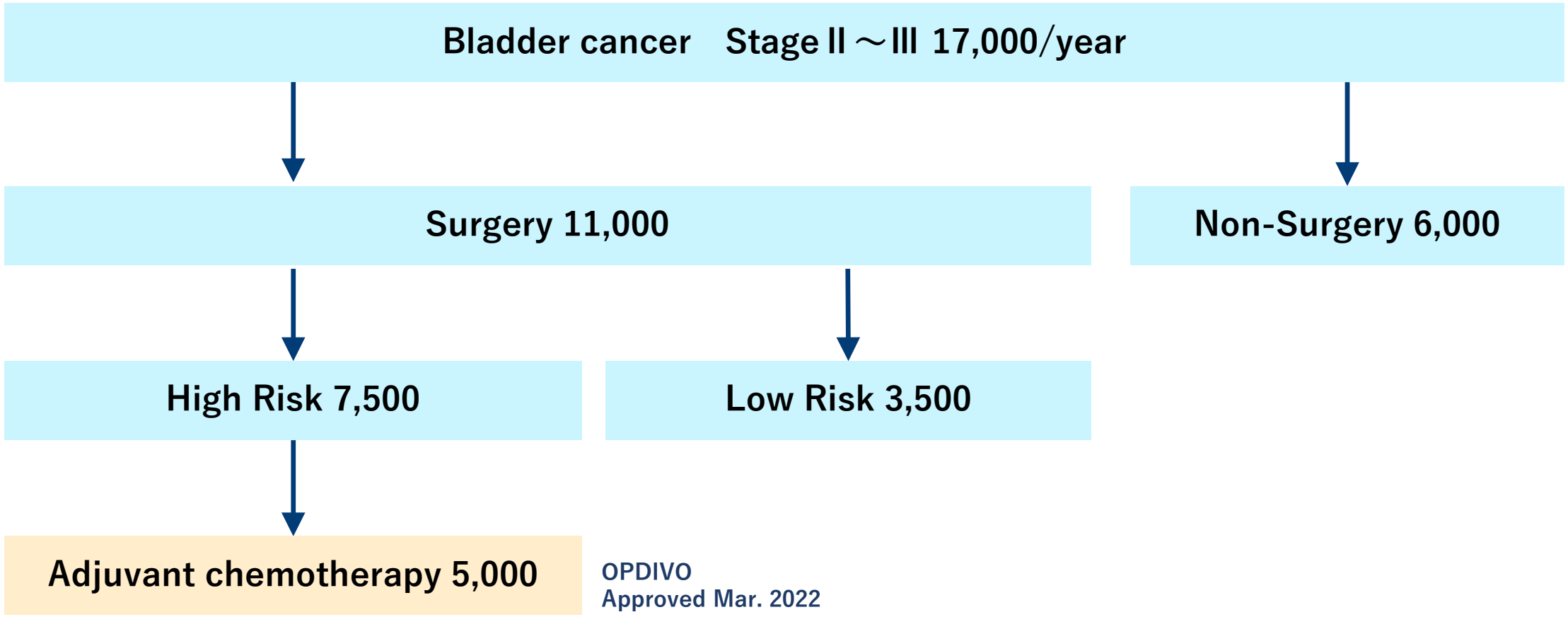
Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



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

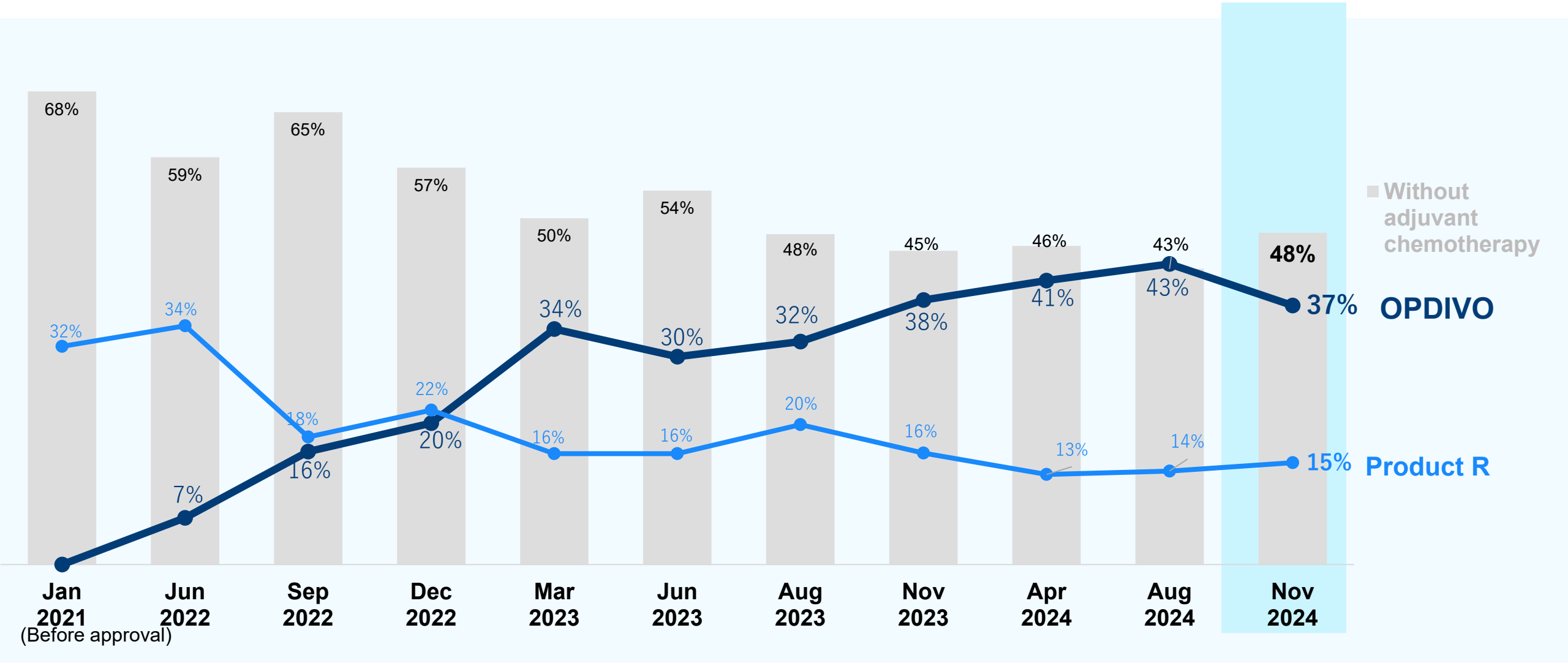
Source: External data（Nov 2020~Nov 2024: n=167~245)

Number of Bladder Cancer(Perioperative)Patients per year in Japan



Estimation based on internal survey (2022)

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

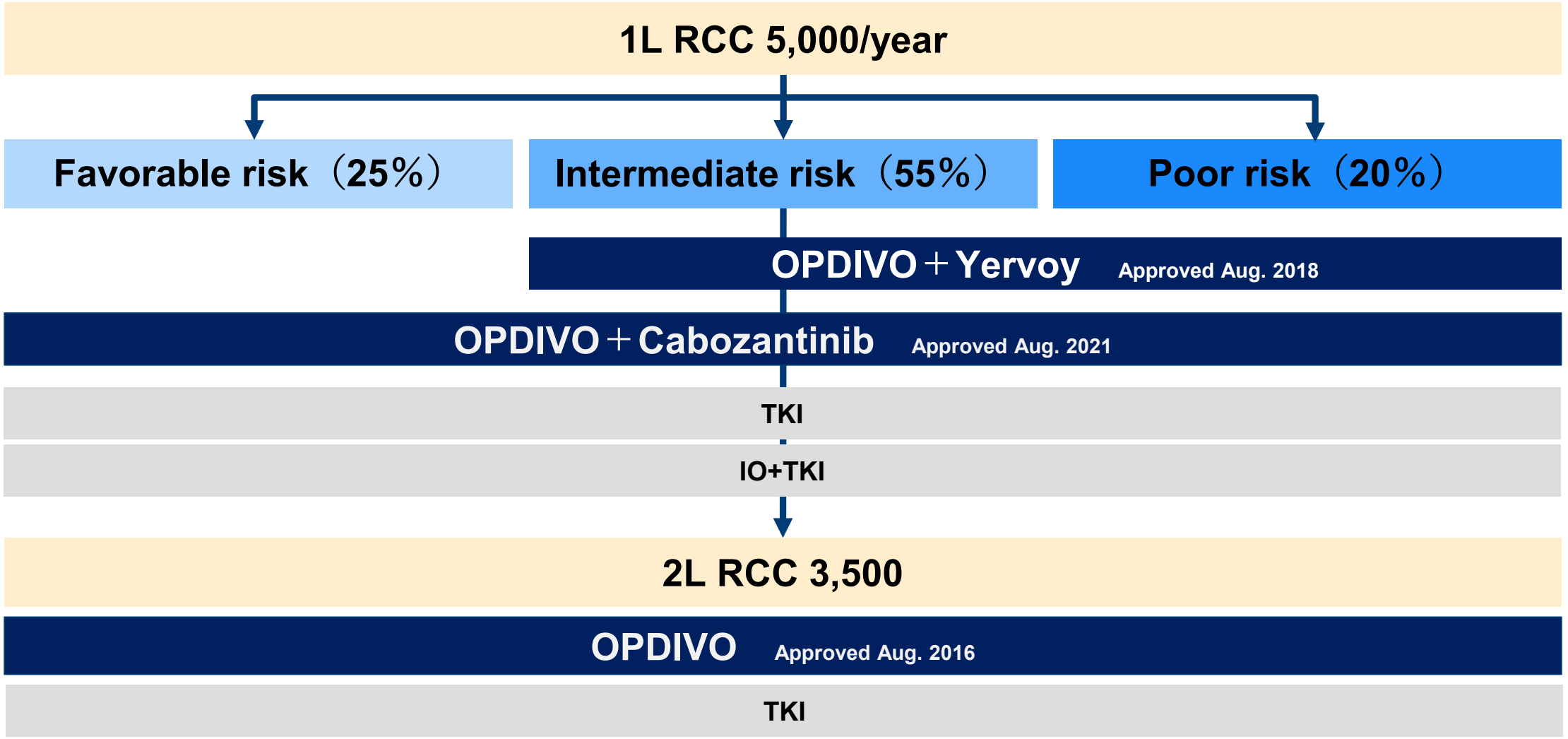


※Patients starting treatment within the last 3 months

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

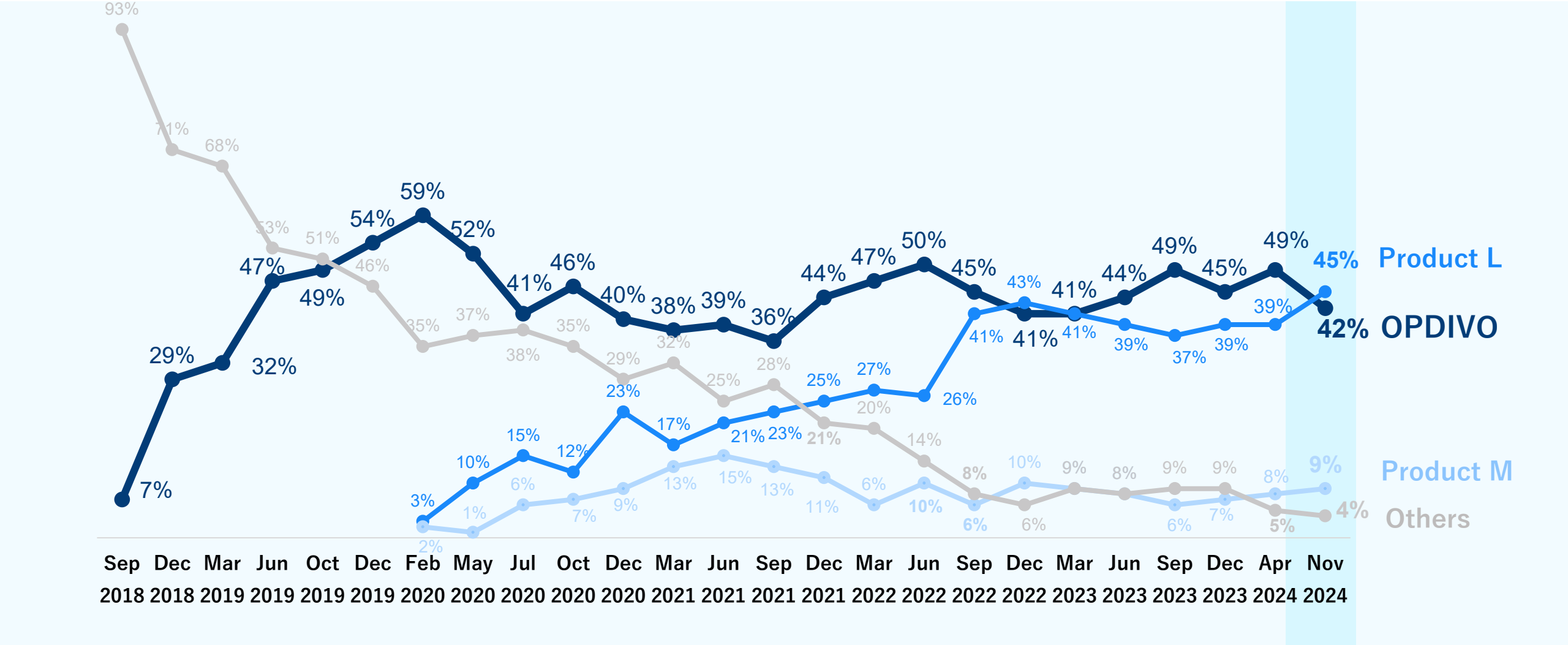
Number of RCC* Patients per year in Japan

* : Unresectable or Metastatic RCC



Estimation based on internal survey (2022)

Prescription Ratio in Patients Newly Treated※ for 1L RCC



※Patients starting treatment within the last 3 months

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

ONO PHARMA

Dedicated to the Fight against Disease and Pain