FY2024 Q2 Financial Results Meeting

November 1, 2024

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

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 営業本部長 Corporate Executive Officer / Executive Director, Sales and Marketing	髙萩　聰 Satoshi Takahagi
執行役員 経営戦略本部 経営管理統括部長 Corporate Officer / Division Director, Corporate Strategy & Planning, 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

Agenda

2025年3月期第2四半期 決算概要 /政策保有株式の縮減について
Material for Financial Announcement FY 2024 Q2 /
Status of Cross-shareholdings （10:00-10:25）

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（10:25-10:35）

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（10:35-10:45）

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

髙萩　聰
Satoshi Takahagi

質疑応答
Q&A Session（10:45-11:00）

Material for Financial Announcement Q2 FY 2024

Highlights of Financial Results for FY2024 Q2

- Starting from the second quarter, the profit and loss (including sales, cost of sales, research and development expenses, and selling, general, and administrative expenses) of Deciphera Pharmaceuticals, Inc. for the three months from July to September will be included in our consolidated financial statements.
- In the second quarter, as a provisional accounting treatment, the entire difference between the acquisition cost and the net assets has been recorded as goodwill. In the third quarter financial statements, we plan to record intangible assets and other items as of the acquisition date through a fair value assessment. (In other words, the amortization expenses for intangible assets recognized through the acquisition are not included in this second quarter.)
- Starting from the fiscal year 2024, we will disclose core-basis financial results to present our performance in our core business. In the second quarter, we will present the full-year consolidated financial forecast on a core basis. (The full-year core-basis financial forecast for the fiscal year ending March 2025 is calculated by deducting provisional amortization expenses for intangible assets related to acquisitions from the full-basis financial forecast for the same period.)
- Regarding the exclusive option and asset purchase agreement for "itolizumab" signed with Equillium, Inc. in the United States in December 2022, we decided not to exercise the option for strategic reasons in October 2024.

FY2024 Q2 : Sales Revenue

Revenue
¥240.3 billion

YoY -18.4 billion
(-7.1%)

Goods and Products Sales
¥163.3 billion

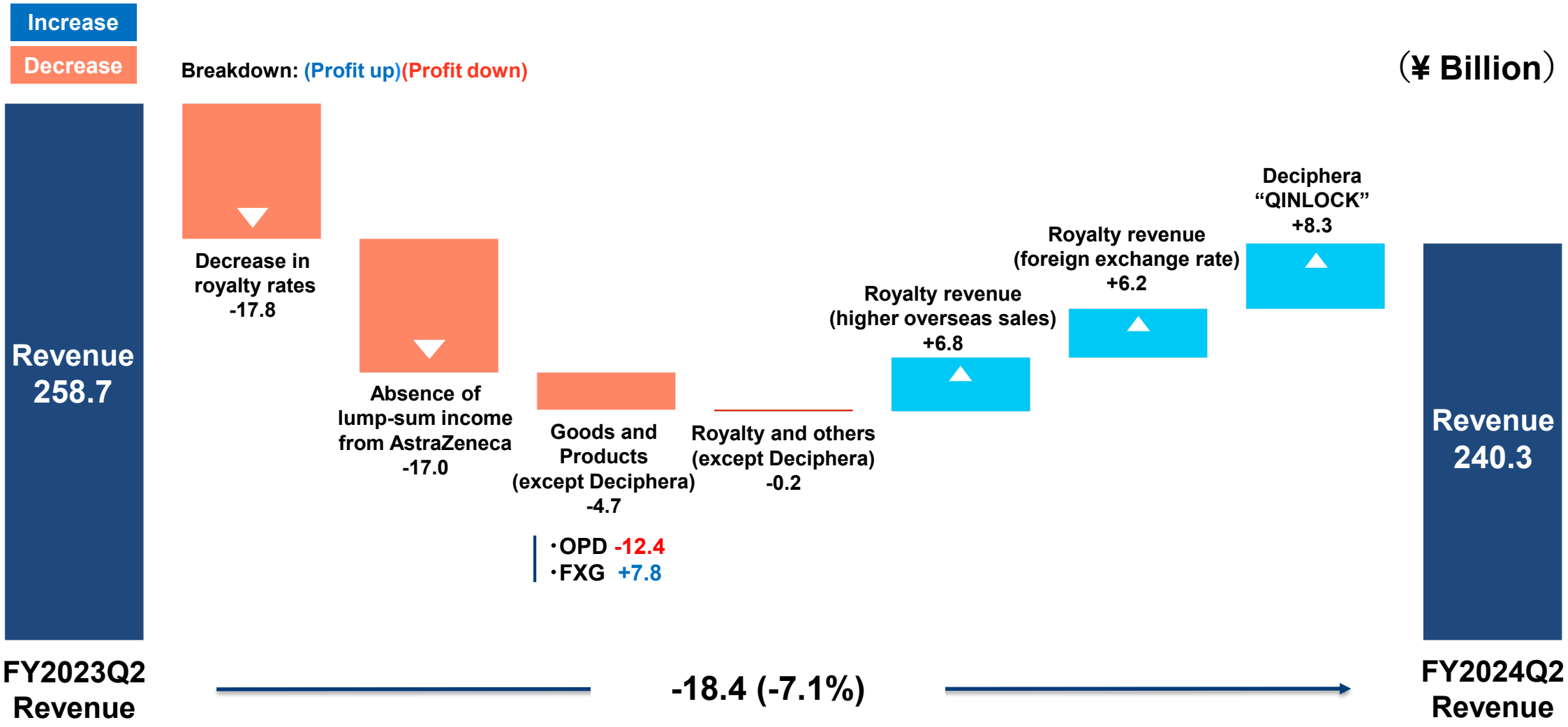
YoY +3.4billion (+2.1%)

Royalty and Others
¥77.0 billion

YoY -21.8 billion (-22.0%)

FY2024 Q2 : 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 Q2 : Sales Revenue by Product (Domestic)

¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	240.3	(18.4)	(7.1%)	450.0
Goods and products	159.9	163.3	3.4	2.1%	304.0
Royalty and others	98.8	77.0	(21.8)	(22.0%)	146.0

Goods and Products (Domestic)	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Opdivo Intravenous Infusion	75.0	62.6	(12.4)	(16.5%)	125.0
Forxiga Tablets	35.9	43.7	7.8	21.7%	83.0
Orencia for Subcutaneous Injection	13.0	13.5	0.5	3.5%	27.0
Glactiv Tablets	10.8	9.6	(1.2)	(11.2%)	18.5
Velexbru Tablets	5.0	5.2	0.2	3.7%	10.0
Kyprolis for Intravenous Infusion	4.6	4.6	(0.0)	(1.0%)	9.5
Parsabiv Intravenous Injection	4.1	4.2	0.0	0.7%	8.5
Ongentys Tablets	3.1	3.8	0.7	21.4%	7.5

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 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 Q2 : Sales Revenue by Product (Overseas) / Royalty

¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	240.3	(18.4)	(7.1%)	450.0
Goods and products	159.9	163.3	3.4	2.1%	304.0
Royalty and others	98.8	77.0	(21.8)	(22.0%)	146.0

Goods and Product（Overseas）	FY2023Q2	FY2024Q2	YoY		
			Change	Change (%)	
OPDIVO	6.1	6.5	0.4	6.9%	
QINLOCK	–	8.1	–	–	

Royalty and others	FY2023Q2	FY2024Q2	YoY		
			Change	Change (%)	
OPDIVO	47.4	56.4	9.0	19.1%	
KEYTRUDA®	25.6	12.8	(12.8)	(50.0%)	

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 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 Q2 : Operating Profit

Operating Profit
¥55.9 billion

YoY -41.2 billion
(-42.4%)

Revenue ¥240.3 billion

YoY -18.4 billion (-7.1%)

R&D Expense ¥68.8 billion

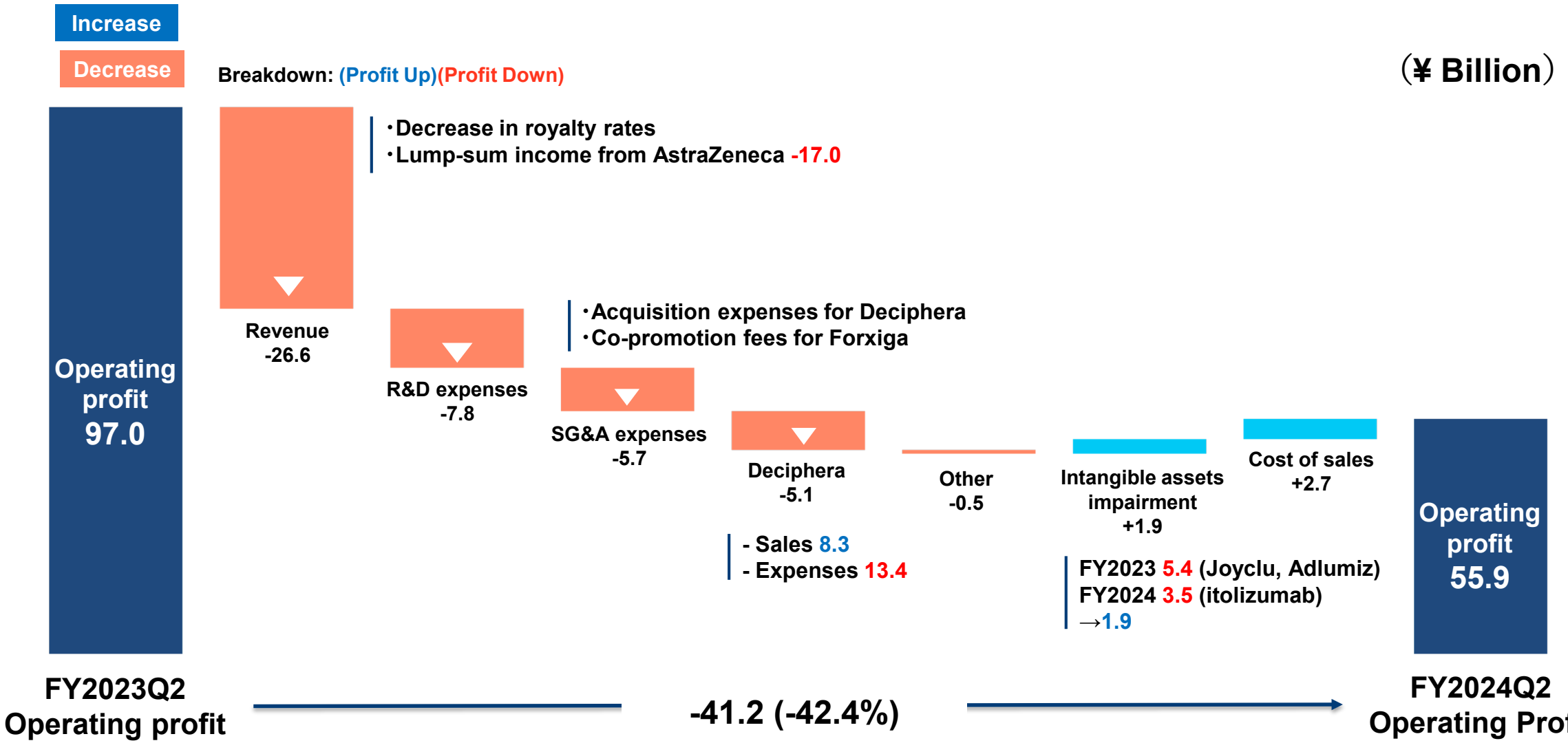
YoY +19.4 billion (+39.4%)

SG&A Expense ¥58.4 billion

YoY +10.8 billion (+22.7%)

FY2024 Q2 : Operating Profit (Breakdown)

・ **Operating profit was decreased by 41.2 billion to 55.9 billion mainly due to increases in R&D and SG&A expenses, despite a decrease in cost of sales.**



FY2024 Q2 : Financial Overview

¥ Billion	FY2023Q2	FY2024Q2	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	258.7	240.3	(18.4)	(7.1%)	450.0
Cost of sales	64.8	56.9	(7.9)	(12.2%)	113.0
R&D expenses	49.4	68.8	19.4	39.4%	112.0
SG&A expenses	47.6	58.4	10.8	22.7%	100.0
Other income	0.9	0.6	(0.3)	(36.0%)	0.5
Other expenses	0.8	0.9	0.1	10.2%	3.5
Operating profit	97.0	55.9	(41.2)	(42.4%)	122.0
Profit before tax	99.3	54.6	(44.7)	(45.0%)	123.0
Profit for the period (attributable to owners of the Company)	74.5	41.6	(32.9)	(44.1%)	91.0

YoY Breakdown

Cost of sales -¥7.9 billion

Main reasons
- Absence of impairment losses on sales licenses recorded in the previous fiscal year -5.4 billion

R&D expenses +¥19.4 billion R&D ratio : 28.6%

Main reasons
- Research costs and development costs for clinical trials
- R&D expenses from Deciphera
- Impairment loss for itolizumab +3.5 billion

SG&A expenses +¥10.8 billion

Main reasons
- Co-promotion fees for Forxiga Tablets
- SG&A expenses from Deciphera
- Expenses associated with the acquisition of Deciphera

* The consolidated financial forecast for the fiscal year ending March 2025, announced on May 9, 2024, is provided.

Introduction of a Core-Basis Result

＜Background for Introducing a Core-Basis Result＞

Previously, IFRS full-basis results have included the impact of transactions that are not related to our core business or are temporary in nature. Additionally, due to the acquisition of Deciphera Pharmaceuticals, Inc., we anticipate amortization expenses for intangible assets acquired through the acquisition in the future. Therefore, starting from the FY 2024, we will disclose the core-basis result to present our performance in our core business.

＜Definition of a Core-Basis Result＞

Core-basis results are calculated by adjusting items not related to the essential performance of our business and temporary items such as those occurring in a single fiscal year from the IFRS full-basis results.

Examples of specific adjustment items include amortization expenses arising from intangible assets acquired through acquisitions or in-licensing, impairment losses, and compensation or settlement from litigation, losses due to disasters, etc.

FY2024 : Financial Forecast (Sales Revenue)

Revenue
¥485.0 billion

YoY -17.7 billion
(-3.5%)

Goods and Products Sales
¥333.0 billion

YoY +16.0 billion (+5.1%)

Royalty and Others
¥152.0 billion

YoY -33.7 billion (-18.1%)

* The forecast of consolidated financial results for the fiscal year ending March 31, 2025, as announced on May 9, 2024, has been revised.

FY2024 : Financial Forecast (Sales by Product)

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%

*Sales of Forxiga Tablets are forecasted to be ¥89.0 billion, an upward revision of ¥6.0 billion from the previous forecast announced on May 5th, 2024.

Goods and Product (Overseas)	FY2023	FY2024 Forecast	YoY	
			Change	Change (%)
OPDIVO	12.0	13.5	1.5	12.5%
QINLOCK	–	23.5	–	–

* 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 : Financial Forecast (Operating Profit)

Operating Profit
¥82.0 billion
YoY -77.9 billion
(-48.7%)

Core Operating Profit
¥110.0 billion

Revenue ¥485.0 billion

YoY -17.7 billion (-3.5%)

R&D Expense ¥147.0 billion

YoY +34.8 billion (+31.0%)

SG&A Expense ¥123.0 billion

YoY +22.7 billion (+22.7%)

FY2024 : Financial Forecast (Changes vs. FY2023)

¥ Billion	FY2023 Actual	FY2024 Revised forecast	Change	Change (%)
Revenue	**502.7**	**485.0**	**(17.7)**	**(3.5%)**
Cost of sales	127.1	130.0	+2.9	+2.3%
R&D expenses	112.2	147.0	+34.8	+31.0%
SG&A expenses	100.3	123.0	+22.7	+22.7%
Operating profit	**159.9**	**82.0**	**(77.9)**	**(48.7%)**
Adjustments	–	**28.0**	–	–
Core operating profit	–	**110.0**	–	–
Profit before tax	**163.7**	**81.5**	**(82.2)**	**(50.2%)**
Profit for the year (attributable to owners of the Company)	**128.0**	**58.0**	**(70.0)**	**(54.7%)**
Core profit for the year	–	**81.0**	–	–

Changes (vs. FY2023)

Cost of sales +¥2.9 billion（2.3%）

Main reason

- Absence of impairment losses on sales licenses recorded in the previous fiscal year .
- Amortization expenses associated with QINLOCK, etc. ¥15.0 billion

R&D expenses +¥34.8 billion (+31.0%)

Main reasons

- R&D expenses from Deciphera +¥26.0 billion
- License agreement with LigaChem BioScience, Inc.

SG&A expenses +¥22.7 billion (+22.7%)

Main reasons

- SG&A expenses from Deciphera +¥15.0 billion
- Expenses associated with the acquisition of Deciphera
- Co-promotion fees for Forxiga Tablets

Adjustment for a core-basis result

Main items

- Amortization expenses associated with QINLOCK and development compounds
- Impairment loss for itolizumab ¥3.5 billion

*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 (Changes vs. Previous Forecast)

The ¥40.0 billion decrease in operating profit compared to the initial forecast is primarily due to significant investments aimed at overcoming the patent expiration of Opdivo and growing into a global specialty pharma company. These investments include costs arising from the acquisition of Deciphera Pharmaceuticals, Inc., which were not factored into the initial forecast, and the license agreement with LigaChem BioScience, Inc. Excluding these factors, we expect to secure profit levels comparable to the initial forecast.

¥ Billion	FY2024 Previous forecast	FY2024 Revised forecast	Change	Change (%)
Revenue	**450.0**	**485.0**	**(35.0)**	**+7.8%**
Cost of sales	113.0	130.0	+17.0	+15.0%
R&D expenses	112.0	147.0	+35.0	+31.3%
SG&A expenses	100.0	123.0	+23.0	+23.0%
Operating profit	**122.0**	**82.0**	**(40.0)**	**(32.8%)**
Adjustments	–	**28.0**	–	–
Core operating profit	–	**110.0**	–	–
Profit before tax	**123.0**	**81.5**	**(41.5)**	**(33.7%)**
Profit for the year (attributable to owners of the Company)	**91.0**	**58.0**	**(33.0)**	**(36.3%)**
Core profit for the year	–	**81.0**	–	–

Breakdown of ¥40.0 billion decrease in operating profit

Revenue +¥35.0 billion

Main reason
- **QINLOCK +¥23.5 billion**

Cost of sales +¥17.0 billion

Main reasons
- **Amortization expenses associated with QINLOCK, etc. +¥15.0 billion**

R&D expenses +¥35.0 billion

Main reasons
- **R&D expenses from Deciphera +¥26.0 billion**
- **License agreement with LigaChem BioScience, Inc.**

SG&A expenses +¥23.0 billion

Main items
- **SG&A expenses from Deciphera +¥15.0 billion**
- **Expenses associated with the acquisition of Deciphera**

Status of Cross-shareholdings

Reduction plan of Cross-shareholdings (published on November 1, 2021)

➢ Reduction plan

・Period: October 2021 to March 2025 (3 and a half years)
・Details of reduction plan:
30% reduction from the end of September 2021 (141.8 billion yen)
※The company plans to reduce its cross-shareholdings to less than 20% of its net assets by the end of March 2022.

	End of September 2021	Expected at the end of March 2025	Plan	
			Reduction	Reduction rate
Market price at the end of September 2021	**¥ 141.8 bil**	**¥ 99.3 bil**	**¥ 42.5 bil**	**30.0%**

➢ Medium-to long-term plan

We aim for the ratio of strategic shareholdings to net assets (on a balance sheet basis) to be less than 10%.

Status of reduction of Cross-shareholdings

	End of September 2021	End of September 2024	Reduction*	Reduction rate
Market price at the end of September 2021	**¥ 141.8 bil**	**¥ 92.4 bil**	**¥ 49.4 bil**	**34.9%**

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of September 2024	Reduction	Reduction rate
Balance sheet accounting amount	**¥ 141.8 bil**	**¥ 97.3 bil**	**¥ 44.5 bil**	**31.4%**

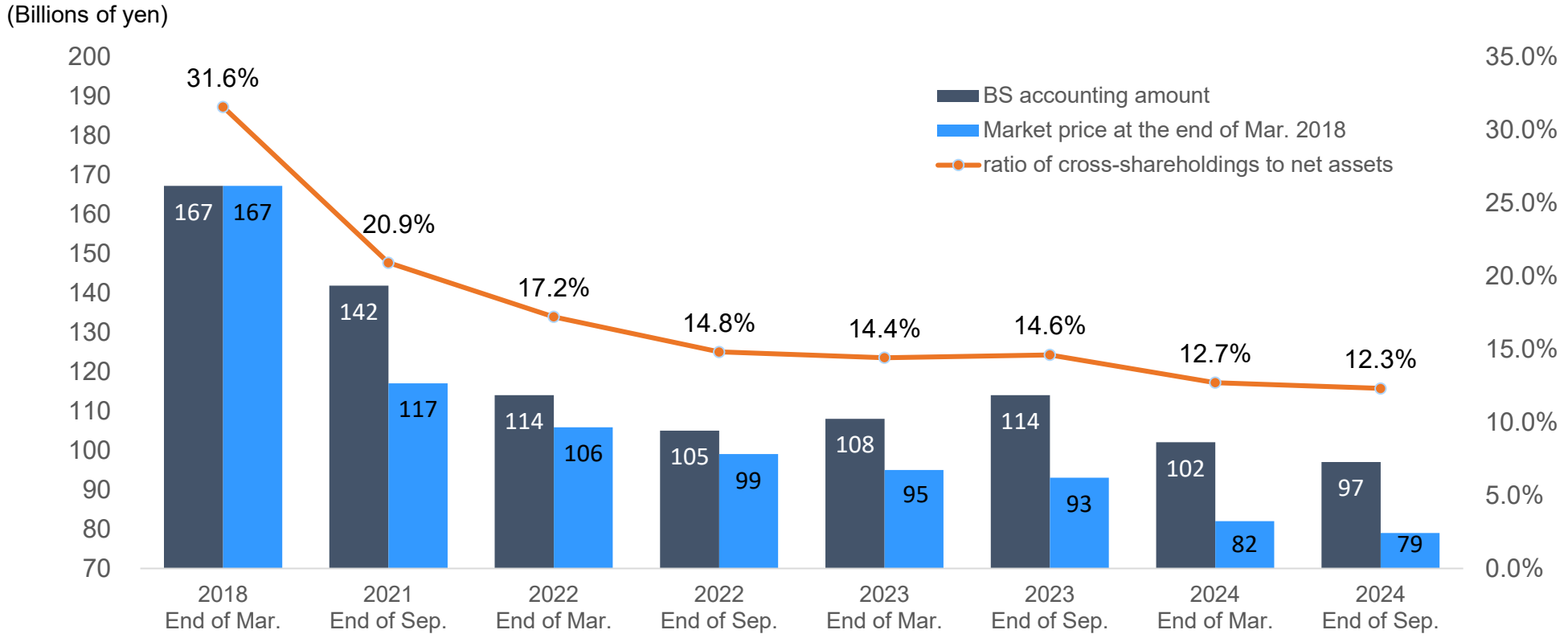
※End of September 2024
Ratio of Cross-shareholdings to net assets：12.3%

Status of reduction of Cross-shareholdings

➢ Reduction plan

- 30% reduction by the end of September 2021 as of the end of March 2018 (111 brands, 167.1 billion yen)
- 30% reduction by the end of March 2025 as of the end of September 2021 (141.8 billion yen)

➢ Changes of reduction



Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of October 24, 2024

Filed | Approved | Met PE

OPDIVO | Other than OPDIVO

FY2023 (results)	FY2024	FY2025
	〔1st-Hepatocellular carcinoma〕 with YERVOY CheckMate-9DW August 2024	〔Neoadjuvant, Adjuvant - Bladder cancer〕 With Chemo ONO-4538-86
〔1st-Urothelial cancer〕 with Chemo CheckMate-901 Dec 2023	〔1st- Colorectal cancer (MSI-H)〕 with YERVOY CheckMate-8HW September 2024	〔Adjuvant Hepatocellular carcinoma〕 CheckMate-9DX
〔Epithelial skin malignancies〕 Investigator-initiated trial Jun 2023	〔 Neoadjuvant, Adjuvant - NSCLC〕 with Chemo CheckMate-77T	〔1st-Urothelial cancer (Cis ineligible)〕 with YERVOY CheckMate-901
BRAFTOVI／MEKTOVI 〔2nd-BRAF-mutant Thyroid cancer〕 May 2023	BRAFTOVI 〔1st-BRAF-mutant Colorectal cancer〕 With Cetuximab and Chemo	ONO-2017 Partial-onset seizures

PE : Primary endpoint

Development status of OPDIVO (1)

As of October 24, 2024

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	with Brentuximab	Ⅲ	–	–	Ⅲ	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	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 October 24, 2024

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	Filed
	MSI-H／dMMR (3rd)	Monotherapy	Approved	–	Approved	Approved	-
		with Ipi	Approved	Approved	Approved	Approved	Approved★★
Hepatocellular carcinoma	Adjuvant	Monotherapy	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Ipi	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 October 24, 2024

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
		with Ipi/TKI	–	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Filed	Approved	Approved	Approved	Approved
		with Ipi	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	Monotherapy	Ⅱ	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Rhabdoid tumor	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	–	–	Filed	Filed

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

Development pipeline (Oncology)

As of October 24, 2024

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		
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma				FY2025 Primary Completion (Part A)		
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*				FY2024 Primary Completion		
	NCT01968109/JP, US, EU	Melanoma*			FY2024 Primary Completion (Actual)			
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*			FY2025 Primary Completion			
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*				FY2025 Primary Completion		
	NCT06547385/JP	Colorectal cancer*			FY2027 Primary Completion			
	NCT06538207/JP	Pancreatic cancer*			FY2024 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-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*			FY2025 Primary Completion			
	NCT06540261/JP	Colorectal cancer*			FY2024 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		

*** : 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 October 24, 2024

Code （Generic name）MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	NCT06579573/JP	Primary generalized tonic-clonic seizures			FY2026 Primary Completion			
	NCT04557085/JP	Partial-onset seizures			FY2024 Primary Completion			
Velexbru Tablet (ONO-4059：tirabrutinib) BTK inhibitor	jRCT2031220043/JP	Pemphigus			FY2026 Completion (jRCT)			
ONO-2910　Enhancement of Schwann cell differentiation	NCT06538272/JP	Chemotherapy-Induced Peripheral Neuropathy		FY2024 Primary Completion				
ONO-2808　S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy		FY2025 Primary completion				
ONO-4685　PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease	FY2024 Completion (jRCT)					
	NCT05332704/EU			FY2024 Primary Completion（Actual）				
ONO-2020　Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease	FY2023 Primary completion (Actual)					
ONO-1110　Endocannabinoid regulation	jRCT2071220100/JP	Pain	FY2024 Completion (jRCT)					
ONO-4915　PD-1 x CD19 bispecific antibody	jRCT2071240056/JP	Autoimmune disease	FY2026 Completion (jRCT)					

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

Development pipeline - Deciphera

As of October 24, 2024

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

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

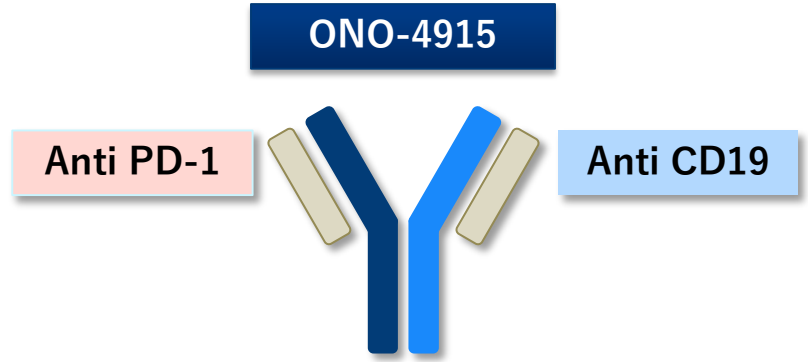
Estimated study completion date shown in jRCT or ClinicaiTrials.gov. Dashed lines indicate studies on healthy adults.

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

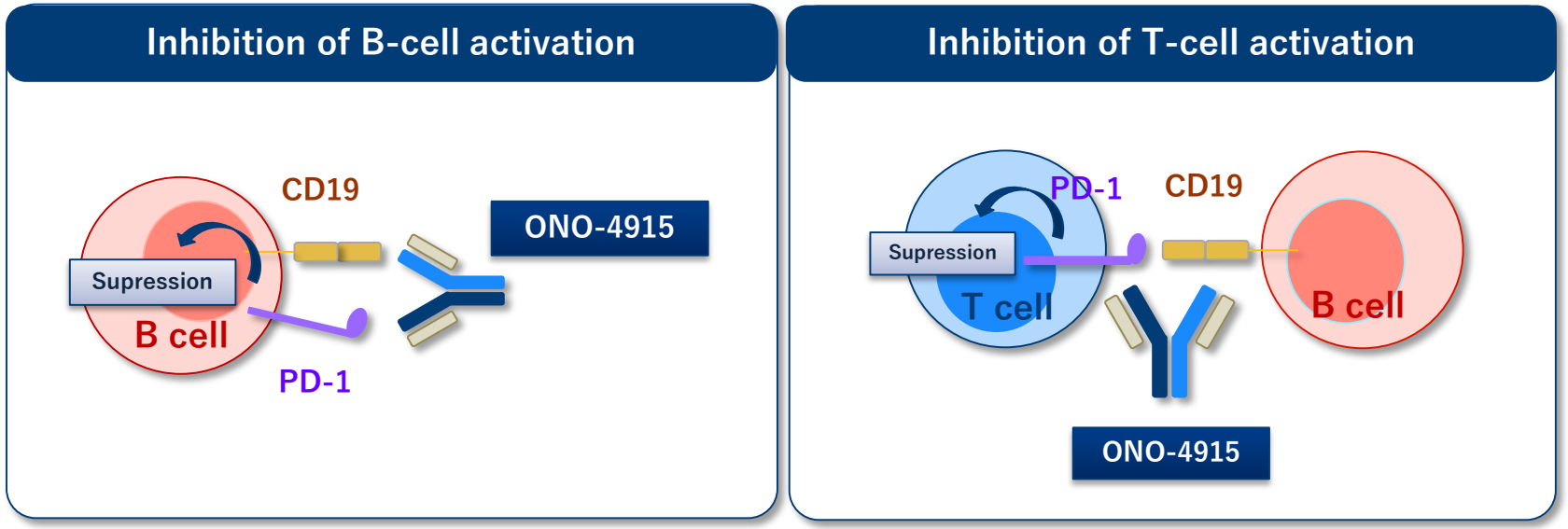
ONO-4915

Initiated Phase I study in Japan for the treatment of autoimmune disease

- Bispecific antibodies targeting PD-1 and CD19
- By binding to PD-1 and CD19 on B cells, ONO-4915 suppresses the activation of B cells involved in autoimmunity through PD-1 signaling
- By binding to PD-1 on T cells and CD19 on B cells, ONO-4915 suppresses the activation of T cells involved in autoimmunity through PD-1 signaling.



Created through drug discovery partnership with Merus (Netherlands)
Biclonics®* drug discovery platform



Biclonics®*：Bispecific antibody that binds simultaneously to two different antigens

Key milestones in FY2024 Q2 (FY ending March 2025)

As of October 24, 2024

(Develpoment pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Urothelial cancer (1L with Chemo) /CheckMate-901	Approved (Oct.2024) in TW
		NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T	Approved (Oct.2024) in US
		Hepatocellular carcinoma (1st with Ipi) /CheckMate-9DW	Filed in US, EU (Aug.2024) in JP (Sep.2024)
		MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Filed in JP (Sep.2024)
	Vimseltinib (DCC-3014)	TGCT	Filing accepted in EU (Jul.2024) in US (Aug.2024)
P2	OPDIVO	Rhabdoid tumor	Started in JP (Sep.2024)
	ONO-2910	Diabetic polyneuropathy	Discontinued (Sep.2024)
P1	ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	Started in JP (Oct.2024)
	ONO-4915	Autoimmune disease	Started in JP (Sep.2024)

Key milestones in FY2024 Q2 (FY ending March 2025)

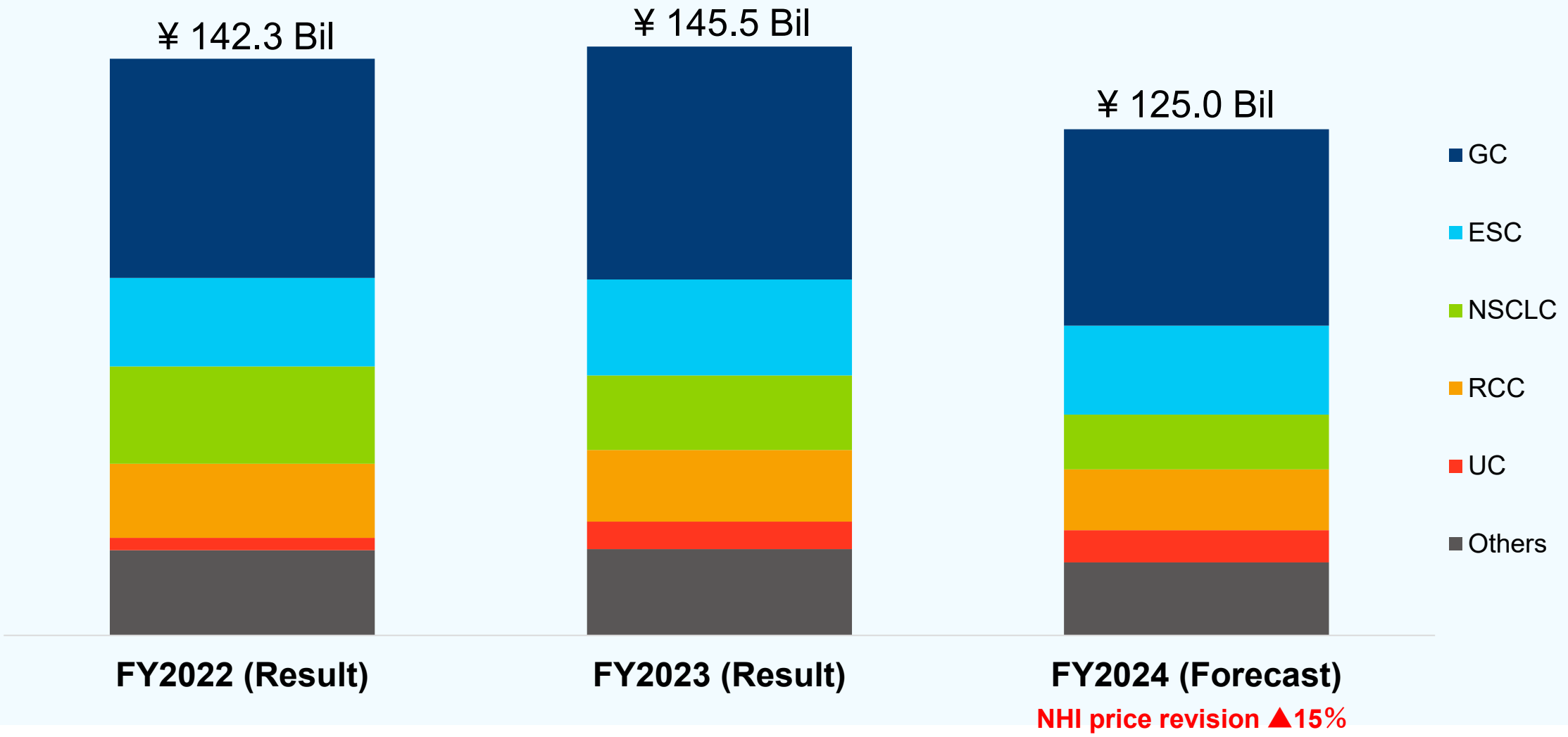
As of October 24, 2024

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

Title	Progress
Ono Enters into a New Option and Research Collaboration Agreement with Monash University to Discover and Create New Anti-GPCR Antibodies in the Autoimmune and Inflammatory Diseases	Started (Aug.2024)
Ono Enters into License Agreement for LCB97, an Antibody-Drug Conjugate, and Research Collaboration and License Agreement to generate novel ADC candidates by leveraging ConjuAll™ ADC platform with LigaChem Biosciences	Started (Oct.2024)
Ono Enters into a Drug Discovery Collaboration and Option Agreement with Shattuck Labs to Generate Bifunctional Fusion Proteins	Discontinued
Ono Enters into Collaboration Agreement with Domain Therapeutics and Université de Montréal for GPCR-Targeted Drug Discovery	
Ono and Equillium Announce Exclusive Option and Asset Purchase Agreement for the Development and Commercialization of Itolizumab	Not exercising option

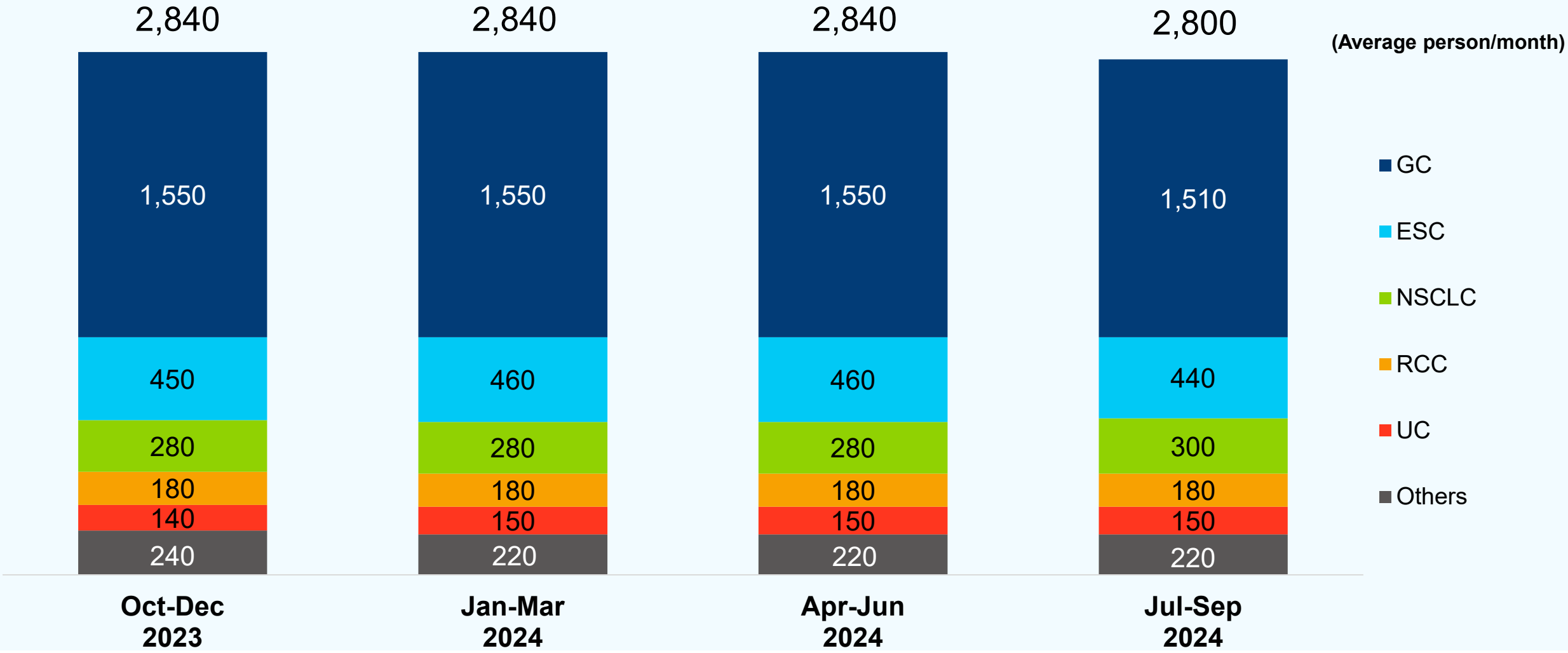
Trend of OPDIVO

Sales Trend of OPDIVO by Each Cancer



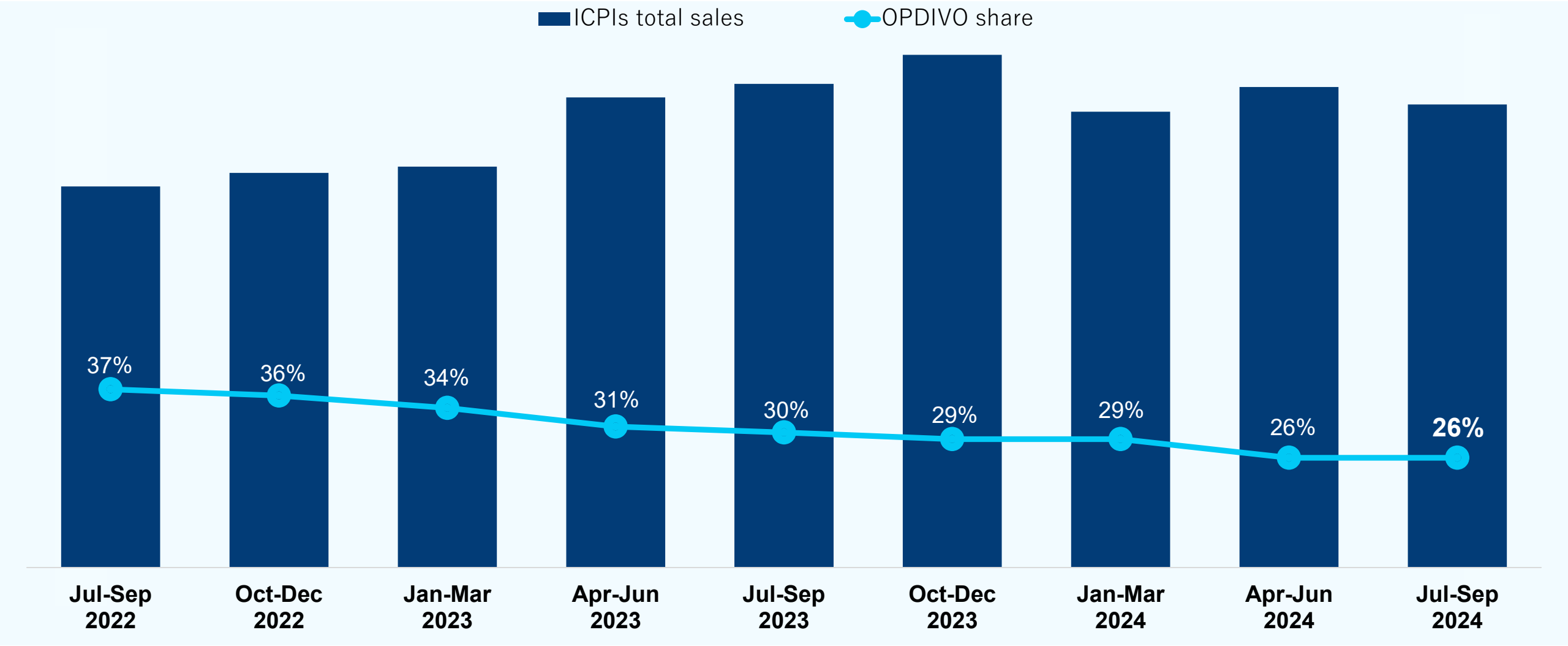
Source: Estimation from external and internal data

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



Source: Estimation from external and internal data

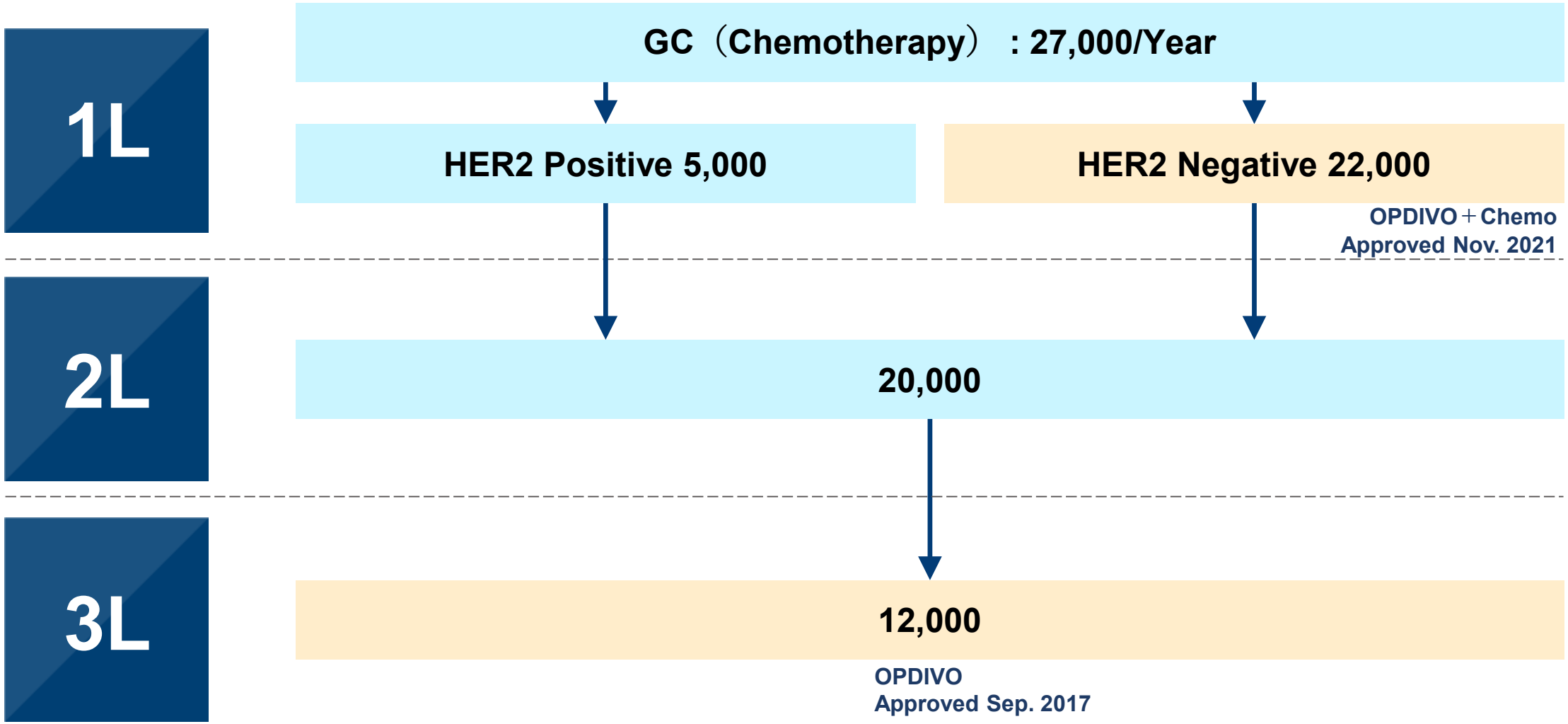
Trend of total sales of ICPIs and OPDIVO share



Source: External data

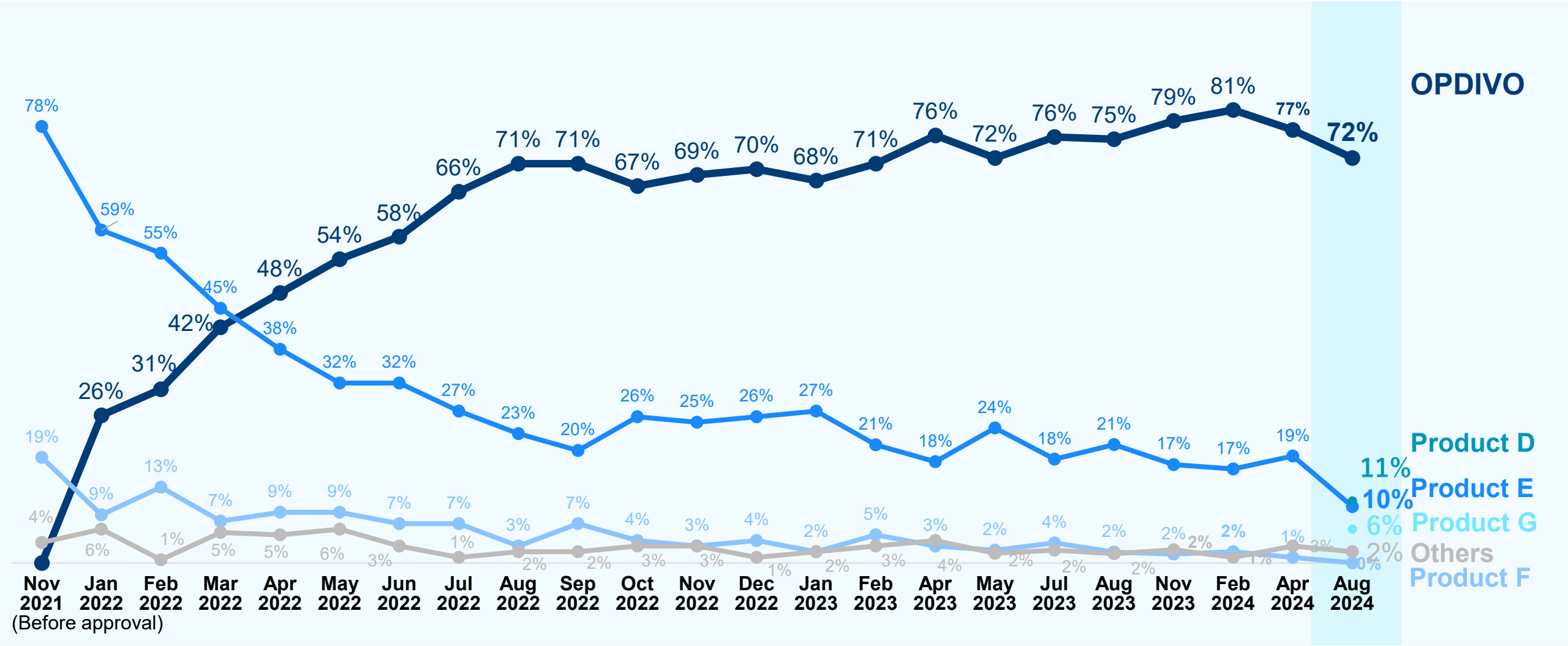
Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC



Estimation based on internal survey (2020)

Prescription Ratio in Patients Newly Treated※ for 1L GC

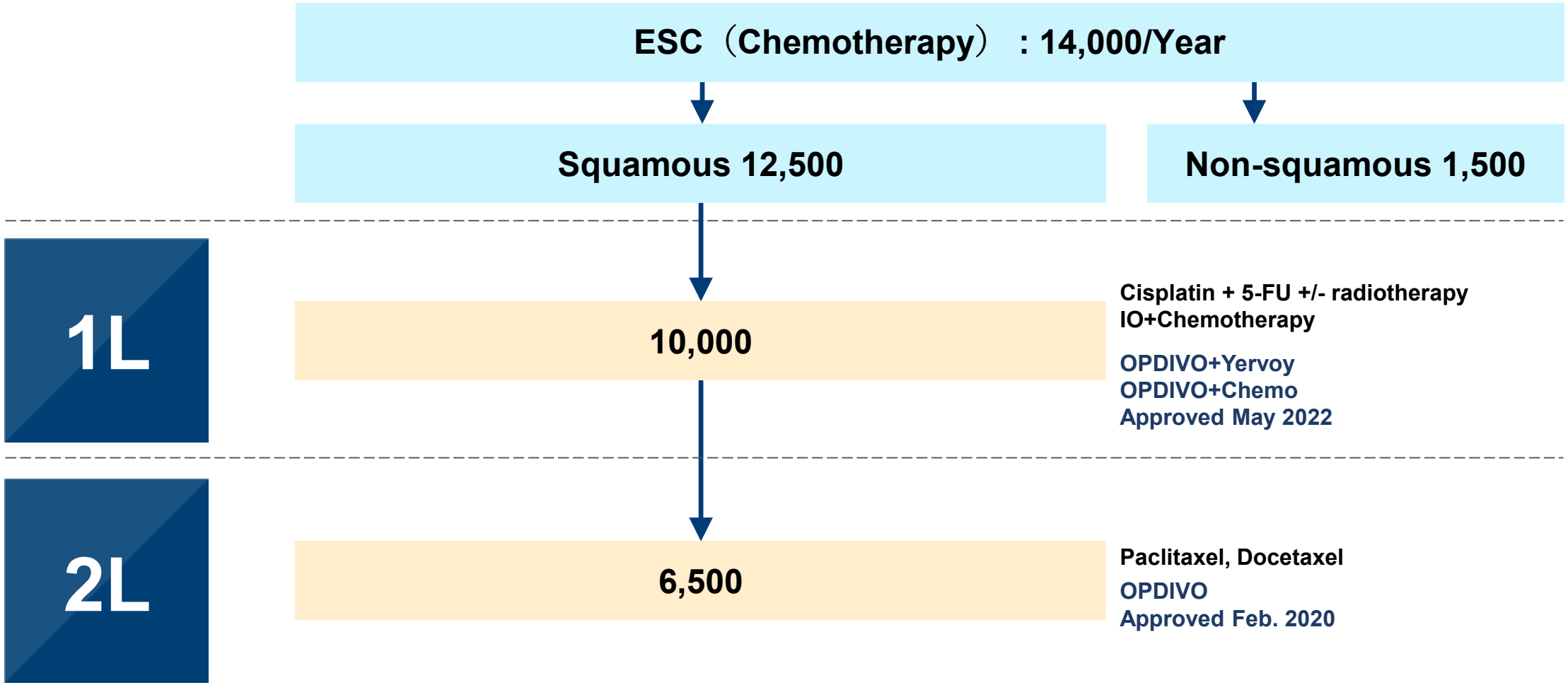


※Patients starting 1L treatment within the last 3 month

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

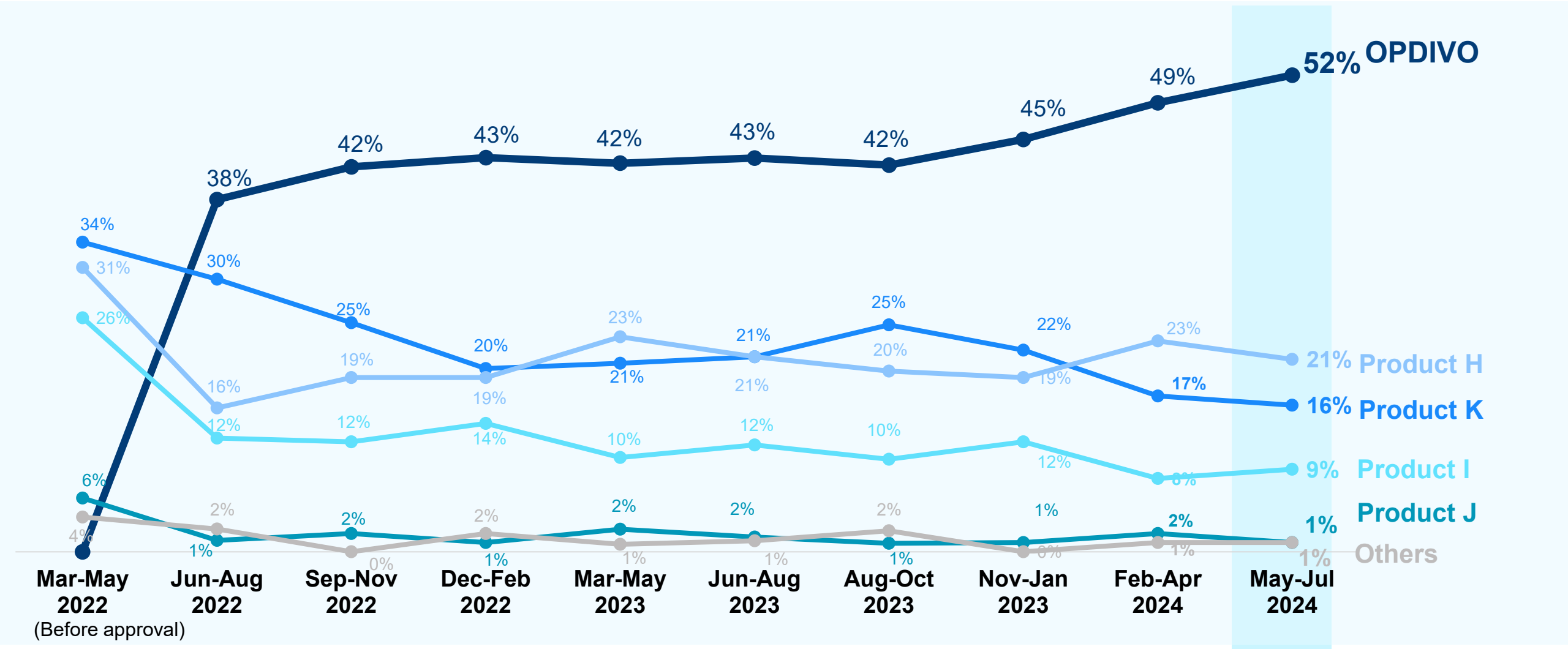
Number of ESC* Patients per year in Japan

* : Unresectable Advanced or Recurrent ESC



Estimation based on internal survey (2022)

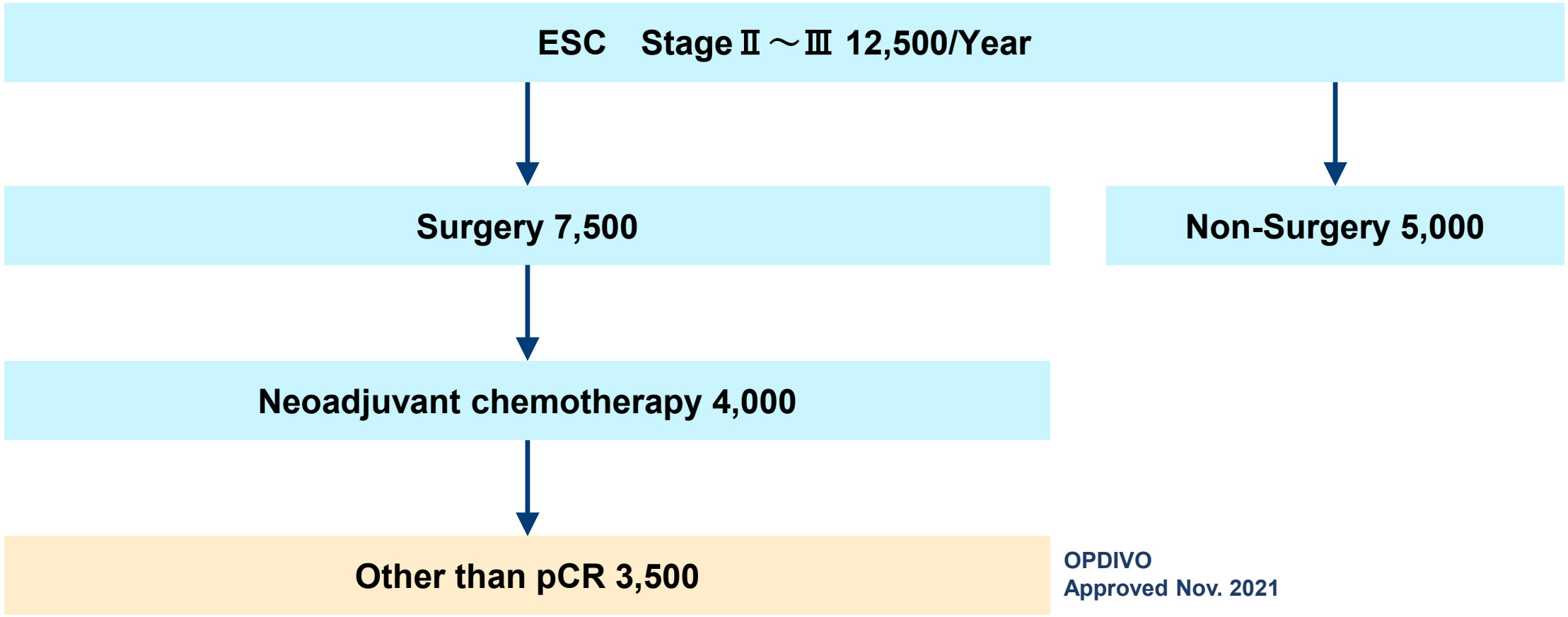
Prescription Ratio in Patients Newly Treated※ for 1L ESC(Squamous Cell Carcinoma)



※Patients starting treatment within the last 3 month

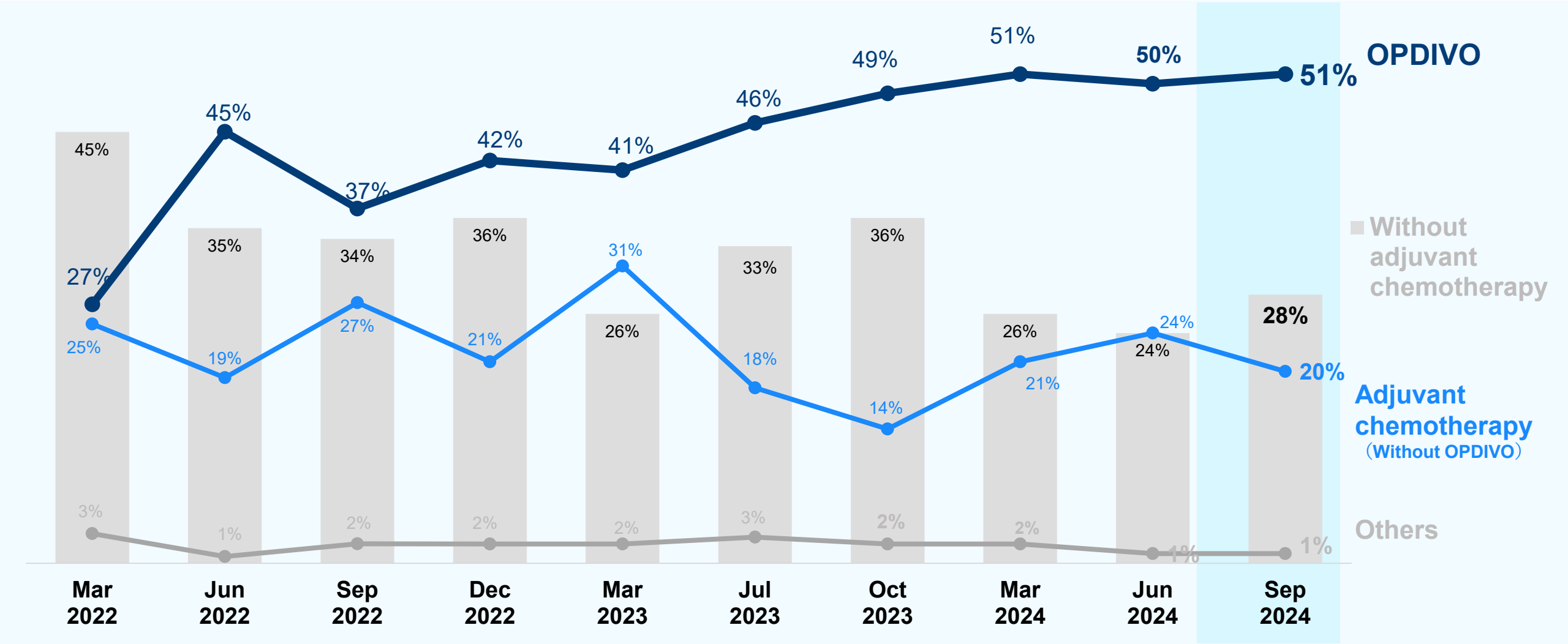
Source: External data（May 2022~Jul 2024: n=150~155）

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)

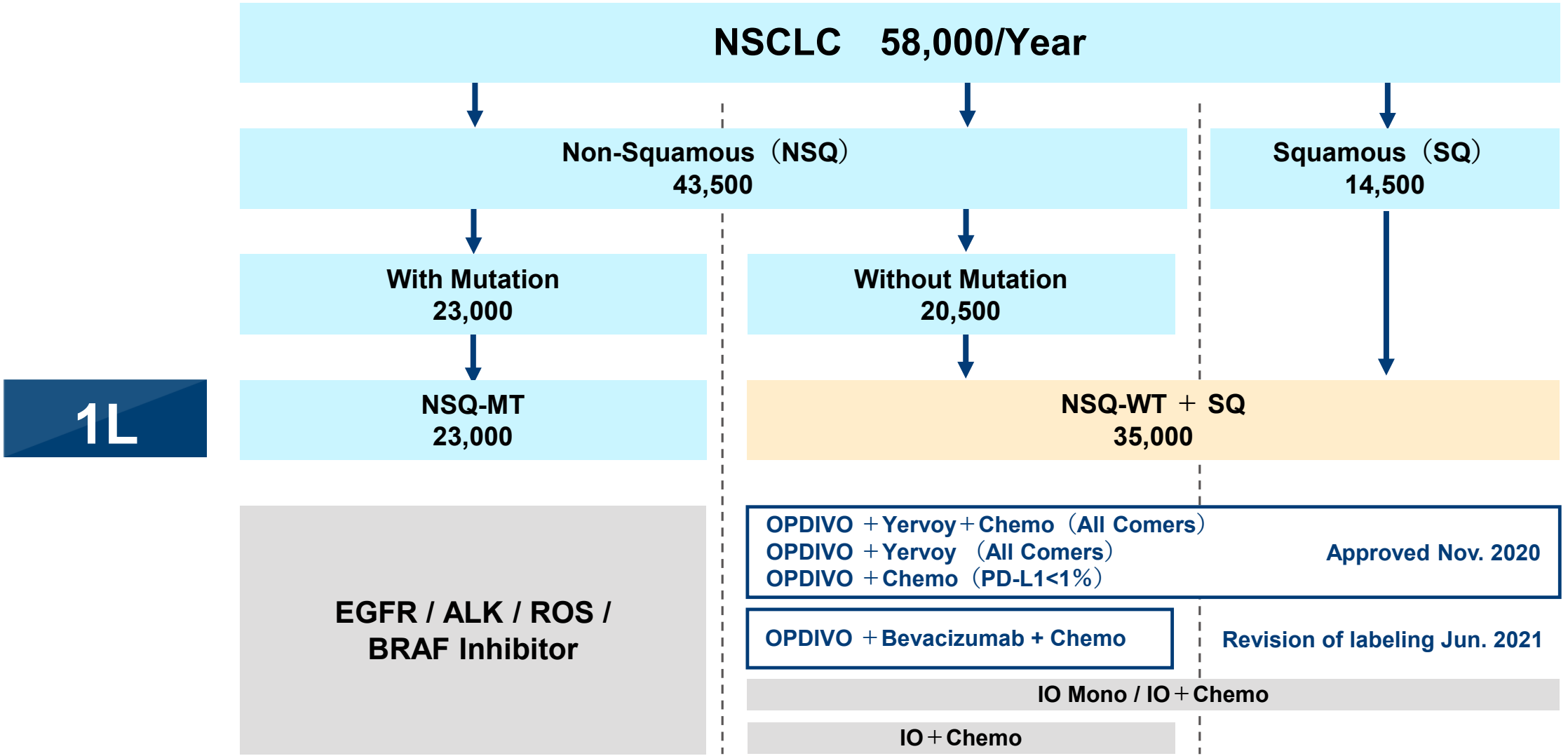


※Patients starting treatment within the last 3 months

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

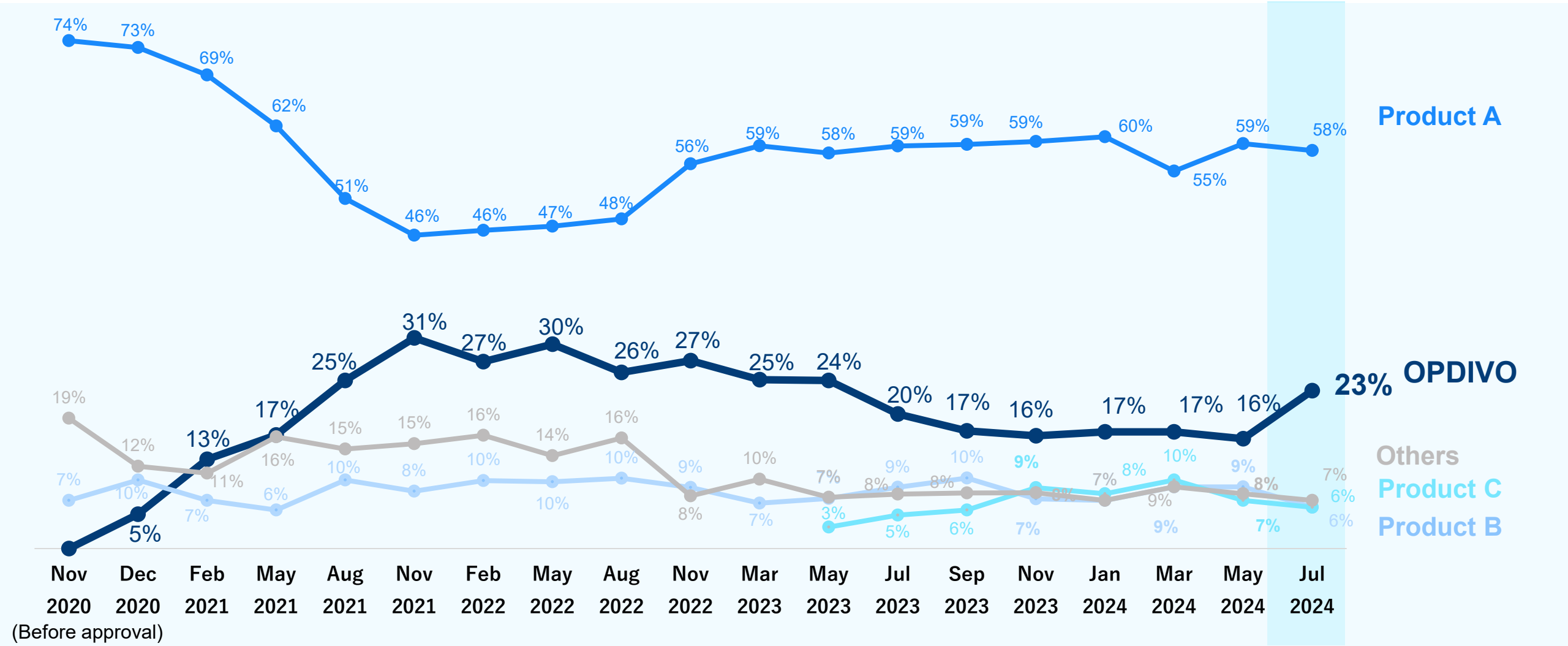
Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC



Estimation based on internal survey (2021)

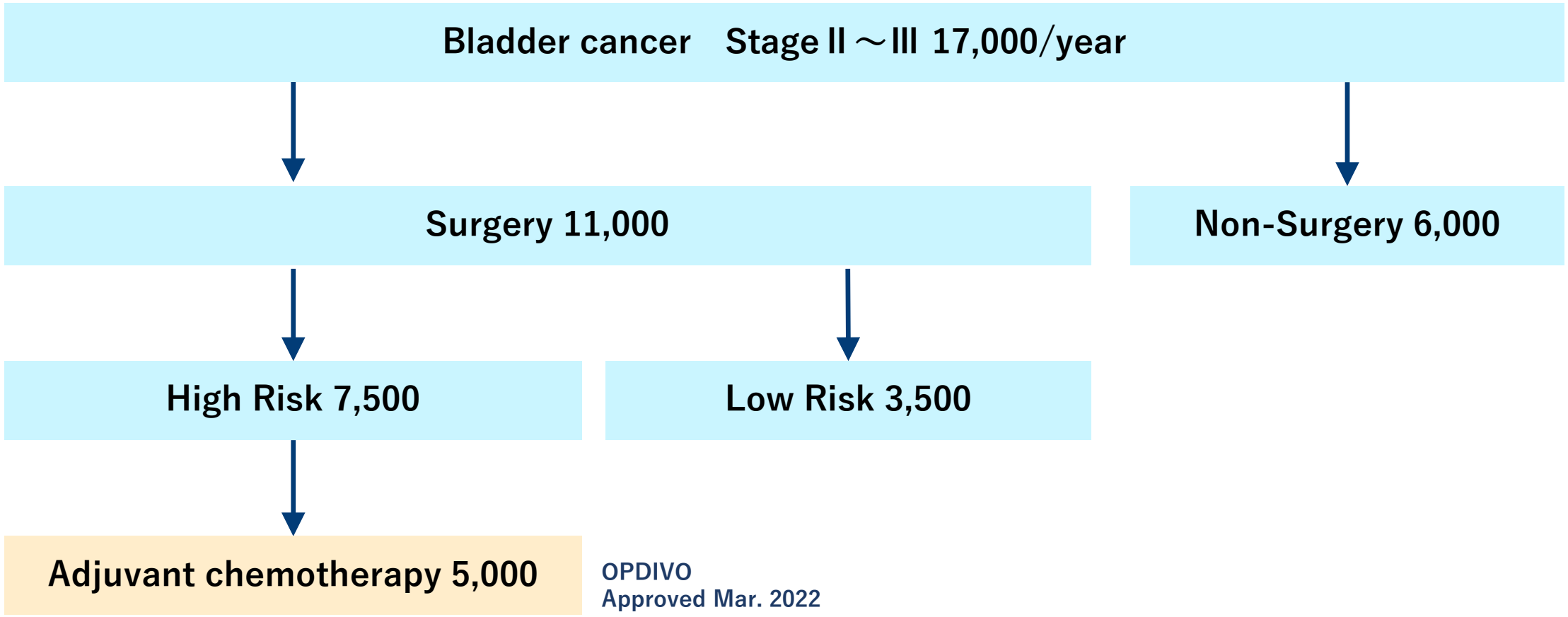
Prescription Ratio in Patients Newly Treated※ for 1L NSCLC



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

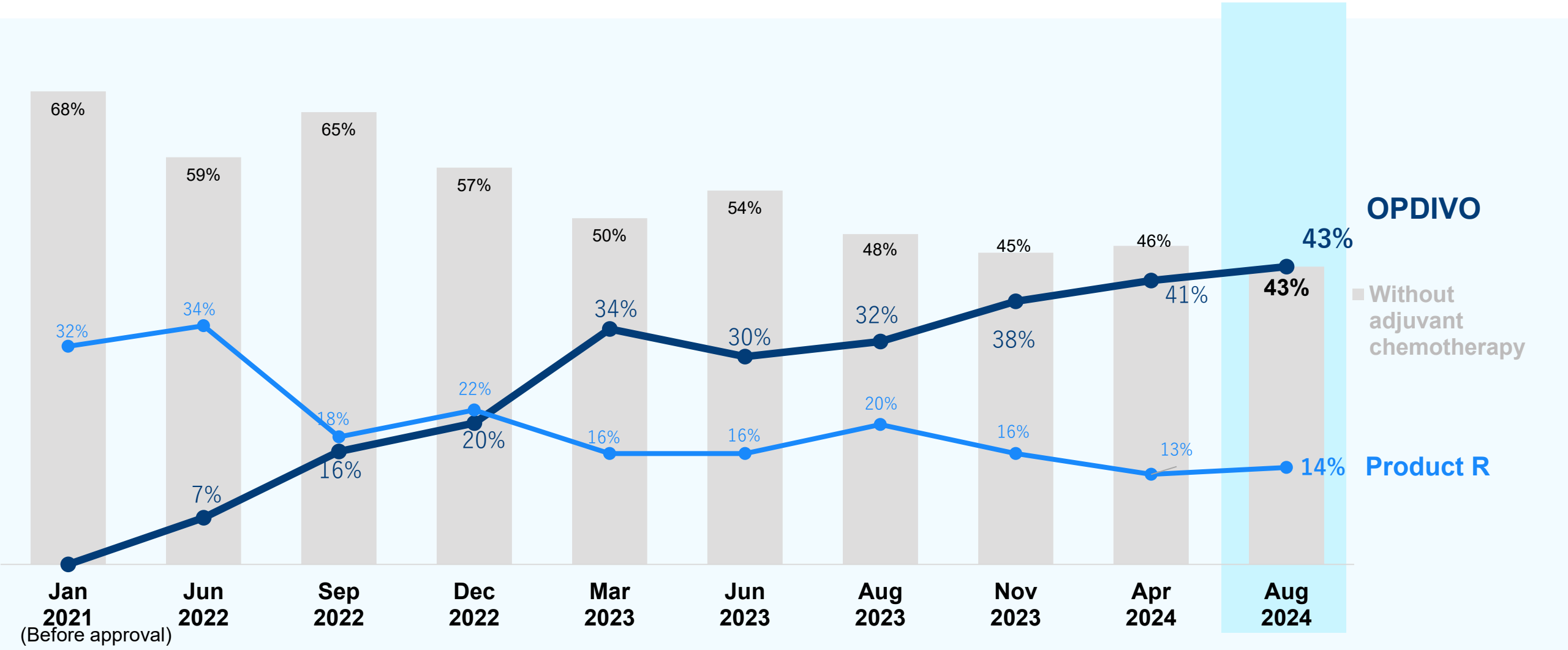
Source: External data（Nov 2020~Sep 2024: n=167~245）

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)

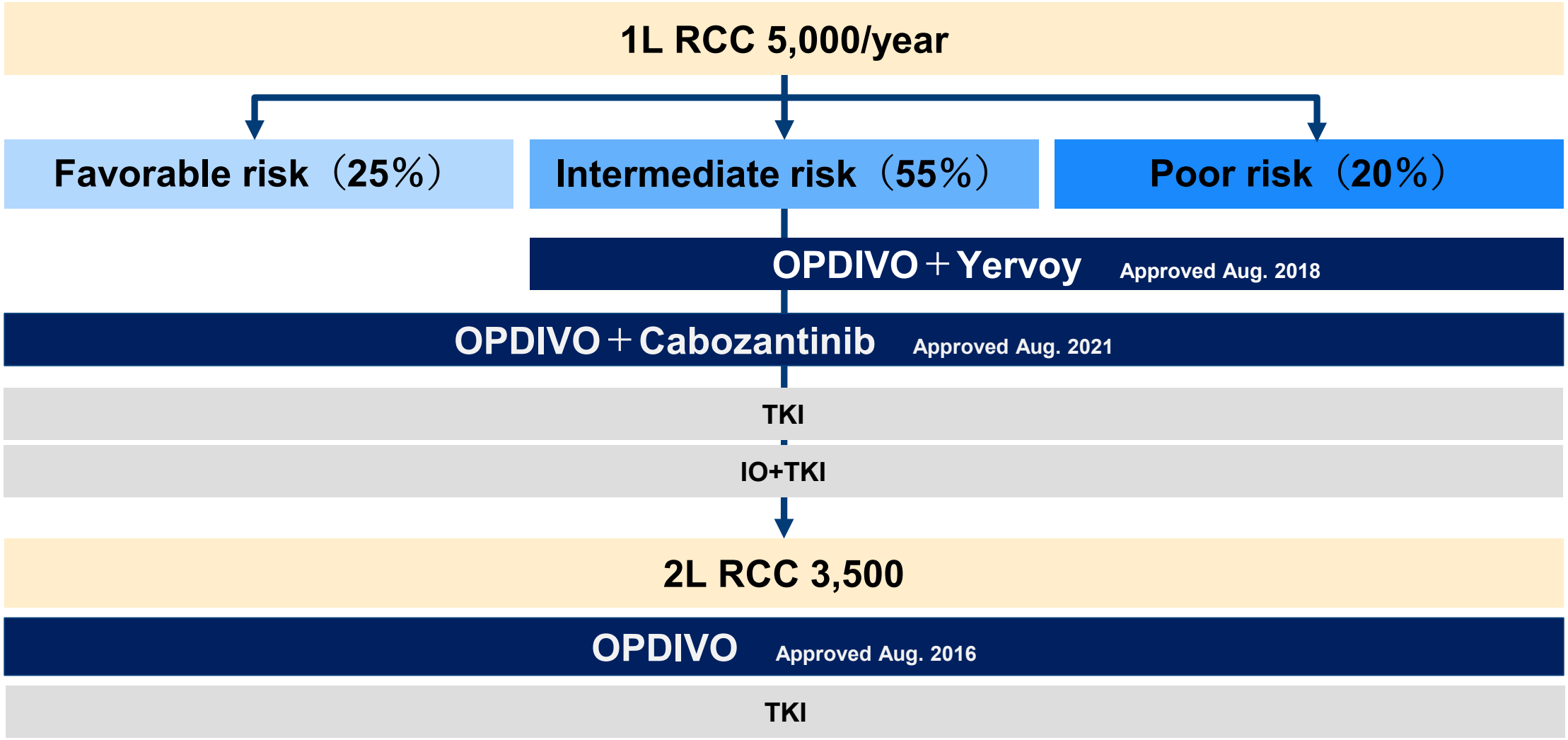


※Patients starting treatment within the last 3 months

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

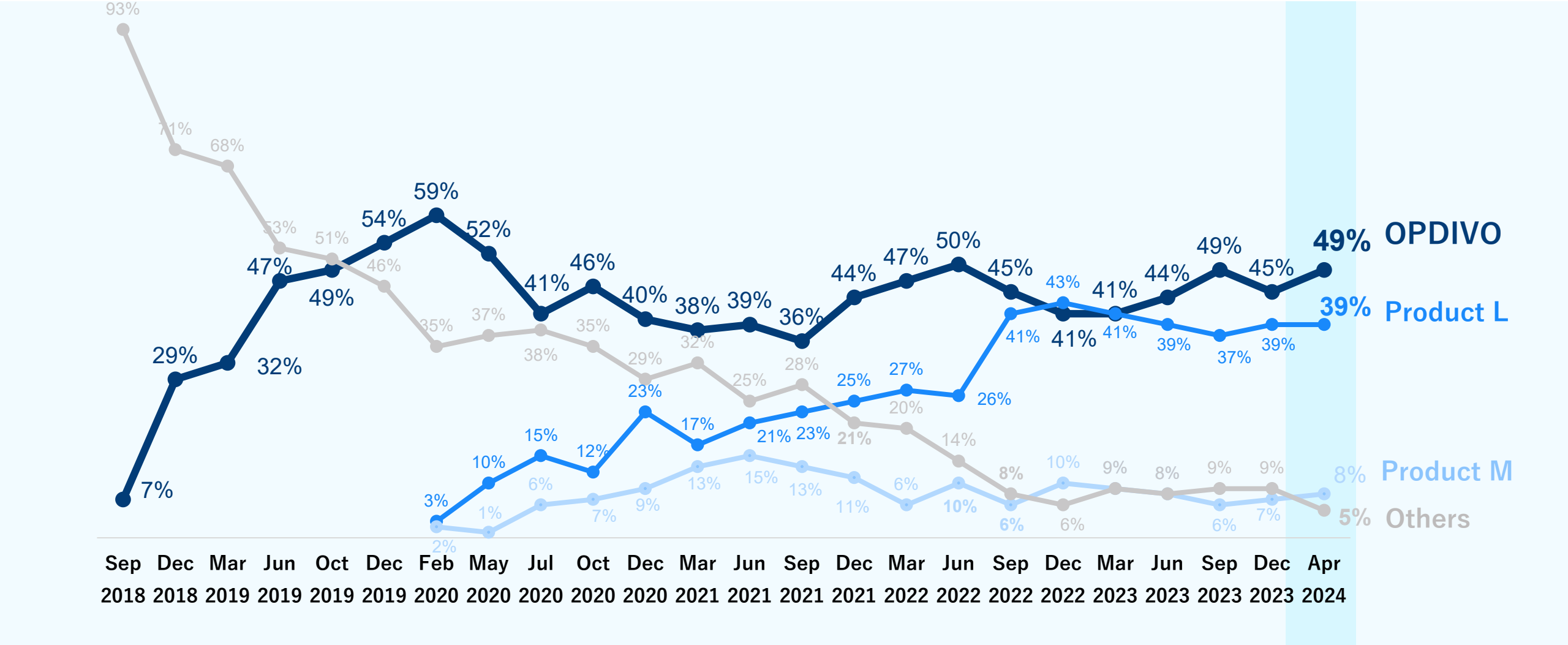
Number of RCC* Patients per year in Japan

* : 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~Apr 2024: n=46~150）

ONO PHARMA

Dedicated to the Fight against Disease and Pain