

2023年度 決算説明会

FY2023 Financial Results Meeting

May 10, 2024



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.

Agenda

2024年3月期決算概要 / 政策保有株式の縮減について (9:30-9:45)

Material for Financial Announcement FY 2023 / Status of Cross-shareholdings

代表取締役会長CEO

Representative Director, Chairman of the Board and CEO

相良 暁

Gyo Sagara

開発品の進捗状況 (9:45-10:00)

Development Pipeline Progress Status

執行役員 開発本部長

Corporate Officer / Executive Director, Clinical Development

岡本 達也

Tatsuya Okamoto

オペジーボの動向 (10:00-10:15)

Trend of OPDIVO

常務執行役員 営業本部長

Corporate Executive Officer /
Executive Director, Sales and Marketing

高萩 聡

Satoshi Takahagi

質疑応答

Q&A Session (10:15-10:30)

Material for Financial Announcement FY 2023

FY2023 : Financial Overview

Sales have increased for 9 consecutive fiscal years, and operating profit and net income have increased for 6 consecutive years.

¥ Billion	FY 2022	FY 2023	YoY		FY2023 (Forecast)	Progress (%)
			Change	Change (%)		
Revenue	447.2	502.7	55.5	12.4%	500.0	100.5%
Cost of sales	110.1	127.1	17.1	15.5%	122.0	104.2%
R&D expenses	95.3	112.2	16.8	17.7%	109.0	102.9%
Ratio of R&D to revenue	21.3%	22.3%			21.8%	
SG&A expenses	89.5	100.3	10.8	12.1%	98.0	102.3%
Other income	0.7	1.2	0.4	60.3%	1.0	117.6%
Other expenses	11.1	4.3	(6.7)	(60.8%)	5.0	86.9%
Operating profit	142.0	159.9	18.0	12.7%	167.0	95.8%
Net financial income	1.6	3.8	2.2	142.1%	2.0	189.9%
Profit before tax	143.5	163.7	20.2	14.1%	169.0	96.9%
Profit for the year (attributable to owners of the Company)	112.7	128.0	15.3	13.5%	126.0	101.6%

- Regarding sales revenue, sales of Opdivo increased by ¥3.1 billion to ¥145.5 billion and sales of Forxiga increased by ¥19.6 billion to ¥76.1 billion. Royalties from Bristol-Myers Squibb Company on Opdivo increased by ¥8.3 billion year on year to ¥97.9 billion, and royalties from Merck & Co., Inc. on Keytruda® increased by ¥7.9 billion year on year to ¥53.0 billion.
- Regarding expenses, combined impairment losses of ¥14.8 billion were recorded for marketing rights and intangible assets associated with compounds under development. Other expenses decreased by ¥6.7 billion year on year, mainly due to the absence of a lump-sum payment associated with the settlement of litigation on patents with Dana-Farber Cancer Institute, Inc.

FY2023 : Sales Revenue



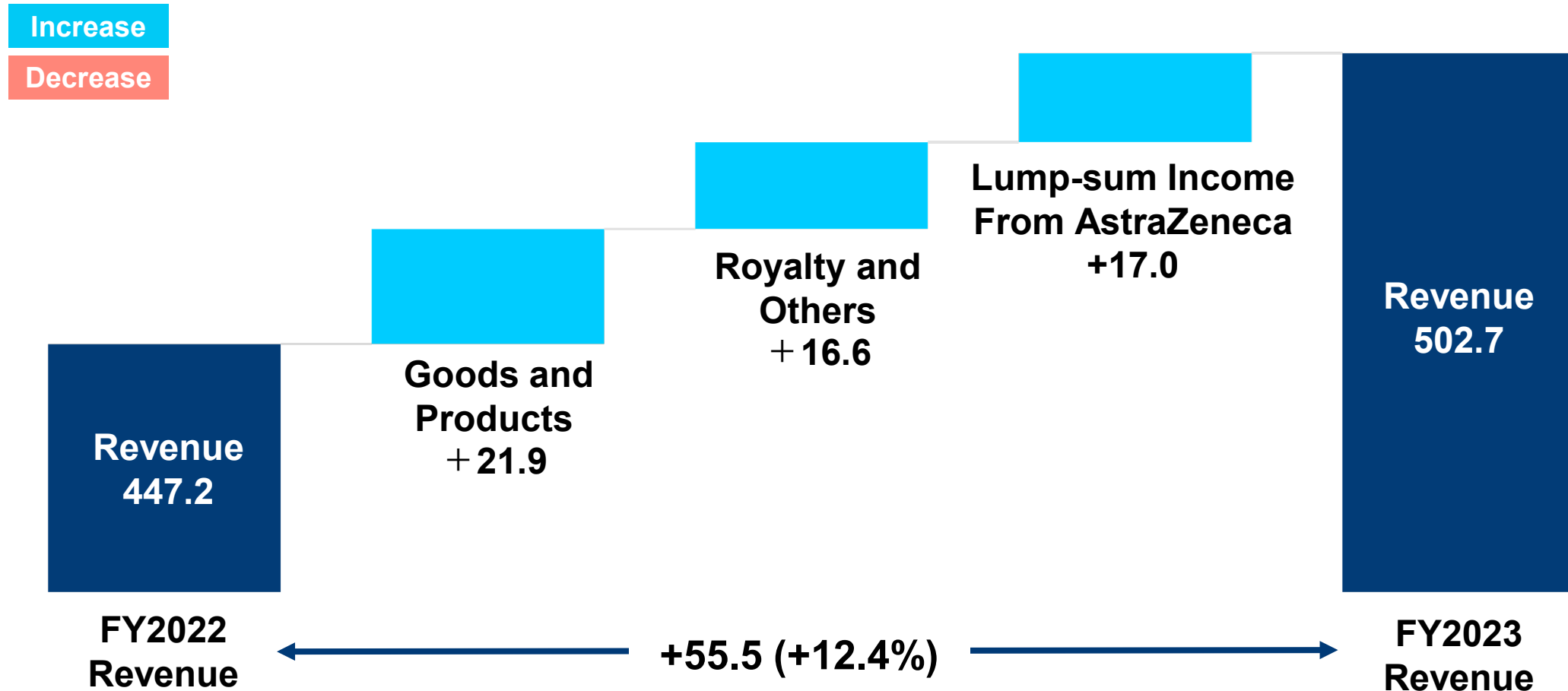
¥ Billion	FY2022	FY2023	YoY		FY2023 Forecast	Progress (%)
			Change	Change (%)		
Revenue	447.2	502.7	55.5	12.4%	500.0	100.5%
Goods and products	295.0	317.0	21.9	7.4%	315.0	100.6%
Royalty and others	152.1	185.7	33.6	22.1%	185.0	100.4%
OPDIVO	89.6	97.9	8.3	9.3%		
KEYTRUDA®	45.2	53.0	7.9	17.4%		

Sales Revenue of Main Products (Gross Sales Basis)						
Opdivo Intravenous Infusion	142.3	145.5	3.1	2.2%	150.0	97.0%
Forxiga Tablets	56.5	76.1	19.6	34.7%	75.0	101.5%
Orencia for Subcutaneous Injection	24.8	25.8	1.1	4.3%	25.5	101.3%
Glactiv Tablets	22.5	21.2	(1.3)	(5.9%)	21.0	100.9%
Velexbru Tablets	8.5	10.2	1.7	19.7%	9.5	107.5%
Kyprolis for Intravenous Infusion	8.7	9.1	0.4	5.1%	8.5	107.6%
Parsabiv Intravenous Injection	8.4	8.2	(0.2)	(2.1%)	8.0	102.9%
Ongentys Tablets	5.0	6.3	1.3	26.8%	6.5	97.1%

FY2023 : Sales Revenue (Breakdown)

Revenue reached a record high due to a significant increase in sales of Forxiga, higher royalty revenue from Bristol-Myers Squibb Company, Merck & Co., Inc., and others, as well as a ¥17.0 billion upfront payment from the settlement of a patent-related lawsuit with AstraZeneca UK Limited.

(¥ Billion)



FY2024 : Financial Forecasts

¥ Billion	FY2023 (Actual)	FY2024 (Forecast)	Change	Change (%)
Revenue	502.7	450.0	(52.7)	(10.5%)
Cost of sales	127.1	113.0	(14.1)	(11.1%)
R&D expenses	112.2	112.0	(0.2)	(0.2%)
Ratio of R&D to revenue	22.3%	24.9%		
SG&A expenses	100.3	100.0	(0.3)	(0.3%)
Other income	1.2	0.5	(0.7)	(57.5%)
Other expenses	4.3	3.5	(0.8)	(19.4%)
Operating profit	159.9	122.0	(37.9)	(23.7%)
Net financial income	3.8	1.0	(2.8)	(73.7%)
Profit before tax	163.7	123.0	(40.7)	(24.9%)
Profit for the year (attributable to owners of the Company)	128.0	91.0	(37.0)	(28.9%)

- Regarding revenue, sales of Opdivo is expected to decrease by ¥20.5 billion year on year to ¥125.0 billion, sales of Forxiga is expected to increase by ¥6.9 billion to ¥83.0 billion, and the royalty rate received from Merck & Co., Inc. for Keytruda[®] is expected to decrease by approximately 60%.
- Cost of sales is expected to decrease by ¥14.1 billion year on year, partly due to the absence of the ¥11.1 billion impairment loss on marketing rights recorded in the fiscal year ended March 31, 2024.
- R&D expenses are expected to decrease by ¥0.2 billion year on year to ¥112.0 billion, and other SG&A expenses are expected to decrease by ¥0.3 billion year on year to ¥100.0 billion.
- The annual exchange rate assumed in this forecast is 1 USD = 145 yen. Foreign exchange sensitivity in case of a depreciation of 1 yen may increase revenue and operating profit by ¥0.6 billion and ¥ 0.2 billion, respectively.

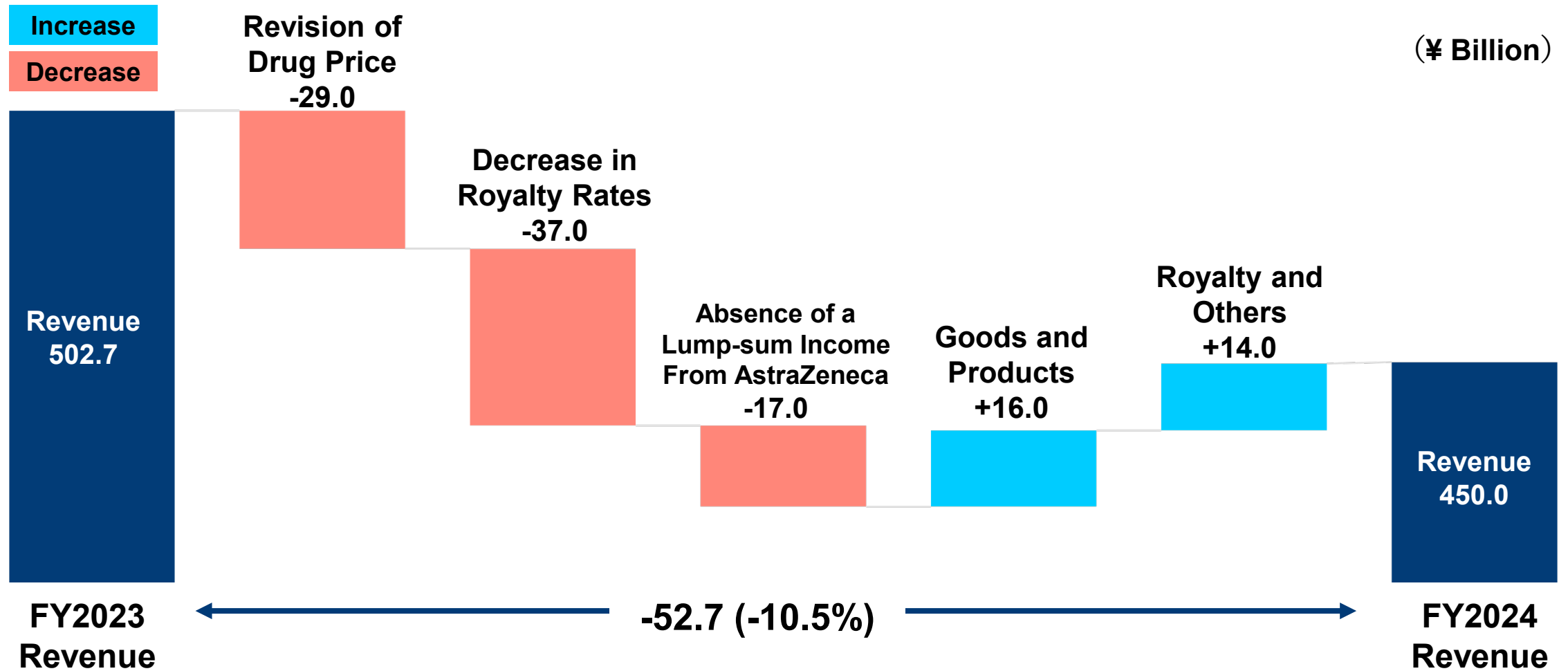
FY2024 : Sales Forecasts

¥ Billion	FY2023 (Actual)	FY2024 (Forecast)	Change	Change (%)
Revenue	502.7	450.0	(52.7)	(10.5%)
Goods and products	317.0	304.0	(13.0)	(4.1%)
Royalty and others	185.7	146.0	(39.7)	(21.4%)

Sales Revenue of Main Products (Gross Sales Basis)				
Opdivo Intravenous Infusion	145.5	125.0	(20.5)	(14.1%)
Forxiga Tablets	76.1	83.0	6.9	9.0%
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%

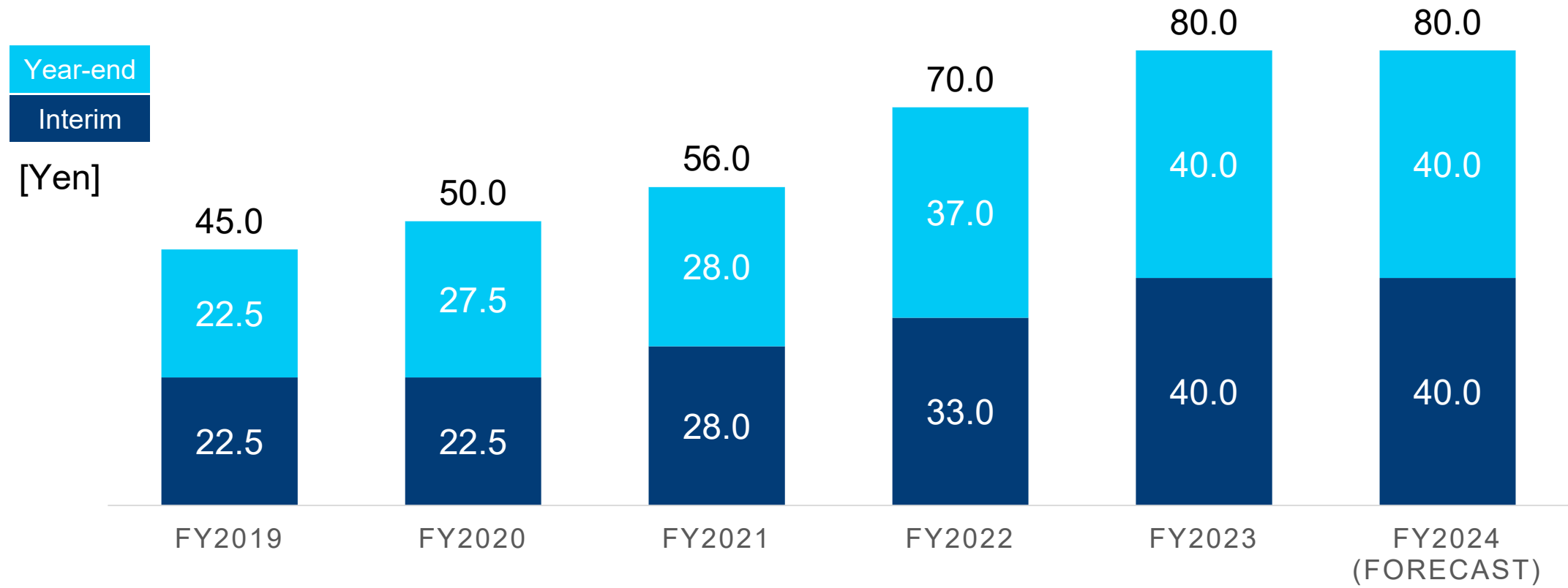
FY2024 : Sales Forecasts (Breakdown)

Revenue is expected to decrease by ¥52.7 billion year-on-year due to the drug price reduction of Opdivo (down 15%), reduction in royalty rate received from Merck & Co., Inc. and others, and the absence of a ¥17.0 billion upfront payment from the settlement of a patent-related lawsuit with AstraZeneca UK Limited.



Profit Distribution (Dividend)

Dividends are to be paid out in accordance with a progressive policy of maintaining or increasing the annual dividend each year, with a target payout ratio of 40%, taking into account the performance of each fiscal year and various indices.



Dividend payout ratio (consolidated)

38.0%

33.1%

34.5%

30.3%

30.0%

41.3%

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 March 2024	Reduction*	Reduction rate
Market price at the end of September 2021	¥ 141.8 bil	¥ 95.8 bil	¥ 46.0 bil	32.4%

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of March 2024	Reduction	Reduction rate
Balance sheet accounting amount	¥ 141.8 bil	¥ 101.5 bil	¥ 40.3 bil	28.4%

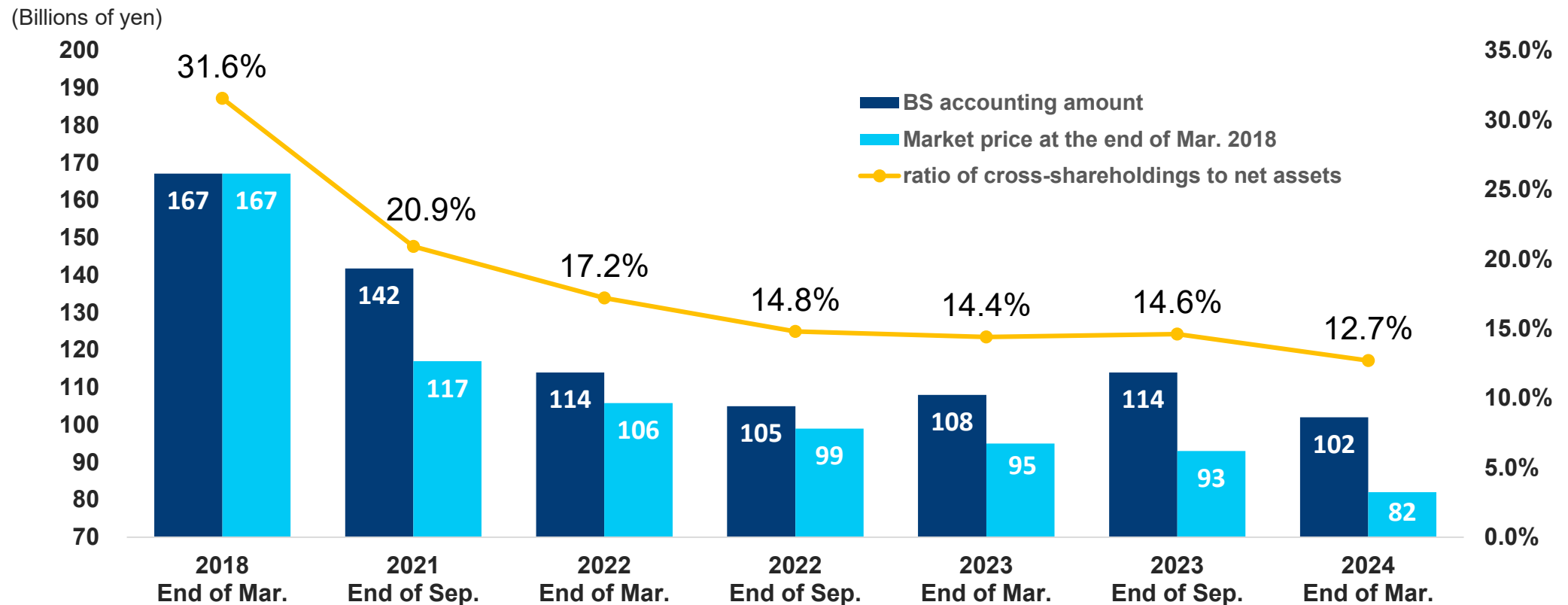
**※End of March 2024
Ratio of Cross-shareholdings to net assets : 12.7%**

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)

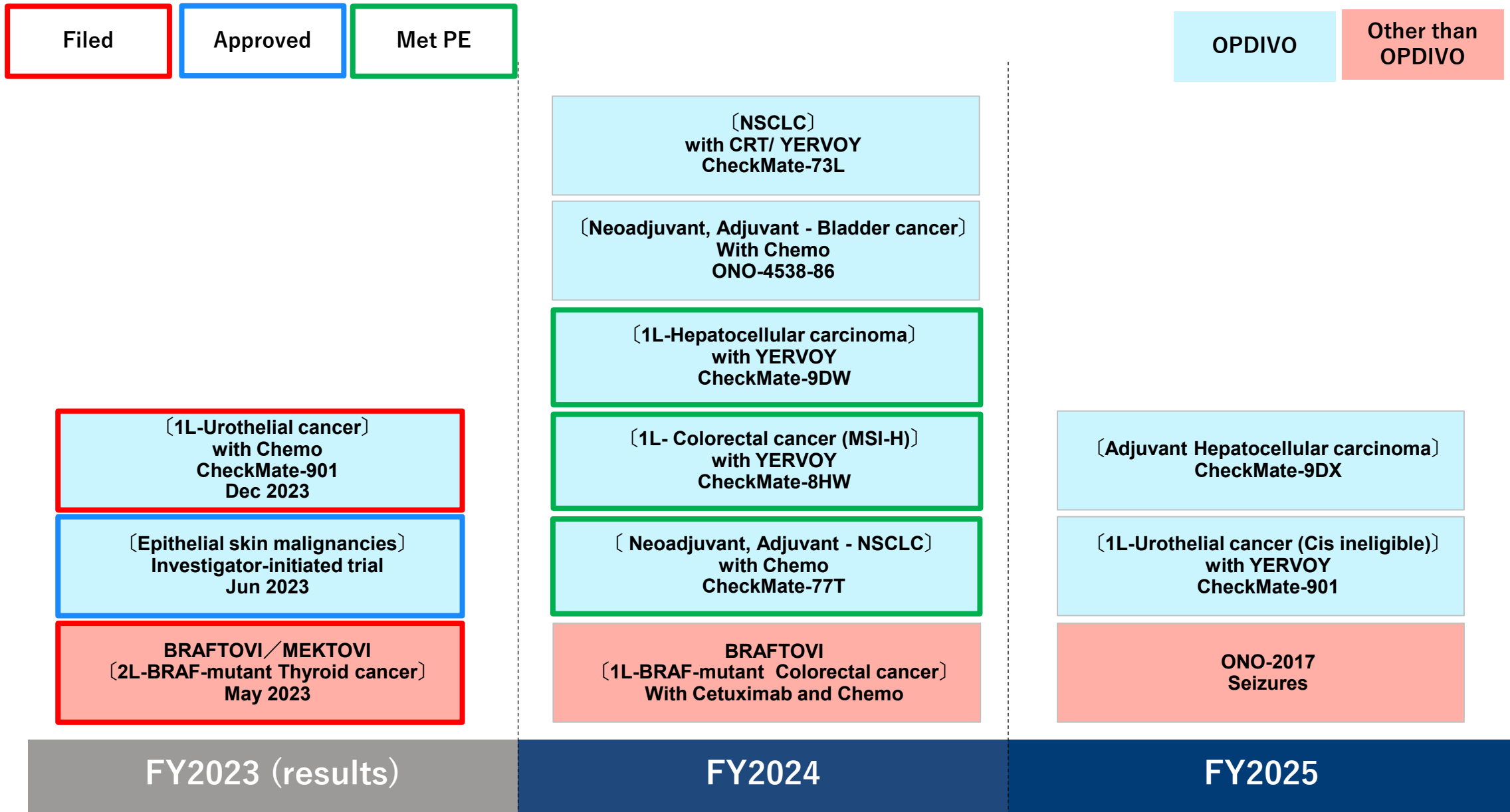
➤ Changes of reduction



Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of May 6, 2024



Development status of OPDIVO (1)



As of May 6, 2024

Target disease	Line of Therapy	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	Approved
	Chemoradiotherapy	with CRT, with CRT/Ipi	III	III	III	III	III
	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
	SOC refractory	Monotherapy	Approved	–	–	–	–
Malignant Mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

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

※Red: Update after May 2023

※Red: Update after 3Q FY2023

Development status of OPDIVO (2)



As of May 6, 2024

Target disease	Line of Therapy	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	III	—	—	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	III	III	III	III	III
	2nd	with Ipi	II	II	Approved	Approved	II

Development status of OPDIVO (3)

As of May 6, 2024

Target disease	Line of Therapy	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	III	III	Approved	Filed
		with Ipi	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
Cancer of unknown primary	—	Monotherapy	Approved	—	—	—	—
Epithelial skin malignancies	1st	Monotherapy	Approved	—	—	—	—
Dosage and Administration	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 (Combination with vorhyaluronidase alfa)	I	—	—	Filed	III

Development pipeline in Japan (Oncology)

As of May 6, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
Braftovi Capsules (encorafenib) BRAF inhibitor	jRCT2011230032/JP	BRAF-mutant thyroid cancer						
								FY2024 Approval
Mektovi Tablets (binimetinib) MEK inhibitor	jRCT2011230032/JP	BRAF-mutant thyroid cancer						
								FY2024 Approval
ONO-4059 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				
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				
	jRCT2031200215/JP	Colorectal cancer*	FY2027	Completion (jRCT)				
	jRCT2031200286/JP	Pancreatic cancer*	FY2024	Completion (jRCT)				
	jRCT2031200346/JP	Non-small cell lung cancer*	FY2024	Completion (jRCT)				
	jRCT2031210364/JP	Hormone receptor-positive, HER2-negative breast cancer	FY2025	Completion (jRCT)				
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	jRCT2031230429/JP	Pancreatic cancer*	FY2027	Completion (jRCT)				
	jRCT2051210045/JP	EGFR-mutated non-small cell lung cancer	FY2024	Completion (jRCT)				
ONO-7913 (magrolimab) Anti-CD47 antibody	jRCT2031210172/JP	Pancreatic cancer*	FY2025	Completion (jRCT)				
	jRCT2051210038/JP	Colorectal cancer*	FY2024	Completion (jRCT)				
ONO-7914 STING agonist	jRCT2031210530/JP	Solid tumor	FY2027	Completion (jRCT)				
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma	FY2025	Primary Completion				
	jRCT2011230051/JP		FY2029	Completion (jRCT)				
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	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 ClinicalTrials.gov

※Red: Update after May 2023

※Red: Update after 3Q FY2023

Development pipeline in Japan (Non-oncology)

As of May 6, 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	jRCT2031210624/JP	Primary generalized tonic-clonic seizures	→				FY2026 Completion (jRCT)		
	NCT04557085/JP	Partial-onset seizures	→				FY2024 Study completion		
Velexbru Tablets (ONO-4059 : tirabrutinib)	jRCT2031220043/JP	Pemphigus	→				FY2026 Completion (jRCT)		
ONO-2910 Enhancement of Schwann cell differentiation	jRCT2061210008/JP	Diabetic polyneuropathy	→				FY2024 Completion (jRCT)		
/US		- - - - - →						
	jRCT2031230173/JP	Chemotherapy-Induced Peripheral Neuropathy	→				FY2025 Completion (jRCT)		
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy	→				FY2025 Study completion		
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease	- - - - - →				FY2024 Completion (jRCT)		
	NCT05332704/EU		→				FY2025 Study completion		
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease	- - - - - →				2023.12 Study completion (Actual)		
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain	- - - - - →				FY2024 Completion (jRCT)		

FY2023 Pipeline Key Milestones

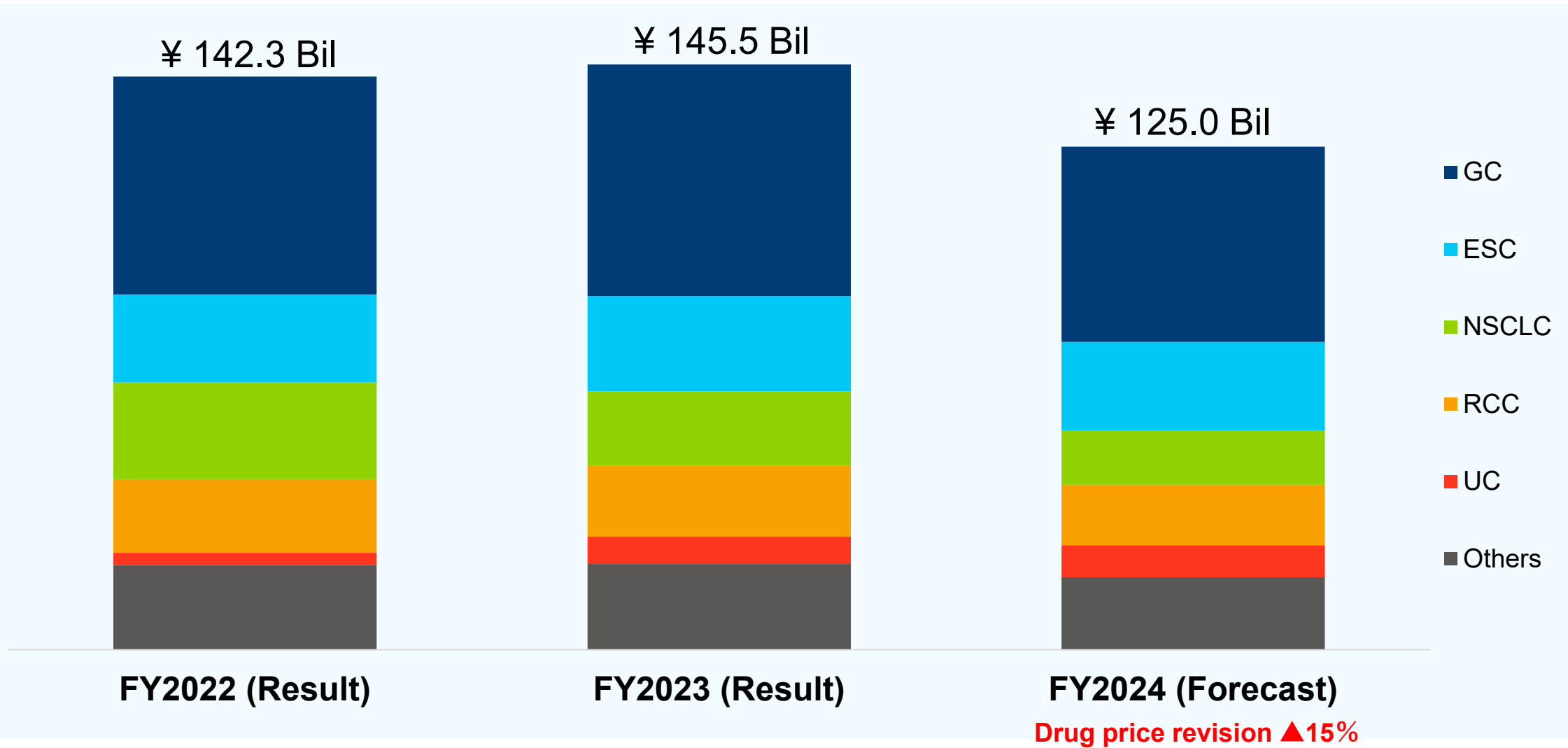


As of May 6, 2024

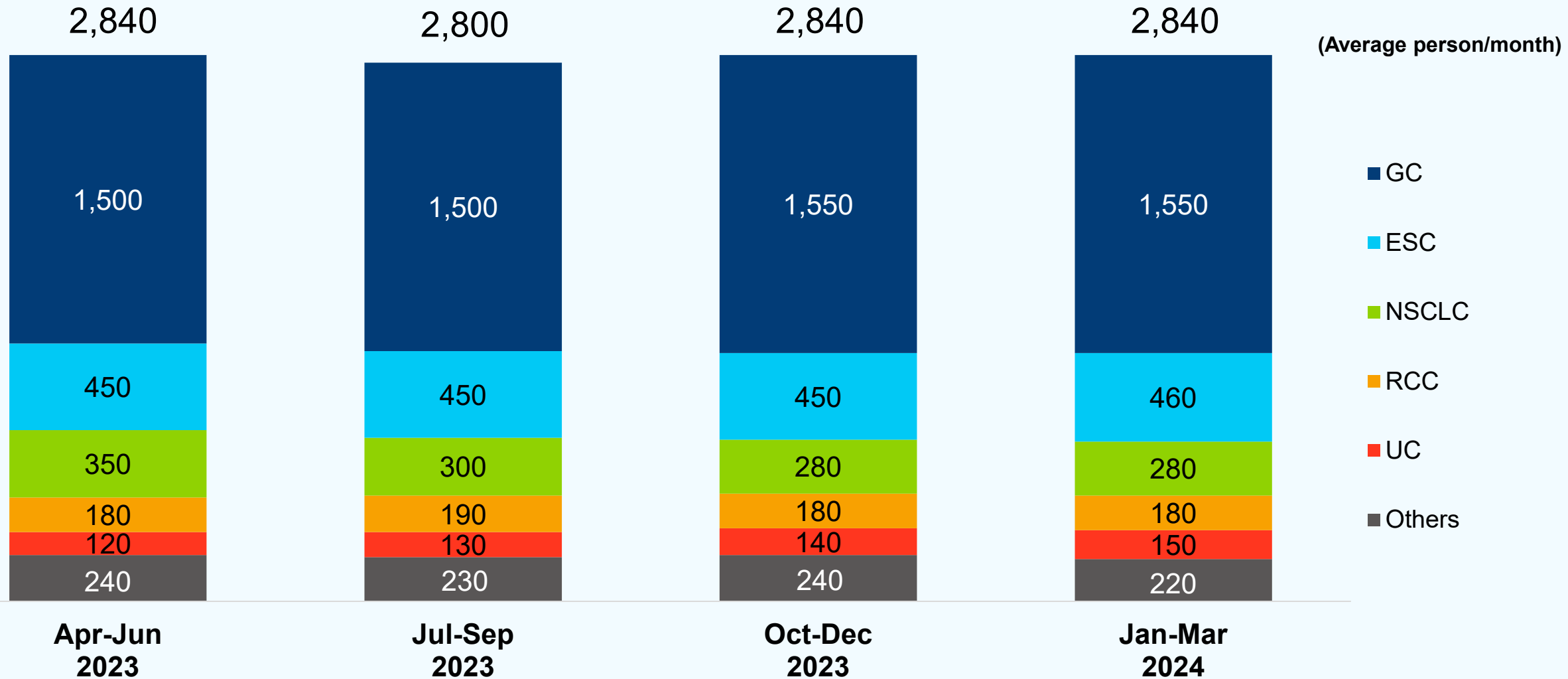
	Product/ Code (Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Malignant Mesothelioma(Excluding Pleura) /Investigator-initiated clinical trial Epithelial skin malignancies/NMSC-PD1 Urothelial cancer (1L with Chemo) /CheckMate-901 NSCLC (Neoadjuvant) /CheckMate-816 NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T MSI-H Colorectal cancer (with YERVOY) /CheckMate-8HW Solid tumor(ONO-4538HSC) /CheckMate-67T	Approved(Nov.2023) Approved(Feb.2024) Filed in EU(Oct.2023)/in JP(Dec.2023) Approved in US(Mar.2024) Approved in EU(Jul.2023) Filing accepted in US, EU(Feb.2024) Achieved PE(Dec.2023) Filed in US(May.2024)
	BRAFTOVI · MEKTOVI	Thyroid cancer	Filed(May.2023)
P3	OPDIVO	Bladder cancer	Discontinued in JP, KR, TW(Aug.2023)
	ONO-7913	TP53-mutant acute myeloid leukemia Acute myeloid leukemia	Discontinued(Oct.2023) Discontinued(Feb.2024)
	ONO-7121	Colorectal cancer	Discontinued(Dec.2023)
P2	ONO-4578 ONO-2910 ONO-2808	Gastric cancer (with Opdivo) Chemotherapy-Induced Peripheral Neuropathy Multiple System Atrophy	Started in JP(Aug.2023)/in KR, TW(Oct.2023) Started(Jun.2023) Started in JP(Feb.2024)/in US(Jul.2024)

Trend of OPDIVO

Sales Trend of OPDIVO by Each Cancer

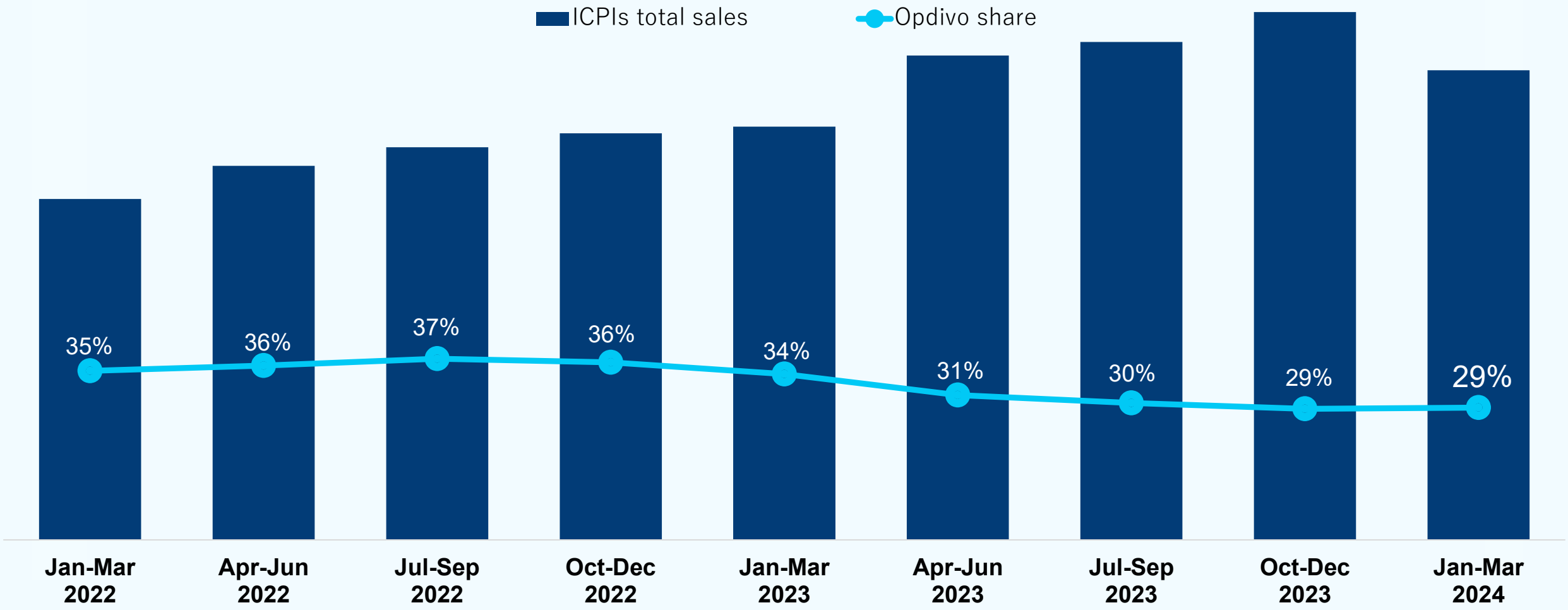


Number of Patients Newly Prescribed with OPDIVO by Each Cancer (Estimation)



Source: Estimation from external and internal data

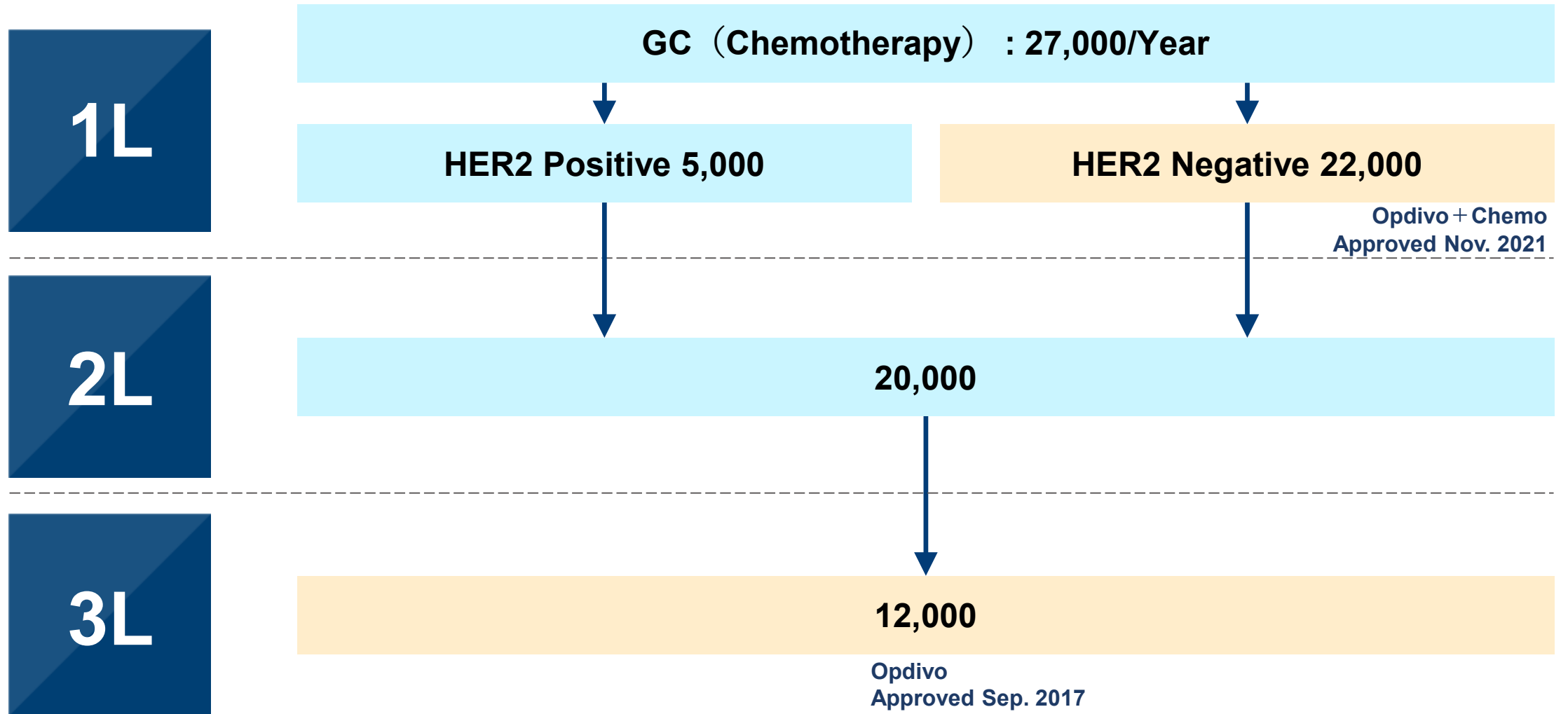
Trend of total sales of ICPIs and OPDIVO share



Source: External data

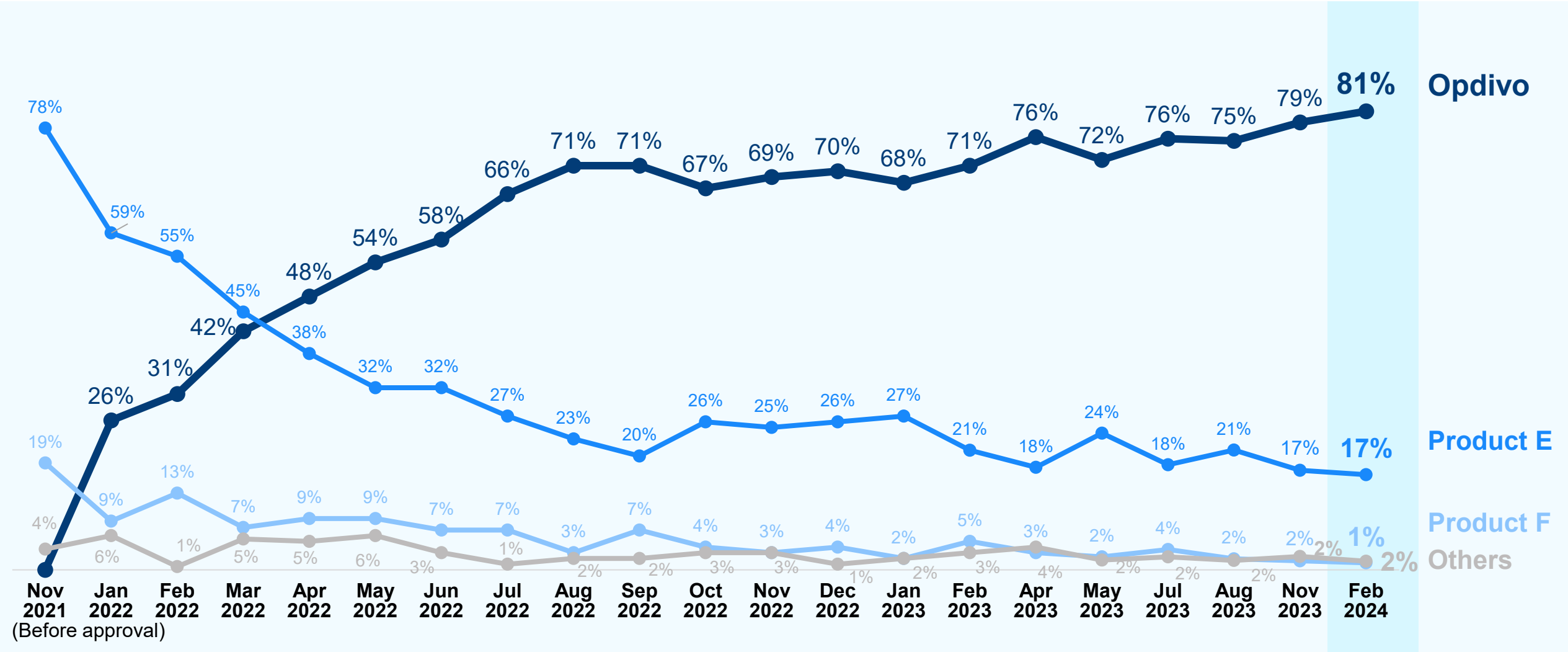
Number of GC* Patients per year in Japan

* : Unresectable Advanced or Recurrent GC



Estimation based on internal survey (2020)

Prescription Ratio in Patients Newly Treated* for 1L GC

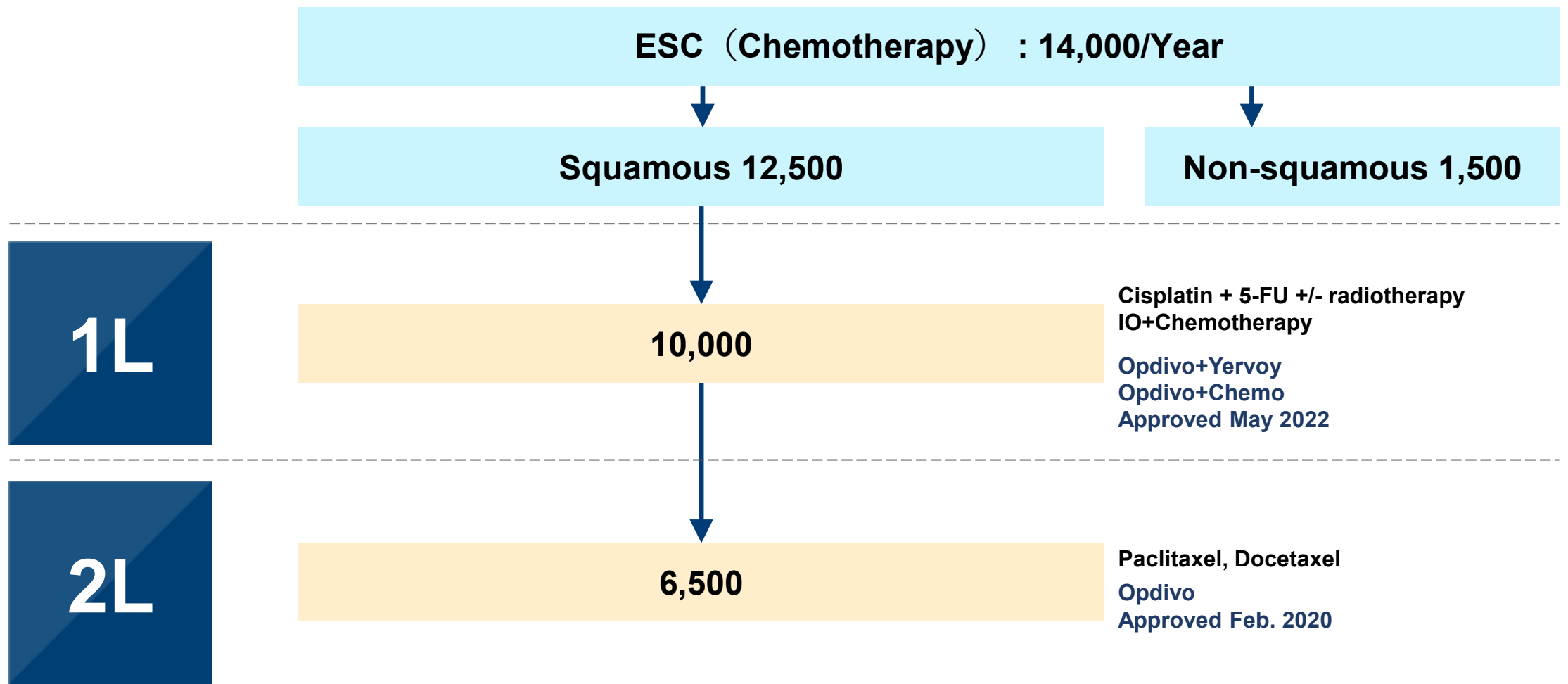


*Patients starting treatment within the last 3 month

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

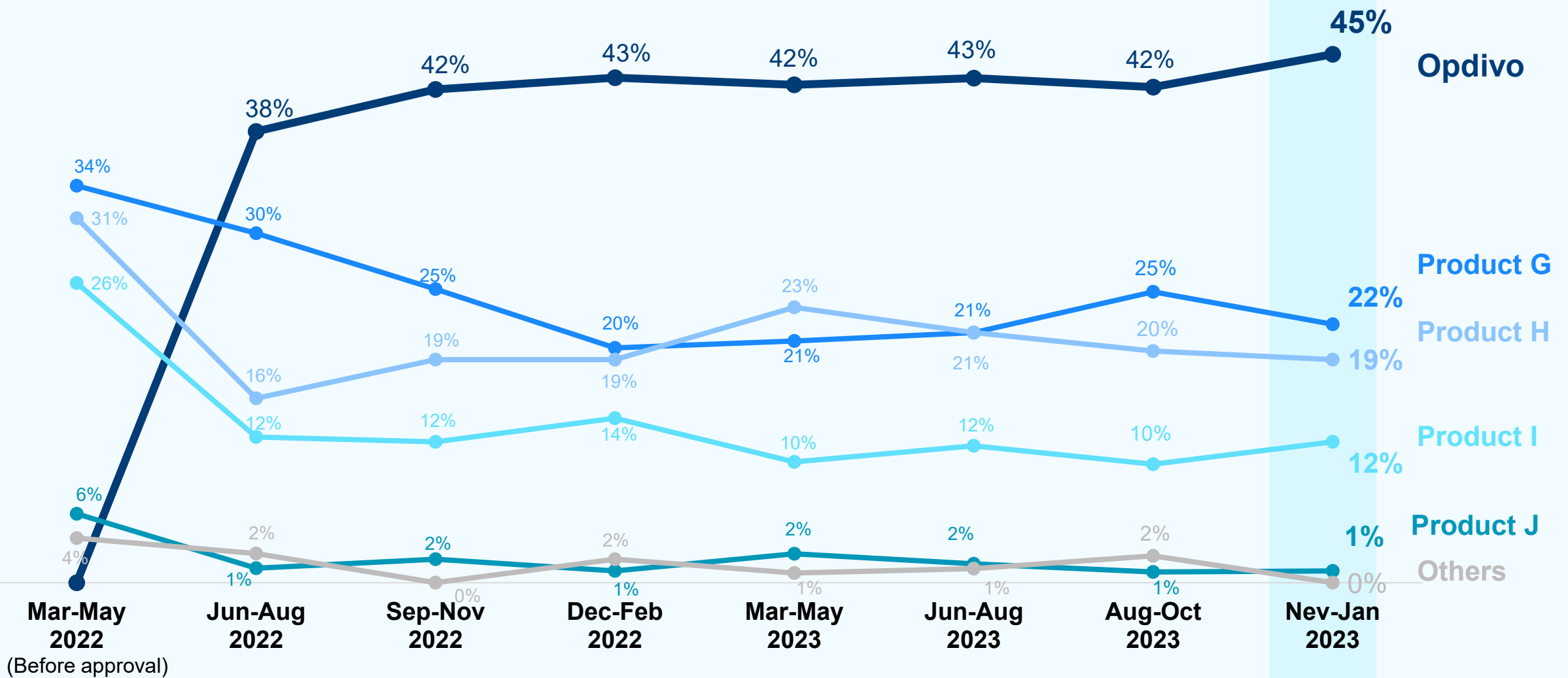
Number of ESC* Patients per year in Japan

* : Unresectable Advanced or Recurrent ESC



Estimation based on internal survey (2022)

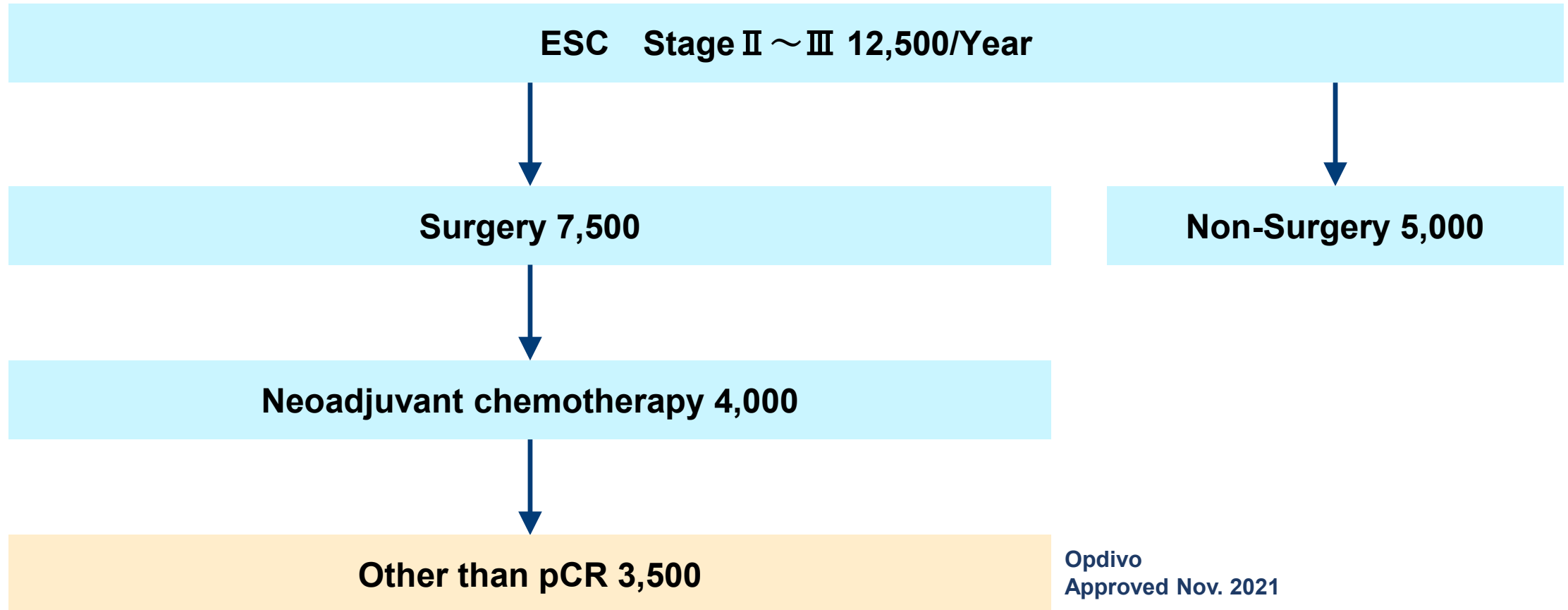
Prescription Ratio in Patients Newly Treated* for 1L ESC(Squamous Cell Carcinoma)



*Patients starting treatment within the last 3 month

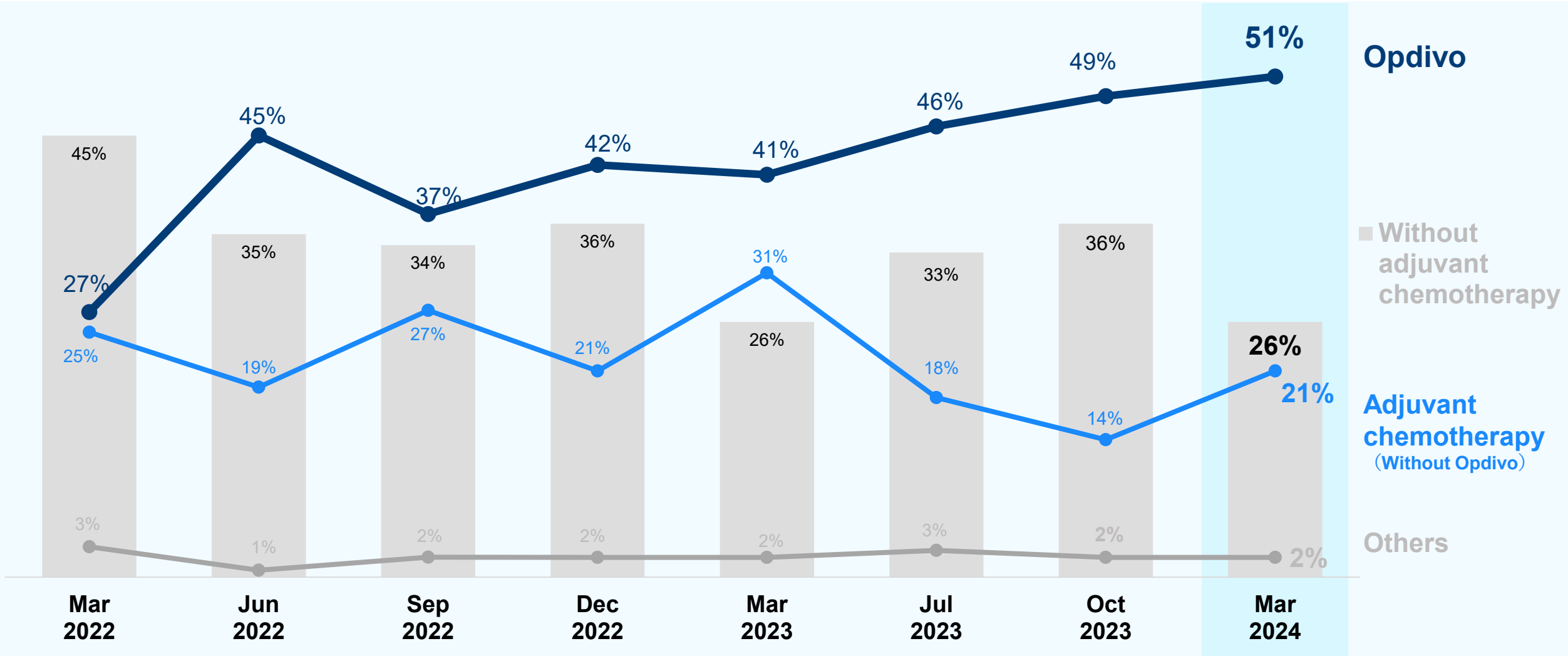
Source: External data (May 2022~Jan 2024: n=150~155)

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)



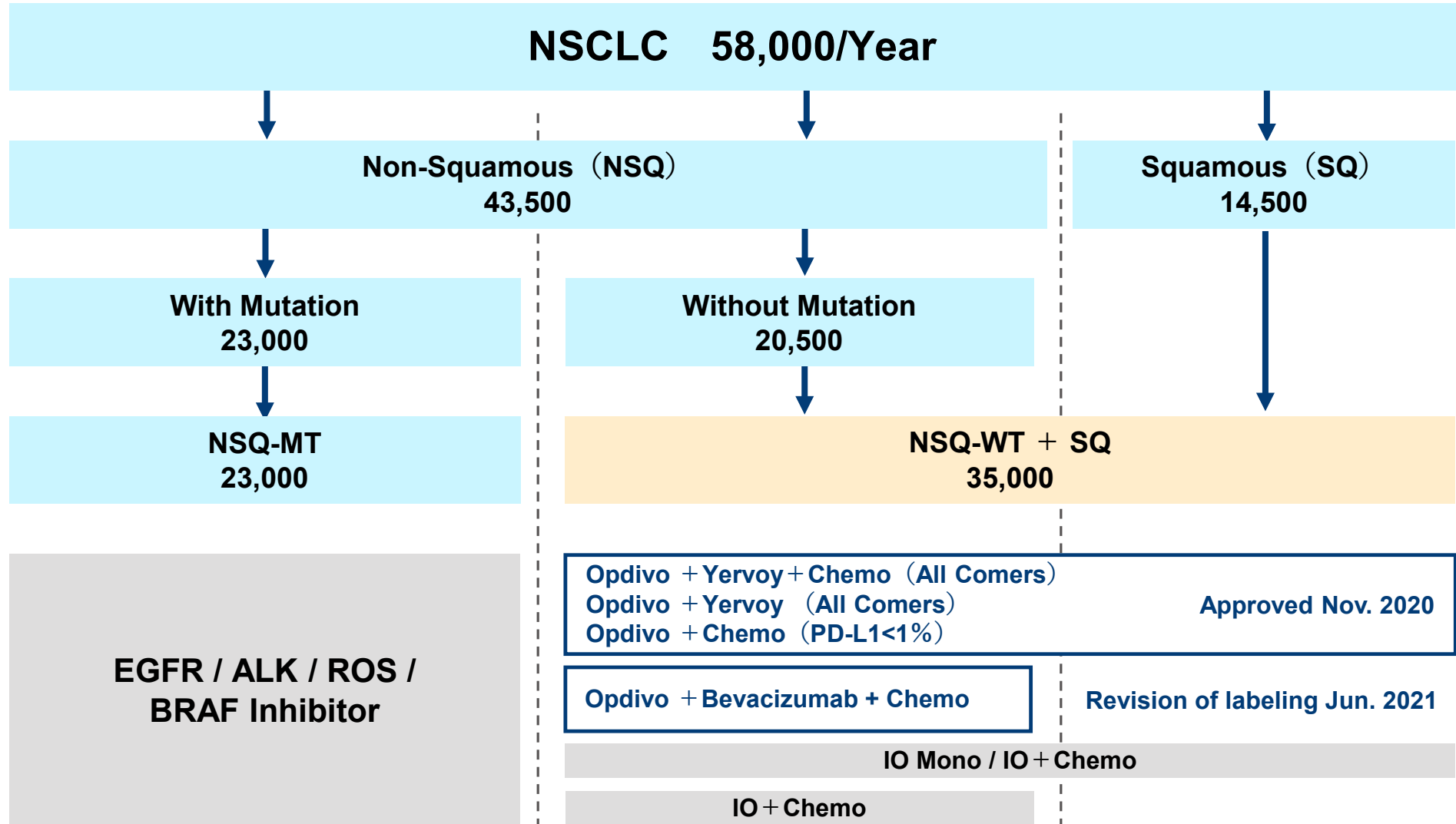
*Patients starting treatment within the last 3 months

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

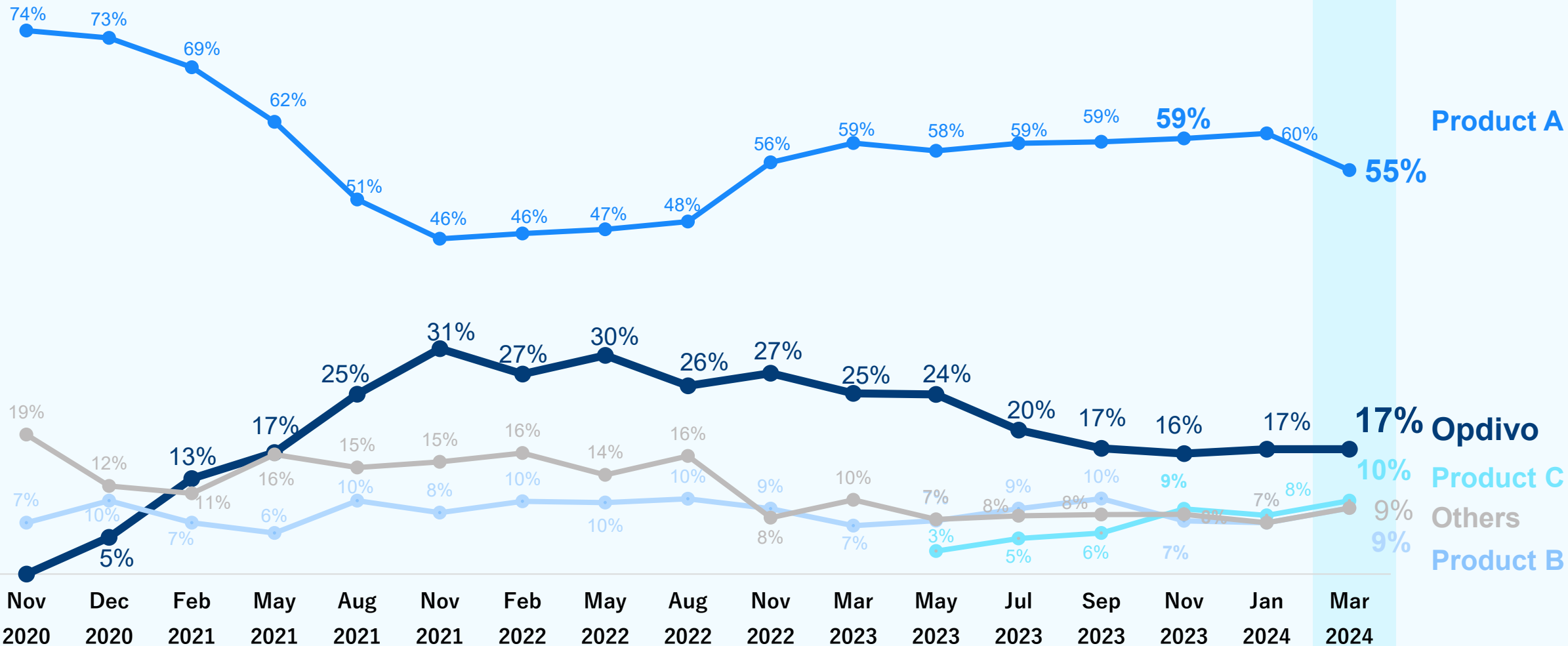
Number of NSCLC* Patients per year in Japan

* Unresectable Advanced or Recurrent NSCLC

1L



Prescription Ratio in Patients Newly Treated* for 1L NSCLC

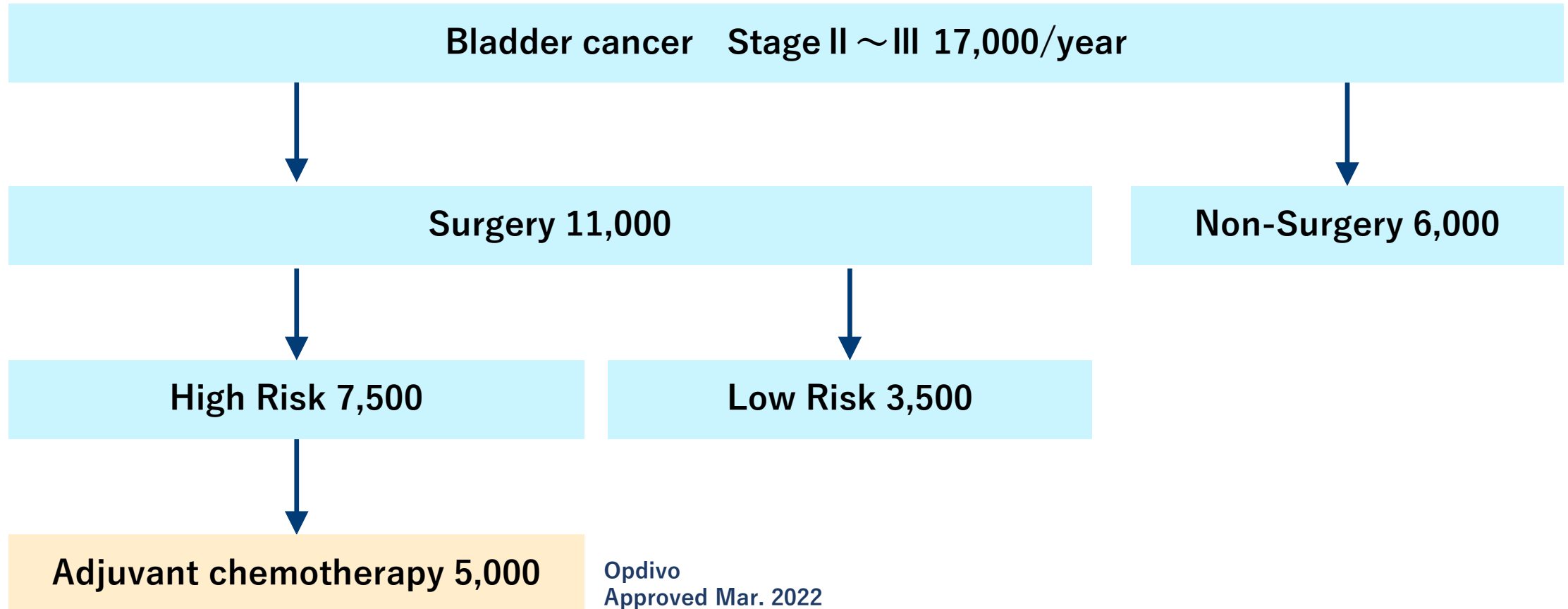


(Before approval)

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

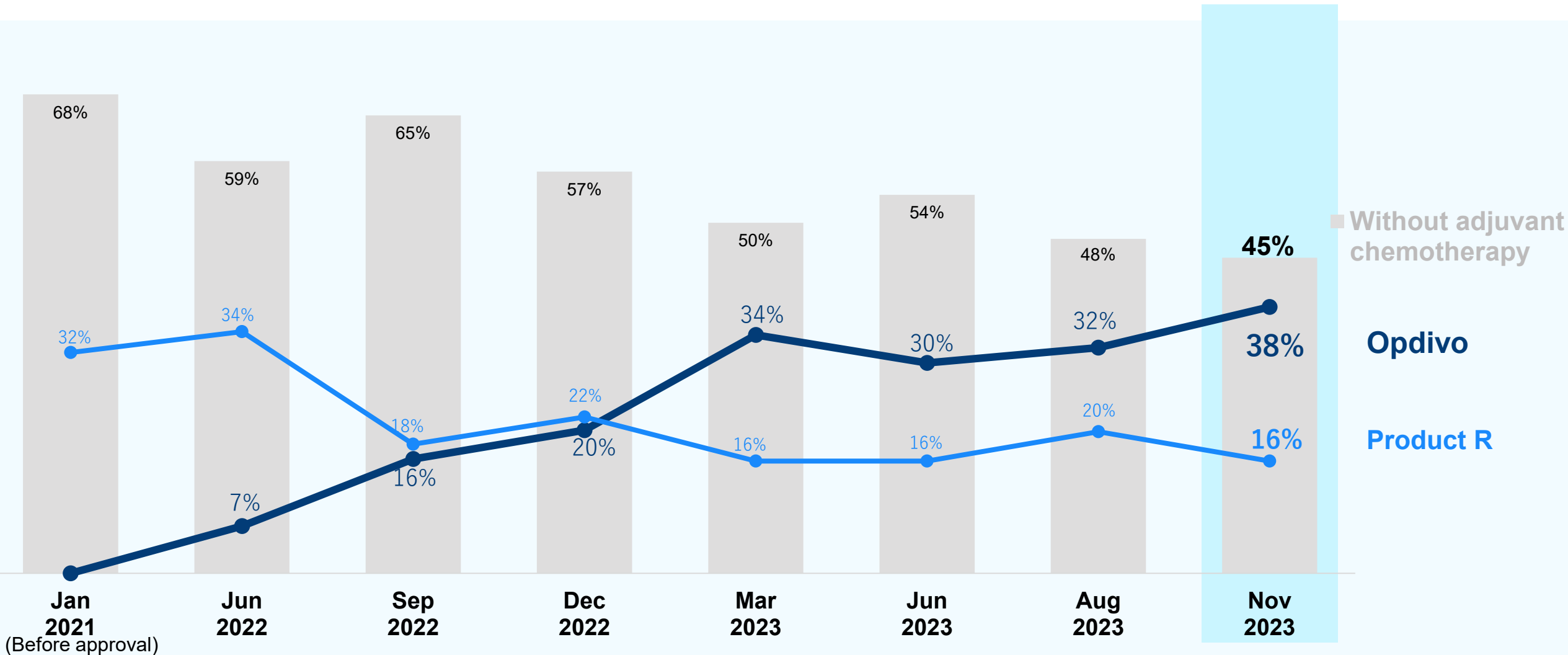
Source: External data (Nov 2020~Mar 2024: n=167~245)

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)



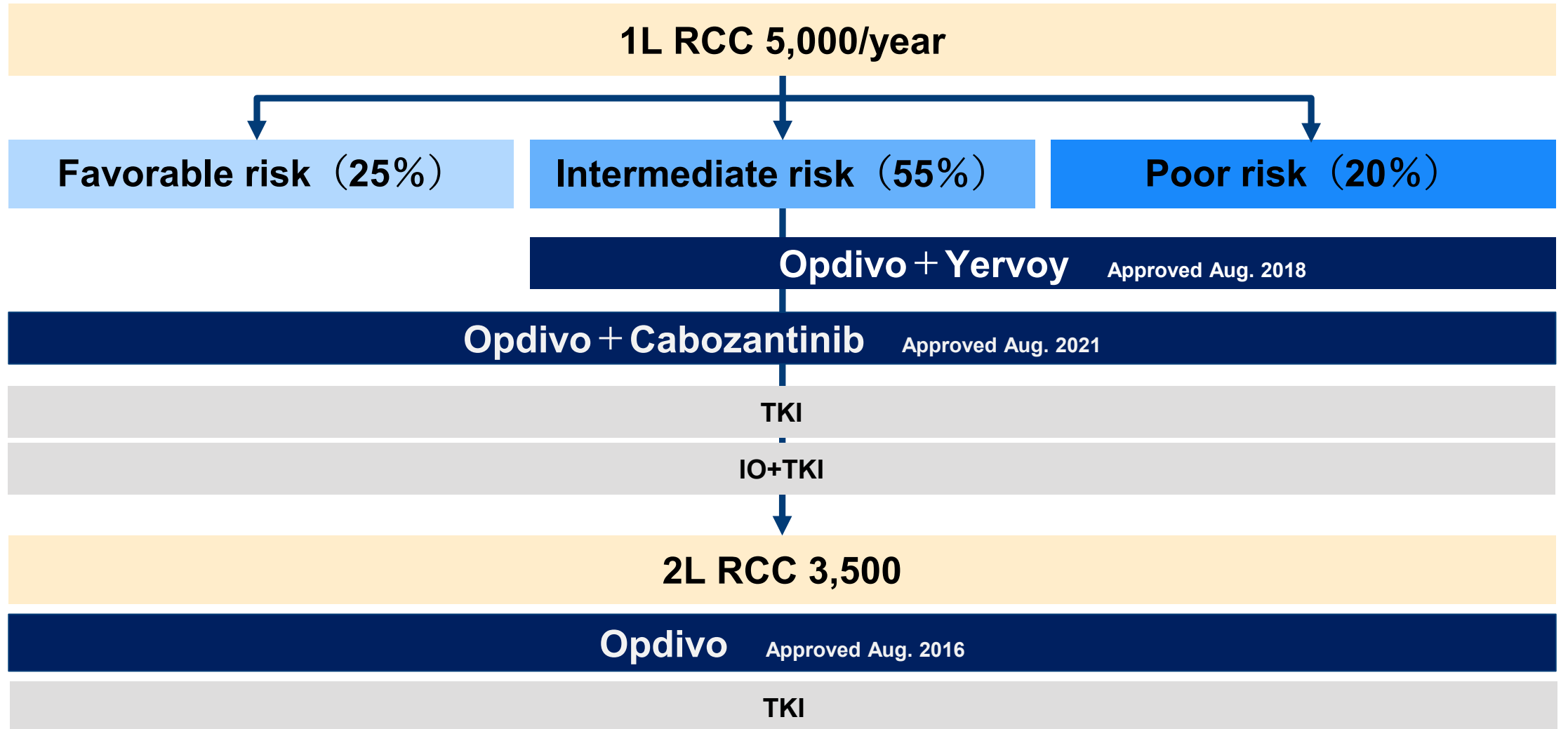
*Patients starting treatment within the last 3 months

Source: External data (Jan 2022~Nov 2023: n=200)

Number of RCC* Patients per year in Japan

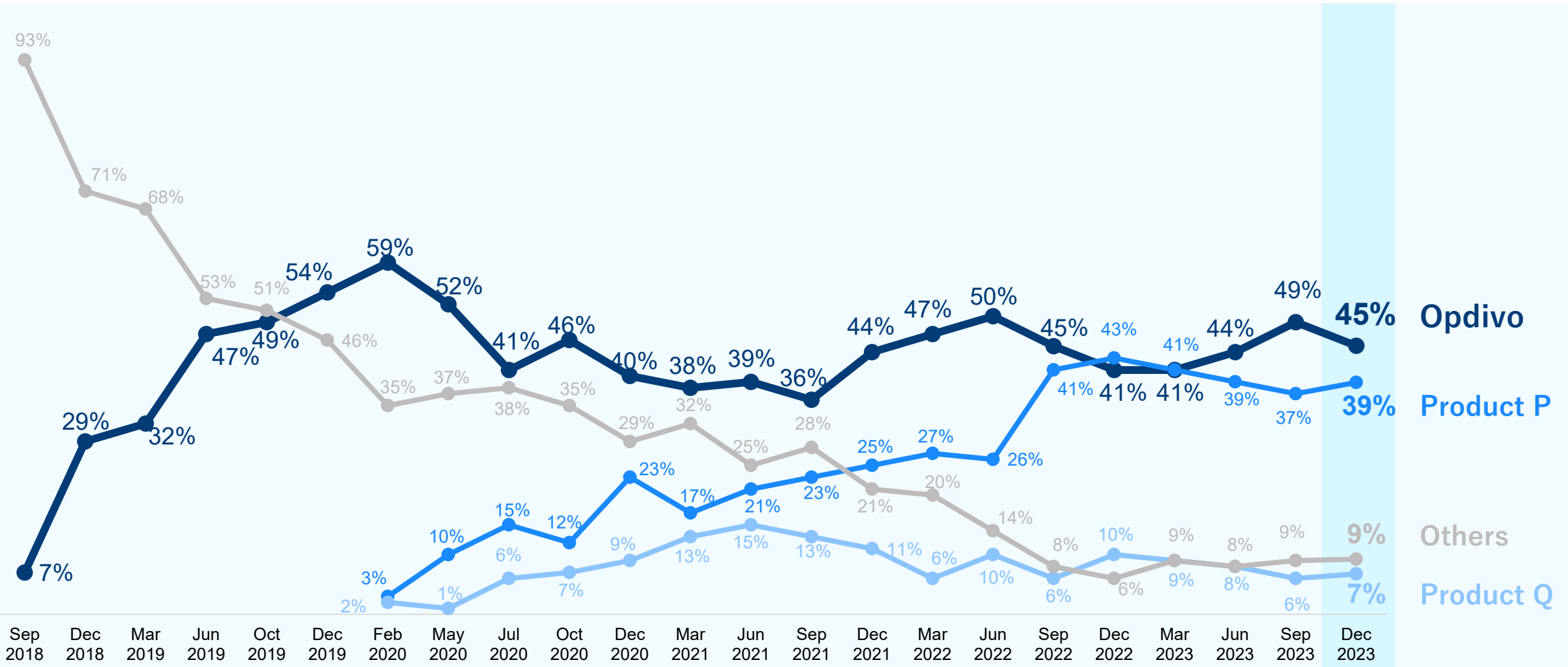


* : Unresectable or Metastatic RCC



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~Dec 2023: n=46~150)



Dedicated to the Fight against Disease and Pain