2025年3月期 決算説明会
FY2024 Financial Results Meeting

May 8, 2025

ONO PHARMA

Today's Attendees

代表取締役 社長 COO **Representative Director, President and Chief Operating Officer**	**滝野　十一** Toichi Takino
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
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

2025年3月期 業績および今後の見通し
Financial Overview FY 2024 / New-term vision （14:00-14:25）

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（14:25-14:40）

執行役員　開発本部長
Corporate Officer / Executive Director, Clinical Development

岡本　達也
Tatsuya Okamoto

オプジーボの動向
Trend of OPDIVO（14:40-14:55）

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

北田　浩一
Hirokazu Kitada

質疑応答
Q&A Session（14:55-15:30）

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.

Key Points of this Meeting

Fiscal year ended March 31, 2025 Full-year results	**Decreased revenue and profit in FY2024 compared to FY2023** ・Revenue, Core Operating Profit, and Core Profit for the Year achieved full-year forecasts ・Full-basis operating profit and profit for the period were not achieved as FORXIGA sales milestones fell short
Fiscal year ended March 31, 2026 Full-Year Forecast	**For the fiscal year ending March 2026, revenue and profit are expected to increase year on year** ・Forecasts reflect 12 months of sales and expenses related to Deciphera ・Increase in OPDIVO Japan sales and royalty income ・Decrease in sales of FORXIGA due to drug price reductions and entry of generic products
R & D	**In March 2025, Ionis will introduce sapablursen to treat polycythemia vera** ・P2 study expected to be completed by the first half of 2025 **Phase 2 study of ONO-4059 to be completed** ・Filing for approval in the US planned by the end of FY2025
Cross-shareholdings Investment Allocation	**Cross-shareholdings: Less than 10% of net assets** ・Reduction to continue **Updated investment allocation planned for 2022 to 2026**

Highlights of Financial Results for FY2024 (Core Basis)

- **Revenue decreased by 3.1% compared to the previous year, totaling ¥486.9 billion, surpassing the revised full-year forecast (announced on October 31, 2024) of ¥485.0 billion.**

  The decrease was due to the revision of drug price of OPDIVO, the decline in royalty income from Merck and others due to lower royalty rates, and the absence of the lump-sum payment of ¥17.0 billion from the settlement of a patent-related lawsuit with AstraZeneca recorded in the previous year. However, this was offset by sales of "FORXIGA Tablets" and "QINLOCK" from the Deciphera Pharmaceuticals, LLC.

- **Expense increased compared to the previous year due to the addition of "research and development expenses", and "selling, general, and administrative expenses" from Deciphera Pharmaceuticals, LLC.**

  · Research and Development Expenses: Continued proactive investment in research and development, including costs related to the drug discovery partnership agreement with LigaChem Biosciences.

  · Selling, General, and Administrative Expenses: Expenses remained at the same level as the previous period, except co-promotion costs for "FORXIGA Tablets".

- **Core operating profit decreased by 37.7% compared to the previous year, totaling ¥112.7 billion, surpassing the revised full-year forecast (announced on October 31, 2024) of ¥110.0 billion.**

FY2024 : Sales Revenue

Revenue
¥486.9 billion

YoY -15.8 billion (-3.1%)

Goods and Products Sales
¥330.8 billion

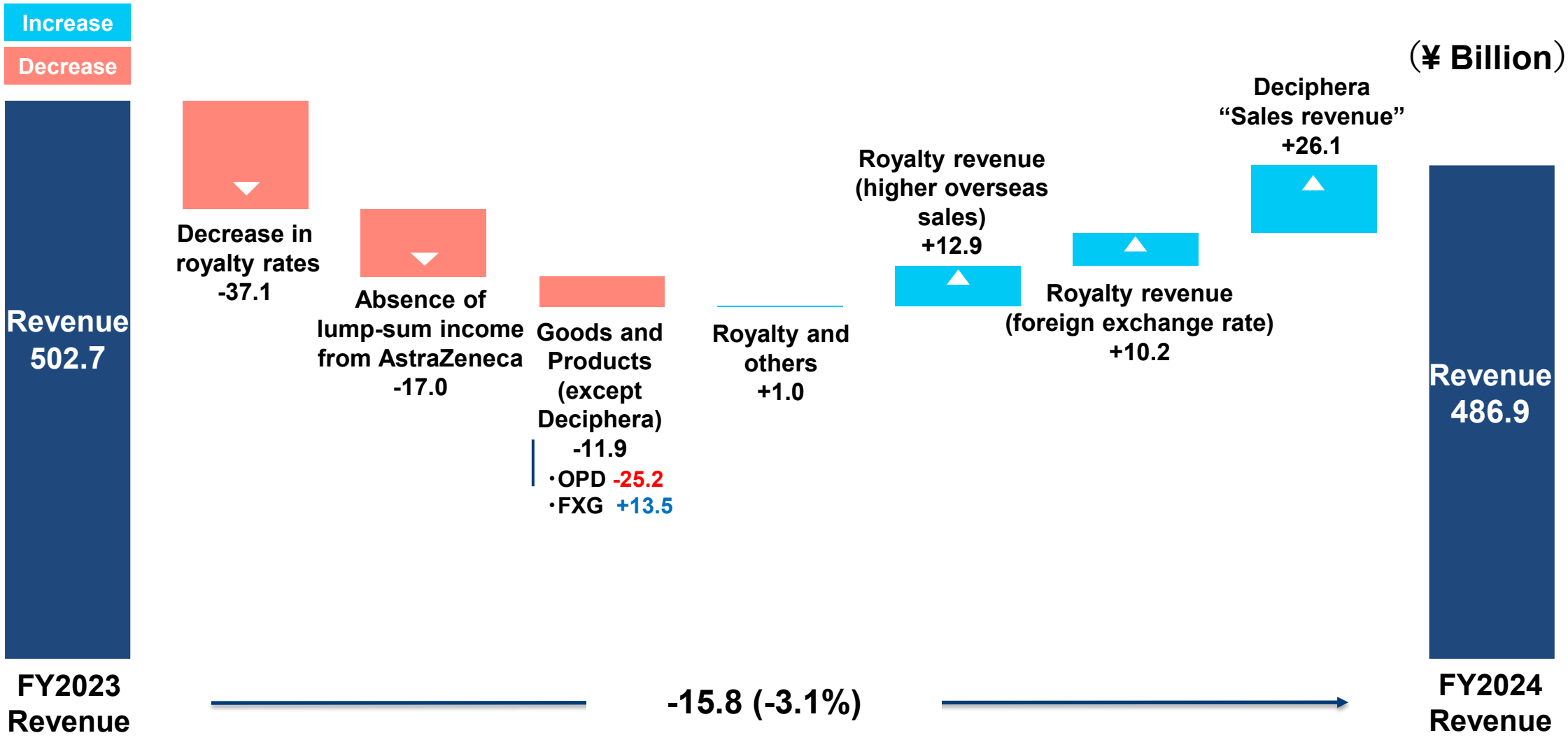
YoY +13.8 billion (+4.3%)

Royalty and Others
¥156.1 billion

YoY -29.6 billion (-15.9%)

FY2024 : 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 : Sales Revenue by Product (Domestic)

¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Goods and products	317.0	330.8	13.8	4.3%	333.0
Royalty and others	185.7	156.1	(29.6)	(15.9%)	152.0

Goods and Products (Domestic)	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
OPDIVO Intravenous Infusion	145.5	120.3	(25.2)	(17.3%)	125.0
FORXIGA Tablets	76.1	89.6	13.5	17.7%	89.0
Orencia for Subcutaneous Injection	25.8	26.6	0.8	3.0%	27.0
Glactiv Tablets	21.2	18.3	(2.8)	(13.4%)	18.5
Velexbru Tablets	10.2	10.5	0.3	3.1%	10.0
Kyprolis for Intravenous Infusion	9.1	8.6	(0.5)	(5.9%)	9.5
Parsabiv Intravenous Injection	8.2	8.4	0.2	2.5%	8.5
Ongentys Tablets	6.3	7.6	1.3	21.0%	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 : Sales Revenue by Product (Overseas) / Royalty

¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Goods and products	317.0	330.8	13.8	4.3%	333.0
Royalty and others	185.7	156.1	(29.6)	(15.9%)	152.0

Goods and Product（Overseas）	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
OPDIVO	12.0	13.1	1.1	9.3%	13.5
QINLOCK	–	25.5	–	–	25.0

Royalty and others	FY2023	FY2024	YoY		
			Change	Change (%)	
OPDIVO	97.9	113.0	15.1	15.4%	
KEYTRUDA®	53.0	26.4	(26.6)	(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 : Core Operating Profit

Core Operating Profit
¥ 112.7 billion

YoY -68.3 billion
(-37.7%)

Revenue ¥ 486.9 billion

YoY -15.8 billion (-3.1%)

R&D Expense ¥143.3 billion

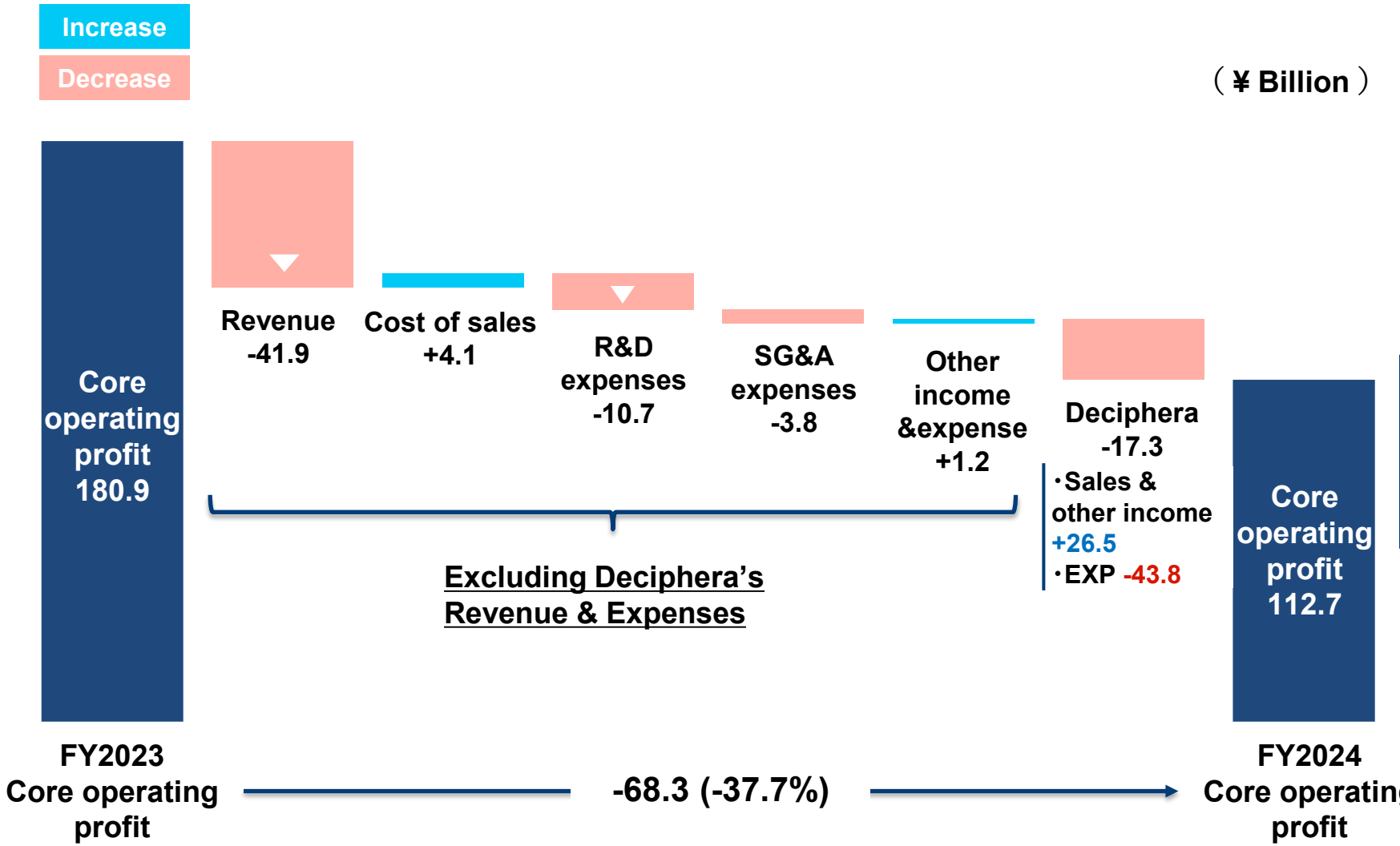
YoY +34.9 billion
(+32.1%)

SG&A Expense ¥122.2 billion

YoY +21.9 billion (+21.8%)

FY2024 : 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 ¥68.3 billion from the same period last year to ¥112.7 billion.



YoY Breakdown

Sales revenue

Main reasons

- Revision of National Health Insurance drug price
- Decrease in royalty rates from Merck & Co, Inc
- Absence of the lump-sum income from AstraZeneca in the previous period -¥17.0 billion

R&D expenses

Main reasons

- Development costs for clinical trials
- Upfront & milestone payment to LigaChem Bioscience, Inc.

SG&A expenses

Main reason

- Increase in co-promotion fee for FORXIGA tablet

FY2024 : Financial Overview (Core)

¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change(%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Cost of sales	109.6	106.9	(2.7)	(2.5%)	109.0
R&D expenses	108.5	143.3	34.9	32.1%	143.0
SG&A expenses	100.3	122.2	21.9	21.8%	120.0
Other income	0.6	1.0	0.4	66.2%	0.5
Other expenses	4.0	2.8	(1.2)	(30.6%)	3.5
Core operating profit	180.9	112.7	(68.3)	(37.7%)	110.0
Core profit before tax	184.7	113.9	(70.8)	(38.3%)	110.5
Core profit for the period (attributable to owners of the Company)	142.5	90.4	(52.2)	(36.6%)	81.0

YoY Breakdown

R&D expenses +¥34.9 billion (+32.1%)

R&D ratio：29.4%

Main reasons

- Development costs for clinical trials
- R&D expenses from Deciphera +¥24.2 billion
- Upfront & Milestone payment to LigaChem Bioscience, Inc.

SG&A expenses +¥21.9 billion (+21.8%)

Main reasons

- Co-promotion fees for FORXIGA Tablets
- SG&A expenses from Deciphera +¥18.1 billion

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

(Ref) FY2024 : Financial Overview (Full Basis)

¥ in Billion	FY2023	FY2024	YoY		FY2024 Forecast*
			Change	Change (%)	
Revenue	502.7	486.9	(15.8)	(3.1%)	485.0
Cost of sales	127.1	147.9	20.8	16.4%	130.0
R&D expenses	112.2	149.9	37.7	33.6%	147.0
SG&A expenses	100.3	125.7	25.4	25.3%	123.0
Operating profit	159.9	59.7	(100.2)	(62.6%)	82.0
Profit before tax	163.7	59.3	(104.4)	(63.8%)	81.5
Profit for the period (attributable to owners of the Company)	128.0	50.0	(77.9)	(60.9%)	58.0

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

YoY Breakdown

Cost of sales +¥20.8 billion

Main reasons

- Amortization expenses for intangible assets and inventory assets evaluated at fair value +¥21.5 billion
- Absence of impairment losses on sales licenses recorded in the previous fiscal year -¥11.1 billion
- Recording of sales milestone associated with FORXIGA +¥13.6 billion

R&D expenses +¥37.7 billion R&D ratio：30.8%

Main reasons

- Increase of development costs for clinical trials
- R&D expenses from Deciphera +¥24.2 billion
- Impairment loss for itolizumab and ONO-7018 +¥6.0 billion
- Upfront & Milestone payment to LigaChem Bioscience, Inc.

SG&A expenses +¥25.4 billion

Main reasons

- Increase of co-promotion fees for FORXIGA Tablets
- R&D expenses from Deciphera +¥18.1 billion
- Expenses associated with the acquisition of Deciphera

(Ref) FY2024 : Reconciliation from Full to Core Basis

¥ in Billion	IFRS (Full) basis	Adjustment			Core basis
		Amortization	Impairment loss	Others	
Sales revenue	**486.9**				**486.9**
Cost of sales	**(147.9)**	14.6		26.5	**(106.9)**
Gross profit	**338.9**	**14.6**	–	**26.5**	**380.0**
R&D costs	**(149.9)**		6.0	0.5	**(143.3)**
SG&A expenses	**(125.7)**			3.5	**(122.2)**
Other income /expenses	**(3.7)**		2.0	(0.2)	**(1.8)**
Operating profit	**59.7**	**14.6**	**8.0**	**30.3**	**112.7**
Operating profit ratio	**12.3%**				**23.1%**
Finance income / Finance cost	**(0.5)**			1.8	**1.2**
Profit before tax	**59.3**	**14.6**	**8.0**	**32.0**	**113.9**
Income tax expense	**(9.2)**	(4.0)	(2.3)	(8.0)	**(23.4)**
Profit for the year	**50.0**	**10.7**	**5.7**	**24.0**	**90.4**

Breakdown

Cost of sales -¥41.1 billion

Main reasons

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- FORXIGA sales milestone ¥13.6 billion
- Amortization expenses related to inventories from PPA

R&D expenses -¥6.5 billion

Main reasons

- Impairment loss from itolizumab ¥3.5 billion
- Impairment loss from ONO-7018 ¥2.5 billion

SG&A expenses and Other income&expense -¥5.3 billion

Main reasons

- Expenses related to the acquisition of Deciphera
- Impairment losses related to the integration of Deciphera＆Ono Pharma US

FY2025 : Financial Forecast

Revenue
¥490.0 billion

YoY +3.1 billion
(+0.6%)

Goods and Products Sales
¥330.0 billion

YoY -0.8 billion (-0.2%)

Royalty and Others
¥160.0 billion

YoY +3.9 billion (+2.5%)

FY2025 : Financial Forecast (Sales by Product)

¥ in Billion

Goods and Products (Domestic)	FY2024	FY2025 Forecast	YoY	
			Change	Change (%)
Opdivo Intravenous Infusion	120.3	125.0	4.7	3.9%
FORXIGA Tablets	89.6	80.0	(9.6)	(10.7%)
Orencia for Subcutaneous Injection	26.6	28.0	1.4	5.2%
Glactiv Tablets	18.3	12.0	(6.3)	(34.6%)
Velexbru Tablets	10.5	11.0	0.5	4.4%
Kyprolis for Intravenous Infusion	8.6	9.0	0.4	4.6%
Parsabiv Intravenous Injection	8.4	9.0	0.6	6.7%
Ongentys Tablets	7.6	9.0	1.4	17.8%

Goods and Product (Overseas)	FY2024	FY2025 Forecast	YoY	
			Change	Change (%)
OPDIVO	13.1	13.5	0.4	2.9%
QINLOCK	25.5	34.0	8.5	33.4%
ROMVIMZA	N/A	5.0	—	–

* 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.

FY2025 : Financial Forecast (Core Operating Profit)

Core Operating Profit

¥ 114.0 billion

YoY +1.3 billion (+1.2%)

Revenue ¥ 490.0 billion

YoY +3.1 billion (+0.6%)

R&D Expense ¥150.0 billion

YoY +6.7 billion (+4.7%)

SG&A Expense ¥120.0 billion

YoY -2.2 billion (-1.8%)

FY2025 : Financial Forecast (Core/Compared to the Previous Year)

¥ in Billion	FY2024 Actual	FY2025 Forecast	Change	Change (%)
Revenue	486.9	490.0	3.1	0.6%
Cost of sales	106.9	103.5	(3.4)	(3.1%)
R&D expenses	143.3	150.0	6.7	4.7%
SG&A expenses	122.2	120.0	(2.2)	(1.8%)
Core operating profit	112.7	114.0	1.3	1.2%
Core profit before tax	113.9	114.0	0.1	0.1%
Income tax expense	23.4	23.0	(0.4)	(1.8%)
Core profit for the year	90.4	91.0	0.6	0.7%

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

Breakdown

Cost of sales -¥3.4 billion (-3.1%)

Main reason

- Decrease in sales related to FORXIGA tablets and long-term listed products

R&D expenses +¥6.7 billion (+4.7%)

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 (-1.8%)

Main reasons

- Promotion of cost efficiency measures

FY2025 : Financial Forecast (Full / Compared to the Previous Year)

¥ 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	17.0	33.9%

Breakdown

Cost of sales -¥12.9 billion (-8.8%)

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 (+0.1%)

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 (-4.5%)

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.
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.

Deciphera Performance Trends

- Acquisition completed in June 2024 and P/L consolidation started in July 2024
- Sales of QINLOCK, already launched, are progressing steadily. Sales in the fiscal year ended in March 2025 were 25.5 billion yen. Sales in the fiscal year ending March 2026 are expected to be 34 billion yen.
- In February 2025, we launched ROMVIMZA, a drug for the treatment of tenosynovial giant cell tumors, in the United States.

Functions of ONO Pharma US will be integrated into Deciphera around July 2025.
Single-year profitability is expected in FY2027.

FY2024 Results (2024.7-2025.3)

Product Sales: 26.1 billion yen (102.4% of plan)
Expenses: 42.3 billion yen
- R&D expenses 24.2 billion yen, SG&A expenses 18.1 billion yen

QINLOCK® (ripretinib) 50 mg tablets

(Approved in 40 + countries)

FY2025 Full-Year Forecast (2025.4-2026.3)

Product sales: Approx. 40 billion yen
Expenses: About 57 billion yen
- R&D expenses approximately 36 billion yen, SG&A expenses approximately 21 billion yen

Romvimza™ (vimseltinib) 30mg Capsules

(Launched in US, EU pending

Forecast Annualized Exchange Rate of ¥145/USD

Projection for the Next 10 Years

+ Increase sales of global products (QINLOCK, ROMVIMZA, VELEXBRU, Sapablursen)
+ Royalties for OPDIVO's subcutaneous formulations and compounds will continue after the expiration of the patent for the intravenous formulation expires
+ Launch of ONO-2017 and Gel-One in Japan
+ Launch of in-house products
- During 2025 to 2026, patents for diabetes-related products (FORXIGA, GLACTIV) will expire.
- Patent expiration for OPDIVO (US 2028, Europe 2030, Japan 2031)

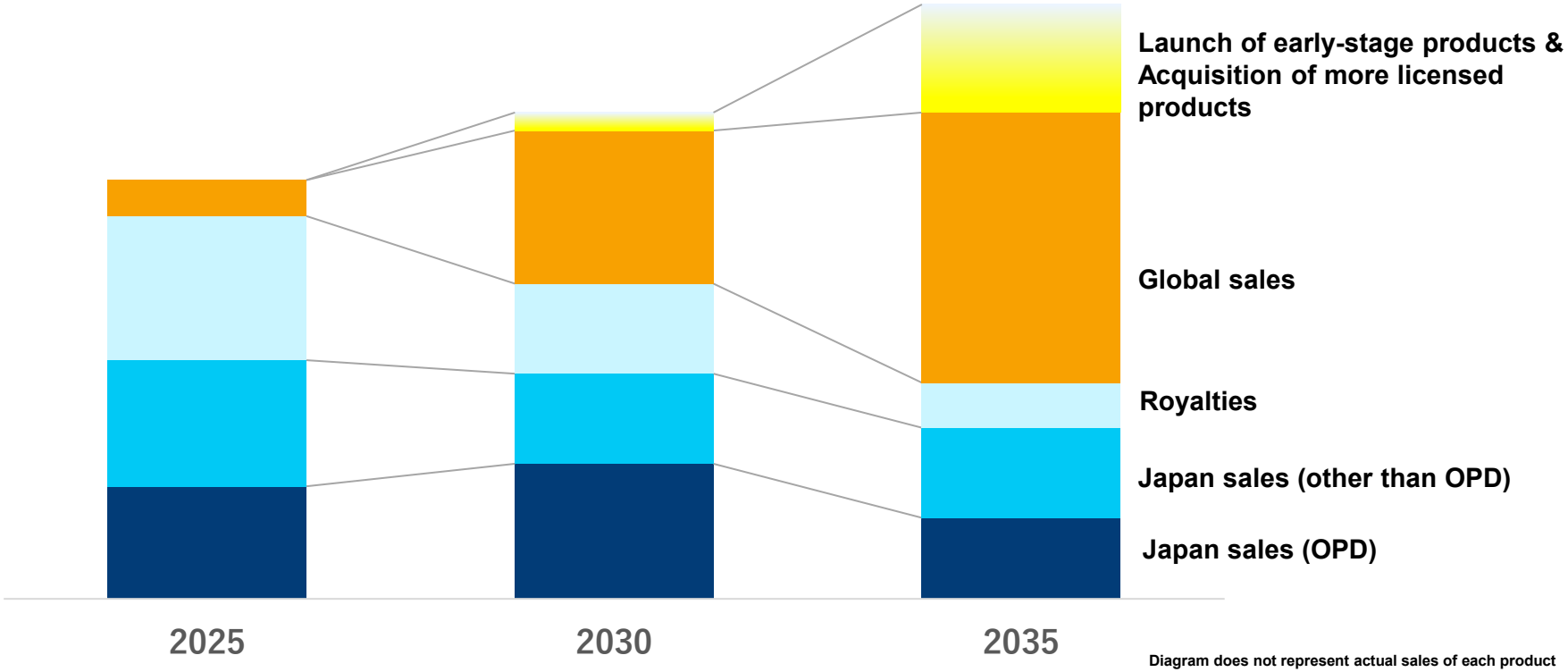


Diagram does not represent actual sales of each product

Results of Reduction of Cross-Shareholdings

➢ Reduction plan (published on November 1, 2021)

– Over the next 3 and a half years, the company will reduce its cross-shareholdings by about 30% as of the end of September 2021 (¥141.8 billion).
– Under the 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%.

➢ **Results of reduction**

・Reduction (Market price at the end of September 2021：￥69.5bil (49.0%)
・The ratio of cross-shareholdings to net assets (on a balance sheet basis)：9.4%

	End of September 2021	End of March 2025	Reduction*	Reduction rate
Market price at the end of September 2021	**¥ 141.8 bil**	**¥ 72.3 bil**	**¥ 69.5 bil**	**49.0%**

*Contain the growth investments after October 2021

(Reference)

	End of September 2021	End of March 2025	Reduction	Reduction rate
Balance sheet accounting amount	**¥ 141.8 bil**	**¥ 74.1 bil**	**¥ 67.7 bil**	**47.7%**

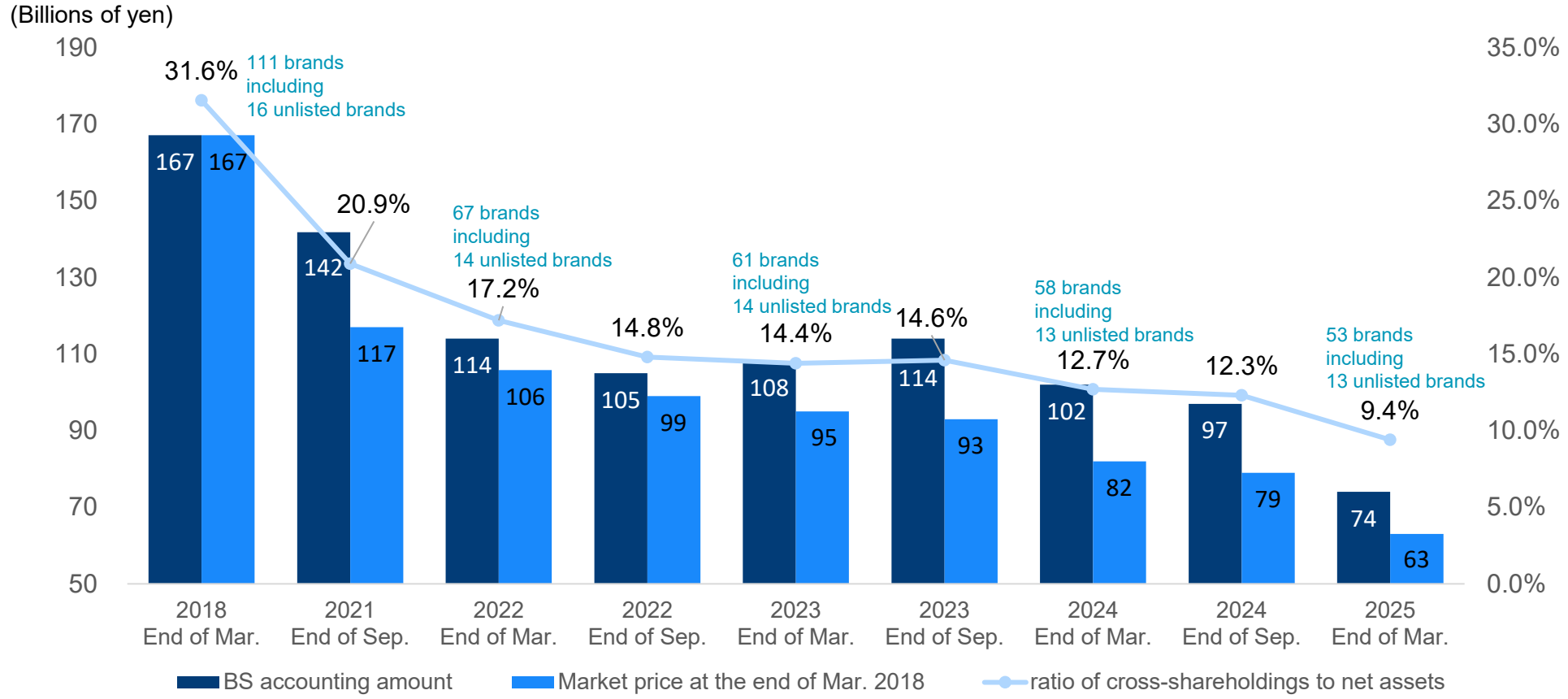
※End of March 2025
Ratio of Cross-shareholdings to net assets：9.4%

Status of reduction of Cross-shareholdings

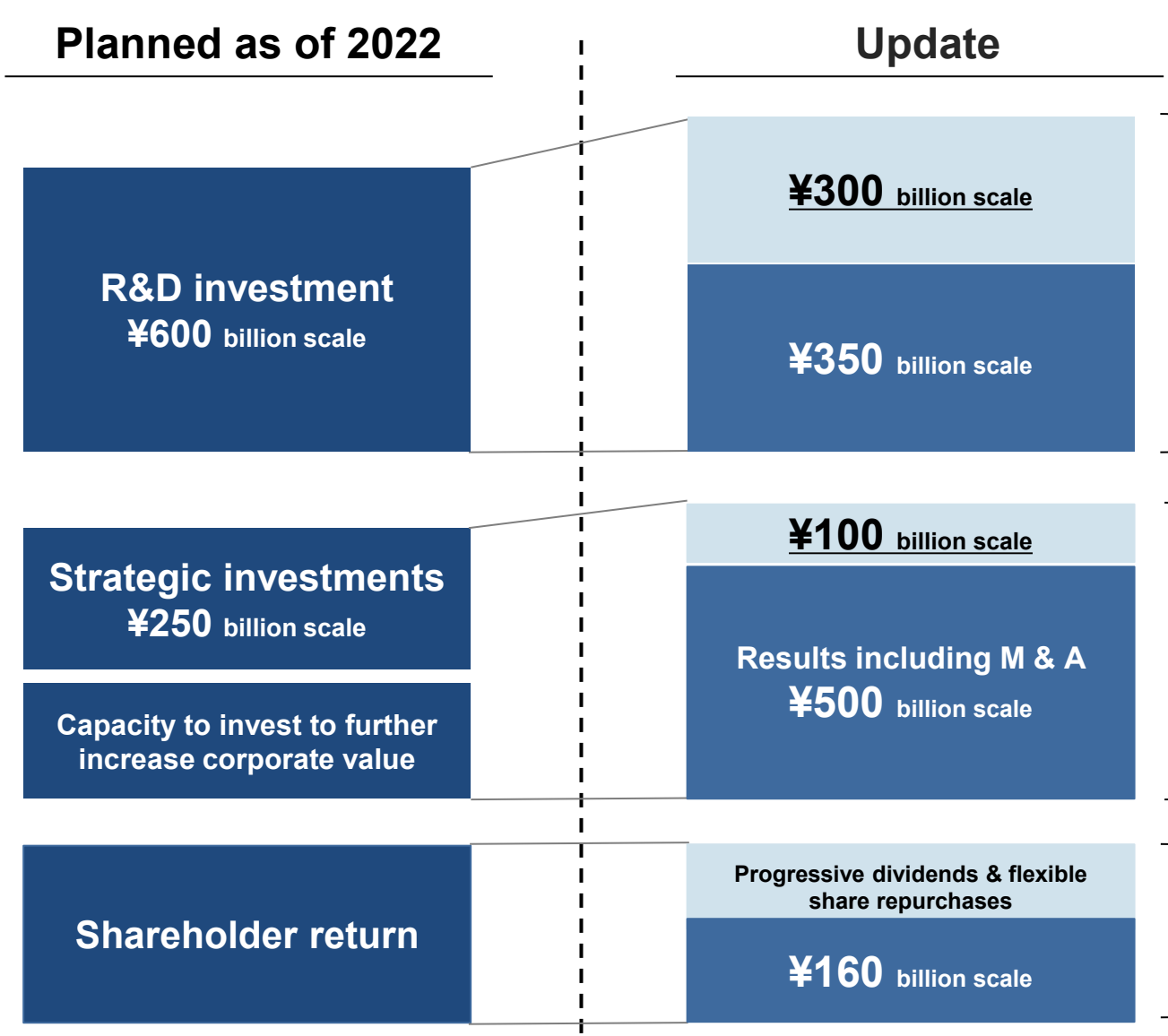
➢ Reduction plan

We will continue to reduce our cross-shareholdings as part of our efforts to enhance corporate value.

➢ Changes of reduction



Update of Investment Allocation (FY 2022 to FY 2026)



: Assumption for FY 2025~ FY 2026

: Result of FY2022～FY2024

R&D

- Continuous R&D investment to strengthen pipeline (R&D cost to revenues of approx. 20 ~ 30%)
- Acquire early pipeline
- Collaboration to expand research platforms
- Investment in drug discovery venture companies

Strategic Investments

- Conduct further M&A if there is any opportunity
- Acquire development pipeline
- Improve overseas bases
- Create healthcare businesses
- Investment in venture companies, etc

Shareholder Return

- Progressive dividends maintained or increased, target payout ratio of 40%
- Annual dividend ¥80 per share (as of the end of March 2025)
- Flexible share buyback according to the situation

Development Pipeline Progress Status

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

As of April 23, 2025

Filed | Approved | Met PE

OPDIVO | Other than OPDIVO

FY2024 (results)

- DCC-3014（ROMVIMZA）〔TGCT〕 July 2024
- DCC-3014（ROMVIMZA）〔TGCT〕 August 2024
- 〔1L-Hepatocellular carcinoma〕 with YERVOY CheckMate-9DW August 2024
- 〔1L- Colorectal cancer (MSI-H)〕 with YERVOY CheckMate-8HW September 2024
- BRAFTOVI 〔1L-BRAF-mutant Colorectal cancer〕 with Cetuximab and FOLFOX December 2024

FY2025

- ONO-4059（VELEXBRU）〔2L-PCNSL〕
- 〔Neoadjuvant, Adjuvant - Bladder cancer〕 with Chemo ONO-4538-86
- 〔Adjuvant Hepatocellular carcinoma〕 CheckMate-9DX
- ONO-2017 〔 Partial-onset seizures 〕
- 〔 Neoadjuvant, Adjuvant - NSCLC〕 with Chemo CheckMate-77T

FY2026

- 〔1L-Gastric cancer〕 with YERVOY and Chemo ONO-4538-113

PE : Primary endpoint

Development status of OPDIVO

As of April 23, 2025

- Approval in FY2024 or filed/awaiting approval
- 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	Filed
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	Filed	Ⅲ	Ⅲ	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant ・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	–	–	–	–
Richter transformation	2nd	Monotherapy	Ⅱ	–	–	–	–
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 Q3 FY2024 in February

Development pipeline (Oncology) ①

As of April 23, 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					
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	NCT04607421/JP, KR and others	1L BRAF-mutant colorectal cancer Combination with Cetuximab and FOLFOX	FY2024.12 Filing accepted					
QINLOCK (ripretinib) KIT inhibitor	NCT05734105/NA, SA, EU, AU, KR, TW	Gastrointestinal Stromal Tumor 2L 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-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*	FY2025 Primary Completion					
	—/US	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-0530（sapablursen） Antisense oligonucleotide targeting TMPRSS6	NCT05143957/US, EU and others	Polycythemia Vera	FY2025 Primary Completion					
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT01968109/JP, US, EU	Melanoma*	FY2024 Primary Completion (Actual)					
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					

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 Q3 FY2024 in February
MOA : Mode of Action

Development pipeline (Oncology) ②

As of April 23, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
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					
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	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-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma	→ FY2025 Primary Completion					
	NCT06547528/JP		→ FY2028 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	NCT06816108/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 Q3 FY2024 in February

Development pipeline (Non-oncology)

As of April 23, 2025

Code （Generic name）MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU	Tenosynovial Giant Cell Tumor			FY2024 FDA: Approval EMA: Filing accepted			
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ 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			
ROMVIMZA 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		
	NCT06805565/JP	Social Anxiety Disorder				FY2026 Primary Completion		
ONO-2020 Epigenetic Regulation	NCT06881836/JP, US	Alzheimer's Disease				FY2026 Primary Completion		
	NCT06803823/JP	Agitation Associated with Dementia Due to Alzheimer's Disease				FY2026 Primary Completion		
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 Q3 FY2024 in February

Sapablursen (ONO-0530)

- **Anti-sense oligonucleotide targeting TMPRSS6[1)]**
- **Ongoing Phase II study for adult polycythemia vera (PV) patients is expected to be completed in 2025**

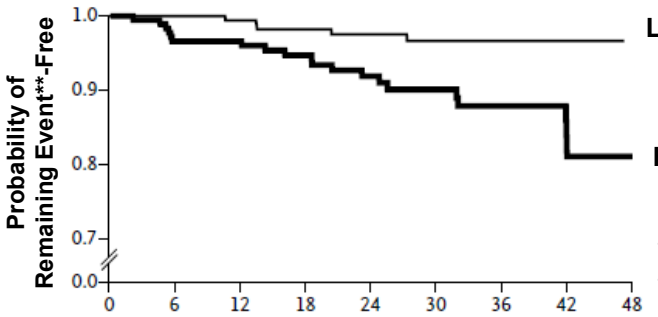
【Polycythemia vera (PV)】

- More than 95% PV patients have a *JAK2* gene mutation, leading to the overproduction of red blood cells.
- PV is a rare and potentially life-threatening hematologic disease with an incidence rate of approximately 2 cases per 100,000 population[2)] and a total of 75,000 patients on treatment in the US[3)]
- In the PV patients with high hematocrit (HCT) have a 3.91 times higher risk of cardiovascular death or thrombotic events compared to patients with low HCT.[4)]
- Quality of life (QOL) is impaired due to symptoms such as headaches, dizziness, and fatigue.
- Standard of care includes phlebotomy, low-dose aspirin and cytoreductive therapy (CRT) to maintain HCT <45% and prevent thrombotic events.
- Patients with high frequent phlebotomy present with iron deficiency. CRT increases the risks of infections and secondary cancers.

【Hypothetical Mechanism of Action】

- Hepcidin is the key regulator of iron homeostasis.
- Sapablursen (ONO-0530) increases hepcidin production through suppressing the TMPRSS6 gene expression, thereby reducing red blood cells in PV patients.

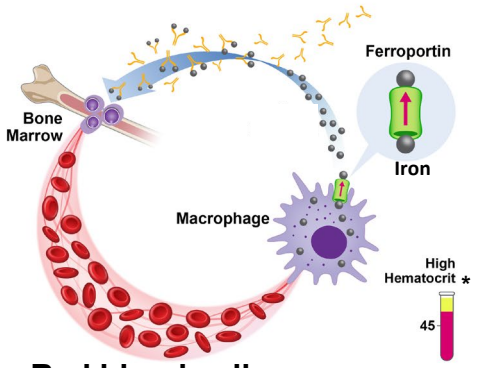
Increase in the risk of cardiovascular death and thrombotic events by PV



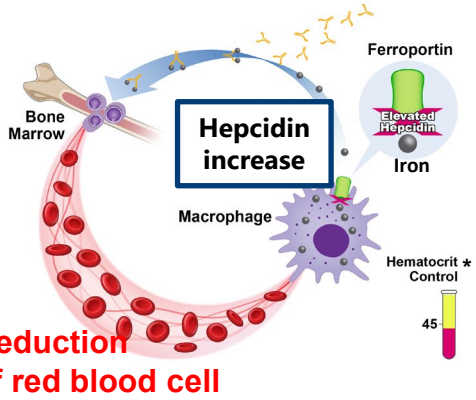
*HCT: Percentage of red blood cells in the blood
**Event: cardiovascular death and major thrombosis

Adapted from Marchioli R, et al. N Engl J Med. 2013;368:22-33.

Polycythemia vera (PV)



Reduction of red blood cells through increased hepcidin production in PV

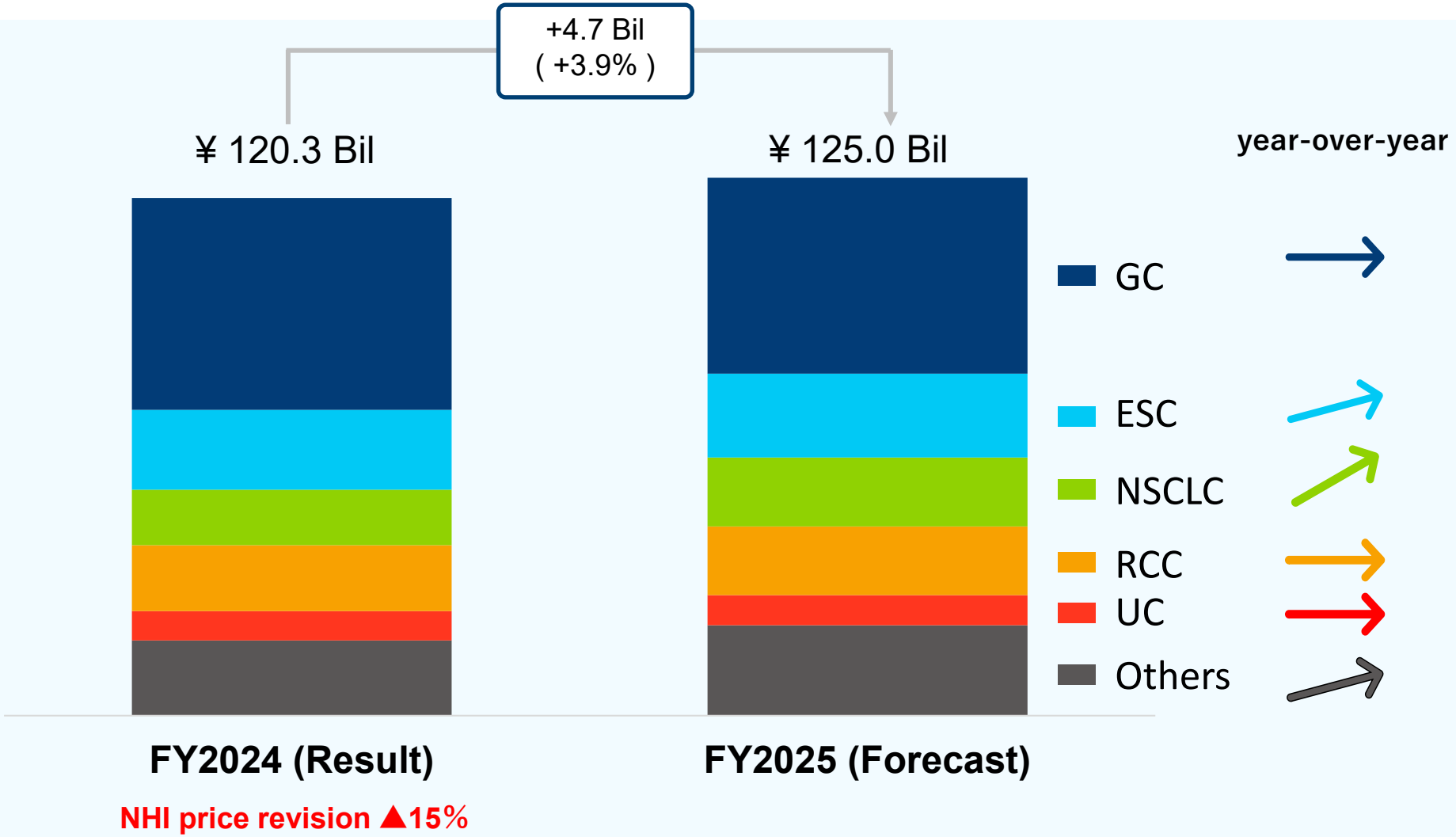


*HCT: Percentage of red blood cells in the blood

1) Ono Entered into License Agreement with Ionis Pharmaceuticals for Sapablursen for the Treatment of Polycythemia Vera in March 2025
2) Blood Cancer Journal (2020) 10:22, 3) Nat Rev Dis Primers. 2025 Apr 17;11(1):26. 4) N Engl J Med. 2013;368:22-33.,

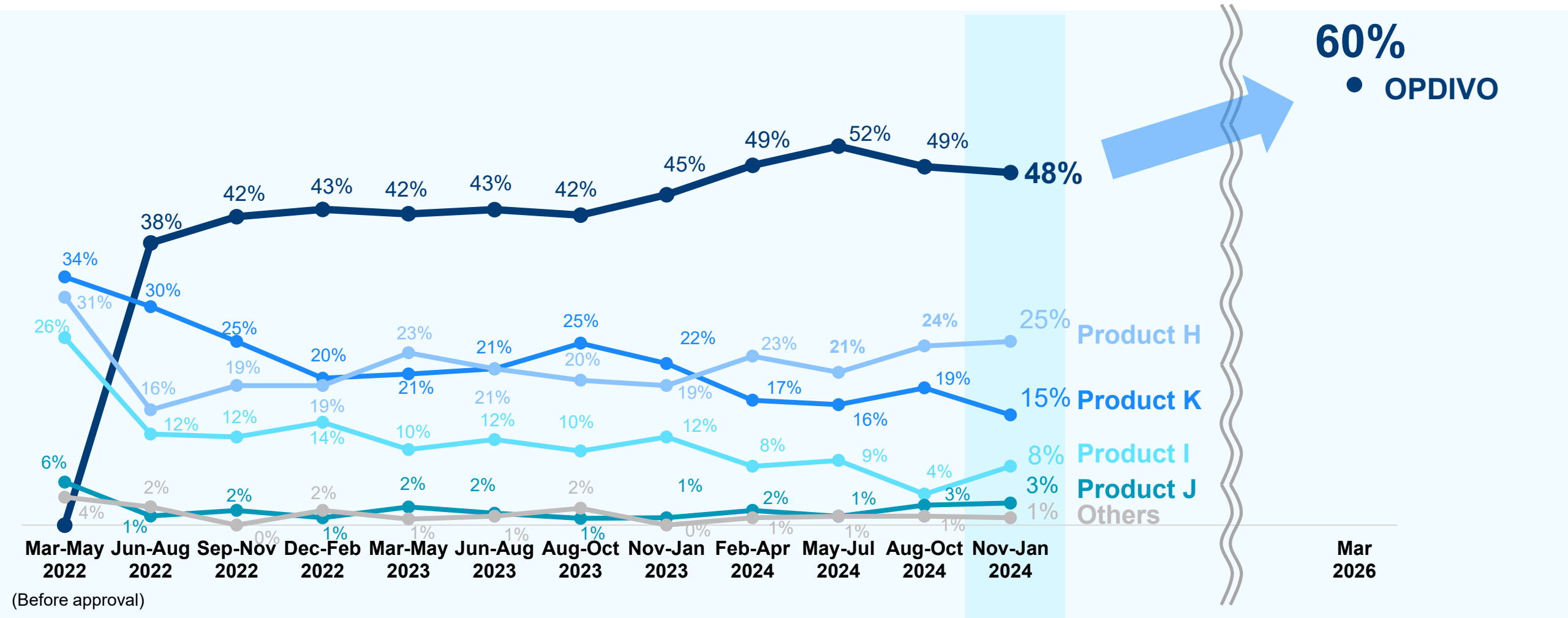
Trend of OPDIVO

Sales Trend of OPDIVO by Each Cancer



Source: Estimation from external and internal data

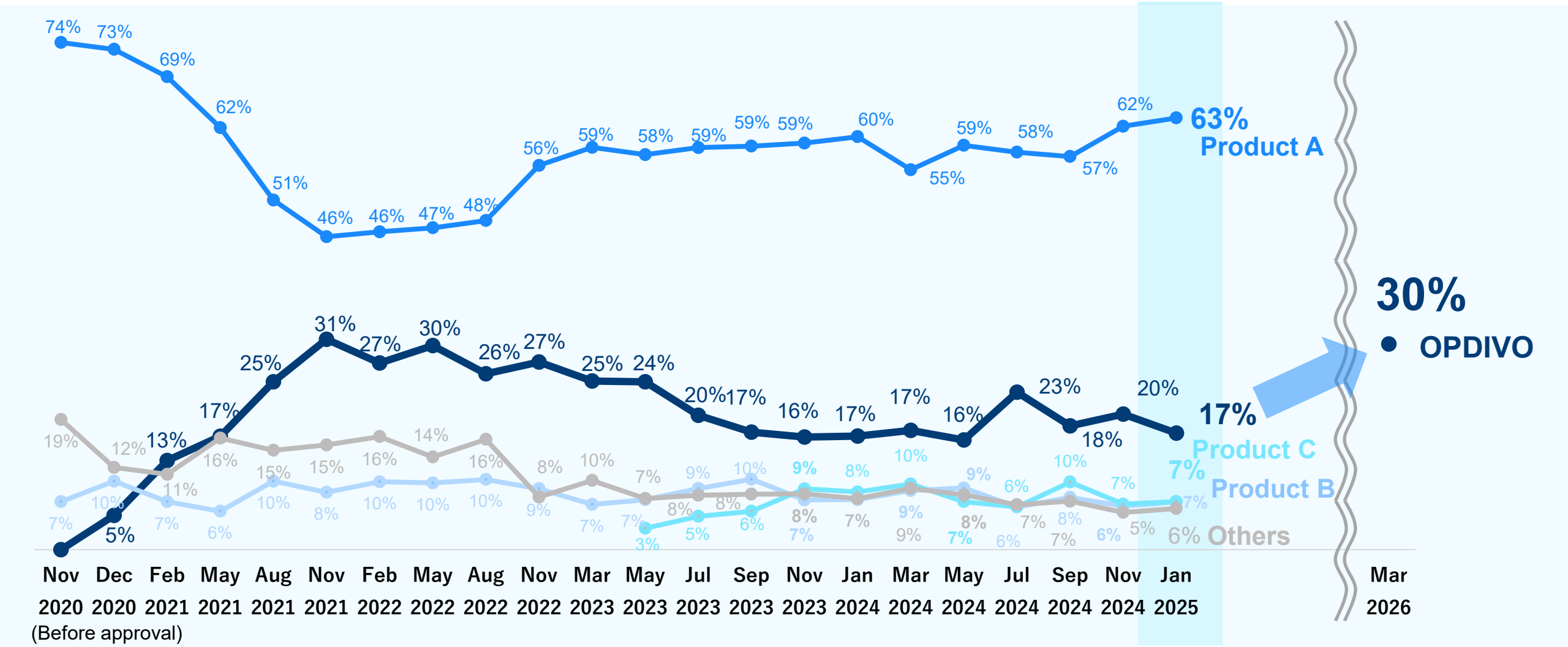
Prescription Ratio in Patients Newly Treated※ for 1L ESC(Squamous Cell Carcinoma)



※Patients starting treatment within the last 3 month

Source: External data（May 2022~Jan 2025: n=150~155)

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~Jan 2025: n=167~245）

Appendix

OPDIVO Approval Track Record (1)

As of April 23, 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 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

OPDIVO Approval Track Record(2)

As of April 23, 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 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

OPDIVO Approval Track Record(3)

As of April 23, 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
	2nd	Monotherapy	–	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	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 2023 financial result in May 2024 ※Red: Update after Q3 FY2024 in February

Key milestones in FY2024 Q4 (FY ending March 2025)

As of April 23, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	ROMVIMZA (vimseltinib)	chronic Graft Versus Host Disease	Approved in US (Feb.2025)
	OPDIVO	MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Approved in US (Apr.2025)
		Hepatocellular carcinoma(1st with Ipi) /CheckMate-9DW	Approved in EU (Mar.2025), US(Apr.2025)
P2		Richter transformation	Started in JP (Jan.2025)
	ONO-2020	Alzheimer's disease	Started in JP (Jan.2025)
	ONO-4578	Colorectal cancer (with OPDIVO)	Started in US (Feb.2025)
P1		Pancreatic cancer	Discontinued (Jan.2025)
	ONO-4482	Hepatocellular carcinoma(with OPDIVO)	Discontinued (Feb.2025)
	ONO-7914	Solid tumor(with OPDIVO)	Discontinued (Feb.2025)
	ONO-7475	Pancreatic cancer(with OPDIVO)	Discontinued (Mar.2025)
	ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	Discontinued (Apr.2025)

Key milestones in FY2024 Q4 (FY ending March 2025)

As of April 23, 2025

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

Title	Progress
Ono Enters into License Agreement with Ionis Pharmaceuticals for Sapablursen for the Treatment of Polycythemia Vera	License-in (2025.3)
Ono Enters into a Basic Agreement with Seikagaku for Co-development and Marketing Collaboration on Gel-One for the treatment of Osteoarthritis in Japan	License-in (2025.4)
Ono Enters into Drug Discovery Collaboration Agreement with Reborna Biosciences to Generate RNA-Targeting Novel Small Molecule in the Central Nervous System Area	Started
Ono Commences Research Collaboration with Jorna Therapeutics to Generate Novel RNA Editing Therapeutics	
Ono Enters into a Research Collaboration Agreement with InveniAI to Identify Novel Therapeutic Targets	Discontinued
ONO Announces a Strategic Drug Discovery Alliance Agreement with Cancer Research UK and LifeArc for Cancer Immunotherapy	
Ono Enters a Drug Discovery Collaboration Agreement with Memo Therapeutics to Discover and Develop Antibody Drugs in the Immuno-oncology Field	
Ono Enters into a Collaboration and Option Agreement with Cue Biopharma for CUE-401, a Bispecific Protein	
Ono Enters into Research Collaboration Agreement with Healx Limited	

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


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