# FY2026 Q2 Financial Results

October 29, 2026

ONO PHARMA

# Forward-Looking Statements

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:

| | |
|---|---|
| **Forward-looking statements:** | This presentation contains forward-looking statements regarding the Company's future plans, strategies, and performance. |
| **Current assumptions:** | These statements are based on current expectations, assumptions, and information available to management at this time. |
| **Risks and uncertainties:** | Forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. |
| **No guarantee of outcomes:** | Forecasts, targets, and projections are not guarantees of future performance or achievement of stated goals. |
| **Official guidance:** | Official financial guidance should be referred to in accordance with relevant regulatory requirements and disclosures. |
| **Product/market risks:** | Risks include, but are not limited to, product development challenges, regulatory approvals, market acceptance, and competition. |
| **Economic/industry risks:** | Additional risks may arise from changes in economic conditions, currency fluctuations, and healthcare policy reforms. |
| **No obligation to update:** | The Company undertakes no obligation to update or revise any forward-looking statements as a result of new information or future events. |
| **Prevailing language:** | In the event of any inconsistency between language versions, the original Japanese language version shall prevail. |

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 Attendees

| | |
|---|---|
| Toichi Takino | Representative Director,<br>President and Chief Operating Officer |
| Masaki Itoh | Corporate Executive Officer /<br>Chief Officer of Finance & Accounting Division |
| Tatsuya Okamoto | Corporate Officer /<br>Executive Vice President, Clinical Development |
| Hirokazu Kitada | Corporate Officer /<br>Executive Vice President, Sales and Marketing |

# Agenda

## FY2026 Q2 Financial Results (16:30-16:55)

**Toichi Takino** — Representative Director, President and Chief Operating Officer

## Pipeline Progress Status (16:55-17:15)

**Tatsuya Okamoto** — Corporate Officer / Executive Vice President, Clinical Development

## Q&A Session (17:15-17:45)

# FY2026Q2 Financial Results

# Key Points

**FY2026Q2 results showed lower revenue but higher profit.**

| | |
|---|---|
| **FY2026Q2 Sales Revenue** | **Revenue decreased by 24.6 JPY billion (9.6%) YoY to 232.5 JPY billion**<br>Japan: Revenue declined due to the termination of the FORXIGA co-promotion agreement.<br>Overseas: Sales of QINLOCK and ROMVIMZA and royalty income continued to grow steadily. |
| **FY2026Q2 Core Profit for the Period** | **Core operating profit increased by 3.6 JPY billion (5.1%) YoY to 73.6 JPY billion, and core profit for the period rose by 2.9 JPY billion (5.5%) YoY to 56.8 JPY billion.**<br>Profit increased due to steady growth in royalty income and overseas products sales, despite the termination of the FORXIGA co-promotion agreement. |
| **FY2026 Financial Forecast** | **No revision to the full-year forecast. Revenue and Profit are expected to decline YoY.**<br>Revenue is expected to be 455.0 JPY bn (-11.8% YoY), mainly due to the termination of the co-promotion agreement with AstraZeneca for FORXIGA. Core operating profit is expected to be 124.0 JPY bn (-9.6 % YoY), reflecting lower revenue and continued R&D investment at approximately 30% of revenue for future growth. |
| **New product R&D topics** | XCOPRI(cenobamate): Approved in Japan.<br>Licensing : Entered into a license agreement with Biohaven(US) for IgG degrader in Japan, South Korea, Taiwan and ASEAN.<br>ONO-1110 : Obtained positive Phase 2 data in three pain indications. |

# FY2026Q2 : Sales Revenue

## Revenue

**232.5 JPY bn**

YoY -24.6 JPY bn (-9.6%)



### Goods and Products Sales

**136.1 JPY bn**

YoY -38.8 JPY bn (-22.2%)



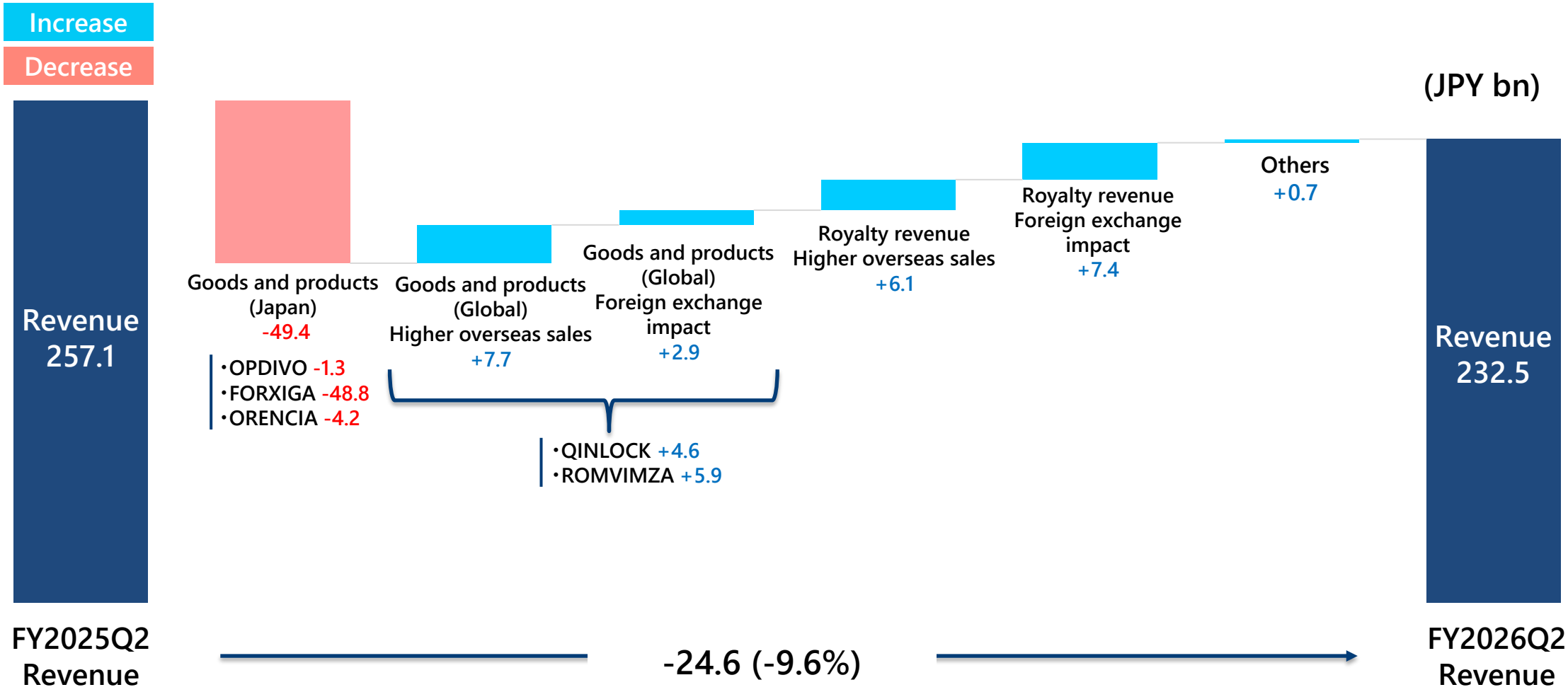
### Royalty and Others

**96.4 JPY bn**

YoY +14.2 JPY bn (+17.3%)

# FY2026Q2 : Sales Revenue (Breakdown)

**Revenue declined by 24.6 JPY billion to 232.5 JPY billion YoY, primarily due to the loss of FORXIGA sales after the co-promotion agreement terminated, despite growth in OPDIVO royalties and Deciphera-related revenue.**



# FY2026Q2: Sales Revenue by Product / Japan

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Goods and products | 175.0 | 136.1 | -38.8 | -22.2% | 270.0 |
| Royalty and others | 82.2 | 96.4 | 14.2 | 17.3% | 185.0 |

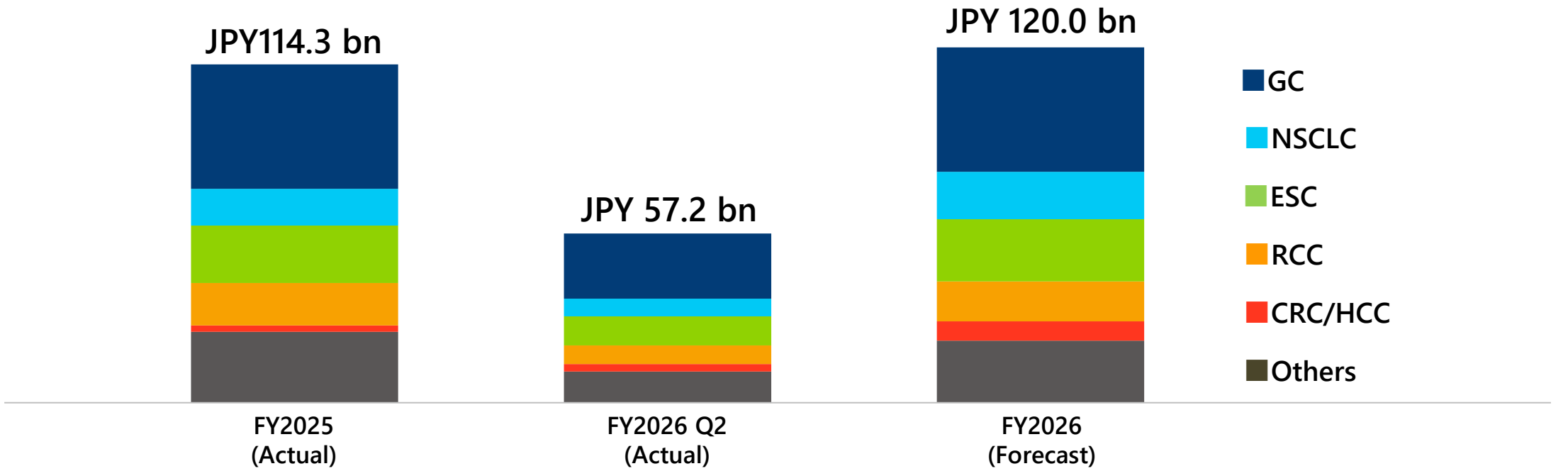
| Goods and Products (Japan) | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| OPDIVO Intravenous Infusion | 58.5 | 57.2 | -1.3 | -2.3% | 120.0 |
| ORENCIA for Subcutaneous Injection | 13.8 | 9.6 | -4.2 | -30.5% | 19.0 |
| VELEXBRU Tablets | 6.0 | 6.1 | 0.1 | 1.6% | 12.0 |
| PARSABIV Intravenous Injection | 4.5 | 5.0 | 0.5 | 11.3% | 10.0 |
| ONGENTYS Tablets | 4.5 | 5.2 | 0.8 | 17.0% | 10.0 |
| GLACTIV Tablets | 6.9 | 6.2 | -0.7 | -10.1% | 9.5 |
| BRAFTOVI Capsules | 2.7 | 4.0 | 1.3 | 50.1% | 8.5 |
| KYPROLIS for Intravenous Infusion | 4.0 | 3.5 | -0.5 | -12.3% | 7.0 |

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

# OPDIVO Sales Trend by Each Cancer

## Progress Status of Key Indications

| | |
|---|---|
| ●GC | : Progressed in line with plan despite impact of competing products. |
| ●NSCLC | : Remains below plan; commercial activities are being reinforced. |
| ●ESC | : Progressed in line with plan despite the entry of a competing product. |
| ●CRC | : Remains slightly below plan; further growth in new prescriptions is expected following guideline revisions. |
| ●HCC | : Remains slightly below plan; further growth in new prescriptions is expected as AE management practices become more widely adopted. |



# FY2026Q2 : Sales Revenue by Product / Overseas / Royalty

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Goods and products | 175.0 | 136.1 | -38.8 | -22.2% | 270.0 |
| Royalty and others | 82.2 | 96.4 | 14.2 | 17.3% | 185.0 |

| Goods and Products (Overseas) | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| QINLOCK® | 18.1 | 22.8 | 4.6 | 25.6% | 43.0 |
| ROMVIMZA® | 2.8 | 8.7 | 5.9 | 215.8% | 19.0 |
| OPDIVO® | 7.2 | 7.2 | -0.0 | -0.3% | 13.0 |

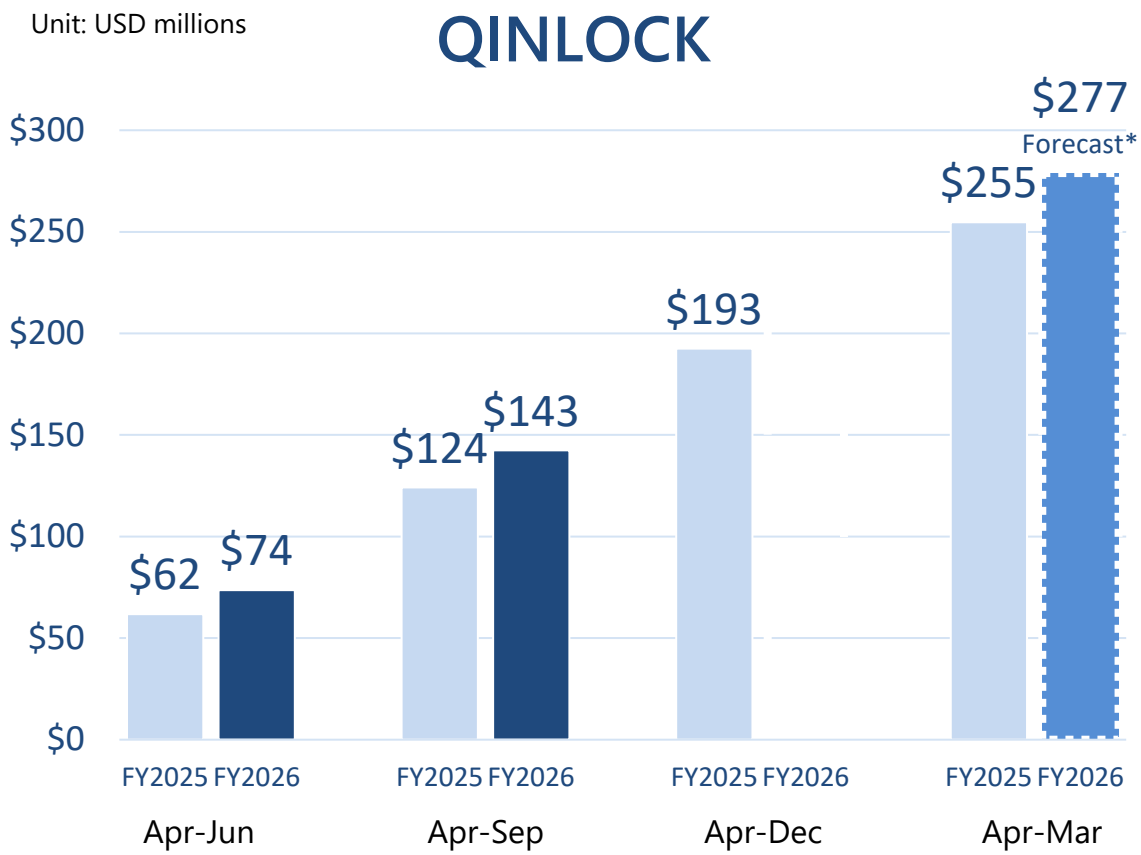
| Royalty and others | FY2025Q2 | FY2026Q2 | YoY | | |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| OPDIVO® | 59.4 | 69.1 | 9.7 | 16.3% | |
| KEYTRUDA® | 13.8 | 16.1 | 2.3 | 16.8% | |

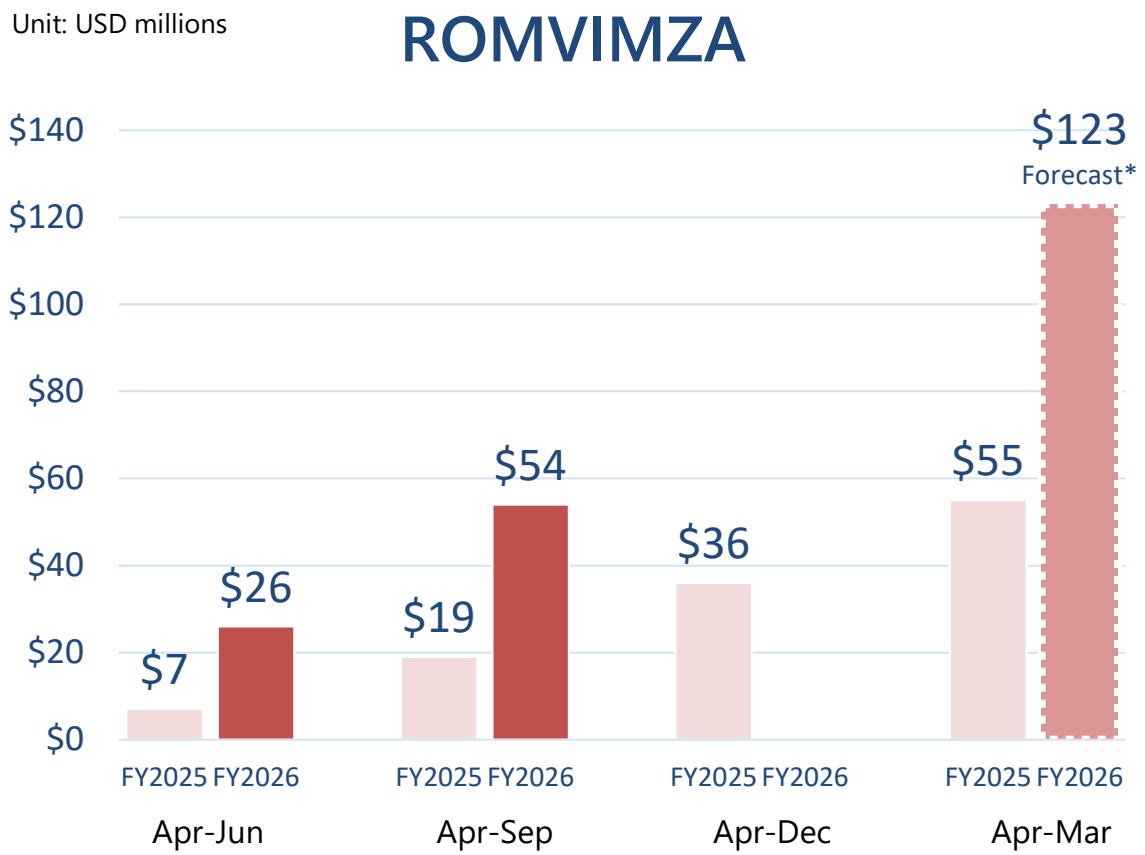
* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

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

# Sales Progress of QINLOCK and ROMVIMZA (USD Basis)

Both products grew compared to the last year and progressed as scheduled compared to the initial announcement.




*FY2026 Full-year forecast converted at an exchange rate of JPY 155/USD:
Qinlock JPY43.0 billion and ROMVIMZA JPY19.0 billion

# FY2026Q2 : Core Operating Profit

## Core Operating Profit
## 73.6 JPY bn
YoY +3.6 JPY bn
(+5.1%)

**Revenue 232.5 JPY bn**
YoY -24.6 JPY bn (-9.6%)

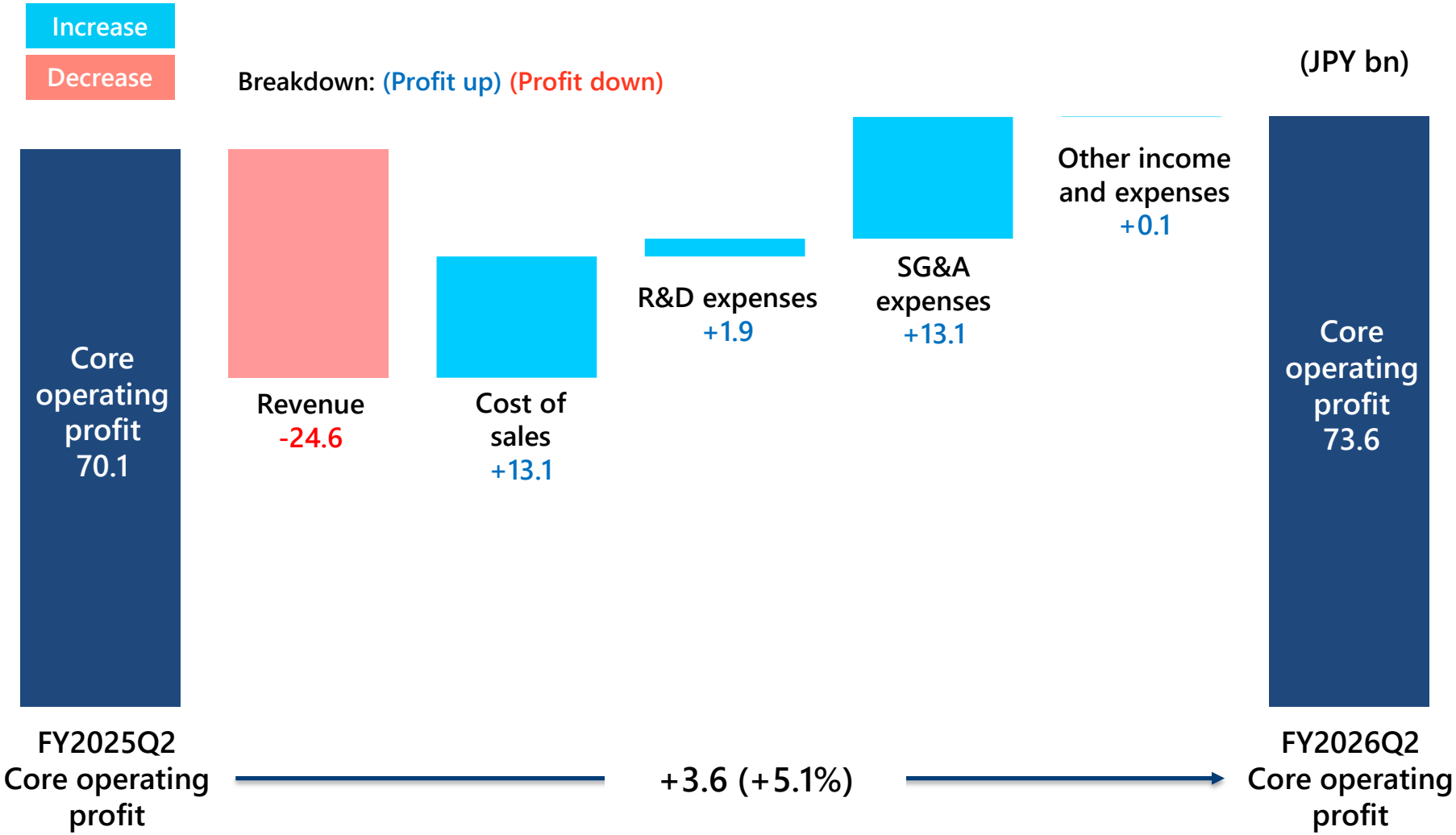
**Cost of Sales 41.7 JPY bn**
YoY -13.1 JPY bn (-23.8%)

**R&D Expense 69.1 JPY bn**
YoY -1.9 JPY bn (-2.7%)

**SG&A Expense 47.9 JPY bn**
YoY -13.1 JPY bn (-21.5%)

# FY2026Q2 : Core Operating Profit (Breakdown)

Core operating profit increased by 3.6 JPY billion YoY to 73.6 JPY billion, driven by the absence of FORXIGA sales-related expenses following the termination of the co-promotion agreement and ongoing cost-efficiency initiatives.




## YoY Breakdown

### Sales revenue

Main reason
- Goods and products : -38.8
- Royalty and others : +14.2

### Cost of sales

Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

### R&D expenses

Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

### SG&A expenses

Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

# FY2026Q2 : Financial Overview (Core)

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Cost of sales | 54.8 | 41.7 | -13.1 | -23.8% | 84.0 |
| R&D expenses | 71.0 | 69.1 | -1.9 | -2.7% | 143.0 |
| SG&A expenses | 61.1 | 47.9 | -13.1 | -21.5% | 101.0 |
| Core operating profit | 70.1 | 73.6 | 3.6 | 5.1% | 124.0 |
| Core profit before tax | 70.7 | 74.1 | 3.4 | 4.9% | 124.0 |
| Core profit for the period (attributable to owners of the Company) | 53.8 | 56.8 | 2.9 | 5.5% | 93.0 |

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

## YoY Breakdown

### Cost of sales -13.1 JPY bn (-23.8%)

COGS ratio : 17.9%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

### R&D expenses -1.9 JPY bn (-2.7%)

R&D ratio：29.7%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

### SG&A expenses -13.1 JPY bn (-21.5%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

### Core operating profit ratio : 31.7%

# (Ref) FY2026Q2 : Financial Overview (Full Basis)

| JPY bn | FY2025Q2 | FY2026Q2 | YoY | | FY2026 Forecast* |
|---|---|---|---|---|---|
| | | | Change | Change(%) | |
| Revenue | 257.1 | 232.5 | -24.6 | -9.6% | 455.0 |
| Cost of sales | 72.0 | 57.4 | -14.5 | -20.2% | 114.0 |
| R&D expenses | 71.0 | 69.1 | -1.9 | -2.7% | 143.0 |
| SG&A expenses | 61.2 | 47.9 | -13.2 | -21.7% | 101.0 |
| Operating profit | 52.1 | 57.9 | 5.8 | 11.2% | 94.0 |
| Profit before tax | 52.2 | 58.4 | 6.2 | 12.0% | 94.0 |
| Profit for the period (attributable to owners of the Company) | 40.1 | 44.9 | 4.8 | 12.1% | 71.0 |

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

## YoY Breakdown

### Cost of sales -14.5JPY bn (-20.2%)

COGS ratio : 24.7%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

### R&D expenses -1.9 JPY bn (-2.7%)

R&D ratio : 29.7%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

### SG&A expenses -13.2 JPY bn (-21.7%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

### Operating profit ratio : 24.9%

# (Ref) FY2026Q2 : Reconciliation from Full to Core Basis

| JPY bn | IFRS (Full) basis | Adjustment | | | | Core basis |
|---|---|---|---|---|---|---|
| | | Amortization | Impairment loss | Others | Total | |
| Revenue | 232.5 | | | | | 232.5 |
| Cost of sales | 57.4 | -12.0 | | -3.7 | -15.7 | 41.7 |
| Gross profit | 175.1 | +12.0 | – | +3.7 | +15.7 | 190.8 |
| R&D expenses | 69.1 | | | | – | 69.1 |
| SG&A expenses | 47.9 | | | | – | 47.9 |
| Other income /expenses (- Exp) | -0.1 | | | | – | -0.1 |
| Operating profit | 57.9 | +12.0 | – | +3.7 | +15.7 | 73.6 |
| Operating profit ratio | 24.9% | | | | – | 31.7% |
| Finance income / Finance cost (- Exp) | 0.5 | | | -0.0 | -0.0 | 0.5 |
| Profit before tax | 58.4 | +12.0 | – | +3.7 | +15.7 | 74.1 |
| Income tax expense | 13.4 | +3.0 | | +0.9 | +3.9 | 17.2 |
| Profit for the period | 44.9 | +9.1 | – | +2.8 | +11.8 | 56.8 |

## Breakdown

### Cost of sales

Main reason

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- Amortization expenses related to inventories from *PPA

### R&D expenses

Main reason

- None

### SG&A expenses and Other income&expense

Main reason

- None

*PPA : Purchase Price Allocation

# FY2026 Financial Forecasts

# FY2026 : Financial Forecast (Core / Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

| JPY bn | FY2025 Actual | FY2026 Forecast | Change | Change (%) |
|---|---|---|---|---|
| Revenue | 515.8 | 455.0 | -60.8 | -11.8% |
| Cost of sales | 107.0 | 84.0 | -23.0 | -21.5% |
| R&D expenses | 145.1 | 143.0 | -2.1 | -1.5% |
| SG&A expenses | 123.6 | 101.0 | -22.6 | -18.3% |
| Core operating profit | 137.1 | 124.0 | -13.1 | -9.6% |
| Core profit before tax | 138.3 | 124.0 | -14.3 | -10.3% |
| Income tax expense | 34.6 | 31.0 | -3.6 | -10.5% |
| Core profit for the year (attributable to owners of the Company) | 103.5 | 93.0 | -10.5 | -10.1% |

**Breakdown**

**Cost of sales -23.0 JPY bn (-21.5%)**

COGS ratio : 18.5%
Main reason

- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

**R&D expenses -2.1 JPY bn (-1.5%)**

R&D ratio: 31.4%
Main reason

- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

**SG&A expenses -22.6 JPY bn (-18.3%)**

SG&A ratio : 22.2%
Main reason

- The termination of co-promotion agreement for FORXIGA Tablets

**Core operating profit ratio : 27.3%**

* The exchange rate assumed in the financial forecast is ¥155 per US dollar.

# FY2026 : Financial Forecast (Full / Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

| JPY bn | FY2025 Actual | FY2026 Forecast | Change | Change (%) |
|---|---|---|---|---|
| Revenue | 515.8 | 455.0 | -60.8 | -11.8% |
| Cost of sales | 141.7 | 114.0 | -27.7 | -19.6% |
| R&D expenses | 147.0 | 143.0 | -4.0 | -2.7% |
| SG&A expenses | 123.7 | 101.0 | -22.7 | -18.3% |
| Operating profit | 92.2 | 94.0 | 1.8 | 1.9% |
| Profit before tax | 92.7 | 94.0 | 1.3 | 1.5% |
| Income tax expense | 22.7 | 23.0 | 0.3 | 1.1% |
| Profit for the year (attributable to owners of the Company) | 69.8 | 71.0 | 1.2 | 1.8% |

## Breakdown

### Cost of sales -27.7 JPY bn (-19.6%)

COGS ratio : 25.1%
Main reason

- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

### R&D expenses -4.0 JPY bn (-2.7%)

R&D ratio: 31.4%
Main reason

- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

### SG&A expenses -22.7 JPY bn (-18.3%)

SG&A ratio : 22.2%
Main reason

- The termination of co-promotion agreement for FORXIGA Tablets

### Operating profit ratio : 20.7%

* The exchange rate assumed in the financial forecast is 155 yen per US dollar.
For the second half of the fiscal year, the sensitivity to exchange rates is assumed to be an increase of 0.8 billion yen in revenue and an increase of 0.2 billion yen in operating profit for every 1-yen depreciation of the yen.

# New product / R&D topics

# Unmet Needs in Epilepsy Care and the Mechanism of Action of Xcopri®

- Patients with persistent seizures despite current therapy need a new option that offers the potential for seizure freedom

## Current Landscape and Unmet Needs in Epilepsy Care

People with Epilepsy in Japan **~1 Million**

Patients with Uncontrolled Seizures **~30%**

Adapted from Chen Z et al. JAMA Neurol. 2018;75(3):279-286

## Patient Perspectives and Concerns

**Patients Who Consider Seizure Freedom Essential for Good Quality of Life**

**75.7%**

**Anxiety, Fear, and Limitations on Daily Life Due to Persistent Seizures**



Anxiety



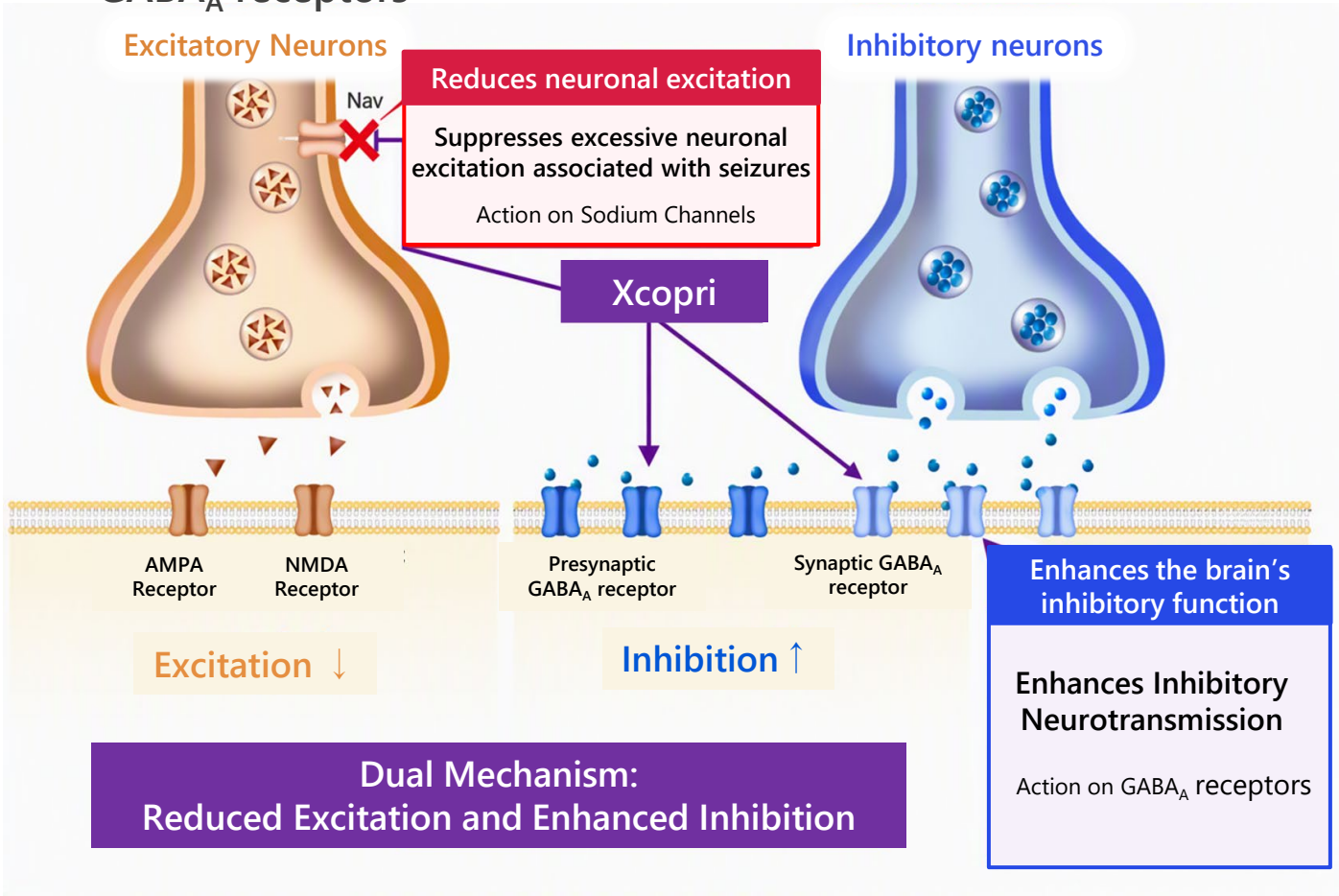
Fear



Limitations on Daily Life

Adapted from Mecarelli O et al. Epilepsy Behav. 2022;137(Pt A):108950
Adapted from Penovich PE et al. Neurol Clin Pract. 2021;11(5):377-384

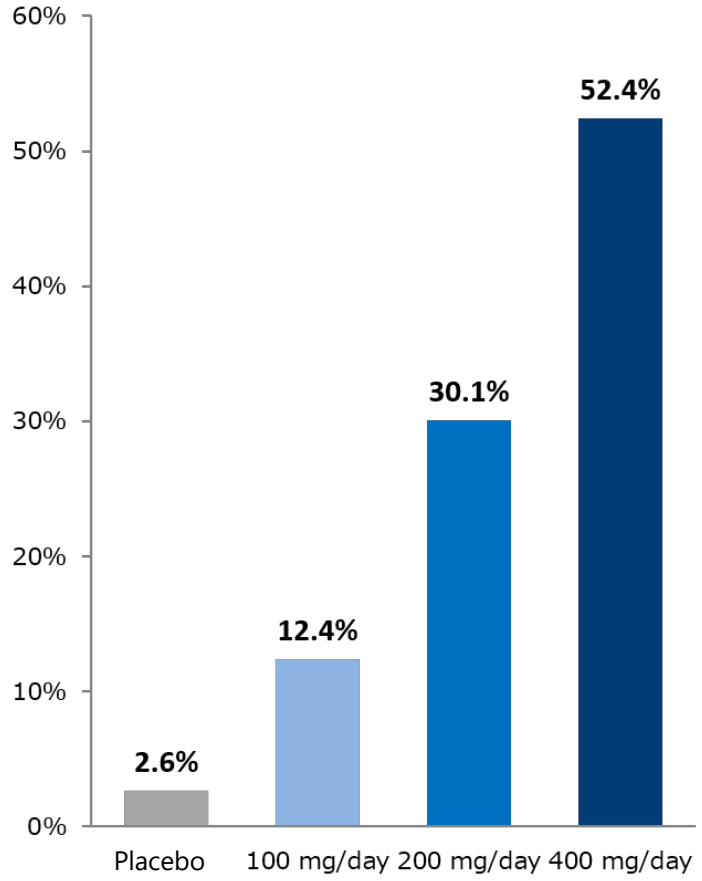
- Suppresses neuronal hyperexcitability through voltage-gated sodium channel inhibition and positive allosteric modulation of $GABA_A$ receptors




Adapted from Ono Pharmaceutical internal data (Action on Sodium Channels), review data for regulatory approval
Adapted from Ono Pharmaceutical internal data (Action on GABAA Receptors), review data for regulatory approval
Adapted from Sharma R et al. Eur J Pharmacol., 2020; 879. 173117

# Xcopri® Global Phase 3 Study Results: Efficacy and Safety

## Efficacy (Seizure Freedom Rate)




## Safety (Major Adverse Drug Reactions)

| | Placebo | Cenobamate 100 mg/day | Cenobamate 200 mg/day | Cenobamate 400 mg/day |
|---|---|---|---|---|
| **Eye disorders** | | | | |
| Diplopia | 1.5 | 2.3 | 3.1 | 13.3 |
| **Gastrointestinal disorders** | | | | |
| Nausea | 2.3 | 2.3 | 1.5 | 8.6 |
| Vomiting | 0.8 | 2.3 | 0 | 10.2 |
| **Injury, poisoning, and procedural complications** | | | | |
| Fall | 0.8 | 0 | 5.4 | 3.1 |
| **Laboratory tests** | | | | |
| γ-glutamyl transferase increased | 6.2 | 7.0 | 13.1 | 16.4 |
| White blood cell count decreased | 2.3 | 1.6 | 6.9 | 2.3 |
| **Metabolism and nutrition disorders** | | | | |
| Decreased appetite | 0.8 | 1.6 | 3.1 | 7.0 |
| **Nervous system disorders** | | | | |
| Dizziness | 10.8 | 19.5 | 36.9 | 64.8 |
| Somnolence | 14.6 | 21.1 | 26.9 | 45.3 |
| Ataxia | 0 | 1.6 | 3.1 | 10.2 |
| Headache | 2.3 | 3.1 | 1.5 | 6.3 |

Ono Pharmaceutical internal data (Asian Phase 3 Study: YKP3089C035 [Double-Blind Period]), review data for regulatory approval

**Key Value Propositions**

**Patient Value**
Toward a Seizure-Free Daily Life

**Clinical Value**
Shifting the Treatment Goal Toward Seizure Freedom

**Business Value**
Providing a New Treatment Option to the Market

# IgG Degraders

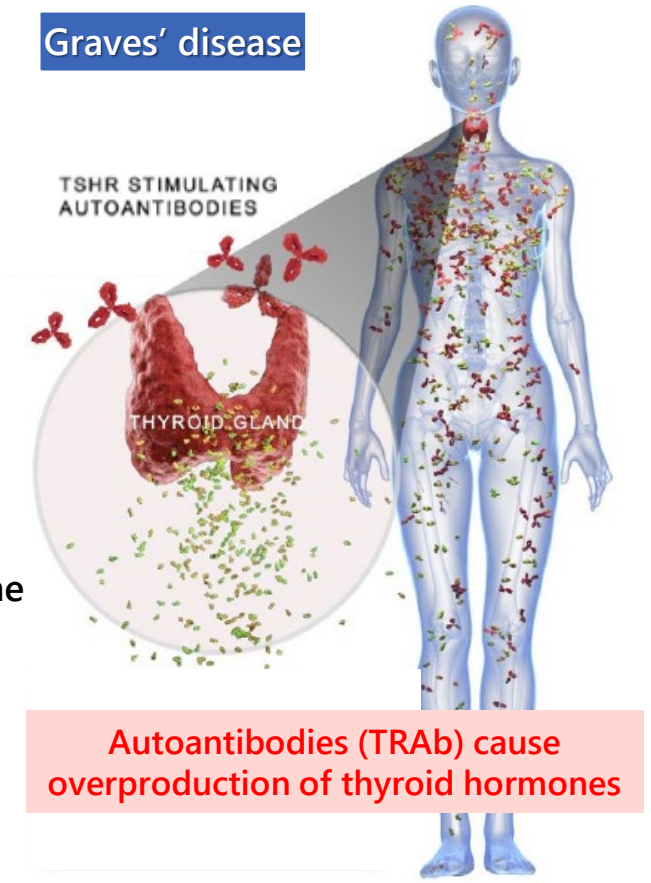
- Ono Pharmaceutical has entered into an exclusive license agreement with Biohaven to develop and commercialize the IgG degrader portfolio in Japan, South Korea, Taiwan, and ASEAN Countries
- IgG degraders are a new class of therapeutics designed to eliminate disease-causing autoantibodies
- BHV-1300, the most advanced program in the IgG degrader portfolio, is currently in global Phase 3 development for Graves' disease

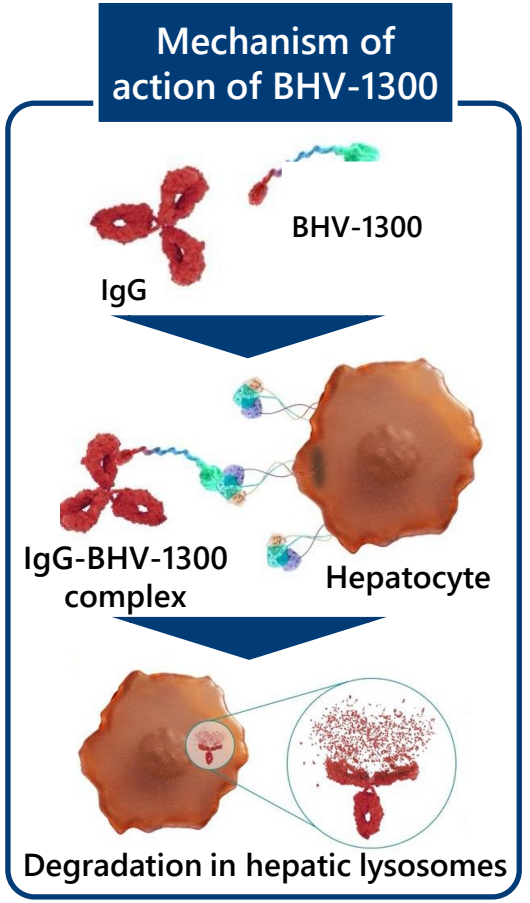
## Graves' disease

- An autoimmune disease caused by autoantibodies (TRAb*), which lead to overproduction of thyroid hormones
- Common symptoms include palpitations, shortness of breath, weight loss, and thyroid eye disease, that negatively impact the patients' QoL
- No approved treatments that target the underlying cause of Graves' disease
- Reported prevalence in Japan: 0.2-3.2 cases/1,000 people[1)]

## BHV-1300

- A new class of therapeutics designed to selectively eliminate the major IgG subclasses, IgG1, IgG2, and IgG4
- In the Phase 1 study in patients with Graves' disease, BHV-1300 has demonstrated reductions in TRAb and normalization of thyroid hormones
- A global Phase 3 study for Graves' disease currently ongoing




*Thyroid Stimulating Hormone Receptor Antibodies

1) https://www.j-endo.jp/modules/patient/index.php?content_id=40

Awsare B, et al. Presentation at American Thyroid Association Annual Meeting. Scottsdale, AZ, September 10–14, 2025

# ONO-4578

## Overview

### Target Indication

**Gastric Cancer 1L**

HER2-negative/PD-L1-positive (CPS≥1)

### Mechanism of Action

**PG receptor (EP4) antagonist / Oral**

## Disease Characteristics

- Annual cases: ~980K worldwide[1]/~143K in Japan[2]
- Annual deaths: ~642K worldwide[1]/ ~51K in Japan[2]
- In Japan, gastric cancer ranks second for incidence after colorectal caner and third for deaths after lung and colorectal cancers.
- PD-L1-positive (CPS≥1): ~80% of HER2-negative gastric cancers[3].

## Phase 3 Study

| Study Start (Estimated) | Primary Completion (Estimated) | |
|---|---|---|
| 2027 Feb. | 2031 Jan. | Chemo-naïve advanced or metastatic gastric cancer HER2-negative/PD-L1-positive (CPS≥1) |

Enrollment

600

RND 1:1

- ONO-4578 + nivolumab + chemotherapy
- Placebo + nivolumab + chemotherapy

Treatment continues until disease progression, unacceptable toxicity, death, investigator decision, or withdrawal of consent.

### Primary Endpoint

- Overall Survival (OS)
- Progression-Free Survival (PFS)

### Secondary Endpoint

- PFS and PFS2 per Investigator Assessment
- Objective Response Rate (ORR)
- Duration of Response (DOR)
- Disease Control Rate (DCR)
- Time to Response (TTR) per BICR

References：
1) Globocan 2024: Stomach Cancer, World, World Health Organization Available at: https://gco.iarc.who.int/media/globocan/factsheets/populations/900-world-fact-sheet.pdf
2) Globocan 2024: Stomach Cancer, Japan, World Health Organization Available at: https://gco.iarc.who.int/media/globocan/factsheets/populations/392-japan-fact-sheet.pdf
3) James Yu and Rutika Mehta. Journal of the National Comprehensive Cancer Network; 2025:23:5

# ONO-2808

## Overview

### Target Indication

**Multiple System Atrophy (MSA)**

MSA-P: Parkinsonian Multiple System Atrophy

### Mechanism of Action

**Sphingosine 1-phosphate receptor 5 (S1P5) agonist / Oral**

## Disease Characteristics

- **Progressive neurodegenerative disease characterized by autonomic dysfunction, parkinsonism, and cerebellar ataxia.**
- **The number of Patients** (estimated in 2019)**:**
  15K-50K in US[1] /~10K in Japan[2]
- **MSA Type**
  - **MSA-P：Parkinsonian type**
    ~70% of cases in Europe and the US[3]
  - **MSA-C：Cerebellar type**
    ~70% of cases in Asia[3]

## Phase 3 Study

| Study Start (Estimated) | Primary Completion (Estimated) | |
|---|---|---|
| **2027 Jan.** | **2029 Oct.** | Participants with MSA-P who meet all eligibility criteria |

Enrollment

**486**

RND 1:1:1

- **ONO-2808 high dose · QD · 48 weeks**
- **ONO-2808 low dose · QD · 48 weeks**
- **Placebo · QD · 48 weeks**

4-week safety follow-up after treatment

## Primary Endpoint

**Change from Baseline in:**

- mUMSARS Part I (excluding Item 11) with Collapsed Scoring (0-3)

## Secondary Endpoint

**Change from Baseline in:**

- **MSA-QoL (Motor subscale / Total) Score**
- **MRI Volumetric Assessments**
- **Total UMSARS Score (Part I and II, all items)**
- **mUMSARS Score**
- **PGI-C (Patient Global Impression of Change) Score**
- **PGI-S (Patient Global Impression of Severity) Score**
- **CGI-C (Clinical Global Impression of Change) Score**
- **CGI-S (Clinical Global Impression of Severity) Score**

References:

1 National Institutes of Health: https://www.ninds.nih.gov/health-information/disorders/multiple-system-atrophy

2 Japan Intractable Diseases Information Center (in Japanese): https://www.nanbyou.or.jp/entry/59, 3 Tetsutaro OZAWA, Osamu ONODERA, et al, Proc. Jpn. Acad., Ser. B 93, 2017

# Tirabrutinib | PCNSL TREATMENT

## DISEASE OVERVIEW

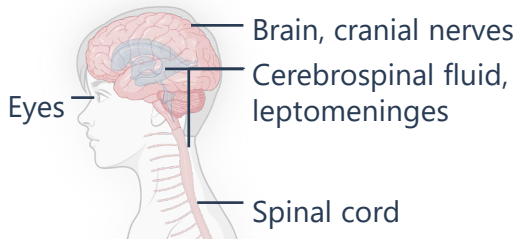
PCNSL accounts for **2%-4%** of all CNS tumors[1,2]

Approximately **75%-95%** of all PCNSL are DLBCL[3,4]

- The remaining cases involve T-cell lymphoma and other B-cell lymphomas[3,4]

PCNSL is mostly confined in the **brain**

- Other sites include the **eyes, leptomeninges, and spinal cord**[4–6]




figure：BioRender.com

## Current US Treatment Landscape

*Annual Incidence: ~1,900 patients*

**1L Treatment**

**Treatment Initiation**

**HD-MTX ± RTX ± TMZ**

**Consolidation:**

| HD-MTX + ASCT | Other Chemo | RD-WBRT |
|---|---|---|

**R/R Treatment**

**HD-MTX retreatment + ASCT + CAR-T cell therapy** | **Non-intensive chemotherapy[7]**

~20%

R/R PCNSL patients receiving retreatments intensive chemotherapy

Lower Potential for Tirabrutinib Use

~80%

R/R PCNSL patients receiving treatments other than intensive chemotherapy[8]

**Higher Potential for Tirabrutinib Use**


1)Hoffman S, et al. Neuro Oncol. 2006;8(1):27-37.
2)Price M, et al. Neuro Oncol. 2024;26(Suppl 6):vi1-85.
3) Wu J, et al. Ther Adv Hematol. 2024;14:20406207241259010.
4)Lv C, et al. Ther Adv Hematol. 2022;13:20406207211066166.
5) Ferreri AJM, et al. Ann Oncol. 2024;35(6):491-507.
6) Hoang-Xuan K, et al. Neuro Oncol. 2023;25(1):37-53.

7)Other includes BTK inhibitors, combo chemo, BSC, investigational agents
8Percentages based on Collective Acumen Quantitative Research (N=78 Oncologists, N=176 Patient Charts) in 2L

# Development Pipeline Progress Status

# Launch Projections - POC Pipeline

As of October 29, 2026

| | FY2026 | FY2027 | FY2028 | FY2029 | FY2030 onward |
|---|---|---|---|---|---|
| US & EU | VELEXBRU R/R PCNSL | QINLOCK® GIST 2L KIT Exon 11+17/18 | | | Global (including Japan): Sapablursen Polycythemia vera; ONO-1110 Peripheral neuropathic pain; ONO-2808 Multiple system atrophy; ONO-1110 Interstitial cystitis / Bladder pain syndrome; ONO-4578 Gastric cancer 1L (with OPDIVO) |
| Japan | XCOPRI® Focal seizures | OPDIVO Anaplastic thyroid cancer | QINLOCK® GIST 2L KIT Exon 11+17/18 | Gel-One® Osteoarthritis | OPDIVO Subcutaneous formulation |
| | QINLOCK® GIST 4L | | VELEXBRU Pemphigus 2L | BHV-1300 Graves' disease | Povetacicept Membranous nephropathy |
| | VELEXBRU R/R SCNSL | | Povetacicept IgA nephropathy | XCOPRI® Pediatric focal seizures / Tonic-clonic seizures | ROMVIMZA® Tenosynovial giant cell tumor |

PCNSL: Primary central nervous system lymphoma
SCNSL: Secondary central nervous system lymphoma
GIST: Gastrointestinal stromal tumor

Approved　Filed / preparing to file　Update after Q1 FY2026 in July

# Development pipeline (Oncology) ①

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| ONO-4059 (tirabrutinib)<br>BTK inhibitor | PCNSL 1L, ≥2L | ■ | ■ | ■ | ■ | ■ | | 2026.2 US : Filed (Part A) | US | NCT04947319 |
| | SCNSL | ■ | ■ | ■ | ■ | ■ | | 2026.6 JP : Filed | JP | jRCT2031220529 |
| | PCNSL ≥2L (confirmatory Study) | ■ | ■ | ■ | ■ | | | FY2027<br>Primary Completion | US | NCT07104032 |
| QINLOCK<br>DCC-2618 (ripretinib) KIT inhibitor | GIST 2L KIT Exon 11+17/18 | ■ | ■ | ■ | ■ | | | FY2027<br>Primary Completion | US, EU, KR, TW and others | NCT05734105 |
| | GIST 4L | ■ | | | | | | FY2027<br>Primary Completion | JP | NCT07618377 |
| ONO-0530 (sapablursen)<br>Antisense oligonucleotide targeting TMPRSS6 | Polycythemia vera (PV) | ■ | ■ | ■ | ■ | | | FY2028<br>Primary Completion | JP, US, EU, KR, TW and others | NCT07429266 |
| ONO-4578 PG receptor (EP4) antagonist | Gastric cancer* | ■ | ■ | ■ | ■ | | | FY2030<br>Primary Completion | JP, US, EU, KR, TW and others | NCT07818070 |
| | Colorectal cancer* | ■ | ■ | ■ | | | | FY2027<br>Primary Completion | JP, US, EU and others | NCT06948448 |
| ONO-4482 (relatlimab) Anti-LAG-3 antibody | Melanoma* | ■ | ■ | | | | | FY2024<br>Primary Completion (Actual) | JP, US, EU and others | NCT01968109 |
| ONO-7427 Anti-CCR8 antibody | Solid tumor* | ■ | ■ | | | | | FY2031<br>Primary Completion | JP, US, EU and others★1 | NCT04895709 |
| DCC-3116 (inlexisertib) ULK inhibitor | Advanced malignancies (with ripretinib) | ■ | ■ | | | | | FY2026<br>Primary Completion | US, EU | NCT05957367 |

PCNSL: Primary central nervous system lymphoma
SCNSL: Relapsed or refractory secondary central nervous system lymphoma
GIST: Gastrointestinal Stromal Tumor

MOA : Mode of Action
* : Combination with OPDIVO

★1 : Development right country: JP
Estimated study completion date shown in jRCT or ClinicaiTrials.gov

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

# Development pipeline (Oncology) ②

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| DCC-3009 Pan-KIT inhibitor | Gastrointestinal Stromal Tumor (GIST) | | | | | | | FY2028 Primary Completion | US | NCT06630234 |
| ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody | T-cell lymphoma | | | | | | | FY2027 Primary Completion | US | NCT05079282 |
| | | | | | | | | FY2028 Primary Completion | JP | NCT06547528 |
| ONO-8250 iPSC-derived HER2 CAR T-cell therapy | HER2-expressing solid tumor | | | | | | | FY2029 Primary Completion | US | NCT06241456 |
| ONO-7428 Anti-ONCOKINE-1 antibody | Solid tumor | | | | | | | FY2029 Primary Completion | JP | NCT06816108 |
| DCC-2812 GCN2 activator | Renal cell carcinoma, urothelial cancer, castration-resistant Prostate cancer | | | | | | | FY2028 Primary Completion | US | NCT06966024 |
| ONO-7429 Anti-L1CAM ADC | Solid tumor | | | | | | | FY2028 Primary Completion | JP | NCT07787208 |

MOA : Mode of Action

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

F : Filed, A : Approval

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

# Development pipeline (Non-oncology) ①

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| XCOPRI<br>ONO-2017 (cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel | Partial-onset seizures | | | | | | | FY2026.9 JP : Approval | JP, KR and others★1 | NCT04557085 |
| | Partial-onset seizures (pediatric) | | | | | | | FY2027 Primary Completion | JP | NCT07594158 |
| | Primary generalized tonic-clonic seizures | | | | | | | FY2026 Primary Completion | JP | NCT06579573 |
| VELEXBRU Tablet<br>(ONO-4059: tirabrutinib) BTK inhibitor | Pemphigus | | | | | | | FY2027 Primary Completion | JP | NCT06696716 |
| ONO-8531 (povetacicept)<br>BAFF/APRIL dual antagonist | IgA nephropathy | | | | | | | FY2027 Primary Completion | JP, US, EU, KR, TW and others★2 | NCT06564142 |
| | Primary membranous nephropathy | | | | ★3 | | | FY2028 Primary Completion | US, EU, KR and others★2 | NCT07204275 |
| ONO-5532 (Gel-One)<br>Cross-linked hyaluronate | Knee osteoarthritis | | | | | | | FY2027 Completion | JP | jRCT2031240621 |
| | Hip osteoarthritis | | | | | | | FY2027 Completion | JP | jRCT2061240110 |
| ONO-2808 S1P5 receptor agonist | Multiple system atrophy (MSA) | | | | | | | FY2029 Primary Completion | JP, US, EU and others | NCT07825402 |
| BHV-1300 IgG Degrader | Graves' disease | | | | | | | FY2027 Primary Completion | US and others★4 | NCT07661056 |
| ROMVIMZA<br>DCC-3014 (vimseltinib) CSF-1R inhibitor | Tenosynovial giant cell tumor (TGCT) | | | | | | | FY2028 Primary Completion | JP | NCT07832747 |
| | Chronic graft versus host disease (cGVHD) | | | | | | | FY2029 Primary Completion | US | NCT06619561 |

F : Filed, A : Approval EU : European countries

★1 : Development right country: JP, ★2 : Development rights countries: JP, KR ★3 : P Ⅱb/Ⅲ, ★4 : Development rights countries: JP, KR, TW, ASEAN
MOA : Mode of Action Estimated study completion date shown in jRCT or ClinicalTrials.gov

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

# Development pipeline (Non-oncology) ②

As of October 29, 2026

| Code (Generic name) MOA, Modality | Target Indication | PI | PI/II | PII | PIII | F | A | Status | Area | ID |
|---|---|---|---|---|---|---|---|---|---|---|
| ONO-1110 Endocannabinoid regulation | Postherpetic neuralgia | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06708416 |
| | Fibromyalgia | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06752590 |
| | Hunner type interstitial cystitis | | | | | | | FY2026 Primary Completion (Actual) | JP | NCT06752603 |
| ONO-2020 Epigenetic Regulation | Alzheimer's disease | | | | | | | FY2026 Primary Completion | JP, US | NCT06881836 |
| | Agitation associated with dementia due to Alzheimer's disease | | | | | | | FY2026 Primary Completion | JP | NCT06803823 |
| ONO-4915 PD-1 x CD19 bispecific antibody | Sjögren's disease | | | | | | | FY2028 Primary Completion | JP | NCT07823790 |
| ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody | Autoimmune disease | | | | | | | FY2024 Completion | JP | jRCT2071220081 |
| | | | | | | | | FY2024 Primary Completion (Actual) | EU | NCT05332704 |
| ONO-2416 | Psychiatric disease | | | | | | | FY2027 Completion | JP | jRCT2071250147 |
| ONO-3310 | Kidney disease | | | | | | | FY2027 Primary Completion | JP | NCT07619157 |
| ONO-6414 | Autoimmune disease | | | | | | | FY2027 Primary Completion | US | NCT07749768 |
| ONO-3401 | Neurological disease | | | | | | | FY2027 Completion | JP | jRCT2071260067 |

MOA : Mode of Action

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

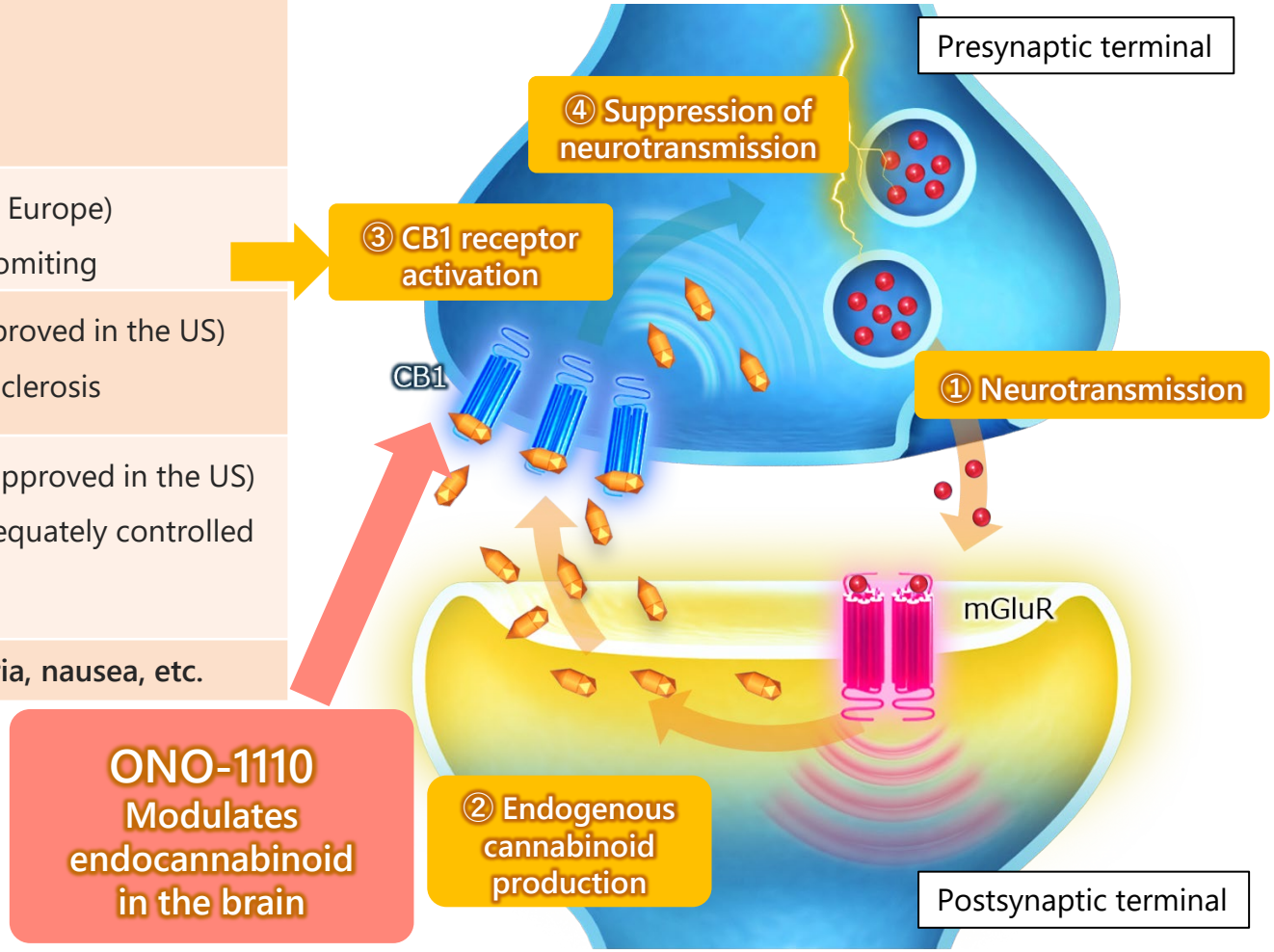
F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after Q1 FY2026 in July

# ONO-1110 MoA

| Approved drugs related to Δ9-THC | |
|---|---|
| **Dronabinol (Synthesized Δ9-THC)** | Marinol®/Syndros® (US Approved)<br>Refractory chemotherapy-induced nausea and vomiting / Loss of appetite with weight loss in AIDS patients |
| **Nabilon (Δ9-THC analog)** | Cesamet®/Canemes® (US, Canada, partially approved in Europe)<br>Refractory cancer chemotherapy-induced nausea and vomiting |
| **Nabiximorus (Plant-derived Δ9-THC + CBD)** | Sativex® (Canada, partially European, Australian, not approved in the US)<br>Moderate to severe spasticity associated with multiple sclerosis |
| **VER-01 (Standardized cannabis flower extract, Main ingredient: Δ9-THC)** | Exilby® (liquid) (approved in Germany and Austria, not approved in the US)<br>Chronic low back pain with a radicular component inadequately controlled by non-opioid analgesics |
| **Side effects: dizziness, drowsiness, disorientation, depressive mood, euphoria, nausea, etc.** | |

| Medical cannabis | |
|---|---|
| **Country Region** | US (some states), Canada, UK, Australia, and others |
| **Main uses** | Cancer chemotherapy-induced nausea and vomiting<br>Loss of appetite with weight loss in AIDS patients<br>Multiple sclerosis, chronic pain<br>Sleep disorders, anxiety disorders, depression, PTSD |



# Target Indications for Phase 2 Trials in Japan

## Chronic pain

### Neuropathic pain

Pain caused by nerve damage

- Postherpetic neuralgia (PHN)

### Nociceptive pain

Pain caused by nociceptor activation due to persistent inflammation or tissue damage

- Interstitial cystitis (IC)

- Fibromyalgia (FM)

### Nociplastic pain

Pain from altered pain perception or function without nerve or tissue damage

## Psychiatric disorders

### Depressive disorders

A condition characterized by a sad, empty, or irritable mood

- Major depressive disorder(MDD)

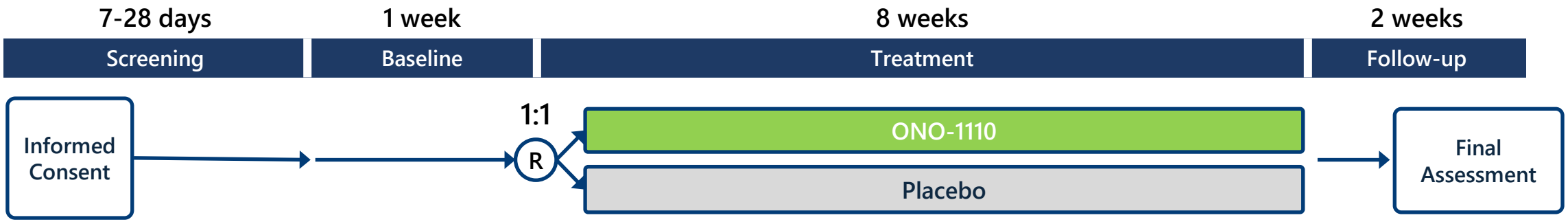
### Anxiety disorders

A condition characterized by excessive fear and anxiety and related behavioral disturbances

- Social anxiety disorder(SAD)

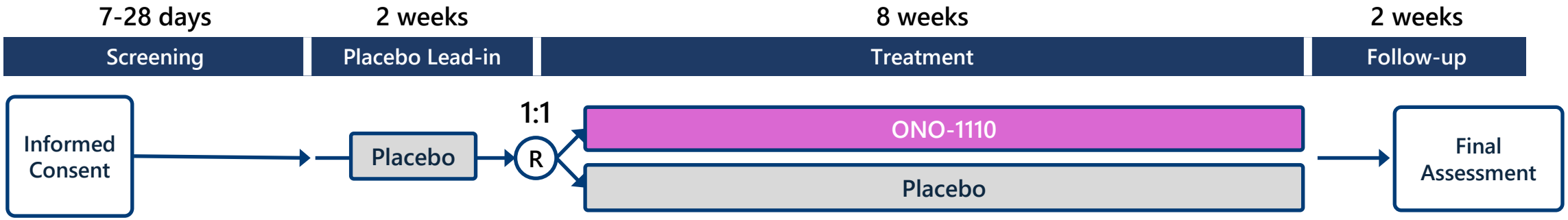
# Overview of ONO-1110-04 Study

| Phase 2a Trial of ONO-1110 in Patients with Postherpetic Neuralgia (ONO-1110-04 Study) | |
|---|---|
| **Objective** | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with postherpetic neuralgia |
| **Study Design** | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| **Patients** | Patients with moderate to severe postherpetic neuralgia |
| **Primary Outcome Measures** | Change in weekly mean of average pain score (NRS) from baseline to Week 8 of the treatment period |
| **Secondary Outcome Measures** | Changes from baseline in: weekly mean worst pain score (NRS), 30% and 50% responder rates, Brief Pain Inventory-Short Form (BPI-SF), Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2), Hospital Anxiety and Depression Scale (HADS), and Patient Global Impression of Change (PGIC); plasma ONO-1110 concentrations |
| **Exploratory Outcome Measures** | Quantitative sensory testing, frequency and amount of rescue medication use |
| **Safety Assessments** | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, Columbia-Suicide Severity Rating Scale (C-SSRS) |
| **Dose Regimen** | XXXXX |
| **Treatment Groups / Sample Size** | Total n=140 (ONO-1110: n=70; placebo: n=70) |
| **Study Schema** | Screening: 7-28 days; Baseline: 1 week; Treatment: 8 weeks; Follow-up: 2 weeks |
| **Study Period** | October 2024 - June 2026; 13-month enrollment period |



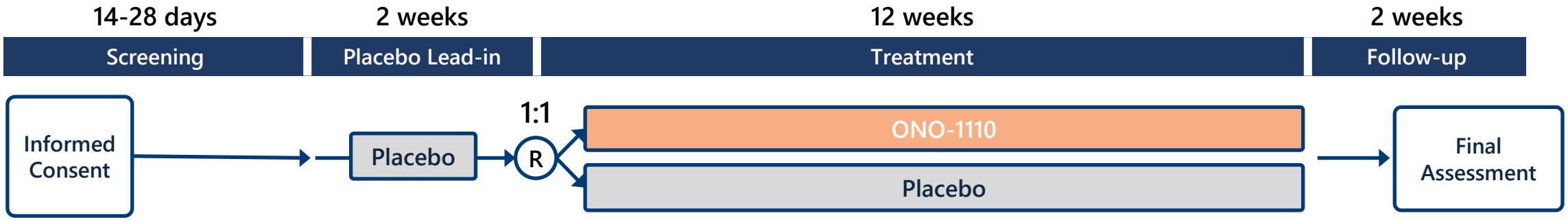
# Overview of ONO-1110-05 Study

| Phase 2a Trial of ONO-1110 in Patients with Fibromyalgia (ONO-1110-05 Study) | |
|---|---|
| **Objective** | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with fibromyalgia |
| **Study Design** | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| **Patients** | Patients with moderate to severe fibromyalgia |
| **Primary Outcome Measures** | Change in weekly mean of average pain score (NRS) from baseline to Week 8 of the treatment period |
| **Secondary Outcome Measures** | Changes from baseline in: weekly mean worst pain score (NRS), 30% and 50% responder rates, Widespread Pain Index (WPI), Symptom Severity Scale (SSS), Japanese version of the Revised Fibromyalgia Impact Questionnaire (JFIQR), PGIC, MOS Sleep Scale, and HADS; plasma ONO-1110 concentrations |
| **Exploratory Outcome Measures** | Quantitative sensory testing, tender point count, activity/sleep/pulse rate measurements, CVR-R, frequency and amount of rescue medication use |
| **Safety Assessments** | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, C-SSRS |
| **Dose Regimen** | XXXXX |
| **Treatment Groups / Sample Size** | Total n=160 (ONO-1110: n=80; placebo: n=80) |
| **Study Schema** | Screening: 7-28 days; Placebo lead-in: 2 weeks; Treatment: 8 weeks; Follow-up: 2 weeks |
| **Study Period** | November 2024 - May 2026; 13-month enrollment period |

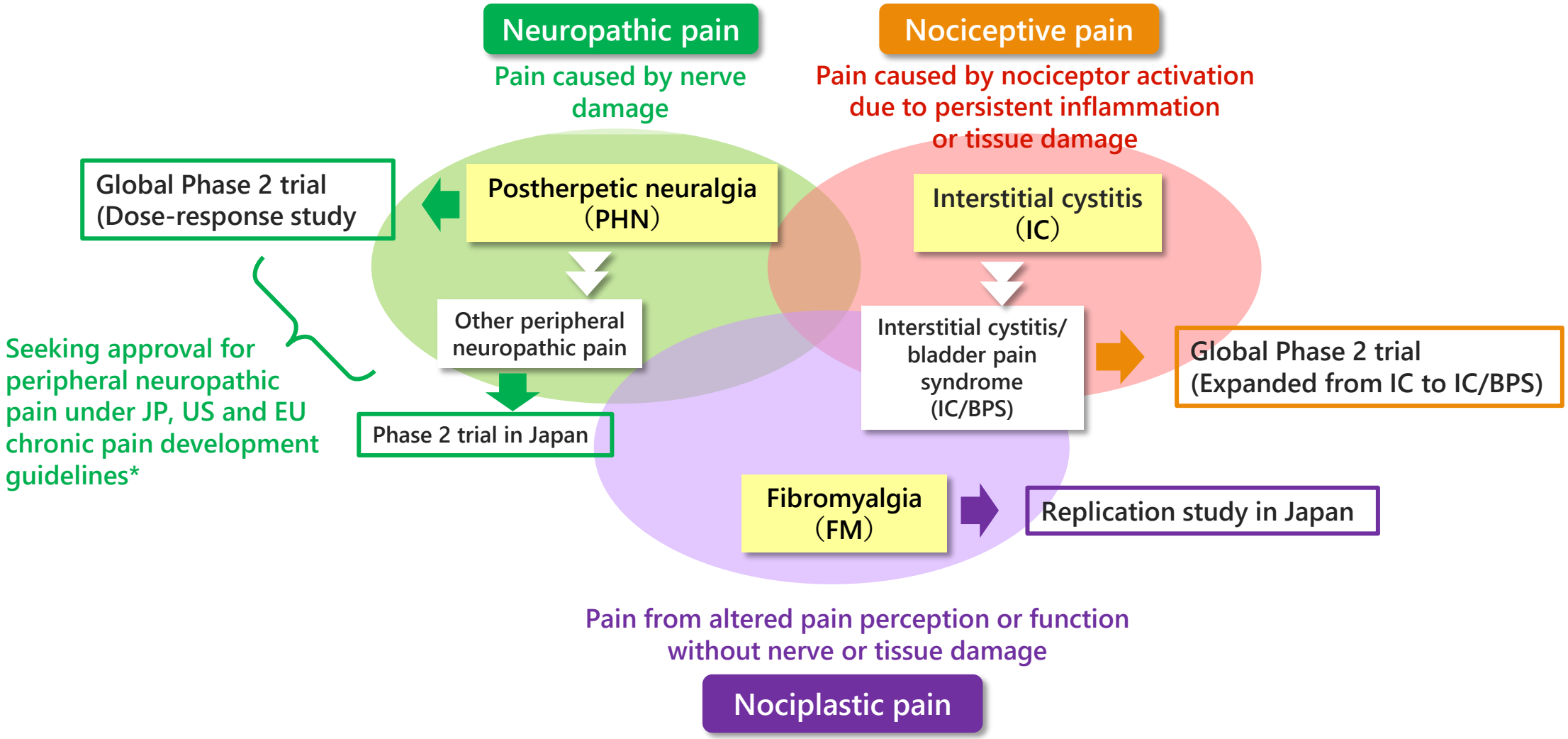


# Overview of ONO-1110-06 Study

| Phase 2a Trial of ONO-1110 in Patients with Hunner Type Interstitial Cystitis (ONO-1110-06 Study) | |
|---|---|
| **Objective** | To evaluate the efficacy and safety of ONO-1110 in Japanese patients with Hunner type interstitial cystitis |
| **Study Design** | Randomized, double-blind, placebo-controlled, parallel group, multi-center trial |
| **Patients** | Patients with moderate to severe Hunner type interstitial cystitis |
| **Primary Outcome Measures** | Change in weekly mean of average pain score (NRS) from baseline to Week 12 of the treatment period |
| **Secondary Outcome Measures** | Changes from baseline in: Weekly mean worst pain score (NRS), 30% and 50% responder rates, Interstitial Cystitis Symptom Index (ICSI), Interstitial Cystitis Problem Index (ICPI), average daytime and nocturnal urinary frequency, mean and maximum voided volume per micturition, urgency episodes, SF-12v2 (health-related quality of life), PGIC, and HADS; plasma ONO-1110 concentrations |
| **Exploratory Outcome Measures** | Frequency and amount of rescue medication use |
| **Safety Assessments** | Adverse events/adverse drug reactions, body weight, vital signs, 12-lead ECG, clinical laboratory tests, C-SSRS |
| **Dose Regimen** | XXXXX |
| **Treatment Groups / Sample Size** | Total n=50 (ONO-1110: n=25; placebo: n=25) |
| **Study Schema** | Screening: 14-28 days; Placebo lead-in: 2 weeks; Treatment: 12 weeks; Follow-up: 2 weeks |
| **Study Period** | January 2025- June 2026; 15-month enrollment period |



# ONO-1110 Development Plan




* Guidelines for the Clinical Evaluation of Drugs for Neuropathic Pain (PMDA, 2020)
Guideline on the clinical development of medicinal products intended for the treatment of pain (EMA, 2017)
Development of Non-Opioid Analgesics for Chronic Pain: Guidance for Industry, Draft Guidance (FDA, May 2026)

# Overview of the Target Diseases

| Disease | Postherpetic neuralgia (PHN) | | Fibromyalgia (FM) | | Interstitial cystitis and bladder pain syndrome (IC/BPS) | |
|---|---|---|---|---|---|---|
| Pathology | A disease in which the shingles rash (such as blisters) disappears and the pain continues even after the shingles have healed. | | Characterized mainly by unknown chronic pain over a wide area of the body, accompanied by a variety of physical, neurological, and psychiatric symptoms, with no abnormalities detected by clinical examination | | A condition characterized by chronic pelvic pain, pressure, or discomfort related to the bladder, accompanied by lower urinary tract symptoms such as increased urination or frequent urination, and without any confusing diseases.<br>If Hunner lesions are present, it is called interstitial cystitis (Hunner type); if not, it is called bladder pain syndrome | |
| Estimated No. of patients | 190K | 140K | 4.73M | 50K | 2.68M | 120K |

**Number of patients is estimated based on internal data**

* Lyrica IF: Combined analysis of side effects in domestic and international clinical trials targeting various diseases

# Appendix

# Development status of OPDIVO

As of October 29, 2026

・Approval or filed/awaiting approval in the past year
・Ongoing key clinical trials for approval

| Target disease | Treatment Line | Treatment | Phase | | | | |
|---|---|---|---|---|---|---|---|
| | | | Japan | Korea | Taiwan | US | EU |
| Non-small cell lung cancer | Neo-adjuvant・Adjuvant | With Chemo | III | Approved | Approved | Approved | Approved |
| Rhabdoid tumor | 2nd | Monotherapy | II | – | – | – | – |
| Richter transformation | 2nd | Monotherapy | II | – | – | – | – |
| Unresectable anaplastic Thyroid Cancer | 1st | With Lenvatinib | Filed | – | – | – | – |
| Solid tumor | – | ONO-4538HSC (Combination with vorhyaluronidase alfa) | I | – | – | Approved | Approved |
| Pediatric malignant solid tumor Epithelioid sarcoma | – | ONO-4538HSC (Combination with vorhyaluronidase alfa) | I / II | – | – | – | – |

※Red: Update after announcement of FY 2025 financial result in May 2026
※Red: Update after FY2026 Q1 in July

# OPDIVO Approval Track Record(1)

As of October 29, 2026

| 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 |
| | 1st | With AVD | – | – | – | 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 2025 financial result in May 2026

# OPDIVO Approval Track Record(2)

As of October 29, 2026

| 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 (1st) | With Ipi | Approved | Approved | Approved | Approved | Approved |
| | MSI-H / dMMR (3rd) | Monotherapy | Approved | – | Approved | Approved | – |
| | | With Ipi | Approved | Approved | Approved | Approved | Approved★★ |
| Hepatocellular carcinoma | 1st | With Ipi | Approved | Approved | Approved | Approved | Approved |
| | 2nd | With Ipi | – | – | Approved | Approved | – |

★★2nd Line

# OPDIVO Approval Track Record(3)

As of October 29, 2026

| Target disease | Treatment Line | Treatment | Phase | | | | |
|---|---|---|---|---|---|---|---|
| | | | Japan | Korea | Taiwan | US | EU |
| Renal cell carcinoma | 1st | With Ipi | Approved | Approved | Approved | Approved | Approved |
| | | With TKI | Approved | Approved | Approved | Approved | Approved |
| | 2nd | Monotherapy | Approved | Approved | Approved | Approved | Approved |
| Urothelial cancer / Bladder cancer | Adjuvant | Monotherapy | Approved | Approved | Approved | Approved | Approved |
| | 1st | With Chemo | Approved | Approved | Approved | Approved | Approved |
| | 2nd | Monotherapy | – | Approved | Approved | Approved | Approved |
| Cancer of unknown primary | 1st | Monotherapy | Approved | – | – | – | – |
| Epithelial skin malignancies | 1st | Monotherapy | Approved | – | – | – | – |
| Flat dose | 240 mg (every 2 weeks) | | Approved | Approved | Approved | Approved | Approved |
| | 360 mg (every 3 weeks) | | Approved | Approved | Approved | Approved | Approved |
| | 480 mg (every 4 weeks) | | Approved | Approved | Approved | Approved | Approved |

# Key milestones in FY2026 Q2 (FY ending March 2027)

As of October 29, 2026

## (Development pipeline)

| | Product/ Code(Generic name) | Target indication/Study name | Progress |
|---|---|---|---|
| Product to be approved | OPDIVO | Non-small cell lung cancer (with chemo) | Approved in KR, TW (Aug.2026) |
| | QINLOCK / DCC-2618 (ripretinib) | GIST 4L | Approved in KR (Oct.2026) |
| | XCOPRI / ONO-2017 (cenobamate) | Partial-onset seizures | Approved in JP (Sep.2026) |
| P3 | OPDIVO | Hepatocellular carcinoma, Adjubant | Discontinued (Aug.2026) |
| | ONO-4578 | Gastric cancer (with OPDIVO and chemo) | Global study started (Aug.2026) |
| | ONO-2808 | MSA | Global study started (Aug.2026) |
| P2 | ROMVIMZA / DCC-3014 (vimseltinib) | TGCT | Started in JP (Jul.2026) |
| | ONO-4915 | Sjögren's disease | Started in JP (Aug.2026) |
| | ONO-1110 | PHN, HIC, FM | P2 Completed (Oct.2026)<br>Preparing for the next clinical trial |
| | | MDD, SAD | Discontinued (Oct.2026) |
| P1 | ONO-4578 | NSCLC (with OPDIVO and standard of care) | Discontinued (Oct.2026) |
| | ONO-3401 | Neurological disease | Started in JP (Jul.2026) |

Events from July 2026 to October 29, 2026

# Key milestones in FY2026 Q2 (FY ending March 2027)

As of October 29, 2026

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

| Title | Progress |
|---|---|
| Ono Pharma Announces an Exclusive License Agreement with Biohaven to Develop and Commercialize IgG Degraders in Japan, South Korea, Taiwan, and ASEAN Countries | Exclusive License Agreement (Oct.2026) |

Events from July 2026 to October 29, 2026



ONO PHARMA

Dedicated to the Fight against Disease and Pain