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) 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 Primary Completion	US	NCT07104032
QINLOCK DCC-2618 (ripretinib) KIT inhibitor	GIST 2L KIT Exon 11+17/18	■	■	■	■			FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
	GIST 4L	■						FY2027 Primary Completion	JP	NCT07618377
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia vera (PV)	■	■	■	■			FY2028 Primary Completion	JP, US, EU, KR, TW and others	NCT07429266
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*	■	■	■	■			FY2030 Primary Completion	JP, US, EU, KR, TW and others	NCT07818070
	Colorectal cancer*	■	■	■				FY2027 Primary Completion	JP, US, EU and others	NCT06948448
ONO-4482 (relatlimab) Anti-LAG-3 antibody	Melanoma*	■	■					FY2024 Primary Completion (Actual)	JP, US, EU and others	NCT01968109
ONO-7427 Anti-CCR8 antibody	Solid tumor*	■	■					FY2031 Primary Completion	JP, US, EU and others★1	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced malignancies (with ripretinib)	■	■					FY2026 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 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 (ONO-4059: tirabrutinib) BTK inhibitor	Pemphigus							FY2027 Primary Completion	JP	NCT06696716
ONO-8531 (povetacicept) 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) 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 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.

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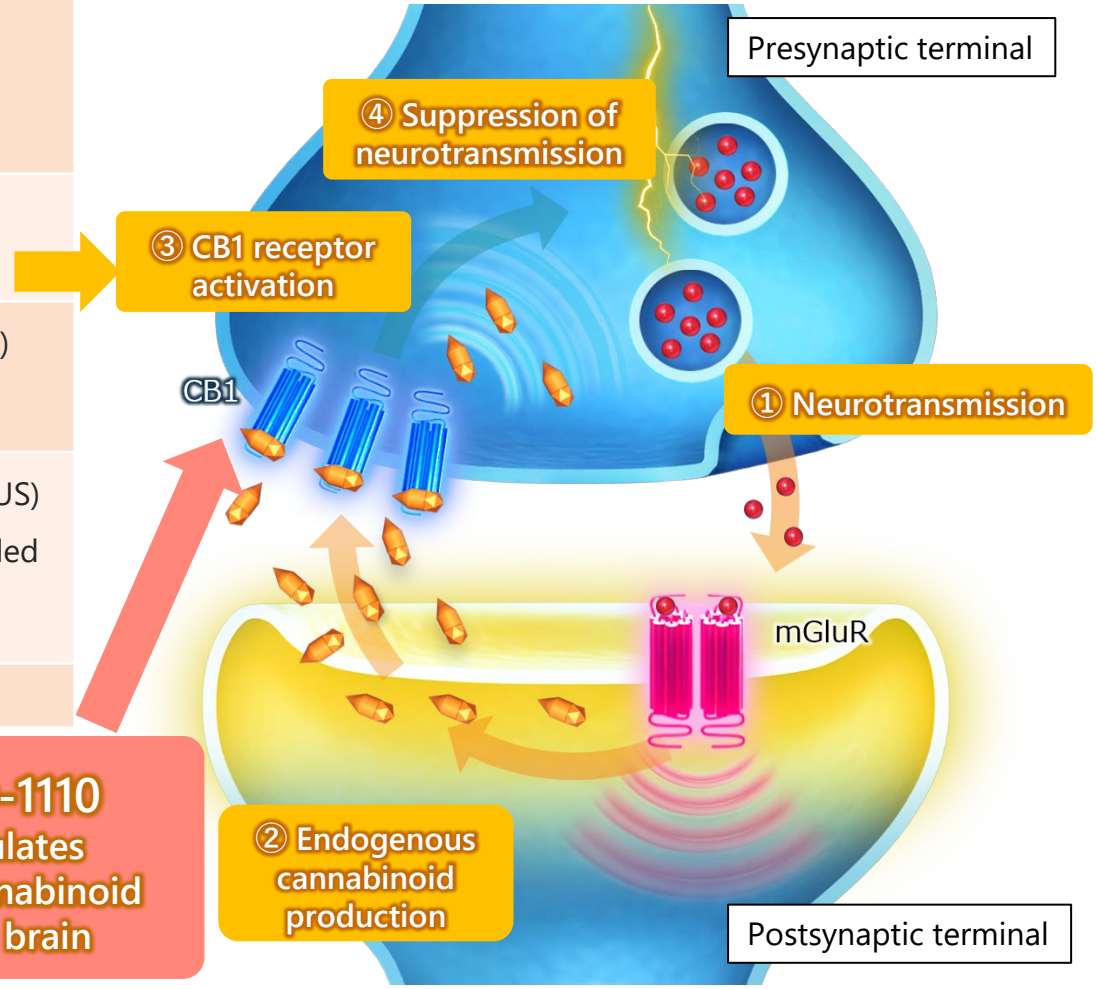
ONO-1110 MoA

Approved drugs related to Δ9-THC	
Dronabinol (Synthesized Δ9-THC)	Marinol®/Syndros® (US Approved) 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) Refractory cancer chemotherapy-induced nausea and vomiting
Nabiximorus (Plant-derived Δ9-THC + CBD)	Sativex® (Canada, partially European, Australian, not approved in the US) 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) 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 Loss of appetite with weight loss in AIDS patients Multiple sclerosis, chronic pain 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)

Nociplastic pain

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

- Fibromyalgia (FM)

Psychiatric disorders

Depressive disorders

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

- Major depressive disorder(MDD)

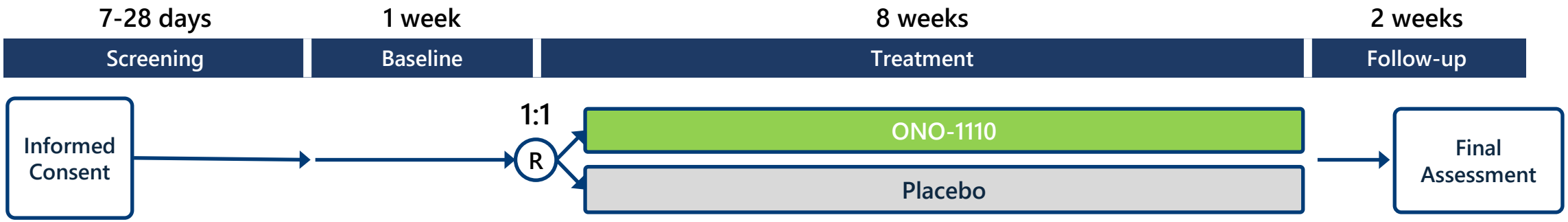
Anxiety disorders

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

- Social anxiety disorder(SAD)

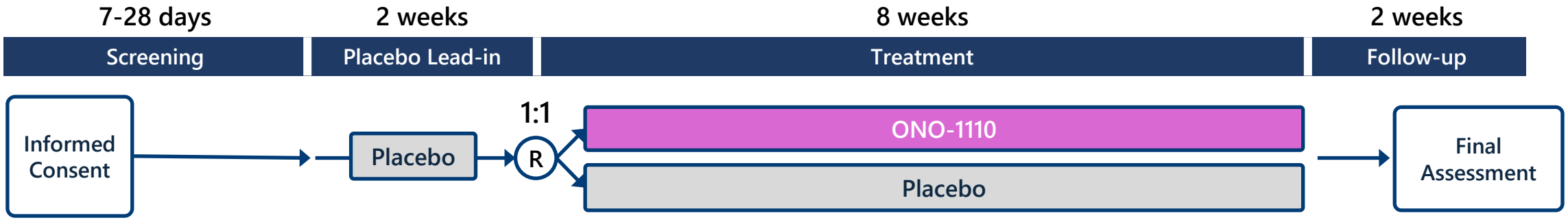
Overview of ONO-1110-04 Study

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



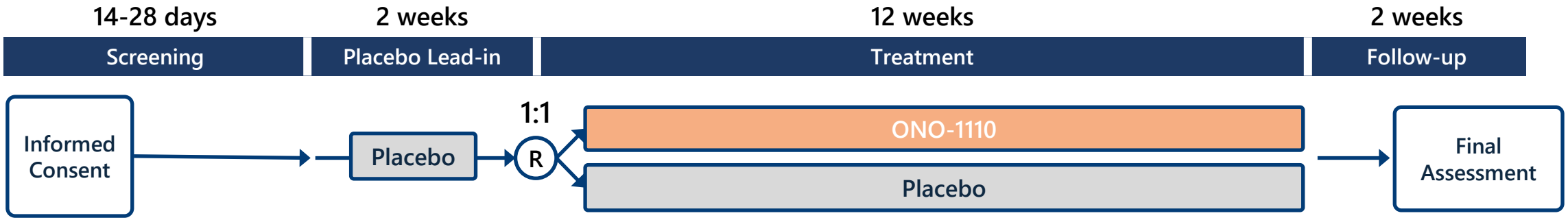
Overview of ONO-1110-05 Study

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

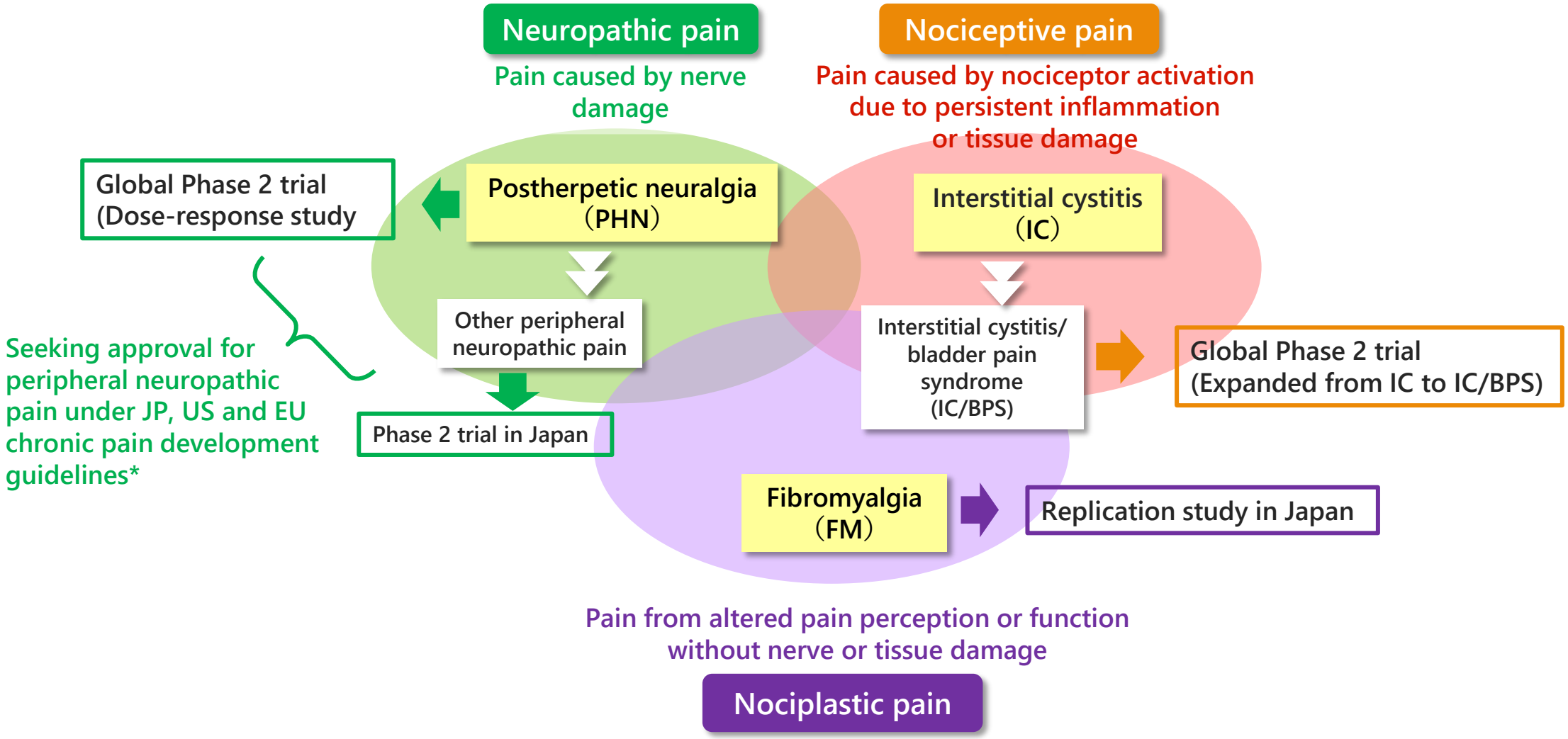


Overview of ONO-1110-06 Study

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. 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