

Development Pipeline Progress Status

Launch Projections - POC Pipeline-

As of May 8, 2026

■ Approved ■ Filed and preparing for filing

	FY2025	FY2026	FY2027	FY2028	FY2029 -	
US 		ONO-4059 (VELEXBRU) PCNSL	QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
EU 	ROMVIMZA TGCT		QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
JP 	OPDIVO HCC 1L OPDIVO MSI-H CRC 1L BRAFTOVI CRC 1L FOLFOX	ONO-2017 cenobamate Partial-onset seizures QINLOCK GIST 4L	OPDIVO HCC Adjuvant	ripretinib (QINLOCK) GIST 2L VELEXBRU Pemphigus 2L ONO-2017 cenobamate Primary generalized tonic-clonic seizures ONO-8531 povetacicept IgAN	ONO-5532 Gel-One Osteoarthritis ONO-2017 cenobamate Partial-onset seizures pediatric vimseltinib (ROMVIMZA) TGCT OPDIVO sc	ONO-0530 sapablursen PV ONO-8531 povetacicept pMN ONO-4578 GC 1L ONO-2808 MSA

PCNSL: Primary Central Nervous System Lymphoma, GIST: Gastrointestinal Stromal Tumor, PV: Polycythemia Vera, GC: Gastric Cancer, MSA: Multiple System Atrophy, TGCT: Tenosynovial Giant Cell Tumor, HCC: Hepatocellular Carcinoma, CRC: Colorectal Cancer, IgAN: IgA Nephropathy, pMN: Primary Membranous Nephropathy

Development pipeline (Oncology) ①



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
BRAFTOVI Capsule (encorafenib) BRAF inhibitor	Colorectal cancer 1L BRAF-mutation (with cetuximab and chemo (FOLFOX))							2025.11 JP : Approval 2026.1 KR : Approval	JP, US, EU, KR, TW and others*1	NCT04607421
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL) 1L, ≥2L							2026.2 US : Filed (Part A)	US	NCT04947319
	Primary central nervous system lymphoma (PCNSL) ≥2L							FY2027 Primary Completion	US	NCT07104032
QINLOCK DCC-2618 (ripretinib) KIT inhibitor	Gastrointestinal Stromal Tumor (GIST) 2L KIT Exon 11+17/18							FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
	Gastrointestinal Stromal Tumor (GIST) 4L							FY2026 Primary Completion	JP	Under registration
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*							FY2025 Primary Completion (Actual)	JP, KR, TW	NCT06256328
	Colorectal cancer*							FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*							FY2026 Primary Completion	JP	NCT06542731
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*							FY2028 Primary Completion	JP, US, EU and others*2	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced Malignancies (with ripretinib)							FY2026 Primary Completion	US, EU	NCT05957367

MOA : Mode of Action
* : Combination with OPDIVO

*1 : Development rights countries: JP, KR, *2 : Development right country: JP
Estimated study completion date shown in jRCT or ClinicalTrials.gov

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2024 financial result in May 2025
※Red: Update after FY2025 Q3 in February

Development pipeline (Oncology) ②



As of May 8, 2026

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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	Under registration

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Development pipeline (Non-oncology) ①



As of May 8, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial Giant Cell Tumor (TGCT)							FY2024 US : Approval FY2025 EU : Approval	US, EU and others	NCT05059262
	chronic Graft Versus Host Disease (cGVHD)							FY2029 Primary Completion	US	NCT06619561
ONO-2017(cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel	Partial-onset seizures							FY2025 JP : Filed	JP, KR and others*1	NCT04557085
	Partial-onset seizures (pediatric)							FY2028 Primary Completion	JP	Under registration
	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							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)							FY2025 Primary Completion (Actual)	JP, US	NCT05923866

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Development pipeline (Non-oncology) ②



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ONO-1110 Endocannabinoid regulation	Postherpetic Neuralgia							FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia							FY2026 Primary Completion	JP	NCT06752590
	Hunner Type Interstitial Cystitis							FY2026 Primary Completion	JP	NCT06752603
	Major Depressive Disorder							FY2026 Primary Completion	JP	NCT06792136
	Social Anxiety Disorder							FY2026 Primary Completion	JP	NCT06805565
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-4685 (besufetamig) PD-1 x CD3 bispecific antibody	Autoimmune disease							FY2024 Completion	JP	jRCT2071220081
								FY2024 Primary Completion (Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2026 Completion	JP	jRCT2071240056
ONO-2416	Psychiatric disorders							FY2027 Completion	JP	jRCT2071250147
ONO-3310	Kidney disease							FY2027 Completion	JP	Under registration
ONO-6414	Autoimmune disease							FY2027 Primary Completion	US	Under registration

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Shaded boxes indicate studies on healthy volunteers.

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ONO-2808

7th World Parkinson Congress

Title : Safety, Tolerability, and Preliminary Efficacy of ONO-2808,
a Sphingosine-1-Phosphate Receptor 5 Agonist, in Multiple System Atrophy

Abstract No. : LBP37.09, Poster session

Time : Wednesday, May 27, 2026 11:30 am – 1:30pm (MST)

ONO-4578

ASCO 2026 (American Society of Clinical Oncology)

Title : ONO-4578 combined with nivolumab and chemotherapy as first-line treatment for patients with
HER2-negative unresectable advanced or recurrent gastric/gastroesophageal junction cancer: a
randomized, double-blind, phase 2 trial (ONO-4578-08)

Abstract No. : 4007, Oral presentation

Time : Monday, June 1, 2026, 9:45 am to 12:45 pm (CT)

Presenter : Sung Hee Lim, Samsung Medical Center, Sungkyunkwan University School of Medicine,
Seoul, Republic of Korea