

Development Pipeline Progress Status

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



As of February 2, 2026

Filed	Approved	Met PE		OPDIVO	Other than OPDIVO
 DCC-3014 (ROMVIMZA) [TGCT] 2024/07⇒2025/09  DCC-3014 (ROMVIMZA) [TGCT] 2024/08⇒2025/02  [1L-Hepatocellular carcinoma] with YERVOY CheckMate-9DW 2024/08⇒2025/06  [1L- Colorectal cancer (MSI-H)] with YERVOY CheckMate-8HW 2024/09⇒2025/08  BRAFTOVI [1L-BRAF-mutant Colorectal cancer] with Cetuximab and FOLFOX 2024/12⇒2025/11			 ONO-4059 (VELEXBRU) [2L-PCNSL]  ONO-2017 (Cenobamate) [Partial-onset seizures] 2025/09  [Neoadjuvant, Adjuvant – NSCLC] with Chemo CheckMate-77T	 DCC-2618 (QINLOCK) [GIST 2L-KIT Exon 11+17/18]  [Neoadjuvant, Adjuvant - Bladder cancer] with Chemo ONO-4538-86  [Adjuvant Hepatocellular carcinoma] CheckMate-9DX	
FY2024 (results)			FY2025	FY2026	

PE : Primary endpoint

Development status of OPDIVO

As of February 2, 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	Ⅲ	Ⅲ	Approved	Approved
Colorectal cancer	MSI-H / dMMR (1st)	with Ipi	Approved	—	Approved	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant ・ Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	—	—	—	—
Richter transformation	2nd	Monotherapy	Ⅱ	—	—	—	—
Solid tumor	—	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	—	—	Approved	Approved

Development pipeline (Oncology) ①

As of February 2, 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 : Filed	JP, US, EU, KR, TW and others* ¹	NCT04607421
QINLOCK DCC-2618 (riporetinib) KIT inhibitor	Gastrointestinal Stromal Tumor (GIST) 2L KIT Exon 11+17/18							FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL) ≥2L							FY2027 Primary Completion	US	NCT07104032
	Primary central nervous system lymphoma (PCNSL) 1L, ≥2L							FY2025 Primary Completion (Actual) (Part A)	US	NCT04947319
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
	Hormone receptor-positive, HER2-negative breast cancer							FY2026 Primary Completion	JP	NCT06570031
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia Vera (PV)							FY2025 Primary Completion (Actual) Presented at ASH	US, EU and others	NCT05143957
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 riporetinib)							FY2026 Primary Completion	US	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 Q2 in October

Development pipeline (Oncology) ②

As of February 2, 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-7913 (magrolimab) Anti CD47 antibody	Pancreatic cancer*							FY2026 Primary Completion	JP	NCT06532344
	Colorectal cancer*							FY2027 Primary Completion	JP	NCT06540261
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2025 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

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※Red: Update after announcement of FY 2024 financial result in May 2025
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Development pipeline (Non-oncology)

As of February 2, 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
	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
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

Development pipeline (Non-oncology)



As of February 2, 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	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 (jRCT)	JP	jRCT2071220081
								FY2024 Primary Completion (Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease							FY2026 Completion (jRCT)	JP	jRCT2071240056

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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