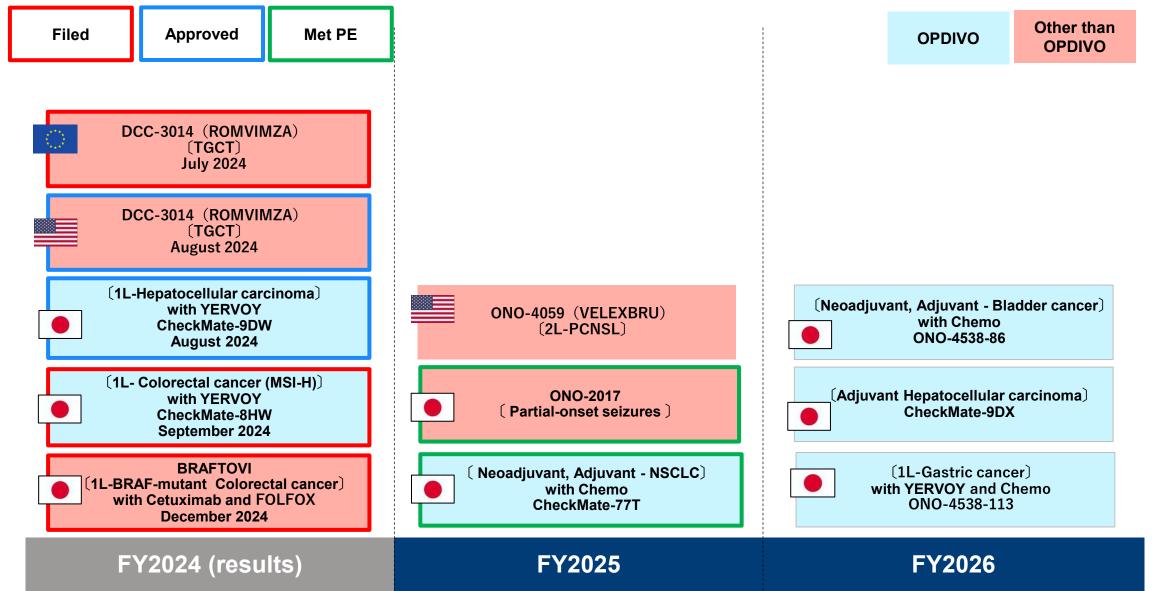
Development Pipeline Progress Status

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



As of August1, 2025



18/30

Development status of OPDIVO



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

Target disease	Treatment Line	Treatment			Phase		
raiget disease	Japan		Japan	Korea	Taiwan	US	EU
Non-small cell lung cancer	Neo-adjuvant · Adjuvant	with Chemo	ш	ш	ш	Approved	Approved
Gastric cancer	1st	with lpi/Chemo	ш	ш	ш	_	_
Colorectal cancer	MSI-H / dMMR (1st)	with lpi	Filed	_	_	Approved	Approved
Hepatocellular	Adjuvant	Monotherapy	ш	ш	ш	ш	ш
carcinoma	1st	with lpi	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Neo-adjuvant • Adjuvant	with Chemo	ш	ш	ш	ш	ш
Rhabdoid tumor	2nd	Monotherapy	п	_	_	_	_
Richter transformation	2nd	Monotherapy	п	_	_	_	_
Solid tumor	_	ONO-4538HSC (Comibination with vorhyaluronidase alfa)	I	_	_	Approved	Approved

Development pipeline (Oncology) 1



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	А	Status	Area	ID
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	BRAF-mutant thyroid cancer							FY2024.12 Filing accepted	JP, US, EU, KR, TW and others*	NCT04607421
QINLOCK (ripretinib) KIT inhibitor	Gastrointestinal Stromal Tumor 2L KIT Exon 11+17/18 (GIST)							FY2025 Primary Completion	US, EU, KR, TW and others	NCT05734105
ONO-4059 (tirabrutinib) BTK inhibitor	Primary central nervous system lymphoma (PCNSL)							FY2025 Primary Completion (Part A) (Actual)	US	NCT04947319
	Gastric cancer*							FY2025 Primary Completion	JP, KR, TW	NCT06256328
ONO-4578 PG receptor (EP4) antagonist	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							FY2025 Primary Completion	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*							FY2025 Primary Completion	JP, US, EU and others	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Solid tumor (with sotorasib)							FY2027 Primary Completion	us	NCT04892017
DCC-3116 (Intextsertib) ULK Inhibitor	Advanced Malignancies (with ripretinib)							FY2026 Primary Completion	US	NCT05957367

MOA : Mode of Action F : Filed, A : Approval EU : European countries

^{*:} Combination with OPDIVO, *: Development rights countries: JP, KR Estimated study completion date shown in jRCT or ClinicaiTrials.gov

Development pipeline (Oncology) 2



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	А	Status	Area	ID
DCC-3084 Pan-RAF inhibitor	Advanced Malignancies							FY2026 Primary Completion	US	NCT06287463
DCC-3009 Pan-KIT inhibitor	Gastrointestinal Stromal Tumor							FY2028 Primary Completion	US	NCT06630234
ONO 7042 (magnetimath) Auti CD47 antibada	Pancreatic cancer*							FY2026 Primary Completion	JP	NCT06532344
ONO-7913 (magrolimab) Anti CD47 antibody	Colorectal cancer*							FY2027 Primary Completion	JP	NCT06540261
ONO 4695 PD 1 v CD2 biomosific antibody	T-cell lymphoma							FY2025 Primary Completion	US	NCT05079282
ONO-4685 PD-1 x CD3 bispecific antibody								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

MOA : Mode of Action F : Filed, A : Approval

Development pipeline (Non-oncology)



As of August1, 2025

Code (Generic name)MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ROMVIMZA	Tenosynovial Giant Cell Tumor							FY2024 FDA: Approval EMA: Filing accepted	US, EU and others	NCT05059262
DCC-3014 (vimseltinib) CSF-1R inhibitor	chronic Graft Versus Host Disease							FY2029 Primary Completion	US	NCT06619561
ONO-2017(cenobamate)Inhibition of voltage- gated sodium currents/positive allosteric	Primary generalized tonic-clonic seizures							FY2026 Primary Completion	JP	NCT06579573
modulator of GABAA ion channel	Partial-onset seizures							FY2024 Primary Completion(Actual)	JP, KR and others★¹	NCT04557085
VELEXBRU Tablet (ONO-4059: tirabrutinib) BTK inhibitor	Pemphigus							FY2027 Primary Completion	JP	NCT06696716
Povetacicept BAFF/APRIL dual antagonist	IgA Nephropathy							FY2028 Primary Completion	JP, US, EU, KR, TW and others*2	NCT06564142
ONO-2808 S1P5 receptor agonist	Multiple System Atrophy							FY2025 Primary Completion	JP, US	NCT05923866
	Postherpetic Neuralgia							FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia							FY2026 Primary Completion	JP	NCT06752590
ONO-1110 Endocannabinoid regulation	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
010 0000 5 1 1/1 17	Alzheimer's Disease							FY2026 Primary Completion	JP, US	NCT06881836
ONO-2020 Epigenetic Regulation	Agitation Associated with Dementia Due to Alzheimer's Disease							FY2026 Primary Completion	JP	NCT06803823
ONO 4605 DD 4 v CD2 biomocific antibody	Autoimmuno dioces							FY2024 Completion (jRCT)	JP	jRCT2071220081
ONO-4685 PD-1 x CD3 bispecific antibody	Autoimmune disease							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 ClinicaiTrials.gov. Shaded boxes indicate studies on healthy volunteers.

F : Filed, A : Approval

Povetacicept





- Ono Pharmaceutical and Vertex enter into strategic agreement to develop and commercialize povetacicept in Japan and South Korea¹⁾
- ◆ Povetacicept is a recombinant fusion protein and a dual antagonist of the BAFF²) and APRIL³) cytokines
- ♦ Povetacicept is in development for multiple serious B cell-mediated diseases, including IgA nephropathy, primary membranous nephropathy

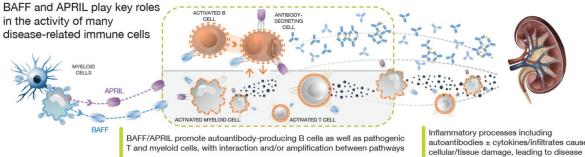
[IgA Nephropathy (IgAN)]

- IgAN results from deposition of circulating immune complexes consisting of autoantibodies in the renal glomerular mesangium
- Up to 72% of adult IgAN patients progress to end-stage renal disease within 20 years
- There are no approved therapies that specifically target the underlying cause of IgAN

[Povetacicept]

- Povetacicept has higher binding affinity and greater potency in preclinical studies versus other inhibitors of BAFF and/or APRIL alone
- Treatment with povetacicept 80 mg every 4 weeks subcutaneously reduced mean UPCR⁴⁾ by 66% ⁵⁾ at 48 weeks
- A global Phase 3 pivotal study (RAINIER study) is currently being conducted in patients with IgAN, including in Japan
 - 1) Ono Pharmaceutical press release (https://www.ono-pharma.com/en/news/20250623.html)
 - 2) A Proliferation Inducing Ligand
 - 3) B Cell Activating Factor
 - 4) Urine protein/creatinine ratio
 - 5) Ju-Young Moon, et al. Presentation at KSN 2025

Glomerulonephritis (e.g., IgAN and primary membranous nephropathy) BAFF and APRIL play key roles in the activity of many.



Dual BAFF/APRIL Inhibition



Potential to
address underlying
autoimmunity
reducing or reversing
cellular/tissue damage

















Appendix

OPDIVO Approval Track Record(1)



As of August1, 2025

Target disease	Treatment Line	Treatment			Phase		
i arget disease	meaunent Line	rreatment	Japan	Korea	Taiwan	us	EU
Malanama	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
Melanoma	1st	Combination drug [†] (relatlimab)	_	_	_	Approved	Approved
	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
		with lpi	Approved	Approved	Approved	Approved	_
Non-small cell lung	1st	with Ipi/Chemo	Approved	Approved	Approved	Approved	Approved
cancer		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	1st	with lpi	Approved	Approved	Approved	Approved	Approved
mesothelioma	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 2024 financial result in May 2025

OPDIVO Approval Track Record(2)



As of August1, 2025

Target disease	Treatment Line	Treatment			Phase		
i ai yet uisease	Treatment Line	Treatment	Japan	Korea	Taiwan	us	EU
Contribution	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
Gastric cancer	3rd	Monotherapy	Approved	Approved	Approved	_	_
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
Esophageal cancer	1st	with Ipi, with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Outomotel company	NACLU (JANANAD (2:-J)	Monotherapy	Approved	_	Approved	Approved	_
Colorectal cancer	MSI-H/dMMR (3rd)	with lpi	Approved	Approved	Approved	Approved	Approved*
Hepatocellular carcinoma	2nd	with lpi	_	_	Approved	Approved	_

OPDIVO Approval Track Record(3)



As of August1, 2025

Target disease	isease Treatment Line Treatment		Phase					
i arget uisease	meaument Line	rreaunent	Japan	Korea	Taiwan	us	EU	
	4-4	with lpi	Approved	Approved	Approved	Approved	Approved	
Renal cell carcinoma	1st	with TKI	Approved	Approved	Approved	Approved	Approved	
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved	
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved	
Urothelial cancer / Bladder cancer	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	_	_	_	_	
	240 mg (e	every 2 weeks)	Approved	Approved	Approved	Approved	Approved	
Flat dose	360 mg (e	every 3 weeks)	Approved	Approved	Approved	Approved	Approved	
	480 mg (e	every 4 weeks)	Approved	Approved	Approved	Approved	Approved	

Key milestones in FY2025 Q1 (FY ending March 2026)



As of August1, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
	ROMVIMZA (vimseltinib)	Tenosynovial Giant Cell Tumor (TGCT)	Positive CHMP Opinion (Jul.2025)
Product to be approved	OPDIVO	Hepatocellular carcinoma(1st with Ipi) /CheckMate-9DW	Approved in JP (Jun.2025) Approved in KR, TW (Jul.2025)
to be approved		NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T	Approved in EU (May.2025)
	OPDIVO Qvantig	Solid tumor/CheckMate-67T	Approved in EU (May.2025)
P1	ONO-7475	EGFR-mutated non-small cell lung cancer (1L with osimertinib)	Discontinued (Jul.2025)

Key milestones in FY2025 Q1 (FY ending March 2026)



As of August1, 2025

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

Title	Progress
Ono Pharmaceutical and Vertex Announce Strategic Agreement to Develop and Commercialize Povetacicept in Japan and South Korea	License-in (Jun.2025)
Ono Enters into a Basic Agreement with Seikagaku for Co-development and Marketing Collaboration on Gel- One for the treatment of Osteoarthritis in Japan	Basic Agreement (Apr.2025)
Ono Commences Research Collaboration with Jorna Therapeutics to Generate Novel RNA Editing Therapeutics	Started
Ono Enters a Drug Discovery Collaboration Agreement with Captor Therapeutics to Develop Small Molecule Protein Degraders for the Treatment of Neurodegenerative Diseases	Discontinued
ONO Enters into Exclusive License Agreement with Chordia Therapeutics on CTX-177, a MALT1 Inhibitor, and its Related Compounds	Discontinued