Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of January 24, 2025

Filed | Approved | Met PE

OPDIVO | Other than OPDIVO

FY2023 (results)

〔1st-Urothelial cancer〕
with Chemo
CheckMate-901
Dec 2023

〔Epithelial skin malignancies〕
Investigator-initiated trial
Jun 2023

BRAFTOVI／MEKTOVI
〔2nd-BRAF-mutant Thyroid cancer〕
May 2023

FY2024

〔1st-Hepatocellular carcinoma〕
with YERVOY
CheckMate-9DW
August 2024

〔1st- Colorectal cancer (MSI-H)〕
with YERVOY
CheckMate-8HW
September 2024

〔 Neoadjuvant, Adjuvant - NSCLC〕
with Chemo
CheckMate-77T

BRAFTOVI
〔1st-BRAF-mutant Colorectal cancer〕
With Cetuximab and Chemo
December 2024

FY2025

〔Neoadjuvant, Adjuvant - Bladder cancer〕
With Chemo
ONO-4538-86

〔Adjuvant Hepatocellular carcinoma〕
CheckMate-9DX

ONO-2017
Partial-onset seizures

PE : Primary endpoint

Development status of OPDIVO (1)

As of January 24, 2025

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
	Neo-adjuvant・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Approved	Filed
	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
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	Standard of care refractory	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

★Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482)

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development status of OPDIVO (2)

As of January 24, 2025

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
		with Ipi/Chemo	Ⅲ	Ⅲ	Ⅲ	–	–
	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	Filed	–	–	Ⅲ	Approved
	MSI-H／dMMR (3rd)	Monotherapy	Approved	–	Approved	Approved	-
		with Ipi	Approved	Approved	Approved	Approved	Approved★★
Hepatocellular carcinoma	Adjuvant	Monotherapy	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	1st	with Ipi	Filed	Ⅲ	Ⅲ	Filed	Filed
	2nd	with Ipi	Ⅱ	Ⅱ	Approved	Approved	Ⅱ

★★2nd Line

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development status of OPDIVO (3)

As of January 24, 2025

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	Neo-adjuvant ・Adjuvant	with Chemo	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Ⅱ	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Rhabdoid tumor	2nd	Monotherapy	Ⅱ	–	–	–	–
Richter transformation	2nd	Monotherapy	Ⅱ	–	–	–	–
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
Solid tumor	–	ONO-4538HSC (Comibination with vorhyaluronidase alfa)	Ⅰ	–	–	Approved	Filed

※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Status of approval of OPDIVO (i.v. and s.c.) in the US

As of January 24, 2025

Indication	Line	TREATMENTS ADMINISTERED	i.v.	s.c.
Melanoma	Adjuvant	Monotherapy	Approval	Approval
	1L	Monotherapy	Approval	Approval
		With YERVOY	Approval	(monotherapy after combination therapy)
	2L	Monotherapy	Approval	Approval
Non-small cell lung cancer	Neoadjuvant	With chemotherapy	Approval	Approval
	Neo-adjuvant /Adjuvant	With chemotherapy	Approval	Approval
	1L	With YERVOY	Approval	
		With YERVOY or with chemotherapy	Approval	
	2L	Monotherapy	Approval	Approval
Hodgkin's lymphoma	Relapsed/refractory	Monotherapy	Approval	
Head and neck cancer	2L	Monotherapy	Approval	Approval
Malignant pleural mesothelioma	1L	With YERVOY	Approval	
Gastric cancer	1L	With chemotherapy	Approval	Approval

Indication	Line	TREATMENTS ADMINISTERED	i.v.	s.c.
Esophageal cancer	Adjuvant	Monotherapy	Approval	Approval
	1L	With YERVOY	Approval	
		With chemotherapy	Approval	Approval
	2L	Monotherapy	Approval	Approval
Colorectal cancer	MSI-H/dMMR (3rd line)	Monotherapy	Approval	Approval
		With YERVOY	Approval	(Following combination therapy monotherapy)
Hepatocellular carcinoma	2L	With YERVOY	Approval	(Following combination therapy monotherapy)
Renal cell carcinoma	1L	With YERVOY	Approval	(Following combination therapy monotherapy)
		With TKI	Approval	Approval
	2L	Monotherapy	Approval	Approval
Urothelial carcinoma/ Bladder cancer	Adjuvant	Monotherapy	Approval	Approval
	1L	With chemotherapy	Approval	Approval
	2L	Monotherapy	Approval	Approval

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Development pipeline (Oncology) ①

As of January 24, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
BRAFTOVI Capsule (Encorafenib) BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer			FY2024.5 Approval			
MEKTOVI Tablet (Binimetinib) MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer			FY2024.5 Approval			
QINLOCK (ripretinib) KIT inhibitor	NCT05734105/NA, SA, EU, AU, KR, TW	Gastrointestinal Stromal Tumor 2nd KIT Exon 11+17/18		FY2025 Primary Completion				
ONO-4059 (tirabrutinib) BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma		FY2025 Primary Completion (Part A)				
ONO-4482 (relatlimab) Anti-LAG-3 antibody	NCT01968109/JP, US, EU	Melanoma*		FY2024 Primary Completion (Actual)				
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*		FY2025 Primary Completion				
	NCT06547385/JP	Colorectal cancer*		FY2027 Primary Completion				
	NCT06542731/JP	Non-small cell lung cancer*		FY2026 Primary Completion				
	NCT06570031/JP	Hormone receptor-positive, HER2-negative breast cancer		FY2025 Primary Completion				
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*		FY2025 Primary Completion				
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor (with sotorasib)		FY2027 Primary completion				
	NCT05957367/US	Advanced Malignancies (with ripretinib)		FY2026 Primary completion				
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Advanced Malignancies		FY2026 Primary completion				
DCC-3009 Pan-KIT inhibitor	NCT06630234/US	Gastrointestinal Stromal Tumor		FY2028 Primary completion				

NA : North America, SA : South America, AU : Australia, EU : European countries
* : Combination with OPDIVO
Estimated study completion date shown in jRCT or ClinicaiTrials.gov

※Red: Update after announcement of FY 2023 financial result in May 2024
※Red: Update after Q1 FY2024 in July
MOA : Mode of Action

Development pipeline (Oncology) ②

As of January 24, 2025

Code (Generic name)MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-7475 (tamnorzatinib) Axl/Mer inhibitor	NCT06532331/JP	Pancreatic cancer*	→ FY2027 Primary Completion					
	NCT06525246/JP	EGFR-mutated non-small cell lung cancer	→ FY2025 Primary Completion					
ONO-7913 (magrolimab) Anti CD47 antibody	NCT06532344/JP	Pancreatic cancer*	→ FY2026 Primary Completion					
	NCT06540261/JP	Colorectal cancer*	→ FY2027 Primary Completion					
ONO-7914 STING agonist	NCT06535009/JP	Solid tumor	→ FY2026 Primary Completion					
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma	→ FY2025 Primary Completion					
	NCT06547528/JP		→ FY2028 Primary Completion					
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	→ FY2027 Primary Completion					
	NCT06622226/JP		→ FY2027 Primary Completion					
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor	→ FY2029 Primary Completion					
ONO-7428 Anti-ONCOKINE-1 antibody	Enrolling/JP	Solid tumor	→ FY2029 Primary Completion					

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

MOA : Mode of Action ※Red: Update after announcement of FY 2023 financial result in May 2024 ※Red: Update after Q1 FY2024 in July

Development pipeline (Non-oncology)

As of January 24, 2025

Code （Generic name） MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
DCC-3014 (vimseltinib) CSF-1R inhibitor	NCT05059262/NA, EU	Tenosynovial Giant Cell Tumor			FY2024 FDA: Filing accepted EMA: Filing accepted			
ONO-2017(cenobamate)Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	NCT06579573/JP	Primary generalized tonic-clonic seizures			FY2026 Primary Completion			
	NCT04557085/JP	Partial-onset seizures			FY2024 Primary Completion(Actual)			
VELEXBRU Tablet (ONO-4059：tirabrutinib) BTK inhibitor	NCT06696716/JP	Pemphigus			FY2027 Primary Completion			
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy		FY2025 Primary Completion				
DCC-3014 (vimseltinib)　CSF-1R inhibitor	NCT06619561/US	chronic Graft Versus Host Disease			FY2029 Primary Completion			
ONO-1110 Endocannabinoid regulation	NCT06708416/JP	Postherpetic Neuralgia			FY2026 Primary Completion			
	NCT06752590/JP	Fibromyalgia			FY2026 Primary Completion			
	NCT06752603/JP	Hunner Type Interstitial Cystitis			FY2026 Primary Completion			
	NCT06792136/JP	Major Depressive Disorder			FY2026 Primary Completion			
	jRCT2031240578/JP	Social Anxiety Disorder			FY2026 Completion (jRCT)			
ONO-2020 Epigenetic Regulation	Enrolling/JP, US	Alzheimer's Disease			FY2026 Primary Completion			
	Enrolling/JP	Agitation Associated with Dementia Due to Alzheimer's Disease			FY2026 Completion (jRCT)			
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease			FY2024 Completion (jRCT)			
	NCT05332704/EU				FY2024 Primary Completion(Actual)			
ONO-4915 PD-1 x CD19 bispecific antibody	jRCT2071240056/JP	Autoimmune disease			FY2026 Completion (jRCT)			

NA : North America,
EU : European countries

Estimated study completion date shown in jRCT or ClinicaiTrials.gov. Dashed lines indicate studies on healthy adults.

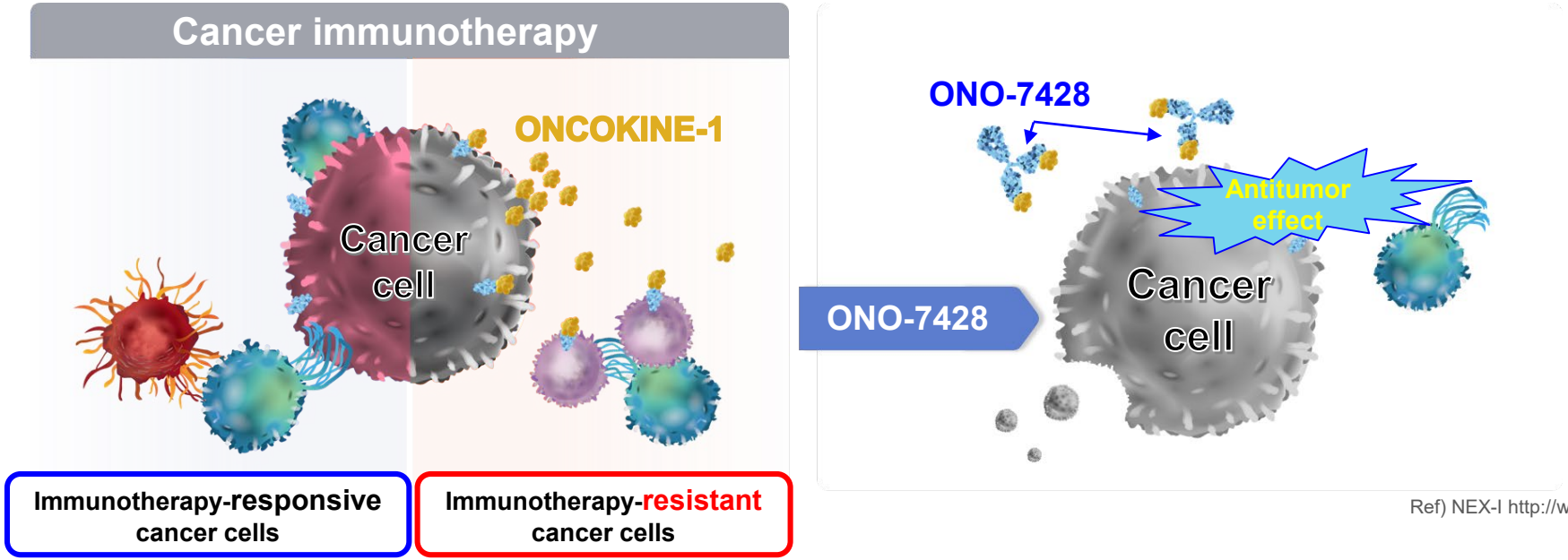
MOA : Mode of Action　※Red: Update after announcement of FY 2023 financial result in May 2024　※Red: Update after Q1 FY2024 in July

ONO-7428

- **First-in-class antibody drug candidate[2] targeting ONCOKINE-1[1]**
- **P1 study in solid tumors initiated in FY2024 2H**

【Hypothetical Mechanism of Action】

- ONCOKINE-1 is a tumor-derived protein involved in the acquisition of resistance to cancer immunotherapy.
- ONCOKINE-1 acts on cancer cells and immune cells, contributing to cancer progression and exacerbation.
- ONO-7428 is a monoclonal antibody targeting ONCOKINE-1, inhibiting its function and exerting antitumor effects.



Ref) NEX-I http://www.nex-i.co.kr/science/technology.php

1) A novel target protein identified by South Korean company NEX-I as a factor leading to cancer immunotherapy resistance.
2) ONO entered into an exclusive global license agreement with NEX-I for the development and commercialization in March 2024.

Key milestones in FY2024 Q3 (FY ending March 2025)

As of January 24, 2025

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO Qvantig	Solid cancer /CheckMate-67T	Approved in US (Dec.2024)
	OPDIVO	Urothelial cancer (1L with Chemo) /CheckMate-901	Approved in JP (Dec.2024)
		MSI-H Colorectal cancer (1st with Ipi) /CheckMate-8HW	Approved in EU (Dec.2024)
	BRAFTOVI	$BRAF^{V600E}$ - Mutant Metastatic Colorectal Cancer	Approved in US (Dec.2024)
		BRAF - Mutant Colorectal Cancer (with Cetuximab and chemo)	Filed in JP (Dec.2024)
P3	OPDIVO	Cis ineligible Urothelial cancer (1L with Ipi) /CheckMate-901	Discontinued (Nov.2024)
P2	OPDIVO	Richter transformation	Started in JP (Jan.2025)
	ONO-2020	Alzheimer's disease	Started in JP/US (Jan.2025)
		Agitation Associated with Dementia Due to Alzheimer's Disease	Started in JP (Nov.2024)
	ONO-1110	Postherpetic Neuralgia, Major Depressive Disorder	Started in JP (Oct.2024)
		Fibromyalgia, Hunner Type Interstitial Cystitis, Social Anxiety Disorder	Started in JP (Nov.2024)
	DCC-3014 (vimseltinib)	chronic Graft Versus Host Disease	Started in US (Nov.2024)
	ONO-2910	Chemotherapy-Induced Peripheral Neuropathy	Discontinued (Dec.2024)
P1	ONO-4578	Pancreatic cancer	Discontinued (Jan.2025)
	ONO-7428	Solid tumor	Started in JP (Nov.2024)
	DCC-3009	GastroIntestinal Stromal Tumor	Started in US (Dec.2024)

Key milestones in FY2024 Q3 (FY ending March 2025)

As of January 24, 2025

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

Title	Progress
Ono Enters into Drug Discovery Collaboration Agreement with Congruence Therapeutics to Generate Novel Small Molecule Correctors in the Oncology Area	Started (Dec.2024)
Ono Enters into Collaboration Agreement with EVQLV to Generate Novel Antibodies against Multiple Targets Utilizing EVQLV's AI-powered Antibody Design Engine for Development of Innovative Antibody Drugs	Discontinued
Ono Enters into a Multi Target R&D Collaboration Agreement with PrecisionLife	
ONO and Knowledge Palette Enter into an Agreement to Expand Research Collaboration on Building a Data-driven New Drug Discovery Platform	
ONO Enters into Collaboration Agreement with Iktos	