Development Pipeline Progress Status

Status of regulatory filing for approval in Japan

As of July 22, 2024

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

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

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

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

FY2025

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

〔Adjuvant Hepatocellular carcinoma〕
CheckMate-9DX

〔1L-Urothelial cancer (Cis ineligible)〕
with YERVOY
CheckMate-901

ONO-2017
Partial-onset seizures

Development status of OPDIVO (1)

As of July 22, 2024

Target disease	Line of Therapy	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	Approved
	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	with Brentuximab	Ⅲ	–	–	Ⅲ	–
		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
	SOC refractory	Monotherapy	Approved	–	–	–	–
Malignant Mesothelioma (Excluding Pleura)	1st or 2nd	Monotherapy	Approved				

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

※Red: Update after May 2024

Development status of OPDIVO (2)

As of July 22, 2024

Target disease	Line of Therapy	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	Ⅲ	–	–	Ⅲ	Filed
	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	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	with Ipi	Ⅱ	Ⅱ	Approved	Approved	Ⅱ

★★2nd Line

※Red: Update after May 2024

Development status of OPDIVO (3)

As of July 22, 2024

Target disease	Line of Therapy	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
		with Ipi/TKI	–	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	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	Filed	Approved	Ⅲ	Approved	Approved
		with Ipi	Ⅲ	Ⅲ	Ⅲ	Ⅲ	Ⅲ
	2nd	Monotherapy	Ⅱ	Approved	Approved	Approved	Approved
Cancer of unknown primary	–	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Dosage and Administration	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	–	–	Filed	Filed

※Red: Update after May 2024

Development pipeline (Oncology)

As of July 22, 2024

Code （Generic name）MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
Braftovi Capsules（Encorafenib）BRAF inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer				FY2024.5 Approval		
Mektovi Tablets（Binimetinib）MEK inhibitor	jRCT2011200018/JP	BRAF-mutant thyroid cancer				FY2024.5 Approval		
ONO-4059（tirabrutinib） BTK inhibitor	NCT04947319/US	Primary central nervous system lymphoma				FY2025 Primary Completion(Part A)		
ONO-4482（relatlimab） Anti-LAG-3 antibody	NCT05337137 /JP, US, EU, KR, TW	Hepatocellular carcinoma*				FY2024 Primary Completion		
	NCT01968109/JP, US, EU	Melanoma*			FY2024 Primary Completion			
ONO-7427 Anti-CCR8 antibody	NCT04895709/JP, US, EU	Solid tumor*			FY2025 Primary Completion			
ONO-4578 PG receptor (EP4) antagonist	NCT06256328/JP, KR, TW	Gastric cancer*				FY2025 Primary Completion		
	jRCT2031200215/JP	Colorectal cancer*		FY2027 Completion（jRCT）				
	jRCT2031200286/JP	Pancreatic cancer*		FY2024 Completion（jRCT）				
	jRCT2031200346/JP	Non-small cell lung cancer*		FY2024 Completion（jRCT）				
	jRCT2031210364/JP	Hormone receptor-positive, HER2-negative breast cancer		FY2025 Completion（jRCT）				
ONO-7475（tamnorzatinib） Axl/Mer inhibitor	jRCT2031230429/JP	Pancreatic cancer*		FY2027 Completion（jRCT）				
	jRCT2051210045/JP	EGFR-mutated non-small cell lung cancer		FY2024 Completion（jRCT）				
ONO-7913（magrolimab） Anti-CD47 antibody	jRCT2031210172/JP	Pancreatic cancer*		FY2025 Completion（jRCT）				
	jRCT2051210038/JP	Colorectal cancer*		FY2024 Completion（jRCT）				
ONO-7914 STING agonist	jRCT2031210530/JP	Solid tumor		FY2027 Completion（jRCT）				
ONO-4685 PD-1 x CD3 bispecific antibody	NCT05079282/US	T-cell lymphoma			FY2025 Primary Completion			
	jRCT2011230051/JP			FY2029 Completion（jRCT）				
ONO-7018 MALT1 inhibitor	NCT05515406/US	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia			FY2027 Primary Completion			
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	NCT06241456/US	HER2-expressing Solid tumor			FY2029 Primary Completion			

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

※Red: Update after May 2024

Development pipeline (Non-oncology)

As of July 22, 2024

Code （Generic name）MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
ONO-2017（cenobamate）Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABAA ion channel	jRCT2031210624/JP	Primary generalized tonic-clonic seizures			FY2026 Completion （jRCT）			
	NCT04557085/JP	Partial-onset seizures			FY2024 Study completion			
Velexbru Tablets (ONO-4059：tirabrutinib) BTK inhibitor	jRCT2031220043/JP	Pemphigus			FY2026 Completion （jRCT）			
ONO-2910 Enhancement of Schwann cell differentiation	jRCT2061210008/JP	Diabetic polyneuropathy		FY2024 Completion （jRCT）				
	·····/US							
	jRCT2031230173/JP	Chemotherapy-Induced Peripheral Neuropathy		FY2025 Completion （jRCT）				
ONO-2808 S1P5 receptor agonist	NCT05923866/JP, US	Multiple System Atrophy		FY2025 Study completion				
ONO-4685 PD-1 x CD3 bispecific antibody	jRCT2071220081/JP	Autoimmune disease	FY2024 Completion （jRCT）					
	NCT05332704/EU		FY2025 Study completion					
ONO-2020 Epigenetic Regulation	NCT05507515/US	Neurodegenerative disease	2023.12 Study completion（Actual）					
ONO-1110 Endocannabinoid regulation	jRCT2071220100/JP	Pain	FY2024 Completion （jRCT）					

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

※Red: Update after May 2024

Development pipeline - Deciphera

As of July 22, 2024

Code （Generic name）MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
QINLOCK（ripretinib）KIT inhibitor	NCT03353753/NA, EU, AU, SG	GIST ≧4th	→	→	→	→	→ FY2020 Approval	
	NCT05734105/NA, SA, EU, AU, KR, TW	GIST 2nd KIT Exon 11+17/18	→	→	→ FY2025 Primary Completion			
DCC-3014（vimseltinib） CSF-1R inhibitor	NCT05059262/NA, EU, AU, HK	TGCT	→	→	→ FY2024 FDA: Planned regulatory filing EMA: Filing accepted	→	→	
DCC-3116 ULK inhibitor	NCT04892017/US	Solid tumor（with sotorasib）	→	→ FY2027 Study completion				
	NCT05957367/US	Solid tumor（with ripretinib）	→	→ FY2026 Study completion				
DCC-3084 Pan-RAF inhibitor	NCT06287463/US	Solid tumor	→	→ FY2026 Study completion				

NA : North America, SA : South America, AU : Australia, SG : Singapore, HK : Hong Kong, KR : Korea, TW : Taiwan, JP : Japan

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

※Red: Update after May 2024

FY2024 1Q Pipeline Key Milestones

As of July 22, 2024

	Product／Code（Generic name）	Target indication/Study name	Progress
Product to be approved	OPDIVO	NSCLC（with CRT, with CRT Ipi）/CheckMate-73L	Discontinued(May.2024)
		Ovarian cancer（1st with rucaparib）	Discontinued(Jun.2024)
		Solid tumor（ONO-4538HSC）/CheckMate-67T	Filing accepted in EU(May.2024)
		Urothelial cancer（1st with Chemo）/CheckMate-901	Approved in EU, KR(Jun.2024)
		Hepatocellular carcinoma（1st with Ipi）/CheckMate-9DW	Approved in EU(Jul.2024)
	BRAFTOVI・MEKTOVI	Thyroid cancer	Approved(May.2024)

（Deciphera）

	Product／Code（Generic name）	Target indication/Study name	Progress
Product to be approved	Vimseltinib	TGCT	Filing accepted in EU(Jul.2024)