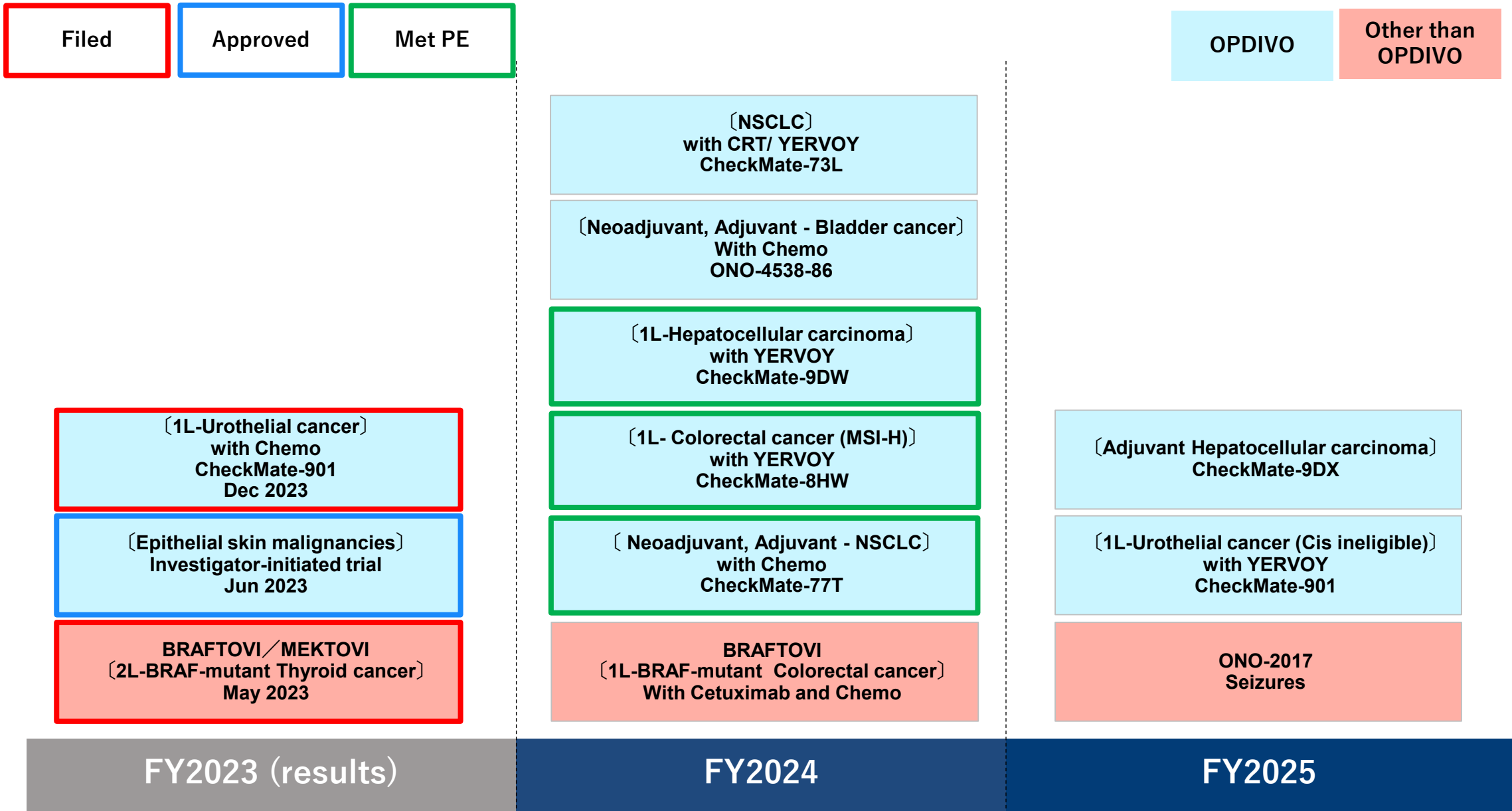


# Development Pipeline Progress Status

# Status of regulatory filing for approval in Japan

As of May 6, 2024



# Development status of OPDIVO (1)



As of May 6, 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
	Chemoradiotherapy	with CRT, with CRT/Ipi	III	III	III	III	III
	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 2023

※Red: Update after 3Q FY2023

# Development status of OPDIVO (2)



As of May 6, 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

# Development status of OPDIVO (3)

As of May 6, 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	III	III	Approved	Filed
		with Ipi	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
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 (Combination with vorhyaluronidase alfa)	I	—	—	Filed	III

# Development pipeline in Japan (Oncology)

As of May 6, 2024

Code (Generic name) MOA, Modality	ID/Area	Target Indication	PI	PI/II	PII	PIII	Filed	Approval
<b>Braftovi Capsules (encorafenib) BRAF inhibitor</b>	jRCT2011230032/JP	<b>BRAF-mutant thyroid cancer</b>						
								FY2024 Approval
<b>Mektovi Tablets (binimetinib) MEK inhibitor</b>	jRCT2011230032/JP	<b>BRAF-mutant thyroid cancer</b>						
								FY2024 Approval
<b>ONO-4059 BTK inhibitor</b>	NCT04947319/US	<b>Primary central nervous system lymphoma</b>	FY2025	Primary Completion (Part A)				
<b>ONO-4482 (relatlimab) Anti-LAG-3 antibody</b>	NCT05337137 /JP, US, EU, KR, TW	<b>Hepatocellular carcinoma*</b>	FY2024	Primary Completion				
	NCT01968109/JP, US, EU	<b>Melanoma*</b>	FY2024	Primary Completion				
<b>ONO-7427 Anti-CCR8 antibody</b>	NCT04895709/JP, US, EU	<b>Solid tumor*</b>	FY2025	Primary Completion				
<b>ONO-4578 PG receptor (EP4) antagonist</b>	NCT06256328/JP, KR, TW	<b>Gastric cancer*</b>	FY2025	Primary Completion				
	jRCT2031200215/JP	<b>Colorectal cancer*</b>	FY2027	Completion (jRCT)				
	jRCT2031200286/JP	<b>Pancreatic cancer*</b>	FY2024	Completion (jRCT)				
	jRCT2031200346/JP	<b>Non-small cell lung cancer*</b>	FY2024	Completion (jRCT)				
	jRCT2031210364/JP	<b>Hormone receptor-positive, HER2-negative breast cancer</b>	FY2025	Completion (jRCT)				
<b>ONO-7475 (tamnorzatinib) Axl/Mer inhibitor</b>	jRCT2031230429/JP	<b>Pancreatic cancer*</b>	FY2027	Completion (jRCT)				
	jRCT2051210045/JP	<b>EGFR-mutated non-small cell lung cancer</b>	FY2024	Completion (jRCT)				
<b>ONO-7913 (magrolimab) Anti-CD47 antibody</b>	jRCT2031210172/JP	<b>Pancreatic cancer*</b>	FY2025	Completion (jRCT)				
	jRCT2051210038/JP	<b>Colorectal cancer*</b>	FY2024	Completion (jRCT)				
<b>ONO-7914 STING agonist</b>	jRCT2031210530/JP	<b>Solid tumor</b>	FY2027	Completion (jRCT)				
<b>ONO-4685 PD-1 x CD3 bispecific antibody</b>	NCT05079282/US	<b>T-cell lymphoma</b>	FY2025	Primary Completion				
	jRCT2011230051/JP		FY2029	Completion (jRCT)				
<b>ONO-7018 MALT1 inhibitor</b>	NCT05515406/US	<b>Non-Hodgkin lymphoma, Chronic lymphocytic leukemia</b>	FY2027	Primary Completion				
<b>ONO-8250 iPSC-derived HER2 CAR T-cell therapy</b>	NCT06241456/US	<b>HER2-expressing Solid tumor</b>	FY2029	Primary Completion				

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

※Red: Update after May 2023

※Red: Update after 3Q FY2023

# Development pipeline in Japan (Non-oncology)

As of May 6, 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)	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)		

# FY2023 Pipeline Key Milestones



As of May 6, 2024

	Product/ Code (Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Malignant Mesothelioma(Excluding Pleura) /Investigator-initiated clinical trial Epithelial skin malignancies/NMSC-PD1 Urothelial cancer (1L with Chemo) /CheckMate-901  NSCLC (Neoadjuvant) /CheckMate-816 NSCLC (Neoadjuvant, Adjuvant) /CheckMate-77T MSI-H Colorectal cancer (with YERVOY) /CheckMate-8HW Solid tumor(ONO-4538HSC) /CheckMate-67T	Approved(Nov.2023)  Approved(Feb.2024) Filed in EU(Oct.2023)/in JP(Dec.2023) Approved in US(Mar.2024) Approved in EU(Jul.2023) Filing accepted in US, EU(Feb.2024) Achieved PE(Dec.2023) Filed in US(May.2024)
	BRAFTOVI · MEKTOVI	Thyroid cancer	Filed(May.2023)
P3	OPDIVO	Bladder cancer	Discontinued in JP, KR, TW(Aug.2023)
	ONO-7913	TP53-mutant acute myeloid leukemia Acute myeloid leukemia	Discontinued(Oct.2023) Discontinued(Feb.2024)
	ONO-7121	Colorectal cancer	Discontinued(Dec.2023)
P2	ONO-4578 ONO-2910 ONO-2808	Gastric cancer (with Opdivo) Chemotherapy-Induced Peripheral Neuropathy Multiple System Atrophy	Started in JP(Aug.2023)/in KR, TW(Oct.2023) Started(Jun.2023) Started in JP(Feb.2024)/in US(Jul.2024)