

# Status of Development Pipeline (As of July 31, 2018)

## Main Status of Development Pipelines (Oncology)

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage				Area*	
			I	II	III	Filed		
Opdivo Intravenous Infusion	Human anti-human PD-1 monoclonal antibody	Malignant pleural mesothelioma	→	→	→	→	(JP) (US, EU)	Co-development with Bristol-Myers Squibb
		Small cell lung cancer	→	→	→	→	(US) (JP, KR, TW, EU)	
		Esophageal cancer	→	→	→	→	(JP, KR, TW, US, EU)	
		Gastric or esophago-gastric junction cancer	→	→	→	→	(JP, KR, TW, US, EU)	
		Hepatocellular carcinoma	→	→	→	→	(JP, KR, EU)	
		Glioblastoma	→	→	→	→	(JP, US, EU)	
		Ovarian cancer	→	→	→	→	(JP, US, EU)	
		Colorectal cancer	→	→	→	→	(JP, EU)	
		Gastric cancer	→	→	→	→	(US, EU)	
		Urothelial carcinoma	→	→	→	→	(JP)	
		Multiple myeloma	→	→	→	→	(US, EU) (JP)	
		Pancreatic cancer	→	→	→	→	(JP, KR, TW, US, EU)	
		Solid tumors (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	→	→	→	→	(JP)	
		Central nervous system lymphoma, Primary testicular lymphoma	→	→	→	→	(JP, US, EU)	
		Diffuse large B cell lymphoma	→	→	→	→	(US, EU)	
		Follicular lymphoma	→	→	→	→	(US, EU)	
		Prostate cancer	→	→	→	→	(US, EU)	
		Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial carcinoma, Ovarian cancer)	→	→	→	→	(US, EU)	
		Virus positive / negative solid carcinoma	→	→	→	→	(JP, KR, TW, US, EU)	
		Biliary tract cancer	→	→	→	→	(JP)	
Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	→	→	→	→	(US, EU)			
Chronic myeloid leukemia	→	→	→	→	(US, EU)			
Yervoy Injection	Anti-CTLA-4 antibody	Renal cell carcinoma	→	→	→	→	(JP) (KR, TW)	Co-development with Bristol-Myers Squibb
		Non-small cell lung cancer	→	→	→	→	(JP, KR, TW)	
		Small cell lung cancer	→	→	→	→	(JP, KR, TW)	
		Head and neck cancer	→	→	→	→	(JP, KR, TW)	
		Gastric cancer	→	→	→	→	(JP, KR, TW)	
		Malignant pleural mesothelioma	→	→	→	→	(JP)	
		Esophageal cancer	→	→	→	→	(JP, KR, TW)	
		Urothelial carcinoma	→	→	→	→	(JP, KR, TW)	
Virus positive / negative solid carcinoma	→	→	→	→	(JP, KR, TW)			
ONO-7702 / Encorafenib	BRAF inhibitor	Melanoma	→	→	→	→	(JP) (KR)	In-license (Array BioPharma)
		Colorectal cancer	→	→	→	→	(JP, KR)	
ONO-7703 / Binimetinib	MEK inhibitor	Melanoma	→	→	→	→	(JP) (KR)	In-license (Array BioPharma)
		Colorectal cancer	→	→	→	→	(JP, KR)	

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage				Area*	
			I	II	III	Filed		
ONO-5371 / Metyrosine	Tyrosine hydroxylase inhibitor	Pheochromocytoma	→				(JP)	In-license (Valeant Pharmaceuticals North America)
Kyprolis for Intravenous Infusion	Proteasome inhibitor	Multiple myeloma	→				(JP)	In-license (Amgen)
ONO-7643 / Anamorelin	Ghrelin mimetic	Cancer anorexia / cachexia	→				(JP)	In-license (Helsinn Healthcare)
ONO-7701 (BMS-986205)	IDO1 inhibitor	Melanoma	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-4687 (BMS-986227) / Cabiralizumab	Anti-CSF-1R antibody	Pancreatic cancer	→				(JP, KR, TW)	Co-development with Bristol-Myers Squibb
ONO-4686 (BMS-986207)	Anti-TIGIT antibody	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-4059 / Tirabrutinib	Bruton's tyrosine kinase (Btk) inhibitor	Central nervous system lymphoma	→				(JP)	In-house
		B cell lymphoma	→				(EU) (US)	Out-license (Gilead Sciences)
ONO-4482 (BMS-986016) / Relatlimab	Anti-LAG-3 antibody	Melanoma	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-7807 (BMS-986258)	Anti-TIM-3 antibody	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-4481 (BMS-663513) / Urelumab	Anti-CD137 antibody	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-4483 (BMS-986015) / Lirilumab	Anti-KIR antibody	Solid tumor	→				(JP)	Co-development with Bristol-Myers Squibb
ONO-4578	PG receptor (EP4) antagonist	Solid tumor	→				(JP)	In-house
ONO-7705	XPO1 inhibitor	Multiple myeloma and non-Hodgkin lymphoma	→				(JP)	In-license (Karyopharm Therapeutics)
ONO-7475	Axl / Mer inhibitor	Acute leukemia	→				(US)	In-house

## Main Status of Development Pipelines (Other than Oncology)

Product (Development Code)	Pharmacological Action, etc.	Proposed Indication	Development Stage				Area*	
			I	II	III	Filed		
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	β <sub>1</sub> blocker (short acting)	Ventricular arrhythmia	→				(JP)	In-house
		Tachyarrhythmia in low cardiac function for pediatric use	→				(JP)	
		Tachyarrhythmia upon sepsis	→				(JP)	
Orencia IV	T-cell activation inhibitor	Lupus nephritis	→				(JP)	Co-development with Bristol-Myers Squibb
Orencia SC	T-cell activation inhibitor	Untreated rheumatoid arthritis	→				(JP)	Co-development with Bristol-Myers Squibb
		Primary Sjögren syndrome	→				(JP)	
		Polymyositis / Dermatomyositis	→				(JP)	
ONO-1162 / Ivabradine	If channel inhibitor	Chronic heart failure	→				(JP)	In-license (Les Laboratoires Servier)
ONO-5704 / SI-613	Hyaluronic acid-NSAID	Osteoarthritis	→				(JP)	In-license (Seikagaku)
ONO-2370 / Opicapone	Long acting COMT inhibitor	Parkinson's disease	→				(JP)	In-license (Bial)
ONO-5704 / SI-613	Hyaluronic acid-NSAID	Enthesopathy	→				(JP)	In-license (Seikagaku)
Opdivo Intravenous Infusion	Human anti-human PD-1 monoclonal antibody	Sepsis	→				(JP)	Co-development with Bristol-Myers Squibb
		Hepatitis C	→				(US, EU)	
		Sepsis	→				(US)	
ONO-4059 / Tirabrutinib	Bruton's tyrosine kinase (Btk) inhibitor	Sjögren syndrome	→				(US, EU)	Out-license (Gilead Sciences)
		Autoimmune disease	→				(JP)	In-house
ONO-5788	Growth hormone secretion inhibitor	Acromegaly	→				(US)	In-house

\*JP / Japan KR / South Korea TW / Taiwan US / United States of America EU / European Union