

Development Pipeline Progress Status



ONO PHARMACEUTICAL CO.,LTD.

Development status of ONO-4538(nivolumab)①

Target Disease	JAPAN	US/EU	KR/TW
Melanoma(2 nd ~)	Launched	Launched (US) Launched (EU)	Approved (KR) Filing (TW)
Melanoma(1 st)	Filing	Approved (US) Approved (EU)	Filing (KR) (TW)
Melanoma(1 st) (combination with Ipilimumab)	II	Approved (US) Filing (EU)	—
Non-small cell lung cancer(2 nd ~)	Approved	Approved (US) Filing (EU) *	Filing (KR) Filing (TW)**
Non-small cell lung cancer(1 st)	III	III	III
Renal cell carcinoma(2 nd)	Filing	Approved(US) Filing(EU)	—
Renal cell carcinoma(1 st) (combination with Ipilimumab)	III	III	III
Head and neck carcinoma	III	III	III
Gastric cancer	III	I / II	III
Small cell lung cancer	III	III	III
Esophageal cancer	III	III	III
Glioblastoma	III	III	—

*SQ NSCLC has approved.

**SQ NCSLC has filed.

Development status of ONO-4538(nivolumab)②

Target Disease	JAPAN	US/EU	KR/TW
Hepatocellular carcinoma	III	III (BMS)	III
Hodgkin lymphoma	II	II (BMS)	—
Ovarian cancer	II	—	—
Urothelial cancer	II	III (BMS)	—
Virus positive, negative solid cartinoma	I / II	I / II (BMS)	I / II
Diffuse large B cell lymphoma(Non-Hodgkin lymphoma)	—	II (BMS)	—
Follicular lymphoma(Non-Hodgkin lymphoma)	—	II (BMS)	—
Colon cancer	—	I / II (BMS)	—
Pancreatic cancer, Small cell lung cancer, Triple negative breast cancer, Urothelial cancer	—	I / II (BMS)	—
Bile duct carcinoma	I	—	—
Hematologic malignancies	—	I (BMS)	—
Chronic myelogenous leukemia	—	I (BMS)	—

red : Hematologic malignancies

Combination clinical trials (OPDIVO & other I-O compounds)

Combination	Cancer type	Phase	Area
Nivolumab + Ipilimumab	Renal cell carcinoma	III	US,EU,JP, KR,TW
	Melanoma	III	US
		II	JP
	NSCLC	III	US,EU,JP, KR,TW
Nivolumab + Lirilumab (Anti-KIR antibody)	Solid tumor	I	US
Nivolumab + BMS-986016 (Anti-LAG-3 antibody)	Solid tumor	I	US,EU,JP
Nivolumab + Urelumab (CD137 receptor agonist)	Solid tumor, Non-Hodgkin Lymphoma	I / II	US,EU,JP
Nivolumab + Mogamulizumab	Solid tumor	I	JP

Global Development Projects

*The most advanced stage is shown

Development Code	Target Disease	Overseas*	JAPAN*
ONO-6950	Bronchial asthma	II	II
ONO-2952	Irritable bowel syndrome (IBS)	II	—
ONO-9054	Glaucoma, Ocular hypertension	II	—
ONO-4059	B-cell lymphoma	I	I
ONO-8055	Underactive bladder	I	—
ONO-2160	Parkinson's disease	—	I
ONO-1266	Portal hypertension	I	—
ONO-4232	Acute heart failure	I	—
ONO-4474	Osteoarthritis	I	—

Development pipeline list in Japan (1)

*The most advanced stage is shown

Development code /Product name /Product candidate name	Planned indication	JAPAN
Proemend (pediatric)	Chemotherapy-induced nausea and vomiting	Filing
ONO-7057 (Carfilzomib)	Multiple myeloma	Filing
ONO-5163	Secondary hyperparathyroidism	Filing
ONO-4164IV (Orencia IV)	Juvenile idiopathic arthritis	III
ONO-4164IV (Orencia IV)	Lupus nephritis	III
ONO-4164IV (Orencia SQ)	Untreated rheumatoid arthritis	III
ONO-7057 (Additional dosing regimen)	Multiple myeloma	III
ONO-1162	Chronic heart failure	III
Onoact (pediatric)	Tachyarrhythmia in low cardiac function	II / III
Onoact IV	ventricular arrhythmia	II / III

Development pipeline list in Japan (2)

*The most advanced stage is shown

Development code /Product name/Product candidate name	Planned indication	JAPAN
ONO-7643	Cancer cachexia	II
ONO-6950	Bronchial asthma	II
ONO-2370 (COMT inhibitor)	Parkinson's disease	II
ONO-5371	Pheochromocytoma	I / II
ONO-7268MX1	Hepatocellular carcinoma	I
ONO-7268MX2	Hepatocellular carcinoma	I
ONO-2160/CD (levodopa pro-drug)	Parkinson's disease	I
ONO-4059	B-cell lymphoma	I