

Development Pipeline Progress Status



ONO PHARMACEUTICAL CO.,LTD.

Development status of ONO-4538 (nivolumab) ①

Target disease	JAPAN	US/EU	KR/TW
Non-small cell lung cancer (2 nd ~)	Approved	Approved	Approved *)
Non-small cell lung cancer (1 st)	Ⅲ	Ⅲ	Ⅲ
Renal cell carcinoma (2 nd ~)	Filing	Approved	Filing (TW)
Renal cell carcinoma (1 st) (combination with Ipilimumab)	Ⅲ	Ⅲ	Ⅲ
Hodgkin lymphoma	Filing	Approved (US) Filing (EU)	-
Head and neck carcinoma	Filing	Filing	Filing (TW) Ⅲ (KR)
Gastric cancer	Ⅲ	I / II	Ⅲ
Small cell lung cancer	Ⅲ	Ⅲ	Ⅲ
Hepatocellular carcinoma	Ⅲ	Ⅲ	Ⅲ
Esophageal cancer	Ⅲ	Ⅲ	Ⅲ
Glioblastoma	Ⅲ	Ⅲ	-
Urothelial cancer	Ⅲ	Ⅲ	Ⅲ
Multiple myeloma	-	Ⅲ	-
Gastro-esophageal junction cancer and esophageal cancer	-	Ⅲ	-

*) : Approved only for squamous NSCLC and under filing for non-squamous NSCLC in Taiwan

Red : Hematologic malignancies Yellow : Change from the announcement in May 2016

Development status of ONO-4538 (nivolumab) ②

Target Disease	JAPAN	US/EU	KR/TW
Diffuse large B cell lymphoma (Non-Hodgkin lymphoma)	-	II	-
Follicular lymphoma (Non-Hodgkin lymphoma)	-	II	-
Ovarian cancer	II	-	-
Virus positive/negative solid carcinoma	I / II	I / II	I / II
Colon cancer	-	I / II	-
Pancreatic cancer, Gastric cancer, Small cell lung cancer, Triple negative breast cancer, Urothelial cancer, Ovarian cancer	-	I / II	-
Malignant pleural mesothelioma	II	-	-
Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma	II	-	-
Bile duct carcinoma	I	-	-
Blood cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	-	I	-
Chronic myelogenous leukemia	-	I	-

Red : Hematologic malignancies

Yellow : Change from the announcement in May 2016

Clinical trials in combination therapy (OPDIVO & other I-O compounds)

Combination therapy	Cancer type	Japan	US/EU	KR/TW
Nivolumab+Ipilimuma	Renal cell carcinoma	Ⅲ	Ⅲ	Ⅲ
	Melanoma	Ⅱ	Approved (US) Approved (EU)	—
	NSCLC	Ⅲ	Ⅲ	Ⅲ
	Small cell lung cancer	Ⅲ	Ⅲ	Ⅲ
	Head and neck cancer	—	Ⅲ	—
Nivolumab+Lirilumab (Anti-KIR antibody)	Solid tumor	—	I	—
Nivolumab+BMS-986016 (Anti-LAG-3 antibody)	Solid tumor	—	I	—
Nivolumab+Urelumab (CD137 receptor agonist)	Solid tumor, Non-Hodgkin lymphoma	I	I / II	—
Nivolumab+Mogamulizumab (Anti-CCR4 antibody)	Solid tumor	I	I	—

Yellow : Change from the announcement in May 2016

Global Development Projects

Development Code	Target Disease	Overseas*	JAPAN*
ONO-2952	Irritable bowel syndrome (IBS)	II	–
ONO-4059	B-cell lymphoma	I	I
ONO-8055	Underactive bladder	I	–
ONO-2160	Parkinson's disease	–	I
ONO-4232	Acute heart failure	I	–
ONO-4474	Osteoarthritis	I	–

*Most advantage stage is shown.

Major development pipeline in Japan (1)

Product name/its candidate /development code	Target indication	Japan
ONO-7057 (carfilzomib)	Multiple myeloma	Approved
ONO-5163	Secondary hyperparathyroidism	Filing
Orencia IV (Pediatric)	Juvenile idiopathic arthritis	III
Orencia IV (Additional indication)	Lupus nephritis	III
Orencia SC (Additional indication)	Untreated rheumatoid arthritis	III
ONO-7057 (Dose change)	Multiple myeloma	III
ONO-1162	Chronic heart failure	III
Onoact (Pediatric: Additional indication)	Tachyarrhythmia in low cardiac function	II / III
Onoact	Ventricular arrhythmia	II / III
ONO-5371	Pheochromocytoma	I / II

*Most advantage stage is shown.

Yellow : Change from the announcement in May 2016

Development pipeline in Japan (2)

Product name/ its candidate/development code	Target indication	Japan
ONO-7643	Cancer cachexia	II
ONO-2370 (COMT inhibitor)	Parkinson's disease	II
ONO-7268MX1	Hepatocellular carcinoma	I
ONO-7268MX2	Hepatocellular carcinoma	I
ONO-2160 (levodopa pro-drug)	Parkinson's disease	I
ONO-4059	B-cell lymphoma	I
ONO-8577	Overactive bladder	I

*Most advantage stage is shown.