

Development Pipeline Progress Status



ONO PHARMACEUTICAL CO.,LTD.

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Development status of OPDIVO (nivolumab) ①

Target disease	JAPAN	US/EU	KR/TW
Melanoma (1 st)	Approved	Approved	Approved
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 ~)	Approved	Approved	Filing (TW)
Renal cell carcinoma (1 st) (combination with Ipilimumab)	Ⅲ	Ⅲ	Ⅲ
Hodgkin lymphoma	Approved	Approved (US) Approved (EU)	—
Head and neck carcinoma	Filing	Approved (US) Filing (EU)	Filing (TW) Ⅲ (KR)
Urothelial cancer	Ⅲ	Filing	Ⅲ
Gastric cancer	Filing	Ⅲ	Ⅲ
Gastro-esophageal junction cancer and esophageal cancer	Ⅲ	Ⅲ	Ⅲ
Small cell lung cancer	Ⅲ	Ⅲ	Ⅲ
Hepatocellular carcinoma	Ⅲ	Ⅲ	Ⅲ
Esophageal cancer	Ⅲ	Ⅲ	Ⅲ
Glioblastoma	Ⅲ	Ⅲ	—

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

Red : Hematologic malignancies

Green : Change from the announcement in November 2016

Development status of OPDIVO (nivolumab) ②

Target Disease	JAPAN	US/EU	KR/TW
Multiple myeloma	—	III	—
Malignant pleural mesothelioma	III	III	—
Ovarian cancer	III	II	II
Central Nervous System Lymphoma, Primary Testicular Lymphoma	II	II	—
Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma	II	—	—
Diffuse large B cell lymphoma (Non-Hodgkin lymphoma)	—	II	—
Follicular lymphoma (Non-Hodgkin lymphoma)	—	II	—
Colon cancer	—	I / II	—
Virus positive/negative solid carcinoma	I / II	I / II	I / II
Pancreatic cancer, Triple Negative Breast cancer (CheckMate-032 study)	—	I / II	—
Biliary tract cancer	I	—	—
Chronic myeloid leukemia	—	I	—
Hepatitis C	—	I	—
Sepsis	—	I (US)	—

Red : Hematologic malignancies

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Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds ①

Combination therapy	Cancer type	Japan	US/EU	KR/TW
Nivolumab + Ipilimumab	Melanoma	II	Approved	—
	Renal cell carcinoma	III	III	III
	Non-small cell lung cancer	III	III	III
	Small cell lung cancer	III	III	III
	Head and neck cancer	—	III	—
	Gastric cancer	III	III	III
	Malignant pleural mesothelioma	III	III	—

Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds ②

Combination therapy	Cancer type	Japan	US/EU	KR/TW
Nivolumab + Lirilumab (Anti-KIR antibody)	Solid tumor	—	I / II	—
Nivolumab + BMS-986016 (Anti-LAG-3 antibody)	Solid tumor	I	I / II	—
Nivolumab + Urelumab (CD137 receptor agonist)	Solid tumor, Non-Hodgkin lymphoma	I	I / II	—
Nivolumab + Mogamulizumab (Anti-CCR4 antibody)	Solid tumor	I	I	—
Nivolumab + BMS-986207 (Anti-TIGIT antibody)	Solid tumor	I (plan)	I	—

Development pipeline in Japan (1)

Product name/its candidate /development code	Target indication	Japan
Parsabiv (ONO-5163)	Secondary hyperparathyroidism	Approved
KYPROLIS (Additional Dosage and Administration)	Multiple myeloma	Filing
Orencia IV (Pediatric)	Juvenile idiopathic arthritis	III
Orencia IV (Additional indication)	Lupus nephritis	III
Orencia IV (Additional indication)	Untreated rheumatoid arthritis	III
Orencia IV (Additional indication)	Primary sjögren syndrome	III
KYPROLIS (Change in Dosage and Administration)	Multiple myeloma	III
ONO-1162	Chronic heart failure	III
ONO-7643	Cancer anorexia/cachexia (for all types of cancers)	III
Onoact (Pediatric)	Tachyarrhythmia in low cardiac function	II / III
Onoact (Additional indication)	Ventricular arrhythmia	II / III
ONO-2370	Parkinson's disease	II
ONO-5371	Pheochromocytoma	I / II

Green : Change from the announcement in November 2016

Development pipeline in Japan (2)

Product name/ its candidate/development code	Target indication	Japan
ONO-7268MX1	Hepatocellular carcinoma	I
ONO-7268MX2	Hepatocellular carcinoma	I
ONO-2160/CD	Parkinson's disease	I
ONO-4059	B-cell lymphoma	I
ONO-8577	Overactive bladder	I
ONO-4578	Solid tumor	I

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