

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	Approved (TW) Approved (KR)
Renal cell carcinoma (1 st)	Filing	Filing	III
Hodgkin lymphoma	Approved	Approved	Approved
Head and neck carcinoma	Approved	Approved	Approved
Urothelial cancer	III	Approved (US) Approved (EU)	Approved
Gastric cancer	Approved	III	Approved (TW) III(KR)
Gastro-esophageal junction cancer and esophageal cancer	III	III	III
Small cell lung cancer	III	III	III
Hepatocellular carcinoma	III	Approved (US) III (EU)	III
Esophageal cancer	III	III	III

*) : Additionally approved for non-squamous NSCLC in Taiwan

Red : Hematologic malignancy

Green : Change from the announcement in May 2017

Development status of OPDIVO (nivolumab) ②

Target disease	JAPAN	US/EU	KR/TW
Glioblastoma	III	III	-
Multiple myeloma	II	III	-
Malignant pleural mesothelioma	Filing	III	-
Ovarian cancer	III	I / 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	-
Colorectal cancer	-	Approved (US) II (EU)	-
Prostate cancer	-	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	-

Red : Hematologic malignancy

Green : Change from the announcement in May 2017

Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds ①

Combination therapy	Cancer type	Japan	US/EU	KR/TW
Nivolumab + Ipilimumab	Melanoma	Filing	Approved	Approved
	Renal cell carcinoma	Filing	Filing	III
	Non-small cell lung cancer	III	III	III
	Small cell lung cancer	III	III	III
	Head and neck cancer	III	III	III
	Gastric cancer	III	III	III
	Malignant pleural mesothelioma	III	III	-
	Esophageal cancer	III	III	III
	Urothelial cancer	III	III	III
	Colorectal cancer	-	II	-
	Ovarian cancer	-	I / II	-
Virus positive/negative solid carcinoma	I / II	I / II	I / II	

Green : Change from the announcement in May 2017

Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds ②

Combination therapy with nivolumab	Cancer type	Japan	US/EU	KR/TW
ONO-7701 (IDO1 inhibitor)	Melanoma	III	III	-
	Solid tumor, Hematologic malignancy	I	I / II	-
ONO-4686 (Anti-TIGIT antibody)	Solid tumor	I / II	I / II	-
ONO-4482 / Relatlimab (Anti-LAG-3 antibody)	Melanoma	I / II	-	-
	Solid tumor	I	I / II	-
ONO-4483 / Lirilumab (Anti-KIR antibody)	Solid tumor	I	I / II	-
ONO-4481 / Urelumab (CD137 receptor agonist)	Solid tumor	I	I / II	-
Mogamulizumab (Anti-CCR4 antibody)	Solid tumor	I	I / II	-
ONO-4687 / Cabiralizumab (Anti-CSF-1R antibody)	Solid tumor, Hematologic malignancy	I	I	-

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Development pipeline in Japan (Oncology, other than OPDIVO)

Product name/its candidate /development code	Target indication	Japan
KYPROLIS (Additional dosage and administration)	Multiple myeloma	Approved
KYPROLIS (Change in dosage and administration)	Multiple myeloma	III
ONO-7643 (Anamorelin)	Cancer anorexia/cachexia (in all types of cancer)	III
ONO-7702 (Encorafenib)	Melanoma	III
ONO-7703 (Binimetinib)	Melanoma	III
ONO-7701 (BMS-986205)	Melanoma	III
ONO-5371 (Metyrosine)	Pheochromocytoma	I / II
ONO-4686 (BMS-986207)	Solid tumor	I / II
ONO-4059 (Tirabrutinib)	Central nervous system lymphoma	I / II
ONO-4482 (Relatlimab)	Melanoma	I / II
ONO-4481 (Urelumab)	Solid tumor	I
ONO-4687 (Cabiralizumab)	Solid tumor and hematologic cancer	I
ONO-4483 (Lirilumab)	Solid tumor	I
ONO-4578	Solid tumor	I

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Development pipeline in Japan (Non-oncology)

Product name/its candidate /development code	Target indication	Japan
Orencia IV (Pediatric)	Juvenile idiopathic arthritis	Filing
Orencia IV (Additional indication)	Lupus nephritis	III
Orencia SC (Additional indication)	Untreated rheumatoid arthritis	III
Orencia SC (Additional indication)	Primary Sjögrens syndrome	III
Orencia SC (Additional indication)	Polymyositis / Dermatomyositis	III
ONO-1162 (Ivabradine)	Chronic heart failure	III
ONO-5704 (SI-613)	Osteoarthritis	III
Onoact (Pediatric)	Tachyarrhythmia in low cardiac function	II / III
Onoact (Additional indication)	Ventricular arrhythmia	II / III
	Tachyarrhythmia upon sepsis	II / III
ONO-2370 (Opicapone)	Parkinson's disease	II
ONO-5704 (SI-613)	Enthesopathy	II
Opdivo (Additional indication)	Sepsis	I / II
ONO-4059 (Tirabrutinib)	Autoimmune disease	I

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Global development projects (Other than OPDIVO)

Development code /Generic name	Target indication /Pharmacological Action	Phase	Area
ONO-7702 (Encorafenib)	Colorectal cancer /BRAF inhibitor	III	KR
	Melanoma /BRAF inhibitor	III	KR
ONO-7703 (Binimetinib)	Colorectal cancer /MEK inhibitor	III	KR
	Melanoma /MEK inhibitor	III	KR
ONO-4059 (Tirabrutinib)	B cell lymphoma /Btk inhibitor	II	EU
	Sjögrens syndrome /Btk inhibitor	II	US/EU
ONO-7579	Solid tumor /Trk inhibitor	I / II	US/EU
ONO-4059 (Tirabrutinib)	B cell lymphoma /Btk inhibitor	I	US
ONO-7475	Acute leukemia / Axl / Mer inhibitor	I	US
ONO-8055	Underactive bladder /PG receptor (EP2 / EP3) agonist	I	EU

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