

Development Pipeline Progress Status



February 1, 2019

Development status of OPDIVO (nivolumab) (1)

Target disease	JAPAN	US/EU	KR/TW
Melanoma (1 st)	Approved	Approved	Approved
Melanoma (Adjuvant Therapy)	Approved	Approved (US) Approved(EU)	III
Non-small cell lung cancer (2 nd ~)	Approved	Approved	Approved
Non-small cell lung cancer (1 st)	III	III(US) Filing(EU)	III
Renal cell carcinoma (2 nd ~)	Approved	Approved	Approved
Renal cell carcinoma (1 st)	Approved	Approved (US) Approved(EU)	Approved
Hodgkin lymphoma	Approved	Approved	Approved
Head and neck carcinoma	Approved	Approved	Approved
Urothelial cancer	III	Approved	Approved
Gastric cancer	Approved	III	Approved
Gastro-esophageal junction cancer and esophageal cancer	III	III	III
Small cell lung cancer	III	Approved (US) III (EU)	III
Hepatocellular carcinoma	III	Approved (US) III (EU)	III(KR) Approved (TW)
Esophageal cancer	III	III	III
Bladder cancer	III	III	III
Glioblastoma	III	III	-

*Red : Change from the announcement in May 2018



Development status of OPDIVO (nivolumab) (2)

Target disease	JAPAN	US/EU	KR/TW
Multiple myeloma	-	III	-
Malignant pleural mesothelioma	Approved	III	-
Ovarian cancer	III	III	-
Colorectal cancer	II / III	Approved (US) II / III (EU)	-
Central nervous system lymphoma, Primary Testicular Lymphoma	II	II	-
Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma	II	-	-
Pancreatic cancer	II	II	II
Diffuse large B cell lymphoma (Non-Hodgkin lymphoma)	-	II	-
Follicular lymphoma (Non-Hodgkin lymphoma)	-	II	-
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	-	-
Blood cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)			
Chronic myeloid leukemia	-	I	-

*Red : Change from the announcement in May 2018



Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds (1)

Combination therapy	Cancer type	Japan	US/EU	KR/TW
Nivolumab + Ipilimumab	Melanoma	Approved	Approved	Approved
	Renal cell carcinoma	Approved	Approved(US) Approved(EU)	Approved
	Non-small cell lung cancer	III	Filing(US) Filing(EU)	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	-	Approved(US) II (EU)	-
	Ovarian cancer	-	I / II	-
	Virus positive/negative solid carcinoma	I / II	I / II	I / II

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Clinical trials in combination therapy

OPDIVO (nivolumab) & other I-O compounds (2)

Development code/ Generic name (Pharmacological action)	Cancer type	Japan	US/EU	KR/TW
ONO-4687 / Cabiralizumab (Anti-CSF-1R antibody)	Pancreatic cancer	II	II	II
ONO-7701 (IDO1 inhibitor)	Melanoma	III	III	-
	Bladder cancer	III	III	III
ONO-4686 (Anti-TIGIT antibody)	Solid tumor	I / II	I / II	-
ONO-7807 (Anti-TIM-3 antibody)	Solid tumor	I / II	I / II	-
ONO-4482 / Relatlimab (Anti-LAG-3 antibody)	Melanoma	I / II	II / III	-
ONO-4483 / Lirilumab (Anti-KIR antibody)	Solid tumor	I	I / II	-
ONO-4481 / Urelumab (CD137 receptor agonist)	Solid tumor	I	I / II	-
ONO-7475 (Axl/Mer inhibitor)	Solid tumor	I	-	-

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Development pipeline in Japan (Oncology, other than OPDIVO) (1)

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
Braftovi (Encorafenib)	Melanoma	BRAF inhibitor
Mektovi (Binimetinib)	Melanoma	MEK inhibitor
Demser (Metyrosine)	Pheochromocytoma	Tyrosine hydroxylase inhibitor
【Filing】		
ONO-7643 (Anamorelin)	Cancer cachexia (in all types of cancer)	Ghrelin mimetic
【Phase III】		
KYPROLIS <Change in dosage and administration>	Multiple myeloma	Proteasome inhibitor
Braftovi (Encorafenib)	Colorectal cancer	BRAF inhibitor
Mektovi (Binimetinib)	Colorectal cancer	MEK inhibitor
ONO-7701 / BMS-986205	Melanoma	IDO1 inhibitor
	Bladder cancer	IDO1 inhibitor

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Development pipeline in Japan (Oncology, other than OPDIVO) (2)

Development code (Generic name)	Target indication	Pharmacological action
【Phase II】		
ONO-4687 (Cabiralizumab)	Pancreatic cancer	Anti-CSF-1R antibody
ONO-4059 (Tirabrutinib)	Primary macroglobulinemia, Lymphoplasmacytic lymphoma	Btk inhibitor
【Phase I / II】		
ONO-4686 / BMS-986207	Solid tumor	Anti-TIGIT antibody
ONO-4059 (Tirabrutinib)	Central nervous system lymphoma	Btk inhibitor
ONO-4482 (Relatlimab)	Melanoma	Anti-LAG-3 antibody
ONO-7807 / BMS-986258	Solid tumor	Anti-TIM-3 antibody
【Phase I】		
ONO-4481 (Urelumab)	Solid tumor	Anti-CD137 antibody
ONO-4483 (Lirilumab)	Solid tumor	Anti-KIR antibody
ONO-4578	Solid tumor	PG receptor (EP4) antagonist
ONO-7705	Multiple myeloma, Non-Hodgkin lymphoma	XPO1 inhibitor
ONO-7475	Solid tumor	Axl / Mer inhibitor

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Development pipeline in Japan (Non-oncology) (1)

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filing】		
Onoact <Additional indication>	Ventricular arrhythmia	β₁ blocker (short acting)
Rivastach Patch <Change of dosage form>	Alzheimer's disease	acetylcholinesterase inhibitor
ONO-1162 (Ivabradine)	Chronic heart failure	HCN channel inhibitor

【Phase III】		
Orencia SC <Additional indication>	Untreated rheumatoid arthritis	T-cell activation inhibitor
Orencia SC <Additional indication>	Primary Sjögrens syndrome	T-cell activation inhibitor
Orencia SC <Additional indication>	Polymyositis/Dermatomyositis	T-cell activation inhibitor
ONO-5704 / SI-613	Osteoarthritis	Hyaluronic acid-NSAID

【Phase II / III】		
Onoact <Pediatric>	Tachyarrhythmia in low cardiac function	β₁ blocker (short acting)
Onoact <Additional indication>	Tachyarrhythmia upon sepsis	β₁ blocker (short acting)

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Development pipeline in Japan (Non-oncology) (2)

Development code (Generic name)	Target indication	Pharmacological action
【Phase II】		
ONO-2370 (Opicapone)	Parkinson's disease	Long acting COMT inhibitor
ONO-5704 / SI-613	Enthesopathy	Hyaluronic acid-NSAID
ONO-4059 (Tirabrutinib)	Pemphigus	Btk inhibitor

【Phase I】		
ONO-7269	Cerebral infarction	FXIa inhibitor

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Global development projects (Other than OPDIVO)

Development code (Generic name)	Target indication	Pharmacological action	Area
【Phase III】			
ONO-7702 (Encorafenib)	Colorectal cancer	BRAF inhibitor	KR
	Melanoma		KR
ONO-7703 (Binimetinib)	Colorectal cancer	MEK inhibitor	KR
	Melanoma		KR
ONO-7701 / BMS-986205	Bladder cancer	IDO1 inhibitor	KR/TW
【Phase II】			
ONO-4059 (Tirabrutinib)	B cell lymphoma	Btk inhibitor	EU
	Sjögrens syndrome		US/EU
ONO-4687 (Cabiralizumab)	Pancreatic cancer	Anti-CSF-1R antibody	KR/TW
【Phase I / II】			
ONO-4578	Solid tumor	PG receptor (EP4) antagonist	US/EU
【Phase I】			
ONO-4059 (Tirabrutinib)	B cell lymphoma	Btk inhibitor	US
ONO-7475	Acute leukemia	Axl / Mer inhibitor	US
ONO-5788	Acromegaly	Growth hormone secretion inhibitor	US
ONO-7684	Thrombosis	FXIa inhibitor	EU

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