

Development Pipeline Progress Status

August 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	Ⅲ(KR) Approved (TW)
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	Approved
Hodgkin lymphoma	Approved	Approved	Approved
Head and neck carcinoma	Approved	Approved	Approved
Gastric cancer	Approved	Ⅲ	Approved
Malignant pleural mesothelioma	Approved	Ⅲ	-
Colorectal cancer (MSI-H)	Filing	Approved (US) Ⅱ / Ⅲ(EU)	Approved(TW)
Esophageal cancer	Filing	Ⅲ	Ⅲ
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)

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*Red : Change from the announcement in May 2019



Development status of OPDIVO (nivolumab) (2)

Target disease	JAPAN	US/EU	KR/TW
Glioblastoma	Ⅲ	Ⅲ	-
Urothelial cancer	Ⅲ	Approved	Approved
Ovarian cancer	Ⅲ	Ⅲ	-
Bladder cancer	Ⅲ	Ⅲ	Ⅲ
Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma	Ⅱ	-	-
Central nervous system lymphoma, Primary Testicular Lymphoma	Ⅱ	Ⅱ	-
Pancreatic cancer	Ⅱ	Ⅱ	Ⅱ
Virus positive/negative solid carcinoma	I / Ⅱ	I / Ⅱ	I / Ⅱ
Biliary tract cancer	I	-	-
Multiple myeloma	-	Ⅲ	-
Diffuse large B cell lymphoma (Non-Hodgkin lymphoma)	-	Ⅱ	-
Follicular lymphoma (Non-Hodgkin lymphoma)	-	Ⅱ	-
Prostate cancer	-	Ⅱ	-
Pancreatic cancer, Triple negative breast cancer	-	I / Ⅱ	-
Blood cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	-	I	-
Chronic myeloid leukemia	-	I	-

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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	Approved	Approved	Approved
	Renal cell carcinoma	Approved	Approved	Approved
	Non-small cell lung cancer	Ⅲ	Ⅲ (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 (MSI-H)	-	Approved (US) Ⅱ (EU)	Approved (TW)
	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-7701 (IDO1 inhibitor)	Bladder cancer	Ⅲ	Ⅲ	Ⅲ
ONO-4687 / Cabiralizumab (Anti-CSF-1R antibody)	Pancreatic cancer	Ⅱ	Ⅱ	Ⅱ
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-7475 (Axl/Mer inhibitor)	Solid tumor	I	-	-
ONO-7911 (PEGylated IL-2)	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
【Filing】		
ONO-7643 (Anamorelin)	Cancer cachexia (in all types of cancer)	Ghrelin mimetic
KYPROLIS <Change in dosage and administration>	Multiple myeloma	Proteasome inhibitor

【Phase III】		
Braftovi (Encorafenib)	Colorectal cancer	BRAF inhibitor
Mektovi (Binimetinib)	Colorectal cancer	MEK inhibitor
ONO-7701 / BMS-986205	Bladder cancer	IDO1 inhibitor

【Phase II】		
ONO-4687 (Cabiralizumab)	Pancreatic cancer	Anti-CSF-1R antibody
ONO-4059 (Tirabrutinib)	Primary macroglobulinemia, Lymphoplasmacytic lymphoma	Btk inhibitor

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

Development code (Generic name)	Target indication	Pharmacological action
【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-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
ONO-7911	Solid tumor	PEGylated IL-2

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

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filing】		
ONO-1162 (Ivabradine)	Chronic heart failure	HCN channel inhibitor
ONO-2370 (Opicapone)	Parkinson's disease	Long acting COMT 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

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

Development code (Generic name)	Target indication	Pharmacological action
【Phase II / III】		
Onoact <Pediatric>	Tachyarrhythmia in low cardiac function	β_1 blocker (short acting)
Onoact <Additional indication>	Tachyarrhythmia upon sepsis	β_1 blocker (short acting)

【Phase II】		
ONO-5704 / SI-613	Enthesopathy	Hyaluronic acid-NSAID
ONO-4059 (Tirabrutinib)	Pemphigus	Btk inhibitor

【Phase I】		
ONO-7269	Cerebral infarction	FXIa inhibitor
ONO-4685	Autoimmune disease	PD-1×CD3 Bispecific antibody

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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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