

Development Pipeline Progress Status

January 31, 2020

Plan for Submissions in Japan

OPDIVO

Non-OPDIVO
Oncology

Non-
Oncology

OPDIVO
M=Mono
C=Combo

<p>Onoact 〔Tachyarrhythmia upon sepsis〕 Aug 2019</p>	<p>ONO-5704 〔Osteoarthritis〕 Jan 2020</p>	<p>〔1L-NSCLC〕 with Chemo and AVASTIN ONO-4538-52</p>	<p>〔Adjuvant-Esophageal cancer〕 Checkmate-577</p>
<p>ONO-2370 〔Parkinson's disease〕 Feb 2019</p>	<p>Kyprolis 〔Multiple myeloma〕 with DARZALE★</p>	<p>〔1L-Gastric cancer〕 with Chemo ATTRACTION-4</p>	<p>〔Adjuvant-Urothelial cancer〕 Checkmate-274</p>
<p>Coralan 〔CHF〕 Dec 2018</p>	<p>BRAFTOVI/MEKTOVI 〔BRAF mutated CRC〕</p>	<p>〔1L-RCC〕 with Cabozantinib CheckMate-9ER</p>	<p>〔1L- 1L-Malignant pleural mesothelioma〕 with YERVOY Checkmate-743</p>
<p>ONO-4059 〔PCNSL〕 Aug 2019</p>	<p>ONO-4059 〔WM/LPL〕 Nov 2019</p>	<p>〔1L-NSCLC〕 with YERVOY and with Chemo CheckMate-648</p>	<p>〔1L-Esophageal cancer〕 with YERVOY and with Chemo CheckMate-648</p>
<p>ONO-7643 〔Cancer cachexia〕 Nov 2018</p>	<p>〔1L-NSCLC〕 with YERVOY and Chemo CheckMate-9LA</p>	<p>〔1L-NSCLC〕 with YERVOY CheckMate-227</p>	<p>〔Neoadjuvant-NSCLC〕 with chemo Checkmate-816</p>
<p>〔2L-Esophageal cancer〕 ATTRACTION-3 May 2019</p>	<p>〔1L-NSCLC〕 with YERVOY CheckMate-227</p>	<p>〔1L-Head and neck cancer〕 with YERVOY Checkmate-651</p>	<p>〔1L-Head and neck cancer〕 with YERVOY Checkmate-651</p>
<p>〔MSI-High CRC〕 CheckMate-142 Mar 2019</p>	<p>〔MSI-High CRC〕 with YERVOY CheckMate-142</p>	<p>〔Adjuvant-Gastric cancer〕 with chemo CheckMate-844</p>	<p>〔Adjuvant-Gastric cancer〕 with chemo CheckMate-844</p>
<p>FY2018(2H)~2019(1H) (results)</p>	<p>FY2019 (2H)</p>	<p>〔1L-Gastric cancer〕 with YERVOY and with Chemo CheckMate-649</p>	<p>〔1L-Gastric cancer〕 with YERVOY and with Chemo CheckMate-649</p>
<p>FY2018(2H)~2019(1H) (results)</p>	<p>FY2019 (2H)</p>	<p>〔1L-Urothelial cancer〕 with YERVOY and with Chemo Checkmate-901</p>	<p>〔1L-Urothelial cancer〕 with YERVOY and with Chemo Checkmate-901</p>
<p>FY2018(2H)~2019(1H) (results)</p>	<p>FY2019 (2H)</p>	<p>FY2020 (1H)</p>	<p>FY2020 (2H)</p>

January 31 2020

★Revision of package insert

Development status of OPDIVO (1)

As of January 24, 2020

Target disease	JAPAN	US/EU	KR/TW
Melanoma (1 st)	Approved	Approved	Approved
Melanoma (Adjuvant Therapy)	Approved	Approved	Approved(KR) Approved(TW)
Non-small cell lung cancer (2 nd ~)	Approved	Approved	Approved
Non-small cell lung cancer (1 st)	Filing	Filing(US) Filing(EU)	III
Renal cell carcinoma (2 nd ~)	Approved	Approved	Approved
Renal cell carcinoma (1 st)	Approved	Approved	Approved
Hodgkin's 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)

Red: Update after May 2019

Development status of OPDIVO (2)

As of January 24, 2020

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	II	-	-
Multiple myeloma	-	III	-
Diffuse large B cell lymphoma (Non-Hodgkin's lymphoma)	-	II	-
Follicular lymphoma (Non-Hodgkin's 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	-

Red: Update after May 2019

Clinical trials in combination therapy

OPDIVO & other Immuno-Oncology compounds (1)

As of January 24, 2020

Product name (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
Yervoy Injection (Ipilimumab) Anti-CTLA-4 antibody	Melanoma	Approved	Approved	Approved
	Renal cell carcinoma	Approved	Approved	Approved
	Non-small cell lung cancer	Filing	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
	Hepatocellular carcinoma	III	Filing(US) III(EU)	III
	Colorectal cancer (MSI-H)	Filing	Approved(US) II(EU)	Approved(TW)
	Ovarian cancer	-	I / II	-
	Virus positive/negative solid carcinoma	I / II	I / II	I / II

Red: Update after May 2019



Clinical trials in combination therapy

OPDIVO & other Immuno-Oncology compounds (2)

As of January 24, 2020

Development code (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
ONO-7701 (Linrodostat) 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-4578 PG receptor (EP4) antagonist	Solid tumor	I	I / II	-
ONO-7475 Axl/Mer inhibitor	Solid tumor	I	-	-
ONO-7911 (Bempegaldesleukin) PEGylated IL-2	Solid tumor	I	I / II	-
	Melanoma	-	III	-
	Renal cell carcinoma	-	III	-

Red: Update after May 2019

Development pipeline in Japan (Oncology, other than OPDIVO)

As of January 24, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filing】		
ONO-7643 (Anamorelin)	Cancer cachexia (in all types of cancer)	Ghrelin mimetic
ONO-4059 (Tirabrutinib)	Central nervous system lymphoma	Btk inhibitor
	Primary macroglobulinemia, Lymphoplasmacytic lymphoma	

【Phase III】		
BRAFTOVI (Encorafenib)	Colorectal cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	Colorectal cancer	MEK inhibitor

【Phase I】		
ONO-4578*	Solid tumor	PG receptor (EP4) antagonist
ONO-7705 (Selinexor)	Multiple myeloma, Non-Hodgkin's lymphoma	XPO1 inhibitor
ONO-7475*	Solid tumor	Axl / Mer inhibitor

*Combination with Opdivo.

Red: Update after May 2019

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

As of January 24, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filing】		
ONO-2370 (Opicapone)	Parkinson's disease	Long acting COMT inhibitor
ONOACT	Tachyarrhythmia upon sepsis	β₁ blocker (short acting)
ONO-5704 · SI-613	Osteoarthritis	Hyaluronic acid-NSAID

【Phase III】		
ORENCIA SC	Untreated rheumatoid arthritis	T-cell activation inhibitor
	Primary Sjögrens syndrome	
	Polymyositis/Dermatomyositis	

Red: Update after May 2019

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

As of January 24, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase II / III】		
ONOACT	Tachyarrhythmia in low cardiac function <Pediatric>	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

Red: Update after May 2019

Global development projects (Other than OPDIVO)

As of January 24, 2020

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-7912・CPI-613 (Devimistat)	Pancreatic cancer	Cancer metabolism inhibitor	KR
	Acute Myeloid Leukemia		KR
【Phase II】			
ONO-4059 (Tirabrutinib)	B cell lymphoma	Btk inhibitor	EU
	Sjögrens syndrome		US/EU
【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-7684	Thrombosis	FXIa inhibitor	EU
ONO-2808	Neurodegenerative disease	S1P5 receptor agonist	EU

*Combination with Opdivo.

Red: Update after May 2019



ONO PHARMACEUTICAL CO.,LTD.

Dedicated to Man's Fight against Disease and Pain