

Development Pipeline Progress Status

Jul 31, 2020

Cautionary Notes

Forecasts and other forward-looking statements included in this document are based on information currently available and certain assumptions that the Company deems reasonable.

Actual performance and other results may differ significantly due to various factors. Such factors include, but are not limited to:

- (i) failures in new product development***
- (ii) changes in general economic conditions due to reform of medical insurance system***
- (iii) failures in obtaining the expected results due to effects of competing products or generic drugs***
- (iv) infringements of the Company's intellectual property rights by third parties***
- (v) stagnation of product supply from the delay in production due to natural disasters, fires and so on***
- (vi) onset of new side effect of post-licensure medical product***
- and, (vii) currency exchange rate fluctuations and interest rate trend.***

Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

Plan for Submissions in Japan

OPDIVO

Non-OPDIVO
Oncology

Non-
Oncology

OPDIVO
M=Mono
C=Combo

2019 (results)	2020年 (1H)	2020 (2H)	2021
<p>[2L-Esophageal cancer] ATTRACTION-3 May 2019 (M)</p>			
<p>Onoact [Tachyarrhythmia upon sepsis] Aug 2019</p>			<p>ONO-4059 [Pemphigus]</p>
<p>ONO-4059 [PCNSL] Aug 2019</p>			<p>ONOACT<Pediatric> [Tachyarrhythmia in low cardiac function]</p>
<p>ONO-4059 [WM/LPL] Nov 2019</p>			<p>[1L-Urothelial cancer] with YERVOY Checkmate-901 (C)</p>
<p>[MSI-High CRC] with YERVOY CheckMate-142 Nov 2019 (C)</p>		<p>[Adjuvant-Gastric cancer] with Chemo ATTRACTION-5 (C)</p>	
<p>[1L-NSCLC] with YERVOY / with Chemo CheckMate-227 Dec 2019 / Feb 2020 (C)</p>		<p>[1L-RCC] with Cabozantinib CheckMate-9ER (C)</p>	
<p>ONO-5704 [Osteoarthritis] Jan 2020</p>		<p>[Adjuvant-Esophageal cancer] Checkmate-577 (M)</p>	
<p>Kyprolis [Multiple myeloma] with DARZALE* Mar 2020</p>		<p>[Adjuvant-Urothelial cancer] Checkmate-274 (M)</p>	<p>[1L-Gastric cancer] with YERVOY CheckMate-649 (C)</p>
<p>BRAFTOVI/MEKTOVI [BRAF mutant CRC] Mar 2020</p>		<p>[1L-Malignant pleural mesothelioma] with YERVOY (C) Checkmate-743</p>	<p>[1L-Esophageal cancer] with YERVOY / with Chemo CheckMate-648 (C)</p>
<p>[1L-NSCLC] with YERVOY + Chemo CheckMate-9LA Mar 2020 (C)</p>		<p>[Neoadjuvant-NSCLC] with Chemo Checkmate-816 (C)</p>	<p>[1L-Head and neck cancer] with YERVOY Checkmate-651 (C)</p>
	<p>[1L-Gastric cancer] with Chemo ATTRACTION-4 (C)</p>	<p>[1L-NSCLC] with Chemo and AVASTIN ONO-4538-52 (C)</p>	<p>[Adjuvant-RCC] with YERVOY CheckMate-914 (C)</p>
		<p>[1L-Gastric cancer] with Chemo CheckMate-649 (C)</p>	<p>[Adjuvant-Hepatocellular carcinoma] Checkmate-9DX (M)</p>

Jul 31, 2020

★Revision of package insert

Development status of OPDIVO (1)

As of Jul 24, 2020

Target disease	JAPAN	US/EU	KR/TW
Melanoma (1 st)	Approved	Approved	Approved
Melanoma (Adjuvant Therapy)	Approved	Approved	Approved
Non-small cell lung cancer (2 nd ~)	Approved	Approved	Approved
Non-small cell lung cancer (1 st)	Filing	Approved(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 cancer	Approved	Approved	Approved
Gastric cancer (3 rd)	Approved	III	Approved
Gastric cancer (1 st)	Filing	-	III
Malignant pleural mesothelioma	Approved	III	-
Colorectal cancer (MSI-H)	Approved	Approved (US) II / III (EU)	Approved(TW)
Esophageal cancer	Approved	Approved (US) III (EU)	Approved(KR) Approved(TW)
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 2020

Development status of OPDIVO (2)

As of Jul 24, 2020

Target disease	JAPAN	US/EU	KR/TW
Glioblastoma	III	III	-
Urothelial cancer	III	Approved	Approved
Ovarian cancer	III	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	III	III	III
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 2020

Clinical trials in combination therapy

OPDIVO & other Immuno-Oncology compounds (1)

As of Jul 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	Approved(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	Approved(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 2020

Clinical trials in combination therapy OPDIVO & other Immuno-Oncology compounds (2)

As of Jul 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	-
	Bladder cancer	-	III	-

Red: Update after May 2020

Development pipeline in Japan (Oncology, other than OPDIVO)

As of Jul 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
VELEXBRU (Tirabrutinib)	Primary macroglobulinemia Lymphoplasmacytic lymphoma	BTK inhibitor
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant colorectal cancer	MEK inhibitor
【Phase I】		
ONO-4578*	Solid tumor	PG receptor (EP4) antagonist
ONO-7475*	Solid tumor	Axl / Mer inhibitor
ONO-7913	Solid tumor	Anti-CD47 mAb
ONO-7912	Pancreatic Cancer	Cancer metabolism inhibitor

*Combination with Opdivo.

Red: Update after May 2020

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

As of Jul 24, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved/Launched】		
ONGENTYS / ONO-2370 (Opicapone)	Parkinson's disease	Long acting COMT inhibitor
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia upon sepsis	Short-active selective β_1 blocker
【Filing】		
ONO-5704 · SI-613	Osteoarthritis	Hyaluronic acid-NSAID
【Phase III】		
ORENCIA SC (Abatacept)	Polymyositis/Dermatomyositis	T-cell activation inhibitor
【Phase II / III】		
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia in low cardiac function <Pediatric>	Short-active selective β_1 blocker

Red: Update after May 2020

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

As of Jul 24 , 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase II】		
ONO-5704 · SI-613	Enthesopathy	Hyaluronic acid-NSAID
VELEXBRU (Tirabrutinib)	Pemphigus	BTK inhibitor

【Phase I】		
ONO-7269	Cerebral infarction	FXIa inhibitor
ONO-4685	Autoimmune disease	PD-1 × CD3 bispecific antibody
ONO-2910	Peripheral nerve disorder	Enhancement of Schwann cell differentiation
FOIPAN (Camostat mesilate)	Novel coronavirus infection (COVID-19)	Protease enzyme inhibitor

Red: Update after May 2020

Global development projects (Other than OPDIVO)

As of Jul 24, 2020

Development code (Generic name)	Target indication	Pharmacological action	Area
【Phase III】			
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor	KR
	BRAF-mutant melanoma		KR
MEKTOVI (Binimetinib)	BRAF-mutant colorectal cancer	MEK inhibitor	KR
	BRAF-mutant melanoma		KR
ONO-7912・CPI-613 (Devimistat)	Pancreatic cancer	Cancer metabolism inhibitor	KR
	Acute myeloid leukemia		KR
【Phase I】			
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 2020



ONO PHARMACEUTICAL CO.,LTD.

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