

Development Pipeline Progress Status

Oct 30, 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

<p>{2L-Esophageal cancer} ATTRACTION-3 May 2019 (M)</p>	<p>{1L-Gastric cancer} with Chemo (C) ATTRACTION-4 May 2020</p>	<p>{Cancer of unknown primary} investigator-initiated trial (M)</p>	
<p>Onoact {Tachyarrhythmia upon sepsis} Aug 2019</p>	<p>2020 (1H)</p>		<p>{1L-Urothelial cancer} with YERVOY (C) CheckMate-901</p>
<p>VELEXBRU {PCNSL} Aug 2019</p>	<p>{1L-RCC} (C) with Cabozantinib CheckMate-9ER Oct 2020</p>	<p>{1L-Gastric cancer} with YERVOY (C) CheckMate-649</p>	
<p>VELEXBRU {WM/LPL} Nov 2019</p>	<p>{1L-Malignant pleural mesothelioma} (C) with YERVOY CheckMate-743 Oct 2020</p>	<p>{1L-Esophageal cancer} with YERVOY / with Chemo (C) CheckMate-648</p>	
<p>{MSI-High CRC} with YERVOY (C) CheckMate-142 Nov 2019</p>	<p>{Adjuvant-Esophageal cancer} (M) CheckMate-577</p>	<p>{1L-Head and neck cancer} with YERVOY (C) CheckMate-651</p>	
<p>{1L-NSCLC} with YERVOY / with Chemo (C) CheckMate-227 Dec 2019 / Feb 2020</p>	<p>{Adjuvant-Urothelial cancer} (M) CheckMate-274</p>	<p>{Neoadjuvant-NSCLC} with Chemo (C) CheckMate-816</p>	
<p>ONO-5704 {Osteoarthritis} Jan 2020</p>	<p>{1L-NSCLC} (C) with Chemo and AVASTIN ONO-4538-52</p>	<p>{Adjuvant-Gastric cancer} with Chemo (C) ATTRACTION-5</p>	<p>FOIPAN (Camostat Mesilate) {COVID-19}</p>
<p>Kyprolis {Multiple myeloma} with DARZALEX* Mar 2020</p>	<p>{1L-Gastric cancer} (C) with Chemo CheckMate-649</p>	<p>{Adjuvant-RCC} with YERVOY (C) CheckMate-914</p>	<p>ONOACT <Pediatric> {Tachyarrhythmia in low cardiac function}</p>
<p>BRAFTOVI/MEKTOVI {BRAF mutant CRC} Mar 2020</p>	<p>{Hodgkin's lymphoma, pediatric} investigator-initiated trial (M)</p>	<p>{Adjuvant-Hepatocellular carcinoma} (M) CheckMate-9DX</p>	<p>ONO-4059 {Pemphigus}</p>
<p>2019 (results)</p>	<p>2020 (2H)</p>	<p>2021</p>	

Oct 27, 2020

★ Revision of package insert

Development status of OPDIVO (1)

As of Oct 27, 2020

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1 st line only)	Approved	Approved	Approved	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	III	III	III	III	III
	1st	with Ipi	Filed	III	III	Approved	–
		with Ipi + Chemo	Filed	III	III	Approved	Filed
		with Chemo	Filed	III	III	–	–
		with Chemo (NSQ)	III	III	III	–	–
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Renal cell carcinoma	Adjuvant	with Ipi	III	–	–	III	III
	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Filed	III	III	Filed	Filed
		with Ipi + TKI	–	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Hodgkin's lymphoma	Relapsed /Refractory	with Brentuximab	III	–	–	III	–
		Monotherapy	Approved	Approved	Approved	Approved	Approved
Head and neck cancer	1st	with Ipi	III	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Filed	–	–	Approved	Filed
	SOC refractory	Monotherapy	Approved	–	–	–	–

Red: Update after May 2020

Development status of OPDIVO (2)

As of Oct 27, 2020

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	Adjuvant	with Chemo	III	III	III	–	–
	1st	with Chemo	Filed	III	III	–	–
		with Ipi, with Chemo	III	III	III	III	III
	3rd	Monotherapy	Approved	Approved	Approved	–	–
Esophageal cancer	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi, with Chemo	III	III	III	III	III
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Filed
Colorectal cancer	1st	with Chemo	II / III	–	–	II / III	II / III
	MSI-H/dMMR (1st)	with Ipi	III	–	–	III	III
	MSI-H/dMMR (3rd)	Monotherapy	Approved	–	Approved	Approved	-
		with Ipi	Approved	–	Approved	Approved	Filed
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi	III	III	III	III	III
	2nd	Monotherapy, with Ipi	II	II	Approved	Approved	II
Biliary tract cancer	2nd	Monotherapy	II	–	–	–	–

Red: Update after May 2020

Development status of OPDIVO (3)

As of Oct 27, 2020

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Urothelial cancer / Bladder cancer	Adjuvant /Neo-adjuvant	with IDO1 inhibitor + Chemo, with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	III	III	III	III	III
	1st	with Ipi, with Chemo	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Glioblastoma	1st (MGMTmethylated)	with chemoradiotherapy	III	–	–	III	III
	1st (MGMT un-methylated)	with radiotherapy	III	–	–	III	III
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
	2nd	Monotherapy	III	–	–	–	–
Small cell lung cancer	3rd	Monotherapy	–	–	–	Approved	–
Dosage and Administration	240 mg (every 2 weeks)		Approved	Approved	III	Approved	Approved
	360 mg (every 3 weeks)		Filed	III	III	Approved	Filed
	480 mg (every 4 weeks)		Approved	Approved	III	Approved	Approved

Red: Update after May 2020

Clinical trials in combination therapy

OPDIVO & other Immuno-Oncology compounds

As of Oct 27, 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-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 Oct 27, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
VELEXBRU (Tirabrutinib)	Primary macroglobulinemia Lymphoplasmacytic lymphoma	BTK inhibitor
【Filed】		
ONO-7643 (Anamorelin)	Cancer cachexia (in all types of cancer)	Ghrelin mimetic
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 antibody
ONO-7912	Pancreatic Cancer	Cancer metabolism inhibitor

*Combination with Opdivo.



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

As of Oct 27, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
ONGENTYS (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 Oct 27, 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	Protease enzyme inhibitor

Red: Update after May 2020

Global development projects (Other than OPDIVO)

As of Oct 27, 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 / II】			
ONO-7475	Acute leukemia	Axl / Mer inhibitor	US
【Phase I】			
ONO-7684	Thrombosis	FXIa inhibitor	EU
ONO-2808	Neurodegenerative disease	S1P5 receptor agonist	EU

*Combination with Opdivo.
Red: Update after May 2020



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