

Development Pipeline Progress Status

August 01, 2022

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
ONOACT<Pediatric> [Tachyarrhythmia in low cardiac function] Oct 2021 [Cancer of unknown primary] investigator-initiated trial Apr 2021 (M) [1L-NSCLC] with Chemo and AVASTIN ONO-4538-52 (C) Jun 2021 (Revision of labeling) [1L-Esophageal cancer] with YERVOY / with Chemo CheckMate-648 (C) Sep 2021							[1L-Urothelial cancer] with YERVOY CheckMate-901 (C) [Perioperative Bladder cancer] With Chemo (C) ONO-4538-86 BRAFTOVI / MEKTOVI [2L-BRAF-mutant thyroid cancer] KYPROLIS [2L-Multiple Myeloma] KRd Therapy Once a week
					[Adjuvant-Gastric cancer] with Chemo (C) ATTRACTION-5 [Adjuvant-Hepatocellular carcinoma] (M) CheckMate-9DX		[1L-Urothelial cancer] with Chemo (C) CheckMate-901
				[Neoadjuvant-NSCLC] with Chemo (C) CheckMate-816 Apr 2022			[1L-Colorectal cancer] with YERVOY MSI-H (C) CheckMate-8HW
				2021 (results)	2022 (1H)	2022 (2H)	2023

As of July 29, 2022

Development status of OPDIVO (1)

As of July 29, 2022

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	Filed	III	III	Approved	Filed
	1st	with Ipi	Approved	Approved	Approved	Approved	—
		with Ipi + Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	—	—	—	—
		with Chemo (NSQ)	Revision of labeling	Approved	Approved	—	—
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Renal cell carcinoma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
		with TKI	Approved	Approved	Approved	Approved	Approved
		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	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	with Ipi	Approved	Approved	Approved	Approved	Approved
	SOC refractory	Monotherapy	Approved	—	—	—	—

Red: Update after May 2022

Development status of OPDIVO (2)

As of July 29, 2022

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	Adjuvant	with Chemo	III	III	III	—	—
	1st	with Chemo	Approved	Approved	Approved	Approved	Approved
		with Ipi + Chemo	III	III	III	—	—
	3rd	Monotherapy	Approved	Approved	Approved	—	—
Esophageal cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	Approved	III	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
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	Approved	Approved*
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

* 2nd line

** With Ipi (US), Monotherapy only (Taiwan)

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Development status of OPDIVO (3)

As of July 29, 2022

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Urothelial cancer / Bladder cancer	Perioperative	with Chemo	III	III	III	III	III
	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	with Ipi, with Chemo	III	III	III	III	III
	2nd	Monotherapy	II	Approved	Approved	Approved	Approved
Ovarian cancer	1st	with Rucaparib	III	III	III	III	III
castration-resistant prostate cancer	1st or 2nd	with Chemo	III	III	III	III	III
Pancreatic cancer	1st	with Chemo	II	II	II	—	—
Virus positive / negative solid carcinoma	Neo-adjuvant, 1st~3rd	Monotherapy, with Ipi (1st~3rd only)	I / II	I / II	I / II	I / II	I / II
Cancer of unknown primary	—	Monotherapy	Approved	—	—	—	—
Dosage and Administration	240 mg (every 2 weeks)		Approved	Approved	III	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	III	Approved	Approved

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Clinical trials in combination therapy

OPDIVO & other Immuno-Oncology compounds

As of July 29, 2022

Development code (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
ONO-4686 Anti-TIGIT antibody	Solid tumor	I / II	I / II	-
ONO-4482 (Relatlimab) Anti-LAG-3 antibody	Melanoma	I / II	Approved★	-
ONO-4578 PG receptor (EP4) antagonist	Solid tumor, Gastric cancer	I	I / II	-
	Colorectal cancer	I	-	-
	Pancreatic cancer	I	-	-
	Non-small cell lung cancer	I	-	-
ONO-7475 Axl/Mer inhibitor	Solid tumor	I	-	-
ONO-7913 (Magrolimab) Anti-CD47 antibody	Pancreatic cancer	I	-	-
	Colorectal cancer	I	-	-
ONO-7119 (Atamparib) PARP7 inhibitor	Solid tumor	I	-	-
ONO-7122 TGF- β inhibitor	Solid tumor	I	-	-
ONO-7914 STING agonist	Solid tumor	I	-	-

★ : fixed-dose combination of nivolumab and relatlimab (US)

Red: Update after May 2022



Development pipeline in Japan (Oncology area other than OPDIVO)

As of July 29, 2022

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase III】		
ONO-7913 (Magrolimab)	TP53-mutant Acute myeloid leukemia	Anti-CD47 antibody
【Phase II】		
BRAFTOVI (Encorafenib)	BRAF-mutant thyroid cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant thyroid cancer	MEK inhibitor
【Phase I】		
ONO-4578	Solid tumor, Gastric cancer *	PG receptor (EP4) antagonist
	Colorectal cancer *	
	Pancreatic cancer *	
	Non-small cell lung cancer *	
	Hormone receptor-positive, HER2-negative breast cancer	
ONO-7475	Solid tumor *	Axl / Mer inhibitor
	EGFR mutation-positive non-small cell lung cancer	
ONO-7913 (Magrolimab)	Solid tumor	Anti-CD47 antibody
	Myelodysplastic syndrome	
	Pancreatic cancer *	
	Colorectal cancer *	

* Combination with Opdivo.

Red: Update after May 2022



Development pipeline in Japan (Non-oncology)

As of July 29, 2022

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Filed】		
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia in low cardiac function <Pediatric>	Short-active selective β_1 blocker
【Phase III】		
ONO-2017 (Cenobamate)	Primary generalized tonic-clonic seizures	Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA _A ion channel
	Partial-onset seizures	
VELEXBRU (ONO-4059:Tirabrutinib)	Pemphigus	BTK inhibitor
【Phase II】		
ONO-2910	Diabetic polyneuropathy	Schwann cell differentiation promoter
【Phase I】		
VELEXBRU (ONO-4059:Tirabrutinib)	Generalized scleroderma	BTK inhibitor
ONO-4685	Autoimmune disease	PD-1 × CD3 bispecific antibody
ONO-2909	Narcolepsy	PG receptor (DP1) antagonist
ONO-2808	Neurodegenerative diseases	S1P5 receptor agonist

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Global development projects (Other than OPDIVO)

As of July 29, 2022

Product name/ Development code (Generic name)	Target indication	Pharmacological action	Area
【Phase III】			
ONO-7913 (Magrolimab)	Acute myeloid leukemia	Anti-CD47 antibody	KR・TW
【Phase II】			
ONO-4059 (Tirabrutinib)	Primary central nervous system lymphoma	BTK inhibitor	US
【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
ONO-4685	T-cell lymphoma	PD-1 x CD3 bispecific antibody	US
	Autoimmune disease		EU
ONO-2020	Neurodegenerative disease	Epigenetic Regulation	US

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