

Development Pipeline Progress Status

May 12, 2021

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

〔1L-Gastric cancer〕 with Chemo (C) ATTRACTION-4 May 2020 〔1L-RCC〕 with Cabozantinib (C) CheckMate-9ER Oct 2020 〔1L-Malignant pleural mesothelioma〕 (C) with YERVOY CheckMate-743 Oct 2020 〔1L-Gastric cancer〕 (C) with Chemo CheckMate-649 Dec 2020 〔Hodgkin's lymphoma, pediatric〕 investigator-initiated trial (M) Jan 2021 〔Adjuvant-Esophageal cancer 〕 (M) CheckMate-577 Feb 2021 〔Adjuvant-Urothelial cancer〕 (M) CheckMate-274 Mar 2021	〔Cancer of unknown primary〕 investigator-initiated trial (M) Apr 2021 〔1L-NSCLC〕 with Chemo and AVASTIN * (C) ONO-4538-52 FOIPAN (Camostat Mesilate) 〔COVID-19〕 〔1L-Esophageal cancer〕 with YERVOY / with Chemo (C) CheckMate-648	ONOACT<Pediatric> 〔Tachyarrhythmia in low cardiac function〕 〔Adjuvant-Gastric cancer〕 with Chemo (C) ATTRACTION-5 〔1L-Urothelial cancer〕 with YERVOY (C) CheckMate-901 〔1L-Head and neck cancer〕 with YERVOY (C) CheckMate-651 〔Neoadjuvant-NSCLC〕 with Chemo (C) CheckMate-816	〔Adjuvant-RCC〕 with YERVOY (C) CheckMate-914 〔Adjuvant- Hepatocellular carcinoma〕 (C) CheckMate-9DX 〔Biliary tract cancer〕 (M) ONO-4538-91 〔1L-Urothelial cancer〕 with Chemo (C) CheckMate-901 KYPROLIS 〔2L-Multiple myeloma〕 KRd Once weekly
2020 (results)	2021 (1H)	2021 (2H)	2022

As of May 6, 2021

* Revision of labeling



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Development status of OPDIVO (1)

As of May 6, 2021

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	Approved	Approved	Approved	Approved	—
		with Ipi + Chemo	Approved	Approved	Approved	Approved	Approved
		with Chemo	Approved	III	—	—	—
		with Chemo (NSQ)	Consultation on revision of labeling	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	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	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



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Development status of OPDIVO (2)

As of May 6, 2021

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	Approved	Filed
		with Ipi	III	III	III	III	III
	3rd	Monotherapy	Approved	Approved	Approved	—	—
Esophageal cancer	Adjuvant	Monotherapy	Filed	III	III	Filed	Filed
	1st	with Ipi, with Chemo	III	III	III	III	III
	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	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

* 2nd line
 * * Monotherapy and with Ipi (US),
 Monotherapy only (Taiwan)



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Development status of OPDIVO (3)

As of May 6, 2021

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	Filed	III	III	Filed	Filed
	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
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

Red: Update after May 2020

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

As of May 6, 2021

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, 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-7911 (Bempegaldesleukin) PEGylated IL-2	Solid tumor	I	I / II	-
	Melanoma	-	Ⅲ	-
	Renal cell carcinoma	-	Ⅲ	-
	Bladder cancer	-	Ⅲ	-

Red: Update after May 2020

*ONO-4578 was out-licensed to BMS in 2017, but the rights were returned.



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Development pipeline in Japan (Oncology area other than OPDIVO)

As of May 6, 2021

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant colorectal cancer	MEK inhibitor
VELEXBRU (Tirabrutinib)	Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma	BTK inhibitor
ADLUMIZ (Anamorelin)	Cancer cachexia (non-small cell lung cancer, gastric cancer, pancreatic cancer, colorectal cancer)	Ghrelin mimetic
【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	
ONO-7475 *	Solid tumor	Axl / Mer inhibitor
ONO-7913	Solid tumor	Anti-CD47 mAb
ONO-7912	Pancreatic Cancer	Cancer metabolism inhibitor

Red: Update after May 2020

* Combination with Opdivo.

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

As of May 6, 2021

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
JOYCLU / ONO-5704 · SI-613	Osteoarthritis (knee joint and hip joint)	Hyaluronic acid-NSAID
ONGENTYS (Opicapone)	Parkinson's disease	Long acting COMT inhibitor
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia associated with sepsis	Short-active selective β 1 blocker
【Phase III】		
ORENCIA (Abatacept)	Polymyositis/Dermatomyositis	T-cell activation inhibitor
FOIPAN (Camostat mesilate)	Novel coronavirus infection	Protease enzyme 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 May 6, 2021

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase II】		
JOYCLU / ONO-5704 · SI-613	Enthesopathy	Hyaluronic acid-NSAID
VELEXBRU (Tirabrutinib)	Pemphigus	BTK inhibitor
ONO-2910	Peripheral neuropathy	Schwann cell differentiation promoter
【Phase I】		
VELEXBRU (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

Red: Update after May 2020



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Global development projects (Other than OPDIVO)

As of May 6, 2021

Development code (Generic name)	Target indication	Pharmacological action	Area
【PhaseⅢ】			
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

Red: Update after May 2020





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