

# Development Pipeline Progress Status

**July 31, 2023**

# 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

OPDIVO  
M=Mono  
C=Combo

FY2022 (results)	FY2023(1H)	FY2023(2H)	FY2024
<p>[Malignant Mesothelioma (Excluding Pleura)] investigator-initiated trial Feb 2023 (M)</p>	<p>[Epithelial skin malignancies] investigator-initiated trial Jun 2023 (M)</p>	<p>[NSCLC] with CRT/ YERVOY CheckMate-73L (C)</p>	<p>[1L-Hepatocellular carcinoma] with YERVOY CheckMate-9DW (C)</p>
<p>[Neoadjuvant-NSCLC] with Chemo CheckMate-816 Apr 2022 (C)</p>	<p>BRAFTOVI/MEKTOVI [2L-BRAF-mutant Thyroid cancer]</p>	<p>[Adjuvant-Renal cell carcinoma] Monotherapy CheckMate-914 (M)</p>	<p>[1L-Urothelial cancer (Cis ineligible)] with YERVOY CheckMate-901 (C)</p>
		<p>[ Neoadjuvant, Adjuvant -NSCLC] with Chemo CheckMate-77T (C)</p>	<p>[1L- Colorectal cancer (MSI-H)] with YERVOY CheckMate-8HW (C)</p>
		<p>[1L-Urothelial cancer] with Chemo CheckMate-901 (C)</p>	<p>ONO-7913 [1L-TP53-mutant Acute Myeloid Leukemia cancer] With Azacitidine</p>
		<p>[Neoadjuvant, Adjuvant -Bladder cancer] With Chemo ONO-4538-86 (C)</p>	<p>BRAFTOVI [1L-BRAF-mutant Colorectal cancer] With Cetuximab and Chemo</p>

As of Jul 27, 2023

# Development status of OPDIVO (1)

As of Jul 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant · 1st · 2nd	Monotherapy, with Ipi (1 <sup>st</sup> line only)	Approved	Approved	Approved	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	with Chemo	Approved	Approved	Approved	Approved	Approved
	Neo-adjuvant · Adjuvant	with Chemo	III	III	III	III	III
	Chemoradiotherapy	with CRT/Ipi	III	III	III	III	III
	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	
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	—	—	—	—
Epithelial skin malignancies	1st	Monotherapy	Filed				

Red: Update after May 2023

# Development status of OPDIVO (2)

As of Jul 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	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	Approved	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	with Ipi	II	II	Approved	Approved	II

\* 2nd line

Red: Update after May 2023

# Development status of OPDIVO (3)

As of Jul 27, 2023

Target disease	Line of Therapy	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	Adjuvant	Monotherapy	III	—	—	III	III
	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	
Urothelial cancer / Bladder cancer	Neo-adjuvant · Adjuvant	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
Cancer of unknown primary	—	Monotherapy	Approved	—	—	—	—
Malignant Mesothelioma (Excluding Pleural)	1st or 2nd	Monotherapy	Filed	—	—	—	—
Dosage and Administration	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved

Red: Update after May 2023

# Clinical trials in combination therapy

## OPDIVO & other Immuno-Oncology compounds

As of Jul 27, 2023

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	-	-
	Colorectal cancer	I	-	-
	Pancreatic cancer	I	-	-
	Non-small cell lung cancer	I	-	-
ONO-7475 (Tamnorzatinib) 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- $\beta$ inhibitor	Solid tumor	I	-	-
ONO-7914 STING agonist	Solid tumor	I	-	-
ONO-7226 Anti-ILT4 antibody	Solid tumor	I	I	-

★ fixed-dose combination of nivolumab and relatlimab

Red: Update after May 2023

# Development pipeline in Japan (Oncology area other than OPDIVO)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action
<b>【Filed】</b>		
<b>BRAFTOVI (Encorafenib)</b>	<b>BRAF-mutant thyroid cancer</b>	<b>BRAF inhibitor</b>
<b>MEKTOVI (Binimetinib)</b>	<b>BRAF-mutant thyroid cancer</b>	<b>MEK inhibitor</b>
<b>【Phase III】</b>		
ONO-7913 (Magrolimab)	TP53-mutant Acute myeloid leukemia	Anti-CD47 antibody
<b>【Phase I】</b>		
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 ( <b>Tamnorzatinib</b> )	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 2023



# Development pipeline in Japan (Non-oncology)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action
<b>【Phase III】</b>		
ONO-2017 (Cenobamate)	Primary generalized tonic-clonic seizures	Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA <sub>A</sub> ion channel
	Partial-onset seizures	
VELEXBRU (ONO-4059 : Tirabrutinib)	Pemphigus	BTK inhibitor
<b>【Phase II】</b>		
ONO-2910	Diabetic polyneuropathy	Schwann cell differentiation promoter
	Chemotherapy-Induced Peripheral Neuropathy	
<b>【Phase I】</b>		
ONO-4685	Autoimmune disease	PD-1 × CD3 bispecific antibody
ONO-7684	Thrombosis	FXIa inhibitor
ONO-1110	Pain	Endocannabinoid regulation

Red: Update after May 2023

# Global development projects (Other than OPDIVO)

As of Jul 27, 2023

Product name/ Development code (Generic name)	Target indication	Pharmacological action	Area
<b>【Phase III】</b>			
ONO-7913 (Magrolimab)	Acute myeloid leukemia	Anti-CD47 antibody	KR · TW
<b>【Phase II】</b>			
ONO-4059 (Tirabrutinib)	Primary central nervous system lymphoma	BTK inhibitor	US
<b>ONO-2808</b>	<b>Multiple System Atrophy</b>	<b>S1P5 receptor agonist</b>	<b>US</b>
<b>【Phase I】</b>			
ONO-7684	Thrombosis	FXIa inhibitor	EU
ONO-4685	T-cell lymphoma	PD-1 x CD3 bispecific antibody	US
	Autoimmune disease		EU
ONO-2020	Neurodegenerative disease	Epigenetic Regulation	US
ONO-7018	Non-Hodgkin lymphoma, Chronic lymphocytic leukemia	MALT1 Inhibitor	US

Red: Update after May 2023



**ONO PHARMACEUTICAL CO.,LTD.**

*Dedicated to the Fight against Disease and Pain*