

# Development Pipeline Progress Status



ONO PHARMACEUTICAL CO.,LTD.

# Development status of ONO-4538(nivolumab)①

Target Disease	JAPAN	US/EU	KOR/TAI
Melanoma(2 <sup>nd</sup> ~)	Launched	Launched (US) Launched (EU)	Approved(KOR) Filing(TAI)
Melanoma(1 <sup>st</sup> )	Filing	Filing(US) Approved(EU)	Filing(KOR)
Melanoma(1 <sup>st</sup> ) (combination with Ipilimumab)	II	Approved(US) Filing(EU)	—
Non-small cell lung cancer(2 <sup>nd</sup> ~)	Filing	Approved (US) Filing (EU) *	Filing (KOR) Filing(TAI)**
Non-small cell lung cancer(1 <sup>st</sup> )	III	III	III
Renal cell carcinoma(2 <sup>nd</sup> )	III	III	—
Renal cell carcinoma(1 <sup>st</sup> ) (combination with Ipilimumab)	III	III	—
Head and neck carcinoma	III	III	III
Gastric cancer	III	I / II	III
Small cell lung cancer	III	III (BMS)	III
Esophageal cancer	III	—	III
Glioblastoma	II	III	—

\*SQ NSCLC has approved.

\*\*SQ NCSLC has filed.

# Development status of ONO-4538(nivolumab)②

Target Disease	JAPAN	US/EU	KOR/TAI
Diffuse large B cell lymphoma( Non-Hodgkin lymphoma )	—	II (BMS)	—
Follicular lymphoma( Non-Hodgkin lymphoma )	—	II (BMS)	—
Hodgkin lymphoma	II	II (BMS)	—
Ovarian cancer	II	—	—
Urothelial cancer	II	II (BMS)	—
Virus positive, negative solid cartinoma	I / II	I / II (BMS)	I / II
Colon cancer	—	I / II (BMS)	—
Pancreatic cancer, Small cell lung cancer, Triple negative breast cancer, Urothelial cancer	—	I / II (BMS)	—
Bile duct carcinoma	I	—	—
Hepatocellular carcinoma	I	I (BMS)	—
Hematologic malignancies	—	I (BMS)	—
Chronic myelogenous leukemia	—	I (BMS)	—

red : Hematologic malignancies

# Combination clinical trials (OPDIVO & other I-O compounds)

Combination	Cancer type	Phase	Area
Nivolumab + Ipilimumab	Renal cell carcinoma	III	US,EU,JP
	Melanoma	III	US
		II	JP
	NSCLC	III	US,EU,JP, KOR
Nivolumab + Lirilumab (Anti-KIR antibody)	Solid tumor	I	US
Nivolumab + BMS-986016 (Anti-LAG-3 antibody)	Solid tumor	I	US,EU,JP
Nivolumab + Urelumab (CD137 receptor agonist)	Solid tumor, Non-Hodgkin Lymphoma	I / II	US,EU,JP
Nivolumab + Mogamulizumab	Solid tumor	I	JP

# Global Development Projects

\*The most advanced stage is shown

Development Code	Target Disease	Overseas*	JAPAN*
ONO-6950	Bronchial asthma	II	II
ONO-2952	Irritable bowel syndrome (IBS)	II	—
ONO-9054	Glaucoma, Ocular hypertension	II	—
ONO-4059	B-cell lymphoma	I	I
ONO-8055	Underactive bladder	I	—
ONO-2160	Parkinson's disease	—	I
ONO-1266	Portal hypertension	I	—
ONO-4232	Acute heart failure	I	—
ONO-4474	Osteoarthritis	I	—

# Development pipeline list in Japan (1)

\*The most advanced stage is shown

Development code /Product name /Product candidate name	Planned indication	JAPAN
<b>Rivastach Patch (Additional dosing regimen)</b>	<b>Dementia of the Alzheimer's type</b>	<b>Approved</b>
<b>Proemend (pediatric)</b>	<b>Chemotherapy-induced nausea and vomiting</b>	<b>Filing</b>
<b>ONO-7057 (Carfilzomib)</b>	<b>Multiple myeloma</b>	<b>Filing</b>
<b>ONO-4164IV (Orencia IV)</b>	<b>Juvenile idiopathic arthritis</b>	<b>III</b>
<b>ONO-4164IV (Orencia IV)</b>	<b>Lupus nephritis</b>	<b>III</b>
<b>ONO-4164IV (Orencia SQ)</b>	<b>Untreated rheumatoid arthritis</b>	<b>III</b>
<b>ONO-7057 (Additional dosing regimen)</b>	<b>Multiple myeloma</b>	<b>III</b>
<b>ONO-5163</b>	<b>Secondary hyperparathyroidism</b>	<b>III</b>
<b>ONO-1162</b>	<b>Chronic heart failure</b>	<b>III</b>
<b>Onoact (pediatric)</b>	<b>Tachyarrhythmia in low cardiac function</b>	<b>II / III</b>
<b>Onoact IV</b>	<b>ventricular arrhythmia</b>	<b>II / III</b>

# Development pipeline list in Japan (2)

\*The most advanced stage is shown

Development code /Product name/Product candidate name	Planned indication	JAPAN
ONO-7643	Cancer cachexia	II
ONO-6950	Bronchial asthma	II
ONO-5371	Pheochromocytoma	I / II
ONO-7268MX1	Hepatocellular carcinoma	I
ONO-7268MX2	Hepatocellular carcinoma	I
ONO-2160/CD (levodopa pro-drug)	Parkinson's disease	I
ONO-2370 (COMT inhibitor)	Parkinson's disease	I
ONO-4059	B-cell lymphoma	I