

Development Pipeline Progress Status



ONO PHARMACEUTICAL CO.,LTD.

Global Development Projects

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****The most advanced stage is shown**

Development Code	Target Disease	Overseas*	Japan*
ONO-4538	Melanoma, Renal cell carcinoma, Non-small cell lung cancer, etc.	Ⅲ (BMS)	filing
ONO-4641	Multiple sclerosis	Ⅲ under preparation (with Merck KGaA)	
ONO-6950	Bronchial asthma	Ⅱ	Ⅰ
ONO-4053	Allergic rhinitis	Ⅱ	Ⅰ
ONO-2952	Irritable bowel syndrome (IBS)	Ⅱ	—
ONO-9054	Glaucoma, Ocular hypertension	Ⅱ	—
ONO-4059	B-cell lymphoma	Ⅰ	—
ONO-8055	Underactive bladder	Ⅰ	—
ONO-8539	Gastroesophageal reflux disease	Ⅰ	—
ONO-2160	Parkinson's disease	—	Ⅰ
ONO-1266	Portal hypertension	Ⅰ	—
ONO-4232	Acute heart failure	Ⅰ	—

Development pipeline list in Japan(1)

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Development code /Product name/Product candidate name	Planned indication	Japan
ONO-4164SC (Orencia SC)	Rheumatoid arthritis	Approved
Glactiv 12.5mg Tablets (additional formulation)	Type II diabetes with severe renal dysfunction	Approved
Onoact (additional indication)	Tachyarrhythmia in low cardiac function	Approved
Glactiv (additional indication)	Type 2 diabetes (combination therapy with rapid-acting insulin secretagogues)	Filing
Opalmon (additional formulation)	Thromboangiitis obliterans, Lumbar spinal stenosis	Filing
ONO—4538	Melanoma	Filing
Proemend (pediatric)	Chemotherapy-induced nausea and vomiting	III
Rivastach Patch (Additional dosing regimen)	Dementia of the Alzheimer's type	III
ONO—4538	Renal cell carcinoma	III
ONO-4164IV (Orencia IV)	Juvenile idiopathic arthritis	III
ONO-4164IV (Orencia IV)	Lupus nephritis	III
ONO—7057	Multiple myeloma	III
ONO—2745	General anesthesia	II / III

Development pipeline list in Japan(2)

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Development code /Product name/Product candidate name	Planned indication	Japan
ONO-7165 (Stimuvax)	Non-small cell lung cancer	II
ONO-4641	Multiple sclerosis	II
ONO-3849	Opioid-induced constipation	II
ONO-7643	Cancer cachexia	II
ONO-4538	Non-small cell lung cancer	II
ONO-4538	esophageal cancer	II
ONO-1162	Chronic heart failure	II
ONO-5163	Secondary hyperparathyroidism	I / II
ONO-6950	Bronchial asthma	I
ONO-7056	Solid Tumor	I
ONO-7268MX1	Hepatic cell carcinoma	I
ONO-7268MX2	Hepatic cell carcinoma	I
ONO-4053	Allergic rhinitis	I
ONO-2160	Parkinson's disease	I

Development status of ONO-4538 (nivolumab)

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Development Code	Target disease	Overseas	Japan
ONO-4538	Renal cell carcinoma	Ⅲ (JP/US/EU, with BMS)	
ONO-4538	Melanoma	Ⅲ (BMS)	filing
ONO-4538	Non-small cell lung cancer	Ⅲ (BMS)	Ⅱ
ONO-4538	Head and neck carcinoma	Ⅲ (BMS)	—
ONO-4538	Glioblastoma	Ⅱ (BMS)	—
ONO-4538	Diffuse large B cell lymphoma	Ⅱ (BMS)	
ONO-4538	Follicular lymphoma	Ⅱ (BMS)	
ONO-4538	Esophageal cancer	—	Ⅱ
ONO-4538	Ovarian Cancer (investigator initiated trial)	—	Ⅱ
ONO-4538	Colon cancer	I / Ⅱ (BMS)	—
ONO-4538	Pancreatic cancer, Gastric cancer, Small cell lung cancer, Triple negative breast cancer	I / Ⅱ (BMS)	—
ONO-4538	Hepatocellular carcinoma	I (BMS)	—
ONO-4538	Hematologic malignancies	I (BMS)	
ONO-4538	Melanoma (combination with Ipilimumab)	I (BMS)	
ONO-4538	Non-small cell lung cancer (combination with existing medication or Ipilimumab [#])	I (BMS)	I
ONO-4538	Renal cell carcinoma (combination with existing medication or Ipilimumab)	I (BMS)	