March 23, 2015

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp

ONO Receives the Approval of the New Drug Application (NDA) for Human Anti-human PD-1 Monoclonal Antibody "OPDIVO®" for the Treatment of Melanoma in South Korea

ONO PHARMACEUTICAL CO., Ltd. (Head Office: Osaka, Japan; President and Representative Director: Gyo Sagara; "ONO") announced that ONO PHARMA KOREA CO., LTD. ("OPKR")※1 has, in South Korea, on March 20, 2015, received the approval, by Ministry of Food and Drug Safety (MFDS), of the new drug application (NDA) for the human anti-human PD-1 monoclonal antibody "OPDIVO® 20mg, 100mg Inj. (Nivolumab, Genetic Recombination)" ("OPDIVO") for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab (product name: Yervoy®) and, if BRAF V600E mutation positive, a BRAF inhibitor. ONO will manufacture its finished product (vial product) and supply it to OPKR.

Melanoma is considered to be a form of tumor characterized by the malignant transformation of pigment-producing cells located in the skin, which has extremely poor prognosis skin cancer. In South Korea, there has been an unmet need for an effective treatment for patients with melanoma, who have limited treatment options available for patients who have been previously treated with approved agents.

OPDIVO is a human anti-human PD-1 monoclonal antibody that blocks PD-1-mediated negative regulation of lymphocytes (i.e., the interaction of PD-1 with its ligands PD-L1 and PD-L2), thereby enhancing the ability of the immune system to recognize cancer cells as foreign and eliminate them.

OPDIVO is the first approved drug targeting PD-1 in South Korea. Accumulating further clinical data is important in ensuring that OPDIVO will be used more safely and effectively. OPKR is committed to taking actions necessary for the proper use of OPDIVO by collecting clinical data on the safety and efficacy of OPDIVO. In addition, ONO and Bristol-Myers Squibb Company ("BMS") will jointly commercialize OPDIVO after the launch in South Korea based on the strategic collaboration agreement※2 in July 2014.

This is the third approval for OPDIVO for the treatment of melanoma, which is also approved in Japan and the United States. In Japan, ONO launched it for unresectable malignant melanoma treatment in September 2014. ONO and BMS are conducting clinical development programs including Renal Cell Carcinoma (RCC), Non-Small Cell Lung Cancer (NSCLC), Head and Neck Cancer, Gastric Cancer, Esophageal Cancer and Hodgkin Lymphoma. In USA, BMS launched Opdivo for the treatment of patients with unresectable or metastatic melanoma and disease

progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor in December 2014. Also, the U.S. Food and Drug Administration (FDA) recently approved OPDIVO for the treatment of patients with metastatic squamous NSCLC with progression on or after platinum-based chemotherapy. BMS has a robust clinical development program in a variety of tumor types overseas, including NSCLC, RCC, Head and Neck Cancer, Blood Cancer, Glioblastoma, Colorectal Cancer, Pancreatic Cancer, Gastric Cancer, Hepatocellular Carcinoma, Triple-Negative Breast Cancer, Small-Cell Lung Cancer, and Bladder Cancer.

Outline of OPDIVO® 20mg/100mg Inj.

Product name	OPDIVO® 20mg, 100mg Inj. (Nivolumab, Genetic Recombination)
Generic name (INN)	Nivolumab
Indication	Unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600E mutation positive, a BRAF inhibitor
Dosage and administration	The recommended dose is 3 mg/kg (body weight) of nivolumab administered as an intravenous infusion over 60 minutes every 2 weeks.
Importing and marketing approval date	March 20, 2015
Manufacturer	ONO PHARMACEUTICAL CO., LTD.
Importer/promoter	ONO PHARMA KOREA CO., LTD.
Co-promoter	BMS Pharmaceutical Korea Limited.

※1　About ONO PHARMA KOREA CO., LTD.

ONO PHARMA KOREA CO., LTD. in Seoul, South Korea was established as an ONO's wholly-owned subsidiary in December 2013. While OPKR continues to support for promotion of licensees in scientific aspect in South Korea, OPKR plans to commercialize specialty products such as anti-cancer agents, including OPDIVO, in the future. OPKR will commit its effort to obtain a further understanding of the use of ONO's products and delivering optimal treatment options to patients in South Korea, where the demand for pharmaceuticals will be increased.

※2　About the agreement for OPDIVO®

OPDIVO is a human anti-human PD-1 monoclonal antibody generated under a research collaboration entered into in May 2005 between ONO and the US-based company Medarex, Inc. When Medarex, Inc. was acquired by BMS in 2009, it also granted BMS its rights to develop and commercialize the human anti-human PD-1 monoclonal antibody in North America. Through the collaboration agreement entered into in September 2011 between ONO and BMS, ONO granted BMS exclusive rights to develop and commercialize OPDIVO in the rest of the world, except in Japan, South Korea and Taiwan where ONO retained all rights to develop and commercialize the compound. In July, 2014, ONO and BMS signed a new collaboration agreement in which the companies agreed to jointly develop and commercialize OPDIVO, ipilimumab and three early-stage immunotherapies in Japan, South Korea and Taiwan.