April 4, 2016

ONO PHARMA KOREA Receives Approval for OPDIVO® (Nivolumab) for Expanded Application of Unresectable or Metastatic Melanoma and Additional Indication of Locally Advanced or Metastatic Non-small Cell Lung Cancer Refractory to Existing Chemotherapy in South Korea

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") and Bristol-Myers Squibb Company (NYSE: BMY) announced that ONO PHARMA KOREA CO., LTD. ("OPKR") has received approval for the partial change in approved items of the manufacturing and marketing approval by Ministry of Food and Drug Safety (MFDS) in South Korea on April 1, 2016, for the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, OPDIVO® Intravenous Infusion 20 mg, 100 mg ("OPDIVO") for expanded application of unresectable or metastatic melanoma and additional indication of locally advanced or metastatic non-small cell lung cancer (NSCLC) refractory to existing chemotherapy. ONO continues to manufacture its finished product to supply it to OPKR.

OPDIVO is a drug targeting at PD-1 first approved in South Korea in March 2015. OPDIVO has been already used for the treatment of unresectable or metastatic melanoma. The approval granted this time allows OPDIVO to be given to patients who have not been previously treated with chemotherapy, in addition to those previously treated with chemotherapy.

In addition, this approval also allows OPDIVO to expand its indication for the treatment of locally advanced or metastatic NSCLC refractory to existing chemotherapy.
Lung cancer is one of the leading causes of cancer-related death worldwide with approximately 17 thousand deaths each year in South Korea. As patients with unresectable or treatment-resistant NSCLC have an extremely poor prognosis, the development of new drugs has been expected.

OPDIVO is the first human anti-human PD-1 monoclonal antibody to receive regulatory approval for the treatment of unresectable melanoma in July 2014 in Japan or anywhere in the world. OPDIVO also received regulatory approval for additional indication of unresectable, advanced or recurrent NSCLC in December 2015. Outside of Japan, Bristol Myers Squibb ("BMS"), with whom ONO collaborates in Japan, South Korea and Taiwan, currently has regulatory approval for OPDIVO in 48 countries globally.

OPKR is committed to taking measures necessary for proper use of OPDIVO by collecting clinical data on the safety and efficacy of OPDIVO, so that it can be properly used. In South Korea, ONO and BMS continue to take co-promotion activities for OPDIVO, based on the strategic collaboration agreement in July 2014.

Outline of OPDIVO® Intravenous Infusion 20mg/100mg

Product name	OPDIVO® Intravenous Infusion 20 mg/100 mg
Generic name (INN)	Nivolumab
Indication	1. Unresectable or metastatic melanoma 1) BRAF V600E wild-type unresectable or metastatic melanoma 2) Unresectable or metastatic melanoma and disease progression following ipilimumab treatment and, if BRAF V600E mutation-positive, a BRAF inhibitor 2. Locally advanced or metastatic non-small cell lung cancer refractory to existing chemotherapy
Dosage and administration	Infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks
Manufacturer	ONO PHARMACEUTICAL CO., LTD.
Importer/distributor	ONO PHARMA KOREA CO., LTD.
Distribution collaboration	BMS Pharmaceutical Korea Limited.

* The underline shows revised parts in accordance with the approval this time.

About ONO PHARMA KOREA CO., LTD.

ONO PHARMA KOREA CO., LTD. (OPKR) in Seoul, South Korea was established as an ONO's wholly-owned subsidiary in December 2013. OPKR plans to commercialize specialty products such as anti-cancer agents, including OPDIVO. OPKR is committed to distribute its products developed internally for further use to the potentially growing market in South Korea

About the ONO and Bristol-Myers Squibb (BMS) Collaboration

In 2011, through the collaboration agreement with BMS, ONO granted BMS exclusive rights to develop and commercialize OPDIVO globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to the compound at the time. In July 2014, ONO and BMS further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

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