ONO PHARMACEUTICAL CO.,LTD.

September 19, 2017

Opdivo® (Nivolumab) Intravenous Infusion Approved for Expanded Use in Unresectable or Metastatic Melanoma in South Korea

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that ONO PHARMA KOREA CO., LTD. ("OPKR"), a Korean subsidiary, received the supplemental approval of Opdivo® Intravenous Infusion 20 mg, 100 mg (Generic name: nivolumab; "Opdivo"), a human anti-human PD-1 (programmed cell death-1) monoclonal antibody, on September 15 by the Ministry of Food and Drug Safety (MFDS) in South Korea, for expanded use for the treatment of patients with unresectable or metastatic melanoma.

Melanoma is a type of cancer that develops from the pigment-containing cells known as melanocytes having a capacity to produce melanin deeply related to skin color, with an estimated about 600 patients* per year in Korea. Opdivo has been approved for the treatment of patients with BRAF V600E wild-type unresectable or metastatic melanoma as a single agent therapy. This approval allows Opdivo to be used in patients with BRAF mutation-positive unresectable or metastatic melanoma. In combination with ipilimumab (Yervoy®), Opdivo has been approved for the treatment of patients with or without BRAF mutation unresectable or metastatic melanoma.

* National cancer center, Annual Report of Cancer Statistics in Korea in 2014

Opdivo is an immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response by blocking the interaction between PD-1 and its ligands. In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, Opdivo received an approval for additional indications of unresectable, advanced or recurrent non-small cell lung cancer in December 2015, unresectable or metastatic renal cell cancer in August 2016, relapsed or refractory classical Hodgkin lymphoma in December 2016 and recurrent or metastatic head and neck cancer in March 2017. In addition, ONO has submitted supplemental application for additional indication of gastric cancer, and is conducting clinical development program including esophageal cancer, gastro-esophageal junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, malignant pleural mesothelioma, ovarian cancer, biliary tract cancer, etc. Opdivo has regulatory approval in more than 60 countries including Japan, Taiwan, US and European Union.

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 Korea, OPKR continues to market Opdivo under the co-promotion with BMS Pharmaceutical Korea Limited, based on the strategic collaboration agreement made between ONO and Bristol-Myers Squibb in July 2014.

Outline of Opdivo® Intravenous Infusion 20 mg, 100 mg

Product name	Opdivo® 20 mg, 100 mg Inj.
Generic name (INN)	Nivolumab
Indication	1. Unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab 2. Locally advanced or metastatic non-small cell lung cancer refractory to existing platinum-based chemotherapy 3. Advanced renal cell carcinoma after prior therapy 4. Classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin 5. Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy 6. Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy or disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
Dosage and administration	Usually, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks
Approval date	September 15, 2017
Manufacturer	Ono Pharmaceutical Co., Ltd.
Importer/distributor	Ono Pharma Korea Co., Ltd.
Distribution collaboration	BMS Pharmaceutical Korea Limited

* Underlined part shows the revised ones due to this approval

About Ono Pharma Korea Co., Ltd.

Ono Pharma Korea Co., Ltd. (OPKR), in Seoul, Korea, was established as an ONO's wholly-owned subsidiary in December 2013. OPKR has started to market specialty products such as anti-cancer agents, including Opdivo. OPKR is committed to distributing and bringing its products developed internally for further penetration into the South Korean market.

About the Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol-Myers Squibb (BMS), Ono Pharmaceutical Co., Ltd. (ONO) granted BMS its territorial rights to develop and commercialize Opdivo globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to Opdivo except the US at the time. In July 2014, ONO and BMS further expanded their strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agent 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