ONO PHARMACEUTICAL CO.,LTD.

March 26, 2018

Opdivo® (Nivolumab) Intravenous Infusion Approved for Supplemental Indication of Advanced or Recurrent Gastric or Gastroesophageal Junction Adenocarcinoma and for Expanded Use in Recurrent or Advanced Classical Hodgkin Lymphoma 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 March 23 by the Ministry of Food and Drug Safety (MFDS) in South Korea, for supplemental indication of advanced or recurrent gastric or gastroesophageal junction adenocarcinoma after two or more prior chemotherapy regimens, and for expanded use in classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and pre/post-transplantation brentuximab vedotin.

Gastric cancer is a type of cancer developing from gastric mucosal epithelium with estimated about 30,000* patients diagnosed with gastric cancer per year in South Korea. Classical Hodgkin lymphoma is a localized or diffuse malignant cell cancer derived from the lymphatic system, with estimated about 280 patients* diagnosed annually in South Korea. While Opdivo has been approved for the treatment of classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin, this approval allows Opdivo to be used irrespective of the order in prior therapy with autologous HSCT or brentuximab vedotin. The development of a new therapeutic drug has been currently expected for the treatment of patients with melanoma who have been previously treated.

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

OPKR is committed to taking measures necessary for proper use of Opdivo by collecting clinical data on the safety and efficacy of Opdivo. In South Korea, OPKR and BMS Pharmaceutical Korea Limited continue to co-promote the sales of Opdivo, 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 pre/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 7. Advanced or recurrent gastric or gastroesophageal junction adenocarcinoma after two or more prior chemotherapy regimens
Dosage and administration	As monotherapy: Usually, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks. In combination with ipilimumab (melanoma): Infuse intravenously at 1 mg/kg (body weight) of nivolumab over 60 minutes, followed by intravenous infusion of ipilimumab on the same day, every 3 weeks for the first 4 doses. Thereafter, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks.
Approval date	March 23, 2018
Manufacturer	Ono Pharmaceutical Co., Ltd.
Importer/distributor	Ono Pharma Korea Co., Ltd.
Distribution collaboration	BMS Pharmaceutical Korea Limited

* Underlined parts show 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 Opdivo

Opdivo is a PD-1 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, recurrent or metastatic head and neck cancer in March 2017, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017. In addition, ONO has submitted supplemental application for treatment of malignant pleural mesothelioma, adjuvant melanoma, etc. and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, biliary tract cancer, etc. Opdivo is currently approved in more than 60 countries, including Japan, South Korea, Taiwan, the US and European Union.

About 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.

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