April 28, 2017

OPDIVO® (Nivolumab) Intravenous Infusion Approved for Supplemental Indication of Advanced Renal Cell Carcinoma Who Have Received Prior Anti-angiogenic Therapy in Taiwan

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") and Bristol-Myers Squibb Company (NYSE: BMY) announced that ONO PHARMA TAIWAN CO., LTD. ("OPTW") has 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 April 27 by the Taiwan Food and Drug Administration (TFDA) in Taiwan, for the treatment of advanced renal cell carcinoma who have received prior anti-angiogenic therapy in Taiwan.

Renal cell carcinoma (RCC) occurs in adult renal parenchyma. In Taiwan, the estimated occurrence cases of renal malignancy is about 1,200 cases (including about 1,100 cases of renal cell cancer) per year with about 500 estimated deaths per year in 2013*. New treatment drugs are expected to be developed for the treatment of advanced RCC patients who have been previously treated.

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.

Bristol-Myers Squibb (BMS) has a robust clinical development program in Opdivo monotherapy and in combination with other therapies in a variety of tumor types overseas. Opdivo has regulatory approval in more than 60 countries as part of the ONO - BMS collaboration.

OPTW 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 Taiwan, OPTW continues to market Opdivo under the co-promotion with BMS (Taiwan) after the launch in Taiwan, based on the strategic collaboration agreement in July 2014.

*: Cancer Registry Annual Report, 2013 TAIWAN

Outline of OPDIVO® Intravenous Infusion 20 mg/100 mg

Product name	OPDIVO® Intravenous Infusion 20 mg/100 mg
Generic name (INN)	Nivolumab (recombinant)
Indication	1. Unresectable or Metastatic Melanoma 1.1 As a single agent, BRAF V600 wild-type unresectable or metastatic melanoma 1.2 As a single agent, unresectable or metastatic BRAF V600 mutation-positive melanoma following Yervoy (ipilimumab) and a BRAF inhibitor 2. Metastatic squamous non-small cell lung cancer Metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy 3. Advanced renal cell carcinoma who have received prior anti-angiogenic therapy
Dosage and administration	Usually, for adults, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks
Approval date	April 27, 2017
Manufacturer	Ono Pharmaceutical Co., Ltd.
Importer/distributor	Ono Pharma Taiwan Co., Ltd.、
Distribution collaboration	Bristol-Myers Squibb (Taiwan) Ltd.

About Ono Pharma Taiwan Co., Ltd.

Ono Pharma Taiwan Co., Ltd. (OPTW), in Taipei, Taiwan, was established as an ONO's wholly-owned subsidiary in December 2014. OPTW plans to market specialty products such as anti-cancer agents, including Opdivo. OPTW will be committed to distributing and bringing its products developed internally for further use to the Taiwanese 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 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.

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