ONO PHARMACEUTICAL CO.,LTD.

September 20, 2017

Opdivo® (Nivolumab) Intravenous Infusion Approved for Expanded Use in Advanced Non-squamous Non-small Cell Lung Cancer which Has Been Previously Treated with Platinum-based Therapy in Taiwan

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that ONO PHARMA TAIWAN CO., LTD. ("OPTW") 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 Taiwan Food and Drug Administration (TFDA) in Taiwan, for the treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy and whose tumors express PD-L1 (IHC PD-L1 expression ≧5%).

This approval allows Opdivo to be used in patients with non-squamous NSCLC with PD-L1 expression ≧5%, in addition to those with squamous NSCLC.

Lung cancer is a form of malignant tumor that arises from cells in the trachea, bronchi and alveoli. In 2014, approximately 12,000* new cases of NSCLC were diagnosed, with about 9,000 deaths in Taiwan. NSCLC accounts for about 80%* of lung cancer cases in Taiwan. Of patients with NSCLC, about 80% have non-squamous NSCLC.

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, US and European Union.

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 Bristol-Myers Squibb (Taiwan) Ltd., based on the strategic collaboration agreement made between ONO and Bristol-Myers Squibb in July 2014.

*: Cancer Registry Annual Report, 2014 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 BRAF V600 wild-type unresectable or metastatic melanoma 1.2 Unresectable or metastatic BRAF V600 mutation-positive melanoma and disease progression following ipilimumab and a BRAF inhibitor 2. Non-small cell lung cancer (NSCLC) 2.1 Advanced squamous non-small cell lung cancer (Squamous NSCLC) with progression on or after platinum-based chemotherapy 2.2 Advanced non-squamous NSCLC with progression on or after platinum-based chemotherapy and whose tumors express PD-L1 (IHC PD-L1 expression ≧5%). Patients with EGFR or ALK genomic tumor aberrations should have disease progression after treatment with EGFR or ALK inhibitor. 3. Renal Cell Carcinoma Advanced renal cell carcinoma after prior anti-angiogenic therapy 4. Squamous cell carcinoma of the head and neck Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy and tumor express PD-L1 (IHC PD-L1 expression ≧1%)
Dosage and administration	Usually, for adults, 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 Taiwan Co., Ltd.、
Distribution collaboration	Bristol-Myers Squibb (Taiwan) Ltd.

* Underlined part shows the revised one according to this approval

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 has started to market specialty products such as anti-cancer agents, including Opdivo. OPTW is committed to distributing and bringing its products developed internally for further penetration into 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 except the US 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 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