ONO PHARMACEUTICAL CO.,LTD.

January 18, 2019

Opdivo® (Nivolumab) Intravenous Infusion
Approved for Expanded Use in Non-Small Cell Lung Cancer
Previously Treated with Platinum-Based Chemotherapy in Taiwan

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that ONO PHARMA TAIWAN CO., LTD. ("OPTW") received the approval of Opdivo® (nivolumab) Intravenous Infusion 20 mg, 100 mg ("Opdivo"), a human anti-human PD-1 monoclonal antibody, on January 17 from the Taiwan Food and Drug Administration (TFDA) in Taiwan, for expanded use for the treatment of patients with advanced non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.

The approval is based on the results from the Phase 3 CheckMate -057 study of Opdivo versus a standard of care in patients with non-squamous NSCLC and the Phase 3 CheckMate -078 study (including about 90% Chinese patients enrolled) of Opdivo versus a standard of care among patients with previously treated NSCLC.

As far as the indication of Opdivo "the treatment of patients with advanced NSCLC with progression on or after platinum-based chemotherapy" is concerned, Opdivo is indicated for all squamous NSCLC regardless of tumor PD-L1 expression, but only for non-squamous NSCLC patients showing tumor PD-L1 expression level ≧5%. This approval permits Opdivo to be used in patients with non-squamous NSCLC regardless of PD-L1 expression levels.

Lung cancer is a form of malignant tumor that arises from cells in the trachea, bronchi and alveoli. It is reported that approximately 13,000* newly cause lung cancer per year, with about 9,000* deaths in Taiwan in 2015. In Taiwan, NSCLC accounts for about 80%* of lung cancer. Of patients with NSCLC, non-squamous NSCLC accounts for about 80%*.

OPTW is committed to taking measures necessary for proper use of Opdivo by collecting clinical data on the safety and efficacy of Opdivo. In Taiwan, OPTW and Bristol-Myers Squibb (Taiwan) Ltd. continues to co-promote the sales of Opdivo, based on the strategic collaboration agreement made between ONO and Bristol-Myers Squibb in July 2014.

*: Cancer Registry Annual Report, 2015 TAIWAN

Outline of Opdivo® Intravenous Infusion 20 mg, 100 mg

Product name	Opdivo® Intravenous Infusion 20 mg, 100 mg
Generic name (INN)	Nivolumab
Indication	1. Unresectable or metastatic melanoma Unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab 2. Non-small cell lung cancer Advanced non-squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression after treatment with EGFR or ALK inhibitor 3. Advanced renal cell carcinoma 3.1 Advanced renal cell carcinoma after prior anti-angiogenic therapy 3.2 Intermediate and poor risk previously untreated advanced renal cell carcinoma in combination therapy with ipilimumab 4. Squamous cell carcinoma of the head and neck Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy 5. Classical Hodgkin lymphoma As monotherapy, classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin 6. Urothelial carcinoma Locally advanced unresectable or metastatic urothelial carcinoma after failure of prior platinum-containing therapy 7. Unresectable advanced or recurrent gastric cancer Advanced or recurrent gastric or gastroesophageal junction (GEJ) adenocarcinoma after two or more prior chemotherapy regimens 8. Hepatocellular carcinoma Hepatocellular carcinoma (HCC) previously treated with sorafenib
Dosage and administration	1. Melanoma As monotherapy, infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes every 2 weeks. In combination with ipilimumab, infuse intravenously at 1 mg/kg (body weight) of Opdivo over 60 minutes, followed by intravenous infusion of ipilimumab at 3 mg/kg on the same day, every 3 weeks for the first 4 doses. Thereafter, infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes every 2 weeks. 2. Renal cell carcinoma As monotherapy, infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes every 2 weeks. In combination with ipilimumab, infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes, followed by intravenous infusion of ipilimumab at 1 mg/kg on the same day, every 3 weeks for the first 4 doses. Thereafter, infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes every 2 weeks.

	3. Non-small cell lung cancer, squamous cell carcinoma of the head and neck, classical Hodgkin lymphoma, urothelial carcinoma, gastric cancer and hepatocellular carcinoma: Infuse intravenously at 3 mg/kg (body weight) of Opdivo over 60 minutes every 2 weeks.
Approval date	January 17, 2019
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 marketed specialty products such as anti-cancer agent, including Opdivo. OPTW is committed to developing and marketing its products created internally for further penetration into the Taiwanese 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, unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017, and unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma, etc. in August 2018. In addition, ONO 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 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.

About ONO and BMS Collaboration

In 2011, through a collaboration agreement made between ONO and BMS, 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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