

January 23, 2018

Opdivo[®] (Nivolumab) Intravenous Infusion Approved in Taiwan for Supplemental Indication of Advanced or Recurrent Gastric Cancer or Gastro-esophageal Junction Cancer

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, from the Taiwan Food and Drug Administration (TFDA) in Taiwan on January 22, for the treatment of patients with advanced or recurrent gastric cancer or gastro-esophageal junction cancer after two or more prior chemotherapy regimens.

Gastric cancer is the fifth most common malignancy in the world and is the third leading cause of cancer-related death^{*1}. It is estimated that there are about 3,800 patients diagnosed with gastric cancer annually, resulting in about 2,350 deaths per year^{*2} in Taiwan. The development of new therapeutic drugs has been currently expected for this previously treated patient population.

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

*1: Globocan 2012. Available at: <http://globocan.iarc.fr/> Accessed March 31, 2014.

*2: 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	<ol style="list-style-type: none"> 1. Unresectable or metastatic melanoma Unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab 2. Non-small cell lung cancer <ol style="list-style-type: none"> 2.1 Advanced squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy 2.2 Advanced non-squamous NSCLC with progression on or after platinum-based chemotherapy and with tumors express PD-L1 (IHC PD-L1 expression $\geq 5\%$). 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 5. Classical Hodgkin lymphoma*¹ 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*² Locally advanced unresectable or metastatic urothelial carcinoma after failure of prior platinum-containing therapy 7. <u>Unresectable advanced or recurrent gastric cancer</u> <u>Advanced or recurrent gastric cancer or gastro-esophageal junction (GEJ) cancer after two or more prior chemotherapy regimens</u>
Dosage and administration	<p>As monotherapy: Usually, for adults, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks.</p> <p>In combination therapy 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.</p>
Approval date	January 22, 2018
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

*¹: This indication is approved under accelerated approval based on overall response rate.

Conditioned approval for this indication may be contingent upon verification and description of conical benefit in confirmatory trials.

*² This indication is approved under accelerated approval based on tumor response rate and duration of response. Conditioned approval for this indication may be contingent upon verification and description of conical benefit in confirmatory trials.

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 agents, including Opdivo. OPTW is committed to distributing and bringing its products developed 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, 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 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

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