

August 16, 2017

Opdivo[®] (Nivolumab) Intravenous Infusion Approved for Supplemental Indication of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Disease Progression on or after 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 August 14 by the Taiwan Food and Drug Administration (TFDA) in Taiwan, for the treatment of patients with 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 $\geq 1\%$).

Squamous cell carcinoma of the head and neck (SCCHN) is a general term describing malignant tumors occurring in the head and neck regions, such as the lip, oral cavity, nasal cavity, paranasal sinuses, epipharynx, oropharynx, hypopharynx, larynx, large salivary gland or mucosal melanoma. It is estimated that there are about 8,500 affected patients* with SCCHN (excluding cancer of the thyroid gland) annually in Taiwan. While platinum-based chemotherapy has been recommended as first therapy for patients with recurrent or metastatic SCCHN, most patients present with recurrent or metastatic SCCHN at an early stage after chemotherapy. As there have been no drugs which had demonstrated an extension of overall survival (OS) among existing therapies, new treatment options are needed for this patient population.

*: Cancer Registry Annual Report, 2014 TAIWAN

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 BMS Taiwan, based on the strategic collaboration agreement made in July 2014.

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<ol style="list-style-type: none">1.1 Unresectable or metastatic melanoma and disease progression following ipilimumab treatment and, if BRAF V600 mutation-positive, a BRAF inhibitor treatment1.2 BRAF V600 wild-type unresectable or metastatic melanoma2. Metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy3. Renal Cell Carcinoma Advanced renal cell carcinoma (RCC) after prior anti-angiogenic therapy4. 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 $\geq 1\%$)
Dosage and administration	Usually, for adults, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks
Approval date	August 14, 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 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.

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