May 9, 2016

ONO PHARMA TAIWAN Receives Approval of OPDIVO® (Nivolumab) for New Drug Application for Unresectable or Metastatic Melanoma and Metastatic Squamous Non-Small Cell Lung Cancer 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 approval of a human anti-human PD-1 (programmed cell death-1) monoclonal antibody, OPDIVO® Intravenous Infusion 20 mg, 100 mg (Nivolumab) ("OPDIVO") on May 6, 2016 by the Taiwan Food and Drug Administration (TFDA) in Taiwan, for the new drug application (NDA) for unresectable or metastatic melanoma and metastatic squamous non-small cell lung cancer (NSCLC). OPDIVO is the first drug targeting at PD-1 to receive the regulatory approval for the treatment of lung cancer in Taiwan. ONO will manufacture its finished product to supply it to OPTW.

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment producing cells (melanocytes) which are related deeply with skin color, and is the most metastatic and aggressive form of skin cancer. In Taiwan, melanoma occurred in approximately 260 cases per year with about 160 deaths in 2013.

Lung cancer is a form of malignant tumor that arises from cells in the trachea, bronchi and alveoli. In Taiwan, lung cancer is one of the leading causes of cancer-related death with about 12,000 new cases and 9,000 deaths in 2012. In Taiwan, NSCLC is one of the most common types of lung cancer, accounting for approximately 90% of lung cancer cases. About 20 % of all NSCLC cases are squamous NSCLC with about 2,000 newly diagnosed cases in Taiwan in 2012. As patients with unresectable or treatment-resistant squamous NSCLC have an extremely poor prognosis, the development of new drugs has been expected.

OPDIVO is the first human anti-human PD-1 monoclonal antibody approved for the indication of unresectable melanoma in July 2014 in Japan or anywhere in the world. OPDIVO also received a supplemental approval for the indication of unresectable, advanced or recurrent non-small cell lung cancer (NSCLC) in December 2015. Outside of Japan, Bristol Myers Squibb (“BMS”), with whom ONO collaborates in Japan, South Korea and Taiwan, currently has regulatory approval for OPDIVO in 50 countries globally.

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 will market OPDIVO under the co-promotion with BMS (Taiwan) after the launch in Taiwan, based on the strategic collaboration agreement 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
Indication	1. Unresectable or Metastatic Melanoma 1) BRAF V600 wild-type unresectable or metastatic melanoma 2) Unresectable or metastatic BRAF V600 mutation-positive melanoma and disease progression following ipilimumab and a BRAF inhibitor 2. Metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy
Dosage and administration	Usually, for adults, infuse intravenously at 3 mg/kg (body weight) of nivolumab over 60 minutes every 2 weeks
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 exclusive rights to develop and commercialize OPDIVO globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to the compound 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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