ONO PHARMA

Press Release

OPDIVO® Intravenous Infusion Approved in Taiwan for the Treatment of Resectable Non-Small Cell Lung Cancer with Neoadjuvant OPDIVO in Combination with Chemotherapy Followed by Surgery and Adjuvant Single-Agent OPDIVO

Osaka, Japan, August 19, 2026－Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; “Ono”) today announced that Ono Pharma Taiwan Co., Ltd. (Taipei, Taiwan; “OPTW”), a Taiwanese subsidiary of Ono, received the additional approval of OPDIVO® Intravenous Infusion (generic name: nivolumab; "OPDIVO"), an anti-PD-1 antibody, on August 19 from the Taiwan Food and Drug Administration (TFDA) in Taiwan, for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements in combination with platinum-doublet chemotherapy, followed by single-agent OPDIVO as adjuvant treatment after surgery.

This approval is based on results from the CheckMate-77T trial(CA209-77T: ONO-4538-96), which evaluated the perioperative regimen of neoadjuvant OPDIVO with platinum-doublet chemotherapy followed by surgery and adjuvant OPDIVO monotherapy (OPDIVO group), compared to neoadjuvant platinum-doublet chemotherapy and placebo followed by surgery and adjuvant placebo monotherapy (placebo group) in adult patients with resectable NSCLC. The trial demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of event free survival (EFS), as assessed by Blinded Independent Central Review (BICR). The trial also demonstrated clinically meaningful improvements in the secondary efficacy endpoints of pathologic complete response (pCR) and major pathologic response (MPR). Additionally, the safety profile of OPDIVO group was consistent with previously reported studies in NSCLC. No new safety signals were identified.

About CheckMate-77T Trial (CA209-77T: ONO-4538-96)

CheckMate-77T is a Phase 3 randomized, double-blind, placebo-controlled, multi-center trial evaluating neoadjuvant OPDIVO with chemotherapy followed by surgery and adjuvant OPDIVO monotherapy versus neoadjuvant placebo plus chemotherapy followed by surgery and adjuvant placebo monotherapy in 461 patients with resectable stage IIA to IIIB NSCLC. The primary endpoint of the trial is EFS. Secondary endpoints include overall survival (OS), pCR and MPR.

About Lung Cancer

Lung cancer is a form of malignant tumor that arises from cells in the trachea, bronchi and alveoli. Lung cancer is divided into two types, small cell lung cancer and NSCLC, depending on the broad histological subtypes. NSCLC is the most common type of lung cancer, accounting for about 80 - 85% of lung cancer.[1] NSCLC is further classified into mainly adenocarcinoma (about 40% of lung cancer), squamous cell carcinoma (about 25%) and large cell carcinoma (about 10%).[2] In Taiwan, it is estimated that approximately 20,000 cases are newly diagnosed with lung cancer per year, with approximately 10,000 deaths resulting from the disease per year, showing the first leading cause of cancer-related death.[3] For some non-metastatic early-stage NSCLC patients, surgery may be able to be used as a singular option for treatment. However, 30% to 55% of patients can develop recurrence, contributing to a need for treatment options administered before surgery (neoadjuvant) and after surgery (adjuvant) to improve long-term outcomes.[4]

About OPDIVO

OPDIVO is a programmed death-1 (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. By harnessing the body's own immune system to fight cancer, OPDIVO has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. OPDIVO is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, the US and European Union.

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 carcinoma 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; unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy in August 2018; MSI-High unresectable advanced or recurrent CRC that has progressed following chemotherapy and unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy in February 2020; cancer of unknown primary in December 2021; adjuvant treatment of urothelial carcinoma in March 2022; malignant mesothelioma (excluding malignant pleural mesothelioma) in November 2023; unresectable advanced or recurrent malignant epithelial tumors in February 2024; and unresectable hepatocellular carcinoma in June 2025.

About the Ono and Bristol Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol Myers Squibb (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 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

About Ono Pharma Taiwan Co., Ltd. (OPTW)

OPTW is an Ono's wholly-owned subsidiary established in December 2014. OPTW has marketed OPDIVO, an anti-PD-1 antibody/anti-neoplastic drug in Taiwan since 2016. OPTW is committed to bringing more innovative new products to meet unmet medical needs to patients in Taiwan as soon as possible.

References:

1. American Cancer Society; What Is Non-Small Cell Lung Cancer?：https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html
2. Non-Small Cell Lung Cancer Treatment (PDQ®)–Health Professional Version, National Cancer Institute: https://www.cancer.gov/types/lung/hp/non-small-cell-lung-treatment-pdq#_12_toc
3. Cancer Registry Annual Report, 2019 Taiwan
4. Cascone T, Awad M, Spicer J, et al. Perioperative Nivolumab in Resectable Lung Cancer. N Engl J Med. 2024;390:1756-1769.

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