ONO PHARMACEUTICAL CO.,LTD.

October 28, 2022

Opdivo® Intravenous Infusion Approved for Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer in Combination with Chemotherapy in South Korea

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) announced that Ono Pharma Korea Co., Ltd. (“OPKR”), a Korean subsidiary of ONO, received the approval of Opdivo® (nivolumab) Intravenous Infusion ("Opdivo"), a human anti-human PD-1 monoclonal antibody, on October 26, 2022 from the Ministry of Food and Drug Safety (MFDS) in South Korea, for neoadjuvant treatment of adult patients with resectable (tumors ≥4cm or node positive) non-small cell lung cancer in combination with platinum-doublet chemotherapy.

This approval is based on the results from a global multi-center, randomized, open-label Phase 3 clinical study, CheckMate -816 study (ONO-4538-55), evaluating Opdivo in combination with chemotherapy compared to chemotherapy alone as a neoadjuvant treatment in patients with resectable non-small cell lung cancer (NSCLC). In this study, three cycles of Opdivo in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoints of event-free survival (EFS) as assessed by Blinded Independent Central Review (BICR) and pathologic complete response (pCR) as assessed by Blinded Independent Pathology Review (BIPR) versus chemotherapy alone when given before surgery. The safety profile of Opdivo in combination with chemotherapy of this study was consistent with previously reported studies in patients with NSCLC.

CheckMate -816 study is a global multi-center, randomized, open-label Phase 3 clinical study, evaluating Opdivo in combination with chemotherapy compared to chemotherapy alone as neoadjuvant treatment in patients with resectable stage IB - IIIA NSCLC (per the 7th edition American Joint Committee on Cancer/Union for International Cancer Control staging criteria), regardless of PD-L1 expression. Patients were randomized to receive either Opdivo 360 mg plus histology-based platinum doublet chemotherapy every three weeks for three cycles, or platinum doublet chemotherapy every three weeks for three cycles, followed by surgery. The primary endpoints of the study are EFS as assessed by BICR, and pCR as assessed by BIPR. Secondary endpoints include overall survival (OS), major pathologic response (MPR), and time to death or distant metastases.

In addition, as for the dosage and administration (D&A) of the approved indication of "first-line treatment of metastatic or recurrent non-small cell lung cancer expressing PD-L1 (≥1%) with no EGFR or ALK genomic tumor aberrations in combination with ipilimumab", the D&A of “Opdivo 360 mg every 3 weeks as an intravenous infusion” was also approved by the MFDS, in addition to the currently approved D&A of “Opdivo 3 mg/kg every 2 weeks as an intravenous infusion.”

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 non-small cell lung cancer (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 South Korea, it is estimated that approximately 29,000 cases are newly diagnosed with lung cancer per year, with approximately 20,000 deaths resulting from the disease per year, showing the first leading cause of cancer-related death[3]. Curative surgery is performed in patients with stages I - IIIA and some patients with stage IIIB NSCLC. However, even if surgery is performed, 30 - 55% of NSCLC patients relapse and die of the disease[4]. Survival rates vary depending on the stage and type of the cancer when diagnosed.

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) Globocan 2020; Patient Fact Sheets, Korea, Republic of. World Health Organization: https://gco.iarc.fr/today/data/factsheets/populations/410-korea-republic-of-fact-sheets.pdf
4) Uramoto H, Tanaka F. Recurrence after surgery in patients with NSCLC. Transl Lung Cancer Res. 2014;3:242-9.

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, China, 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, microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer 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, and adjuvant treatment of urothelial carcinoma in March 2022.

In addition, ONO is conducting clinical development program including hepatocellular carcinoma, ovarian cancer, bladder cancer, prostate cancer, pancreatic cancer, biliary tract cancer, etc.

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 Korea Co., Ltd.

Ono Pharma Korea Co., Ltd. (Seoul, Korea; "OPKR") is an ONO's wholly-owned subsidiary established in December 2013. OPKR has established our own sales organization in South Korea and marketed Opdivo, an anti-PD-1 antibody/anti-neoplastic drug through our own sales organization since 2015. OPKR has been committed to developing and marketing innovative new products to meet unmet medical needs and bring them to patients in South Korea as soon as possible.

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