ONO PHARMACEUTICAL CO.,LTD.

January 5, 2022

Opdivo® Intravenous Infusion Approved for the Adjuvant Treatment of Esophageal Cancer or Gastroesophageal Junction Cancer in Taiwan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that Ono Pharma Taiwan Co., Ltd. ("OPTW"), a Taiwanese subsidiary of ONO, received the additional approval of Opdivo® (nivolumab) Intravenous Infusion 20 mg, 100 mg Inj. ("Opdivo"), a human anti-human PD-1 monoclonal antibody, on December 29, 2021 in Taiwan from the Taiwan Food and Drug Administration (TFDA) for the adjuvant treatment of patients with completely resected esophageal cancer or gastroesophageal junction cancer with residual pathologic disease who have received neoadjuvant concurrent chemoradiotherapy.

This approval is based on the result from a global multi-center, randomized, double-blind Phase 3 clinical study, CheckMate -577 study (ONO-4538-43), evaluating Opdivo monotherapy as an adjuvant treatment in patients with resected esophageal cancer or gastroesophageal junction cancer, compared to placebo. In this study, Opdivo showed a statistically significant improvement in disease-free survival (DFS), the primary endpoint of the study, compared to placebo. The safety profile of Opdivo in this study was consistent with previously reported studies of Opdivo monotherapy.

About CheckMate -577 Study (ONO-4538-43)

CheckMate -577 study is a global multi-center, randomized, double-blind Phase 3 clinical study, evaluating Opdivo monotherapy as an adjuvant treatment in patients with resected esophageal cancer (ESC) or gastroesophageal junction cancer (GEJC) who have received neoadjuvant chemoradiotherapy (CRT) and have not achieved a pathological complete response. Following neoadjuvant CRT and complete tumor surgical resection (also known as trimodality therapy), patients were randomized to receive Opdivo or placebo. In patients receiving Opdivo, it was administered at 240 mg every two weeks for 16 weeks followed by Opdivo 480 mg every four weeks until disease recurrence, unacceptable toxicity or withdrawal of consent, with a maximum of one year total treatment duration. The primary endpoint of the study is disease-free survival (DFS) and the secondary endpoint is overall survival (OS).

About Esophageal Cancer and Gastroesophageal Junction Cancer

Esophageal cancer (ESC) is a malignant tumor that occurs in the inner layer (mucosa) of the esophagus and grows outside (toward the deeper layer). There are two main histological types of ESC; squamous cell carcinoma (SCC) and adenocarcinoma. SCC is the predominant type accounting for about 90% of all ESC in Taiwan. It is estimated that about 2,800 new cases[1)] are diagnosed with ESC per year in Taiwan and approximately 1,900 deaths[1)] per year resulting from this disease. Gastroesophageal junction cancer (GEJC) is a malignant tumor that occurs in the area of the body that connects the lower part of the esophagus to the stomach[2)].

1) Cancer Registry Annual Report, 2018 Taiwan
2) American Cancer Society. What is Cancer of the Esophagus? https://www.cancer.org/cancer/esophagus-cancer/about/what-is-cancer-of-the-esophagus.html. Updated March 20, 2020. Accessed April 26, 2021.

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, and 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, and cancer of unknown primary in December 2021.

In addition, ONO has submitted supplemental application for the adjuvant treatment of urothelial cancer, and is conducting clinical development program including hepatocellular carcinoma, ovarian cancer, bladder cancer, prostate cancer, pancreatic cancer, biliary tract cancer, etc.

About 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 their 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.

Ono Pharma Taiwan Co., Ltd. (Taipei, Taiwan, "OPTW") is an ONO's wholly-owned subsidiary established in in December 2014. OPTW has established its own sales organization in Taiwan and marketed Opdivo, an anti-PD-1 antibody/ anti-neoplastic drug since 2016. OPTW is committed to bringing more innovative new products to meet unmet medical needs to patients in Taiwan as soon as possible.

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