ONO PHARMACEUTICAL CO.,LTD.

April 12, 2022

Opdivo® Intravenous Infusion Approved in Taiwan for the Adjuvant Treatment of Urothelial Carcinoma

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 an additional approval for Opdivo® (nivolumab) Intravenous Infusion ("Opdivo"), a human anti-human PD-1 monoclonal antibody, on April 11 in Taiwan from the Taiwan Food and Drug Administration (TFDA) for the adjuvant treatment of patients with urothelial carcinoma at high risk of recurrence after radical resection.

This approval is based on the results from the global multi-center, randomized, double-blind Phase 3 CheckMate -274 study (ONO-4538-33), evaluating Opdivo monotherapy compared to placebo as an adjuvant treatment in patients with muscle-invasive urothelial carcinoma at a high risk of recurrence after radical surgery. In this study, Opdivo showed a statistically significant improvement in disease-free survival (DFS), compared to placebo, both in all randomized patients and in patients whose tumor cells express PD-L1 ≥1%, the primary endpoints of the study. The safety profile of Opdivo in this study was consistent with previously reported studies with Opdivo in solid tumors.

About CheckMate -274 Study (ONO-4538-33)

CheckMate -274 study is a global multi-center, randomized, double-blind Phase 3 study evaluating Opdivo monotherapy compared to placebo in patients who have undergone radical resection of muscle-invasive urothelial carcinoma originating in the bladder or upper urinary tract (renal pelvis or ureter) and are at a high risk of recurrence. In this study, patients were randomized 1:1 to receive Opdivo 240 mg or placebo every two weeks. Patients continued treatment for up to one year, until disease recurrence, unacceptable toxicity or withdrawal of consent. The primary endpoints of the study are disease-free survival (DFS) in all randomized patients and in patients whose tumor cells express PD-L1 ≥1%. Key secondary endpoints are overall survival (OS), non-urothelial tract recurrence free survival and disease-specific survival.

About Urothelial Carcinoma

Urothelial carcinoma is a tumor that begins in the renal pelvis, ureter, bladder and urethra, most of which is bladder cancer. Histopathologically, urothelial carcinoma (transitional epithelial cancer) accounts for more than 90% of bladder cancer[1)]. It is estimated that about 2,400 new cases of bladder cancer are diagnosed per year and about 1,100 deaths per year result from this disease in Taiwan[2)].

1): Lynch CF, Cohen MB. Urinary System. Cancer. 1995;75:316-29.
2): Cancer Registry Annual Report, 2019 Taiwan

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 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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