ONO PHARMA

Press Release

Opdivo® Intravenous Infusion Approved in Taiwan in Combination with Cisplatin and Gemcitabine for the First-Line Treatment of Adult Patients with Unresectable or Metastatic Urothelial Carcinoma

Osaka, Japan, October 10, 2024 - Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Toichi Takino; "Ono") today announced that Ono Pharma Taiwan Co., Ltd., a Taiwanese subsidiary of Ono, received the additional approval of Opdivo® (nivolumab) Intravenous Infusion ("Opdivo"), an anti-PD-1 antibody, in combination with cisplatin and gemcitabine, on October 9 from the Taiwan Food and Drug Administration (TFDA) in Taiwan, for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.

This approval is based on results from the Phase 3 CheckMate -901 study (CA209-901: ONO-4538-56), evaluating Opdivo in combination with cisplatin and gemcitabine followed by Opdivo monotherapy, compared to cisplatin-gemcitabine alone, in patients with previously untreated unresectable or metastatic urothelial carcinoma (UC). In this study, Opdivo in combination with cisplatin and gemcitabine followed by Opdivo monotherapy demonstrated statistically significant and clinically meaningful improvements in the primary efficacy endpoints of overall survival (OS) and progression-free survival (PFS) as assessed by Blinded Independent Central Review (BICR), compared to chemotherapy alone. The safety profile of the regimens in this study was consistent with the known safety profiles of the individual components of the regimen. No new safety concerns were identified.

With respect to the indication of UC, Opdivo monotherapy was approved in Taiwan for the treatment of "locally advanced unresectable or metastatic urothelial carcinoma after failure of prior platinum-containing therapy" in October 2017, and "adjuvant treatment in patients with urothelial carcinoma at a high risk of recurrence after undergoing radical resection" in April 2022.

About CheckMate -901 Study (CA209-901: ONO-4538-56)

CheckMate -901 is a randomized, open-label Phase 3 study, evaluating Opdivo in combination with Yervoy® (ipilimumab) or Opdivo in combination with cisplatin and gemcitabine followed by Opdivo monotherapy compared to standard-of-care cisplatin-gemcitabine alone, in patients with previously untreated unresectable or metastatic urothelial carcinoma.

In the CheckMate -901 sub-study, cisplatin-eligible patients were randomized to receive either Opdivo 360 mg in combination with cisplatin-gemcitabine every three weeks for up to six cycles followed by Opdivo 480 mg monotherapy every 4 weeks until disease progression or death up to a maximum of two years, or cisplatin-gemcitabine alone every three weeks for up to six cycles. The primary endpoints of this study were overall survival (OS) and progression-free survival (PFS) assessed by Blinded Independent Central Review (BICR). The OS and PFS outcomes are based on the final efficacy analyses of these endpoints.

The CheckMate -901 primary study is ongoing to assess Opdivo plus Yervoy versus standard-of-care chemotherapy.

About Urothelial Carcinoma

Bladder cancer is the ninth most common cancer in the world, with more than 610,000 new cases diagnosed in 2022 and more than 220,000 people die from it each year. Urothelial carcinoma (UC), which most frequently begins in the cells that line the inside of the bladder, accounts for approximately 90% of bladder cancer cases. In addition to the bladder, UC can occur in other parts of the urinary tract, including the ureters and renal pelvis. The majority of UC is diagnosed at an early stage, but rates of recurrence and disease progression are high. Approximately 50% of patients

who undergo radical surgery will experience disease recurrence, especially within the first two to three years after surgical removal of the bladder or kidney. For patients whose disease recurs as metastatic cancer, the prognosis is poor, with a median overall survival of approximately 12 to 14 months when treated with systemic therapy.

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, 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, adjuvant treatment of urothelial carcinoma in March 2022, malignant mesothelioma (excluding malignant pleural mesothelioma) in November 2023, and unresectable advanced or recurrent malignant epithelial tumors in February 2024.

In addition, Ono has submitted a supplemental application for the treatment of hepatocellular carcinoma.

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 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.

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