ONO PHARMACEUTICAL CO.,LTD.

May 18, 2022

Opdivo® Intravenous Infusion Approved for the Treatment of Previously Untreated or Advanced Renal Cell Carcinoma in Combination with Cabozantinib 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 ("Opdivo"), a human anti-human PD-1 monoclonal antibody, on May 17, 2022 in Taiwan from the Taiwan Food and Drug Administration (TFDA) for the treatment of previously untreated or advanced renal cell carcinoma in combination with cabozantinib.

This approval is based on the result from the global, multi-center, randomized, open-label Phase 3 CheckMate -9ER study, evaluating Opdivo and cabozantinib combination therapy versus sunitinib alone in patients with previously untreated advanced or metastatic renal cell carcinoma (RCC). In this study, Opdivo and cabozantinib combination therapy demonstrated a significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS) as assessed by the blinded independent central review (BICR), compared to sunitinib alone at the final analysis, as well as the secondary endpoints of overall survival (OS) and objective response rate (ORR) as assessed by the BICR. The safety profiles of Opdivo and cabozantinib combination therapy observed in the study were consistent with the previously reported safety profile of each product.

About Checkmate -9ER Study

CheckMate -9ER study is a global, multi-center, randomized, open-label Phase 3 study, evaluating Opdivo and cabozantinib combination therapy in patients with previously untreated advanced or metastatic RCC, versus sunitinib alone. Patients were randomized 1:1 to the Opdivo and cabozantinib combination therapy group receiving Opdivo 240 mg by intravenous infusion every 2 weeks and cabozantinib 40 mg orally once daily, or the control group receiving sunitinib 50 mg orally once daily for 4 weeks, followed by a 2-week non-treatment period until disease progression or unacceptable toxicity. The primary endpoint of the study was progression-free survival (PFS) as assessed by the blinded independent central review (BICR). The secondary endpoints were overall survival (OS) and objective response rate (ORR) as assessed by the BICR.

About Kidney Cancer

Kidney cancer is a malignant tumor arising from the renal parenchyma. Among kidney cancer, renal cell carcinoma (RCC) is the most common cancer, constituting almost 90% of all kidney cancer[1]. It is estimated that 1,615 new cases of kidney cancer are diagnosed per year (RCC: about 1,530) and 599 deaths per year result from this disease in Taiwan[2].

1: The epidemiology of renal cell carcinoma. Euro Urol. 2011;60;615-621.
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, 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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