ONO PHARMACEUTICAL CO.,LTD.

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Ono Announces Results from Phase 3 Clinical Study Evaluating Opdivo in Combination with Chemotherapy as Adjuvant Treatment in Patients with Gastric Cancer and Esophagogastric Junction Cancer

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President and CEO, Gyo Sagara; "ONO") today announced that Opdivo® (generic name: nivolumab) Intravenous Infusion ("Opdivo"), a human PD-1 monoclonal antibody, in combination with chemotherapy as adjuvant treatment did not demonstrate a significant extension of relapse-free survival (RFS) as assessed by the Independent Radiologic Review Committee (IRRC), in patients with pathologic Stage III (pStage III) gastric cancer and esophagogastric junction cancer after curative resection in the final analysis of Phase 3 ATTRACTION-5 study (ONO-4538-38), evaluating Opdivo in combination with chemotherapy, versus placebo in combination with chemotherapy.

About ATTRACTION-5 study (ONO-4538-38)

ATTRACTION-5 study is a multi-center, randomized, double-blind Phase 3 study, conducted in Japan, South Korea, Taiwan and China, evaluating Opdivo in combination with chemotherapy (tegafur-gimeracil-oteracil potassium: S-1 monotherapy therapy up to 1 year, or capecitabine + oxaliplatin: CapeOX therapy up to 6 months), in patients with pStage III gastric cancer and esophagogastric junction cancer after curative resection undergoing postoperative adjuvant chemotherapy, versus placebo in combination with S-1 monotherapy or CapeOX therapy. In this study, patients received either Opdivo 360 mg or placebo every 3 weeks up to 1 year, in combination with chemotherapy. The primary endpoint of the study was RFS as assessed by the Independent Radiologic Review Committee (IRRC). The secondary endpoints were RFS as assessed by the investigators and overall survival (OS).

About Gastric Cancer

It is estimated that about 138,000 new cases with gastric cancer are diagnosed per year in Japan[1)] (about 1,089,000 cases worldwide[2)]) and about 46,000 deaths per year in Japan[1)] (about 769,000 worldwide[2)]) resulting from this disease, which is the 2nd most common type of cancer following lung cancer in Japan. In patients with pStage III gastric cancer, recurrence rates remain particularly high after resection, and a new treatment option is needed for patients with this disease [3), 4)].

1) : Globocan 2020: Japan, World Health Organization. Available at: https://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf
2) : Globocan 2020: World, World Health Organization. Available at: https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf
3) : M Sasako et. al. J Clin Oncol. 2011 Nov 20;29(33):4387-93.
4) : SH Noh et. al. Lancet Oncol. 2014 Nov;15(12):1389-96.

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 a clinical development program including hepatocellular carcinoma, ovarian cancer, bladder cancer, prostate 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.

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