ONO PHARMACEUTICAL CO.,LTD.

November 10, 2016

Opdivo® (nivolumab) Intravenous Infusion Demonstrates a Significant Extension in Overall Survival Versus Placebo in Patients with Unresectable Advanced or Recurrent Gastric Cancer Refractory to or Intolerant of Standard Therapy in Phase III Clinical Study (ONO-4538-12 Study)

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced today the result from a randomized, double-blind Phase III clinical study with Opdivo® Intravenous Infusion ("Opdivo"), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody (ONO-4538-12 study) conducted by ONO. In the final analysis, the Opdivo treatment group demonstrated a significant extension in overall survival (OS), the primary endpoint, versus the placebo group, in patients with unresectable advanced or recurrent gastric cancer refractory to or intolerant of standard therapy.

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. Opdivo is the first one to demonstrate the extension of OS in patients with unresectable advanced or recurrent gastric cancer in the world.

The result of this study will be presented at a future scientific conference.

Gastric cancer is the fifth most common malignancy with about new 950,000 patients per year in the world and the third leading cause of cancer death with about 720,000 deaths per year reported worldwide*. The progress of chemotherapy has been realizing higher efficacy in tumor shrinkage (objective response rate) as a treatment of unresectable advanced or recurrent gastric cancer. However, it is still difficult to achieve complete cures by the treatment with chemotherapies. There is a need for a novel therapeutic drug in this patient population, because the target treatment with chemotherapies is even now to delay the onset timing of clinical symptoms and extend survival period associated with cancer progression**.

In Japan, Opdivo was launched by ONO for the treatment of unresectable melanoma in September 2014. Thereafter, it was approved for an additional indication of unresectable, advanced or recurrent non-small cell lung cancer in December 2015 and then unresectable or metastatic renal cell cancer in August 2016. In addition, ONO has submitted supplemental applications for additional indications of Hodgkin lymphoma and head and neck cancer, and is conducting clinical development programs including esophageal cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, ovarian cancer, urothelial cancer, malignant pleural mesothelioma, biliary tract cancer, etc.

Bristol-Myers Squibb (BMS) has a robust clinical development program in Opdivo monotherapy and in combination with other therapies in a variety of tumor types overseas. Opdivo has regulatory approval in 57 countries as part of the ONO - BMS collaboration.

In Japan, ONO and BMS (and BMS Japan subsidiary, BMSKK) have formed a strategic partnership that includes co-development, co-commercialization and co-promotion of multiple immunotherapies for patients with cancer.

* : Globocan 2012. Available at: http://globocan.iarc.fr/ . Accessed March 31, 2014.

** : Japanese gastric treatment guideline (ver. 4), Japanese Gastric Cancer Association

About ONO-4538-12 Study

This study is a multicenter, double-blind, randomized, placebo-controlled Phase III clinical study aiming to evaluate the efficacy on overall survival (OS) as the primary endpoint and safety of ONO-4538 (Opdivo; nivolumab) in patients with unresectable advanced or recurrent gastric cancer (including esophagogastric junction cancer) refractory to or intolerant of standard therapy. In this study, ONO-4538 (3 mg/kg) or placebo was administered every 2 weeks. Treatment was continued until disease progression, or onset of severe adverse events is observed. The primary endpoint, OS was assessed for the superiority of ONO-4538 versus placebo.

About the ONO and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol-Myers Squibb, 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 the compound 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 agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

Contact
ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp