

December 27, 2016

**ONO Submits Supplemental Application of OPDIVO® (Nivolumab)
for Unresectable Advanced or Recurrent Gastric Cancer for a Partial Change
in Approved Items of Manufacturing and Marketing Approval in Japan**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) and Bristol-Myers Squibb Company (NYSE: BMY) announced today that ONO submitted a supplemental application for OPDIVO® Intravenous Infusion 20 mg and 100 mg (“Opdivo”), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, for the treatment of unresectable advanced or recurrent gastric cancer for a partial change in the approved items of the manufacturing and marketing approval in Japan on December 27, 2016.

This regulatory application is based on the result of a multi-center, randomized, double-blind placebo-controlled Phase III study with Opdivo (ONO-4538-12 study), evaluating the efficacy and safety of Opdivo in patients with unresectable advanced or recurrent gastric cancer refractory to or intolerant of standard therapy. In the final analysis of this study, the Opdivo treatment group demonstrated a significant extension in overall survival (OS), the primary endpoint, versus the placebo group. In the data of 5.6 months after patient was randomized lastly, median OS was 5.32 months with Opdivo versus 4.14 months with placebo (hazard ratio [HR], 0.63; 95% confidence interval [CI], 0.50 - 0.78; $p < 0.0001$). OS rates at 6 months were 46.4% with Opdivo versus 34.7% with placebo, and OS rates at 12 months were 26.6% with Opdivo versus 10.9% with placebo. Grade ≥ 3 drug-related adverse events (AEs) occurred in 11.5% of Opdivo and 5.5% of placebo; 2.7% of Opdivo and 2.5% of placebo discontinued the study treatment due to drug-related AEs (any grade).

The result from this study will be presented at the 2017 Gastrointestinal Cancer Symposium to be held at San Francisco, CA, USA from January 19 - 21, 2017.

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**.

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.

In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. ONO received an approval for additional indication of unresectable, advanced or recurrent non-small cell lung cancer in December 2015, unresectable or metastatic renal cell cancer in August 2016 and relapsed or refractory classical Hodgkin lymphoma in December 2016. In addition, ONO has submitted supplemental application for additional indication of head and neck cancer, and is conducting clinical development program including esophageal cancer, gastro-esophageal junction cancer and esophageal cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, malignant pleural mesothelioma, ovarian cancer, 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.

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