ONO PHARMACEUTICAL CO.,LTD.

September 30, 2019

Adjuvant Treatment with Opdivo (nivolumab) Continues to Demonstrate Extended Recurrence-Free Survival at Three Years in Resected High-Risk Melanoma Patients

This information is intended to notify the press release issued on September 28 by Bristol-Myers Squibb. Please click https://www.bms.com/media/press-releases.html for the original press release.

First paragraph extracted from the original press release:

(PRINCETON, NJ, September 28, 2019) – Bristol-Myers Squibb Company (NYSE: BMY) today announced results of a three-year analysis of efficacy data from the Phase 3 CheckMate -238 study evaluating adjuvant use of Opdivo (nivolumab) 3 mg/kg versus Yervoy (ipilimumab) 10 mg/kg in patients with Stage III or Stage IV melanoma who were at high risk of recurrence following complete surgical resection. At three years of follow-up, Opdivo continues to demonstrate superior recurrence-free survival (RFS) compared to Yervoy, the active control, with RFS rates of 58% and 45%, respectively (HR 0.68; p<0.0001). Distant-metastasis-free survival (DMFS) also continues to be significantly longer for Opdivo, with 36-month rates of 66% and 58%, respectively (hazard ratio 0.78, p=0.044). Both RFS and DMFS benefit continue to be observed across key subgroups, including disease stages, BRAF mutation status and PD-L1 expression. No new safety data were generated as part of the 36-month analysis.

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 Pharmaceutical Co., Ltd. ("ONO") launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, 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, 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, and unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma, etc. in August 2018.

In addition, ONO has submitted a supplemental application for indication of MSI-H unresectable advanced or recurrent colorectal cancer and esophageal cancer, and is also conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, bladder cancer, ovarian cancer, colorectal cancer, biliary tract cancer, etc.

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