ONO PHARMACEUTICAL CO.,LTD.

September 30, 2019

Bristol-Myers Squibb Announces Final Results from CheckMate -227 Part 1 Demonstrating Superior Overall Survival for Opdivo (nivolumab) Plus Low-Dose Yervoy (ipilimumab) vs. Chemotherapy in Advanced Non-Small Cell Lung Cancer

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 from Part 1 of the Phase 3 CheckMate -227 trial evaluating Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) as first-line treatment for patients with advanced non-small cell lung cancer (NSCLC). Opdivo plus low-dose Yervoy met the independent co-primary endpoint of overall survival, demonstrating superior benefit compared to chemotherapy in patients whose tumors expressed PD-L1 ≥1% [Hazard Ratio (HR) 0.79; 97.72% Confidence Interval (CI): 0.65 to 0.96). Additionally, in an exploratory analysis, results showed improved overall survival for patients treated with the combination of Opdivo plus low-dose Yervoy with PD-L1 <1% (HR 0.62; 95% CI: 0.48 to 0.78]. The two-year survival rate for patients treated with the combination regimen was 40% for both patients whose tumors expressed PD-L1 ≥1% and patients whose tumors expressed PD-L1 <1%. In the chemotherapy control arm, two-year survival rates were 33% and 23%, respectively.

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