ONO PHARMACEUTICAL CO.,LTD.

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Bristol-Myers Squibb Announces Update on CheckMate -915 for Opdivo (nivolumab) Plus Yervoy (ipilimumab) Versus Opdivo Alone in Patients with Resected High-Risk Melanoma and PD-L1 <1%

This information is intended to notify the press release issued on November 20 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, November 20, 2019) – Bristol-Myers Squibb Company (NYSE: BMY) today announced results for one of the co-primary endpoints from CheckMate -915, a randomized Phase 3 study evaluating Opdivo (nivolumab) plus Yervoy (ipilimumab) versus Opdivo alone for the adjuvant treatment of patients who have had a complete surgical removal of stage IIIb/c/d or stage IV (no evidence of disease) melanoma. A statistically significant benefit was not reached for the co-primary endpoint of recurrence-free survival (RFS) in patients whose tumors expressed PD-L1 <1%. The Data Monitoring Committee recommended that the study continue unchanged. The study remains double-blinded and will continue to assess the other co-primary endpoint of RFS in the all-comer (intent-to-treat) population.

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, 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 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, 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 supplemental applications for the treatment of MSI-H colorectal cancer and esophageal cancer, and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, colorectal cancer, pancreatic cancer, biliary tract cancer, etc.

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