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European Medicines Agency Validates Bristol-Myers Squibb's Type II Variation Application for Opdivo (nivolumab) for Treatment of Patients with Resected High-Risk Advanced Melanoma

(PRINCETON, NJ, October 30, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the European Medicines Agency (EMA) validated its type II variation application, which seeks to expand the current indications for Opdivo (nivolumab) to include the treatment of patients with melanoma who are at high risk of disease recurrence following complete surgical resection. Validation of the application confirms the submission is complete and begins the EMA's centralized review process. The type II variation submitted is based on data from CheckMate -238, an ongoing phase 3, randomized double-blind study of Opdivo 3 mg/kg versus Yervoy (ipilimumab) 10 mg/kg in patients who have undergone complete resection of stage IIIb/c or stage IV melanoma, in which Opdivo met its primary endpoint of recurrence-free survival.

Bristol-Myers Squibb (BMS) has a robust clinical development program for Opdivo monotherapy and in combination with other Immuno-Oncology and non-Immuno-Oncology therapies across more than 350 clinical trials. BMS is studying Opdivo in approximately 50 types of cancer, across solid tumors and hematologic malignancies, and is utilizing its translational medicine capabilities to tailor approaches with the goal of providing maximal benefit for individual patients.

In Japan, Ono Pharmaceutical Co., Ltd. (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, relapsed or refractory classical Hodgkin lymphoma in December 2016 and recurrent or metastatic head and neck cancer in March 2017, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017. In addition, ONO is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, malignant pleural mesothelioma, ovarian cancer, biliary tract cancer, etc. Opdivo is currently approved in more than 60 countries, including Japan, the United States and the European Union.

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.

Please click here for the press release distributed by BMS.

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