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U.S. Food and Drug Administration (FDA) Accepts Bristol-Myers Squibb's Application for Opdivo (nivolumab) Plus Yervoy (ipilimumab) in Intermediate- and Poor-Risk Patients with Advanced Renal Cell Carcinoma and Grants Priority Review

(PRINCETON, N.J., December 13, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the U.S. Food and Drug Administration (FDA) has accepted its supplemental Biologics License Application (sBLA) for priority review of Opdivo (nivolumab) plus Yervoy (ipilimumab) to treat intermediate- and poor-risk patients with advanced renal cell carcinoma (RCC). The FDA also previously granted Breakthrough Therapy Designation for this application, which is the 2nd indication for which the Opdivo plus Yervoy combination has received this designation. The application is based on data from the phase 3 CheckMate -214 study, which was stopped early based on the recommendation of an independent Data Monitoring Committee following a planned interim analysis of overall survival. The application has an action date of April 16, 2018.

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.

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