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Bristol-Myers Squibb Receives FDA Approval for Opdivo (nivolumab) as Adjuvant Therapy in Patients with Completely Resected Melanoma with Lymph Node Involvement or Metastatic Disease

(PRINCETON, N.J., December 20, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the U.S. Food and Drug Administration (FDA) has approved Opdivo (nivolumab) injection for intravenous use for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. The purpose of adjuvant therapy is to reduce the risk of recurrence following surgical removal of the tumor and lymph nodes that contain cancer. In the Phase 3 CheckMate -238 trial, Opdivo significantly improved recurrence-free survival (RFS) versus an active comparator, Yervoy (ipilimumab), in patients with stage IIIB/C or stage IV melanoma after surgery. This benefit was observed across important subgroups, including in both BRAF mutant and BRAF wild-type patients. Opdivo is the first and only agent approved for the adjuvant treatment of melanoma based on a head-to-head trial against an active comparator with a proven overall survival benefit.

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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