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Opdivo (nivolumab) 3 mg/kg Demonstrates Sustained, Superior Recurrence-Free Survival Versus Yervoy (ipilimumab) 10 mg/kg for Broad Range of Patients with Resected Stage III or IV Melanoma

(PRINCETON, NJ, June 4, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced updated results from the Phase 3 CheckMate -238 trial evaluating Opdivo (nivolumab) versus Yervoy (ipilimumab) in patients with stage IIIB/C or stage IV melanoma who are at high risk of recurrence following complete surgical resection. In updated results from the study, Opdivo continued to demonstrate statistically longer recurrence-free survival (RFS) of 62.6%, the primary endpoint of the study, versus 50.2% for Yervoy (HR: 0.66, P<0.0001) at a minimum follow-up of 24 months across key subgroups, including disease stages and BRAF mutation status.

No new safety data were generated as part of the 24-month analysis. As previously reported from the 18-month analysis, Opdivo demonstrated a significantly lower rate of adverse events (AEs) leading to discontinuation (9.7% of patients in the Opdivo arm compared to 42.6% of patients in the Yervoy arm) and treatment-related grade 3/4 AEs (14.4% of patients in the Opdivo arm compared to 45.9% in the Yervoy arm).

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 has submitted supplemental application for treatment of malignant pleural mesothelioma, adjuvant melanoma, etc. and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, biliary tract cancer, etc. Opdivo is currently approved in more than 60 countries, including Japan, South Korea, Taiwan, the US and 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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