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Opdivo (nivolumab) in Combination with Yervoy (ipilimumab) Demonstrates Clinical Activity in Previously Treated Patients with dMMR or MSI-H Metastatic Colorectal Cancer

(PRINCETON, N.J., January 20, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced new data from a cohort of the phase 2 CheckMate -142 trial evaluating Opdivo (nivolumab) and Yervoy (ipilimumab) for the treatment of patients with DNA mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer (mCRC). With a median of 13.4 months of follow-up, the primary endpoint of objective response rate (ORR) per investigator assessment was 55% (95% CI: 45.2 to 63.8). Responses were durable, with median duration of response not yet reached and 94% of responses ongoing at time of data cutoff. The overall survival (OS) rate at one year was 85% (95% CI: 77.0 to 90.2), and median OS was not yet reached. Grade 3-4 treatment-related adverse events (TRAEs) occurred in 32% of patients receiving the Opdivo plus Yervoy combination. Patients received mCRC combination dosing of Opdivo (3 mg/kg) plus Yervoy (1 mg/kg) every three weeks for four doses, followed by Opdivo (3 mg/kg) every two weeks until disease progression, death or unacceptable toxicity.

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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