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# Bristol-Myers Squibb Receives FDA Approval for Opdivo (nivolumab) in MSI-H or dMMR Metastatic Colorectal Cancer That Has Progressed Following Treatment with a Fluoropyrimidine, Oxaliplatin, and Irinotecan

(PRINCETON, NJ, August 1, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced the U.S. Food and Drug Administration (FDA) has approved Opdivo (nivolumab) injection for intravenous use for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The recommended dose is 240 milligrams administered as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity. In the CheckMate -142 trial, among patients (53/74) who received prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, 28% (95% CI: 17-42; 15/53) responded to treatment with Opdivo. The percentage of patients with a complete response was 1.9% (1/53) and the percentage of patients with a partial response was 26% (14/53). Among these responders, the median duration of response was not reached (range: 2.8+-22.1+ months). Among all enrolled patients, 32% (95% CI: 22-44; 24/74) responded to treatment with Opdivo; 2.7% (2/74) experienced a complete response, 30% (22/74) experienced a partial response.

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. In addition, ONO has submitted supplemental application for additional indication of gastric cancer, and is conducting clinical development program including esophageal cancer, gastro-esophageal 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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