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U.S. Food and Drug Administration (FDA) Accepts Bristol-Myers Squibb's Application for Opdivo (nivolumab) Plus Yervoy (ipilimumab) for Previously Treated Patients with MSI-H or dMMR Metastatic Colorectal Cancer for Priority Review

(PRINCETON, NJ, March 27, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the U.S. Food and Drug Administration (FDA) accepted its supplemental Biologics License Application (sBLA) for Opdivo (nivolumab) in combination with Yervoy (ipilimumab) for the treatment of adults 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. The FDA granted the application priority review and, in February 2018, granted the combination Breakthrough Therapy Designation for this potential indication, recognizing the need for new treatment approaches in this patient population. The FDA action date is July 10, 2018.

This application is based on data from the ongoing Phase 2 CheckMate -142 study evaluating the Opdivo and Yervoy combination in previously treated patients with MSI-H or dMMR mCRC. Data from this study were presented in January at the 2018 Gastrointestinal Cancers Symposium and published simultaneously in the Journal of Clinical Oncology.

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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