

July 12, 2018

**Opdivo + Low-Dose Yervoy is the First Immuno-Oncology Combination
Approved for MSI-H/dMMR mCRC Patients Who Progressed Following Treatment
with a Fluoropyrimidine, Oxaliplatin and Irinotecan**

(PRINCETON, NJ, July 11, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced Opdivo (nivolumab) 3 mg/kg plus low-dose Yervoy (ipilimumab) 1 mg/kg (injections for intravenous use) received approval from the U.S. Food and Drug Administration (FDA) for the treatment of adult and pediatric patients 12 years and older 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.¹ Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response (DOR).¹ Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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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