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Bristol-Myers Squibb Receives Positive CHMP Opinion Recommending Approval of Opdivo (nivolumab) for the Adjuvant Treatment of Adult Patients with Melanoma
First and only PD-1 agent to receive positive CHMP opinion in the adjuvant setting

(PRINCETON, NJ, June 29, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended expanded approval of the current indications for Opdivo (nivolumab) to include the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. This is the first time the CHMP has recommended a PD-1 inhibitor as an adjuvant treatment for any type of cancer. The CHMP recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU).

The CHMP recommendation is based on data from the phase 3 CheckMate -238 trial, an ongoing, randomized double-blind study of Opdivo 3 mg/kg versus Yervoy (ipilimumab) 10 mg/kg in patients who have undergone complete resection of stage IIIB/C or stage IV melanoma according to the AJCC Cancer Staging Manual 7th edition. The U.S. Food and Drug Administration (FDA) expanded the approval of Opdivo to include the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection in December 2017.

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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