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Bristol-Myers Squibb's Opdivo® (nivolumab) Receives FDA Approval for the Treatment of Hepatocellular Carcinoma Patients Previously Treated with Sorafenib

(PRINCETON, NJ, September 22, 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 patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. Approval for this indication has been granted under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. In the CheckMate -040 trial, 14.3%* (95% CI: 9.2-20.8; 22/154) of patients responded to treatment with Opdivo. The percentage of patients with a complete response was 1.9% (3/154) and the percentage of patients with a partial response was 12.3% (19/154). Among responders (n=22), responses ranged from 3.2 to 38.2+ months; 91% of those patients had responses of six months or longer and 55% had responses of 12 months or longer. (*: BICR-assessed based on RECIST v1.1)

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, 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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