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Opdivo Plus Yervoy Combination Delivered Overall Survival Benefit Across PD-L1 Expression Levels in Intermediate- and Poor-Risk Patients with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma

(PRINCETON, N.J., November 7, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from a new exploratory analysis of the phase 3 CheckMate -214 trial evaluating Opdivo (nivolumab) plus Yervoy (ipilimumab) versus the standard of care, sunitinib, in intermediate- and poor-risk patients with previously untreated advanced or metastatic renal cell carcinoma (RCC). In an exploratory analysis of PD-L1 expression subgroups, an overall survival (OS) advantage was seen with the Opdivo plus Yervoy combination over sunitinib in both the PD-L1 expression level <1% [HR= 0.73, (CI: 95% 0.56 to 0.96)] and ≥1% subgroups [HR= 0.45 (CI: 95% 0.29 to 0.71)]. The median overall survival (OS) was not reached for the Opdivo plus Yervoy combination or sunitinib for those with PD-L1 levels < 1%, and for patients with PD-L1 expression levels ≥1%, the median OS was not reached for the combination and was 19.6 months for sunitinib. The safety profile of Opdivo plus Yervoy was consistent with that of previous reports.

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, esophago-gastric 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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