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Opdivo Plus Yervoy Combination Demonstrated Superior Overall Survival and Showed Durable Responses in Patients with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma in Phase 3 CheckMate -214 Trial

(PRINCETON, NJ, September 10, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from the Phase 3 CheckMate -214 trial evaluating Opdivo (nivolumab) plus Yervoy (ipilimumab) versus sunitinib in patients with previously untreated advanced or metastatic renal cell carcinoma (RCC), including data on key subgroups. With a minimum follow-up of 17.5 months, Opdivo in combination with Yervoy reduced the risk of death 37% (HR 0.63; 99.8% CI: 0.44 to 0.89; P < 0.0001) compared with sunitinib, the current standard of care, in an interim analysis of overall survival (OS) in intermediate- and poor-risk patients, the co-primary endpoint. The median OS had not yet been reached for the combination and was 26 months for sunitinib (95% CI: 22.1 to NA).

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. In addition, ONO has submitted supplemental application for additional indication of gastric cancer, and 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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