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Bristol-Myers Squibb Announces Topline Results from CheckMate -214, a Phase 3 Study of Opdivo in Combination with Yervoy in Intermediate and Poor-Risk Patients with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma

(PRINCETON, N.J., August 15, 2017) - Bristol-Myers Squibb Company (NYSE: BMY) announced topline results from the CheckMate -214 trial investigating Opdivo (nivolumab) in combination with Yervoy (ipilimumab) versus sunitinib in intermediate and poor-risk patients previously untreated advanced or metastatic renal cell carcinoma. The combination met the co-primary endpoint of objective response rate (ORR) and achieved a 41.6% ORR versus 26.5% for sunitinib. Median duration of response was not reached for the combination of Opdivo and Yervoy and was 18.17 months for sunitinib. While there was an improvement in progression-free survival (PFS) (HR=0.82, [99.1% CI 0.64 – 1.05]; stratified 2-sided p=0.03), it did not reach statistical significance. The median PFS was 11.56 months (95% CI 8.71 – 15.51) for the Opdivo and Yervoy combination versus 8.38 months (95% CI 7.03-10.81) for sunitinib, The study will continue as planned to allow the third co-primary endpoint of overall survival to mature. The tolerability profile observed in CheckMate-214 was consistent with that observed in previously reported studies of this dosing schedule.

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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