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Opdivo (nivolumab) Plus Low-Dose (1mg/kg) Yervoy (ipilimumab) Provided Significant and Sustained Health-Related Quality of Life Improvements in Intermediate- and Poor-Risk Patients with Advanced Renal Cell Carcinoma in CheckMate -214 Study

(PRINCETON, NJ, June 1, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced patient-reported outcomes data from the Phase 3 CheckMate -214 trial in intermediate- and poor-risk patients with advanced renal cell carcinoma (RCC) treated with the Immuno-Oncology combination Opdivo (nivolumab) plus low-dose (1mg/kg) Yervoy (ipilimumab) versus sunitinib over a two-year follow-up period. Patients in the study treated with Opdivo plus low-dose Yervoy reported significant benefits in disease-related symptoms and improvements to their cancer-related quality of life and well-being. These benefits occurred early during Opdivo plus low-dose (1mg/kg) Yervoy combination therapy and were largely maintained throughout the treatment period and through Opdivo maintenance therapy.

Relative to the current standard of care, patients in the Opdivo plus low-dose Yervoy arm reported fewer kidney cancer symptoms as measured by the NCCN Functional Assessment of Cancer Therapy-Kidney Symptom Index (FKSI-19). This benefit was significant at all but one post-baseline time point through two years of follow-up ($P<0.05$). Time to deterioration (TTD) in FKSI-19 total score was also significantly delayed with Opdivo plus low-dose Yervoy versus sunitinib (HR 0.54; 95% CI, 0.46–0.63; $P < 0.0001$).

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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