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U.S. Food and Drug Administration Approves Opdivo® (nivolumab) + Yervoy® (ipilimumab) Combination as First-Line Treatment for Patients with Intermediate- and Poor-Risk Advanced Renal Cell Carcinoma

(PRINCETON, NJ, APRIL 16, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that Opdivo (nivolumab) 3 mg/kg plus Yervoy (ipilimumab) 1 mg/kg (injections for intravenous use) was approved by the U.S. Food and Drug Administration (FDA) as the first Immuno-Oncology combination therapy for previously untreated patients with intermediate- and poor-risk advanced renal cell carcinoma (RCC). In the Phase 3 CheckMate -214 clinical trial, the Opdivo + Yervoy combination demonstrated a significant and unprecedented increase in overall survival (OS) in this patient population compared to a current standard of care, sunitinib. An OS benefit was observed regardless of PD-L1 expression level. Opdivo + Yervoy also delivered durable responses, with a higher objective response rate (ORR) compared to sunitinib. Patients in the CheckMate -214 trial received four cycles of the Opdivo + low-dose Yervoy combination, followed by Opdivo maintenance therapy. In the combination arm of the trial, 79% of patients received all four doses of Opdivo + Yervoy and went on to the Opdivo monotherapy phase. Flexible dosing options are available during the Opdivo maintenance phase (480 mg infused every four weeks or 240 mg infused every two weeks).

In CheckMate -214, the combination was associated with fewer overall Grade 3 or 4 adverse events than sunitinib (65% versus 76%). Treatment discontinuation due to adverse events occurred in 31% of patients in the Opdivo + Yervoy arm, compared to 21% in the sunitinib arm. Fifty-four percent (54%) of patients receiving Opdivo + Yervoy and 43% of patients receiving sunitinib had a dose delay for an adverse reaction. In the sunitinib group, 53% of patients required a dose reduction, which was not permitted for patients treated with the Opdivo + Yervoy combination. Serious adverse reactions occurred in 59% of patients receiving Opdivo + Yervoy and in 43% of patients receiving sunitinib.

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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