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Encouraging Response Observed with Opdivo (nivolumab) Plus Investigational IDO1 Inhibitor, BMS-986205, in Heavily Pre-Treated Patients with Advanced Cancers in Phase 1/2a Study CA017-003

(PRINCETON, N.J., November 10, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced updated results for Opdivo (nivolumab) plus BMS-986205, a selective, once-daily oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor from the ongoing Phase 1/2a dose escalation and expansion study, CA017-003. In the dose escalation phase, the maximum tolerated dose (primary endpoint) of BMS-986205 in combination with Opdivo was 200 mg. Based on safety and pharmacodynamic data, the recommended dose for further study was determined to be 100 mg. In the dose expansion phase, findings for anti-tumor activity (primary endpoint) were reported in two cohorts – heavily pre-treated bladder (n=25) and cervical cancer patients (n=22). In the bladder cancer cohort, the objective response rate (ORR) and disease control rate (DCR) were 32% and 44%, respectively. In the cervical cancer cohort, the ORR was 14% and DCR was 64%. The study also measured ORR by PD-L1 expression levels; in patients who express PD-L1 ≥1%, ORR was 46% and 25% in the bladder (n=13) and cervical cancer cohorts (n=12), respectively. In patients who express PD-L1 <1%, ORR was 22% in the bladder cancer cohort (n=9); no response was observed in cervical cancer patients (n=7). Response was observed regardless of prior lines of therapy.

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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