ONO PHARMACEUTICAL CO.,LTD.

Bristol-Myers Squibb

September 11, 2017

Two Pivotal Opdivo (nivolumab) Trials Show Three-Year Survival Benefit in Patients with Previously Treated Advanced Non-Small Cell Lung Cancer

(PRINCETON, N.J., September 8, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced three-year overall survival (OS) data from CheckMate -017 and CheckMate -057, two pivotal Phase 3 randomized studies evaluating Opdivo versus docetaxel in patients with previously treated metastatic non-small cell lung cancer (NSCLC). In CheckMate -017, a trial in previously treated squamous NSCLC, 16% of patients treated with Opdivo were alive at three years (21/135) versus 6% of those treated with docetaxel (8/137) (HR 0.62; 95% CI: 0.48 to 0.80). In CheckMate -057, a trial in previously treated non-squamous NSCLC, 18% of patients treated with Opdivo were alive at three years (49/292) versus 9% of those treated with docetaxel (26/290) (HR 0.73; 95% CI: 0.62 to 0.88). Similar to prior reports, an OS benefit was observed across histologies, and three-year survivors included patients whose tumors expressed PD-L1 and those that did not. With three years' minimum follow-up, no new safety signals were identified for Opdivo, and the safety profile across both trials was consistent with prior reports.

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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