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Opdivo (nivolumab), First PD-1 Inhibitor to Demonstrate Superior Survival Benefit Compared with Chemotherapy in a Predominantly Chinese Population with Previously Treated Non-Small Cell Lung Cancer (NSCLC)

(PRINCETON, NJ, APRIL 13, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from the pivotal, randomized Phase 3 CheckMate -078 trial evaluating Opdivo (nivolumab) versus docetaxel in a predominantly Chinese population with previously treated advanced non-small cell lung cancer (NSCLC). In the study, Opdivo demonstrated a statistically significant benefit versus docetaxel on the primary endpoint of overall survival (OS; HR 0.68; 97.7% CI: 0.52 to 0.90; p=0.0006). An OS benefit was observed regardless of PD-L1 expression or tumor histology. Additionally, the two secondary endpoints of objective response rate (ORR) and median duration of response (mDOR) demonstrated durability with Opdivo compared with docetaxel (ORR: 17% vs. 4%; mDOR: not reached vs. 5.3 months, respectively).

Findings will be presented on Monday, April 16 from 4:05-4:20 PM CDT during the Updates in Immuno-Oncology Trials session at the American Association for Cancer Research (AACR) Annual Meeting 2018 in Chicago (Abstract #CT114).

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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