June 5, 2018

Opdivo Plus Chemotherapy Showed Improved Progression-Free Survival Versus Chemotherapy in First-Line Lung Cancer Patients with PD-L1 <1%, in CheckMate -227 Study to Be Presented at ASCO 2018

(PRINCETON, NJ, June 1, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from a part of the Phase 3 CheckMate -227 trial that evaluated Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) and Opdivo plus chemotherapy versus chemotherapy in patients with first-line advanced non-small cell lung cancer (NSCLC) with PD-L1 expression <1%, across squamous and non-squamous tumor histologies (Part 1b).

Data show that Opdivo plus chemotherapy (n=177) extended progression-free survival (PFS) versus chemotherapy (n=186) in patients with PD-L1 expression <1% (HR 0.74; 95% CI: 0.58 to 0.94). PFS is a secondary endpoint for Opdivo plus chemotherapy in Part 1b of the study, and results are based on a descriptive analysis.

In an exploratory analysis of patients with high tumor mutational burden (TMB) ≥10 mutations/megabase (mut/Mb) and PD-L1 expression <1%, the one-year PFS rates were 45% with Opdivo plus low-dose Yervoy (n=38), 27% with Opdivo plus chemotherapy (n=43) and 8% with chemotherapy (n=48). In patients with low TMB (<10 mut/Mb) and PD-L1 <1%, the one-year PFS rate was 18% with both Opdivo plus low-dose Yervoy (n=52) and Opdivo plus chemotherapy (n=54) and was 16% with chemotherapy (n=59).

In this report, Grade 3-4 treatment-related adverse events (TRAEs) were observed in 25% of patients who received Opdivo plus low-dose Yervoy, 52% with Opdivo plus chemotherapy and 35% with chemotherapy. The most common select Grade 3-4 TRAEs with Opdivo plus low-dose Yervoy were hepatic (8%), gastrointestinal (3%), endocrine (3%), skin (3%), diarrhea (2%), anemia (2%), fatigue (1%), asthenia (1%) and nausea (1%). The most common Grade 3-4 TRAEs with Opdivo plus chemotherapy were anemia (17%), neutropenia (12%), decreased neutrophil count (10%), fatigue (5%), hepatic (3%), decreased appetite (2%), nausea (2%), gastrointestinal (2%), diarrhea (1%), skin (1%) and endocrine (0.6%).

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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