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Pivotal Phase 3 CheckMate -227 Study Demonstrates Superior Progression-Free Survival (PFS) with the Opdivo Plus Yervoy Combination Versus Chemotherapy in First-Line Non-Small Cell Lung Cancer (NSCLC) Patients with High Tumor Mutation Burden (TMB)

(PRINCETON, NJ, February 5, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the ongoing Phase 3 CheckMate -227 study met its co-primary endpoint of progression-free survival (PFS) with the Opdivo (nivolumab) plus Yervoy (ipilimumab) combination versus chemotherapy in first-line advanced non-small cell lung cancer (NSCLC) patients whose tumors have high (≥ 10 mutations/megabase, mut/mb) tumor mutation burden (TMB), regardless of PD-L1 expression. In the study, TMB was evaluated using Foundation Medicine's (Nasdaq: FMI) analytically validated assay FoundationOne CDx. Additionally, based on an interim analysis for overall survival (OS), the Data Monitoring Committee recommended that the study continue. The safety profile was consistent with previously reported findings in first-line NSCLC for the combination schedule of Opdivo 3 mg/kg every two weeks and low-dose Yervoy (1 mg/kg) every six weeks. .

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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