April 17, 2018

Opdivo Plus Low-Dose Yervoy Combination Reduces the Risk of Progression or Death by 42% Versus Chemotherapy in First-Line Lung Cancer Patients with High Tumor Mutational Burden (TMB)

(PRINCETON, NJ, APRIL 16, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced initial results from the pivotal Phase 3 study, CheckMate -227, evaluating the Opdivo (nivolumab) 3 mg/kg plus low-dose Yervoy (ipilimumab, 1 mg/kg) combination in first-line advanced non-small cell lung cancer (NSCLC) patients with high tumor mutational burden (TMB) ≥10 mutations/megabase (mut/Mb). In the study, the combination demonstrated a superior benefit for the co-primary endpoint of progression-free survival (PFS) versus chemotherapy (HR 0.58; 97.5% CI: 0.41 to 0.81; p=0.0002). The PFS benefit was observed regardless of PD-L1 expression levels and in both squamous and non-squamous tumor histology. Additionally, based on an early descriptive analysis, encouraging overall survival was observed with the combination versus chemotherapy in patients with high TMB ≥10 mut/Mb (HR 0.79; 95% CI: 0.56 to 1.10).

Grade 3-4 treatment-related adverse events (AEs) with the combination were skin reactions (34%), endocrine (23%), gastrointestinal (18%), hepatic (15%), pulmonary (8%), hypersensitivity (4%) and renal (4%) events. Overall, treatment-related deaths occurred in 1% of patients treated in both the combination and chemotherapy arms.

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.

Contact
ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp