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U.S. Food and Drug Administration (FDA) Accepts Application for Opdivo Plus Low-Dose Yervoy for Treatment of First-Line Non-Small Cell Lung Cancer in Patients with Tumor Mutational Burden ≥10 mut/Mb

(PRINCETON, NJ, June 21, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the U.S. Food and Drug Administration (FDA) has accepted its supplemental Biologics License Application (sBLA) for Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) for the treatment of first-line advanced non-small cell lung cancer (NSCLC) in patients with tumor mutational burden (TMB) ≥10 mutations per megabase (mut/Mb). The target FDA action date is February 20, 2019.

The application was based on results from Part 1 of CheckMate -227, the first and only global Phase 3 study to evaluate an I-O/I-O regimen versus chemotherapy in a population of first-line NSCLC patients with TMB ≥10 mut/Mb, across squamous and non-squamous tumor histologies and the PD-L1 expression spectrum. These data were presented at the American Association for Cancer Research Annual Meeting 2018 and published in The New England Journal of Medicine.

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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