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**European Medicines Agency Validates Bristol-Myers Squibb's Type II Variation  
Application for Opdivo Plus Yervoy Combination for Treatment of  
First-Line Metastatic Non-Small Cell Lung Cancer (NSCLC)**

(PRINCETON, NJ, May 3, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the European Medicines Agency (EMA) validated a type II variation application for the Opdivo (nivolumab) plus Yervoy (ipilimumab) combination for treatment in adult patients with first-line metastatic non-small cell lung cancer (NSCLC) who have tumor mutational burden (TMB)  $\geq 10$  mutations/megabase (mut/Mb). Validation of the application confirms the submission is complete and begins the EMA's centralized review process.

The application is based on data from Part 1 of CheckMate -227, a global Phase 3 study evaluating Opdivo-based regimens versus chemotherapy in patients with first-line advanced NSCLC across squamous and non-squamous histologies. Initial results from this study were presented at the American Association for Cancer Research Annual Meeting in April 2018 and simultaneously 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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