ONO PHARMACEUTICAL CO.,LTD.

February 3, 2020

Bristol-Myers Squibb Withdraws European Application of Opdivo (nivolumab) Plus Yervoy (ipilimumab) for the First-Line Treatment of Advanced Non-Small Cell Lung Cancer

This information is intended to notify the press release issued on January 31 by Bristol-Myers Squibb. Please click https://www.bms.com/media/press-releases.html for the original press release.

First paragraph extracted from the original press release:

(PRINCETON, NJ, January 31, 2020) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the company has withdrawn its application in the European Union (EU) for the combination of Opdivo (nivolumab) and Yervoy (ipilimumab) for the treatment of advanced non-small cell lung cancer (NSCLC) based on data from CheckMate -227. The application was originally filed in 2018 for patients with first-line NSCLC who have tumor mutational burden ≥10 mutations/megabase, based on the final analysis of progression-free survival, a co-primary endpoint in the trial. The application was subsequently amended to include the statistically significant result of overall survival, a co-primary endpoint, from CheckMate -227 Part 1a evaluating Opdivo plus Yervoy versus chemotherapy in patients whose tumors expressed PD-L1 ≥1%.

About Opdivo

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response by blocking the interaction between PD-1 and its ligands. By harnessing the body's own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. Opdivo is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.

In Japan, Ono Pharmaceutical Co., Ltd. ("ONO") launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, Opdivo received an approval for additional indications 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, recurrent or metastatic head and neck cancer in March 2017, unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017, unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma, etc. in August 2018.

In addition, ONO has submitted supplemental applications for the treatment of MSI-H colorectal cancer and esophageal cancer, and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, colorectal cancer, pancreatic cancer, biliary tract cancer, etc.

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