

January 16, 2020

**U.S. Food and Drug Administration Accepts for Priority Review
Bristol-Myers Squibb's Application for Opdivo (nivolumab) Plus Yervoy (ipilimumab)
in First-Line Non-Small Cell Lung Cancer**

This information is intended to notify the press release issued on January 15 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 15, 2020) – Bristol-Myers Squibb Company (NYSE: BMY) today announced the U.S. Food and Drug Administration (FDA) has accepted its supplemental Biologics License Application (sBLA) for Opdivo (nivolumab) in combination with Yervoy (ipilimumab) for the first-line treatment of patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations. The FDA has granted the application Priority Review with a Prescription Drug User Fee Act (PDUFA) goal date of May 15, 2020.

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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