

April 9, 2020

Bristol Myers Squibb Announces Acceptance of U.S. and EU Regulatory Filings for Opdivo (nivolumab) Plus Yervoy (ipilimumab) Combined with Limited Chemotherapy in First-Line Lung Cancer

This information is intended to notify the press release issued on April 8 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, April 8, 2020) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has accepted its supplemental Biologics License Application (sBLA) for Opdivo (nivolumab) plus Yervoy (ipilimumab), administered concomitantly with a limited course of chemotherapy, 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 granted this application Priority Review with a Prescription Drug User Fee Act (PDUFA) goal date of August 6, 2020, in addition to granting Fast Track designation.

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 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 in August 2018, and microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy and unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy in February 2020.

In addition, ONO is conducting clinical development program including esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, pancreatic cancer, biliary tract cancer, etc.

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