

August 20, 2018

**U.S. Food and Drug Administration Approves Opdivo® (nivolumab)
as the First New Medication in Nearly 20 Years for Certain Patients with
Previously Treated Small Cell Lung Cancer**

This information is intended to notify the press release issued on Aug. 17 by Bristol-Myers Squibb. Please click <https://www.bms.com/media/press-releases.html> for the original press release by BMS.

(1st paragraph of the press release)

(PRINCETON, NJ, August 17, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that Opdivo (nivolumab) received approval from the U.S. Food and Drug Administration (FDA) as the first and only Immuno-Oncology treatment option for patients with metastatic small cell lung cancer (SCLC) whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy. Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

About Opdivo

Opdivo is an anti-PD-1 antibody 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, and is the first PD-1 immune checkpoint inhibitor approved in Japan all over the world in July 2014. Opdivo is currently approved in more than 60 countries, including Japan, South Korea, Taiwan, the US and European Union.

In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, 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, 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.

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