

October 22, 2018

**Bristol-Myers Squibb Provides Update on the Ongoing Regulatory Review of Opdivo Plus Low-Dose Yervoy in First-Line Lung Cancer Patients with Tumor Mutational Burden  $\geq 10$  mut/Mb**

*This information is intended to notify the press release issued on Oct. 19 by Bristol-Myers Squibb. Please click <https://www.bms.com/media/press-releases.html> for the original press release by BMS.*

1<sup>st</sup> paragraph of the press release:

(PRINCETON, NJ, October 19, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced updates regarding regulatory actions by health authorities in the United States (U.S.) and European Union (EU) for the ongoing review of its applications for an indication in metastatic first-line non-small cell lung cancer with Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) in patients with tumor mutational burden (TMB)  $\geq 10$  mutations/megabase (mut/Mb). Both applications are based on data from Part 1 of the ongoing Phase 3 CheckMate -227 trial.

**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, unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017, and unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma, etc. in August 2018. In addition, ONO 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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