

November 16, 2018

Bristol-Myers Squibb Receives Positive CHMP Opinion Recommending Approval of Opdivo (nivolumab) Plus Low-Dose Yervoy (ipilimumab) as First-Line Treatment for Patients with Intermediate- and Poor-Risk Advanced Renal Cell Carcinoma

This information is intended to notify the press release issued on November 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, November 15, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency adopted a positive opinion recommending approval of the Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) combination to include first-line treatment for patients with intermediate- and poor-risk advanced renal cell carcinoma (RCC). This recommendation will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU).

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 65 countries, including the US and European Union, China, and Japan.

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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