

October 23, 2018

Opdivo (nivolumab) Plus Low-Dose Yervoy (ipilimumab) Demonstrates Durable Clinical Benefit in Previously Untreated Patients with MSI-H or dMMR Metastatic Colorectal Cancer

This information is intended to notify the press release issued on October 22 by Bristol-Myers Squibb. Please click <https://www.bms.com/media/press-releases.html> for the original press release.

First paragraph of the press release:

(PRINCETON, NJ, October 22, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) today announced new data from a cohort of the CheckMate -142 study in which Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) demonstrated durable clinical benefit as a first-line treatment in patients with microsatellite instability-high (MSI-H) or DNA mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC). With a median follow-up of 13.8 months, the primary endpoint of investigator-assessed objective response rate (ORR) was 60% (95% CI: 44.3 to 74.3), with a 7% complete response (CR) rate. Patient responses to the combination treatment were durable; at the time of data cutoff, the median duration of response (DOR) had not yet been reached and 82% of responding patients had ongoing responses. Among the patients who responded, 74% have had responses lasting more than six months.

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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