

June 25, 2019

Bristol-Myers Squibb Announces Results from CheckMate -459 Study Evaluating Opdivo (nivolumab) as a First-Line Treatment for Patients with Unresectable Hepatocellular Carcinoma

This information is intended to notify the press release issued on June 24 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, June 24, 2019) – Bristol-Myers Squibb Company (NYSE: BMY) today announced topline results from CheckMate -459, a randomized Phase 3 study evaluating Opdivo (nivolumab) versus sorafenib as a first-line treatment in patients with unresectable hepatocellular carcinoma (HCC). The trial did not achieve statistical significance for its primary endpoint of overall survival (OS) per the pre-specified analysis (HR=0.85 [95% CI: 0.72-1.02]; p=0.0752). No new safety signals were observed with Opdivo. The full study results will be presented at an upcoming medical meeting.

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 Pharmaceutical Co., Ltd. ("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 has submitted a supplemental application for indication of MSI-H unresectable advanced or recurrent colorectal cancer and esophageal cancer, and is also conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, bladder cancer, ovarian cancer, colorectal cancer, biliary tract cancer, etc.

Contact:

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp