ONO PHARMACEUTICAL CO.,LTD.

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Bristol-Myers Squibb Provides Update on Phase 3 Opdivo (nivolumab) CheckMate -548 Trial in Patients with Newly Diagnosed MGMT-Methylated Glioblastoma Multiforme

This information is intended to notify the press release issued on September 5 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, September 5, 2019) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the Phase 3 CheckMate -548 trial evaluating the addition of *Opdivo* (nivolumab) to the current standard of care (temozolomide and radiation therapy) versus the standard of care alone did not meet one of its primary endpoints, progression-free survival (PFS), in patients with newly diagnosed glioblastoma multiforme (GBM) that is O6-methylguanine-DNA methyltransferase (MGMT)-methylated. The data monitoring committee recommended that the trial continue as planned to allow the other primary endpoint, overall survival (OS), to mature. The company remains blinded to all study data.

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.

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