ONO PHARMACEUTICAL CO.,LTD.

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CheckMate -9LA, a Phase 3 Trial Evaluating Opdivo (nivolumab) Plus Low-Dose Yervoy (ipilimumab) Combined with Chemotherapy, Meets Primary Endpoint Demonstrating Superior Overall Survival Compared to Chemotherapy Alone in First-Line Lung 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 extracted from the original press release:

(PRINCETON, NJ, October 22, 2019) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that CheckMate -9LA, a pivotal Phase 3 trial evaluating Opdivo (nivolumab) plus low-dose Yervoy (ipilimumab) given concomitantly with two cycles of chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC), met its primary endpoint of superior overall survival (OS) at a pre-specified interim analysis. The comparator in this study was chemotherapy alone for up to four cycles followed by optional maintenance therapy. The safety profile of Opdivo plus low-dose Yervoy and two cycles of chemotherapy in CheckMate -9LA was reflective of the known safety profiles of the immunotherapy and chemotherapy components in first-line NSCLC.

About Opdivo

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor 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. By harnessing the body's own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. Opdivo is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.

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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