ONO PHARMACEUTICAL CO.,LTD.

October 5, 2020

Bristol Myers Squibb Announces Update on CheckMate -915 Evaluating Opdivo (nivolumab) Plus Yervoy (ipilimumab) Versus Opdivo in Resected High-Risk Melanoma Patients

This information is intended to notify the press release issued on October 2 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 2, 2020) – Bristol Myers Squibb (NYSE: BMY) today announced results for the co-primary endpoint for CheckMate -915, a randomized Phase 3 study evaluating Opdivo (nivolumab) plus Yervoy (ipilimumab) versus Opdivo for patients who have had a complete surgical removal of stage IIIb/c/d or stage IV melanoma. The addition of Yervoy to Opdivo in this trial did not result in a statistically significant improvement in recurrence-free survival (RFS) in the all-comer (intent-to-treat) population. CheckMate -915 reinforced the established benefit of Opdivo monotherapy as a standard of care in the adjuvant setting. The safety profiles for Opdivo monotherapy and the combination of Opdivo plus Yervoy were consistent with previously reported studies at this dose and schedule (Opdivo 240 mg intravenously every two weeks plus Yervoy 1 mg/kg every six weeks or Opdivo 480 mg every four weeks for up to one year), with no new safety signals observed.

About Opdivo

Opdivo is a programmed cell 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 launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, Opdivo received an approval for additional indications of unresectable, advanced or recurrent non-small cell lung cancer in December 2015, unresectable or metastatic renal cell carcinoma 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, unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma in August 2018, and microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy, and unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy in February 2020.

In addition, ONO is conducting clinical development program including esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, pancreatic cancer, biliary tract cancer, etc.

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