ONO PHARMACEUTICAL CO.,LTD.

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# Three-Year Data from CheckMate -227 Confirm Durable, Long-Term Survival Benefit for Opdivo (nivolumab) Plus Yervoy (ipilimumab) vs. Chemotherapy in Metastatic First-Line Non-Small Cell Lung Cancer Patients with PD-L1 ≥1%

This information is intended to notify the press release issued on May 13 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, May 13, 2020) – Bristol-Myers Squibb Company (NYSE: BMY) today announced three-year follow-up results from Part 1 of the Phase 3 CheckMate -227 trial, demonstrating that *Opdivo* (nivolumab) plus *Yervoy* (ipilimumab) provided sustained improvements in overall survival (OS) and additional efficacy measures as a first-line treatment for patients with metastatic non-small cell lung cancer (NSCLC). With a median follow-up of more than three years (43.1 months), *Opdivo* plus *Yervoy* continued to show a survival benefit compared to chemotherapy [Hazard Ratio (HR): 0.79; 95% Confidence Interval (CI): 0.67 to 0.93] among patients whose tumors expressed PD-L1 ≥1%. Three-year OS rates in this population were 33% for *Opdivo* plus *Yervoy,* compared to 22% for chemotherapy alone. *Opdivo* plus *Yervoy* also delayed disease progression or death among these patients, with a three-year progression-free survival (PFS) rate of 18% with the combination versus 4% with chemotherapy alone.

## 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 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, 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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