ONO PHARMACEUTICAL CO.,LTD.

September 23, 2020

Opdivo (nivolumab) Plus Chemotherapy Demonstrated Significant Overall and Progression-Free Survival Benefits Versus Chemotherapy in First-Line Treatment of Gastric and Esophageal Cancers

This information is intended to notify the press release issued on September 21 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 21, 2020) – Bristol Myers Squibb (NYSE: BMY) today announced primary results from CheckMate -649, the pivotal Phase 3 trial in which first-line treatment with *Opdivo* (nivolumab) plus chemotherapy showed a statistically significant and clinically meaningful improvement in the overall survival (OS) and progression-free survival (PFS) of patients with unresectable advanced or metastatic gastric cancer, gastroesophageal junction (GEJ) cancer or esophageal adenocarcinoma compared to treatment with chemotherapy alone. *Opdivo* is the first PD-1 inhibitor to demonstrate superior OS and PFS in combination with chemotherapy when compared to chemotherapy alone in patients with gastric cancer, GEJ cancer or esophageal adenocarcinoma. The OS and PFS benefits were observed in patients whose tumors express PD-L1 with a combined positive score (CPS) ≥ 5, achieving both of the trial's primary endpoints. The OS benefit was also observed in the all-randomized trial population.

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.

Contact:
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono.co.jp