

August 12, 2020

## **CheckMate -649, a Phase 3 Trial Evaluating Opdivo (nivolumab) Plus Chemotherapy vs. Chemotherapy, Meets Primary Endpoints Demonstrating Superior Overall Survival and Progression-Free Survival in First-Line Treatment of Gastric and Esophageal Cancers**

This information is intended to notify the press release issued on August 11 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, August 11, 2020) – Bristol Myers Squibb Company (NYSE: BMY) today announced that CheckMate -649, a pivotal Phase 3 trial evaluating *Opdivo* (nivolumab) plus chemotherapy compared to chemotherapy alone as a first-line treatment for metastatic gastric cancer, gastroesophageal junction (GEJ) cancer or esophageal adenocarcinoma, met both primary endpoints of overall survival (OS) at a pre-specified interim analysis and progression-free survival (PFS) at final analysis in patients whose tumors express PD-L1 with a combined positive score (CPS)  $\geq 5$ . The OS benefit was also observed in the all-randomized population. *Opdivo* is the first and only 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 safety profiles of *Opdivo* and chemotherapy in this trial are reflective of the known safety profiles of *Opdivo* and chemotherapy in first-line gastric and esophageal cancers.

### **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.

### **Contact:**

Ono Pharmaceutical Co., Ltd.  
Corporate Communications  
[public\\_relations@ono.co.jp](mailto:public_relations@ono.co.jp)