October 17, 2017

Opdivo Alone or Combined with Yervoy Shows Encouraging Response and Survival Rates in Recurrent Small Cell Lung Cancer Patients with High Tumor Mutation Burden, in Exploratory Analysis from Phase 1/2 Study CheckMate -032

(PRINCETON, NJ, September 10, 2017) – Bristol-Myers Squibb Company (NYSE: BMY) announced data evaluating Opdivo (nivolumab) and Opdivo plus Yervoy (ipilimumab) in previously treated small cell lung cancer (SCLC) patients whose tumors were evaluable for tumor mutation burden (TMB), from the Phase 1/2 CheckMate -032 trial. The primary objective of this trial was objective response rate (ORR) as assessed by a blinded independent central review (BICR), for which results were previously presented; in the pooled intent-to-treat (ITT) population (n=401), the ORR was 11% with Opdivo alone and 22% with the combination. Among the ITT population, 211 (53%) patients had an evaluable TMB result for these analyses and were divided into subgroups of high, medium and low levels of TMB.

Bristol-Myers Squibb (BMS) has a robust clinical development program for Opdivo monotherapy and in combination with other Immuno-Oncology and non-Immuno-Oncology therapies across more than 350 clinical trials. BMS is studying Opdivo in approximately 50 types of cancer, across solid tumors and hematologic malignancies, and is utilizing its translational medicine capabilities to tailor approaches with the goal of providing maximal benefit for individual patients.

In Japan, Ono Pharmaceutical Co., Ltd. (ONO) launched Opdivo for the treatment of unresectable melanoma in September 2014. 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 and recurrent or metastatic head and neck cancer in March 2017, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017. In addition, ONO is conducting clinical development program including esophageal cancer, gastro-esophageal junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, malignant pleural mesothelioma, ovarian cancer, biliary tract cancer, etc. Opdivo is currently approved in more than 60 countries, including Japan, the United States and the European Union.

In Japan, ONO and BMS (and BMS Japan subsidiary BMSKK) have formed a strategic partnership that includes co-development, co-commercialization, and co-promotion of multiple immunotherapies for patients with cancer.

Please click here for the press release distributed by BMS.

Contact
ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp