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In CheckMate -141, Opdivo (nivolumab) Demonstrated Sustained Overall Survival (OS) Advantage over Standard of Care in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

(PRINCETON, NJ, April 16, 2018) – Bristol-Myers Squibb Company (NYSE: BMY) announced two-year overall survival (OS) data from CheckMate -141, a Phase 3 open-label, randomized trial evaluating Opdivo (nivolumab) compared with investigator's choice chemotherapy (cetuximab, docetaxel or methotrexate) in patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) after failure on platinum-based therapy. Patients treated with Opdivo experienced a 32% reduction in the risk of death after a minimum two years of follow-up (HR 0.68; 95% CI: 0.54 to 0.86), with a median OS of 7.7 months (95% CI: 5.7 to 8.8) compared with 5.1 months (95% CI: 4.0 to 6.2) for standard chemotherapy. The two-year survival rate for Opdivo was 16.9% (95% CI: 12.4 to 22.0) versus 6.0% (95% CI: 2.7 to 11.3) for standard chemotherapy. The safety profile for Opdivo at two-year follow-up was consistent with previous analyses from the study.

There were no statistically significant differences between the two arms for PFS (HR 0.87; 95% CI: 0.68 to 1.11) for Opdivo and investigator's choice, respectively. The safety profile of Opdivo with a two-year follow-up was consistent with previous analyses and with prior studies of Opdivo in patients with melanoma and non-small cell lung cancer. Grade 3-4 treatment-related adverse reactions occurred in 15.3% of patients receiving Opdivo versus 36.9% of patients receiving investigator's choice.

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 has submitted supplemental application for treatment of malignant pleural mesothelioma, adjuvant melanoma, etc. and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, biliary tract cancer, etc. Opdivo is currently approved in more than 60 countries, including Japan, South Korea, Taiwan, the US and 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.

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