

August 9, 2016

**Influence of Clinical Results from CheckMate-026,  
a Phase III Study of Opdivo® (nivolumab) in Treatment-Naïve Patients  
with Advanced Non-Small Cell Lung Cancer**

Bristol-Myers Squibb Company (NYSE: BMY) announced on August 5, 2016 (local time) that CheckMate-026 (global collaborative clinical trial), a trial investigating the use of Opdivo (nivolumab) as monotherapy did not meet its primary endpoint of progression-free survival in patients with previously untreated advanced non-small cell lung cancer (NSCLC) whose tumors expressed PD-L1 at  $\geq 5\%$ .

Ono Pharmaceutical Co., Ltd. (ONO) announces an influence of this clinical trial result (CheckMate-026) on the currently approved indications and ongoing clinical trials of Opdivo in Japan as follows:

- The result does not affect the use of Opdivo in the currently approved indications in Japan, i.e., unresectable melanoma and unresectable, advanced or recurrent NSCLC.
- The result does not affect the regulational review process for additional applications of Opdivo for renal cell cancer, Hodgkin lymphoma and head and neck cancer in Japan.
- The result does not affect the ongoing clinical trials of Opdivo in Japan for gastric cancer, esophageal cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, etc. These clinical trial continue to be conducted.
- CheckMate-227 (global collaborative clinical trial) to evaluate a possibility of Opdivo as monotherapy and combination therapy of Opdivo and Yervoy, and Opdivo and chemotherapy for previously untreated NSCLC continues to be conducted.

In Japan, 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. In addition, ONO has submitted supplemental applications for additional indications of Renal Cell Cancer, Hodgkin Lymphoma and Head and Neck Cancer, and is conducting clinical development program including Gastric Cancer, Esophageal Cancer, Small Cell Lung Cancer, Hepatocellular Carcinoma, Glioblastoma, Ovarian Cancer, Urothelial Cancer, Malignant Pleural Mesothelioma, Biliary Tract Cancer, etc.

In abroad, Bristol-Myers Squibb has a robust clinical development program in Opdivo monotherapy and in combination therapy with other therapeutic drugs in a variety of tumor types overseas, including Glioblastoma, Small Cell Lung Cancer, Urothelial Cancer, Hepatocellular Carcinoma, Esophageal Cancer, Colorectal Cancer, Solid Tumors (Triple-Negative Breast Cancer, Gastric Cancer, Pancreatic Cancer), Blood Cancer, etc.

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