December 22, 2017

ONO Submits Supplemental Application of Opdivo® (Nivolumab) for Dosage and Administration of Single Dosing Regimen in Japan for a Partial Change in Approved Items of Manufacturing and Marketing Approval

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara;) and Bristol-Myers Squibb Company (NYSE: BMY) announced today that Ono Pharmaceutical Co., Ltd. ("ONO") submitted a supplemental application of Opdivo® Intravenous Infusion 20 mg and 100 mg ("Opdivo"), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, in Japan for dosage and administration of single dosing regimen for a partial change in the approved items of the manufacturing and marketing approval.

This application is aiming to change the current dosage and administration of "infuse 3 mg/kg (body weight) every 2 weeks over 1 hour intravenously" to "infuse at 240 mg every 2 weeks over 30 minutes intravenously" in the currently approved following indications:

- Unresectable melanoma,
- Unresectable, advanced or recurrent non-small cell lung cancer,
- Unresectable or metastatic renal cell carcinoma,
- Relapsed or refractory classical Hodgkin lymphoma,
- Recurrent or metastatic head and neck cancer, and
- Unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy

This application is based on the population pharmacokinetics (PPK) model, exposure-response (E-R) model and the results of clinical studies conducted so far.

In association with the change, ONO expects that this will lead to a reduction of leftover or unused product.

About Opdivo

Opdivo is a programmed 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.

In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, 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, 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, esophago-gastric

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, South Korea, Taiwan, the US and European Union.

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 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.

About the Ono Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol-Myers Squibb (BMS), Ono Pharmaceutical Co., Ltd. (ONO) granted BMS its territorial rights to develop and commercialize Opdivo globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to Opdivo except the US at the time. In July 2014, ONO and BMS further expanded their strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agent and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

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