December 22, 2017

ONO Submit Supplemental Application of Opdivo® (Nivolumab)
for Expanded Use of the Adjuvant Treatment of Melanoma 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; "ONO") 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 expanded use of the adjuvant treatment of patients with melanoma, for a partial change in approved items of the manufacturing and marketing approval.

This application is aiming to seek for the potential use to reduce risk of the recurrence after resection.

This application is based on the result of a global Phase III multi-center, randomized, double-blind comparative study with Opdivo, including Japan (ONO-4538-21/CA209-238 study) versus Yervoy® (generic name: ipilimumab) in patients with stage IIIb/c or stage IV melanoma, who are at high risk of disease recurrence following complete surgical resection. In this study, Opdivo 3 mg/kg (every 2 weeks) met the primary endpoint of recurrence-free survival (RFS) by significantly decreasing the risk of disease recurrence compared to Yervoy 10 mg/kg (every 3 weeks for 4 doses and then every 12 weeks starting at week 24).

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) which are related deeply with the skin color, and said to be the most metastatic and deadliest form of the disease. It is reported that the number of melanoma patients is about 4,000 patients [*1] with about 700 deaths [*2] per year in Japan.

*1: CANCER STATISTICS IN JAPAN 2013, Patient Survey (Basic Disease Classification), Ministry of Health, Labour and Welfare 2011
*2: Vital Statistics, Ministry of Health, Labour and Welfare 2012

About Adjuvant Therapy in Melanoma

Melanoma is separated into five staging categories (stages 0 to 4) based on the in-situ feature, thickness and ulceration of the tumor, whether the cancer has spread to the lymph nodes, and how far the cancer has spread beyond lymph nodes.

Stage III melanoma has reached the regional lymph nodes but has not yet spread to distant lymph nodes or to other parts of the body (metastasized), and requires surgical resection of the primary tumor as well as the involved lymph nodes. Some patients may also be treated with adjuvant therapy.

Despite surgical intervention and possible adjuvant treatment, the majority of stage IIIb and IIIc melanoma patients (71% and 85%, respectively)* experience disease recurrence within five years.

* : Romano, E., Scordo, M., Dusza, S., Coit, D. and Chapman, P. Site and Timing of First Relapse in Stage III Melanoma Patients: Implications for Follow-Up Guidelines. J Clin Oncol. 2010; 28(18), pp.3042-3047.

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, 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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