April 24, 2017

Opdivo® (nivolumab) Designated for the Treatment of Biliary Tract Cancer Under the SAKIGAKE Designation System

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") and Bristol-Myers Squibb Company (NYSE: BMY) announced that Opdivo® Intravenous Infusion ("Opdivo"), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, was designated on April 21 for the treatment of biliary tract cancer under the SAKIGAKE Designation System established by the the Ministry of Health, Labour and Welfare (MHLW).

The Sakigake Designation System has been implemented under the trial by the MHLW since April 2015, aiming at the provision of the leading-edge global therapeutic drugs to patients in Japan ahead of the rest of the world. This designation offers Opdivo priority consultation and review.

About Sakigake Designation System

<Requirements for designation>

For the designation of pharmaceutical drugs, the following all 4 criteria should be fulfilled:

1) Innovation of investigational product
2) Seriousness of target diseases
3) Extremely high efficacy on target diseases
4) Intension for early development and application in Japan ahead of the world

<Priority handling for designated drugs>

1) Priority consultation
2) Enhancement of prior evaluation
3) Priority review
4) Selection of review partner (Concierge) designated in the PMDA
5) Settlement of re-examination period

For details of SAKIGAKE Designation System, please refer to the following link for the Ministry of Health, Labour and Welfare (MHLW)

http://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/140729-01.html

About Opdivo

Opdivo is an 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, Opdivo 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 on March 24, 2017. In addition, ONO has submitted supplemental application for additional indication of gastric cancer, and 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.
Bristol-Myers Squibb (BMS) has a robust clinical development program in Opdivo monotherapy and in combination with other therapies in a variety of tumor types overseas. Opdivo has regulatory approval in more than 60 countries as part of the ONO - BMS collaboration.

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 and BMS Collaboration

In 2011, through a collaboration agreement with BMS, 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 the compound at the time. In July 2014, ONO and BMS further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

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