ONO PHARMACEUTICAL CO.,LTD.

October 20, 2020

U.S. Food and Drug Administration Accepts for Priority Review Applications for OPDIVO® (nivolumab) in Combination with CABOMETYX® (cabozantinib) in Advanced Renal Cell Carcinoma

This information is intended to notify the press release issued on October 19 by Bristol Myers Squibb. Please click https://www.bms.com/media/press-releases.html for the original press release.

First paragraph extracted from the original press release:

(PRINCETON, NJ, October 19, 2020) – Bristol Myers Squibb (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) and supplemental New Drug Application (sNDA), respectively, for OPDIVO® (nivolumab) in combination with CABOMETYX® (cabozantinib) for patients with advanced renal cell carcinoma (RCC). The FDA granted Priority Review to both applications and assigned a Prescription Drug User Fee Act (PDUFA) goal date, or target action date, of February 20, 2021.

About Opdivo

Opdivo is a programmed cell 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. By harnessing the body's own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. Opdivo is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.

In Japan, ONO launched Opdivo for the treatment of unresectable melanoma in September 2014. Thereafter, Opdivo received an approval for additional indications of unresectable, advanced or recurrent non-small cell lung cancer in December 2015, unresectable or metastatic renal cell carcinoma in August 2016, relapsed or refractory classical Hodgkin lymphoma in December 2016, recurrent or metastatic head and neck cancer in March 2017, unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy in September 2017, unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma in August 2018, and microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy, and unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy in February 2020.

In addition, ONO is conducting clinical development program including esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, pancreatic cancer, biliary tract cancer, etc.

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