ONO PHARMACEUTICAL CO.,LTD.

November 27, 2019

ONO Submits Supplemental Application for Additional Opdivo® Intravenous Infusion Monotherapy Dosage and Schedule in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced today that ONO submitted a supplemental application for a partial change in the approved items of the manufacturing and marketing approval of Opdivo® (generic name: nivolumab) Intravenous Infusion ("Opdivo"), a human anti-human programmed death-1 (PD-1) monoclonal antibody, in Japan to include additional monotherapy dosage and schedule.

This application is aiming to add a dosage and administration of "infuse at 480 mg every 4 weeks over 30 minutes intravenously" to the current dosage and administration of "infuse at 240 mg every 2 weeks over 30 minutes intravenously" in the currently approved indications.

This partial change application will offer additional treatment options for dosage and administration (dose intervals), so it is possible to design a flexible treatment plan according to patient's medical condition and clinical course. In addition, we expect that this will lead to improvement in the convenience of patients and medical staff because the number of visits by patients and the burden on patients and medical staff may be reduced.

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. 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 cancer 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, etc. in August 2018.

In addition, ONO has submitted supplemental applications for the treatment of microsatellite instable High (MSI-H) colorectal cancer and esophageal cancer, and is conducting clinical development program including esophageal cancer, esophago-gastric junction cancer, small cell lung cancer, hepatocellular carcinoma, glioblastoma, urothelial cancer, ovarian cancer, bladder cancer, colorectal cancer, pancreatic cancer, biliary tract cancer, etc.

About the ONO and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with Bristol-Myers Squibb (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 Opdivo except the US 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 agent and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

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