ONO PHARMA

Press Release

January 6, 2025

Ono Pharmaceutical Co., Ltd.

U.S. Food and Drug Administration Approves Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy) Injection, for Subcutaneous Use in Most Previously Approved Adult, Solid Tumor Opdivo® (nivolumab) Indications

This material is intended to notify the press release issued on December 27 (local time) by Bristol Myers Squibb, our license partner for Opdivo.

Please click https://www.bms.com/media/press-releases.html for the original press release.

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, the US and European Union.

About Approval Status of Opdivo in Japan

In Japan, Ono Pharmaceutical Co., Ltd. (Ono) received an approval of Opdivo for the treatment of unresectable melanoma in July 2014 and launched Opdivo in Japan in September 2014.

Thereafter, Ono received supplemental approvals for the 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 in August 2018, 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, cancer of unknown primary in December 2021, adjuvant treatment of urothelial carcinoma in March 2022, malignant mesothelioma (excluding malignant pleural mesothelioma) in November 2023 and unresectable advanced or recurrent malignant epithelial tumors in February 2024.

In addition, Ono has submitted a supplemental application for the treatment of hepatocellular carcinoma.

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