ONO PHARMACEUTICAL CO.,LTD.

October 5, 2020

U.S. Food and Drug Administration Approves Opdivo® (nivolumab) + Yervoy® (ipilimumab) as the First and Only Immunotherapy Treatment for Previously Untreated Unresectable Malignant Pleural Mesothelioma

This information is intended to notify the press release issued on October 2 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 2, 2020) – Bristol Myers Squibb (NYSE: BMY) today announced that Opdivo (nivolumab) 360 mg every three weeks plus Yervoy (ipilimumab) 1 mg/kg every six weeks (injections for intravenous use) was approved by the U.S. Food and Drug Administration (FDA) for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM). This approval is based on a pre-specified interim analysis from the Phase 3 CheckMate -743 trial in which Opdivo + Yervoy (n=303) demonstrated superior overall survival (OS) versus the platinum-based standard of care chemotherapy (n=302) (Hazard Ratio [HR]: 0.74 [95% Confidence Interval [CI]: 0.61 to 0.89]; P=0.002), with a median OS (mOS) of 18.1 months (95% CI: 16.8 to 21.5) versus 14.1 months (95% CI: 12.5 to 16.2), respectively. These results were observed after 22.1 months of minimum follow-up.3 At two years, 41% of patients treated with Opdivo + Yervoy were alive and 27% with chemotherapy.

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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