

March 12, 2020

**U.S. Food and Drug Administration Approves Opdivo® (nivolumab) + Yervoy®  
(ipilimumab) for Patients with Hepatocellular Carcinoma (HCC)  
Previously Treated with Sorafenib**

This information is intended to notify the press release issued on March 11 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, March 11, 2020) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that *Opdivo* (nivolumab) 1 mg/kg plus *Yervoy* (ipilimumab) 3 mg/kg (injections for intravenous use) was approved by the U.S. Food and Drug Administration (FDA) to treat hepatocellular carcinoma (HCC) in patients who have been previously treated with sorafenib.<sup>1,2</sup> Approval for this indication has been granted under accelerated approval based on overall response rate and duration of response seen in the *Opdivo* + *Yervoy* cohort of the Phase 1/2 CheckMate - 040 trial.<sup>1,2,3</sup> Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.<sup>1,2</sup>

**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 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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