

March 18, 2016

ONO Submits Supplemental Application of OPDIVO[®] (Nivolumab) for Additional Indication of Relapsed or Refractory Hodgkin's Lymphoma

ONO PHARMACEUTICAL CO.,LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") and Bristol-Myers Squibb Company (NYSE: BMY) announced today that ONO has submitted a supplemental application for approval for the additional indication of OPDIVO[®] Intravenous Infusion 20mg, 100mg ("OPDIVO"), the human anti-human PD-1 (programmed cell death-1) monoclonal antibody, for the treatment of relapsed or refractory Hodgkin's lymphoma.

Hodgkin's lymphoma is a localized or diffuse malignant cell cancer derived from the lymphatic system. It is estimated that there are about 2,000 patients with Hodgkin's lymphoma annually in Japan. The disease is initially treated with chemotherapy and radiation therapy. When patients relapse or are treatment-resistant, the treatment will be shifted to chemotherapy or autologous hematopoietic stem cell transplantation. Patients with recurrent or refractory Hodgkin's lymphoma have a poor prognosis, and new treatment options are needed. ONO hopes that OPDIVO will offer a new treatment option to these patients with Hodgkin's lymphoma

OPDIVO was designated to be an orphan drug for the indication of Hodgkin's lymphoma and under priority review on March 16, 2016 by the Ministry of Health, Labour and Welfare (MHLW).

OPDIVO was the first human anti-human PD-1 monoclonal antibody to receive regulatory approval for the indication of unresectable melanoma in July 2014 in Japan or anywhere in the world. OPDIVO also received approval for an additional indication of unresectable, advanced or recurrent non-small cell lung cancer (NSCLC) in December 2015. This is the first filing for OPDIVO in a hematological cancer in Japan. Outside of Japan, Bristol Myers Squibb, with whom ONO collaborates in Japan, South Korea and Taiwan, currently has regulatory approval for OPDIVO in 48 countries globally.

In Japan, ONO and Bristol-Myers Squibb (and BMS Japan subsidiary BMKK) have formed a strategic partnership that includes co-development, co-commercialization, and co-promotion of multiple immunotherapies for patients with cancer.

About ONO PHARMACEUTICAL CO., LTD.

ONO PHARMACEUTICAL CO., LTD, headquartered in Osaka, Japan, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific areas. It focuses especially on the oncology and diabetes areas. For more information, please visit the company's website at <http://www.ono.co.jp/eng/index.html>.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on [LinkedIn](#), [Twitter](#), and [YouTube](#).

About the ONO and Bristol-Myers Squibb Collaboration

In 2011, through a collaboration agreement with ONO, Bristol-Myers Squibb expanded its territorial rights to develop and commercialize OPDIVO globally except in Japan, South Korea and Taiwan, where ONO had retained all rights to the compound at the time. In July 2014, ONO and Bristol-Myers Squibb further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

Contact

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