October 2, 2014

Bristol-Myers Squibb Announces Multiple Regulatory Milestones for Opdivo (nivolumab) in the U.S. and European Union

Bristol-Myers Squibb ("BMS") announced multiple regulatory milestones for Opdivo , an investigational PD-1 immune checkpoint inhibitor, in the U.S. and European Union on September 26(EST). FDA accepted for priority review the Biologics License Application for previously treated advanced melanoma based on data from first Phase 3 randomized trial of Opdivo. Agency granted second breakthrough therapy designation for Opdivo.
European Medicines Agency validated the Marketing Authorization Application for advanced melanoma. Accelerated assessment has also been granted for this application.

Opdivo is a human anti-human PD-1 monoclonal antibody generated under a research collaboration entered into in May 2005 between ONO PHARMACEUTICAL CO.,LTD. ("ONO") and the US-based company Medarex,Inc. When Medarex, Inc. was acquired by BMS in 2009, it also granted BMS its rights to develop and commercialize the human anti-human PD-1 monoclonal antibody in North America. Through the collaboration agreement entered into in September 2011 between ONO and BMS, ONO granted BMS exclusive rights to develop and commercialize Opdivo in the rest of the world, except in Japan, Korea and Taiwan where ONO had retained all rights to develop and commercialize the compound. On July 23, 2014, ONO and BMS signed a new collaboration agreement in which the companies agreed to jointly develop and commercialize Opdivo, ipilimumab and three early-stage immunotherapies in Japan, South Korea and Taiwan.

Furthermore, BMS has a robust clinical development program in a variety of tumor types overseas, including: Non-Small Cell Lung Cancer (NSCLC), Renal Cell Carcinoma (RCC), Melanoma, Head and Neck Cancer, Blood Cancer, Glioblastoma, Colorectal Cancer, Pancreatic Cancer, Gastric Cancer, Hepatocellular Carcinoma, Triple-Negative Breast Cancer, Small-Cell Cancer, Bladder Cancer. In Japan, ONO has launched it for melanoma treatment in September 2014. Also, ONO is conducting clinical development programs including RCC, NSCLC, Head and Neck Cancer, Gastric Cancer and esophageal cancer.

Attached from the following page is the press release made by BMS for your information.

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Bristol-Myers Squibb Announces Multiple Regulatory Milestones for *Opdivo* (nivolumab) in the U.S. and European Union

- ***FDA accepts for priority review the Biologics License Application for previously treated advanced melanoma, based on data from first Phase 3 randomized trial of a PD-1 immune checkpoint inhibitor; agency grants second breakthrough therapy designation for Opdivo***

- ***European Medicines Agency validates the marketing authorization application for advanced melanoma; accelerated assessment also granted***

(PRINCETON, NJ, September 26, 2014) – Bristol-Myers Squibb Company (NYSE: BMY) today announced multiple regulatory milestones for *Opdivo* (nivolumab), an investigational PD-1 immune checkpoint inhibitor, in the U.S. and European Union. In the U.S., the Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application (BLA) for previously treated advanced melanoma and the Prescription Drug User Fee Act (PDUFA) goal date for a decision is March 30, 2015. The FDA also granted *Opdivo* Breakthrough Therapy status for this indication. In the European Union, the European Medicines Agency (EMA) has validated for review the Marketing Authorization Application (MAA) for *Opdivo* in advanced melanoma. The application has also been granted accelerated assessment by the EMA's Committee for Medicinal Products for Human Use (CHMP).

"The filing acceptance and validation of our *Opdivo* applications by the FDA and EMA represent significant steps forward in our commitment to delivering innovative immuno-oncology treatments to patients with cancer around the world," said Michael Giordano, MD, senior vice president, Head of Oncology Development, Bristol-Myers Squibb. "Additionally, the Breakthrough Therapy Designation and the accelerated assessment for advanced melanoma underscore our focus on developing treatments for diseases in which a significant unmet medical need remains."

About the U.S. Biologics License Application

The U.S. BLA is based on data from CheckMate -037, a multinational, multicenter, randomized open-label Phase 3 trial evaluating *Opdivo* compared to the physician's choice of either dacarbazine (DTIC) or carboplatin/paclitaxel in patients with unresectable or metastatic melanoma who have been previously treated with *Yervoy* and, if BRAF-mutation positive, a BRAF inhibitor. Interim data from Checkmate -037 will be highlighted at an ESMO 2014 Congress press briefing on September 29 in the morning and presented during the Presidential Symposium at 4 p.m. CEST (Abstract #LBA3_PR).

In the U.S., priority review status is granted for applications for drugs that treat a serious condition and, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Breakthrough Therapy Designation, according to the FDA, is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for this designation require preliminary clinical evidence that demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

About the E.U. Marketing Authorization Applications

The MAA submitted to the EMA in advanced melanoma is also supported by data from CheckMate -037. Accelerated assessment procedure may be requested for medicinal products of major interest from the point of view of public health and, in particular, from the point of view of therapeutic innovation. The acceptance of accelerated assessment by the CHMP could shorten the review time of *Opdivo* in advanced melanoma by approximately two months.

About *Opdivo*

Cancer cells may exploit "regulatory" pathways, such as checkpoint pathways, to hide from the immune system and shield the tumor from immune attack. *Opdivo* is an investigational, fully-human PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 (programmed death-1) expressed on activated T-cells.

Bristol-Myers Squibb has a broad, global development program to study *Opdivo* in multiple tumor types consisting of more than 35 trials – as monotherapy or in combination with other therapies – in which more than 7,000 patients have been enrolled worldwide. Among these are several potentially registrational trials in non-small cell lung cancer (NSCLC), melanoma, renal cell carcinoma (RCC), head and neck cancer, glioblastoma and non-Hodgkin lymphoma.

In 2013, the FDA granted Fast Track designation for *Opdivo* in NSCLC, melanoma and RCC. In April 2014, the company initiated a rolling submission with the FDA for *Opdivo* in third-line pre-treated squamous cell NSCLC and expects to complete the submission by year-end. The FDA granted its first Breakthrough Therapy Designation for *Opdivo* in May 2014 for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and brentuximab. On July 4, Ono Pharmaceutical Co. announced that *Opdivo* received manufacturing and marketing approval in Japan for the treatment of patients with unresectable melanoma, making *Opdivo* the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world.

Bristol-Myers Squibb has proposed the name *Opdivo* (pronounced op-dee-voh), which, if approved by health authorities, will serve as the trademark for nivolumab.

About Advanced Melanoma

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease, and occurs when cancer spreads beyond the surface of the skin to the other organs, such as the lymph nodes, lungs, brain or other areas of the body. The incidence of melanoma has been increasing for at least 30 years. In 2012, an estimated 232,130 melanoma cases were diagnosed globally. Melanoma is mostly curable when treated in its early stages. However, in its late stages, the average survival rate has historically been just six months with a one-year mortality rate of 75 percent, making it one of the most aggressive forms of cancer.

Immuno-Oncology at Bristol-Myers Squibb

Surgery, radiation, cytotoxic or targeted therapies have represented the mainstay of cancer treatment over the last several decades, but long-term survival and a positive quality of life have remained elusive for many patients with advanced disease.

To address this unmet medical need, Bristol-Myers Squibb is leading advances in the innovative field of immuno-oncology, which involves agents whose primary mechanism is to work directly with the body's immune system to fight cancer. The company is exploring a variety of compounds and immunotherapeutic approaches for patients with different types of cancer, including researching the potential of combining immuno-oncology agents that target different and complementary pathways in the treatment of cancer.

Bristol-Myers Squibb is committed to advancing the science of immuno-oncology, with the goal of changing survival expectations and the way patients live with cancer.

About the Bristol-Myers Squibb and Ono Pharmaceutical Collaboration

In 2011, through a collaboration agreement with Ono Pharmaceutical, 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. On July 23, 2014, Bristol-Myers Squibb and Ono Pharmaceutical further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regiments – for patients with cancer in Japan, South Korea and Taiwan.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global pharmaceutical 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 www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that Opdivo will receive regulatory approval in the U.S. or, if approved, that it will become a commercially successful product. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2013 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.