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Human Anti-human PD-1 Monoclonal Antibody OPDIVO®
Bristol-Myers Squibb plans for Third Quarter Submission of a Biologics License Application for Previously Treated Advanced Melanoma

Bristol-Myers Squibb Company ("BMY") announced the company is planning a third quarter submission of a Biologics Licensing Application (BLA) for the human anti-human PD-1 monoclonal antibody Opdivo® for previously treated advanced melanoma following discussions with the U.S. Food and Drug Administration (FDA) on Phase 3 trial in patients with previously treated advanced melanoma (Checkmate -037) on July 10 (US time).

OPDIVO® is a human anti-human PD-1 monoclonal antibody generated under a research collaboration entered into in May 2005 between ONO and the US-based company Medarex, Inc. When Medarex, Inc. was acquired by Bristol-Myers Squibb Company ("BMY") in 2009, it also granted BMY 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 BMY, ONO granted BMY exclusive rights to develop and commercialize OPDIVO® in the rest of the world, except in Japan, Korea and Taiwan where ONO has retained all rights to develop and commercialize the compound.

BMY is conducting studies in NSCLC, RCC, melanoma, head and neck carcinoma, hematologic malignancies, glioblastoma, colon cancer, pancreatic cancer and gastric cancer and so on in the overseas countries where BMY has the rights to develop and commercialize the compound. On the other hand, in Japan, Ono received manufacturing and marketing approval for the treatment of unresectable melanoma in July 4, 2014. Also Ono is conducting Phase 2 studies in NSCLC and esophageal cancer, and a global Phase 3 study in RCC.

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

Bristol-Myers Squibb

Bristol-Myers Squibb Announces Plans for Third Quarter Submission of a Biologics License Application for *Opdivo*® (nivolumab), an Investigational PD-1 Immune Checkpoint Inhibitor, for Previously Treated Advanced Melanoma

(Princeton, NJ – July 10, 2014) – Bristol-Myers Squibb Company (NYSE: BMS) today announced that, following discussions with the U.S. Food and Drug Administration (FDA), the company is planning a third quarter submission of a Biologics Licensing Application (BLA) for *Opdivo*® (nivolumab) for previously treated advanced melanoma. This will mark the second tumor type for which Bristol-Myers Squibb has a regulatory submission underway for *Opdivo* in the U.S.

"We continue to collaborate closely with the FDA on *Opdivo* and the planned submission in advanced melanoma represents an important step forward in our company's commitment to deliver innovative treatment options for patients with cancer," said Michael Giordano, MD, Head of Oncology Development, Bristol-Myers Squibb.

The advanced melanoma BLA is based on data from Checkmate -037, a multinational, multicenter, randomized open-label Phase 3 trial evaluating *Opdivo* compared to dacarbazine (DTIC) or carboplatin/paclitaxel in patients with unresectable or metastatic melanoma who have been previously treated with *Yervoy*® (ipilimumab) and, if BRAF-mutation positive, a BRAF inhibitor regimen.

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

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. We are investigating whether by blocking this pathway, *Opdivo* would enable the immune system to resume its ability to recognize, attack and destroy cancer 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*® (nivolumab) 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 *Opdivo* Breakthrough Therapy Designation in May 2014 for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and brentuximab. On July 4th, 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.

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

Through a collaboration agreement with Ono Pharmaceutical in 2011, Bristol-Myers Squibb expanded its territorial rights to develop and commercialize *Opdivo*® (nivolumab) globally except in Japan, Korea and Taiwan, where Ono has retained all rights to the compound.

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.

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