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Fully Human Anti-PD-1 Antibody Nivolumab ("ONO-4538/BMS-936558") Demonstrates Superior Overall Survival Compared to Dacarbazine in Phase 3 First-Line Melanoma Study (CheckMate -066)

Bristol-Myers Squibb Company ("BMY") announced a randomized blinded comparative Phase 3 study evaluating nivolumab ("ONO-4538/BMS-936558"), a fully human anti-PD-1 antibody, versus dacarbazine in patients with previously untreated BRAF wild-type advanced melanoma (CheckMate -066) was stopped early because an analysis conducted by the independent Data Monitoring Committee showed evidence of superior overall survival in patients receiving nivolumab compared to the dacarbazine arm, on June 24 (US time). Patients in the trial will be unblinded and patients who were randomized to dacarbazine will be allowed to cross over to nivolumab.

Nivolumab, a fully human anti-PD-1 antibody, is an investigational cancer immunotherapy generated under a research collaboration entered into in May 2005 between Ono Pharmaceutical Co., Ltd. ("Ono") and Medarex, Inc. When Medarex, Inc. was acquired by BMY in 2009, it also granted BMY its rights to develop and commercialize the anti-PD-1 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 nivolumab 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, hematologicmalignancies, 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 filed an application to obtain a manufacturing and marketing approval for treatment of melanoma in Dec 2013. 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

Phase 3 First-Line Melanoma Study of Nivolumab, an Investigational PD-1 Checkpoint Inhibitor, Demonstrates Superior Overall Survival Compared to Dacarbazine; Study Stopped Early

(PRINCETON, NJ, June 24, 2014) – Bristol-Myers Squibb Company (NYSE:BMY) today announced that a randomized blinded comparative Phase 3 study evaluating nivolumab versus dacarbazine (DTIC) in patients with previously untreated BRAF wild-type advanced melanoma was stopped early because an analysis conducted by the independent Data Monitoring Committee (DMC) showed evidence of superior overall survival in patients receiving nivolumab compared to the control arm. Patients in the trial will be unblinded and allowed to cross over to nivolumab. The Company will share these data with health authorities.

"The outcome of CheckMate -066 is an important milestone in the field of immuno-oncology as it represents the first well-controlled, randomized Phase 3 trial of an investigational PD-1 checkpoint inhibitor to demonstrate an overall survival benefit," said Michael Giordano, MD, Head of Oncology Development. "Bristol-Myers Squibb is committed to continuing to lead advances in immuno-oncology and to executing our strategy to provide patients with the best opportunity to achieve the potential for long term survival."

CheckMate -066 investigators have been informed of the decision to stop the blinded comparative portion of the trial. Bristol-Myers Squibb will ensure that patients are informed of the opportunity to continue or start treatment with nivolumab in an open-label extension as part of the Company's commitment to characterize long-term survival. The study, which was designed in consultation with the Committee for Medicinal Products for Human Use (CHMP), was primarily conducted in countries where DTIC is a commonly-used treatment in the first-line setting, including Canada, but not at U.S. trial sites. The Company will complete a full evaluation of the final CheckMate -066 data and work with investigators on the future presentation and publication of the results.

About the Study

CheckMate -066 is a Phase 3 randomized, double-blind study of patients with previously untreated BRAF wild-type unresectable Stage III and IV melanoma. The trial enrolled 418 patients who were randomized to receive either nivolumab 3 mg/kg every two weeks or DTIC 1000 mg/m^2

every three weeks. The primary endpoint was overall survival. Secondary endpoints included progression free survival and objective response rate.

About Nivolumab

Cancer cells may exploit "regulatory" pathways, such as checkpoint pathways, to hide from the immune system and shield the tumor from immune attack. Nivolumab 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, nivolumab 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 nivolumab 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 melanoma, renal cell carcinoma (RCC), head and neck cancer, glioblastoma and non-Hodgkin lymphoma. In 2013, the FDA granted Fast Track designation for nivolumab in NSCLC, melanoma and RCC. In May 2014, the FDA granted nivolumab Breakthrough Therapy Designation for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and brentuximab.

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 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%, 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 a rapidly evolving field of cancer research and treatment known as 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 Partnership

Through a collaboration agreement with Ono Pharmaceutical in 2011, Bristol-Myers Squibb expanded its territorial rights to develop and commercialize nivolumab (BMS-936558/ONO-4538) 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 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 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 nivolumab will receive regulatory approval 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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