Bristol-Myers Squibb Announces Collaboration to Evaluate Opdivo (nivolumab) in Combination with Targeted Therapies from Novartis to Treat Non-Small Cell Lung Cancer (NSCLC)

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Studies will evaluate Bristol-Myers Squibb’s investigational PD-1 immune checkpoint inhibitor Opdivo (nivolumab) in combination with Novartis’ Zykadia (ceritinib), INC280 and EGF816

NEW YORK--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today the establishment of a clinical trial collaboration to evaluate the safety, tolerability and preliminary efficacy of combining Bristol-Myers Squibb’s investigational PD-1 immune checkpoint inhibitor Opdivo (nivolumab) with three molecularly targeted oncology therapies (Zykadia (ceritinib), INC280 and EGF816) from Novartis (NYSE: NVS). Novartis will conduct two Phase 1/2 studies focused on non-small cell lung cancer (NSCLC).

“Bristol-Myers Squibb is committed to advancing the science, research and development of immunotherapy as an innovative approach to treating cancer in multiple tumor types,” said Michael Giordano, senior vice president, Oncology Development, Bristol-Myers Squibb. “Combining Opdivo with select targeted agents from Novartis complements our broad global development strategy of immuno-oncology combinations across the spectrum of lung cancer settings, and supports our goal of improving outcomes for patients. We look forward to working with Novartis to fully explore how the combination of these agents can potentially advance care for lung cancer patients.”

One trial will evaluate the combination of Opdivo with Zykadia (ceritinib), an FDA-approved treatment for patients with anaplastic lymphoma kinase-positive (ALK+) metastatic NSCLC who have progressed on or are intolerant to crizotinib. A second study will investigate Opdivo with INC280, a potent and highly selective inhibitor of c-MET receptor tyrosine kinase, and EGF816, a potent, third-generation EGFR tyrosine kinase inhibitor that is active against T790 mutations. INC280 and EGF816 are currently being investigated in various Phase 1/2 NSCLC trials.

Opdivo is part of a new class of cancer treatments known as immunotherapies designed to harness the body’s own immune system in fighting cancer, and targets distinct regulatory components of the immune system. Zykadia, INC280 and EGF816 have each demonstrated evidence of targeting specific molecules responsible for tumor growth in NSCLC patient populations. Despite advancements, treatment for lung cancer remains a significant medical need, and the studies will explore the potential of enhanced anti-tumor response using a combined immunotherapy and targeted molecular approach. 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.

Additional details of the collaboration were not disclosed.

**About Opdivo (nivolumab)**

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 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. On September 26, Bristol-Myers Squibb announced that the FDA 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 EMA also validated for review the MAA for nivolumab in NSCLC.

**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 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, please visit [www.bms.com](http://www.bms.com) or follow us on Twitter at [http://twitter.com/bmsnews](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 in the U.S. either as a single agent or in a combination regimen, 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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English

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