Investigational PD-1 Immune Checkpoint Inhibitor Nivolumab Receives U.S. FDA Breakthrough Therapy Designation for Hodgkin Lymphoma

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- Designation granted for nivolumab for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant followed by brentuximab

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that the U.S. Food and Drug Administration (FDA) has granted the investigational PD-1 immune checkpoint inhibitor nivolumab Breakthrough Therapy Designation for the treatment of patients with Hodgkin lymphoma (HL) after failure of autologous stem cell transplant and brentuximab. The designation is based on data from a cohort of patients with HL in the company's ongoing Phase 1b study of relapsed and refractory hematological malignancies.

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

“The Breakthrough Therapy Designation granted by the FDA for nivolumab continues to support the development of innovative approaches designed to advance how cancer is treated,” said Michael Giordano, senior vice president, Head of Development, Oncology & Immunosciences. “It is our goal to change the way patients live with cancer, especially in areas of high unmet medical need like Hodgkin lymphoma where patients may be underserved by currently available treatment options.”

**About Hodgkin Lymphoma**

Hodgkin lymphoma (HL), also known as Hodgkin disease, is a cancer of the lymphatic system, which originates in the white blood cells. HL is one of two main types of lymphomas. The five-year survival rate for advanced HL is approximately 65 percent in the U.S. If patients with relapsed and refractory HL progress within one year after receiving autologous stem cell transplant (the standard of care), the median survival is just 1.3 years after progression. The median age of diagnosis is 38 in the U.S. This year, more than 9,100 new cases are estimated to be diagnosed with more than 1,100 deaths expected.

**About Nivolumab**

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 (NSCLC), 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.

**Immu-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. This includes conducting research on 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 about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

Bristol-Myers Squibb Forward-Looking Statements

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 the compound mentioned in this release will move into full product development, that the clinical trials of the compound mentioned in this release will move into full product development, that the clinical trials of this compound will support regulatory filings, or that the compound 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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