Bristol-Myers Squibb and AbbVie Receive U.S. FDA Breakthrough Therapy Designation for Elotuzumab, an Investigational Humanized Monoclonal Antibody for Multiple Myeloma

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Designation granted for investigational agent elotuzumab in combination with lenalidomide and dexamethasone for treatment of multiple myeloma in patients who have received one or more prior therapies

PRINCETON, N.J. & NORTH CHICAGO, III.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and AbbVie (NYSE:ABBV) today announced that the U.S. Food and Drug Administration (FDA) has granted elotuzumab, an investigational humanized monoclonal antibody, Breakthrough Therapy Designation for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one or more prior therapies. The designation is based on findings from a randomized Phase 2, open-label study that evaluated two dose levels of elotuzumab in combination with lenalidomide and low-dose dexamethasone in previously-treated patients, including the 10 mg/kg dose that is being studied in Phase 3 trials. Data from the Phase 2 trial were most recently presented at the 18th Annual Congress of the European Hematology Association (EHA) in 2013 (click here to view press release).

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.

“Despite recent advances in the treatment of relapsed or refractory multiple myeloma, it remains an area of unmet need,” said Michael Giordano, senior vice president, Head of Development, Oncology & Immunosciences, Bristol-Myers Squibb. “This Breakthrough Therapy Designation underscores the potential of elotuzumab in this setting and reinforces Bristol-Myers Squibb’s longstanding commitment to the research and development of novel medicines to treat hematologic malignancies.”

About Elotuzumab

Elotuzumab is a humanized IgG1 monoclonal antibody targeted against Signaling Lymphocyte Activation Molecule (SLAMF7, also called CS1), a glycoprotein expressed on myeloma and Natural Killer cells but not detectable in normal tissue. The company is investigating whether through both direct activation and engagement of Natural Killer cells, elotuzumab may selectively target and kill SLAMF7 expressing myeloma cells.

Elotuzumab is being studied as a monotherapy in smoldering myeloma and in combination with other therapies in first-line and relapsed or refractory multiple myeloma. A clinical development program for the agent is underway, including Phase 3 trials in first-line multiple myeloma (ELOQUENT-1) and relapsed or refractory multiple myeloma (ELOQUENT-2). Elotuzumab is also being investigated in a randomized Phase 2 study of bortezomib and dexamethasone in relapsed or refractory multiple myeloma.

Elotuzumab is being co-developed with AbbVie, with Bristol-Myers Squibb leading the commercialization of the agent.

About Multiple Myeloma

Multiple myeloma is a progressive hematologic cancer that originates in the bone marrow. It is the second most common blood cancer and remains incurable, with a 5-year survival rate of 44.9%. In 2014, it
is estimated that approximately 24,050 new cases will be diagnosed in the U.S. and more than 11,000 Americans will die from the disease. Globally, an estimated 750,000 people are living with myeloma.

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.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie employs approximately 25,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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 compounds mentioned in this release will move into full product development, that the clinical trials of these compounds will support regulatory filings, or that the compounds will receive regulatory approvals or, if approved, that they will become commercially successful products. 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.

AbbVie Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words “believe,” “expect,” “anticipate,” “project” and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie’s operations is set forth in Item 1A, “Risk Factors,” in our 2012 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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