



Amgen Receives FDA Breakthrough Therapy Designation For Investigational BiTE® Antibody Blinatumomab In Acute Lymphoblastic Leukemia

July 1, 2014

Breakthrough Designation Reinforces Significant Unmet Need in the Treatment of This Highly Aggressive Cancer

THOUSAND OAKS, Calif., July 1, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to investigational bispecific T cell engager (BiTE®) antibody blinatumomab, for adults with Philadelphia-negative (Ph-) relapsed/refractory B-precursor acute lymphoblastic leukemia (ALL), a rapidly progressing cancer of the blood and bone marrow¹.

The Breakthrough Therapy Designation was based on the results of a Phase 2 trial of 189 adult patients with Ph- relapsed/refractory B-precursor ALL treated with blinatumomab. Data from the Phase 2 trial were most recently presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) and the 19th Congress of the European Hematology Association (EHA).

"There is a high unmet need for new medicines to treat relapsed and refractory ALL patients, who have very few treatment options," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The results from the Phase 2 trial evaluating blinatumomab in adult patients with relapsed or refractory ALL are encouraging and provide a strong basis for a regulatory filing later this year and potential approval in this serious disease."

The FDA states that 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. A Breakthrough Therapy Designation conveys all of the fast-track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review².

In the U.S. alone, it is estimated that over 6,000 cases of ALL were diagnosed in 2013, and in the European Union, more than 7,000 cases of ALL are diagnosed each year^{3,4}. In adult patients with relapsed or refractory ALL, median overall survival is just three to five months⁵.

About BiTE® Technology

Bispecific T cell engager (BiTE®) antibodies are a type of immunotherapy being investigated for use in fighting cancer by helping to engage the body's immune system to detect and target malignant cells. The modified antibodies are designed to engage two different targets simultaneously, thereby juxtaposing T cells (a type of white blood cell capable of killing other cells perceived as threats) to cancer cells. BiTE antibodies help place the T cells within reach of the targeted cell, with the intent of allowing it to inject toxins and trigger the cell to die (apoptosis). BiTE antibodies are currently being investigated for their potential to treat a wide variety of cancers. For more information on BiTE antibodies, visit www.biteantibodies.com.

About Blinatumomab

Blinatumomab is an investigational BiTE® antibody designed to direct the body's cell-destroying T cells against target cells expressing CD19, a protein found on the surface of B-cell derived leukemias and lymphomas. Blinatumomab is the first of the BiTE antibodies and Amgen has received orphan drug designation from the FDA for the treatment of ALL, chronic lymphocytic leukemia (CLL), hairy cell leukemia, polymorphocytic leukemia and indolent B cell lymphoma and from the European Medicines Agency for the treatment of indolent B cell lymphoma, ALL, CLL and mantle cell leukemia (MCL). Blinatumomab is also being investigated for its potential to treat pediatric relapsed/refractory ALL, relapsed/refractory Philadelphia positive (Ph+) B-precursor ALL, minimal residual disease positive (MRD+) B-precursor ALL, relapsed/refractory non-Hodgkin's lymphoma (NHL), including relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

About ALL

Acute lymphoblastic leukemia (ALL) is an aggressive cancer of the blood and bone marrow — the spongy tissue inside bones where blood cells are made¹. The disease progresses rapidly and affects immature blood cells, rather than mature ones¹. Worldwide, ALL accounts for more than 12 percent of leukemia. Of the 42,000 people diagnosed worldwide, 31,000 will die from the disease. Patients with ALL have abnormal white blood cells (lymphocytes) that crowd out healthy white blood cells, red blood cells and platelets, leading to infection, anemia (fatigue), easy bleeding and serious side effects⁶.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on [www.twitter.com/amgen](https://twitter.com/amgen).

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of July 1, 2014, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to integrate the operations of companies we have acquired may not be successful.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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