Amgen's BiTE® Antibody Blinatumomab (AMG 103) Achieved High Rate Of Complete Response In Adult Patients With Relapsed Or Refractory Acute Lymphoblastic Leukemia

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Greater than 70 Percent of Patients in the Study Achieved Complete Response
Median Survival 9.0 Months, with a Median Follow-up of 10.7 Months

THOUSAND OAKS, Calif., May 16, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced updated results from a Phase 2 study that showed treatment with blinatumomab (AMG 103) helped achieve a high-rate of complete response (CR) in 72 percent of adult patients with relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL) treated in the study. Blinatumomab is the first of a new class of agents called bi-specific T cell engagers (BiTE®) antibodies, designed to harness the body's cell-destroying T cells to kill cancer cells. Blinatumomab targets cells expressing CD19, a protein found on the surface of B-cell derived leukemias and lymphomas, such as ALL. Full results of the study will be presented during an oral abstract session at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) on June 4 (Abstract Number 6500; Oral Presentation, 8:00 a.m. - 8:15 a.m. CDT, E354a).

In this Phase 2 single-arm dose-ranging trial, 26 of the 36 patients treated with blinatumomab across all of the tested doses and schedules achieved a CR or complete response with partial hematologic recovery (CRh*). All but two patients achieved a molecular response, meaning there was no evidence of leukemic cells by polymerase chain reaction.

For patients who received the selected dose and schedule, the most common adverse events were grade one or two and included pyrexia (70 percent), headache (39 percent), tremor (30 percent) and fatigue (30 percent). These were most frequently seen at the onset of treatment in cycle one. Reversible central nervous system events led to treatment interruptions in six patients with two patients permanently discontinuing treatment. Cytokine release syndrome led to treatment interruption in two patients. One patient had a fatal event of fungal infection that the investigator considered related to treatment.

At the time of the analysis, median survival was 9.0 (8.2, 15.8) months with a median follow-up period of 10.7 months. In the group of patients who received the selected dose, median survival was 8.5 months. The median duration of response in the 26 patients who responded to treatment was 8.9 months.

"For these patients with limited treatment options, the remission rate observed in the trial is a vast improvement over the current standard of care," said Professor Max Topp, Department of Internal Medicine II, University of Wuerzburg and chair of the study. "These results also represent significant progress in our research of immunotherapies; a new approach to fighting cancer that we believe could make a real difference for patients."

In addition to the results from this study, data from studies of 12 Amgen investigational molecules and marketed products will be presented at the ASCO Annual Meeting. These include results from studies of the immunotherapy talimogene laherparepvec, pipeline molecules such as rilotumumab (AMG 102) and AMG 386 and marketed products. A complete listing of Amgen abstracts of interest can be found at wwwext.amgen.com/media/amgen_asco_2012.html. Abstracts are available online at www.asco.org.

Phase 2 Study Design

This Phase 2 dose-ranging study evaluated the efficacy, safety and tolerability of blinatumomab in adult patients with B-precursor ALL who had relapsed following treatment with standard front-line chemotherapy or allogeneic stem cell transplant. Patients received blinatumomab for 28 days followed by two weeks off therapy over a six week treatment cycle, for up to five treatment cycles. Patients received a continuous intravenous infusion of blinatumomab at an initial dose of five or 15 micrograms per meter squared per day, ranging up to 30 micrograms for the remainder of the treatment. The primary endpoint of the study was the rate of CR/CRh*. Secondary endpoints included molecular response rate, duration of response and overall survival. As of April 13, 2012, all 36 patients were evaluable for efficacy and safety.

About Blinatumomab

Blinatumomab (AMG 103) is a bispecific T cell engager (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. The modified antibodies are designed to engage two different targets simultaneously, thereby juxtaposing T cells to cancer cells. Blinatumomab is the first of the BiTE antibodies and Amgen has received orphan drug designation from the U.S. Food and Drug Administration for the treatment of ALL, chronic lymphocytic leukemia (CLL), hairy cell leukemia, prolymphocytic 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).

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 made. The disease progresses rapidly and affects immature blood cells, rather than mature ones.(1) Worldwide, ALL accounts for more than 12 percent of leukemia. Of the 42,000 people diagnosed worldwide, 31,000 will die from the disease.(2) 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 effects.(3,4)

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed

to advancing science to dramatically improve people's lives. To learn more about our pioneering science and vital medicines, visit http://www.amgen.com/. Follow us on http://twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs 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, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen'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 May 16, 2012 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 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 products liability claims. 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 are affected by the reimbursement policies imposed by third-party payors, 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 we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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(1) Definition of Acute lymphocytic leukemia.Mayo Clinic. http://www.mayoclinic.com/health/acute-lymphocytic-leukemia/DS00558. Accessed April 16, 2012.

(2) World. Globocan 2008 website. http://globocan.iarc.fr/factsheet.asp. Accessed May 4, 2012.

(3) Causes of Acute lymphocytic leukemia.Mayo Clinic. http://www.mayoclinic.com/health/acute-lymphocytic-leukemia/DS00558/DSECTION=causes%20. Accessed April 16, 2012.

(4) Symptoms of Acute lymphocytic leukemia**.** Mayo Clinic. http://www.mayoclinic.com/health/acute-lymphocytic-leukemia/DS00558/DSECTION=symptoms. Accessed April 16, 2012.

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