Romiplostim Data Show Potential Long-Term Efficacy and Safety in Adults with Chronic ITP

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Results Show Romiplostim Increased and Sustained Platelet Counts with Extended Treatment

COPENHAGEN, Denmark--(BUSINESS WIRE)--June 15, 2008--Amgen Inc. (NASDAQ: AMGN) today announced updated results from the ongoing, open-label extension study on the long-term safety and efficacy of romiplostim in adult patients with chronic immune thrombocytopenic purpura (ITP), a chronic and serious autoimmune disorder characterized by low platelet counts in the blood. The updated results continue to show that romiplostim increased and sustained platelet counts with extended treatment, and reduced the need for concurrent and rescue ITP medications.

The updated results from the long-term study show that overall 87 percent of patients achieved a platelet response defined as a platelet count of 50,000 platelets per microliter or doubling of the baseline platelet count (124/142). The overall median baseline platelet count was 17,000 platelets per microliter. The average treatment period was 65 weeks, and the longest duration of treatment was 156 weeks. The results were presented today as an oral presentation at the 13th Congress of the European Hematology Association (Abstract # 1421).

"Currently, romiplostim is the only thrombopoietic treatment for adult chronic ITP for which there is three years of follow-up data," said Professor Adrian Newland, Department of Haematology, The Royal London Hospital, Whitechapel, London, UK. "This is the longest ITP study and the findings demonstrate the potential of romiplostim as a long-term treatment option for a patient population with limited treatment options."

Additional data presented include:

-- Platelet response achieved: Overall, 87 percent (124/142) of patients achieved a platelet response. A platelet response was achieved by 30 percent (42/138) of patients after the first dose and by 51 percent (71/138) of patients after the third dose.

-- Platelet counts increased: Platelet counts of romiplostim-treated patients were increased from baseline by 20,000 platelets per microliter more than half of the time in 86 percent of patients and more than four-fifths of the time in 57 percent of patients.

-- Platelet counts maintained: Ad hoc analysis showed response durability, defined as platelet counts greater than 50,000 platelets per microliter, was maintained for greater than or equal to 10 consecutive weeks in 78 percent of patients (102/131), greater than or equal to 25 weeks in 54 percent of patients (66/122), and greater than or equal to 52 consecutive weeks in 35 percent of patients (29/84).

-- Discontinuation or reduction of concurrent ITP medications: Of patients receiving concurrent ITP medications (such as corticosteroids) at baseline, 84 percent of patients (27/32) discontinued or reduced their dose by greater than 25 percent.

-- Decreased use of rescue medications: Patients using rescue medications (defined as any additional ITP medicines needed to increase platelet counts) decreased from 23 percent (33/142) during weeks 1-12 to 15 percent during weeks 24-36, and remaining between 12-18 percent during weeks 130-132.

In this study, adverse events (AEs) did not increase in frequency during the course of the trial. AEs were reported in 95 percent of patients, with most mild to moderate in severity and transient in duration. The most common were headache (37 percent), nasopharyngitis (32 percent), contusion, fatigue and epistaxis (each 30 percent).

Treatment-related and serious AEs were reported in 36 percent and 31 percent of patients, respectively. Nine percent of serious AEs were considered treatment-related. Of the patients who discontinued treatment, seven percent (10/142) stopped due to AEs.

Bone marrow reticulin was reported in samples from eight patients with no evidence of collagen fibrosis or chronic idiopathic myelofibrosis. Thrombotic/thromboembolic events were reported in seven patients, of which six had pre-existing risk factors. To date, one patient developed a neutralizing antibody to romiplostim; however, it did not cross react with thrombopoietin and it was absent upon re-testing four months after romiplostim treatment was stopped.

About the Study

This ongoing, open-label study is assessing the safety and efficacy of long-term administration of romiplostim in both splenectomized and non-splenectomized adult chronic ITP patients. As of July 13, 2007, 143 patients had enrolled and 142 were treated with romiplostim. Sixty-seven percent of patients were female, and of the enrolled patients, 60 percent had undergone a splenectomy (removal of the spleen).

Eligible patients had completed a previous ITP romiplostim study, and had a baseline platelet count of less than 50,000 platelets per microliter, with no significant change in medical history. The romiplostim starting dose was 1 ug/kg by subcutaneous injection and was adjusted to maintain a platelet count between 50,000 and 250,000 platelets per microliter.

About Adult ITP

Platelets are blood cells needed to prevent bleeding. Low platelet counts leave adult ITP patients open to sudden serious bleeding events, making it impossible to arrest blood flow. The risk for serious bleeding events increases when platelet counts drop to less than 30,000 platelets per microliter.

There are limited approved treatments (i.e., corticosteroids, immunglobulins) or surgical therapy (removal of the spleen) available to adult patients with chronic ITP. Currently, there are 140,000 treated chronic ITP patients in the U.S. and Europe. ITP affects about twice as many adult women as men.

With ITP, platelets are destroyed by the patient's own immune system. ITP has historically been considered a disease of platelet destruction. However,

recent data also suggest that the body's natural platelet production processes are unable to compensate for low levels of platelets in the blood. Increasing the rate of platelet production may address low platelet levels associated with ITP.

About Romiplostim

Romiplostim, Amgen's first peptibody, is a novel engineered therapeutic fusion protein with attributes of both peptides and antibodies, but is distinct from each. Romiplostim works similarly to thrombopoietin (TPO), a natural protein in the body. Romiplostim stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells that produce platelets.

Amgen has filed for regulatory approval of romiplostim for use in the treatment of thrombocytopenia in adults with chronic ITP in the United States (U.S.), European Union, Australia and Canada. Regulatory authorities in the U.S., Australia and Canada have granted priority review of Amgen's application.

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 and 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 disorder, rheumatoid arthritis, 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 our vital medicines, visit www.amgen.com.

Forward-Looking Statement

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 June 15, 2008 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. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the FDA for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. 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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