Amgen to Discuss Romiplostim Application at FDA ODAC Meeting

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Orphan Drug Romiplostim Reviewed as Potential New Treatment Approach for Serious Bleeding Disorder

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--March 12, 2008--Amgen Inc. (NASDAQ: AMGN) will discuss the proposed Biologic License Application (BLA) for romiplostim, an investigational thrombopoietin mimetic peptibody, for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) today at the Oncologic Drugs Advisory Committee (ODAC). Patients with chronic ITP, a serious autoimmune disorder characterized by low platelet counts in the blood (thrombocytopenia) face the risk of bleeding events. Treatment of thrombocytopenia in adult patients with chronic ITP is considered an unmet medical need by the U.S. Food and Drug Administration (FDA) and has received orphan drug designation.

Proposed Indication

The proposed indication for romiplostim submitted to the FDA is for the treatment of thrombocytopenia in adults with chronic ITP who have not undergone splenectomy (removal of the spleen) and have had an inadequate response or are intolerant to corticosteroids and/or immunoglobulins; or patients who have had their spleen removed and have an inadequate response to the procedure.

Amgen's Commitment to Risk Management

Amgen is committed to a robust risk management program for romiplostim. The proposed comprehensive risk management program includes additional clinical studies and a variety of measures designed to ensure appropriate use of romiplostim in ITP patients.

"By stimulating platelet production, romiplostim represents a potentially new approach to the management of chronic ITP," said David J. Kuter, M.D., D. Phil., Chief of Hematology, Massachusetts General Hospital, Boston. "Romiplostim would be an important treatment option for adult patients affected by this disease."

Amgen filed for regulatory approval of romiplostim with the FDA in October 2007 and was granted priority review. Regulatory filings in the European Union (EU), Canada and Australia were also filed in 2007 and are currently under review. Orphan designation was granted for romiplostim in 2003 by the FDA. An orphan disease is defined as a condition that affects fewer than 200,000 people nationwide. Romiplostim also has received orphan designation for the proposed indication in the EU (2005), Switzerland (2005) and Japan (2006).

About Romiplostim

Romiplostim is an investigational protein ("peptibody"), containing two components--a "binding" peptide linked to a larger protein. Developed by Amgen, peptibodies are engineered therapeutic molecules that can bind to human drug targets and contain peptides linked to the constant domains of antibodies. Romiplostim works similarly to thrombopoietin (TPO), a natural protein in the body. The binding peptide component of romiplostim stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells that produce platelets.

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 FDA approved treatments (i.e., corticosteroids, immunglobulins) or surgical therapy (removal of the spleen) for adult patients with chronic ITP. There are an estimated 60,000 adult patients with chronic ITP in the United States. 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 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 March 12, 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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