Phase 2 Study Suggests That Extended Dosing of Aranesp(R) is as Efficacious as Weekly Dosing

September 26, 2007

Aranesp Combined Patient Level Analyses Provide Additional Evidence of Efficacy and Safety

BARCELONA, Spain--(BUSINESS WIRE)--Sept. 26, 2007--Amgen (NASDAQ:AMGN) today announced data from a Phase 2, randomized, multicenter, open-label study that suggest extended dosing of Aranesp(R) (darbepoetin alfa) paired with chemotherapy treatment (every two or every three weeks depending on chemotherapy regimen) appeared to be efficacious with respect to changes in hemoglobin (Hb), with no unexpected adverse events observed when compared to weekly dosing.

Additionally, results from two combined patient level analyses suggest that patients treated with Aranesp experienced a decrease in blood transfusions and improvement in hematologic response. These analyses do not suggest a negative impact on overall survival or progression-free survival between patients receiving chemotherapy treatment with Aranesp and those that did not receive Aranesp treatment. These data were presented at the 14th European Cancer Conference (ECCO) in Barcelona, Spain (Abstract # 1.141, 1.120, 1.104).

About the Phase 2 Study

This Phase 2 study is the first prospective trial illustrating how various Aranesp dosing regimens can be paired with chemotherapy administered across a range of dosing schedules.

"Flexibility in dosing is important for physicians to optimize anemia management and meet patient needs," said Timothy Rearden, M.D., Hematology Oncology Consultant, Inc. "In this study, Aranesp was consistently effective regardless of dosing frequency, providing healthcare professionals with the ability to adapt Aranesp treatment as required."

The mean change in Hb from baseline to week 13 was comparable between extended dosing (every two or every three weeks depending on chemotherapy regimen) and weekly dosing. The percentage of patients who achieved a Hb greater than or equal to 11 g/dL by Kaplan-Meier estimates was also similar (76 percent for weekly dosing and 71 percent for extended dosing).

The trial was a Phase 2, 25-week open-label study to evaluate non-inferiority of Aranesp in patients with anemia as a result of chemotherapy treatment who were randomized 1:1 to either an extended dosing schedule (n=378) or a weekly schedule (n=374).

Patients in the arm receiving an extended dose schedule of Aranesp received 300 mcg Q2W if chemotherapy treatment (CTX) was QW, Q2W, or Q4W or 500 mcg Q3W if CTX was Q3W. Patients in the arm receiving a weekly schedule of Aranesp (DA-QW) received 150 mcg QW regardless of CTX schedule. The QW and Q2W fixed dosing schedules utilized in this study are not approved dosing options. Q3W 500 mcg fixed dosing is the recommended initial dose with alternate weight based dosing options available at QW and Q3W.

Stratification factors were chemotherapy cycle length, screening Hb (less than 10 g/dL versus greater than or equal to 10 g/dL) and type of cancer (lung/gynecological versus other cancers). The primary endpoint was change in Hb from baseline to week 13. Demographics between the two groups were broadly similar.

Aranesp Combined Patient Level Analyses Results

Two combined analyses reported patient level data from six Amgen-sponsored, placebo-controlled, randomized trials of Aranesp to treat anemia as a result of chemotherapy in patients with screening Hb less than or equal to 11 - 13 g/dL, nonmyeloid malignancies, greater than or equal to one prior chemotherapy cycle, and additional planned chemotherapy cycles. Amgen presented the results of these combined patient level analyses at the U.S. Food and Drug Administration's Oncologic Drugs Advisory Committee meeting in May 2007.

While preserving initial randomization, patient level data from 2,112 patients was analyzed to determine differences between Aranesp (n=1,200) treatment and placebo (n=912). The results suggest that patients treated with Aranesp experienced a decrease in blood transfusions, improvement in hematologic response, and an expected increased risk of thromboembolic events (TE). No differences in risks of death, disease progression or progression-free survival were observed between the two groups.

"The results of these combined patient level analyses further add to the large scientific body of evidence that ESAs are safe and effective when used according to their approved label. The increased risk of TEs has long been observed and appropriately represented for in class labeling for ESAs," said Heinz Ludwig, M.D., Center for Oncology and Haematology, Wilhelminen Hospital, Vienna, Austria.

The Aranesp group had an approximate 54 percent relative risk reduction for transfusions (HR: 0.46, 95 percent CI: 0.39, 0.55) and also were approximately more than twice as likely to achieve a hematopoietic response (HR: 2.40, 95 percent CI: 2.10, 2.75). The relative risk for TEs was approximately 50 percent higher in the Aranesp group (HR: 1.57, 95 percent CI: 1.10, 2.26). The rates of TEs were eight percent in patients treated with Aranesp and five percent in placebo patients. These rates are similar to what has been reported in current product labeling.

A second combined analysis evaluated the association between achieved Hb levels or rates of Hb increase and safety outcomes in anemic cancer patients undergoing chemotherapy. The analysis included 1,200 patients treated with Aranesp. Achieving a Hb greater than 12 or 13 g/dL or a Hb increase of greater than 1 g/dL in 14 days or greater than 2 g in 28 days did not appear to be associated with an increased risk of death or disease progression. Risk of TEs was not clearly related to achieving Hb of greater than 12 or greater than 13, although rates of rise greater than 1g in 14 days and greater than 2 g in 28 days were associated with a trend towards increased risk. These risks of TEs are consistent with those already noted in ESA product labels.

A similar pattern was seen when deaths were identified during a study's follow-up period. No increased risk of disease progression and progression-free survival was seen in patients who achieved a Hb greater than 12 g/dL, Hb greater than 13 g/dL, a Hb increase of greater than 1 g/dL in 14 days or greater than 2 g in 28 days. It should be recognized that in this combined analysis, the patients ability to respond is an important potential

confounder.

The results of the combined analyses presented at ECCO appear to suggest that patients receiving chemotherapy who are able to reach a Hb level of above 12 g/dL do not experience an increased risk of on-study death and disease progression. A higher rate of TEs was associated with increased rates of Hb increase, which is a recognized risk in this patient population treated with ESAs. These data provide further information regarding the relationship of achieved Hb and safety outcomes for Aranesp.

About Aranesp

Aranesp is a recombinant erythropoiesis-stimulating protein (a protein that stimulates production of red blood cells, which carry oxygen). Amgen revolutionised the treatment of anaemia with the development of recombinant erythropoietin, Epoetin alfa. Building on this heritage, Amgen developed Aranesp, a unique erythropoiesis stimulating protein, which contains two additional sialic acid-containing carbohydrate chains compared to the epoetin alfa and epoetin beta molecule and remains in the bloodstream longer than epoetin alfa and epoetin beta as demonstrated by its longer half-life.

Aranesp was granted marketing authorisation by the European Commission in 2001 for the treatment of anaemia associated with chronic renal failure (CRF), also known as chronic kidney disease (CKD), in adults and paediatric subjects 11 years of age or older. In 2002, the European Commission approved Aranesp for the treatment of anemia in adult cancer patients receiving chemotherapy with solid tumors. This patient population was subsequently expanded in 2003 to include treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Approval was granted in 2004 for extended dosing intervals of once-every-three-weeks in the treatment of anemia in adult cancer patients with non-myeloid malignancies who are receiving chemotherapy and up to once-per-month Aranesp administration in the treatment of anemia in CKD patients not on dialysis. In 2006, the Aranesp label was updated to allow CKD patients on dialysis to switch from rHuEPO one to three times a week to Aranesp every two weeks. In 2007, the Aranesp label was updated to allow for treatment of anaemia associated with CRF, in all European paediatric patients on dialysis or not on dialysis.

Aranesp was approved by the U.S. Food and Drug Administration (FDA) in September 2001 for the treatment of anemia associated with CRF for patients on dialysis and patients not on dialysis. In July 2002, the FDA approved weekly dosing of Aranesp for the treatment of anemia caused by concomitantly administered chemotherapy in patients with nonmyeloid malignancies and in March 2006, the FDA approved every-three-week dosing in these patients.

Important EU Aranesp Safety Information

Aranesp is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; regional guidelines should be referred to for target and maximum hemoglobin levels, and dose adjustment rules should be performed in line with regional prescribing information.

The most commonly reported side effects in clinical trials were arthralgia, edema, injection site pain and thromembolic event reactions. Prescribers are recommended to consult regional prescribing information before prescribing Aranesp, including side-effects, precautions and contra-indications.

Important U.S. Aranesp Safety Information

Use the lowest dose of Aranesp(R) that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion.

Aranesp(R) and other erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular events when administered to target a hemoglobin of greater than 12 g/dL

Cancer Patients: Use of ESAs

- Shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a hemoglobin of greater than 12 g/dL,
- Shortened overall survival and increased deaths attributed to disease progression at 4 months in patients with metastatic breast cancer receiving chemotherapy when administered to target a hemoglobin of greater than 12 g/dL,
- Increased the risk of death when administered to target a hemoglobin of 12 g/dL in patients with active malignant disease receiving neither chemotherapy or radiation therapy. ESAs are not indicated for this population.

Patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving Epoetin alfa who were not receiving prophylactic anticoagulation. Aranesp(R) is not approved for this indication.

Aranesp is contraindicated in patients with uncontrolled hypertension.

About Amgen

Amgen discovers, develops 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 disease, 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 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 Sept. 25, 2007, 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 health care 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) or European Medicines Agency (EMEA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA, EMEA or comparable regulatory body 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 or EMEA 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, EMEA or comparable regulatory body can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the applicable FDA- or EMEA-approved labeling for the products, and not the information discussed in this news release.

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SOURCE: Amgen