Amgen Announces Interim Results of Aranesp(R) "PREPARE" Study in Breast Cancer Patients

November 30, 2007

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Nov. 30, 2007--Amgen, Inc. (NASDAQ: AMGN) today announced that it had received interim results from the independent investigator-sponsored "PREPARE" study, an open-label, randomized, multicenter Phase 3 study of Aranesp(R) (darbepoetin alfa) in 733 neoadjuvant breast cancer patients receiving dose-dense, dose-intense preoperative chemotherapy compared to a standard preoperative chemotherapy regimen.

Initiated in 2002, the PREPARE study was developed, conducted and analyzed by the independent German Gynecological Oncology Study Group (AGO) and the German Breast Group. It was designed to evaluate the effects of preoperative chemotherapy using a sequential dose-dense and dose-intensified regimen of epirubicin, paclitaxel, and CMF compared to preoperative sequential administration of epirubicin and cyclophosphamide followed by paclitaxel in patients with breast cancer, with respect to event-free and overall survival, with or without Aranesp to prevent anemia and to potentially augment the therapeutic effects of the chemotherapy regimens. This study assessed both an experimental use of the drug to prevent anemia and an off-label regimen.

Interim Results

The pre-specified interim results relate to the study period when chemotherapy and Aranesp were administered, and specifically address the tumor response to chemotherapy at the time of surgery. In this analysis, there was no significant difference between the Aranesp and control groups.

The primary long-term follow up endpoints of the PREPARE study, including relapse-free survival time and overall survival, were designed to be analyzed when a pre-specified number of events had been observed. Available data as of Oct. 30, 2007, show numerically more deaths (37/377 for control and 50/356 for Aranesp) and tumor progression events (70/377 for control and 88/356 for Aranesp) on the Aranesp arm compared to the control group in the long-term follow up. A formal statistical analysis of survival is anticipated in early 2009.

"This interim analysis shows that the use of Aranesp to support neo-adjuvant chemotherapy has no significant impact on tumor response to chemotherapy at the time of surgery. No definitive conclusions should be drawn from the interim results of the long-term follow up until the final study report is completed," said the principal investigator Professor Michael Untch, M.D. of the AGO. "During the treatment period, there were as expected, no deaths, and we continue to monitor long-term follow-up results."

In the PREPARE study, patients were randomized to two different chemotherapy regimens and were then randomized to receive either no treatment or Aranesp (at a dose of 4.5 ug/kg every two weeks) to prevent anemia by maintaining hemoglobin concentrations between 12.5 g/dL and 13 g/dL, with dose withholding at levels greater than or equal to 13 g/dL. Patients in both groups entered the study with a mean hemoglobin level of 13.6 g/dL. In the study, Aranesp-treated patients maintained mean hemoglobin levels of 13.6 g/dL by the end of chemotherapy whereas subjects in the control group decreased to 12.6 g/dL.

These interim study results have been submitted to regulatory agencies, including the U.S. Food and Drug Administration (FDA). The final results will be submitted when available.

Aranesp Pharmacovigilance Program Update

The PREPARE study is one of five randomized, prospective clinical studies that are part of Amgen's current ongoing pharmacovigilance program, which was undertaken in agreement with the FDA following the Oncologic Drug Advisory Committee meeting in May 2004. Amgen has promptly submitted to regulatory agencies, including the FDA, all available data from the PREPARE study. Final data from two remaining pharmacovigilance studies including an additional breast cancer study are expected in 2009-2010.

Amgen recently announced the addition of six new proposed clinical trials to address the safety of ESAs in specific tumor types when used to treat anemia in cancer patients on chemotherapy. Upon agreement with the FDA, these studies will be added to the ongoing pharmacovigilance program. Based on the safety signals observed with higher hemoglobins, an additional study to evaluate the effect of hemoglobin targets on the risk/benefit profile of ESAs is also planned.

About Aranesp

Aranesp was approved by the FDA in September 2001 for the treatment of anemia associated with chronic renal failure (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 Aranesp Safety Information

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and TUMOR PROGRESSION

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

-- ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with advanced breast, head and neck, lymphoid, and non-small cell lung malignancies when dosed to target a hemoglobin of greater than or equal to 12 g/dL.

-- The risks of shortened survival and tumor progression have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL.

-- To minimize these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.

-- Use only for treatment of anemia due to concomitant myelosuppressive chemotherapy.

-- Discontinue following the completion of a chemotherapy course.

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 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 Nov. 30, 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 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 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 U.S. Food and Drug Administration (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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