Phase 3 Study Shows Majority of Neutropenia with Related Fever and Hospitalization Occurs in First Treatment Cycle for Breast Cancer Patients Not Receiving Neulasta

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The Largest Randomized Placebo-Controlled Study to Date for Neulasta Supports First and Subsequent Cycle Administration

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 10, 2004-- Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that new data from a Phase 3 study show that the majority of neutropenic complications occur in the first cycle of chemotherapy treatment for breast cancer patients who are not administered Neulasta(R) (pegfilgrastim). The study found that administering Neulasta beginning in the first and subsequent cycles of chemotherapy reduced the rate of infection, as manifested by febrile neutropenia (low white blood cell count with fever), by more than 90 percent. Hospitalization and the use of intravenous anti-infectives in breast cancer patients were also significantly lower in the group receiving Neulasta in the first and subsequent cycles of chemotherapy. The results were presented by the study's lead investigator, Charles Vogel, M.D., Cancer Research Network, Plantation, Fla., at the 27th Annual San Antonio Breast Cancer Symposium (SABCS). (SABCS Abstract # 5044)

"Patients in the placebo arm not only experienced significantly more neutropenic events than patients in the Neulasta arm, but more than 65 percent of these events occurred in the first cycle of treatment, emphasizing the importance of early protection," said Dr. Vogel. "This study suggests that Neulasta used in first and subsequent cycles of chemotherapy achieves maximum clinical benefit."

Febrile (or feverish) neutropenia is the most common presentation of infection in patients receiving chemotherapy. Infection in this setting can be serious and even life threatening because chemotherapy can compromise the patient's ability to fight infection.

Breast cancer patients (Stage 1-4, ECOG performance of 0-2) receiving 100 mg/m(2) docetaxel every three weeks for up to four cycles were randomized to receive either 6 mg Neulasta (n=463) or placebo (n=465) once-per-cycle on the day after docetaxel administration for up to four cycles. Docetaxel is associated with an average reported febrile neutropenia incidence of approximately 10 to 20 percent in the absence of growth factor support. Febrile neutropenia was defined as fever with a temperature equal to or greater than 38.2 degrees C and an absolute neutrophil count (ANC) less than 0.5 x 10(9)/L measured the same day or the day after fever was documented.

First-cycle administration of Neulasta resulted in a 91 percent reduction in the incidence of febrile neutropenia occurring in the first cycle of chemotherapy; an 89 percent reduction in the incidence of hospitalization and an 83 percent reduction in the incidence of intravenous anti-infective use.

Specifically, in the first cycle, one percent of patients in the Neulasta arm (2/463) developed febrile neutropenia compared with 11 percent of patients in the placebo arm (52/465). Neulasta was also associated with a significantly lower incidence of hospitalizations with one percent of patients requiring hospitalization (5/463) in the first cycle versus nine percent of patients receiving placebo (43/465). One percent of patients in the Neulasta arm (5/463) required intravenous anti-infectives in the first cycle versus six percent of patients in the placebo arm (30/465).

In addition, in cycles two through four, less than one percent of patients in the Neulasta arm (1/458) developed febrile neutropenia compared with six percent of patients in the placebo arm (26/454). During these cycles, less than one percent of patients in the Neulasta arm (1/458) were hospitalized versus five percent in the placebo arm (21/454). Less than one percent of patients in the Neulasta arm (3/458) required intravenous anti-infectives in the subsequent cycles compared to four percent in the placebo arm (19/454).

Neulasta was well tolerated in this study with an adverse event profile similar to placebo. Bone pain was a frequently observed adverse event in both arms of the study (31 percent with Neulasta versus 27 percent with placebo).

About Neulasta

Neulasta was approved by the U.S. Food and Drug Administration (FDA) in 2002 for decreasing the incidence of infection, as manifested by neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Similar indications for Neulasta were approved in Europe and Australia the same year.

Rare cases of splenic rupture and sickle cell crises have been reported in postmarketing experience. Allergic reactions, including anaphylaxis, have also been reported. The majority of these reactions occurred upon initial exposure. However, in rare cases, allergic reactions, including anaphylaxis, recurred within days after discontinuing anti-allergic treatment. In clinical trials, the only serious adverse event not attributed to the underlying disease or chemotherapy was a case of hypoxia. The most common adverse event attributed to Neulasta was bone pain, reported in 26 percent of patients. While not reported in patients receiving Neulasta, rare events of adult respiratory distress syndrome have been reported in patients receiving the parent compound, Filgrastim.

About Amgen

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

Forward-Looking Statement

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2003, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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 side effects or manufacturing problems with our products after they are on the market. In addition, sales of our products are affected by the availability of reimbursement and the reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible US legislation affecting pharmaceutical pricing and reimbursement. Government 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 it 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 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.

Full prescribing information for Neulasta(R) is available via fax by calling 800-772-6436. Consumers can call 866-611-DRUG (3784) for more information.

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at www.amgen.com. Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.

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