Large Community-Based Clinical Trial in Older Cancer Patients Suggests Benefits of Neulasta in First and Subsequent Cycles Of Chemotherapy

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ORLANDO, Fla.--(BUSINESS WIRE)--May 15, 2005--Amgen Inc., (NASDAQ:AMGN) the world's largest biotechnology company, today announced that an initial report from a study of 701 older cancer patients with solid tumors demonstrates Neulasta(R) (pegfilgrastim) administered beginning in the first cycle of myelosuppressive chemotherapy resulted in reductions in febrile neutropenia (low white blood cell count with fever) and related complications, compared to those who received Neulasta in later chemotherapy cycles after developing a low white blood cell count. The study results were presented at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO). (Abstract #8111)

"Despite the fact that more than 60 percent of cancers are diagnosed in patients 65 years or older, these patients may be under-represented in clinical trials and may also be under-treated, partly due to concern over treatment side effects, such as neutropenia, which may lead to hospitalizations and dose delays or reductions," said Lodovico Balducci, M.D., professor of medicine and oncology, University of South Florida College of Medicine, and division chief of the Senior Adult Oncology Program at the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Fla. "This is the largest, prospective study of older patients demonstrating the feasibility of community-based clinical trials in these patients, as well as the ability of these patients to undergo myelosuppressive chemotherapy."

The study showed a decrease of approximately 60 percent in the incidence of febrile neutropenia across all cycles (4 percent versus 10 percent, respectively), as well as a 50 percent decrease in chemotherapy dose reductions (7 percent versus 14 percent) in patients receiving Neulasta beginning in the first cycle of chemotherapy compared to those who received Neulasta in later cycles. Febrile neutropenia, the primary endpoint of the study, was defined as an absolute neutrophil count (ANC) less than 1 x 10(9)/L and temperature greater than or equal to 38 degrees C. Further, patients receiving Neulasta in the first cycle of chemotherapy experienced almost half the number of neutropenia-related hospitalizations (5 percent versus 9 percent) and a decrease in antibiotic use due to neutropenia compared to those who received Neulasta in later cycles.

The 701 older patients (65 years and older) with lung, breast or ovarian cancer in this study were randomized to receive Neulasta in the first cycle of myelosuppressive chemotherapy (n=349) or Neulasta in second and subsequent chemotherapy cycles at the physician's discretion (n=352).

In this study, serious adverse events were reported less frequently in patients receiving Neulasta in the first and subsequent cycles of chemotherapy than in the group receiving second and subsequent cycle Neulasta. The most frequently reported serious adverse events were febrile neutropenia, neutropenia, pneumonia and dehydration.

About Neutropenia

Neutropenia is an abnormally low level of neutrophils, an important infection-fighting white blood cell (WBC), in the blood stream. An abnormally low WBC count can be serious because the body's ability to fight off infections becomes impaired, and even a minor case of the flu can become life-threatening. Because of its potential dangers, chemotherapy-induced neutropenia, may cause a patient's chemotherapy to be put on hold or the dose reduced, which can potentially compromise the chemotherapy's effectiveness.

Studies have shown that neutropenia occurs most frequently in the early cycles of chemotherapy, with the majority of febrile (or feverish) neutropenic events occurring in cycles one and two. Approximately half of the 1.3 million patients receiving chemotherapy are at risk for developing neutropenia.

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 febrile neutropenia, in patients with non-myeloid 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, 2004, 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 U.S. 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 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.

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

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