FDA Expands Neulasta(R) Label; New Label Extends First-Cycle Protection From Infection To Cancer Patients Receiving Moderately Myelosuppressive Chemotherapy

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THOUSAND OAKS, Calif., Sep 15, 2005 (BUSINESS WIRE) -- Amgen (Nasdaq: AMGN), the world's largest biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) approved an update to the Neulasta(R) (pegfilgrastim) prescribing information to include data from a landmark Phase 3 study demonstrating the white blood cell booster helps protect patients with most types of cancer undergoing moderately myelosuppressive chemotherapy from infection, as manifested by febrile neutropenia (low white blood cell count with fever), one of the most serious side effects of chemotherapy.

Previously, first and subsequent cycle administration of Neulasta to stimulate production of infection-fighting white blood cells was indicated for patients receiving myelosuppressive chemotherapy associated with a more than 30 to 40 percent risk of febrile neutropenia. Administration of Neulasta beginning in the first cycle of chemotherapy is now approved for patients receiving myelosuppressive chemotherapy associated with at least a 17 percent risk of febrile neutropenia. Myelosuppressive chemotherapy is toxic to the bone marrow where white blood cells, red blood cells and platelets are produced.

"The Phase 3 study demonstrated that administering Neulasta beginning in the first chemotherapy cycle reduced the incidence of febrile neutropenia by 94 percent," said Willard Dere, M.D., chief medical officer and senior vice president of Global Development at Amgen. "With this approval and Neulasta's once-per-cycle dosing, physicians can help protect appropriate patients proactively before their white blood cell counts become dangerously low."

The expanded label was based on a randomized, placebo-controlled study of 928 metastatic or non-metastatic breast cancer patients that was published in the Journal of Clinical Oncology earlier this year. First and subsequent-cycle administration of Neulasta resulted in a 94 percent reduction in the incidence of febrile neutropenia (1 percent versus 17 percent with placebo), a 93 percent reduction in the incidence of hospitalization (1 percent versus 14 percent with placebo) and an 80 percent reduction in the incidence of intravenous anti-infective use (2 percent versus 10 percent with placebo), compared to placebo, in patients receiving moderately myelosuppressive chemotherapy.

"Approximately two-thirds of neutropenic complications happen in the first cycle of chemotherapy," said study lead investigator Charles Vogel, M.D., Cancer Research Network, Plantation, Fla. "This study demonstrates that administering Neulasta beginning in the first cycle of chemotherapy reduces the chance of patients developing an infection."

About Neutropenia

Neutropenia is an abnormally low level of neutrophils, important infection-fighting white blood cells, in the blood stream. Neutropenia can put some patients at risk for severe infections and interruptions in cancer treatment. In fact, complications associated with a low white blood cell count are a common cause of dose reductions or delays in chemotherapy.

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.

Although white blood cell boosters have been available for more than a decade, only 17 percent of patients receiving myelosuppressive chemotherapy currently receive proactive first-cycle protection from neutropenic complications, which include infection, hospitalization and anti-infective use. 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 a placebo-controlled trial, bone pain occurred at a higher incidence in Neulasta treated patients as compared to placebo-treated patients (31 percent vs. 26 percent). The most common adverse events reported in either active or placebo controlled trials were consistent with the underlying cancer diagnosis and its treatment with chemotherapy, with the exception of bone pain. 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 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 broad and deep 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 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.

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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