



## **FDA Approves Amgen's Neulasta for Serious and Frequent Chemotherapy Side Effect**

February 1, 2002

THOUSAND OAKS, Calif., Jan 31, 2002 -- Amgen (Nasdaq:AMGN) today announced that the U.S. Food and Drug Administration has approved Neulasta(TM) (pegfilgrastim). Neulasta, administered as a single fixed dose per chemotherapy cycle, for decreasing the incidence of infection, as manifested by febrile neutropenia (fever associated with a severe drop in infection-fighting white blood cells) in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs.

Febrile neutropenia is a serious and common complication of many cancer chemotherapies. Chemotherapy kills normal cells as well as cancer cells, including those that protect against infection. This often results in neutropenia, a severe drop in a type of white blood cell called a neutrophil that plays a vital role in defending the body against most types of infection.

The clinical trials showed that Neulasta is safe and well-tolerated. In clinical trials, the most common adverse event attributed to Neulasta therapy following some forms of chemotherapy in patients (n = 465) was mild to moderate bone pain, reported in 26 percent of patients. In most cases, bone pain was controlled with non-narcotic pain relievers such as acetaminophen. The most serious adverse event not attributed to the disease or the chemotherapy was a single case of hypoxia (insufficient oxygen in the blood). Neulasta has not been studied in peripheral blood progenitor cell mobilization and should not be used in this setting.

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

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent Form 10-Q. Amgen conducts research in the biotechnology/pharmaceutical field where movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. In addition, sales of our products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers. These government regulations and reimbursement policies may affect the development, usage and pricing of 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.

Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Amgen. Amgen is providing this information as of January 31, 2002 and expressly disclaims any duty to update information contained in this press release.

The Neulasta prescribing information, a product photo and other media tools are available at [www.NEULASTA.com](http://www.NEULASTA.com). Prescribing information is also available via fax by calling (800) 772-6436. Consumers can call 866-611-DRUG (3784) or access [www.NEULASTA.com](http://www.NEULASTA.com) for more information about Neulasta.

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