UPDATE: FDA Approves Amgen's Neulasta for Serious and Frequent Chemotherapy Side Effect

February 1, 2002

THOUSAND OAKS, Calif., Feb 1, 2002 -- Amgen (Nasdaq:AMGN) yesterday announced that the U.S. Food and Drug Administration approved Neulasta(TM) (pegfilgrastim). Neulasta, administered as a single fixed dose per chemotherapy cycle, is indicated 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 associated with a clinically significant incidence of febrile neutropenia.

Febrile neutropenia is a serious and common complication of many cancer chemotherapies. Up to half of cancer chemotherapy patients develop severe neutropenia, potentially placing them at risk for life-threatening infections. On average, less than 10 percent of these patients receive proactive protection from neutropenia and studies have shown that 30 percent to 40 percent of patients receiving certain types of chemotherapy who do not get a white blood cell booster will experience neutropenia with fever. Thousands of patients are hospitalized for neutropenia and its complications each year, in an age when most chemotherapy patients are treated in the outpatient setting.

"Neulasta will make it easy for physicians to protect patients against neutropenia and its consequences," said Kevin Sharer, Amgen Chief Executive Officer. "Neulasta is the third Amgen product approved in the last six months that will make an important difference in the lives of patients. It will be available in early April."

Until now, NEUPOGEN(R) (Filgrastim), Amgen's other white blood cell stimulating product, was the only prescription drug shown to decrease risk of infection and hospitalization as a result of chemotherapy induced neutropenia. However, the burden of daily dosing (sometimes for as many as 14 consecutive days) has led many healthcare professionals to wait to intervene with NEUPOGEN until after a chemotherapy patient developed a neutropenic infection.

"The less frequent dosing of Neulasta means that patients will require fewer painful injections, fewer office visits for those injections and fewer disruptions to their lives at a time when they are overwhelmed with a serious disease," said Dr. Frankie Ann Holmes, a lead clinical trial investigator and associate director of research at U.S. Oncology in Houston. "This approval means that hundreds of thousands of chemotherapy patients at risk for infection may now receive Neulasta as protection at the onset of each treatment cycle before complications arise."

Neulasta

Neulasta(TM) is a protein that stimulates the production of infection-fighting white blood cells (neutrophils) that are depleted by cytotoxic chemotherapy.

Due to the relatively short time it remains circulating in the blood, NEUPOGEN(R) (Filgrastim) requires up to 2 weeks of daily injections following each cycle of chemotherapy. Almost half of chemotherapy patients who receive NEUPOGEN require 10 or more daily injections.

With Neulasta, a polyethylene glycol molecule or "PEG" unit is added to enlarge the Filgrastim molecule, thereby extending its half-life and causing it to be removed more slowly from the body. This allows for administration in a single dose per chemotherapy cycle.

Self-regulation (neutrophil-mediated clearance) of Neulasta allows the drug to remain in the blood throughout the time during which a patient is neutropenic -- when it is needed -- and then be cleared rapidly when it is no longer needed (as neutrophils recover toward normal levels).

Proven in Clinical Trials

Data from two pivotal phase 3 studies in breast cancer patients (n=310 with 100 mcg/kg dose; n=157 with fixed 6 mg dose) demonstrated a single dose of Neulasta provided protection from infection comparable to a mean of 11 daily injections of NEUPOGEN (5 mcg/kg/day), reducing both the duration of severe neutropenia and the frequency of neutropenia with fever. The randomized, double-blind trials were conducted in breast cancer patients undergoing up to 4 cycles of chemotherapy with doxorubicin and docetaxel.

Days of severe neutropenia were comparable between treatment groups in all cycles. The mean duration of severe neutropenia in cycle 1 appeared to be no different for patients in the Neulasta and NEUPOGEN groups: respectively an average of 1.8 days versus 1.6 days in the fixed dose trial, and 1.7 days versus 1.6 days in the by-weight dosing trial. The average weight of these patients was 160 lbs (72.4 kg) with more than 76 percent of the patients weighing 154 lbs (70 kg) or more. Neulasta was comparable to NEUPOGEN with respect to rates of febrile neutropenia across all chemotherapy cycles in both studies.

Data from phase 2 studies in patients with various malignancies undergoing a variety of chemotherapy regimens further support the safety and efficacy of Neulasta. These studies in patients with breast cancer, thoracic tumors (including lung cancer), non-Hodgkin's lymphoma and Hodgkin's disease showed efficacy of a single injection of Neulasta (100 mcg/kg) that was similar to daily injections of NEUPOGEN (5 mcg/kg/day).

Safety Tested

The clinical trials showed that Neulasta(TM) is safe and well-tolerated. In clinical trials, the most common adverse event attributed to Neulasta therapy following combination chemotherapy in patients (n=465) with lymphoma and solid tumors was bone pain reported in 26 percent of patients. In most cases, bone pain was controlled with non-narcotic analgesics. The most serious adverse event attributed to Neulasta was low oxygen in the blood, reported in one patient. While not reported in patients receiving

Neulasta, rare events of adult respiratory distress syndrome, splenic rupture, and sickle cell crisis have been reported in patients receiving the parent compound, NEUPOGEN(R).

Neutropenia

Neutropenia is a serious and frequent side effect of chemotherapy treatment. 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. With fewer white blood cells to fight off infection, even a minor case of the flu can become life threatening.

Cancer patients who are at an increased risk of neutropenia include the elderly, patients with pre-existing neutropenia, prior chemotherapy or radiation treatment, and co-morbid conditions that leave patients immunocompromised. Patients aged 70 and older receiving moderately toxic chemotherapy are at high risk for neutropenic infection, and suffer increased severity of infections and longer durations of hospitalization. Yet 90 percent of elderly cancer chemotherapy patients do not receive protection against neutropenic complications. Within the next 20 years, persons aged 70 and older will represent the majority of cancer patients receiving chemotherapy.

Approximately 1.4 million U.S. patients received chemotherapy in 2001. About 1.27 million new cancer cases were expected in 2001.

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 February 1, 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. Prescribing information is also available via fax by calling (800) 772-6436. Consumers can call 866-611-DRUG (3784) or access www.NEULASTA.com for more information about Neulasta.

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