



Amgen Receives CPMP Recommendation For European Union Marketing Approval Of Neulasta For The Reduction Of Chemotherapy - Induced Neutropenia

June 3, 2002

THOUSAND OAKS, Calif., USA and LUCERNE, Switzerland, -- June 3, 2002 -- Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the European Committee on Proprietary Medicinal Products (CPMP) has recommended approval of pegfilgrastim (Neulasta/Neupopeg) for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

The CPMP's recommendation will be forwarded to the European Commission for its approval of the marketing authorization.

Neutropenia is a serious and frequent side effect of chemotherapy treatment. In addition to killing cancer cells, chemotherapy also kills normal cells, including those that protect against infection. This often results in neutropenia, a severe drop in the numbers of a type of white blood cell called neutrophils, which play a vital role in defending the body against most types of infection. With a severe drop in white blood cells, even a seemingly minor infection can become life threatening.

Neupogen(R) /Granulokine(R) (filgrastim), Amgen's other white blood cell stimulating product, has been shown to decrease the risk of infection and hospitalization as a result of chemotherapy-induced neutropenia. However, the burden of daily injections (which sometimes continue for as many as 14 consecutive days) has led many healthcare professionals to wait until after a chemotherapy patient has developed a neutropenic infection before administering filgrastim. Neulasta is a long-acting form of filgrastim which allows for once-per-chemotherapy cycle dosing. In addition to reducing the burden associated with daily injections, simple, once-per-chemotherapy-cycle administration of Neulasta may increase adherence to treatment regimens and eliminate the potential for missed doses of growth factor.

"This once-per-cycle product can have a very positive impact on patients' quality of life," said Professor Martine Piccart, of the Institute Jules Bordet, in Belgium, an investigator in the pivotal, fixed dose, pegfilgrastim study conducted in Europe.

Neulasta is a pegylated recombinant protein that stimulates the production of neutrophils that are depleted by cytotoxic chemotherapy.

Due to the relatively short time it remains circulating in the blood, filgrastim requires up to two weeks of daily injections following each cycle of chemotherapy. Almost half of chemotherapy patients who receive filgrastim require 10 or more daily injections. With Neulasta, a polyethylene glycol molecule or "PEG" unit is covalently bound to the filgrastim molecule, extending its half-life and causing it to be cleared more slowly from the body mainly through neutrophil and neutrophil precursor-mediated clearance mechanisms. This allows for a single dose per chemotherapy cycle.

Consistent with self-regulation through neutrophil-mediated clearance of Neulasta, the drug remains in the blood throughout the time during which a patient is neutropenic -- when it is needed most -- and then is cleared rapidly as neutrophils rise toward normal levels.

Data from two pivotal phase 3 studies in breast cancer patients demonstrated that a single dose of Neulasta provided protection from infection comparable to a median of 11 daily injections of filgrastim, reducing both the duration of severe neutropenia and the frequency of neutropenia with fever.

The clinical trials showed that Neulasta is as safe and well-tolerated as filgrastim. In these clinical trials (n=465), the most common adverse event attributed to Neulasta therapy following chemotherapy was bone pain, which was reported in 26 percent of patients. In most cases, bone pain was mild to moderate, and controlled with non-narcotic analgesics.

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 June 3, 2002, and expressly disclaims any duty to update information contained in this press release.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology. Amgen is headquartered in Thousand Oaks, CA, USA, with European headquarters in Lucerne, Switzerland.

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