Phase 3 Study Shows First-Cycle Administration of Neulasta Significantly Lowers Incidence of Infection and Hospitalization

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Study Evaluates 928 Breast Cancer Patients Receiving
Neulasta(R) In The First and Subsequent Cycles of Moderately
Myelosuppressive Chemotherapy

Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced data from a Phase 3 study showing that administration of Neulasta(R) (pegfilgrastim) in the first and subsequent cycles of chemotherapy significantly lowers the rate of infection, as manifested by febrile neutropenia (low white blood cell count with fever), hospitalization and the use of intravenous anti-infectives in breast cancer patients receiving moderately myelosuppressive (strong) chemotherapy. The results will be presented by one of the study's lead investigators, Lee Schwartzberg, M.D., medical director of The West Clinic, Memphis, Tenn., in a plenary session tomorrow at the Multinational Association of Supportive Care in Cancer (MASCC) Annual Meeting. (MASCC Abstract #A-52)

"This study provides compelling evidence that administering Neulasta in the first and subsequent cycles of moderately myelosuppressive chemotherapy can significantly reduce the risk of potentially life-threatening infections that can result in hospitalizations and require IV antibiotics," said Schwartzberg. "Approximately 600,000 chemotherapy patients are at risk for developing neutropenia, which has traditionally been treated reactively. Doctors usually reserve proactive use of Neulasta for only those patients considered at very high risk of developing chemotherapy-induced neutropenia."

Data from the randomized, double-blind, placebo-controlled study of 928 patients show that first and subsequent-cycle administration of Neulasta resulted in a 94 percent reduction in the incidence of febrile neutropenia, a 93 percent reduction in the incidence of hospitalization and an 80 percent reduction in the incidence of intravenous anti-infective use in patients previously considered at moderate risk for neutropenic complications.

Specifically, one percent of patients in the Neulasta arm (6/463) developed febrile neutropenia compared with 17 percent of patients in the placebo arm (78/465). Neulasta was also associated with a significantly lower incidence of hospitalizations with one percent of patients (6/463) requiring hospitalization versus 14 percent of patients receiving placebo (64/465). Two percent of patients in the Neulasta arm (7/463) required intravenous anti-infectives versus 10 percent of patients in the placebo arm (48/465). Febrile neutropenia occurred most often in placebo patients during the first cycle of chemotherapy (65 percent). There were two deaths from septic shock on the placebo arm compared to zero in the Neulasta arm.

"This study may give physicians the evidence they need to help protect cancer patients from chemotherapy-induced neutropenic complications beginning in the first cycle of chemotherapy treatment," added Schwartzberg.

Breast cancer patients (Stage 1-4; ECOG performance of 0-2) receiving 100 mg/m2 docetaxel every three weeks for up to four cycles were randomized to receive either 6 mg Neulasta (n=463) or placebo (n=465) once-per-cycle on the day after docetaxel administration for up to four cycles. Docetaxel is associated with an average reported febrile neutropenia incidence of approximately 10 to 20 percent in the absence of growth factor support. Febrile neutropenia was defined as a temperature greater than or equal to 38.2 degrees C and an absolute neutrophil count (ANC) less than 0.5 x 109/L measured the same day or the day after fever was documented.

Neulasta was well-tolerated in this study. Bone pain was the most frequently observed adverse event in both arms of the study (31 percent with Neulasta versus 27 percent with placebo). A lower percentage of serious adverse events were reported for Neulasta patients compared with placebo patients (12 percent versus 24 percent); this difference was attributable to the lower percentage of febrile neutropenia events reported in Neulasta patients compared with placebo patients.

About Neulasta

Neulasta was approved by the U.S. Food and Drug Administration in 2002 for decreasing the incidence of infection, as manifested by chemotherapy-induced neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs with a clinically significant incidence of febrile neutropenia. Similar indications for Neulasta were approved in Europe and Australia the same year.

In clinical studies, 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. The only serious adverse event not attributed to the underlying disease or chemotherapy was a case of hypoxia. In postmarketing experience, allergic reaction has been reported rarely, and splenic rupture, very rarely. While not reported in patients receiving Neulasta, rare events of adult respiratory distress syndrome and sickle cell crisis have been reported in patients receiving the parent compound, NEUPOGEN(R) (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 Statements

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended December 31, 2003, and in our 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. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing our products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. In addition, sales of our products are affected by reimbursement policies imposed by first 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 US legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We, or others could identify side effects or manufacturing problems with our products after they are on the market. 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. Discovery or identification of new product candidates cannot be guaranteed and 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. 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. Further, some raw materials, medical devices, and component parts for our products are supplied by sole first party suppliers.

Full prescribing information for Neulasta is available 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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