Amgen Announces Results From Phase 3 PAVES Study Evaluating Neulasta® (pegfilgrastim) In Patients With Colorectal Cancer

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Study Shows Neulasta Reduced the Incidence of Febrile Neutropenia in Patients With Colorectal Cancer Receiving FOLFOX or FOLFIRI and Bevacizumab

THOUSAND OAKS, Calif., Jan. 26, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today results from Pegfilgrastim and Anti-VEGF Evaluation Study (PAVES), a Phase 3 trial which evaluated Neulasta® (pegfilgrastim) in 845 patients receiving FOLFOX or FOLFIRI and bevacizumab for the first-line treatment of locally-advanced or metastatic colorectal cancer. FOLFOX and FOLFIRI are two of the most commonly used chemotherapy regimens for colorectal cancer.

The study met its primary endpoint, with Neulasta significantly reducing the incidence of febrile neutropenia. Febrile neutropenia is a low white blood cell count accompanied by a fever.[1] In the study, the incidence of grade 3 or 4 febrile neutropenia in patients receiving Neulasta across the first four cycles of chemotherapy was 2.4 percent compared to 5.7 percent in the placebo group (OR=0.41, *p*=0.014). A similar incidence of grade 3 or higher adverse events was seen in both arms of the trial (28 percent placebo; 27 percent Neulasta).

"This analysis showed that PAVES met its primary endpoint, with Neulasta significantly reducing the incidence of febrile neutropenia in patients with colorectal cancer," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "In addition to providing new data on Neulasta, we believe PAVES will provide valuable information to the oncology community on commonly-used chemotherapy regimens."

Full results will be presented on Saturday, Jan. 26 during the 2013 Gastrointestinal Cancers Symposium, General Poster Session C (C1) by Tamas Pinter, M.D., the PAVES principal investigator, Aladar Korhaz Hospital, Onkoradiologiai Osztaly, Gyor, Hungary (Late Breaking Abstract No. 445).

Follow-up results of PAVES looking at additional endpoints, including mature data on overall survival, overall response rate, time to progression and progression-free survival, will be presented at a future date.

About PAVES

PAVES is a Phase 3, randomized, double-blind, placebo-controlled trial evaluating Neulasta in 845 patients receiving FOLFOX or FOLFIRI and bevacizumab for the first-line treatment of locally-advanced or metastatic colorectal cancer. The trial was multicenter and multinational. All patients received treatment with either FOLFOX or FOLFIRI plus bevacizumab and were randomized to one of two treatment arms that also received either placebo or 6 mg of Neulasta at least 24 hours after each cycle of chemotherapy. The primary endpoint was the incidence of grade 3 or 4 febrile neutropenia during the first four cycles. The study was not designed to define the febrile neutropenia rate of FOLFOX or FOLFIRI plus bevacizumab. Other endpoints include overall response rate, progression-free survival, overall survival, time to progression and adverse events.

About Febrile Neutropenia

One of the most common side effects of myelosuppressive chemotherapy is a low white blood cell count.[2] An abnormally low level of neutrophils, an important infection-fighting white blood cell, is called neutropenia.[2] The fewer neutrophils a patient has – and the longer the neutrophil count remains low – the greater the risk of developing a potentially serious infection.[2, 3]

Febrile neutropenia is neutropenia complicated by a fever.[1] Fever is frequently a sign of infection and, in patients receiving myelosuppressive chemotherapy, it can sometimes be the only sign.[2] Febrile neutropenia is a medical emergency and is associated with several potential downstream consequences.[2, 4]

About Neulasta

Neulasta was approved by the U.S. Food and Drug Administration (FDA) in 2002 to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.[5] Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or Filgrastim.

Fatal splenic rupture can occur. Evaluate for splenomegaly or splenic rupture in patients with left upper abdominal or shoulder pain. Acute respiratory distress syndrome (ARDS) can occur. Evaluate for ARDS in patients who develop fever, lung infiltrates, or respiratory distress. Discontinue Neulasta in patients with ARDS. Serious allergic reactions, including anaphylaxis, can occur. Permanently discontinue Neulasta in patients with serious allergic reactions. Severe and sometimes fatal sickle cell crises have been reported.

Most common adverse reactions (≥ 5% difference in incidence) in placebo-controlled clinical trials are bone pain and pain in extremity.

To see the full Neulasta Safety Information, visit www.amgen.com/medpro/products.html.

About Amgen

Amgen discovers, develops, manufactures 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, bone disease and other serious illnesses. With a deep and broad 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. Follow us on www.twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Jan. 26, 2013, and expressly disclaims any duty to update information contained in this news release.

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 safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' 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 relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (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.

CONTACT: Amgen, Thousand Oaks
Ashleigh Koss, 805-313-6151 (media)
Arvind Sood, 805-447-1060 (investors)

[1] Dictionary of Cancer Terms: Febrile Neutropenia. National Cancer Institute website. Available at www.cancer.gov/dictionary?CdrID=415543. Accessed January 7, 2013.

[2] "Chemotherapy and You" brochure. National Cancer Institute website. www.cancer.gov/cancertopics/coping/chemotherapy-and-you/page7#SE8. Accessed January 7, 2013.

[3] Bodey GP, et al. *Ann Intern Med.* 1966;64: 328–340.

[4] Kuderer N, et al. *Cancer.* 2006: 2006;106:2258–66.

[5] Neulasta® (pegfilgrastim) prescribing information, Amgen.

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