



First Patients Dosed with Amgen's AMG 162 In Phase 3 Studies for Postmenopausal Osteoporosis and Treatment-Induced Bone Loss

August 10, 2004

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Aug. 10, 2004--Amgen Inc. (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the first patients have been dosed in two pivotal Phase 3 trials of AMG 162, the company's fully human monoclonal antibody being investigated for potential use in postmenopausal osteoporosis and treatment-induced bone loss (TIBL).

AMG 162 is an investigational, fully human monoclonal antibody that specifically binds to and inhibits RANK Ligand, the primary mediator of bone resorption. Amgen scientists have confirmed that RANK Ligand is the protein responsible for activating osteoclasts, the cells that break down bone. Excessive RANK Ligand has been linked as the primary cause of a broad range of bone loss conditions including osteoporosis, treatment-induced bone loss, bone erosions in rheumatoid arthritis (RA), and bone metastases, all of which are being investigated by Amgen. AMG 162 is being investigated for its impact on RANK Ligand and the potential to protect against bone loss.

"Many different factors can lead to bone loss, but they all converge on the RANK Ligand pathway," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development, Amgen. "In earlier trials, AMG 162 has demonstrated that it is a potent and fast-acting inhibitor of osteoclasts which may impact a number of bone loss conditions; we are pleased to be simultaneously moving a potentially important therapeutic into pivotal studies in two distinct diseases."

About Osteoporosis

Osteoporosis is a disease that causes bones to become brittle and susceptible to fracture. According to the International Osteoporosis Foundation, approximately 200 million women worldwide currently suffer from osteoporosis. Of those, nearly half will experience a related fracture that may significantly limit mobility, preventing an active and independent lifestyle, or that may even shorten lifespan.

About Treatment-Induced Bone Loss

Treatment-induced bone loss (TIBL) includes bone loss associated with the use of glucocorticoids, immunosuppressives and hormone ablative therapies. The prevalence of TIBL in the U.S. is estimated to be around 290,000, however only a small fraction of these patients receive treatment.

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 Amgen's Form 10-K for the year ended December 31, 2003, and in Amgen's 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. 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 side effects or manufacturing problems with our products after they are on the market.

In addition, sales of our products are affected by the availability of reimbursement and the reimbursement policies imposed by third 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 U.S. legislation affecting pharmaceutical pricing and reimbursement. Government 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 it 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 related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of

the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, 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
Andrea Rothschild, 805-447-4587 (media)
Laura Biswas, 805-447-1060 (investors)

SOURCE: Amgen