Amgen's Phase 2 Study of GDNF for Advanced Parkinson's Disease Fails to Meet Primary Endpoint; Six Months of Treatment Showed Biological Effect But No Clinical Improvement

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THOUSAND OAKS, Calif.--(BUSINESS WIRE)--June 28, 2004--Amgen (Nasdaq:AMGN), the world's largest biotechnology company, today announced that the Phase 2 study of its novel glial cell line-derived neurotrophic factor, or GDNF, for the treatment of advanced Parkinson's disease did not meet the primary study endpoint upon completion of six months of the double-blind treatment phase of the study. In the study, GDNF was safe and well-tolerated.

The Phase 2 randomized, double-blind placebo-controlled study involved 34 patients with advanced Parkinson's disease who received direct, continuous infusion of GDNF into the putamen, a region of the brain known to be affected by Parkinson's disease. The primary endpoint of the study was improvement of symptoms as defined by the Unified Parkinson's Disease Rating Scale, a measurement tool that assesses the status of patients suffering from Parkinson's disease. Initial analysis of the preliminary data showed no clinical improvement compared to placebo following six months of treatment, despite evidence of alteration in brain function. All patients in the trial are receiving GDNF in an open label extension study.

"We are currently analyzing the data to understand why this study differs from the long-term improvement of the patients, who have been treated with GDNF for close to three years in an ongoing open-label study being conducted in the United Kingdom," said Beth Seidenberg, M.D., chief medical officer and senior vice president, Amgen. "We are committed to understanding if a different approach, including evaluating a higher dose, may yield an outcome that is consistent with the open label study."

Further details about the trial will be available when all data analyses are complete. Data from the study are being submitted for presentation at the annual meeting of the American Neurological Association in October.

Amgen's recombinant GDNF protein is a duplicate of a naturally occurring GDNF found in the central nervous system that promotes the growth, regeneration and protection of specific nervous tissue.

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.

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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