Denosumab Osteoporosis Study Met Primary and All Secondary Bone Mineral Density Endpoints in a Head-to-Head Comparison with Weekly Alendronate (FOSAMAX(R))

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THOUSAND OAKS, Calif., Jan 24, 2008 (BUSINESS WIRE) -- Amgen (NASDAQ:AMGN) today announced findings from a head-to-head, double-blind study comparing the effects of twice-yearly subcutaneous injections of denosumab versus weekly oral doses of alendronate (FOSAMAX(R)) on bone mineral density (BMD) in postmenopausal women with low bone mineral density. The study met primary and all secondary endpoints.

In this one-year, non-pivotal study, denosumab treatment achieved significantly greater BMD gains at the total hip, hip trochanter and distal radius compared with alendronate. For the primary endpoint, the relative magnitude of BMD improvement at the total hip was approximately 40 percent greater in the denosumab versus the alendronate group. The changes in BMD in the alendronate group were consistent with previously reported studies.

The incidence and types of adverse events observed in this study were similar between the denosumab and alendronate treatment groups. The most common adverse events across both treatment arms were arthralgia, back pain, constipation and dyspepsia.

"We are very encouraged by the results of this head-to-head study directly comparing denosumab with alendronate, a widely used osteoporosis treatment," said Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "The complete analysis of data from this trial will be presented in a peer-reviewed forum later this year. In addition, we are looking forward with great anticipation to the results of our large, pivotal Phase 3 registrational study evaluating the ability of denosumab to reduce fracture risk in women with post-menopausal osteoporosis.

Study Design

A total of 1,189 women with postmenopausal osteoporosis were randomized 1:1 to receive denosumab or alendronate and followed for one year to assess changes in BMD. The study primary endpoint was to evaluate the effect of denosumab on percent change from baseline in BMD at the total hip compared to alendronate. Secondary endpoints were to evaluate the effect of denosumab on percent change from baseline in BMD at the lumbar spine, hip trochanter, femoral neck and distal radius compared to alendronate.

About Denosumab

Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, the essential mediator of osteoclasts (the cells that break down bone). Denosumab inhibits all stages of osteoclast activity through a targeted mechanism that does not incorporate into bone matrix. Denosumab is being studied in a range of bone loss conditions including postmenopausal osteoporosis, rheumatoid arthritis, cancer treatment-induced bone loss (in breast cancer and prostate cancer patients), as well as for its potential to delay bone metastases and inhibit and treat bone destruction across many stages of cancer.

About Amgen

Amgen discovers, develops 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, 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.

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 Dec. 14, 2007 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 health care cost containment as well as United States (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 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 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.

FOSAMAX is a registered trademark of Merck & Co., Inc.

SOURCE: Amgen

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