# Amgen Announces Phase 2 Study Results for Brodalumab in Moderate to Severe Plaque Psoriasis Published in the New England Journal of Medicine

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**Brodalumab Moving Into Phase 3 for Moderate to Severe Psoriasis**

THOUSAND OAKS, Calif., March 28, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today that results from a Phase 2 trial evaluating the safety and efficacy of brodalumab (formerly AMG 827) in 198 patients with moderate to severe plaque psoriasis were published in the *New England Journal of Medicine*. The 12-week, dose-ranging study achieved its primary endpoint with the mean percentage improvement in psoriasis area and severity index (PASI) score higher in all brodalumab groups compared to placebo ($p<0.001$). Brodalumab is a human monoclonal antibody that selectively binds to and blocks signaling via the interleukin-17 (IL-17) receptor, thereby stopping the binding of several IL-17 family members associated with psoriasis. The majority of subjects treated with brodalumab 210 mg every other week achieved total clearance of their skin disease (PASI 100 of 62 percent).

PASI score is a measure of psoriatic plaque redness, scaling and thickness and the extent of involvement in each region of the body. Treatment efficacy is often measured by the reduction of PASI from baseline (i.e., a 75 percent reduction is known as PASI 75, a 90 percent reduction is known as PASI 90 and a PASI 100 is total clearance of skin disease).

"There are a variety of treatment options available to those living with psoriasis, yet these options are unable to help many patients achieve their therapeutic goals," explained Kim Papp, M.D., Ph.D., the study's lead author and director at Probity Medical Research, Ontario, Canada. "In this Phase 2 study, brodalumab showed a high level of response in patients with moderate to severe plaque psoriasis with a rapid onset of action within days. Based on these results, additional clinical trials are warranted to further assess the safety and efficacy of brodalumab."

Psoriasis affects approximately 125 million people worldwide and is a chronic disease of the immune system that causes the skin cells to grow at an accelerated rate. Although there are several types of psoriasis, approximately 80 percent of patients have plaque psoriasis, which can cause painful and itchy red, scaly patches to appear on the skin.

**Detailed Results**
In this study, treatment with brodalumab every other week resulted in mean improvements in PASI scores of 85.9 percent (140 mg), 86.3 percent (210 mg) and 45.0 percent (70 mg) versus 16.0 percent with placebo (all $p<0.001$). A monthly dose of brodalumab at 280 mg was associated with a mean PASI improvement of 76 percent. Approximately 30 percent of patients in the placebo group had worsening psoriasis.

The study also evaluated secondary endpoints including PASI 75, PASI 90 and PASI 100, which indicate 75 percent, 90 percent and 100 percent reductions in patient PASI scores from baseline, respectively. In patients dosed with 140 mg of brodalumab, 77 percent achieved a 75 percent reduction in their PASI score, 72 percent achieved a 90 percent reduction and 38 percent experienced total clearance (PASI 100) (all $p<0.001$). In patients dosed with 210 mg of brodalumab, 82 percent achieved a 75 percent reduction, 75 percent achieved a 90 percent reduction and 62 percent experienced total clearance (PASI 100) (all $p<0.001$).

The most commonly reported adverse events in the combined brodalumab groups were common cold (eight percent), upper respiratory tract infection (eight percent) and injection site redness (six percent). Two cases of grade three neutropenia were reported in the 210 mg brodalumab group.

**Study Design**
The study was a Phase 2, randomized, double-blind, placebo-controlled, dose-ranging trial designed to assess the efficacy and safety of brodalumab in moderate to severe plaque psoriasis. Patients with a PASI ≥12 and affected body surface area ≥10 percent were randomized to receive brodalumab (70, 140 or 210 mg at day one and weeks 1, 2, 4, 6, 8 and 10 or 280 mg monthly) or placebo.

**About Brodalumab (AMG 827)**
Brodalumab (AMG 827) is a highly-selective human monoclonal antibody that binds to and blocks signaling via the IL-17 receptor. The IL-17 pathway plays an important role in inducing and promoting inflammatory disease processes.

Brodalumab is the only investigational treatment in development that blocks the IL-17 *receptor*, thereby blocking several of the IL-17 ligands at once from sending signals to the body. Currently, other agents in development seek to target the individual IL-17 *ligands*. By stopping IL-17 ligands from binding with the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation and other ailments.

Brodalumab is currently being investigated for the treatment of psoriasis (Phase 2 and planned Phase 3), psoriatic arthritis (Phase 2) and asthma (Phase 2).

**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 http://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 March 28, 2012 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 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. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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