# Amgen Presents First Phase 2 Data For AMG 334 In The Prevention Of Episodic Migraine

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**Patients Reported Significant Reductions in Monthly Migraine Days in First Dose-Ranging Study of CGRP Receptor Antagonist**

**Episodic Migraine Program Expected to Move into Phase 3 in 2015**

THOUSAND OAKS, Calif., May 15, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the first results from its global Phase 2, double-blind, placebo-controlled study evaluating the efficacy and safety of AMG 334 for the prevention of episodic migraine. The study met its primary endpoint of reducing monthly mean migraine days compared with placebo. The data were presented at the 17th Congress of the International Headache Society (IHC 2015) in Valencia, Spain.

AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine by inhibiting the calcitonin gene-related peptide (CGRP) receptor that is believed to transmit signals that can cause incapacitating pain.

In the trial, 483 patients were randomized to subcutaneous monthly placebo or AMG 334 (7 mg, 21 mg or 70 mg) in a 3:2:2:2 ratio, respectively. Patients had a mean baseline of 8.7 migraine days per month. The primary endpoint was the change from baseline in monthly migraine days at week 12. Patients randomized to the 70 mg dose group observed a statistically significant 3.4-day reduction in monthly migraine days compared with 2.28 days observed in the placebo group ($p$=0.021).

"Migraine is a complicated, underdiagnosed neurological condition that has significant impact on the everyday activities of those who live with it, and for the millions of people around the world who are affected by this disease, significant unmet therapeutic need persists," said Sean E. Harper, M.D., executive vice president, Research and Development at Amgen. "We are encouraged by these Phase 2 data, which further validate AMG 334 as a potential preventive treatment for episodic migraine."

Secondary study endpoints included a 50 percent responder rate, monthly migraine attacks, and safety and tolerability. Key exploratory endpoints included change in monthly headache days and change in monthly acute migraine-specific medication use days. AMG 334 demonstrated a statistically significant increase in the 50 percent responder rate compared with placebo (47 percent vs. 30 percent, respectively). Furthermore, reductions in monthly headache days (-3.54 vs. -2.39) and monthly migraine-specific medication use days (-1.64 vs. -.69) were also statistically significant in patients taking the 70 mg AMG 334 dose compared with placebo, respectively.

The dose tolerability profile of AMG 334 was similar to placebo across all dosing groups. The most commonly reported adverse events included fatigue, influenza, nasopharyngitis, arthralgia and back pain. No Grade 4 or 5 adverse events were reported.

**About Migraine**

Migraine has been declared one of the top 10 most disabling conditions in the world, with more than 10 percent of the worldwide population suffering from the condition.[1] More complex than just a headache, migraines involve incapacitating head pain and physical impairment, frequently accompanied by nausea, vomiting, and aura-related sound or other sensory disturbances.[2] Migraine has a tremendous impact on patients' everyday lives, including work productivity and social interactions.[3,4] Approximately 50 percent of people living with migraine will go undiagnosed.[5]

**About AMG 334**

AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 inhibits the CGRP receptor, rather than CGRP itself, which is believed to transmit signals that can cause incapacitating pain.

AMG 334 is currently under investigation in several large global, randomized, double-blind, placebo-controlled studies to evaluate its safety and efficacy in migraine prevention.

**About Amgen**

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

**Forward-Looking Statements**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen, we or us) 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 reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'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, we are providing this information as of May 15, 2015, and expressly

disclaim 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 and our partners 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 product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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 (including products of our wholly-owned subsidiaries) are affected by the reimbursement policies imposed by third-party payers, 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 and our partners routinely obtain patents for our and their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' 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. Our efforts to integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase common stock.

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, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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