Amgen Presents Open-Label Extension Data From Ongoing Phase 2 Study Of AMG 334 In The Prevention Of Episodic Migraine

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Patients Experienced Sustained Reductions in Monthly Migraine Days and Consistent Safety Profile From Blinded Phase at 52 Weeks

Nearly 1 in 5 Patients Saw 100 Percent Reduction in Monthly Migraine Days at One Year

THOUSAND OAKS, Calif., June 19, 2015 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced positive interim results from its open-label extension of the global Phase 2, double-blind, placebo-controlled study evaluating the safety and efficacy of AMG 334 for the prevention of episodic migraine. Patients who entered the open-label phase received AMG 334 70 mg monthly and experienced a sustained reduction in monthly migraine days at week 52. The data were presented at the 57th Annual Scientific Meeting of the American Headache Society (AHS) on June 19, 2015, in Washington, D.C.

At one year, patients receiving AMG 334 70 mg experienced an average of a -4.9-day reduction from a baseline of 8.7 mean monthly migraine days, regardless of treatment received during the blinded phase. The 50 percent responder rate (greater than 50 percent reduction in monthly migraine days) was 62 percent at 52 weeks. Additional responder rates were reported for the first time: at 52 weeks the 75 percent responder rate was 38 percent and the 100 percent responder rate was 19 percent.

"These long-term data further demonstrate that AMG 334 provided meaningful benefit to these patients with fewer migraine days and more days with the ability to participate in work and social activities each month," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The sustained safety and efficacy shown in this interim analysis adds to the growing body of evidence that reinforces the potential of AMG 334 for patients with this debilitating condition. We look forward to advancing the program to help fill an unmet need in migraine prevention."

The open-label portion of the Phase 2 study included 383 patients. All patients received AMG 334 70 mg starting at week 12 for up to 256 weeks. Safety and tolerability were evaluated monthly and this interim analysis includes data up to week 52. Additional efficacy endpoints included the change in monthly migraine-specific medication use days and patient-reported outcomes using the Migraine Disability Assessment (MIDAS) questionnaire.

Patients reported a nearly 50 percent reduction of monthly migraine-specific medication use days of -2 at 52 weeks, from a baseline of 4.3 days per month. In addition to clinical measures, patients self-reported the impact of headache and migraine on their daily activities. At one year, using the MIDAS tool, patients reported an improvement of approximately 12 days over the previous three months in their ability to function in work, home and social situations. According to the Migraine Research Foundation, migraine costs American employers more than $13 billion each year as a result of 113 million lost work days.

The safety and tolerability profile during the open-label phase was similar to that observed in the blinded phase of the study. The most commonly reported adverse events included fatigue, influenza, nasopharyngitis, arthralgia and back pain. No Grade 4 or 5 adverse events were reported. Serious adverse events were reported in 13 patients, one of which was deemed treatment-related. Less than 5 percent of patients discontinued the study during the open-label phase due to adverse events.

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 poses a significant burden to society, costing American employers more than $13 billion each year as a result of 113 million lost work days due to migraine.[3] Migraine also has a tremendous impact on patients' everyday lives, including work productivity and social interactions.[3,4] More than half 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 targets the calcitonin gene-related peptide (CGRP) receptor, which is believed to transmit signals that can cause incapacitating pain.

AMG 334 is currently under evaluation 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 the world's largest independent biotechnology company, 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 June 19, 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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