Amgen Announces Erenumab (AMG 334) Significantly Reduces Patients' Monthly Migraine Days In Phase 2 Study For The Prevention Of Chronic Migraine

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Chronic Migraine Study Meets Primary Endpoint, Demonstrating Efficacy and Safety of Erenumab in Patients With Chronic Migraine Over 12 Weeks of Treatment
Erenumab Co-Developed by Amgen and Novartis

THOUSAND OAKS, Calif., June 8, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced positive top-line results from the global Phase 2 study evaluating the efficacy and safety of erenumab (AMG 334) in chronic migraine prevention. The study met its primary endpoint of change in monthly migraine days. The reduction in migraine days was statistically significant for both the 70 mg and 140 mg doses.

"Migraine is the sixth leading cause of disability worldwide. Three to seven million Americans spend more than half of each month living with the debilitating symptoms of chronic migraine," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These positive results are exciting because they add to the growing body of evidence supporting erenumab for the prevention of migraine. We look forward to Phase 3 episodic migraine data later this year."

At baseline, patients enrolled in this study were experiencing approximately 18 migraine days per month. Patients were randomized to receive either placebo, or one of two erenumab doses — 70 mg or 140 mg — subcutaneously, once monthly. Patients experienced a 6.6-day reduction from baseline in monthly migraine days in each of the erenumab treatment arms as compared to a 4.2-day reduction in the placebo arm, a statistically significant reduction in each erenumab treatment arm.

The safety profile of erenumab was similar to placebo across both treatment arms. No adverse event was reported in greater than five percent of patients treated with erenumab; the most common adverse events were injection site pain, upper respiratory tract infection and nausea.

Additional analyses of these data are ongoing and will be submitted to a future medical meeting and for publication.

About the 20120295 Study
The 20120295 study is a global Phase 2, randomized, 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in chronic migraine prevention. In the study, 667 patients were randomized to receive once-monthly subcutaneous placebo or erenumab (70 mg or 140 mg) in a 3:2:2 ratio, respectively. The primary endpoint was change in monthly migraine days from baseline to the last four weeks of the 12-week treatment phase in patients with chronic migraine (the number of migraine days between weeks 9 and 12). Secondary study endpoints included reduction of at least 50 percent from baseline in monthly migraine days, change from baseline in monthly acute migraine-specific medication days and change from baseline in cumulative monthly headache hours.

About Erenumab
Erenumab is a fully human monoclonal antibody under investigation for the prevention of migraine. Erenumab specifically targets the Calcitonin-Gene-Related-Peptide (CGRP) receptor, which is believed to transmit signals that can cause incapacitating pain. Erenumab is currently under evaluation in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention.

About Migraine
Migraine involves incapacitating head pain and physical impairment, frequently accompanied by nausea, vomiting, and aura-related sound or other sensory disturbances.[1] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated with more than 40 percent of people going undiagnosed.[2,3] In the U.S., between three and seven million Americans suffer from chronic migraine, with at least 15 headache days per month with at least eight days being migraine.[4]

About Amgen and Novartis Neuroscience Collaboration
In August 2015, Amgen entered into a global collaboration with Novartis to jointly develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease (AD). The collaboration focuses on investigational Amgen drugs in the migraine field, including erenumab (currently in Phase 3 studies for episodic migraine and a Phase 2 study for chronic migraine) and AMG 301 (currently in a Phase 1 study for migraine). For the migraine program, Amgen retains commercialization rights in the U.S., Canada and Japan, and Novartis has commercialization rights in Europe and rest of world. Also, the companies are partnering in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. Novartis' oral therapy CNP520 (currently in a Phase 1/2a study for AD) will be the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as follow-on molecules.

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 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. 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, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, 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. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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 results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. 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. Further, 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, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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 our 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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