Amgen Presents Positive Data At EHMTIC 2016 Demonstrating Erenumab Significantly Reduces Monthly Migraine Days In Patients With Chronic Migraine

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Significantly Greater Proportion of Patients on Erenumab Experienced a 50 Percent or More Reduction in Number of Migraine Days Compared to Placebo
Chronic Migraine Patients Experience 15 or More Headache Days per Month
Erenumab is Co-Developed by Amgen and Novartis for the Prevention of Migraine

THOUSAND OAKS, Calif., Sept. 15, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced detailed global Phase 2 results showing erenumab demonstrated a statistically significant reduction in monthly migraine days compared with placebo in patients with chronic migraine. The data will be presented in posters #P057 and #P058 at the 5th European Headache and Migraine Trust International Congress (EHMTIC) in Glasgow, Scotland.

"Chronic migraine patients lose more than half of their life to migraines with 15 or more headache days a month, facing intolerable pain and physical impairment," said Stewart Tepper, M.D., professor of neurology at the Geisel School of Medicine at Dartmouth. "As a neurologist, these findings are exciting because they demonstrate that erenumab could serve as an important new therapy option for reducing the burden of this often-disabling disease."

The study included 667 patients (mean age 42.1, 79.0 percent female) who were randomized to receive either subcutaneous placebo (n=286) or subcutaneous erenumab 70 mg (n=191) or 140 mg (n=190) once a month. Patients had a mean baseline of 18.0 migraine days per month and a mean baseline of 21.1 headache days per month. Patients randomized to both erenumab dose groups experienced a statistically significant 6.6-day reduction from baseline in mean monthly migraine days compared with 4.2 days observed in the placebo group (p<0.001). All endpoint assessments compared the last four weeks of the 12-week treatment phase to baseline.

A reduction of 50 percent or more in number of monthly migraine days was observed in 40 percent and 41 percent (70 mg and 140 mg doses, respectively) of individuals in the erenumab groups at week 12, representing a significantly higher likelihood of response compared to 24 percent of those receiving placebo (both p<0.001). Reductions in monthly acute migraine-specific medication days were 3.5 days and 4.1 days in the 70 mg and 140 mg groups, respectively, representing significant improvements from baseline compared to a 1.6-day reduction in those receiving placebo (both doses p<0.001 versus baseline).

All groups showed numeric improvements in cumulative monthly headache hours. Compared to a 55.2-hour reduction versus baseline in the placebo group, reductions were 64.8 hours for 70 mg erenumab and 74.5 hours for 140 mg erenumab.

In an analysis of exploratory endpoints, both doses of erenumab were associated with significant improvements in health-related quality of life, headache impact, disability, and level of pain interference, compared to placebo.*

"Erenumab is specifically designed to prevent migraine by blocking a receptor that is believed to have a critical role in mediating the incapacitating pain of migraine," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The results from this global chronic migraine study are exciting because they support the efficacy of erenumab for a patient population that has had few therapeutic options. We look forward to advancing erenumab to help provide a potential new treatment option for patients with this debilitating disease."

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 (in placebo, 70 mg erenumab, 140 mg erenumab groups, respectively) were injection site pain (1.1 percent, 3.7 percent, 3.7 percent), upper respiratory tract infection (1.4 percent, 2.6 percent, 3.2 percent) and nausea (2.5 percent, 2.1 percent, 3.2 percent).

The World Health Organization ranks migraine as one of the most debilitating of all illnesses.[1,2] Chronic migraine is the most disabling form of the disease, and is associated with personal and societal burdens of pain, disability and financial cost.[3]

Results from Phase 3 studies investigating erenumab in episodic migraine are expected later this year. Erenumab is being co-developed by Amgen and Novartis. As part of the collaboration, Amgen retains commercialization rights in the U.S., Canada and Japan, and Novartis holds rights in Europe and rest of world.

*Assessment tools for exploratory endpoints including the Headache Impact Test (HIT-6™), the Migraine Disability Assessment (MIDAS), the Migraine-Specific Quality-of-Life Questionnaire (MSQ), and the Patient Reported Outcome Measurement Information System (PROMIS®). Pain Interference Scale Short Form. Exploratory endpoints were not adjusted for multiplicity.

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 nine 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 specifically designed for the prevention of migraine. Erenumab targets and blocks the Calcitonin-Gene-Related-Peptide (CGRP) receptor, thought to be pivotal in the genesis of migraine. Erenumab is currently being studied in several large global,

randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention.

About Migraine
Migraine sufferers face intolerable pain and physical impairment, which is frequently accompanied by nausea, sensitivity to light, noise and other sensations and can cause significant disruption of daily activities.[4] 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.[5,6] In the U.S., approximately 38 million people suffer from migraine: about four million with chronic migraine[4] (experiencing at least 15 headache days per month, of which eight or more days have migraine features) and over 30 million with episodic migraine (less than 15 migraine days a month).[3]

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 as well as open-label studies in episodic and chronic migraine) and AMG 301 (currently in Phase 1). 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 novel 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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