Amgen Announces Erenumab Significantly Reduces Monthly Migraine Days In Patients With Episodic Migraine In Second Phase 3 Study

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STRIVE Study Met its Primary Endpoint, Adding to Body of Episodic Migraine Prevention Data
Migraine Ranked one of the Most Debilitating Diseases by the World Health Organization
Erenumab Co-Developed by Amgen and Novartis

THOUSAND OAKS, Calif., Nov. 16, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced positive top-line results for erenumab from a global Phase 3, randomized, double-blind, placebo-controlled **ST**udy to evaluate the efficacy and safety of erenumab in mig**R**a**I**ne pre**VE**ntion (STRIVE). These data showed the STRIVE study met the primary endpoint, demonstrating statistically significant reductions from baseline in monthly migraine days in patients with episodic migraine treated with either 70 mg or 140 mg erenumab compared with placebo. Erenumab is specifically designed to prevent migraine by blocking the Calcitonin Gene-Related Peptide (CGRP) receptor, which is believed to have a critical role in mediating the incapacitating pain of migraine.

"Migraine is ranked one of the most debilitating diseases by the World Health Organization, yet it is often under-diagnosed and under-treated. People who experience migraine battle the disease for many years and it has significant impact on their everyday activities," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The results of this study are important because they confirm the results from our previous studies and add to our body of research in episodic migraine. We look forward to working with regulatory authorities to pursue approval of erenumab and making this novel migraine prevention treatment available to patients and physicians."

Patients enrolled in STRIVE were randomized to receive either placebo, or one of two erenumab doses – 70 mg or 140 mg – subcutaneously, once monthly for six months. At baseline, patients were experiencing an average of 8.3 migraine days per month. Patients in the erenumab 70 mg and 140 mg treatment arms experienced reductions of 3.2 and 3.7 days from baseline in monthly migraine days, respectively, as compared to a 1.8-day reduction in the placebo arm.These results were statistically significant.

The safety profile of erenumab was comparable to placebo across both treatment arms and was consistent with previously reported studies. The most frequently reported adverse events were nasopharyngitis, upper respiratory tract infection and sinusitis.

Further analysis of STRIVE data is ongoing and will be submitted to a future medical conference and for publication.

Two other positive trials—ARISE, a Phase 3 study of erenumab in episodic migraine prevention, and the Phase 2 study of erenumab in chronic migraine prevention—were announced earlier this year. Combined together, almost 2,200 patients with chronic and episodic migraine have participated in these three erenumab clinical trials. These data will help support discussions with regulatory agencies, with filing anticipated in 2017.

Erenumab is being co-developed by Amgen and Novartis. As part of the collaboration, Amgen retained commercialization rights in the U.S., Canada and Japan, and Novartis has rights in Europe and rest of world.

About STRIVE
STRIVE (20120296) is a global Phase 3, multicenter, randomized 24-week, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in episodic migraine prevention. In the study, 955 patients were randomized to receive once-monthly subcutaneous placebo or erenumab (70 mg or 140 mg) in a 1:1:1 ratio. Patients enrolled in STRIVE were experiencing an average of 8.3 migraine days per month. The primary endpoint was change in mean monthly migraine days from baseline over the last three months of the double-blind treatment phase of the study (months 4, 5, 6). Secondary study endpoints assessed at six months included reduction of at least 50 percent from baseline in mean monthly migraine days, change from baseline in mean monthly acute migraine-specific medication days, and reductions from baseline in both mean impact on everyday activities domain and mean physical impairment domain scores on the Migraine Physical Function Impact Diary (MPFID).

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 being studied in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention.

About Migraine
People with migraine face intolerable pain and physical impairment, which is frequently accompanied by nausea, vomiting and significant disruption of daily activities.[1] The World Health Organization ranks migraine as one of the most debilitating illnesses.[2] 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.[3,4] Worldwide, approximately 90 percent of people diagnosed with migraine have episodic migraine, which is characterized by up to 14 migraine days a month.[5,6] The remaining 10 percent have chronic migraine, which is characterized by at least 15 headache days per month, of which eight or more are migraine days, for more than three months.

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 a Phase 1 study). 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 2 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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