



Amgen Reports Aimovig™ (Erenumab) Met All Primary And Secondary Endpoints In Unique Phase 3b Study In Episodic Migraine Patients Who Have Failed Multiple Prior Preventive Treatments

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LIBERTY is the First Migraine Prevention Trial of its Kind Conducted Specifically in Patients Who Have Tried Multiple Therapies Without Success, and are in Need of Additional Treatment Options

The Trial Met its Primary Endpoint of Percentage of Patients on Aimovig Achieving at Least a 50 Percent Reduction of Migraine Days Versus Placebo, and all Secondary Endpoints

Results Add to the Consistent Efficacy, Safety and Tolerability Profile of Aimovig Across the Spectrum of Migraine, Even in More Difficult to Treat Patients

THOUSAND OAKS, Calif., Jan. 22, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced positive results from the Phase 3b LIBERTY study assessing the efficacy and safety of Aimovig™ (erenumab) 140 mg in patients with episodic migraine who had experienced two to four previous preventive treatment failures, due to lack of efficacy or intolerable side effects. The study met its primary endpoint, with significantly more patients taking Aimovig experiencing at least a 50 percent reduction from baseline in their monthly migraine days as compared to placebo. LIBERTY also met all secondary endpoints, including reduction of monthly migraine days, reduction in days needing acute (rescue) medication, improvement in scores on the Migraine Physical Function Impact Diary (MPFID) tool, and 75 percent and 100 percent responder rates (number of patients experiencing at least a 75 percent or 100 percent reduction in monthly migraine days compared to placebo). The safety data are consistent with previous studies of Aimovig to date. Full data will be presented at an upcoming scientific meeting.

Aimovig is the only investigational fully human monoclonal antibody, designed to selectively block the calcitonin gene-related peptide (CGRP) receptor, which plays a critical role in migraine activation. These results are the first positive placebo-controlled data ever reported in an episodic patient population consisting entirely of those who have tried and failed two to four preventive medications due to lack of efficacy or intolerable side effects.

"We've purposely designed a clinical program for Aimovig that examined a broad spectrum of migraine patients, ranging from those who have never tried a preventive treatment to patients who have tried and failed such treatments," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These data in patients with multiple treatment failures, who are not only considered difficult to treat but also have few options available, add to the consistent body of evidence for Aimovig. We look forward to working with regulators to bring the first preventive option specifically developed for migraine to patients worldwide."

The safety, efficacy and tolerability of Aimovig have been assessed in more than 3,000 patients, including an ongoing open-label extension of up to five years in duration. Aimovig was the first investigational therapy targeting the CGRP pathway to receive U.S. Food and Drug Administration (FDA) and European Medicines Agency regulatory filing acceptance. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of May 17, 2018. If approved, it will be administered once-monthly using a self-injection device. If approved, Novartis and Amgen will co-commercialize Aimovig in the U.S. Amgen has exclusive commercialization rights to the drug in Japan and Novartis has exclusive rights to commercialize in rest of world.

About LIBERTY

LIBERTY (NCT03096834) is a Phase 3b, multicenter, randomized 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in patients with episodic migraine (defined in the trial as four to 14 migraine days per month at baseline) who have failed up to four prior preventive treatments for migraine. In the study, 246 participants with episodic migraine who had two to four previous treatment failures were randomized to receive Aimovig 140 mg or placebo during the 12-week double-blind treatment phase. The primary endpoint was the percentage of patients with at least a 50 percent reduction of monthly migraine days from baseline over the last four weeks of the double-blind treatment phase of the study (weeks 9-12).¹ The study includes an ongoing 52-week open-label extension study.

Secondary endpoints assessed during the same time period included: change from baseline in monthly migraine days, change from baseline in the number of monthly acute migraine-specific medication treatment days, and change from baseline in the MPFID physical impairment and impact on everyday activities domain scores. The MPFID is a scale developed to measure these two domains. The scale has been validated in line with FDA Patient Reported Outcomes Guidance.² Percentages of patients with a 75 percent response rate and 100 percent response rate to erenumab were also assessed as secondary endpoints.

About Aimovig™ (erenumab)

Aimovig is the only treatment specifically designed to prevent migraine by blocking the CGRP receptor, which is associated with migraine activation. Aimovig has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. The safety, efficacy and tolerability of Aimovig has been assessed in more than 3,000 patients, including an ongoing open-label extension of up to five years in duration. Regulatory submissions have been filed in the U.S. and Europe.

About Migraine

People with frequent migraine may lose more than half their life to migraine days.³ Migraine robs individuals of time with their families, productivity at home and at work, and their livelihoods. Migraine sufferers endure debilitating pain, physical impairment, and live in constant dread of the next attack – all of which is compounded by a widespread misperception of the disease.⁴ The World Health Organization ranks migraine as one of the most debilitating illnesses.⁴ For the approximately 10 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.⁵ Approximately 3.5 million of these patients are currently on a preventive therapy, but up to 80 percent discontinue these within one year.^{6,7} Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.

About Amgen and Novartis Neuroscience Collaboration

In August 2015, Amgen entered into a global collaboration with Novartis to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig (Biologics License Application submitted to FDA in May 2017) and AMG 301 (currently in Phase 2 development). In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the U.S. For the migraine programs, Amgen retains exclusive commercialization rights in the U.S. (other than for Aimovig as described as above) and Japan, and Novartis has exclusive commercialization rights in Europe, Canada and rest of world. Also, the companies are collaborating in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in Alzheimer's disease. The oral therapy CNP520 (currently in Phase 3 for Alzheimer's disease) is 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 current reports on 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, including our devices, 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. 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, including Puerto Rico, 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. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. 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.

*The trade name Aimovig™ is provisionally approved for use by the U.S. Food and Drug Administration.


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