Amgen And Novartis Present New Data Demonstrating Long-Term Efficacy, Safety And Tolerability Of Aimovig™ (erenumab-aooe) In Patients With Chronic And Episodic Migraine

June 28, 2018

Results From a One-Year Study of Efficacy and Safety of Aimovig in Chronic Migraine and Data From a Three-Year Analysis Assessing Safety and Tolerability of Aimovig in Episodic Migraine Will be Presented at the American Headache Society Annual Meeting

Aimovig Showed Robust Efficacy in Patients With Chronic Migraine, With Reductions in Monthly Migraine Days Sustained Throughout the Study

Established Safety Profile of Aimovig Reinforced With Chronic and Episodic Migraine Data

THOUSAND OAKS, Calif., June 28, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the results of two open-label extension (OLE) studies of Aimovig™ (erenumab-aooe) in patients with chronic and episodic migraine, respectively, will be presented at the 60th Annual Scientific Meeting of the American Headache Society (AHS) in San Francisco. Results from a one-year study in chronic migraine patients reinforced the established safety and efficacy profile of Aimovig in long-term use. In addition, a three-year interim analysis from an ongoing five-year study of episodic migraine patients, the longest running study of a calcitonin gene-related peptide (CGRP) therapy, reinforced the long-term safety and tolerability of Aimovig. Aimovig is the first and only FDA-approved therapy targeting the CGRP pathway.

In the one-year OLE study in chronic migraine, the primary and secondary outcome measures of the study were long-term safety and efficacy, respectively.[1] The safety results after one year were consistent with the established safety profile of Aimovig in previous studies. The most frequent adverse events (AEs) greater than 2.0 per 100-subject-years were viral upper respiratory tract infection, upper respiratory tract infection, sinusitis, arthralgia and migraine. In the double-blind treatment phase, no differences were observed in the safety events between Aimovig and placebo.

The efficacy data showed sustained benefits up to one year. Patients taking Aimovig 140 mg and 70 mg (based on last dose received) achieved reductions of average monthly migraine days of 10.5 and 8.5 days, respectively, compared to a baseline of 18.1 (at the time of enrollment into the placebo-controlled study, after one year of treatment). Patients treated with Aimovig experienced reductions in monthly migraine days of:

- 50 percent or more: 67 percent on 140 mg and 53 percent on 70 mg
- 75 percent or more: 42 percent on 140 mg and 27 percent on 70 mg
- 100 percent reduction: 13 percent on 140 mg and 6 percent on 70 mg

"These data showing sustained efficacy and consistent safety and tolerability of Aimovig over an extended period of time are important for migraine patients and their clinicians to know," said Stewart J. Tepper, M.D., professor of neurology at the Geisel School of Medicine at Dartmouth Medical School. "Collectively these data reinforce the safety and tolerability of Aimovig, and having a treatment specifically designed for migraine has the potential to truly improve the lives of those living with this neurological disease."

The five-year OLE study in episodic migraine is assessing the long-term safety and tolerability of Aimovig.[2] The results at the three-year interim data analysis showed Aimovig had a safety profile consistent with the spectrum and rate of AEs seen in shorter-term placebo-controlled studies, no new AEs and no new causally-related serious AEs. The most frequent AEs were viral upper respiratory tract infection, upper respiratory tract infection, sinusitis, influenza and back pain. There was no increase in cardiovascular events over time and no meaningful changes in systolic/diastolic blood pressure or heart rate up to the ~3.2-year follow-up.[2]

"On the heels of the recent FDA approval of Aimovig for the preventive treatment of migraine in adults, the results of these open-label extension studies are encouraging as they contribute to a growing and extensive body of evidence that support the use of Aimovig across the spectrum of migraine," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These data underscore our commitment to building robust clinical programs in both chronic and episodic migraine that further demonstrate the clinical utility of Aimovig. Our underlying goal is to improve the lives of people living with this debilitating disease."

Additional data in patients with chronic migraine are being presented at the AHS meeting, including long-term efficacy of Aimovig in patients with overuse of acute medication, long-term efficacy of Aimovig in patients who failed prior prophylactic treatment, and efficacy of Aimovig at varying dosage strengths in the Phase 3 STRIVE study.

About the Open-Label Extension Study in Chronic Migraine

After the 12-week randomized, double-blind placebo-controlled parent study, eligible patients could enroll in the OLE study. 451 patients completed the study receiving either Aimovig 70 mg, 140 mg or changing from 70 mg to 140 mg during the course of the study.[1] Of the 609 patients who enrolled in the study, 199 increased their dose from 70 mg to 140 mg by week 28.[1]

The primary outcome measure of the study was long-term safety. The secondary outcome measure was efficacy, as determined by four measures: change from baseline to week 52 in monthly migraine days (MMD), monthly acute migraine-specific medication days, monthly cumulative hours of headache, and proportion of patients achieving at least a 50 percent reduction in MMD.

About the Open-Label Extension Study in Episodic Migraine

Following a 12-week randomized, placebo-controlled phase of a (Phase 2) study of Aimovig in adults with episodic migraine, patients could continue into the open-label extension phase, initially receiving 70 mg Aimovig monthly. A protocol amendment increased the dosage to 140 mg monthly to assess long-term safety of the higher dose. Safety and tolerability were assessed by monitoring AEs, electrocardiograms, laboratory assessments and vital signs. Of the 383 patients who enrolled in the open-label extension, 235 patients (61.3 percent) remained in the OLE study at the data cutoff point for this interim analysis, all having received Aimovig for at least three years. The study is continuing for up to five years of treatment.

Safety and efficacy data after four and five years of treatment will be reported in the future.

About Aimovig™ (erenumab-aooe)
Aimovig is the only FDA-approved treatment specifically developed to prevent migraine by blocking the CGRP-R, which is associated with migraine. Aimovig has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its efficacy and safety in migraine prevention. More than 3,000 patients have participated in the Aimovig clinical program across four placebo-controlled Phase 2 and Phase 3 clinical studies and their open-label extensions.

U.S. Aimovig Indication

Aimovig is indicated for the preventive treatment of migraine in adults.

U.S. Aimovig Important Safety Information

- The most common adverse reactions in clinical studies (≥ 3% of Aimovig™-treated patients and more often than placebo) were injection site reactions and constipation.

Please visit www.amgen.com or www.aimovig.com for Full U.S. Prescribing Information.

About Migraine
People with frequent migraine may lose more than half their life to migraine. They 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.[3] The 2016 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[4] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.[3]

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 (approved by the FDA in May 2018 for the preventive treatment of migraine in adults) 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 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. At the center of the Amgen and Novartis neuroscience collaboration is the shared mission to fight migraine and the stereotypes and misperceptions surrounding this debilitating disease.

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. 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. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by several 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Andrea Fassacesia, 805-905-2575 (media)
Arvind Sood, 805-447-1060 (investors)

References

[1] Tepper S, et al. Assessment of the Long-Term Safety and Efficacy of Erenumab During Open-Label Treatment of Subjects With Chronic Migraine. Data presented at 60th Annual Scientific Meeting of the American Headache Society, San Francisco, June 2018.

[2] Ashina M, et al. Long-term Safety and Tolerability of Erenumab: Three-plus Year Results from an Ongoing Open-Label Extension Study in Episodic Migraine. Data presented at 60th Annual Scientific Meeting of the American Headache Society, San Francisco, June 2018.

[3] Lipton RB, et al. Migraine prevalence, disease burden, and the need for preventative therapy. *Neurology.* 2007; 68(5):343-9.

[4] GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet.* 2017;388:1545-1602.

View original content with multimedia:http://www.prnewswire.com/news-releases/amgen-and-novartis-present-new-data-demonstrating-long-term-efficacy-safety-and-tolerability-of-aimovig-erenumab-aooe-in-patients-with-chronic-and-episodic-migraine-300674373.html

SOURCE Amgen