Amgen To Highlight Extensive Long-Term Safety And Efficacy Data Of Aimovig® (erenumab-aooe) Across The Spectrum Of Migraine At AAN Annual Meeting

May 2, 2019

After Long-Term Aimovig Treatment, Two-Thirds of Chronic Migraine Patients Converted to Episodic Migraine, Experiencing 11 Fewer Migraine Days per Month on Average

Separate Study Showed the Majority of Episodic Migraine Patients on Aimovig Reported at Least a 50 Percent Reduction in Monthly Migraine Days at One Year, With One in Five Being Completely Migraine-Free

Aimovig is the Most Prescribed Anti-CGRP Therapy - Approximately 200,000 Patients in the U.S. Have Been Prescribed Aimovig Since Launch[1]

THOUSAND OAKS, Calif., May 2, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present new long-term data of Aimovig® (erenumab-aooe) across the migraine spectrum at the 2019 American Academy of Neurology (AAN) Annual Meeting in Philadelphia. Data from a one-year open-label extension (OLE) trial following a three-month double blind study in patients with chronic migraine (15 or more headache days per month) showed sustained efficacy and safety in this patient population, including a potential for conversion to episodic migraine (4-14 headache days a month). Additionally, one-year results of the Phase 3 STRIVE study reinforced the sustained efficacy and safety profile of Aimovig in patients with episodic migraine, including patients who had tried and failed prior preventive treatments.

Migraine is a highly debilitating disease that has a profound and limiting impact on peoples' lives, including time spent with family and friends, or at work.[2,3] Aimovig, co-commercialized in the U.S. by Amgen and Novartis, is the first and only FDA-approved treatment that prevents migraine by targeting the calcitonin gene-related peptide (CGRP) receptor. It is self-administered once monthly via the SureClick® autoinjector, does not require a loading dose and is easy to use.[1]

"We are pleased to see new efficacy and safety results for Aimovig, which was the first CGRP therapy approved by the FDA in May 2018 and has the longest post-approval treatment experience of any CGRP therapy," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "These long-term results further establish the benefit of Aimovig across the spectrum of patients with migraine."

Data in Chronic Migraine

An exploratory analysis of one-year OLE data from the pivotal study evaluating the efficacy and safety of Aimovig in chronic migraine prevention assessed the conversion rate from chronic to episodic migraine.[4] The results at 52 weeks showed more than two-thirds of patients with chronic migraine on Aimovig converted to episodic migraine by the last dose received. Patients converting to episodic migraine showed a reduction of 11 monthly migraine days (MMD) at week 52, from a baseline of 17 MMD. Both doses had high conversion rates, with the Aimovig 140 mg dose numerically higher (76 percent) compared to Aimovig 70 mg (69 percent).

"Millions of people with chronic migraine spend at least half of each month living with the debilitating symptoms of this disease," said Stewart Tepper, M.D., Neurology Professor at the Geisel School of Medicine at Dartmouth Medical School. "We are encouraged by these new findings, which show that long-term erenumab treatment increases the likelihood that a patient with chronic migraine will experience a meaningful reduction in migraine days."

Further data from the study evaluating the long-term efficacy and safety results of Aimovig in patients with chronic migraine during open-label treatment are being presented at AAN.

Data in Episodic Migraine

One-year results of the Phase 3 STRIVE study (including 24-week double-blind phase and 28-week active treatment phase [ATP]) showed Aimovig provided sustained efficacy in the prevention of episodic migraine and a safety profile comparable to that observed in prior studies.[5]

At week 52, patients receiving Aimovig 70 mg or 140 mg from week 24 onward had an average of 4.2 and 4.6 fewer MMD, respectively, compared to study baseline (8.3 MMD). They also continued to experience improvements during the ATP (1.1 and 1.8 fewer MMD, respectively). In addition, an analysis of responder rates from baseline showed more than six out of 10 patients on either dose of Aimovig had 50 percent fewer MMD; around four out of 10 had 75 percent fewer MMD; and one in five were migraine-free at week 52.

Additional data from STRIVE and the OLE phase of the LIBERTY study in patients taking Aimovig with episodic migraine who had failed prior preventive treatments are being presented at AAN.

About the Open-Label Extension Study in Chronic Migraine

The OLE of the pivotal parent study (NCT02066415) was a 52-week, multicenter study (OLE, NCT02174861) evaluating the long-term efficacy and safety of Aimovig in chronic migraine prevention in patients taking Aimovig 70 mg and 140 mg. Patients initially enrolled received 70 mg of Aimovig monthly. The protocol was amended for patients to receive 140 mg of Aimovig. Patients who had completed the week-28 visit at the time of the amendment continued to receive Aimovig 70 mg, and patients who had enrolled but had not completed the week-28 visit at the time of the amendment increased from 70 mg to 140 mg of Aimovig at the next visit such that these patients would have the opportunity to receive at least six months of Aimovig 140 mg during the 52-week study. All patients who enrolled after the amendment received Aimovig 140 mg throughout the study.

Proportions of episodic migraine converters/nonconverters based on observed data were summarized throughout the OLE (overall population) and by last dose received (70 mg or 140 mg). Efficacy data were collected at weeks 1–12, 21–24, 37–40, and 49–52; endpoints included change from parent study baseline in monthly migraine days (MMD) and proportion of patients with ≥50 percent reduction from parent study baseline in MMD.

About STRIVE

STRIVE (Study to Evaluate the Efficacy and Safety of Erenumab in Migraine Prevention, NCT02456740) is a global Phase 3, multicenter, randomized

24-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in episodic migraine (characterized in this study as ≥4 to <15 migraine days per month and <15 headache days per month on average across the three months before screening) prevention. In the study, 955 patients were randomized to receive once-monthly subcutaneous placebo, or Aimovig (70 mg or 140 mg) in a 1:1:1 ratio. Patients experienced between four and 14 migraine days each month, with an average of 8.3 migraine days per month at baseline. 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 and 6). Secondary study endpoints assessed included reduction of at least 50 percent from baseline in mean MMD, change from baseline in mean monthly acute migraine-specific medication days, and changes from baseline in both mean impact on everyday activities domain and mean physical impairment domain scores on the Migraine Physical Function Impact Diary (MPFID).

At week-24 (ATP baseline), 845 patients were re-randomized (1:1) to Aimovig 70 mg or 140 mg for the subsequent 28-week dose-blinded ATP. Assessments included MMD; monthly acute migraine-specific medication days (MSMD); proportion of patients achieving a ≥50 percent, ≥75 percent, and 100 percent reduction in MMD (responder rates: RR); and safety.

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.

INDICATION
Aimovig® (erenumab-aooe) is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION
Contraindication: Aimovig® is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Reactions have included anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, angioedema, and anaphylaxis, have been reported with Aimovig® in post marketing experience. Most reactions were not serious and occurred within hours of administration, although some occurred more than one week after administration. If a serious or severe reaction occurs, discontinue Aimovig® and initiate appropriate therapy.

Adverse Reactions: 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 see Aimovig® full 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 2017 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[6] 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). 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.

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 its 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. While Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

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