Amgen Announces Five-Year Data That Reinforce The Safety And Efficacy Profile Of Aimovig® (erenumab-aooe) In Adult Patients With Episodic Migraine

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Results Presented at the Migraine Trust Virtual Symposium Highlight Long-Term Benefit of Aimovig

Aimovig Has the Longest Duration of Safety and Efficacy Trial Data for Any Anti-CGRP Pathway Therapy

Five-Year Open-label Extension Study Shows Patients Continued to Experience a Sustained Benefit; Aimovig Maintained a Consistent Safety Profile

THOUSAND OAKS, Calif., Oct. 3, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that results reinforcing the long-term safety and efficacy profile of Aimovig® (erenumab-aooe) in patients with episodic migraine (EM) are being presented at the Migraine Trust Virtual Symposium. Results from the five-year, open-label treatment period of a Phase 2 study in episodic migraine prevention (NCT01952574) showed Aimovig helped patients achieve sustained reductions in monthly migraine days (MMD) and in use of acute migraine-specific medication (AMSM), such as triptans. Additionally, the safety profile was consistent with what was observed in the double-blind treatment phase of the study, with no increases in adverse event rates over five years of exposure.[1]

"These important data highlight the sustained efficacy, safety and tolerability profile of Aimovig, and provide crucial information for patients and doctors managing migraine," said Dr. Messoud Ashina, professor of neurology in the Faculty of Health and Medical Sciences at the University of Copenhagen. "The study reinforces the potential of Aimovig to reduce monthly migraine days over the long term for people living with this debilitating, yet underdiagnosed disease. For my patients, more migraine-free days means they're able to get back to the things that are important to them, like spending more time with family and friends, and being able to go to work."[1-4]

The five-year, open-label treatment phase enrolled 383 patients with episodic migraine who completed a 12-week double-blind, placebo-controlled treatment period (DBTP).[1] Among the 216 patients who completed the open-label treatment phase, there was an average MMD reduction of 5.3 days from the DBTP baseline of 8.7 days.[1] By the end of the study, patients who used AMSM to treat their migraine headaches experienced an average reduction in AMSM use of 4.4 days from the DBTP baseline of 6.2 days.[1] The most common side effects were nasopharyngitis, upper respiratory tract infection, and influenza.[1]

"Aimovig continues to have the longest safety and efficacy trial data among treatments for migraine in the calcitonin gene-related peptide class of medications," said Darryl Sleep, M.D., senior vice president, Global Medical, and chief medical officer at Amgen. "Many people with this debilitating neurological disease live in dread of the next attack.[3] As the first FDA-approved treatment and most prescribed preventive therapy in this class, Aimovig continues to be at the forefront of preventive migraine treatment and clinical research.[5,6] These long-term results further demonstrate the potential of Aimovig to help the millions of patients who may be candidates for preventive treatment."[1,2,7,8]

Additional studies highlighting Aimovig will be presented at the Migraine Trust Virtual Symposium, including interim results of the LIBERTY open-label extension study, as well as efficacy and safety results of Aimovig in the EMPOwER study. These studies reinforce the safety and efficacy profile of Aimovig for patients of various backgrounds across the episodic migraine spectrum.

- Interim two-year results of the open-label extension study of the LIBERTY study (NCT03096834) showed sustained efficacy and no increases in adverse events rates for patients with episodic migraine taking Aimovig who failed 2-4 prior preventive treatments.[9]
- Results of the Phase 3 EMPOwER study (NCT03333109) highlighted the efficacy and safety of Aimovig in adult patients with episodic migraine from Asia, the Middle East and Latin America.[10,11]

About the Open Label Extension Phase of the Phase 2 Study in Episodic Migraine Prevention (NCT01952574)
After a 12-week randomized, double-blind, placebo-controlled period, 383 eligible adult patients with episodic migraine (defined in the trial as 4 to 14 migraine days and less than 15 headache days per month at baseline) were enrolled in the open-label treatment phase.[1,12] All patients initially received 70 mg Aimovig monthly, with 250 patients increasing their dosage to 140 mg monthly after a protocol amendment to assess long-term safety of the higher dose.[1,12,13] Safety and tolerability were assessed by monitoring adverse events, electrocardiograms, laboratory assessments, and vital signs.[1]

No new safety signals or increases in adverse event rates were observed over five years of exposure with Aimovig as compared to the DBTP, in which the safety and tolerability profiles of Aimovig were in line with other clinical trial data.[1] The most common side effects were nasopharyngitis, upper respiratory tract infection, and influenza.

About Aimovig® (erenumab-aooe)
Aimovig, co-marketed in the U.S. by Amgen and Novartis, is the first and only FDA and EMA-approved migraine preventive treatment that targets the calcitonin gene-related peptide (CGRP) receptor, which is associated with migraine.[5,14] Aimovig has been studied in several large, global, randomized, double-blind, placebo-controlled studies to assess its efficacy and safety in migraine prevention.[15,16] Aimovig is self-administered once monthly via the easy-to-use SureClick® autoinjector, without a required loading dose.[16] More than 3,000 patients participated in registrational trials of Aimovig across four placebo-controlled Phase 2 and Phase 3 clinical studies and their open-label extensions.[1,9,10,15,16]

Aimovig is also being evaluated through CATALYST, a comprehensive evidence generation program initiated by Amgen and Novartis that includes over 7,500 patients across 14 ongoing clinical trials and a robust assessment of real-world evidence. Spanning over 39 countries globally, CATALYST clinical trials will explore the role of Aimovig in comparative studies, assessing impact on novel migraine outcomes, understanding predictive biomarkers and expanding Aimovig's use in additional study populations. To date, more than 440,000 patients across 44 countries worldwide have been prescribed Aimovig for the preventive treatment of migraine in adults.[18]

AIMOVIG 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.

Constipation with Serious Complications: Constipation with serious complications has been reported following the use of Aimovig® in the postmarketing setting. There were cases that required hospitalization, including cases where surgery was necessary. The onset of constipation was reported after the first dose in a majority of these cases, but patients also reported later on in treatment. Aimovig® was discontinued in most reported cases. Constipation was one of the most common (up to 3%) adverse reactions reported in clinical studies.

Monitor patients treated with Aimovig® for severe constipation and manage as clinically appropriate. Concurrent use of medications associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

Hypertension: Development of hypertension and worsening of pre-existing hypertension have been reported following the use of Aimovig® in the postmarketing setting. Many of the patients had pre-existing hypertension or risk factors for hypertension. There were cases requiring pharmacological treatment and, in some cases, hospitalization. Hypertension may occur at any time during treatment but was most frequently reported within seven days of dose administration. In the majority of the cases, the onset or worsening of hypertension was reported after the first dose. Aimovig® was discontinued in many of the reported cases.

Monitor patients treated with Aimovig® for new-onset hypertension, or worsening of pre-existing hypertension, and consider whether discontinuation of Aimovig® is warranted if evaluation fails to establish an alternative etiology.

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 attacks may lose more than half their life to migraine.[12] One attack could last up to three days.[12] 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.[3,19] The 2017 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[20] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.[2,4]

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. 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).[5] 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. 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 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.

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla® (apremilast) acquisition (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), as well as 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, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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 in 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. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. 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, 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 collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology 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 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. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

Any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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