FDA Approves Aimovig™ (erenumab-aooe), A Novel Treatment Developed Specifically For Migraine Prevention

May 17, 2018

Migraine is a Severe Neurologic Disease That Profoundly Impacts Millions of Patients in the United States

Aimovig is the First and Only FDA-Approved Treatment to Block the Calcitonin Gene-Related Peptide Receptor (CGRP-R), Which Plays an Important Role in Migraine

Aimovig was Consistently Shown to Reduce Monthly Migraine Days, Including in More Difficult-to-Treat Populations, With Many Patients Achieving at Least a 50 Percent Reduction

THOUSAND OAKS, Calif., May 17, 2018 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved Aimovig™ (erenumab-aooe) for the preventive treatment of migraine in adults. Aimovig is a novel therapeutic approach as the first and only FDA-approved treatment specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R) – which is believed to play a critical role in migraine. Aimovig 70 mg is self-administered once monthly via Amgen's device, the SureClick® autoinjector, and does not require a loading dose. Some patients may benefit from a dosage of 140 mg once monthly.

To view the Multimedia News Release, go to: https://www.multivu.com/players/English/8004556-amgen-aimovig-fda-approval/.

"Migraine is a serious neurological disease that has dramatic effects on patients' lives. Migraine patients experience excruciating headache pain, often accompanied by other symptoms such as nausea and vomiting, and many live in constant dread of the next attack," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The FDA approval of Aimovig represents a long-awaited and important therapeutic development for patients and their physicians who are in need of additional treatment options for the prevention of migraine."

In Phase 2 and 3 studies in chronic and episodic migraine, Aimovig resulted in significant reductions in monthly migraine days and use of acute migraine medications compared to placebo. These effects on monthly migraine days have been shown to be sustained for up to 15 months in an ongoing open-label extension study in episodic migraine (four to 14 headache days per month).

A dedicated Phase 3b study (LIBERTY) in difficult-to-treat populations – those with episodic migraine who have failed two to four prior treatments – showed that patients taking Aimovig had nearly three-fold higher odds of having their migraine days cut by half or more compared to placebo.

The efficacy, tolerability and safety of Aimovig has been assessed in more than 3,000 patients, including LIBERTY and an ongoing open-label extension of up to five years in duration. In clinical studies of Aimovig, the most common adverse reactions were injection site reactions and constipation.

"Having a treatment designed to specifically address the complex nature of migraine is an important and welcome step forward in headache medicine. Aimovig offers self-administration with proven efficacy across a spectrum of patients, including in those who have previously tried other preventive therapies without success," said Stewart J. Tepper, M.D., professor of neurology at the Geisel School of Medicine at Dartmouth Medical School. "Importantly, in clinical trials, Aimovig patients were able to start and stay on therapy – with a discontinuation rate of two percent due to adverse events – and experienced sustained migraine prevention."

"For years, the migraine community has been advocating for new treatment options that are specifically designed to treat migraine, a debilitating and often stigmatized disease," said Kevin Lenaburg, executive director of the Coalition For Headache And Migraine Patients (CHAMP), which represents 12 national headache and migraine patient advocacy groups. "Today we celebrate the tireless work of researchers to better understand the biology of migraine and their ability to bring a new therapeutic approach to the millions of Americans who are seeking fewer migraine days. On behalf of the community, we would also like to thank the thousands of clinical trial patients whose unwavering commitment made this progress possible."

Amgen and Novartis are committed to supporting the migraine community and to helping appropriate patients with affordable access to Aimovig. The Aimovig Ally ™product support program has been created to help patients navigate insurance coverage and identify potential access resources for those who are uninsured or underinsured.

The U.S. list price of Aimovig is $575 for once monthly 70 or 140 mg single-use prefilled SureClick® autoinjector(s), or $6,900 annually. The price of Aimovig reflects the value it brings to patients and society, including the financial impact on sufferers, caregivers and employers, while also factoring in critical issues such as patient affordability, and fair and timely access.

While out-of-pocket costs will vary depending on insurance status, the Aimovig Copay Program may be able to help reduce a patient's out-of-pocket costs to as little as $5 per month for eligible patients with commercial insurance. For more information about Aimovig Ally™ and the Aimovig Copay Program, please visit www.aimovig.com.

Aimovig is expected to be available to patients within one week.

"In addition to bringing a new therapeutic option to patients in the U.S., Amgen also has a commitment to reshape the public's perception of this stigmatized disease," said Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen. "We have pledged a mission to help change misconceptions, stereotyping and even judgment that people with migraine face on a daily basis. Through educational programs and initiatives, we hope to promote more meaningful connectivity and dialogue among patients, physicians, employers and payers."

The European Medicines Agency (EMA) Marketing Authorization Application (MAA) for Aimovig is under review. The companies expect approval in the EU in the coming months.

Amgen to Webcast Investor Call on Aimovig FDA Approval

Amgen will host a webcast call for the investment community on Friday, May 18, 2018, at 6 a.m. PT / 9 a.m. ET. Anthony C. Hooper, executive vice

president of Global Commercial Operations at Amgen, and Paul Hudson, chief executive officer of Novartis Pharmaceuticals, will participate to discuss the recent FDA approval of Aimovig.

Live audio of the investor call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

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.

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]

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.[2] The 2016 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[3] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.[2]

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 the Amgen and Novartis Migraine Mission
Migraine has gone under-appreciated and under-treated for too long. In addition to bringing Aimovig to market, Amgen and Novartis have committed to leading the charge together against migraine misperceptions. Through outreach and education our goal is to challenge public perception of migraine disease, assist people in getting the treatment they need and facilitate informed communication among people with migraine and those who live and work with them, including co-workers, employers and insurers. Future initiatives will include a focus on addressing how stigma against migraine manifests in the workplace: migraine gets in between people and their careers, and in between employee and employer. We hope our workplace program will serve as an example to coworkers, employers and human resources to help each party understand why and how they should treat migraine as a serious 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.

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.

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