New Data Demonstrate Aimovig™ (erenumab) Reduced Monthly Migraine Days In Patients Who Failed Previous Preventive Therapies

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Aimovig Reduced Monthly Migraine Days for Patients With Chronic Migraine and Prior Treatment Failure, a Population With Significant Unmet Need

Results From New Dedicated Cardiovascular Study Support Overall Safety Profile Observed in Aimovig Clinical Study Program

Aimovig is the Only Investigational Biologic Product Specifically Designed to Prevent Migraine by Blocking the CGRP Receptor, Which is Associated With Migraine Activation

THOUSAND OAKS, Calif., Sept. 7, 2017 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new data in patients with high unmet need, providing further evidence of the efficacy of Aimovig™* (erenumab) for migraine prevention. Aimovig is the first and only investigational biologic product specifically designed to prevent migraine by blocking the calcitonin gene-related peptide (CGRP) receptor, which is associated in migraine activation. The data include a pre-planned sub-analysis from the pivotal Phase 2 chronic migraine study, demonstrating that Aimovig reduced the number of monthly migraine days (MMDs) in patients who have failed previous preventive therapies. Additionally, results from a dedicated study in patients with stable angina adds further support to the safety profile of Aimovig. These results will be presented at the 18th Congress of the International Headache Society in Vancouver, Canada.

"Data from our robust clinical development program continue to show that Aimovig has demonstrated efficacy in a broad range of patients, including hard-to-treat chronic migraine sufferers who have previously tried and failed other preventive therapies," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Separately, new results from a treadmill safety study showed no adverse cardiovascular effect compared to placebo in patients with coronary artery disease and stable angina, which complements our extensive safety database and ongoing long-term extension studies of Aimovig for migraine prevention."

Studies have shown that up to 80 percent of people with migraine discontinue preventive treatment within one year. In a pre-specified sub-analysis from the Phase 2 study, Aimovig showed benefits for people with chronic migraine who have previously tried and failed preventive treatments. At the end of the 12-week study, patients who had failed two or more prior preventive treatments experienced a reduction of 7.0 days and 5.4 days in the Aimovig 140 mg and 70 mg, respectively, compared to placebo reduction of 2.7 days (p<0.001). Furthermore, in the Aimovig treated arms, the odds of cutting migraine days in at least half was three-to-four fold higher than in the placebo arm (140 mg: 41.3 percent, 70 mg: 35.6 percent, placebo: 14.2 percent (p<0.001 for both doses versus placebo).

The safety profile of Aimovig was similar to placebo across both treatment arms in the Phase 2 study. No adverse event was reported in greater than five percent of patients treated with Aimovig; the most common adverse events were injection site pain, upper respiratory tract infection and nausea.

Aimovig was tested in a group of patients with stable angina due to coronary artery disease. A treadmill "stress test" is often used to gauge how well a patient's heart can handle exercise. The study met it primary endpoint of noninferiority, showing no difference in exercise time among participants receiving Aimovig or placebo. The treatment difference in mean change from baseline in exercise time was –11.0 seconds (90 percent confidence interval –44.9, 22.9). In addition, no significant differences were seen between the two groups in time to onset of angina or time to onset of electrocardiogram change consistent with onset of myocardial ischemia. Adverse events were reported in 27 percent of patients receiving Aimovig and in 32 percent of patients receiving placebo. The most frequent treatment-emergent adverse events (reported in >2 percent of patients) were headache (4.5 percent) and viral upper respiratory infection (4.5 percent) in the Aimovig group, and were hypotension (4.5 percent), influenza (4.5 percent) and viral infection (4.5 percent) in the placebo group.

"While the community has watched the next generation of migraine preventives with excitement, because CGRP has a vasodilatory effect, there have been questions about a potential impact on cardiovascular function especially in at-risk populations," said Amaal J. Starling, M.D., assistant professor of neurology at the Mayo Clinic in Scottsdale, Ariz., and a study co-author. "The results of this study provide some evidence that CGRP receptor inhibition did not aggravate myocardial ischemia in at-risk population of patients with stable angina compared to placebo and contribute to the growing body of evidence supporting the safety profile of Aimovig."

These results are consistent with the known safety profile of Aimovig, as seen across the broad clinical program involving more than 2,600 migraine patients.

Regulatory submissions for Aimovig have been filed in the United States (U.S.) and Europe. The U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) target action date of May 17, 2018. 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 Aimovig™ (erenumab)

Aimovig is the only investigational biologic product 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. More than 2,600 patients have been exposed to Aimovig across the four placebo-controlled Phase 2 and Phase 3 clinical studies and their open-label extension.

About the Phase 2 Study

The 20120295 study is a global Phase 2, randomized, 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in chronic migraine prevention. In the study, 667 patients were randomized to receive once-monthly subcutaneous placebo or Aimovig (70 mg or 140 mg) in a 3:2:2 ratio, respectively. The primary endpoint was change in MMDs from baseline to the last four weeks of the 12-week treatment phase in

patients with chronic migraine (the number of migraine days between weeks nine and 12). Secondary study endpoints included reduction of at least 50 percent from baseline in monthly migraine days, change from baseline in monthly acute migraine-specific medication days and change from baseline in cumulative monthly headache hours.

About the Treadmill Cardiovascular Safety Study

The 20140254 study is a double-blind, placebo-controlled cardiovascular safety study in patients with stable angina due to documented coronary artery disease. Patients were randomized 1:1 to a single intravenous infusion of Aimovig 140 mg or placebo stratified by baseline treadmill exercise test (TET) (<7 minutes or ≥7 minutes) defined as the average TET of two qualifying exercise tolerance tests (ETTs) performed during screening. Following study drug administration on Day 1, a post-administration ETT was conducted. The primary endpoint was the change from baseline in exercise duration as measured by TET with a non-inferiority margin of –90 seconds. Secondary efficacy endpoints included time to onset of ≥1 mm ST-segment depression and time to onset of exercise-induced angina during the ETT. Safety follow-up visits occurred every 2-4 weeks for 12 weeks. Adverse events were reported by 14 percent of Aimovig-treated patients and by 27 percent of placebo patients and were consistent with the known safety profile of erenumab.

About Migraine

People with frequent migraine may lose more than half their life to migraine days.[1] Migraine robs individuals of time with their families, and impacts their daily activities at home and at work. Migraine patients endure debilitating pain, incapacitating 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 World Health Organization ranks migraine as one of the most debilitating illnesses.[2] For the approximately 10 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.[3] Approximately 3.5 million of these patients are currently on a preventive therapy, but up to 80 percent discontinue these within one year.[3,4] 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

Since 2015, Amgen and Novartis have collaborated to jointly develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease (AD). This includes investigational Amgen drugs in the migraine field, including Aimovig (Biologics License Application accepted by the FDA in July 2017) and AMG 301 (currently in Phase 1 development). In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the U.S. For the migraine program, Amgen retains exclusive rights in Japan, and Novartis has exclusive rights in Europe, Canada and rest of world. The companies are also partnering in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD.

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 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. FDA.

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