



Amgen Presents First-Of-Its-Kind Data At AAN Annual Meeting Reinforcing Robust And Consistent Efficacy Of Aimovig™ (erenumab) For Migraine Patients With Multiple Treatment Failures

April 17, 2018

The LIBERTY Trial was Conducted in Patients who Have Tried Two to Four Therapies Without Success -- a Uniquely Difficult-to-Treat Population Often Excluded From Migraine Prevention Trials

Patients Taking Aimovig had Nearly Three-Fold Higher Odds of Having Their Migraine Days cut by Half or More Compared to Placebo

Safety and Tolerability Were Consistent With Results Seen in the Pivotal Clinical Program; Over 97 Percent of Those Taking Aimovig Completed the Double-Blind Treatment Phase

Data Selected by the American Academy of Neurology Science Committee as one of the Most Noteworthy Presentations at 2018 Annual Meeting

THOUSAND OAKS, Calif., April 17, 2018 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced full results from the Phase 3b LIBERTY trial of Aimovig™ (erenumab) in episodic migraine patients who had previously failed two to four preventive treatments, due to lack of efficacy or to intolerable side effects.¹ The data, which will be presented at the 70th Annual Meeting of the American Academy of Neurology (AAN) in Los Angeles, show the potential of Aimovig as an effective preventive treatment option for these patients, who have tried several treatment options without gaining relief. Aimovig is the only investigational fully human monoclonal antibody under regulatory review that was designed to selectively block the calcitonin gene-related peptide (CGRP) receptor, which plays a critical role in migraine activation. LIBERTY is the first study to investigate a treatment targeting the CGRP pathway specifically in this challenging patient population.

In LIBERTY, 246 patients who had experienced two to four previous preventive treatment failures were randomized to receive monthly subcutaneous injections of either Aimovig 140 mg or placebo for 12 weeks. Patients taking Aimovig had nearly three-fold higher odds of having their migraine days cut by at least 50 percent, with more than twice as many patients taking Aimovig achieving this reduction compared to placebo (weeks 9-12: 30.3 percent with Aimovig, 13.7 percent with placebo, $p < 0.002$, odds ratio 2.73).

"We are encouraged by these new findings, which add to the growing body of clinical evidence supporting potential use of Aimovig across a broad spectrum of patients with migraine, all of whom live with what is considered one of the most disabling diseases," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These data support the overall efficacy and safety profile we have seen consistently during extensive clinical study of Aimovig, and speak to its potential to help fill treatment gaps in more difficult patient populations whose migraine has not been adequately managed with current therapies."

In the study, patients taking Aimovig also had statistically significant and clinically meaningful improvements from baseline compared to placebo across all secondary endpoints:

- Reduction in monthly migraine days
- Decrease in monthly acute migraine-specific drug use
- 75 percent or greater reduction in monthly migraine days
- 100 percent reduction in monthly migraine days
- Improved physical functioning and ability to complete everyday activities as measured by the Migraine Physical Function Impact Diary (MPFID)

Over 97 percent of Aimovig patients completed the double-blind phase of the LIBERTY study. There were no adverse events leading to discontinuation of treatment in the Aimovig group, while 0.8 percent of those in the placebo group experienced adverse events leading to discontinuation of treatment.

"The LIBERTY study distinctively demonstrates the ability of an anti-CGRP receptor antibody to significantly reduce migraine frequency and its associated burden in patients who could not find the relief they need from currently available preventive treatment options," said professor Uwe Reuter, managing medical director at Charité Universitätsmedizin in Berlin. "These compelling data offer new hope of fewer migraine days to those people with migraine who may have cycled through current standard of care unsuccessfully for years due to lack of efficacy and tolerability."

The long-term open label extension phase of the study is ongoing. LIBERTY contributes to an extensive body of evidence, across the spectrum of migraine, in support of the efficacy, safety and tolerability profile of Aimovig. Aimovig has been studied in four placebo-controlled Phase 2 and Phase 3 clinical studies involving more than 3,000 patients and continues to be studied in an ongoing open-label extension for up to five years in duration.

The U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) target action date of May 17, 2018, for Aimovig and the European Medicines Agency has validated the Marketing Authorization Application (MAA) for Aimovig. If approved, it will be administered once-monthly using a self-injection device. If approved, Amgen and Novartis 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 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 The study includes an ongoing 52-week open-label extension study.

Secondary endpoints assessed during the same time period included: change from baseline in monthly migraine days, change from baseline in the number of monthly acute migraine-specific medication treatment days and change from baseline in the Migraine Physical Function Impact Diary (MPFID) physical impairment and impact on everyday activities domain scores. The MPFID is a scale developed to measure these two domains. The scale has been validated in line with FDA Patient Reported Outcomes Guidance.² Percentages of patients with a 75 percent response rate and 100 percent response rate to Aimovig were also assessed as secondary endpoints.

About Aimovig™ (erenumab)

Aimovig is the only investigational treatment under regulatory review that was 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 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 Migraine

People with frequent migraine may lose more than half their life to migraine days. Migraine robs individuals of time with their families, productivity at home and at work, and their livelihoods.³ People with migraine endure debilitating pain and 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 World Health Organization ranks migraine among the top 10 causes of years lived with disability worldwide.⁴ For the approximately 8 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.^{3,5,6} 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 (Biologics License Application submitted to FDA in May 2017) 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.

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 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.

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. Food and Drug Administration.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Kristen Neese, 805-313-8267 (media)
Arvind Sood, 805-447-1060 (investors)

References

- ¹ Reuter, U et al. Efficacy and safety of erenumab in episodic migraine patients with 2–4 prior preventive treatment failures: Results from the Phase 3b LIBERTY study. Emerging science abstract presented at AAN, 24 April 2018, Los Angeles.
- ² Kawata AK et al. Psychometric Evaluation of a Novel Instrument Assessing the Impact of Migraine on Physical Functioning: The Migraine Physical Function Impact Diary. *Headache*. 2017; 57(9) 1385-1398.
- 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.
- ⁵ Buse DC, et al. Chronic migraine prevalence, disability, and sociodemographic factors: results from the American Migraine Prevalence and Prevention Study. *Headache*. 2012; 52(10): 1456-70.
- ⁶ U.S. Census Bureau Age and Sex 2012-2016 Estimates. Available: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_16_5YR_S0101&prodType%20=table.



 View original content with multimedia: <http://www.prnewswire.com/news-releases/amgen-presents-first-of-its-kind-data-at-aan-annual-meeting-reinforcing-robust-and-consistent-efficacy-of-aimovig-erenumab-for-migraine-patients-with-multiple-treatment-failures-300631565.html>

SOURCE Amgen