FDA Accepts Biologics License Application For Aimovig™ (erenumab)

July 20, 2017

Aimovig is an Investigative Migraine-Specific Preventive Therapy Designed for Patients With High Unmet Need
Migraine is Associated With Pain, Disability and Nearly $25 Billion in Annual U.S. Healthcare Costs[1],[2]

THOUSAND OAKS, Calif., July 20, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for Aimovig™ (erenumab) for the prevention of migraine in patients experiencing four or more migraine days per month. If approved, Aimovig is expected to be the first-and-only monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) receptor, specifically designed for the prevention of migraine.

"Migraine is a serious neurological disease that has a substantial economic burden for both patients and the healthcare system, yet it continues to be under recognized and under treated," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are pleased to advance Aimovig, our migraine-specific preventive therapy, to help address the unmet need in this community and potentially mitigate the overall burden of this disease for patients who have already tried other therapeutic options."

The BLA for Aimovig includes data from pivotal studies of more than 2,600 patients experiencing four or more days of migraine per month. Phase 2 and Phase 3 clinical studies of Aimovig versus placebo have demonstrated a reduction in the number of migraine-affected days, disability and acute medication use for patients with episodic and chronic migraine. The safety profile of Aimovig was similar to placebo across all treatment arms in the Phase 2 and Phase 3 studies for up to six months. The most common adverse events across the studies were upper respiratory tract infection, injection site pain, nausea and nasopharyngitis.

The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of May 17, 2018.

Aimovig will be jointly commercialized in the U.S. by Amgen and Novartis.

About Aimovig™ (erenumab)
Aimovig is the only fully human monoclonal antibody specifically designed for the prevention of migraine that has been filed with the FDA. Aimovig specifically inhibits the receptor of the calcitonin gene-related peptide (CGRP), which is thought to play a causal role in migraine pathophysiology. Aimovig has been studied in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention.

About Migraine
Migraine is a distinct neurological disease.[3] People with migraine lose a substantial portion of their lives to this illness, experiencing significant physical impairment, frequently accompanied by head pain, nausea, vomiting and meaningful disruption of daily activities.[3] The World Health Organization ranks migraine as one of the most debilitating illnesses.[4] For the approximately 10 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.[5] Approximately 3.5 million of these patients are currently on a preventive therapy, but up to 80 percent discontinue these within one year.[5,6] 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
In August 2015, Amgen entered into a global collaboration with Novartis to jointly develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease (AD). The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig (BLA 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. Also, the companies are collaborating in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. The oral therapy CNP520 (currently in Phase 3 for AD) 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 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. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. 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 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.

*The trade name Aimovig™ is provisionally approved for use by the U.S. Food and Drug Administration.

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