



Amgen Announces Expanded Commercial Collaboration With Novartis For Erenumab In Migraine

April 24, 2017

Collaboration Designed to Maximize the Launch of First-in-Class Program and to More Effectively Reach People Living With Migraine

THOUSAND OAKS, Calif., April 24, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced an expanded commercial collaboration with Novartis for erenumab, which is being investigated for the prevention of migraine. This expanded commercial collaboration builds on a global neuroscience collaboration in Alzheimer's disease and migraine established in 2015 between Novartis and Amgen. This expanded collaboration leverages Novartis' strong and established presence in neuroscience to more effectively reach people with migraine. The companies have agreed to combine capabilities to co-commercialize erenumab in the U.S. Amgen retains exclusive commercialization rights in Japan. Novartis gains exclusive rights to commercialize erenumab in Canada, and retains its existing commercialization rights in rest of the world. The companies will continue global co-development.

Erenumab is a fully human monoclonal antibody specifically designed to target and block the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to have a critical role in mediating the incapacitating pain of migraine. Positive data from a Phase 2 study and positive top-line results for two Phase 3 studies in migraine prevention were announced in 2016. Detailed results from the Phase 3 studies will be presented at the annual meeting of the American Academy of Neurology and submitted for publication. These data will help support discussions with regulatory agencies, with filing anticipated in the second quarter of 2017.

Under the terms of the agreement, Amgen will receive milestone payments from Novartis expected to begin in 2017. Novartis will share U.S. commercialization costs with Amgen. Amgen will book sales of erenumab in the U.S., and will pay a royalty to Novartis on net sales in the U.S. Novartis will book sales in the rest of the world, excluding Japan, and will pay Amgen royalties on the net sales in those countries. Amgen will book sales in Japan, since it will remain an exclusive territory for the Company. Novartis will assume agreed upon remaining global development costs up to a cap and share global development costs thereafter.

"Migraine is a debilitating disease and today many patients are sub-optimally treated due to tolerability issues with existing therapies," said Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen. "Combining the U.S. capabilities of Amgen and Novartis in preparation for the launch of erenumab can create meaningful value over the life of this first-in-class program by enabling us to more effectively, and perhaps even more rapidly, reach people who live with the impact of migraine on a daily basis."

This is an expansion of a global collaboration with Novartis announced in September 2015 in neuroscience, involving joint development and commercialization of pioneering treatments in the field of Alzheimer's disease and migraine.

About Erenumab

Erenumab is a fully human monoclonal antibody specifically designed for the prevention of migraine. Erenumab targets and blocks the Calcitonin Gene-Related Peptide (CGRP) receptor, thought to be pivotal in the genesis of migraine. Erenumab has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. Positive results from a Phase 2 study and positive top-line data from two Phase 3 studies in migraine prevention were announced in 2016. These data will help support discussions with regulatory agencies, with filings anticipated in 2017.

About Migraine

Migraine is a distinct neurological disease.¹ 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.¹ 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 because of intolerable side effects or limited efficacy.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

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](https://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 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.

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References

1. Migraine Research Foundation. Migraine Fact Sheet. 2015. Available: <http://www.migraineresearchfoundation.org/fact-sheet.html>. Accessed April 7, 2017.
2. World Health Organization. Headache Disorder Fact Sheet. Available: <http://www.who.int/mediacentre/factsheets/fs277/en/>. Accessed April 7, 2017.
3. Lipton RB, et al. Migraine prevalence, disease burden, and the need for preventative therapy. *Neurology*. 2007; 68(5):343-9.
4. Marketscan data on file. 3-24-2017. Ref Type: Data File



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