Amgen Presents Erenumab Data At The 59th Annual Scientific Meeting of the American Headache Society

June 8, 2017

Data From Broad Clinical Program Show Investigational Erenumab is Effective at Preventing Migraine in Patients Experiencing Four or More Migraine Days a Month

THOUSAND OAKS, Calif., June 8, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present 19 scientific abstracts at the 59th Annual Scientific Meeting of the American Headache Society (AHS) held June 8-11 in Boston. These include a new analysis from a pivotal Phase 2 study highlighting the efficacy of erenumab in patients with 15 or more headache days a month (chronic migraine) and a recent history of acute migraine medication overuse. Additionally, Amgen will present detailed clinical results and patient-reported outcomes data from two Phase 3 studies of erenumab, STRIVE and ARISE, for the prevention of migraine in patients who experience between four and 14 headache days a month (episodic migraine).

"Migraine is a disabling disease for many patients. It disrupts daily living and the ability to function and participate in activities with loved ones," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The data from our clinical program demonstrate that erenumab has a sustained effect in significantly reducing the number of days people suffer from migraine each month. Based on the benefit-risk profile seen in clinical studies, erenumab is poised to become the first migraine-specific preventive option blocking the calcitonin gene-related peptide, or CGRP, receptor that could help get many patients back to doing the things they love."

Excessive use of acute pain-relief medications is common among people who suffer from migraine as they desperately try to control the symptoms. Among the patients experiencing 15 or more headache days a month in the erenumab Phase 2 study (n=667), 41 percent met strict criteria for medication overuse. Compared to a 3.5-day reduction in placebo, both dosages of erenumab reduced mean monthly migraine days by 6.6 by the end of the study (both $p<0.001$ versus placebo). Furthermore, days requiring acute pain-relief medications were also significantly reduced in both dosage arms (2.1-day reduction for placebo, compared to 5.4 days for erenumab 70 mg and 4.9 for erenumab 140 mg; both $p<0.001$ versus placebo).

Detailed results from the positive six-month STRIVE study of erenumab 70 mg and 140 mg, and the positive three-month ARISE study of erenumab 70 mg will also be presented at the meeting. These data include both primary and secondary endpoints, evaluating the reduction in monthly migraine days and the percentage of patients who responded to erenumab. Results from STRIVE have been submitted for peer-reviewed publication.

The safety profile of erenumab was similar to placebo across all treatment arms in the Phase 2 and Phase 3 studies. The most common adverse events across the studies were upper respiratory tract infection, injection site pain, nausea and nasopharyngitis.

Erenumab is a human monoclonal antibody specifically designed for the prevention of migraine. Erenumab specifically inhibits the CGRP receptor, believed to play a critical role in mediating the incapacitating pain of migraine. Across the four placebo-controlled Phase 2 and Phase 3 clinical studies, more than 2,600 patients have been exposed to erenumab.

These data support the first submissions in the United States (U.S.) and European Union for a CGRP pathway inhibitor in migraine prevention. In addition, an ongoing extension trial is underway evaluating people with migraine for up to five years.

Amgen and Novartis will co-commercialize erenumab 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.

Amgen-sponsored abstracts at the 2017 Annual Scientific Meeting of the AHS include:

Clinical Studies

- **Early Onset of Efficacy in a Phase 2 Clinical Trial of Erenumab in Patients with Chronic Migraine**
  Poster #PS24, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **A Multicenter, Open-label, Pharmacokinetic Drug Interaction Study of Erenumab (AMG 334) and a Combined Oral Contraceptive in Healthy Female Subjects (Ph1b DDI OC)**
  Poster #PS23, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Chronic Migraine Treatment with Erenumab: Responder Rates**
  Poster #PS33, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Efficacy of Erenumab for the Treatment of Patients with Chronic Migraine in Presence of Medication Overuse**
  Poster #PS32, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Erenumab (AMG 334) in Migraine Prevention: Primary Results of the STRIVE Trial**
  Platform Presentation #IOR04, Saturday, June 10, 8:30 – 8:40 a.m. ET
- **A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Erenumab in Migraine Prevention: Primary Results of the ARISE Trial**
  Poster #PS21, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Erenumab (AMG 334) in Chronic Migraine Prevention**
  Platform Presentation #IOR07, Saturday, June 10, 9 – 9:10 a.m. ET

- **Patient Reported Outcomes in Chronic Migraine Patients Receiving Placebo or Erenumab (AMG 334) in a Phase 2 Randomized, Double-Blind Study**
  Poster #PS34, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Patient-Reported Outcomes from the STRIVE Trial: A Phase 3, Randomized, Double-Blind Study of Erenumab in Subjects with Episodic Migraine**
  Poster #PS35 Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Patient-Reported Outcomes from the ARISE Trial: A Phase 3, Randomized, Double-Blind Study of Erenumab in Subjects with Episodic Migraine**
  Poster #PS22, Saturday, June 10, 6:30 a.m. – 5 p.m. ET

Global Health Economics

- **The Impact of Physical Functioning in Adults with Chronic and Episodic Migraine**
  Poster #PF47, Friday, June 9, 6:30 a.m. – 5 p.m. ET
- **Patient Satisfaction with Current Prophylactic Migraine Medications**
  Poster #PF02, Friday, June 9, 6:30 a.m. – 5 p.m. ET
- **Risk of Cerebrovascular Events in Migraine Patients Treated with Prophylactic Medications**
  Poster #PF66, Friday, June 9, 6:30 a.m. – 5 p.m. ET
- **Development and Psychometric Validation of the Migraine Functional Impact Questionnaire (MFIQ): a New Instrument Measuring the Impact of Migraine on Physical, Social, and Emotional Functioning**
  Poster #PF40, Friday, June 9, 6:30 a.m. – 5 p.m. ET
- **How much change in headache-related disability is clinically meaningful? Estimating minimally important difference (MID) or change in MIDAS using data from the AMPP Study**
  Poster #PF52, Friday, June 9, 6:30 a.m. – 5 p.m. ET
- **Improving Communications Between People with Migraine and Healthcare Professionals for Optimized Migraine Management: A Modified Delphi Approach to Designing a Migraine Tracker App**
  Poster #PS61, Saturday, June 10, 6:30 a.m. – 5 p.m. ET
- **Healthcare Costs and Utilization and Medication Treatment Patterns Among Migraine Patients: A Retrospective Analysis**
  Poster #PS58, Saturday, June 10, 6:30 a.m. – 5 p.m. ET

Center for Observational Research

- **Risk of Cardiovascular Events in Migraine Patients Treated with Prophylactic Medications**
  Poster #PF03, Friday, June 9, 6:30 a.m. – 5 p.m. ET

Late-Breaking Research

- **Effect of Anti-CGRP Receptor Antibody AA58 on CGRP Receptor Internalization and Trafficking**
  Late-Breaking Poster #PF85LB, Friday, June 9, 6:30 a.m. – 5 p.m. ET

About the 20120295 Study
The 20120295 study is a global Phase 2, randomized, 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in chronic migraine prevention. In the study, 667 patients were randomized to receive once-monthly subcutaneous placebo or erenumab (70 mg or 140 mg) in a 3:2:2 ratio, respectively. The primary endpoint was change in monthly migraine days 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 Erenumab Phase 3 Studies
STRIVE (STudy to evaluate the efficacy and safety of erenumab in migRaIne preVEntion, 20120296) is a global Phase 3, multicenter, randomized six-month, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in episodic migraine prevention. In the study, 955 patients were randomized to receive once-monthly subcutaneous placebo or erenumab (70 mg or 140 mg) in a 1:1:1 ratio. Patients enrolled in STRIVE were experiencing an average of 8.3 migraine days per month at baseline. The primary endpoint was change from baseline in mean monthly migraine days over the last three months of the double-blind treatment phase of the study (months 4, 5, 6). Secondary study endpoints included reduction of at least 50 percent from baseline in mean monthly migraine days, change from baseline in mean monthly acute migraine-specific medication days, and reductions from baseline in both mean impact on everyday activities domain and mean physical impairment domain scores on the Migraine Physical Function Impact Diary (MPFID).

ARISE (A Phase 3, RandomIzed, double-blind, placebo-controlled Study to Evaluate the efficacy and safety of erenumab in migraine prevention, 20120297) is a global Phase 3, multicenter, randomized, three-month, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in episodic migraine prevention. In the study, 577 patients were randomized to receive once-monthly subcutaneous placebo or erenumab (70 mg) in a 1:1 ratio. Study participants who completed the double-blinded portion had the option to continue in a long-term safety extension. Patients enrolled in ARISE were experiencing an average 8.3 migraine days each month at baseline. The primary endpoint was change from baseline in monthly migraine days from baseline to the last four weeks of the three-month treatment phase (the number of migraine days between weeks 9 and 12). Secondary study endpoints included reduction of at least 50 percent from baseline in monthly migraine days and change from baseline in monthly acute migraine-specific medication treatment days. The MPFID assessed two other secondary endpoints.

About Erenumab
Erenumab is a human monoclonal antibody specifically designed for the prevention of migraine. Erenumab specifically inhibits the receptor of the calcitonin gene-related peptide (CGRP) which is thought to play a causal role in migraine pathophysiology. Erenumab 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.[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.[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
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 erenumab (Biologics License Application submitted to U.S. FDA in May 2017) and AMG 301 (currently in Phase 1 development). In April 2017, the collaboration was expanded to include co-commercialization of erenumab 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 partnering 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 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. 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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. 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.

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References

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[2]Headache disorders - Fact sheets. World Health Organization. http://www.who.int/mediacentre/factsheets/fs277/en/. Accessed March 3, 2017.
[3]Marketscan data on file. March 31, 2017. Ref Type: Data File
[4]Hepp Z et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. Cephalalgia. 2015; 35(6):478-88.