Amgen And Novartis Announce Expanded Collaboration With Banner Alzheimer's Institute In Pioneering Prevention Program

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Parties to Collaborate on a New Generation Study 2, Assessing Whether Investigational Drug CNP520 Can Prevent or Delay the Symptoms of Alzheimer's Disease

Clinical Trial is Part of the Generation Program, Which Includes Cognitively Healthy People at Genetic Risk of Developing Alzheimer's Disease

Generation Study 2 Aims to Include a Broader High-Risk Population, as Compared to the Ongoing Generation Study 1

44 Million People Globally are Estimated to Have Alzheimer's Disease or a Related Dementia, With One New Case Diagnosed Every Three Seconds(1,2)

THOUSAND OAKS, Calif., Nov. 2, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Novartis today announced an expanded collaboration with the Banner Alzheimer's Institute (BAI) to initiate a new trial – the Alzheimer's Prevention Initiative (API) Generation Study 2. This trial follows the launch of the Generation Study 1, and will determine whether the BACE1 inhibitor CNP520 can prevent or delay the onset of Alzheimer's disease symptoms in a high-risk population. BACE1 is an enzyme that plays an important role in the production of Amyloid β, a protein which accumulates in the brains of individuals with Alzheimer's disease years before clinical symptoms begin. More information on the sites participating in Generation Study 2 can be found at ClinicalTrials.gov and in the website www.GenerationProgram.com.

"As a leader in the challenging fight to unlock the biology of serious illnesses like Alzheimer's disease, we are pleased to support the launch of the Generation Study 2 with our partners at Novartis and Banner Alzheimer's Institute to further explore promising potential therapeutic options for this highly debilitating disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Through the unique combination of genetic testing and counseling in cognitively healthy adults, the Generation Study 2 exhibits an innovative clinical approach that may offer insight towards Alzheimer's prevention for those at highest risk for developing the disease."

The Generation Study 2 started enrolling participants in the United States (U.S.) in August 2017, and will eventually include more than 180 sites in more than 20 countries around the world. This five-year study will recruit approximately 2,000 cognitively healthy participants, ages 60 to 75, who are at high risk of developing Alzheimer's based on their age and who carry either two copies of the apolipoprotein E (APOE) 4 gene or one copy of the gene with evidence of elevated brain amyloid. This is different from the Generation Study 1, which only targeted those who carry two copies of the APOE4 gene. APOE4 is the major genetic risk factor for late-onset Alzheimer's disease. Roughly one in four people carry a single copy of the APOE4 gene, but only about two percent of the world's population carry two copies.[3] Eligible participants will be randomized to receive placebo or one of two doses of CNP520 (15 mg or 50 mg), co-developed by Amgen and Novartis.

"This expanded collaboration builds upon the API Generation Study 1 which launched last year, and is another step in our effort to take clinical trials to a critical new stage," said Pierre N. Tariot, M.D., co-director of API and director of BAI, a division of Banner Health, one of the largest nonprofit healthcare systems in the U.S. "This approach continues to shift the Alzheimer's research paradigm from reversing disease damage to attacking its root cause before symptoms surface. It is our hope that by conducting research targeting the disease at earlier stages, we will have a better chance of delaying or preventing the onset of the disease."

Participants will be recruited via multiple venues, including the Alzheimer's Prevention Registry's GeneMatch program (www.endALZnow.org/GeneMatch) in the U.S. GeneMatch is a first-of-its-kind program designed to identify a large group of people interested in volunteering for Alzheimer's prevention research studies, based in part on their APOE genetic information.

About the Generation Program

The Generation Program consists of two pivotal Phase 2/3 studies. The studies are testing whether investigational anti-amyloid treatments might prevent or delay the emergence of symptoms of Alzheimer's disease in people at particularly high risk for developing the disease at older ages because of their genetic status.

The Generation Study 2 is examining whether the BACE1 inhibitor CNP520 can prevent or delay the onset of the symptoms of the disease in individuals who are at high risk of developing Alzheimer's because of their age and because they carry either one or two copies of the APOE4 gene. Those with one copy will require evidence of elevated brain amyloid.

About Alzheimer's Prevention Initiative

The Alzheimer's Prevention Initiative (API) is an international collaborative research effort formed to launch a new era of Alzheimer's prevention research. Led by the Banner Alzheimer's Institute, the API conducts prevention trials in cognitively healthy people at increased genetic risk for Alzheimer's disease. It will continue to establish the brain imaging, biological and cognitive measurements needed to rapidly test promising prevention therapies and provide registries to support enrollment in future prevention trials. API is intended to provide the scientific means, accelerated approval pathway with the cooperation of the regulatory agencies and enrollment resources needed to evaluate the range of promising Alzheimer's prevention therapies and find ones that work. For more information, go to www.banneralz.org.

About Amgen and Novartis Neuroscience Collaboration

Since 2015, Amgen and Novartis have collaborated to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. This includes investigational Amgen drugs in the migraine field, including Aimovig™ (erenumab) (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 programs, Amgen retains exclusive commercialization rights in the U.S. (other than for Aimovig) and Japan, and Novartis has exclusive commercialization rights in Europe, Canada and rest of world. The companies are also collaborating in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in Alzheimer's disease.

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 in 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. 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. Food and Drug Administration.

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3. Genin et al 2011; Liu at al 2013; Jansen et al 2015

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