Amgen Enters Into Neuroscience Collaboration With Novartis For Alzheimer's Disease And Migraine Programs

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Global Co-Development and Co-Commercialization Agreement in Alzheimer's Disease With Novartis' Phase 1/2a BACE Inhibitor as the Lead

Preventative Treatment Approach Directed at Genetically Predisposed Individuals at Risk of Developing Alzheimer's Disease; Builds on Amgen's Genetic Validation Strategy

Global Co-Development Agreement More Rapidly Advances Amgen's Migraine Programs, Including AMG 334 in Phase 3

Amgen Retains Migraine Commercialization Rights in the U.S., Japan and Canada; Provides Novartis With Rights to Commercialize Migraine Programs in Europe and Rest of World; Leverages Novartis' Strong Commercial Neuroscience Presence

THOUSAND OAKS, Calif., Sept. 1, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced a neuroscience collaboration with Novartis in the areas of Alzheimer's disease and migraine. The collaboration accelerates Amgen's potential entry into Alzheimer's disease by teaming up with Novartis on a differentiated and genetically validated Alzheimer's disease program directed at genetically predisposed individuals at risk of developing Alzheimer's disease. The collaboration also enables Amgen to focus on the commercialization of its migraine programs in the U.S., Canada and Japan, while leveraging Novartis' strong commercial capabilities in neuroscience throughout Europe and other markets worldwide.

The agreement combines each company's BACE (beta-site APP-cleaving enzyme-1) programs targeting Alzheimer's disease into a global co-commercialization and co-development arrangement. Novartis' Phase 1/2a BACE inhibitor (CNP520) will be the lead molecule and each company's pre-clinical BACE inhibitor programs will be potential follow-ons. Amgen will make upfront and milestone payments, and will be responsible for disproportional research and development (R&D) costs for an agreed-upon period followed by a 50/50 cost and profit share arrangement. CNP520 is planned to be included in a pioneering prevention study, in collaboration with the Banner Alzheimer's Institute. Amgen was the first company to clone the BACE gene and subsequent genetic validation of the BACE target has been confirmed by Amgen subsidiary deCODE Genetics.

As part of the collaboration, Novartis receives global co-development rights and commercial rights outside of the U.S., Canada and Japan to the investigative molecules in Amgen's migraine portfolio program. This includes AMG 334 in Phase 3 and AMG 301 in Phase 1, as well as an option to commercialize an additional early-stage Amgen molecule in these territories. In exchange for territory rights, Novartis will fund disproportional amounts of global R&D expenses for an agreed-upon period on the migraine programs and pay Amgen double-digit royalties on sales.

"We are very pleased to be joining forces with Novartis on two important neuroscience programs where there remains high unmet medical need," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Our collaboration on BACE inhibition reflects Amgen's strategic focus on genetically validated drug candidates while our collaboration in migraine creates an opportunity to more rapidly advance AMG 334 on a global scale."

About CNP520

Novartis' CNP520 is an oral drug designed to prevent the production of different forms of amyloid and has the potential to prevent, slow or delay the symptoms associated with Alzheimer's disease. It is currently in Phase 1/2a trials.

About Amgen's BACE Research

BACE (beta-site APP-cleaving enzyme-1) initiates the production of beta amyloid (Ab), the primary constituent of amyloid plaques that are believed to play a key role in the etiology of Alzheimer's disease. It is hypothesized that inhibiting BACE could reduce the production of amyloid plaques. Amgen was the first to clone and characterize BACE in a 1999 *Science* publication.[1] Amgen subsidiary deCODE Genetics subsequently added corroborating human genetic evidence of its link to Alzheimer's disease in a 2012 *Nature* publication.[2] Amgen has a number of preclinical candidates targeting BACE inhibition.

About Novartis' Collaboration with the Banner Alzheimer's Institute

In collaboration with the Banner Alzheimer's Institute (BAI), Novartis is conducting a pioneering prevention study. The study with BAI is part of a ground-breaking research program known as the Alzheimer's Prevention Initiative and will involve more than 1,300 cognitively healthy adults, ages 60 to 75, with a genetic risk of developing symptoms of Alzheimer's disease because they inherited two genetic copies of the apolipoprotein E epsilon 4 (APOE4) allele – one from each parent. About 2 percent of the world's population has this genetic profile, which is strongly linked to late-onset Alzheimer's disease. One in four people carries one copy of the APOE4 gene. Participants in the study will be given either CNP520, CAD106 (not included in the collaboration with Amgen), or placebo. Pending regulatory approval, the study is planned to start in late 2015/early 2016 in sites in North America and Europe.

About Alzheimer's Disease

Alzheimer's disease, the most common type of dementia, is a progressive neurodegenerative disease that begins with microscopic changes in the brain. Alzheimer's disease causes problems with memory, thinking and behavior. Symptoms of the disease develop slowly and worsen over time. Two important components of Alzheimer's disease are amyloid plaques and inflammation, the combination of which is believed to lead to a loss of synapses and neuronal death. The disease continuum can span decades with the initial amyloid accumulation occurring many years before the first signs of memory loss appear. It is estimated that approximately 44 million people globally have Alzheimer's disease or a related dementia.[3] The global direct costs of Alzheimer's disease are estimated to be more than $600 billion.[4]

About AMG 334

AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 targets the calcitonin gene-related peptide (CGRP) receptor, which is believed to transmit signals that can cause incapacitating pain. AMG 334 is currently under evaluation in several large

global, randomized, double-blind, placebo-controlled studies to evaluate its safety and efficacy in migraine prevention.

About AMG 301
AMG 301 is a monoclonal antibody being investigated for the treatment of migraine.

About Migraine
Migraine has been declared one of the top 10 most disabling conditions in the world, with more than 10 percent of the worldwide population suffering from the condition.[5] More complex than just a headache, migraines involve incapacitating head pain and physical impairment, frequently accompanied by nausea, vomiting, and aura-related sound or other sensory disturbances.[6] Migraine also has a tremendous impact on patients' everyday lives, including work productivity and social interactions.[7,8] More than half of people living with migraine will go undiagnosed.[9]

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 biologics manufacturing 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 Inc. and its subsidiaries (Amgen) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. 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 (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of Sept. 1, 2015, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. 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 Amgen and its partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products are affected by the 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of Amgen's products offered by patents and patent applications may be challenged, invalidated or circumvented by its competitors and there can be no guarantee of Amgen's or its partners' ability to obtain or maintain patent protection for Amgen's products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations. Amgen's efforts to integrate the operations of companies it has acquired may not be successful. Amgen may experience difficulties, delays or unexpected costs and not achieve anticipated cost savings from its ongoing restructuring plan. Amgen's business performance could affect or limit the ability of Amgen's Board of Directors to declare a dividend or their ability to pay a dividend or repurchase Amgen common stock.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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