Amgen, Novartis And Banner Alzheimer's Institute Discontinue Clinical Research Program With BACE Inhibitor CNP520 For Alzheimer's Prevention

July 11, 2019

After Review of Clinical Data, the Sponsors Concluded That the Potential Benefit for Participants in the Studies Did Not Outweigh the Risk

THOUSAND OAKS, Calif., July 11, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN), Novartis and Banner Alzheimer's Institute today announced the collective decision to discontinue investigation of the BACE1 inhibitor CNP520 (umibecestat) in two pivotal Phase 2/3 studies in the Alzheimer's Prevention Initiative Generation Program. An assessment of unblinded data during a regular pre-planned review identified worsening in some measures of cognitive function. The sponsors concluded that the potential benefit for participants in the studies did not outweigh the risk.

The Generation Program was designed to research the safety and efficacy of CNP520 for the prevention or delay of the onset of Alzheimer's disease in people at high risk for developing symptoms based on age and their genetic status.

Investigators are being informed of the decision and will be contacting their study participants to discontinue the investigational treatment and discuss next steps, including follow-up appointments as appropriate.

Alzheimer's is a complex disease and one of the largest challenges facing healthcare today. The Generation Program sponsors are grateful to the study participants, their study partners, and the medical community who took part in the Generation Program and made important contributions to advancing Alzheimer's research.

"Our team joins the millions whose lives are impacted by Alzheimer's disease in our disappointment that the Generation Program did not yield a treatment for Alzheimer's disease prevention," said David Reese, M.D., executive vice president of Research and Development at Amgen. "We still believe amyloid plays an important but complex role in Alzheimer's disease. Although the outcomes of the research program did not lead to the results we aimed for, we are committed to sharing our findings to help advance the medical and scientific community one step further toward finding a prevention for this devastating disease."

The study sponsors intend to gain a better understanding of the Generation Program's data upon further analysis. Relevant data will be presented at a future scientific venue to continue to contribute to the increasing body of knowledge in Alzheimer's research.

About the Amgen and Novartis Neuroscience Collaboration
In August 2015, Amgen entered into a global collaboration with Novartis to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease.

The studies are sponsored by Amgen and Novartis, in collaboration with Banner Alzheimer's Institute. Novartis is the regulatory sponsor, while Amgen and Novartis are co-development partners.

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 the world's largest independent biotechnology company, 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.

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 its 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 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 to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. 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 its products, including its devices, after they are on the market.

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