



**EMBARGOED UNTIL NOVEMBER 2 at 4:30 PM ET**

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**Banner Alzheimer's Institute, Novartis, and Amgen Expand Collaboration in Pioneering Alzheimer's Prevention Program**

*Second study to probe whether an investigational drug can prevent or delay the emergence of symptoms in high-risk older adults*

Phoenix, AZ (Nov. 2, 2017)—Researchers from the Banner Alzheimer's Institute (BAI), Novartis, and Amgen today announced another step forward in the international effort to prevent Alzheimer's disease. The new study, known as the Alzheimer's Prevention Initiative (API) Generation Study 2, will focus on high-risk older adults to determine whether an investigational drug can prevent or delay the emergence of symptoms by combatting the accumulation of amyloid plaques, the protein fragments that form between nerve cells in the brain as a prime hallmark of Alzheimer's.

"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, MD, co-director of API and director of BAI, a division of Banner Health, one of the largest nonprofit healthcare systems in the United States. "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 targeting people earlier, we will have a better chance of delaying or preventing the onset of the disease."

The five-year Generation Study 2 will involve more than 2,000 cognitively healthy volunteers, ages 60 to 75, who are at high risk of developing symptoms of Alzheimer's because of their age and because they carry either one or two copies of the e4 type of the apolipoprotein E (APOE) gene, the major genetic risk factor for late-onset Alzheimer's disease. Eligible participants will be randomized to receive one of two doses of the investigational anti-amyloid compound CNP520 (15 mg or 50 mg), co-developed by Novartis Pharmaceutical Corporation and biotechnology company Amgen, or a placebo. The Generation Study 2 began enrolling participants in August and will be conducted at more than 180 sites in more than 20 countries around the world.

Both studies are part of a research effort known as the API Generation Program. The first trial, Generation Study 1, is examining whether two investigational anti-amyloid compounds –

CAD106, an active immunotherapy, and CNP520 – can prevent or delay the emergence of symptoms of Alzheimer’s among higher-risk cognitively healthy older adults who have two copies of the e4 type of the APOE gene, one from each parent.

Roughly one in four people carry a single copy of the e4 type of the APOE gene, but only about two percent of the world’s population carries two copies. The Generation Study 2 will include volunteers with two copies, as well as those with one copy who already show evidence of elevated brain amyloid. Both these groups are at particularly elevated risk of developing symptoms of Alzheimer’s by age 85.

The API Generation Program is the first to incorporate both genetic testing and counseling in addition to amyloid disclosure education into the study screening process. For both studies, prospective participants referred to the trial will be required to learn their APOE test results. Only those who learn they have one or two copies may be eligible to participate in the study. In Generation Study 2, testing will also determine the participant’s amyloid status, which will be disclosed by qualified medical personnel. Genetic counseling will be provided in person or by phone.

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

“An estimated 80 percent of studies fail to meet their recruitment goals, which can delay important research efforts,” said Jessica Langbaum, PhD principal scientist at BAI and associate director of the API. “The GeneMatch program is helping us to identify eligible volunteers for the Generation Study 2 at an accelerated rate, which will be vital to the study’s success.”

Formed in 2011, API is championed by BAI and supported by the National Institutes of Health to accelerate Alzheimer’s prevention research by evaluating the most promising therapies in cognitively normal people who – based on age and genetic background – are at the highest risk of developing Alzheimer’s disease symptoms.

“We are excited about the opportunity to work with our Novartis and Amgen colleagues to further accelerate the evaluation of promising prevention therapies, so it may be possible to find ones that work for the widest range of people at risk for developing Alzheimer’s,” said Eric M. Reiman, MD, API co-director and BAI’s executive director. “Once again, we are also excited about the opportunity that this public-private partnership provides to advance Alzheimer’s prevention research in ways that will have the maximum public benefit.”

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### **About Banner Alzheimer's Institute**

Banner Alzheimer's Institute (BAI) is a nonprofit organization dedicated to the goal of ending Alzheimer's disease without losing another generation. It is helping to launch a new era of Alzheimer's research—detection, treatment and prevention at the pre-symptomatic stage—and to establish a comprehensive model of care that can be the national standard. BAI was founded in 2006 by Phoenix-based Banner Health, one of the country's largest nonprofit healthcare systems. For more information, go to [www.banneralz.org](http://www.banneralz.org).

### **About Alzheimer's Prevention Initiative**

The Alzheimer's Prevention Initiative (API) is an international collaborative formed to launch a new era of Alzheimer's prevention research. Led by the Banner Alzheimer's Institute, the API will conduct 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 and enrollment resources needed to evaluate the range of promising Alzheimer's prevention therapies and find ones that work without losing another generation. For more information, go to [www.banneralz.org](http://www.banneralz.org).

### **About the Generation Program**

The Generation Program consists of two pivotal phase 2/3 studies – Generation Study 1 and Generation Study 2. The trials are testing whether investigational anti-amyloid study medications might prevent or delay the emergence of symptoms of Alzheimer's in people at particularly high risk for developing symptoms of Alzheimer's at older ages because of their genetic status.

These trials are part of a collaboration between Banner Alzheimer's Institute (BAI), Amgen, and Novartis and are part of a groundbreaking research effort known as the Alzheimer's Prevention Initiative (API), an international collaboration formed to further Alzheimer's prevention research.