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Pioneering Alzheimer's Prevention Study Starts Enrolling High-Risk Older Adults

Researchers study whether two new drugs can reduce or eliminate protein linked to Alzheimer's

PHOENIX, AZ (August 23, 2016)—Researchers from the Banner Alzheimer's Institute (BAI) today announced they have begun enrolling the first participants in a multi-site study to determine whether two investigational anti-amyloid compounds—an active immunotherapy and an oral medication—can prevent or delay the emergence of symptoms of Alzheimer's in people identified by genetic markers as being at particularly high risk for developing the disease at older ages.

The five-year Alzheimer's Prevention Initiative (API) Generation Study will involve more than 1,300 cognitively healthy older adults, ages 60 to 75, who are at high risk of developing symptoms of Alzheimer's because they inherited two copies of the e4 type of the apolipoprotein (APOE) gene—one from each parent. Roughly one in four people carry a single copy of the e4 type of the APOE gene, which is strongly linked to late-onset Alzheimer's, and about two percent of the world's population carries two copies.

"Enrolling the first participants into the Generation Study marks a major milestone for the trial and for Alzheimer's prevention research in general," said Pierre N. Tariot, MD, one of the API leaders and director of BAI, a division of Banner Health, one of the largest nonprofit healthcare systems in the United States. "By studying this high-risk population, we hope to assess each treatment's potential to preserve memory and thinking as well as their effects on biological measures of the disease."

The study is sponsored by Novartis, a Swiss pharmaceutical company, and Amgen, a biotechnology company based in Thousand Oaks, CA, in collaboration with BAI, with funding from the National Institute on Aging, part of the National Institutes of Health (NIH), as well as the Alzheimer's Association, FBRI, GHR Foundation and Banner Alzheimer's Foundation.

The Generation Study is part of the API, an international collaborative led by BAI to accelerate the evaluation of promising treatments. It will enroll at about 90 sites across North America,

Europe and Australia, including BAI's headquarters in Phoenix. Since some participants in the study will not yet have brain amyloid deposits at the time they are enrolled, the study can address whether treating before or after this event occurs may be more advantageous.

Study participants will receive either the active immunotherapy (CAD106) developed by Novartis, or the oral medication (CNP520), subject to regulatory approval, developed by Novartis, in collaboration with Amgen, or a placebo. The two drugs will be tested separately and are intended to stop the accumulation of amyloid.

In addition to testing these two investigational treatments in individuals at especially high risk for Alzheimer's, the Generation Study is among the API efforts intended to help find faster ways to test the range of promising treatments in other individuals who, based on their genetic background or biological features, are at increased risk for Alzheimer's, and to provide a public resource of data and biological samples to advance scientific research against this disease.

"We are excited to extend our approach to the evaluation of prevention therapies to individuals at the highest known risk for developing the common form of Alzheimer's that strikes at older ages," said Eric M. Reiman, MD, the other API leader and executive director of BAI. "And, we are excited about the chance to work with our collaborators from Novartis and Amgen, our academic colleagues, and our valued research participants in the effort to find effective prevention therapies as soon as possible."

The API Generation Study is the first to incorporate genetic testing and counseling into the study screening process. Participants will be required to learn whether they carry none, one or two copies of the e4 type of the APOE gene. Only those who learn they have two copies will be invited to participate in the study. The API Generation Study will be providing genetic counseling in person, by phone or through video-conferencing.

"We understand that learning one's genetic risk for Alzheimer's disease may be emotionally impactful," said Jessica Langbaum, PhD, principal scientist at BAI, associate director of API, and principal investigator of GeneMatch. "To support study participants, we will provide them access to trained professionals who specialize in helping people better understand the results of genetic testing."

Participants will be recruited via multiple venues, including the Alzheimer's Prevention Registry's GeneMatch program (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.

The API Generation Study is an important complement to the ongoing API Autosomal Dominant Alzheimer's Disease (ADAD) trial in Colombia, South America, which focuses on cognitively unimpaired members of extended families affected by a rare genetic mutation that makes carriers virtually certain to develop Alzheimer's symptoms by their 40s or 50s.

Alzheimer's is a debilitating and incurable disease that is estimated to affect as many as 5.1 million Americans age 65 and older, and more than 46 million people worldwide.

For more information on the API Generation Study visit www.generationstudy.com.

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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.

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.

About GeneMatch

GeneMatch is a research program of the Alzheimer's Prevention Registry to help identify individuals who are willing to participate in research studies based in part on their APOE genetic information, the major genetic risk factor for late-onset Alzheimer's disease. The program is optional for people who are enrolled in the Alzheimer's Prevention Registry. It will enroll people who are between 55 and 75 years of age, reside in the U.S. and do not have a diagnosis of dementia or other cognitive impairment syndrome. For more information, go to <https://www.endalznw.org/genematch>.