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CONTACT: Alzheimer’s Association AAIC newsroom, 202-249-4002, media@alz.org
Michael Campea, Alzheimer’s Association, 312-978-4372, mcampea@alz.org

LANDMARK 10-YEAR ALZHEIMER’S STUDY
INCREASES PACE OF DISCOVERY

Alzheimer's & Dementia: The Journal of the Alzheimer's Association Publishes Special Issue on Neuroimaging Initiative’s Contributions Toward Advancing Alzheimer’s Drug Therapies

WASHINGTON, D.C., July 17, 2015 – As leading dementia and neuroscience researchers and clinicians converge on Washington, D.C., for the Alzheimer’s Association International Conference 2015 (July 18-23), Alzheimer’s & Dementia: The Journal of the Alzheimer's Association is publishing a special issue today focused on the expansive impact of a preeminent study in Alzheimer’s disease research.

Advancements in treatment for heart disease, stroke and cancer can be traced back to the use of imaging technologies that help to visualize these diseases inside the body. Just a decade ago, physicians and scientists had no way of seeing or measuring the hallmark amyloid brain plaques and tau tangles of Alzheimer’s in people living with the disease. In an effort to change that, the Alzheimer’s Disease Neuroimaging Initiative (ADNI) launched in 2004 to identify and understand markers of Alzheimer’s in body fluids and brain tissue, and measures of memory to improve early diagnosis and accelerate the discovery of new treatments.

Authors representing several core focus areas of ADNI and other related perspectives catalogue a decade of the initiative’s findings and contributions to Alzheimer’s disease research in the Alzheimer's & Dementia ADNI special issue, which publishes on July 17 and features 11 papers, including a foreword and an introduction.

“As we prepare for the largest gathering of leading researchers from around the world focused on Alzheimer's and other dementias, it is an ideal time to reflect on ADNI’s groundbreaking role in advancing Alzheimer’s disease research,” said Maria Carrillo, Ph.D., chief science officer for the Alzheimer’s Association. “Numerous findings being presented at AAIC 2015 involve the use of imaging technologies and other methods for detecting and tracking Alzheimer’s disease in living people that may not have yet been possible without the efforts and findings of ADNI.”
Led by the U.S. National Institutes of Health (NIH) with private sector support driven by the Foundation for the NIH (FNIH), ADNI is a landmark public-private partnership in Alzheimer’s disease research. It was initially funded for $60 million in 2004, with $40 million from the NIH’s National Institute on Aging (NIA) and other NIH institutes and centers, and $20 million from pharmaceutical companies, nonprofits and foundations, including the Alzheimer’s Association and the Alzheimer’s Drug Discovery Foundation. After six years, the initiative was extended by an NIH Grand Opportunities grant for $24 million and was known as ADNI-GO. In 2010 it was competitively renewed as ADNI 2 with $60 million in NIH and private funding.

“ADNI is an innovative model for building public-private collaborations to fund long-term disease studies aimed at ending the devastation wrought by Alzheimer’s,” said Neil Buckholtz, director of the Division of Neuroscience at the NIA, who helped found ADNI and is a co-author of a paper in the ADNI special journal issue. “This public-private partnership overcomes traditional barriers and unites stakeholders—from federal agencies, academia, industry and advocacy groups—in a concerted effort that makes such large-scale, high-impact research possible.”

Today, there are more than 1,000 study participants in ADNI, including cognitively healthy individuals, people with mild cognitive impairment (a condition which may precede Alzheimer’s), and people with Alzheimer’s disease, who undergo observations at 57 locations across the United States and Canada.

Researchers regularly give ADNI participants memory tests, administer brain imaging, perform fluid biomarker analyses, and conduct other tests over a long period of time to find markers that can be reliably measured to indicate changes suggestive of disease, or the likelihood of later developing a disease. As they relate to Alzheimer’s, these benchmarks, or biomarkers as they are known to researchers, may ultimately predict who is at risk for developing Alzheimer’s and help researchers better understand how the disease progresses in the brain, potentially speeding the search for preventions or treatments that slow or stop the disease. This research has also provided evidence that Alzheimer’s likely begins years, maybe even decades, before thinking and memory problems appear. Through ADNI, data and biofluid samples are made available free of charge to qualified researchers.

“A groundbreaking feature of ADNI from its beginning was the resolve to make all data generated available in real time to qualified researchers worldwide,” said Michael Weiner, M.D., ADNI’s principal investigator. “With this approach, the first decade of ADNI has been characterized by outstanding innovation and progress.” Weiner is with the Center for Imaging of Neurodegenerative Disease at the San Francisco Veterans Affairs Medical Center, and is a professor of medicine, radiology, psychiatry, and neurology at the University of California, San Francisco.

ADNI partners agreed to an open-access approach to data sharing, establishing there would be no intellectual property or other limitations placed on data and samples produced through the initiative. A sophisticated infrastructure was developed to facilitate the storage, curating and sharing of ADNI, imaging, biomarker, clinical and genetic information.

Because of this access, ADNI data have been queried millions of times from investigators around the world, including those in governmental, academic, and company research organizations, note the
authors of a paper in the ADNI special journal issue. As of February 2015, there have been over 7 million downloads of ADNI data worldwide and over 924 publications using ADNI data, they add.

The papers in the ADNI special journal issue also highlight the initiative’s influence on accelerating Alzheimer’s disease research, including clinical trials. ADNI studies helped establish brain-imaging techniques, such as positron emission tomography (PET), which uses a chemical tracer to visualize amyloid plaque accumulation in the brain. The Alzheimer’s Association provided funding to include amyloid PET imaging in ADNI. The findings provided support for approval of the first amyloid PET imaging agent by the U.S. Food and Drug Administration (FDA) in 2012. As of today, there are three amyloid PET imaging agents approved by both the FDA and the European Medicines Agency.

ADNI also produced protocols for amyloid PET imaging to ensure consistency of imaging procedures and data collection so information could be shared across multiple research sites. Similar protocols were developed by ADNI for magnetic resonance imaging and cerebrospinal fluid analysis for biomarkers of Alzheimer’s.

“ADNI has resulted in a major shift in the design and implementation of Alzheimer’s clinical drug trials. Researchers are now using amyloid PET imaging or cerebrospinal fluid analysis to enroll individuals who are known to have the hallmark brain changes of Alzheimer’s, and often before cognitive symptoms appear,” said Enchi Liu, Ph.D, senior director at Janssen Research & Development, LLC., and a co-author of a paper in the ADNI special journal issue. “This breakthrough allows researchers to test therapies earlier in the disease process and specifically on people who actually have amyloid accumulation. The benefit is shorter, more cost-effective trials. Without ADNI providing a forum for industry, government and academia to work together, this transformation would have taken much longer.”

ADNI biomarker data was also used in developing a widely accepted model of Alzheimer’s disease progression, suggesting the order of brain changes that occur in Alzheimer’s, report several papers in the ADNI special journal issue.

“ADNI has given us tools to better understand the trajectory of Alzheimer’s disease, which has influenced the field in dramatic ways,” said Buckholtz. “In fact, these outcomes have led us to revise the diagnostic criteria for Alzheimer’s disease.”

Released in 2011, the National Institute on Aging/Alzheimer’s Association Diagnostic Guidelines for Alzheimer’s Disease expand the definition of Alzheimer’s to include two new phases of the disease: (1) presymptomatic and (2) mildly symptomatic but pre-dementia (mild cognitive impairment), along with (3) dementia caused by Alzheimer’s. The guidelines acknowledge the current thinking that Alzheimer’s begins creating distinct and measurable changes in the brains of affected people years before there is noticeable decline in memory and thinking abilities.

There are also a number of initiatives modeled on ADNI, writes Weiner in the introduction to the ADNI special journal issue. Worldwide ADNI, sponsored by the Alzheimer’s Association, has established eight similar initiatives in Europe, Asia, Australia, and South America which aim to track
Alzheimer’s disease progression in diverse ethnic groups and from which standardized data are available to the international research community, he adds.

Weiner also points out in the issue that ADNI has been granted funding to conduct a tau PET imaging pilot study and that data from the study is expected to contribute to a renewal of ADNI, which would begin in 2016. It would be called ADNI 3, he notes, and would include tau amyloid PET in addition to extending currently active investigations, over a five year study.

There is some evidence that levels of tau in the brain are more closely associated with cognitive decline in Alzheimer’s than levels of amyloid. Therefore, like amyloid, identifying the early buildup of tau in the brain is considered a strong candidate for early detection and diagnosis of Alzheimer’s and for identifying volunteers for clinical studies.

About Alzheimer’s & Dementia: The Journal of the Alzheimer’s Association
The mission of Alzheimer’s & Dementia: The Journal of the Alzheimer’s Association (www.alzheimersanddementia.com) is to bridge the knowledge gaps across a wide range of bench-to-bedside investigation. The journal creates a forum for rapid communication of new findings, ideas and perspectives; increases knowledge in diverse disciplines to promote early detection/diagnosis and/or interventions; and provides the scientific impetus for new initiatives or public policies concerning research on prevention and new models of health services. The Alzheimer’s & Dementia umbrella includes the companion open-access journals: Alzheimer’s & Dementia: Diagnosis, Assessment & Disease Monitoring (www.dadm.alzdem.com) and Alzheimer’s & Dementia: Translational Research & Clinical Interventions (www.trci.alzdem.com).

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