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FOR IMMEDIATE RELEASE

Alzheimer's Association Announces New Initiative to Speed Safe Drug Development for Alzheimer's Disease

CHICAGO (April 25, 2006) – The Alzheimer's Association has announced a new initiative to elevate the urgency of Alzheimer's disease and ensure that safe treatments to delay, slow or prevent the disease are developed, tested and made available to the public as quickly as possible.

Today, 4.5 million people have Alzheimer's disease in the United States and as baby boomers age that number could grow to as many as 16 million by 2050. Not only is Alzheimer's devastating for those afflicted and their families, but it also threatens to overwhelm the U.S. economy and bankrupt the healthcare system.

There are more than 50 compounds being tested to treat Alzheimer's and nearly every major pharmaceutical company is working on this problem, as are private organizations, such as the Alzheimer's Association, as well as the federal government. The pace of discovery is expected to pick up dramatically in the future and the Alzheimer's Association wants to ensure that all promising treatments can be tested and, if safe and effective, made available to the public.

The Alzheimer's Association Effective Treatments Initiative will bring together a multi-disciplinary advisory committee of leading scientists, individuals with early-stage Alzheimer's disease and their families, experts on the Food and Drug Administration (FDA) process and others to guide the Initiative. The Association will also seek input from government agencies and the pharmaceutical industry. The Initiative has four goals:

- **Educate the public about value of clinical studies including clinical trials and increase enrollment in such studies.** Recent high-profile drug safety stories in the media have cast a negative light on drug testing procedures, which may contribute to slower enrollments in essential trials to evaluate new drugs. Drug safety is critical, but all drugs carry some risk and it is important that the public understand the potential benefits as well as risks of clinical trials. The Initiative will also work to remove obstacles to participation in trials, such as geographical barriers and difficulties with patient or surrogate consent.
- **Raise profile and priority of Alzheimer's at all levels of drug development.** A higher priority on Alzheimer's disease is needed to ensure rapid review of promising interventions. Working with the FDA, the Alzheimer's Association has and will continue to pursue all possible

means to speed up the development and review of safe drugs for Alzheimer's disease, including increased resources for FDA.

- **Involve patients in drug development and review processes.** Currently, there are no formal processes to involve those most directly affected by Alzheimer's disease – the patients and their family caregivers – in the drug review process. The Association believes that these voices are vital to ensure safe and effective drugs are made available as quickly as possible. Thus, the Association will work with the relevant organizations and government agencies to establish a formal mechanism for Alzheimer patients and their families to participate in drug development oversight, review and regulation.
- **Increase private and public funding for Alzheimer's research.** Basic and clinical research fuels the pipeline for discovering potential treatments and much of this research is funded by the federal government. Unfortunately, federal funding for Alzheimer's disease research at the National Institutes of Health (NIH) has been declining in the past few years since reaching a plateau in 2003, thereby threatening the treatment pipeline and potentially slowing scientific progress on new treatment development. The Alzheimer's Association has set a goal of \$1 billion annually for federal research funding for Alzheimer's, an increase of \$350 million over current spending.

“This is a devastating disease and the need for treatments is more urgent than ever with 77 million baby boomers beginning to turn 60 this year,” said Stephen McConnell, vice president of advocacy and public policy, Alzheimer's Association. “The Alzheimer's Association is taking the lead to make the urgency of the disease and its treatments known to the public and federal government officials, who have it in their power to reduce the disability of the disease, save lives and spare families the burdens of caregiving.”

Leading up to the Initiative, the Alzheimer's Association convened a Research Roundtable in December 2005 to discuss the risks and benefits of clinical trials among leading scientists, and individuals with Alzheimer's and their families. Outcomes of the meetings are scheduled to appear in the Alzheimer's Association journal, *Alzheimer's & Dementia*, July 2006 issue. These discussions will continue under the Effective Treatments Initiative. The importance of clinical trials to develop safe, effective treatments was also identified among the priorities of the Alzheimer's Association Early Stage Initiative, which includes individuals with early stage Alzheimer's disease, and focuses on increasing awareness of the unique challenges facing people in the early stages of the disease.

“People with Alzheimer's and their families are speaking up and demanding more information about and access to clinical trials and the process of drug development,” said McConnell. “Through this Initiative, the Alzheimer's Association is responding to our constituents and furthering our mission, which

is to ensure care and support for those living with Alzheimer's disease and an all-out effort to eliminate the disease as soon as possible."

The Alzheimer's Association will also be coordinating its Initiative with other organizations having similar or complimentary goals, such as the ACT-AD coalition currently being formed to increase the priority of Alzheimer treatments within the federal regulatory process.

"We welcome all efforts to increase attention to this devastating disease," added McConnell. "We can't afford to waste a single day in our quest to create a world without Alzheimer's disease."

About the Alzheimer's Association:

The Alzheimer's Association, the world leader in Alzheimer research and support, is the first and largest voluntary health organization dedicated to finding prevention methods, treatments and an eventual cure for Alzheimer's. For more than 25 years, the donor-supported, not-for-profit Alzheimer's Association has provided reliable information and care consultation; created supportive services for families; increased funding for dementia research; and influenced public policy changes.

The Alzheimer's Association's vision is a world without Alzheimer's and its dual mission is to eliminate Alzheimer's disease through the advancement of research and to enhance care and support for individuals, their families and caregivers.

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