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ALZHEIMER'S ASSOCIATION STATEMENT

FDA Advisory Committee Decision on Florbetapir PET Amyloid Imaging January 21, 2011

The U.S. Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs Advisory Committee did not recommend approval of florbetapir (Amyvid, Lilly/Avid) injection for imaging amyloid plaques based on the currently available data. At the same time, the committee did vote to recommend approval of florbetapir conditional on development and implementation by the company of a training program for users on how to accurately and consistently read the scans. They must train readers in a consistent technique and then re-evaluate florbetapir scans from both a recent phase III and a previous phase II clinical trial.

The committee said florbetapir appears to help detect brain plaques associated with Alzheimer's but that more data is needed to show (1) that the scans can be properly read and interpreted, and (2) that the scans are accurate and beneficial in the population of patients who would be most likely to get the scan (and not just those specially chosen to be in a clinical trial).

Florbetapir is a radioactive dye proposed for use in Positron Emission Tomography (PET) imaging of beta-amyloid plaque deposits to help rule out Alzheimer's disease.

The Alzheimer's Association supports an FDA advisory committee recommendation of approval of florbetapir, once its current questions are thoroughly answered, but we acknowledge that it is a double-edged sword.

On one hand, FDA approval of this product will expand the clinical and research opportunities for amyloid imaging by making this brain imaging tool more widely available to the field. On the other hand, the fact that all of the potential uses of this product are not crystal clear tempers our enthusiasm. Further research is needed to understand the appropriate use of florbetapir-PET imaging — or any other imaging technology — in Alzheimer diagnosis.

In the doctor's office, having a negative scan using this tool (meaning no detectable amyloid buildup in the brain) may be helpful to clinicians in ruling out Alzheimer's disease as the cause of the memory and thinking changes that the person being tested is experiencing. However, a positive scan (showing that there is amyloid buildup in the brain) has limited utility at this point. Having amyloid buildup in your brain does not mean for certain that you have Alzheimer's disease.

Important note of clarification: While a negative scan with this brain imaging tool may be able to help rule out Alzheimer's as a cause of the memory and behavior changes the person is experiencing, it should not be interpreted to mean that the person is well. It most likely means that another cause, other than Alzheimer's disease — such as vascular dementia caused by small strokes, or the interaction of multiple drugs the person is taking, or complications of alcoholism, or any one of a number of possible causes for dementia — still has to be found for the problems

he or she is experiencing. Nonetheless, Alzheimer's disease is the most common cause of dementia in older adults.

Despite the concerns and complications, we believe it is valuable to the Alzheimer field — to the pursuit of better Alzheimer diagnostics, treatments and preventions — to have this product more widely available.

Because so many unanswered questions remain about Alzheimer diagnosis and treatment, next steps for Alzheimer research are very important. Most importantly, we need to correct the chronic underfunding of Alzheimer's disease research by the U.S. federal government. As the leading care, research and advocacy organization for Alzheimer's disease, the Alzheimer's Association plans to work closely with the Administration, the Secretary of Health and Human Services and members of Congress to ensure swift, aggressive implementation of the recently-passed National Alzheimer's Project Act. To get involved, visit www.alz.org.

In the biomarkers area, the Alzheimer's Association is proud to be a sponsor of the Alzheimer's Disease Neuroimaging Initiative (ADNI) and a major sponsor of World Wide ADNI (WW-ADNI) as part of our global research strategy to defeat Alzheimer's. ADNI's mission is to develop biomarkers of Alzheimer's in elderly subjects. A major goal of the study has been to establish and validate MRI and PET images, cerebral spinal fluid, and blood biomarkers as predictors of the disease. WW-ADNI unites leading international investigators in a common effort to:

- Help predict and monitor the onset and progression of Alzheimer's disease.
- Establish globally recognized standards to identify and diagnose Alzheimer's disease.
- Document cognitive changes linked to physical changes.
- Share data across the international research community.

For more information, visit www.alz.org/research/funding/partnerships/WW-ADNI_overview.asp

Alzheimer's is the sixth-leading cause of death in U.S. adults. Distressingly, of the 10 leading causes of death, Alzheimer's is by far the fastest growing – increasing more than 50 percent from 2000 to 2007. Alzheimer's disease kills more Americans than breast cancer and prostate cancer combined. And, Alzheimer's is the only one of the top 10 causes of death where we have no method to prevent it, cure it, or slow its progression.

The Alzheimer's Association is the leading U.S. voluntary health organization in Alzheimer care, support and research. Its mission is to eliminate Alzheimer's disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. The Association's vision is a world without Alzheimer's disease. For more information, visit www.alz.org.

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Contact:

Niles Frantz, Alzheimer's Association, PR Department
312-335-5777, niles.frantz@alz.org