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ALZHEIMER’S ASSOCIATION STATEMENT ON FDA APPROVAL OF FLORBETAPIR (AMYVID)

Chicago, IL (April 6, 2012) – Eli Lilly and Company and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, today announced U.S. Food and Drug Administration (FDA) approval of florbetapir (Amyvid), its radioactive dye for use with positron emission tomography (PET) for visualization of amyloid plaque buildup in the brain.

According to the prescribing information, Amyvid is “for PET imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline.”

It further states that, “A negative Amyvid scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of Alzheimer's Disease at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's Disease. A positive Amyvid scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with Alzheimer's Disease, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Amyvid is an adjunct to other diagnostic evaluations.”

In other words, if a person with dementia does not have amyloid buildup in their brain, then the cause of the dementia is very likely to be something other than Alzheimer's disease. Other causes of dementia include: neurodegenerative diseases other than Alzheimer’s, strokes and other cardiovascular malfunctions (vascular dementia), thyroid problems, drug interactions, chronic alcoholism, and vitamin deficiencies. Certain psychiatric disorders, such as depression, can masquerade as dementia.

If a scan shows that a person with memory impairment has amyloid buildup in their brain, this increases the likelihood that the memory impairment is caused by Alzheimer’s disease, but it remains “likelihood,” not 100 percent certainty. So, a positive Amyvid scan does not establish a diagnosis of Alzheimer's Disease, or other cognitive disorder.

If a person without memory symptoms has amyloid buildup, it does not necessarily mean that they will develop Alzheimer’s disease. Many people have amyloid in their brains but are cognitively normal. More research is needed to understand the appropriate use of florbetapir-PET imaging – or any other imaging technology – in Alzheimer’s diagnosis.
The Alzheimer’s Association supports FDA approval of florbetapir, but acknowledges 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. Again, additional research is needed to clarify the role of florbetapir-PET imaging in Alzheimer’s.

The Alzheimer’s Association is also concerned about the possibility of less than scrupulous operators offering imaging services and making unrealistic promises about the value of florbetapir imaging to sometimes vulnerable and worried individuals. As such, we recommend that people get access to this test only in the context of a complete evaluation of medical/neurological status and with appropriate expert consultation.

Despite these concerns, the Alzheimer’s Association believes that it is valuable to the Alzheimer’s field – to the pursuit of better Alzheimer diagnostics, treatments and preventions – to have this product more widely available.

The Alzheimer's Association has convened a task force with the Society of Nuclear Medicine to develop recommendations for the use of amyloid imaging for physicians, imaging and other medical specialists, Alzheimer families and the general public.

**Dementia: Definition**
Dementia is not a specific disease. It is a term that describes a wide range of symptoms associated with a decline in memory and other thinking skills severe enough to reduce a person's ability to perform everyday activities. Alzheimer's disease accounts for 60 to 80 percent of dementia cases. Vascular dementia, which occurs after strokes, and dementia with Lewy Bodies are two other common types of progressive dementia. There are many other conditions that can cause symptoms of dementia, including some that are reversible.

**Alzheimer’s Disease Statistics**
Today, an estimated 5.4 million people are living with Alzheimer’s disease. Alzheimer’s doesn’t just affect individuals – it affects entire families. According to the Alzheimer’s Association 2012 *Alzheimer’s Disease Facts and Figures*, there are 15.2 million caregivers of individuals with Alzheimer’s and other dementias who provide 17.4 billion hours of unpaid care valued at more than $210 billion.

Someone develops Alzheimer’s every 68 seconds. While the greatest risk factor for developing Alzheimer’s disease is age, Alzheimer’s is not normal aging. Alzheimer’s is the sixth-leading cause of death in the U.S. and the only cause of death among the top 10 that cannot be prevented, cured or even slowed.

**Alzheimer’s Association**
The Alzheimer's Association is the world’s leading voluntary health organization in Alzheimer’s care, support and research. Our 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. Please visit www.alz.org.