Date: October 19, 2012

For Release: Immediately

Refer to: Morry Smulevitz +1 (317) 457-3294 (mobile), smulevitzmb@lilly.com

Maya Robotti +1 (347) 446-1208 (mobile), mrobotti@chamberlainpr.com

Amyvid (Florbetapir 18F) Solution for Injection Recommended for Approval in Europe as a Diagnostic Tool for Imaging Beta-Amyloid Plaques - a Common Neuropathological Feature of Alzheimer's Disease

Milestone reflects Eli Lilly and Company's commitment to bring new diagnostic tool to physicians evaluating patients' cognitive decline

INDIANAPOLIS - Eli Lilly and Company (NYSE: LLY) and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, today announced a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in Europe. The CHMP recommended approval of Amyvid (Florbetapir 18F) solution for injection as a diagnostic radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Amyvid should be used in conjunction with a clinical evaluation.

A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD.

A positive scan does not independently establish a diagnosis of AD or other cognitive disorder since neuritic plaque deposition in grey matter may be present in asymptomatic elderly and some neurodegenerative dementias (AD, Lewy body dementia, Parkinson's disease dementia). Additional limitations exist for use in patients with mild cognitive impairment (MCI) and are included in the label.

Image interpretation errors in the estimation of brain beta-amyloid neuritic plaque density, including false negatives, have been observed. Amyvid images should only be interpreted by readers trained in the interpretation of PET images with florbetapir (18F). The efficacy of Amyvid for predicting development of AD or monitoring response to therapy has not been established.

The positive opinion is now referred for final action to the European Commission, which has the authority to approve medicines for the European Union (EU). The Commission usually decides on CHMP recommendations within three months.

"The potential benefit of an Amyvid scan is that it enables physicians to assess the density of beta-amyloid plaques in the brain," said Diane Bakaysa, Amyvid global brand leader. "If approved by the European Commission, Amyvid used in conjunction with a clinical evaluation may provide valuable information for doctors when evaluating patients suspected of having Alzheimer's disease or

other causes of cognitive decline."

Confirming the absence or presence of beta-amyloid plaques in patients being evaluated for AD and other causes of cognitive impairment is important because there are many causes of cognitive impairment, including AD, neurological disorders, blood vessel-related disorders causing vascular dementia, movement disorders, such as Parkinson's and Huntington's diseases, brain tumors, normal pressure hydrocephalus, traumatic brain injury and infections such as HIV.

The positive opinion was based on data submitted by Lilly, including several trials supporting the safety, technical and diagnostic performance of Amyvid. In the pivotal study involving end of life patients, the diagnostic performance of Amyvid to detect the cortical neuritic plaque density (no or sparse versus moderate or frequent) was evaluated in 59 subjects who underwent an Amyvid PET scan and subsequently had neuropathological evaluation of beta-amyloid deposition in the brain post-mortem. In the 59 subjects, a blinded PET reading by five nuclear medicine physicians resulted in a majority read sensitivity of 92 percent (95 percent CI: 78 - 98 percent) and specificity of 100 percent (95 percent CI: 80 - 100 percent). In a study of 47 young (<40 years), healthy volunteers, presumed to be free of beta-amyloid, all Amyvid PET scans were negative.

Adverse reactions have been collected in clinical studies involving 555 subjects and 665 administrations of Amyvid solution for injection. No serious adverse reactions related to Amyvid administration have been reported. The only adverse reaction considered to be common (defined as ≥1/100 to <1/10) is headache. Uncommon (defined as ≥1/1,000 to <1/100) adverse reactions reported included dysgeusia, flushing, nausea, pruritis, urticarial and infusion site rash.

Amyvid was approved by the United States (U.S.) Food and Drug Administration (FDA) for use in the U.S. in April 2012.

About Alzheimer's Disease

Alzheimer's disease, the most common form of dementia, causes progressive decline in memory and other aspects of cognition. Alzheimer's disease is a fatal illness, accounting for 60 to 80 percent of dementia cases. Researchers do not know exactly what causes AD and there are currently no approved treatments shown to slow the progression of this devastating disease, only treatment options that reduce certain symptoms of the disease.2 Alzheimer's Disease International (ADI) estimates that there are currently 35.6 million people with dementia worldwide, with 7.7 million new cases each year (which implies one new case every four seconds). The number of people affected is estimated to be over 115 million by 2050.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

This press release contains forward-looking statements about the potential of Amyvid. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development, commercialization and regulatory review. There is no guarantee that the product will receive additional regulatory approvals. There is also no guarantee that Amyvidwill continue to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update

forward-looking statements.

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Eli Lilly and Company

Lilly Corporate Center

Indianapolis, Indiana 46285

U.S.A.

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