Statement from Lilly and Avid on FDA Advisory Committee Recommendation for Amyvid™ (Florbetapir) NDA

INDIANAPOLIS and PHILADELPHIA, Jan. 20, 2011 /PRNewswire/ -- The U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Drugs Advisory Committee decided today that it could not recommend approval of Amyvid™ (florbetapir) at this time based on the currently available data (13-3); but, voted unanimously (16-0) to recommend approval of Amyvid conditional on a reader training program that demonstrates reader accuracy and consistency through a re-read of previously acquired scans. The Committee supported that efficacy was established and there were no significant safety concerns raised.

Amyvid is a molecular imaging tool under investigation for the detection of beta-amyloid plaque in the brain. The Committee stated that a negative scan would be clinically useful in indicating that Alzheimer's pathology is unlikely to be the cause of a patient's cognitive decline.

Lilly acquired Avid Radiopharmaceuticals, Inc. in December 2010. Amyvid is Avid's lead candidate and was the first beta-amyloid imaging compound to enter multi-center, investigational new drug (IND) clinical studies in the United States. Amyvid was recently assigned priority review designation by the FDA.

"We appreciate the careful and thoughtful review of our data today by the Committee," said Daniel M. Skovronsky, M.D., Ph.D., CEO, Avid Radiopharmaceuticals, Inc. "We are encouraged that they recommended a clear path toward approval."

The FDA will consider the panel's recommendation in its review of Amyvid. The FDA takes the advice of its Advisory Committees into consideration when reviewing investigational drugs, but is not bound by their recommendations.

About Amyvid

Amyvid is an imaging tool indicated for Positron Emission Tomography (PET) imaging of beta-amyloid plaque in the brain. It's being investigated for the potential use in ruling out Alzheimer's disease. In addition to the pivotal Phase III "Image-to-Autopsy" study, other clinical studies are also being conducted in the E.U., North and South America, Australia and Asia.

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. Additional information about Lilly is available at www.lilly.com.

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This press release contains forward-looking statements about Amyvid (Florbetapir) for use as a molecular imaging tool for the detection of beta-amyloid plaque in the brain. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that florbetapir will be approved by the FDA on the anticipated timeline or at all, or that that it, will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. The company undertakes no duty to update forward-looking statements.

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