Lilly and Avid Receive Complete Response Letter from FDA for Amyvid™ (florbetapir F 18 injection)

INDIANAPOLIS and PHILADELPHIA, March 18, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and its wholly owned subsidiary, Avid Radiopharmaceuticals, Inc., have received a complete response letter from the U.S. Food and Drug Administration (FDA) for their New Drug Application (NDA) for Amyvid™ (florbetapir F 18 injection), a Positron Emission Tomography (PET) imaging agent under investigation for the detection of beta-amyloid plaque in the brains of living patients.

The complete response was primarily focused on the need to establish a reader training program for market implementation that helps to ensure reader accuracy and consistency of interpretations of existing Amyvid scans.

"Lilly and Avid have been engaged in an active and ongoing dialogue with the FDA," said Wei-Li Shao, Lilly brand director for Amyvid. "We remain confident in the data submission package for Amyvid."

Since questions on the reader training program were raised by FDA reviewers late last year, Lilly and Avid have been working to address these questions and will continue to do so in an ongoing dialogue with the FDA.

About Amyvid™ (florbetapir F 18 injection)

Amyvid is a molecular imaging agent under investigation for PET imaging of beta-amyloid plaque in the brain. Clinical studies for Amyvid are 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 F 18 injection) for use as a molecular imaging tool for the detection of β-amyloid (beta-amyloid) plaque in the brains of living patients. 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 Amyvid 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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