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Lilly Joins the Imaging Dementia - Evidence for Amyloid Scanning (IDEAS) Study

Study Seeks to Assess the Impact of a Brain Positron Emission Tomography (PET) Scan on Patient-Oriented Outcomes

INDIANAPOLIS, Oct. 7, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, today announced financial commitment and continued scientific partnership to support the recently established Imaging Dementia - Evidence for Amyloid Scanning (IDEAS) Study.

The IDEAS Study will assess the clinical usefulness and value in using an amyloid brain positron emission tomography (PET) scan in certain situations when evaluating Alzheimer's disease (AD) and other dementias. Amyvid™ (Florbetapir-F18 Injection), Lilly's FDA-approved radioactive PET diagnostic agent for the estimation of beta-amyloid neuritic plaque density in the brain, will be one diagnostic agent available for use in the study. It is important to note that a positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder. Information about Amyvid reader training can be accessed at https://amyvid.myregistrationp.com/amyvid/login.do.

Manufactured in and distributed from 30 radiopharmacy facilities throughout the United States, Amyvid is currently supplied to a robust network of PET imaging sites by Siemens' PETNET Solutions and Cardinal Health. Amyvid for intravenous use is supplied in 10 mL, 30 mL, or 50 mL multidose vials containing 500-1900 MBq/mL Florbetapir F-18.

"Lilly is pleased to support and participate in this important study," said David Ricks, Lilly Senior Vice President and President of Lilly Bio-Medicines. "Alzheimer's disease is one of the most devastating diseases of our time, and we are committed to ensuring that patients and physicians have appropriate and reliable access to this adjunctive diagnostic tool."

Mark Mintun, MD, President of Avid Radiopharmaceuticals represents Lilly on the IDEAS Study Steering Committee. "We hope this study will add important new data to a growing body of evidence demonstrating the value beta-amyloid imaging may bring to patients with cognitive impairment being evaluated for Alzheimer's disease and other causes of cognitive decline," explained Mintun.

About the IDEAS Study
The IDEAS Study (www.IDEAS-Study.org) is led by the Alzheimer's Association and managed by the American College of Radiology (ACR) and the American College of Radiology Imaging Network (ACRIN). Funding and support for the study is provided by the Alzheimer's Association, the Centers for Medicare & Medicaid Services (CMS), and a consortium of industry stakeholders. A total of 18,488 Medicare beneficiaries age 65 and older meeting specific Appropriate Use Criteria (AUC) will be enrolled over 24 months at sites throughout the United States as part of the CMS Coverage with Evidence Development (CED) program.

The IDEAS study will establish an open-label, longitudinal cohort study to assess whether the impact of amyloid PET on patient management results in improvements in health outcomes. Specifically, the study will determine the clinical usefulness and value in using an amyloid brain PET scan in certain situations when evaluating Alzheimer's and other dementias. In diagnostically uncertain cases, knowledge of amyloid status may lead to changes in patient management, such as earlier counseling and prescription of appropriate drugs, which may translate into improved long-term outcomes. The study hypothesis is that amyloid PET will decrease uncertainty and increase confidence in the underlying cause of cognitive impairment, that this will translate into earlier counseling and interventions in these domains, and that these interventions will lead to improved health outcomes.[1]

Imaging sites certified in brain PET and dementia specialists meeting certain ACR-defined criteria will be able to apply to participate in the study on the IDEAS Study website (www.IDEAS-Study.org). Through the online application process, ACR will assess imaging site and dementia specialist eligibility and ultimately decide which sites can join the study. Specific study inquiries or expressions of interest in participation should be directed to ACR via the IDEAS study-dedicated email address (IDEAS-Study@acr.org).

About Alzheimer's Disease
Alzheimer's disease is a fatal illness that causes progressive decline in memory and other aspects of cognition. It is the most

common form of dementia, accounting for 60 to 80 percent of dementia cases.[2] There are currently an estimated 46.8 million people living with dementia worldwide.[3] The number of people affected by dementia is expected to be nearly 74 million in 2030 and 131 million in 2050.[3] Estimates vary, but experts suggest that as many as 5.3 million Americans may have Alzheimer's disease.[2]

Indication and Important Safety Information for Amyvid™ (Florbetapir F 18 Injection)[4]
Amyvid is a radioactive diagnostic agent for Positron Emission Tomography (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 (AD) and other causes of cognitive decline. A negative Amyvid scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. 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 AD, 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.

Limitations of Use:

- A positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder
- Safety and effectiveness of Amyvid have not been established for:
  - Predicting development of dementia or other neurologic condition
  - Monitoring responses to therapies

WARNINGS AND PRECAUTIONS

Risk for Image Misinterpretation and Other Errors

- Errors may occur in the Amyvid estimation of brain neuritic plaque density during image interpretation
- Image interpretation should be performed independently of the patient's clinical information. The use of clinical information in the interpretation of Amyvid images has not been evaluated and may lead to errors. Other errors may be due to extensive brain atrophy that limits the ability to distinguish gray and white matter on the Amyvid scan as well as motion artifacts that distort the image
- Amyvid scan results are indicative of the brain neuritic amyloid plaque content only at the time of image acquisition and a negative scan result does not preclude the development of brain amyloid in the future

Radiation Risk

- Amyvid, similar to other radiopharmaceuticals, contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure

MOST COMMON ADVERSE REACTIONS

- The most common adverse reactions reported in clinical trials were headache (1.8%), musculoskeletal pain (0.7%), blood pressure increased (0.7%), nausea (0.7%), fatigue (0.5%), and injection site reaction (0.5%)

Please see Full Prescribing Information for Amyvid.
http://pi.lilly.com/us/amyvid-uspi.pdf.

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About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels. **(P-LLY)**

This press release contains certain forward-looking statements about florbetapir F 18, a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. This release reflects Lilly's current beliefs; however, as with any pharmaceutical product,

there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that florbetapir F 18 will 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.

[1] ClinicalTrials.gov, "Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study," https://clinicaltrials.gov/ct2/show/NCT02420756?titles=IDEAS&rank=1. Accessed May 14, 2015.

[2] Alzheimer's Association. 2015 Alzheimer's Disease Facts and Figures. *Alzheimer's & Dementia* 2015;11(3)332+.

[3] Alzheimer's Disease International and World Health Organization Dementia Statistics. Available at: http://www.alz.co.uk/research/statistics. Accessed May 27, 2015.

[4] Amyvid [package insert]. Indianapolis, IN: Lilly USA, LLC; 2012.

Refer to: Nicole Hebert; hebert_nicole@lilly.com; 317.701.9984 (Lilly)

AMYViD™

Florbetapir F 18 Injection

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/lilly-joins-the-imaging-dementia---evidence-for-amyloid-scanning-ideas-study-300154978.html

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