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Amyvid™ (Florbetapir F 18 Injection) Recommended for Approval in Europe as a Diagnostic Tool for PET Imaging of Beta-Amyloid Plaque Density

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

INDIANAPOLIS, Oct. 19, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, today announced they received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in Europe, recommending approval of Amyvid (Florbetapir F 18) 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 and other causes of cognitive impairment. Amyvid should be used in conjunction with a clinical evaluation.

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.

"If approved in the European Union, Amyvid may offer an innovative and appropriate adjunct to other diagnostic evaluations for adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive impairment," said Diane Bakaysa, Amyvid global brand leader. "We are pleased by the recommendation as it brings us one step closer to providing Amyvid to physicians and their patients who may benefit from the tool."

Amyvid for intravenous use was approved by the U.S. Food and Drug Administration (FDA) in April 2012 and is supplied in 10 mL, 30 mL, or 50 mL multidose vials containing 500-1900 MBq/mL Florbetapir F 18. Amyvid is a radioactive diagnostic agent indicated for PET imaging of the brain to estimate beta-amyloid neuritic plaque density in patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline.¹

A negative Amyvid scan indicates sparse to no amyloid plaques are currently present, which is inconsistent with a neuropathological diagnosis of Alzheimer's Disease and reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's Disease. A positive Amyvid scan indicates moderate to frequent amyloid plaques are present; this amount of amyloid plaque is present in patients with Alzheimer's Disease, but may also be present in patients with other types of neurologic conditions and in older people with normal cognition.¹

It's important to note that Amyvid is an adjunct to other diagnostic evaluations. A positive Amyvid scan does not establish a diagnosis of Alzheimer's Disease or other cognitive disorder. Additionally, the safety and effectiveness of Amyvid have not been established for predicting development of dementia or other neurologic condition, or monitoring responses to therapies.¹

About Amyvid¹

Amyvid is a radioactive diagnostic agent, tagged with a radioisotope called fluorine-18. Once Amyvid is injected into a vein, it travels through the bloodstream and into the brain, binding to amyloid plaques. Amyvid produces a positron signal, which is detected by a PET scanner and used to create a brain image. A physician who should have successfully completed Amyvid reader training then interprets the image to evaluate as positive or negative for significant levels of amyloid plaques (i.e., moderate to frequent levels of neuritic plaques) in the brain. This information is reported back to the referring physician, who then determines the next steps in the evaluation and management of the patient.

Indications and Usage

In the United States, Amyvid is indicated 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. Additionally, the safety and effectiveness of Amyvid have not been established for predicting development of dementia or other neurologic condition, or monitoring responses to therapies.¹

Important Safety Information

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 (0.8%), fatigue (0.6%), nausea (0.6%)

For Full Prescribing Information for Amyvid, visit <http://pi.lilly.com/us/amyvid-uspi.pdf>.
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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 certain forward-looking statements about Amyvid™, 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 Amyvid will prove 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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[1] Amyvid [package insert]. Indianapolis, IN: Lilly USA, LLC; 2012.

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