**GE Healthcare Announces FDA Approval of Vizamyl™ (Flutemetamol F18 Injection) for Detection of Beta Amyloid**

*—New PET Imaging Agent Provides Brain Scans in Color –*

**Princeton, NJ – October 25, 2013** – GE Healthcare today announced the U.S. Food and Drug Administration (FDA) approval of Vizamyl™ (Flutemetamol F18 injection), a radioactive diagnostic agent 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) or other causes of cognitive decline. Vizamyl is an adjunct to other diagnostic evaluations.1 Vizamyl is the only PET imaging tracer for detection of amyloid approved by FDA for visual interpretation of color images rather than black and white assessment, and will be commercially available in 2014.[[1]](#endnote-1)

Increased levels of beta amyloid plaque is a defining pathological feature of AD, the most common form of dementia and the sixth leading cause of death in the United States.[[2]](#endnote-2) Normally, beta amyloid is broken down and eliminated, but in individuals with AD, amyloid plaque builds up and can negatively impact neuronal function.[[3]](#endnote-3) Currently, possible or probable AD is diagnosed following a thorough clinical examination.2

“Vizamyl represents a new and important option to augment the current methods we have available to evaluate patients with symptoms of Alzheimer’s disease,” said William E. Klunk, M.D., Ph.D., Co-director, Alzheimer Disease Research Center, and Distinguished Professor of Psychiatry and Neurology at the University of Pittsburgh. “The ability to detect or exclude the presence of beta amyloid plaques in the brain may help physicians make more accurate assessments of patients with suspected cognitive disorders, including AD.”

**Clinical Trial Results Supporting FDA Approval**

The FDA approval of Vizamyl is based on review of pivotal and supportive data from a series of clinical trials, including Phase III brain autopsy and biopsy studies which showed high sensitivity and specificity for visual interpretation of [18F]flutemetamol PET images compared to beta amyloid brain pathology. Data from these studies were presented at the Alzheimer's Association International Conference 2012 (AAIC 2012) in Vancouver and the American Academy of Neurology’s (AAN) 64th Annual Meeting in New Orleans. [[4]](#endnote-4),[[5]](#endnote-5)

Additionally, GE Healthcare developed and validated an electronic reader training program (ETP) to instruct physicians in accurate interpretation of Vizamyl images. In the validating clinical trial, the ETP was effective (high sensitivity, specificity, and reader agreement) in training readers who were naïve to amyloid imaging. Images should be interpreted only by readers who have completed the GE Healthcare electronic reader training program that will be made available free of charge to healthcare professionals who want to conduct and interpret Vizamyl imaging.

In the clinical trials, Vizamyl was generally well tolerated. The most common adverse reactions reported in clinical trials were flushing, increased blood pressure, headache, nausea and dizziness, and occurred at rates 2% or less.1 One subject had a serious hypersensitivity reaction (flushing, dyspnea, and chest pressure) within minutes following Vizamyl administration and recovered with treatment.

“The approval of Vizamyl for PET imaging underscores GE Healthcare’s commitment to provide medical imaging that to help physicians deliver better care to more people,” said Kieran Murphy, President and CEO, GE Healthcare Life Sciences. “We hope that Vizamyl will help advance treatment options by helping to enroll the right people into the right clinical trials, which may lead to disease-modifying medications.”

# **Important Risk and Safety Information about Vizamyl (Flutemetamol F18 Injection)**

**INDICATIONS AND USAGE:** Vizamyl is indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β 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 scan indicates sparse to no neuritic plaques, inconsistent with a 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 scan indicates moderate to frequent amyloid neuritic plaques; this amount of amyloid neuritic plaque has been shown to be present in patients with AD, but may also be present in patients with other neurologic conditions as well as in older people with normal cognition. Vizamyl is an adjunct to other diagnostic evaluations. **Limitations**: A positive scan does not establish a diagnosis of AD or other cognitive disorder. Safety and effectiveness of Vizamyl have not been established for predicting development of dementia or other neurologic conditions or for monitoring responses to therapies. **CONTRAINDICATIONS:** Known hypersensitivity to Vizamyl, or any excipient, including polysorbate 80. **WARNINGS AND PRECAUTIONS: Hypersensitivity Reactions:** Reactions such as flushing and dyspnea have been observed within minutes following administration, and may occur in patients with no history of exposure to Vizamyl. **Image Misinterpretation**: Errors may occur while interpreting Vizamyl PET images. Image interpretation is performed independently of the patient’s clinical information; the use of clinical information in the interpretation of Vizamyl images has not been evaluated and may lead to errors. Extensive brain atrophy may limit the ability to distinguish grey and white matter on a Vizamyl scan. Motion artifacts may distort the image. Images should be interpreted only by readers who have completed a reader training program available from GE Healthcare. **Radiation Risk**: Like all radiopharmaceuticals, Vizamyl contributes to a patient’s long-term, cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure. **ADVERSE REACTIONS**: The most commonly reported adverse reactions in NDA clinical trials were: flushing, increased blood pressure, headache, nausea, and dizziness. **DRUG INTERACTIONS:** Drug-drug interaction studies have not been performed in patients to establish the extent, if any, to which concomitant medications may alter Vizamyl image results. **SPECIFIC POPULATIONS: Pregnancy:** It is not known whether Vizamyl can cause fetal harm when administered to a pregnant woman or if it can affect reproduction capacity. Radiopharmaceuticals, including Vizamyl, have the potential to cause fetal harm, the likelihood of which depends on the stage of fetal development, and the magnitude of the radiopharmaceutical dose. Vizamyl should be given to a pregnant woman only if clearly needed. **Nursing Mothers:** It is not known whether flutemetamol is excreted in human milk. Because many drugs are excreted in human milk and there is a potential for radiation exposure to nursing infants, avoid use of Vizamyl in a breastfeeding mother or have the mother temporarily interrupt breastfeeding for 24 hours after exposure. **Pediatric Use:** Vizamyl is not indicated for use in pediatric patients. **Geriatric Use:** No overall differences in safety were observed between older and younger subjects. **OVERDOSAGE:** The clinical consequence of overdose with Vizamyl has not been reported. It is unknown whether or not flutemetamol is dialyzable. In case of overdose of radioactivity, hydration and frequent urination should be encouraged.

# Prior to Vizamyl (flutemetamol F18) administration, please read the Full Prescribing Information

About GE Healthcare

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1. Vizamyl Prescribing Information. 2013. [↑](#endnote-ref-1)
2. Alzheimer’s Association. Alzheimer’s disease facts and figures. *Alzheimer’s & Dementia.* 2012;8:131–168. [↑](#endnote-ref-2)
3. Rodrigue K, Kennedy K, Park D. Beta-amyloid deposition and the aging brain. *Neuropsychol Rev. 2009*;19:436–450. [↑](#endnote-ref-3)
4. Ikonomovic M, Buckley C, Smith A et al. [18F]Flutemetamol injection PET images reflect brain amyloid levels. Data presented at Alzheimer's Association® International Conference 2012 (AAIC 2012), Vancouver, BC, Canada. [↑](#endnote-ref-4)
5. Wolk D, Gamez J, Sadowsky C et. al. Brain autopsy and *in vivo* cortical brain biopsy trials show a strong concordance between [18F]Flutemetamol PET and amyloid-β pathology. Poster presented at: 64th Annual Meeting of the American Academy of Neurology, April 21-28, 2012; New Orleans, LA. [↑](#endnote-ref-5)