GE β-Amyloid Agent Approved

The U.S. Food and Drug Administration (FDA) announced on October 25 the approval of Vizamyl (flutemetamol F-18 injection), for PET imaging of β-amyloid neuritic plaque density in adults being evaluated for Alzheimer disease (AD) and dementia. Vizamyl is manufactured for GE Healthcare by Medi-Physics, Inc. (Arlington Heights, IL). Vizamyl is only the second diagnostic drug available for visualizing β-amyloid on PET. In 2012, the FDA approved Amyvid (florbetapir F-18 injection) to evaluate adults for AD and other causes of cognitive decline. A press release issued by GE on October 25 indicated that Vizamyl is the only PET imaging tracer for detection of β-amyloid approved by FDA for visual interpretation of color images rather than black-and-white assessment and will be commercially available in 2014.

"Many Americans are evaluated every year to determine the cause of diminishing neurologic functions, such as memory and judgment, that raise the possibility of AD," said Shaw Chen, MD, deputy director of the Office of Drug Evaluation IV in the FDA Center for Drug Evaluation and Research. "Imaging drugs like Vizamyl provide physicians with important tools to help evaluate patients for AD and dementia." The FDA approval of Vizamyl was based on review of pivotal and supporting data from a series of clinical trials, including phase III brain autopsy and biopsy studies showing high sensitivity and specificity for visual interpretation of ^{18}F-flutemetamol PET images in β-amyloid brain pathology. Data from these studies were presented at the Alzheimer's Association International Conference 2012 in Vancouver, Canada, and the American Academy of Neurology 64th Annual Meeting in New Orleans, LA.

GE Healthcare has 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 (with high sensitivity, specificity, and reader agreement) in training readers naïve to amyloid imaging. The GE Healthcare electronic reader training program will be made available free of charge to health care professionals who want to conduct and interpret Vizamyl imaging.

The FDA cautioned that Vizamyl is not indicated to predict development of AD or to assess or monitor treatment response. Safety risks associated with Vizamyl include hypersensitivity reactions and risks associated with image misinterpretation and radiation exposure. Common side effects associated with Vizamyl include flushing, headache, increased blood pressure, nausea, and dizziness.

U.S. Food and Drug Administration
Silver Spring, MD
GE Healthcare
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to cognitive decline and AD. The multidisciplinary team will analyze clinical, pathology, genomic, and other large-scale molecular data from more than 1,000 volunteers in previous studies. The project hopes eventually to identify compounds that normalize the activity of dysfunctional nodes in molecular networks and to identify drugs for novel therapeutic targets.

Integrative Biology Approach to Complexity of AD; Icahn School of Medicine at Mount Sinai (New York, NY). This 5-year study will apply innovative analytic methods to large-scale molecular, cellular, and clinical data from AD patients to construct biological network models and gain new insights into the complex mechanisms of the disease. Cellular, animal, and computational models will be used to validate actions of individual genes and entire molecular networks predicted to drive the disease.

A Systems Approach to Targeting Innate Immunity in Alzheimer's; University of Florida (Gainesville). This 5-year study builds on genetic and pathologic evidence suggesting that both the innate immune system and brain inflammation have significant roles in AD. To identify and characterize novel therapeutic targets within the innate immune system, this study will use a systems biology approach to integrate genomic, gene expression, and pathology data from AD patients and AD mouse models and analyze them in novel ways.

Most of these projects are supported not only by NIH but by consortia of private and public groups interested in addressing the challenges of neurodegenerative disease. Many of these activities are taking place under the umbrella of the 2011 National Alzheimer's Project Act, which calls for stepped-up national effort and coordination on research, care, and services for AD and related dementias. The law mandated that the Department of Health and Human Services establish a National Plan to Address Alzheimer's Disease. For additional information on research milestones and progress under the plan, see: http://aspe.hhs.gov/daltcp/napa/milestones/index.shtml.

National Institutes of Health