New [18F]Flutemetamol Data Presented by GE Healthcare at 7th Annual Human Amyloid Imaging Conference

The Associated Press

MIAMI--(BUSINESS WIRE)--Jan 18, 2013--Study data presented by GE Healthcare at the 7 th Annual Human Amyloid Imaging (HAI) meeting in Miami suggest that GE Healthcare's electronic training program (ETP) used to teach interpretation of images taken using the investigational PET imaging agent [18 F]flutemetamol was highly effective in training inexperienced readers.

In the study 1, five physician readers (3 nuclear medicine physicians and 2 radiologists) inexperienced in amyloid imaging and independently trained with the ETP, interpreted 305 [18 F]flutemetamol image sets blinded to patient information (i.e., a forced choice between normal or abnormal for brain amyloid). For the 135 patient images for which a standard of truth in regard to histopathological brain amyloid status was available, the majority read values for sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were 94%, 92%, 87%, and 96% respectively. Inter-reader agreement was 81% (kappa 0.83). Intra-reader reproducibility was 93% to 100%.

"The results of this study demonstrated that the ETP was highly effective in training inexperienced readers to read [18 F]flutemetamol PET images with high NPV and reproducibility, in addition to high sensitivity, specificity, and PPV, and further supports the potential role of [18 F]flutemetamol in helping physicians detect amyloid deposits in the brain," said Jonathan Allis, Ph.D., General Manager, PET, GE Healthcare Medical Diagnostics. "PET imaging with [18 F]flutemetamol has the potential to be part of a larger diagnostic workup that may help doctors rule out Alzheimer's disease by reliably showing the absence of beta amyloid deposits in patients with unexplained loss of cognitive function." Earlier this month, GE Healthcare announced that regulatory bodies in the United States and Europe had accepted for review its marketing applications for [18 F]flutemetamol. A New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) for [18 F]flutemetamol use in the visual detection of beta amyloid in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other cognitive disorders. A Marketing Authorisation Application (MAA) was submitted to the European Medicines Agency for [18 F]flutemetamol use in the visual detection of beta amyloid in the brains of adult patients who are being evaluated for AD.

In addition to data from the ETP study, the NDA and MAA submissions are based on data from a series of clinical trials, including Phase III brain autopsy and biopsy studies, which showed high sensitivity and specificity for visual image reads as well as strong concordance between [18 F]flutemetamol PET images and beta amyloid brain pathology.

The accumulation of beta amyloid in the brain is a key pathological characteristic of AD, which is primarily diagnosed following thorough clinical examinations (i.e., medical history, physical, neurological, psychiatric and neuropsychological exams, laboratory tests and magnetic resonance imaging (MRI) or computed tomography (CT) scans). [18 F]Flutemetamol is being studied to determine its ability to detect beta amyloid deposition in living humans.

GE'S COMMITMENT TO IMAGING RESEARCH [18 F]Flutemetamol is one component of a broad portfolio of investigational diagnostic solutions that GE Healthcare is currently developing in the Alzheimer's field. GE Healthcare is taking a comprehensive approach to understanding AD through its ongoing research to uncover the causes, risks, and physical effects of the disease. GE Healthcare offers a broad portfolio of imaging resources including cyclotrons and chemistry systems to manufacture PET imaging agents, PET and MR scanners to scan patients, and is developing image analysis software to provide quantification, optimized visualization and reporting tools.

Additionally, GE Healthcare is collaborating with the pharmaceutical industry to assist in their development of the next generation of therapies. To that end, we are working with potential partners in the industry to understand their strategic needs, and helping to provide imaging support for clinical trials of therapeutic agents.

ABOUT GE HEALTHCARE GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement, and performance solutions services helps our customers deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access, and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our web site at www.gehealthcare.com.

For our latest news, please visit http://newsroom.gehealthcare.com 1 Sherwin P, Wolber J, Longenecker, F, et al. Effectiveness of an electronic training program to teach interpretation of [18F]flutemetamol PET amyloid images. Data presented at 7 th Annual Human Amyloid Imaging Meeting, January 16-18, 2013.

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