Phase III Results for Investigational Imaging Agent [18F]Flutemetamol Demonstrate Ability to Accurately Detect Beta Amyloid in Living Patients

The Associated Press

STOCKHOLM--(BUSINESS WIRE)--Sep 11, 2012--GE Healthcare today announced pooled results from phase III brain autopsy and biopsy studies on the investigational PET amyloid imaging agent, [18 F]flutemetamol, which showed a strong concordance between [18 F]flutemetamol images and Alzheimer's disease-associated beta amyloid brain pathology. 1 [18 F]Flutemetamol is a PET imaging agent being developed by GE Healthcare for the detection of beta amyloid deposits in the brain. The data from the phase III studies further confirm the potential application of [18 F]flutemetamol as an imaging agent to detect beta amyloid plaques.

The data was presented at the 16 th Congress of the European Federation of Neurological Societies (EFNS) in Stockholm, Sweden, and provide support for an application for regulatory approval of [18 F]flutemetamol, which is intended to be filed in the US and EU later this year.

"We are encouraged that [18 F]flutemetamol PET images accurately and consistently reflected beta amyloid levels in living patients," said Ville Leinonen, MD, PhD, board certified Neurosurgeon and Director of Kuopio University Hospital NPH Group, Kuopio, Finland. "Currently, Alzheimer's disease is confirmed during autopsy studies, but if we can detect beta amyloid earlier , we can help physicians make a more timely clinical diagnosis that can impact disease management and treatment decisions." The clinical development program examined a number of subjects including 180 end-of-life subjects (69 of whom were followed to autopsy) and 49 subjects with suspected Normal Pressure Hydrocephalus (NPH) – a progressive condition associated with dementia, gait abnormalities and urinary incontinence – who underwent in vivo cortical biopsy. All participants received [18 F]flutemetamol injection. Beta amyloid was evaluated using Bielschowsky silver stain and/or the beta amyloid peptide specific antibody – 4G8. The PET images were then read by trained physicians, who identified the images as normal or abnormal.

For patients from the four separate biopsy studies [18 F]flutemetamol detected beta amyloid with a median sensitivity ranging from 75-100 percent and specificity ranging from 99-100 percent. A similar range was also found for autopsied subjects. Further, the visual assessment of all images showed a high level of agreement among readers.

The accumulation of beta amyloid in the brain is believed to play a role in the degeneration of neurons in AD and is one of several pathological characteristics implicated in the development of AD. Currently, AD is confirmed by histopathological identification of core features, including beta amyloid plaques, in

post-mortem brain samples. 2 Targeted amyloid imaging agents are being studied to determine their ability to help physicians detect amyloid deposition in living humans.

“We know that Alzheimer’s disease-related biomarkers such as beta amyloid may appear decades before clinical symptoms are observed, and the results from these studies demonstrate the potential of [18 F]flutemetamol to detect such biomarkers in living patients,” said Jonathan Allis, General Manager, PET, GE Healthcare Medical Diagnostics. “These study results and the recently updated EFNS guidelines on the use of neuroimaging for the diagnosis of dementia, which back the clinical utility of amyloid imaging in the evaluation of AD under certain conditions, further support the potential regulatory approval of [18 F]flutemetamol, and we look forward to filing for regulatory approval later this year in the US and EU.” 3 [18 F]Flutemetamol is one component of a broad portfolio of 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. For example, the company is partnering with the pharmaceutical industry to identify a biosignature - or biological indicator - may help physicians diagnose AD before the onset of clinical symptoms.

GE Healthcare offers a broad portfolio of imaging resources that support accurate visualization of the signs of neurodegenerative diseases via state-of-the-art scanners – including MRI, PET, and CT – that deliver clear visualization of the brain. In addition, an expanding portfolio of imaging agents is being developed to enhance visual evidence of disease and innovative software applications to aid physicians in image interpretation and determination of disease management. More specifically, its portfolio today includes cyclotrons and chemistry systems to manufacture PET imaging agents, PET and MR scanners to scan patients, and image analysis software to interpret the results.

GE Healthcare has been a key contributor to the Alzheimer’s Disease Neuroimaging Initiative (ADNI) since its inception. GE Healthcare also plays a key role in PredictAD, an EU-funded research project to develop solutions to enable earlier diagnosis of AD, and in the Coalition Against Major Diseases (CAMD).

Additionally, the combination of different business offerings positions GE Healthcare in a good position to offer an integrated global diagnostics solution to assist the pharmaceutical industry in its development of the next generation of therapies. To that end, it is working with potential partners in the industry to understand their strategic needs and design solutions, and help provide imaging support for pivotal therapy trials.

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 Rinne J, Gamez J, Sadowsky C, et. al. A strong concordance between [18F] flutemetamol PET and amyloid-β pathology demonstrated in brain autopsyand in-vivo cortical biopsy trials. Data presented at the 16 th Congress of the European Federation of Neurological Societies 2 Dementia: Hope Through Research. National Institute of Neurological Disorders and Stroke website. http://www.ninds.nih.gov/disorders/dementias/detail_dementia.htm. Accessed July 13, 2011.

3 Filippia M, Agostaa F, Barkhofb F, et. al. (2012) EFNS task force: the use of neuroimaging in the diagnosis of dementia. European Journal of Neurology. doi:10.1111/j.1468-1331.2012.03859
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