Final Phase 3 Results for GE Healthcare Investigational Imaging Agent Flutemetamol Presented at Alzheimer’s Association International Conference®

The Associated Press

VANCOUVER, British Columbia--(BUSINESS WIRE)--Jul 17, 2012--GE Healthcare today announced the final results from a phase 3 study of the investigational PET amyloid imaging agent, [18 F]flutemetamol in terminally ill patients who had agreed to undergo postmortem brain autopsy. 1 The data showed strong concordance (sensitivity and specificity) between [18 F]flutemetamol PET images and beta amyloid brain histopathology. These data confirm the potential of [18 F]flutemetamol as an imaging agent to detect beta amyloid plaque, a pathology associated with Alzheimer’s disease (AD), in living patients.

The data were presented at the Alzheimer's Association International Conference 2012 (AAIC 2012) in Vancouver and support an application for regulatory approval of [18 F]flutemetamol, which is intended to be filed later this year. [18 F]Flutemetamol is a GE Healthcare PET imaging agent in development for the detection of beta amyloid deposits in the brain.

“Currently, definite AD diagnosis requires postmortem examination of the brain for pathology such as neuritic beta amyloid plaques,” said Milos Ikonomovic, MD, Associate Professor of Neurology, Department of Neurology, University of Pittsburgh Medical Center, presenter of the study. “Because the ability to detect brain amyloid deposits in vivo may allow physicians to make a more accurate clinical diagnosis and potentially could enhance patient management, we were pleased to see that flutemetamol PET images accurately and consistently reflected fibrillar beta amyloid levels as detected later using postmortem histopathology analyses.” The study presented at AAIC 2012 examined the autopsied brains of 68 subjects who had received [18 F]flutemetamol imaging in life to detect the presence of brain beta amyloid pathology. The images were then evaluated visually by independent trained readers, and the flutemetamol retention in the brain was quantified using a standardized uptake value ratio (SUVR). The brains of subjects who subsequently died were evaluated histopathologically and compared to interpretations of flutemetamol PET scans.

[18 F]Flutemetamol showed the ability to detect beta amyloid with a majority read sensitivity of 86 percent and specificity of 92 percent. Sensitivity is the percentage of amyloid-positive brains that are correctly identified by [18 F]]flutemetamol image readers as abnormal, corresponding to positive amyloid pathology. Comparison within and between image readers documented strong consistency of interpretation.

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 its development. Currently, AD is confirmed by histopathological identification of core features, including beta amyloid plaques, in postmortem brain samples. 2 Targeted amyloid imaging agents are being studied to determine their ability to help physicians detect amyloid deposition in living humans.

“The detection of beta amyloid plaque invivo may enable physicians to clinically diagnose AD earlier, potentially improving patient care,” said Jonathan Allis, General Manager, PET, GE Healthcare Medical Diagnostics. “Flutemetamol imaging has the potential to be part of a larger diagnostic workup that may help doctors rule out AD by reliably showing the absence of amyloid deposits in patients with unexplained loss of cognitive function. We are pleased to report that flutemetamol acted as anticipated in this study and look forward to filing with the FDA.” [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, that 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, our 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 our different business offerings positions us well to offer an integrated global diagnostics solution to assist the pharmaceutical industry in its 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 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 Ikonomovich M, Buckley C, Smith A et al. [18 F]Flutemetamol injection PET images reflect brain amyloid levels. Data presented at Alzheimer's Association ® International Conference 2012 (AAIC 2012), Vancouver, BC, Canada.

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.

CONTACT: GE Healthcare Aleisia Gibson 609 514 6046 (office) 201 289 3832 (mobile) Aleisia.gibson@ge.com or Scott Lerman 609 514 6346 (office) 609 937 9253 (mobile) scott.lerman@ge.com KEYWORD: UNITED KINGDOM UNITED STATES EUROPE NORTH AMERICA CANADA INDUSTRY KEYWORD: HEALTH BIOTECHNOLOGY CLINICAL TRIALS MENTAL HEALTH PHARMACEUTICAL SOURCE: GE Healthcare Copyright Business Wire 2012 PUB: 07/17/2012 09:00 AM/DISC: 07/17/2012 09:00 AM http://www.businesswire.com/news/home/20120717005933/

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