Merck and GE Healthcare Collaborate on Use of Imaging Biomarkers for Investigational BACE inhibitor Clinical Development Program

The Associated Press

WHITEHOUSE STATION, N.J. & PRINCETON, N.J.--(BUSINESS WIRE)--Dec 18, 2012--Merck (NYSE: MRK), known as MSD outside the United States and Canada, and GE Healthcare today announced a clinical study collaboration, license and supply agreement for use of [18 F]Flutemetamol, an investigational positron emission tomography (PET) imaging agent, to support Merck's development of MK-8931, a novel oral beta amyloid precursor protein site cleaving enzyme (BACE) inhibitor and Merck's lead investigational candidate for Alzheimer's disease (AD).

Accumulation of beta amyloid in the brain is a pathological characteristic related to Alzheimer’s disease. Currently, AD is diagnosed by clinical examination (i.e., medical history, physical, neurological, psychiatric and neuropsychological exams, laboratory tests and Magnetic Resonance Imaging [MRI] or Computed Tomography [CT] scan). An AD diagnosis can only be confirmed through histopathological identification of characteristic features, including beta amyloid plaques, in post-mortem brain samples.

"There is a serious unmet need for a reliable method for measuring beta amyloid deposits to help physicians diagnose Alzheimer’s disease at its different stages and study its progression," said Darryle Schoepp, Ph.D., senior vice president, head of neuroscience and ophthalmology, Merck Research Laboratories. "This agreement will allow us to employ an investigational imaging agent to help identify patients who might benefit from an anti-amyloid therapy and enable clinical evaluation of our lead BACE inhibitor candidate for Alzheimer's disease, MK-8931." Under the agreement, GE Healthcare will supply [18 F]Flutemetamol to help select patients for clinical trials and evaluate this investigational agent as a companion diagnostic tool. A joint Merck and GE Healthcare Imaging Advisory Committee will oversee the planned imaging studies.

“In clinical trials, [18 F]Flutemetamol demonstrated consistent performance in the visual detection of beta amyloid in the brain when compared with histopathology data,” said Jonathan Allis, general manager, PET, GE Healthcare Medical Diagnostics. “[18 F]Flutemetamol imaging 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 amyloid deposits in patients with unexplained loss of cognitive function.” About Merck’s BACE Inhibitor Development Program and MK-8931 Merck is advancing several innovative programs in Alzheimer's disease, including candidates designed to modify disease progression as well as improve symptom control. Merck's lead candidate in disease modification is MK-8931, an investigational oral BACE inhibitor.

Results of Phase I clinical studies demonstrated that MK-8931 can reduce cerebral spinal fluid (CSF) beta amyloid by greater than 90 percent in healthy volunteers without dose limiting side effects. Based on these results, Merck is moving forward with a global, multi-center Phase II/III clinical trial, called EPOCH, to evaluate the safety and efficacy of MK-8931 versus placebo in patients with mild-to-moderate AD. For more information about the EPOCH study please visit www.ADstudyinfo.com or call 1-855-55-EPOCH (37624). Information is also available at www.clinicaltrials.gov.

About [18 F]Flutemetamol [18 F]Flutemetamol is an investigational PET imaging agent being developed by GE Healthcare for the detection of beta amyloid deposits in the brain. Pooled results from Phase III brain autopsy and biopsy studies showed a strong concordance between [18F]Flutemetamol images and AD-associated beta amyloid brain pathology. Phase III studies demonstrated [18F]Flutemetamol visual detection of beta amyloid with a majority read sensitivity of 86 percent and specificity of 92 percent.

About Alzheimer's Disease and Amyloid Hypothesis Alzheimer’s disease (AD) is a devastating, irreversible and ultimately fatal disease that progressively destroys neurons in the brain, leading to a deterioration of cognitive function. The symptoms include loss of memory that progresses into behavioral changes, alterations in thinking and reasoning skills that interfere with daily activities, and dementia. AD is the most common cause of dementia, accounting for approximately 50-75 percent of the estimated 35 million dementia cases globally. 1,2 About 5.4 million people in the United States are currently living with AD. 3 There are currently no disease-modifying treatments available for AD, and current treatment options are limited to providing symptomatic improvements with only modest and short-term effects.

While the exact cause of AD remains unknown, a current prevailing theory asserts that AD occurs due to the accumulation of beta amyloid proteins in the brain. Beta amyloid precursor protein site cleaving enzyme (BACE) is believed to be a key enzyme in the production of beta amyloid peptide. Evidence suggests that inhibiting BACE decreases the production of beta amyloid and may therefore reduce amyloid plaque formation and modify disease progression.

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.

About Merck Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Merck Forward-Looking Statement This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2011 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

1 Alzheimer’s Disease International. Types of Dementia: Alzheimer’s Disease. Available at: http://www.alz.co.uk/info/alzheimers-disease.

2 Alzheimer’s Disease International. Dementia Statistics. Available at: http://www.alz.co.uk/research/statistics.

3 Alzheimer’s Association. Alzheimer’s Fact and Figures. Available at: http://www.alz.org/alzheimers_disease_facts_and_figures.asp
Photos/Multimedia Gallery

Available:http://www.businesswire.com/multimedia/home/20121218005719/en/ CONTACT: Media Contacts: Merck Caroline Lappetito, 267-305-7639 or GE Aleisia Gibson, 201-289-3832 or Investor Relations Contacts: Merck Carol Ferguson, 908-423-4465 KEYWORD: UNITED KINGDOM UNITED STATES EUROPE NORTH AMERICA NEW JERSEY INDUSTRY KEYWORD: HEALTH MEDICAL DEVICES MENTAL HEALTH PHARMACEUTICAL SOURCE: Merck Copyright Business Wire 2012 PUB: 12/18/2012 07:30 AM/DISC: 12/18/2012 07:30 AM http://www.businesswire.com/news/home/20121218005719/

Source URL (retrieved on *12/18/2014 - 6:45am*):
http://www.mdtmag.com/news/2012/12/merck-and-ge-healthcare-collaborate-use-imaging-biomarkers-investigational-bace-inhibitor-clinical-development-program?qt-most_popular=0&qt-recent_content=0