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Study Results of GAMMAGARD S/D and GAMMAGARD LIQUID in Patients with Mild-to-Moderate Alzheimer's Disease Announced

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CHICAGO, April 17 /PRNewswire-FirstCall/ -- New York-Presbyterian Hospital/Weill Cornell Medical Center and Baxter International Inc. (NYSE: BAX) announced results of a six-month, placebo-controlled Phase II study of 24 patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID [Immune Globulin Intravenous (IGIV)] for the treatment of mild-to-moderate Alzheimer's disease today at the American Academy of Neurology (AAN) annual meeting in Chicago. The study met the primary endpoint criteria favoring GAMMAGARD LIQUID and GAMMAGARD S/D over placebo on measures of cognitive function and global impression of change, which are common measures of outcome in Alzheimer's disease clinical trials. The study also met secondary endpoints that measured changes in beta-amyloid and anti-amyloid antibody levels in blood and cerebrospinal fluid. Results show findings indicative of potential efficacy and tolerability. Key findings throughout six months included: measurements of clinical outcome, behavioral outcome and cognitive performance in Alzheimer's patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID compared to placebo. Twelve-

to-18 month data will be available later this year.

Secondary endpoint results suggest that levels of antibodies against beta-amyloid were observed to have increased in the blood and cerebrospinal fluid of patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID, while the levels of beta-amyloid increased in the blood. Beta-amyloid is a substance thought to contribute to the degeneration of the brain in Alzheimer's disease. Clearing this substance from the central nervous system, therefore is hypothesized to help remove or reduce the building blocks of Alzheimer's.

The primary and secondary endpoint data were reported by the lead researcher for the trial, Dr. Norman Relkin, director of the Memory Disorders Program and behavioral neurologist and neuroscientist at New York-Presbyterian/Weill Cornell Medical Center, and associate professor of clinical neurology at Weill Cornell Medical College in New York City.

"This was the first placebo-controlled clinical trial of GAMMAGARD for Alzheimer's disease and the results are clearly promising," Dr. Relkin commented.

Baxter supported the study and provided GAMMAGARD LIQUID and GAMMAGARD S/D for the trial. GAMMAGARD S/D and GAMMAGARD LIQUID, marketed as KIOVIG in the European Union, contain a broad spectrum of immunoglobulins (antibodies) and are indicated as an immunoglobulin replacement therapy that boosts the immune system in patients with primary immunodeficiency disorders.

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The precise mechanisms of GAMMAGARD S/D and GAMMAGARD LIQUID's effects in Alzheimer's disease are not known.

"These study results reflect Baxter's support of innovative science and commitment to meeting a critical, unmet medical need," said Hartmut J. Ehrlich, MD, vice president of global research and development for Baxter's BioScience business. "While results of Baxter's mid-stage development work in Alzheimer's disease treatment are promising, further investigation in a larger Phase III study is required."

Phase II Study Design

In the double-blind, placebo-controlled Phase II study, 24 patients in the United States with mild-to-moderate Alzheimer's disease, who were maintained on standard treatment therapy, were randomly assigned to receive GAMMAGARD LIQUID (eight patients), GAMMAGARD S/D (eight patients) or saline placebo (eight patients) for six months. The study included a comparison of four dosing regimens of GAMMAGARD, with doses ranging from 0.2 g/kg every two weeks to 0.8 g/kg every month. The safety and tolerability of the treatment and clinical outcomes of 24 patients were assessed at the beginning of the study and after three and six months. The study is an ongoing, open-label study extended to 18 months to examine the long-term effects of the treatment.

Cognitive, behavioral and functional measures were collected at baseline, three months and six months of treatment. The primary endpoints of the Phase II trial were cognitive function (as measured by the ADAS-cog) and global impression of change (as assessed by the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) change rating). The secondary endpoints measured changes in beta-amyloid and anti-amyloid antibody levels in blood and cerebrospinal fluid. Safety and tolerability of GAMMAGARD S/D and GAMMAGARD LIQUID treatment in Alzheimer's patients were also assessed relative to placebo.

Phase II Study Results

In August 2007, Baxter and New York-Presbyterian/Weill Cornell announced preliminary Phase II results based on six-month data, indicating the study provided encouragement to carry out a Phase III trial. The criteria for going forward with a Phase III trial were favorable outcomes in GAMMAGARD S/D and GAMMAGARD LIQUID-treated patients relative to those given placebo. The final results of the study re-affirm the decision of Baxter and the ADCS to pursue a multi-center, Phase III study evaluating the role of GAMMAGARD LIQUID for the treatment of patients with mild-to-moderate Alzheimer's disease. The decision was based on results of two completed, open-label clinical studies and the preliminary six-month interim analysis of the Phase II trial.

The Phase II study follows an earlier Phase I study in eight patients carried out at New York-Presbyterian/Weill Cornell that was published in the journal *Neurobiology of Aging* in February 2008.

Cognitive Function and Global Impression of Change Findings (Primary Endpoints)

After six months, the group of patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID averaged 1.52 points higher than placebo-treated patients (+0.27 versus -1.25) on the ADCS-CGIC score, a commonly used measure of outcome in Alzheimer's disease clinical trials. The ADCS-CGIC is used in Alzheimer's trials to assess clinically relevant overall changes in Alzheimer's disease patients determined by patient and caregiver interviews.

Patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID had fewer behavior-related adverse events during the six-month trial and had a more favorable behavioral outcome as measured by the Neuropsychiatric Inventory, a scale used to measure behavioral problems in Alzheimer's patients. The average change in ADAS-Cog score -- a common cognitive testing measure -- at six months of treatment was numerically improved in patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID than placebo (-0.38 versus +2.61), although this difference did not reach statistical significance in the relatively small number of patients studied.

Levels of Beta-Amyloid (Secondary Endpoints)

Dr. Relkin also reported observations that levels of antibodies against beta-amyloid increased in the cerebrospinal fluid and blood of patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID, while the levels of beta-amyloid in the blood increased. The antibody and beta-amyloid levels were assessed using ELISA immunosorbant assay, a method used to detect antibodies, and observations were analyzed using parametric statistical analysis.

Tolerability

The study also met its endpoint in assessing the tolerability of GAMMAGARD S/D and GAMMAGARD LIQUID in Alzheimer's patients. The only treatment-related adverse events that occurred at a

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greater frequency with GAMMAGARD S/D and GAMMAGARD LIQUID treatment as compared to placebo were rash and a transient drop in blood count (in most cases, hemoglobin (Hgb) levels returned to within 1 Hgb unit of baseline within three to six months).

Brain Metabolism (Additional, Observational Finding)

Dr. Lisa Mosconi, assistant professor of psychiatry at New York University Medical Center, worked with the New York-Presbyterian/Weill Cornell group on the analysis of brain imaging data from the study and also presented findings at the AAN meeting. She reported that GAMMAGARD-treated participants had observable changes in brain metabolism. While energy metabolism in the brain was an exploratory endpoint in the study it was preserved or improved in 10 out of 13 patients after six months of GAMMAGARD S/D and GAMMAGARD LIQUID treatment.

"Brain metabolism usually decreases progressively in patients with Alzheimer's disease," said Dr Mosconi. "The changes on PET scans of these Alzheimer's patients after six months of GAMMAGARD S/D and GAMMAGARD LIQUID are encouraging."

The Phase II study also evaluated brain metabolism in patients treated with GAMMAGARD S/D and GAMMAGARD LIQUID compared to those who received placebo based on 18F-fluoro-deoxyglucose Positron Emission Tomography (PET) (FDG-PET) scans, which are sometimes used in the diagnosis of Alzheimer's disease. Across brain regions usually affected by Alzheimer's disease, in this study the GAMMAGARD S/D and GAMMAGARD LIQUID groups were observed to show 16 percent higher brain metabolism after treatment compared to placebo (12-18 percent increase in the hippocampi, 14-17 percent increase in parieto-temporal cortices and 21-24 percent increase in the thalami).

Phase III Study

The Phase III study is sponsored by the National Institutes of Health (NIH) and Baxter. The study protocol was submitted to the U.S. Food and Drug Administration for review, with the intention of initiating patient recruitment later in 2008. The trial will include approximately 35 leading academic centers in the United States that are members of the Alzheimer's Disease Cooperative Study (ADCS). The involvement of the ADCS and NIH in the conduct of the Phase III trial will ensure the highest level of independent scientific evaluation of the potential role of GAMMAGARD S/D and GAMMAGARD LIQUID in the treatment of Alzheimer's.

About Alzheimer's Disease

Alzheimer's disease is the most common form of dementia, a clinical condition that involves the decline or loss of memory and other cognitive abilities. A progressive and ultimately fatal disease marked by severe brain tissue deterioration, Alzheimer's disease initially involves the parts of the brain that control thought, memory and language. According to the Alzheimer's Association, an estimated 5.2 million American have Alzheimer's, including one out of eight people age 65 and older. The number of new Alzheimer's disease cases diagnosed annually is expected to reach 454,000 by 2010, with 959,000 new cases a year by 2050. By that time, the number of people age 65 and older with Alzheimer's disease could reach as high as 16 million.

About GAMMAGARD LIQUID and GAMMAGARD S/D

GAMMAGARD LIQUID

GAMMAGARD LIQUID is indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include but are not limited to congenital X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Important Safety Information

GAMMAGARD LIQUID is contraindicated in patients with known anaphylactic or severe hypersensitivity responses to Immune Globulin (Human). Patients with severe selective IgA deficiency (IgA < 0.05 g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction.

Immune Globulin Intravenous (Human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentration available and the minimum rate of infusion practicable. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number.



Glycine, an amino acid, is used as a stabilizer. GAMMAGARD LIQUID does not contain sucrose.

GAMMAGARD LIQUID is made from human plasma. It may carry a risk of transmitting infectious agents, viruses, and theoretically, the Creutzfeldt- Jakob disease (CJD) agent.

Components used in the packaging of this product are latex-free.

Thrombotic events have been reported in association with IGIV. Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity, hypercoagulable disorders, and prolonged periods of immobilization.

IGIV products can contain blood group antibodies that may cause a positive direct antiglobulin reaction and, rarely, hemolysis.

Aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Various mild and moderate reactions, such as headache, fever, fatigue, chills, flushing, dizziness, urticaria, wheezing or chest tightness, nausea, vomiting, rigors, back pain, chest pain, muscle cramps, and changes in blood pressure may occur with infusions of Immune Globulin Intravenous (Human).

For full prescribing information, please visit <http://www.gammagardliquid.com>.

GAMMAGARD S/D [Immune Globulin Intravenous (Human)]

GAMMAGARD S/D is indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include but are not limited to congenital X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

GAMMAGARD S/D must not be used in patients with selective IgA deficiency (IgA < 0.05 g/L) where the IgA deficiency is the only abnormality of concern.

Important Safety Information

Patients may experience severe hypersensitivity reactions or anaphylaxis in the setting of detectable IgA levels following infusion of GAMMAGARD S/D.

Immune Globulin Intravenous (Human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentration available and the minimum rate of infusion practicable. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number.

GAMMAGARD S/D does not contain sucrose.

GAMMAGARD S/D is made from human plasma. It may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Certain components used in the packaging of GAMMAGARD S/D contain natural rubber latex.

IGIV products can contain blood group antibodies that may cause a positive direct antiglobulin reaction and, rarely, hemolysis.

Thrombotic events have been reported in association with IGIV. Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity, hypercoagulable disorders, and prolonged periods of immobilization.

Various minor reactions, such as mild to moderate hypotension, headache, fatigue, chills, backache, leg cramps, lightheadedness, fever, urticaria, flushing, slight elevation of blood pressure, nausea and vomiting, may occasionally occur.

For full prescribing information, please visit:
<http://www.immunedisease.com/US/patients/safety.html#gamma>

About New York-Presbyterian Hospital/Weill Cornell Medical Center

New York-Presbyterian Hospital/Weill Cornell Medical Center, located in New York City, is one of the leading academic medical centers in the world, comprising the teaching hospital New York-Presbyterian and Weill Cornell Medical College, the medical school of Cornell University. New York-Presbyterian/Weill Cornell provides state-of-the-art inpatient, ambulatory and preventive care in all areas of medicine, and is committed to excellence in patient care, education, research and community service. Weill Cornell physician-scientists have been responsible for many medical advances -- from the development of the Pap test for cervical cancer to the synthesis of penicillin, the first successful embryo-biopsy pregnancy and birth in the U.S., the first clinical trial for gene therapy for Parkinson's disease, the first indication of bone marrow's critical role in tumor growth, and, most recently, the world's first successful use of deep brain stimulation to treat a minimally-conscious brain-injured patient. New York-Presbyterian, which is ranked sixth on the U.S. News & World Report list of top hospitals, also comprises New York-Presbyterian Hospital/Columbia University Medical Center, Morgan Stanley Children's Hospital of New York-Presbyterian, New York-Presbyterian Hospital/Westchester Division and New York-Presbyterian Hospital/The Allen Pavilion. Weill Cornell Medical College is the first U.S. medical college to offer a medical degree overseas and maintains a strong global presence in Austria, Brazil, Haiti, Tanzania, Turkey and Qatar. For more information, visit <http://www.nyp.org> and <http://www.med.cornell.edu>.

About Baxter

Baxter International Inc., through its subsidiaries, assists healthcare professionals and their patients with treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other indications. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

This release includes forward-looking statements concerning GAMMAGARD S/D and GAMMAGARD LIQUID [Immune Globulin Intravenous (IGIV)] relating to clinical trials as well as potential future uses of the products. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: continued review of Phase II data and the limited number of patients studied to date; additional regulatory and other steps required prior to the initiation of the larger Phase III study described in the release; and other risks identified in Baxter's most recent filing on Form 10-K and other Securities and Exchange Commission filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.

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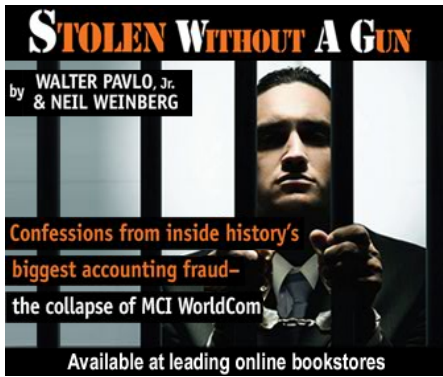
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