ABBOTT PRESENTS RESULTS OF CLINICAL STUDIES EVALUATING ITS INVESTIGATIONAL TREATMENT FOR ADVANCED PARKINSON'S DISEASE

New Long-Term Study Results Presented at 16th International Congress of Parkinson's Disease and Movement Disorders

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DUBLIN, June 18, 2012 /PRNewswire/ -- Today Abbott (NYSE: ABT) announced results from five abstracts evaluating levodopa-carbidopa intestinal gel (LCIG), its investigational compound for advanced Parkinson's disease. The abstracts include the results from the second interim analysis of a long-term safety and tolerability trial, as well as secondary endpoint analyses from the Phase 3 pivotal trial. All of the abstracts were presented at The 16th International Congress of Parkinson's Disease and Movement Disorders, June 17-21 in Dublin, Ireland.

LCIG is currently approved in 40 countries. In the U.S., LCIG is an investigational therapy that is currently being evaluated in patients with advanced Parkinson's disease in additional Phase 3 clinical trials. In these trials, levodopa-carbidopa is administered in gel form, directly into the small intestine via a procedurally-implanted tube connected to a portable pump that delivers continuous supply of LCIG during awake hours.

Long-Term Safety and Tolerability
In a 54 week open-label safety and tolerability study of 354 patients with advanced Parkinson's disease, the primary endpoint of safety showed adverse events (AEs) were mostly mild to moderate, were generally associated with the Percutaneous Endoscopic Gastrostomy (PEG) tube placement procedure and its complications, were transient, and resolved over time.

In the secondary endpoint analysis from the open-label study, patients experienced an average daily "off" time of 6.7 hours, and 7.7 hours of "on" time without troublesome dyskinesia at baseline. "Off" time refers to periods of poor mobility, slowness and stiffness experienced by patients with Parkinson's disease, while "on" time refers to periods of good motor symptom control. At week 54, mean daily "off" time had decreased an average of 4.5 hours, and "on" time without troublesome dyskinesia had increased by 5.1 hours. "On" time with troublesome dyskinesia decreased an average of 0.6 hours.

"Despite the many advances that have been made over the years in treating patients with Parkinson's disease, managing motor complications such as wearing off in the advanced stages of the condition continues to be challenging for physicians, patients and their caregivers," said Dr. C.W. Olanow, M.D., Professor of Neurology and Neuroscience at the Mount Sinai School of Medicine in New York City. "Data from the various clinical trials evaluating LCIG suggest that patients with advanced Parkinson's disease may benefit from continuous intestinal infusion of levodopa and carbidopa."

The most common treatment emergent AEs were complication of device insertion (33.1 percent), abdominal pain (30.0 percent), procedural pain (21.7 percent) and nausea (16.1 percent). The most common serious treatment emergent AEs were complication of device insertion (6.5 percent), abdominal pain (3.1 percent) peritonitis (2.8 percent) and polyneuropathy (2.8 percent). Twenty-six patients (7.3 percent) withdrew due to at least one AE; 17 of these patients withdrew due to at least one serious AE. Gastrointestinal- and PEG-related issues were the most common cause of withdrawal from the study.
Phase 3 Efficacy
Functional and quality of life secondary endpoint analyses from a twelve-week double-blind, double-dummy pivotal trial of 71 patients comparing LCIG to standard levodopa-carbidopa immediate release (LC-IR) tablets were also presented. The primary endpoint of this study showed a reduction in mean daily "off" time of 4.0 hours, a statistically significant difference of 1.91 fewer hours spent in "off" time with LCIG compared to LC-IR tablets. These data were previously presented at the American Academy of Neurology Annual Meeting (April 21-28, 2012, New Orleans, Louisiana). The most common adverse events were complication of device insertion (51 percent), abdominal pain (42 percent), procedural pain (32 percent), nausea (25 percent), constipation (21 percent), orthostatic hypotension (18 percent), post-operative wound infection (17 percent), and incision site erythema (16 percent).

"We are pleased to showcase the clinical trial results being presented for LCIG in patients with advanced Parkinson’s disease," said Robert Lenz, M.D., divisional vice president, Global Pharmaceutical Research and Development, Abbott. "Obtaining pivotal and supportive clinical data is a critical stage in the overall development process of LCIG and further supports our efforts to develop LCIG for advanced PD patients in the U.S. who are in need of alternative therapies."

It is estimated that at least three million people worldwide have been diagnosed with Parkinson's disease. As the disease progresses, the effect of oral medications may not last as long and can cause increasing side effects. Patients with advanced Parkinson's disease may experience fluctuations between bradykinetic (slowness of movement) and hyperdyskinetic (involuntary movement) states.

Other abstracts presented were:

Abstract 385: "Randomized, Double-blind, Double-dummy Study of Continuous Infusion of Levodopa-carbidopa Intestinal Gel in Patients with Advanced Parkinson's Disease: Functional and Quality-of-Life Outcomes."

- Kiebertz K, et al.; Monday, June 18, 12:45 - 14:15 CET / 6:45 - 8:15 a.m. CDT.

Abstract 436: "Levodopa-carbidopa Intestinal Gel in Parkinson’s Disease Patients with Severe Motor Fluctuations: Interim Quality-of-Life Endpoints in an Ongoing, Open-label Study."

- Standaert DG, et al.; Monday, June 18, 12:45 - 14:15 CET / 6:45 - 8:15 a.m. CDT.

Abstract 410: "Stable Levodopa Plasma Levels with Jejunal Infusion of Levodopa-Carbidopa Intestinal Gel in Advanced Parkinson's Disease Patients."

- Nyholm D, et al.; Monday, June 18, 12:45 - 14:15 CET / 6:45 - 8:15 a.m. CDT.

About Parkinson's Disease
Parkinson's disease is a progressive and chronic movement disorder that leads to tremor, muscle rigidity, slowness of movement and difficulty with balance. It is classified as a movement disorder, which results from the loss of dopamine-producing brain cells. The symptoms of Parkinson's disease begin when approximately 60-80 percent of the dopamine-producing cells in the brain are lost and symptoms continue to worsen slowly over the course of time. While there is no known cure for the disease, there are treatments available to help reduce symptoms.

About Abbott's Neuroscience and Pain Research
Abbott is conducting innovative research in neuroscience, where it has developed compounds that target receptors in the brain that help regulate mood, memory and other neurological functions. Abbott has 11 compounds in human studies for conditions such as schizophrenia, pain and Alzheimer's disease, in addition to Parkinson's disease and multiple sclerosis.

About Abbott
Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries.

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