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ADAGIO trial results show Azilect® slows progression of Parkinson's disease

Lundbeck's partner Teva Pharmaceutical Industries Ltd. has announced today that results of the phase III ADAGIO trial were presented during the 12th Congress of European Federation of Neurological Societies (EFNS) in Madrid, Spain. The ADAGIO study showed that Parkinson's disease patients who took Azilect® (rasagiline) 1mg tablets once-daily upon entry into the trial, demonstrated a significant improvement compared to those who initiated therapy with the drug nine months later. The 1mg dose met all three primary endpoints, as well as the secondary endpoint, with statistical significance.

The primary analysis included three hierarchical endpoints based on Total-UPDRS (Unified Parkinson's Disease Rating Scale) scores: A) superiority of slopes in weeks 12-36 (-0.05; p=0.013, 95%CI -0.08,-0.01), B) change from baseline to week 72 (-1.7 units; p=0.025, 95%CI -3.15,-0.21), and C) non-inferiority of slopes (0.15 margin) in weeks 48-72 (0.0; 90%CI -0.04,0.04). The safety profile of Azilect® seen in the ADAGIO study was similar to previous experience with Azilect®.

Main results were presented at the congress by Professor Olivier Rascol, M.D., Ph.D., Department of Clinical Pharmacology, University Hospital, Toulouse, France, one of two principal investigators of the trial.

"The rigorous trial design and the fact that all three primary endpoints were met with statistical significance reinforce the quality of the data, supporting the potential for Azilect® to have an effect on disease progression," said Prof. Rascol. "The successful outcome of the study provides further rationale for the early use of Azilect® among Parkinson's disease patients," he added.

"Delaying disease progression is the most important unmet need in the management of Parkinson's disease," stated Prof. C. Warren Olanow, professor and chairman of the Department of Neurology at the Mount Sinai School of Medicine, New York, NY, and ADAGIO co-principal investigator. "The ADAGIO study, the first of its kind, was prospectively designed to demonstrate if Azilect® can slow down the progression of Parkinson's disease. Results of the study show that early treatment with once-daily rasagiline 1mg tablets provided significant clinical benefits that were not obtained by those patients where initiation of Azilect® therapy was delayed by nine months."

The ADAGIO study, one of the largest conducted in Parkinson's disease, included 1,176 patients with very early Parkinson's disease in 14 countries and 129 medical

centers who were randomized to receive rasagiline 1 or 2 mg/day for 72 weeks (early start) or placebo for 36 weeks followed by rasagiline 1 or 2 mg/day for 36 weeks (delayed start).

Description of the trial results can be found online (http://www.abstracts2view.com/ana) in the abstract submitted by Prof. Olanow and Prof. Rascol to the 133rd Annual Meeting of the American Neurological Association, Salt Lake City, UT, September 21-24, 2008. Prof. Olanow will be presenting these results during the Works in Progress poster session on Tuesday, September 23, 2008. The abstract was also chosen to be presented orally by Prof. Olanow on Tuesday from 11:45am-noon.

The results of the ADAGIO trial are expected to be submitted to the regulatory authorities in Europe with the aim to have the results incorporated into the label for Azilect®.

Lundbeck markets Azilect® in Europe, jointly with Teva in a number of countries. In addition Lundbeck markets Azilect® in some countries outside Europe.

About the study
ADAGIO is a randomized, multi-center, double-blind, placebo-controlled, parallel-group study prospectively examining rasagiline's potential disease-modifying effects in 1,176 patients with early, untreated Parkinson's disease. Patients from 129 centers in 14 countries were randomized to early-start treatment (72 weeks rasagiline 1 or 2 mg once daily) or delayed-start treatment (36 weeks placebo followed by 36 weeks rasagiline 1 or 2 mg once daily [active treatment phase]). The primary analyses of the trial were based on change in total UPDRS (Unified Parkinson's Disease Rating Scale) and included slope superiority of rasagiline over placebo in the placebo-controlled phase, change from baseline to week 72, and non-inferiority of early-start vs. delayed-start slopes during weeks 48-72 of the active phase. UPDRS is the most commonly used rating scale to assess disease status.

About Azilect®
Azilect® 1mg tablets (rasagiline tablets) are indicated for the treatment of the signs and symptoms of Parkinson's disease both as initial therapy alone and to be added to levodopa later in the disease.

For more information on Azilect®, please visit www.azilect.com.

About Parkinson's disease
Parkinson's disease is an age-related degenerative disorder of the brain. Symptoms can include: tremor, stiffness, slowness of movement, and impaired balance. An estimated four million people worldwide suffer from the disease, which usually affects people over the age of 60.

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The content of this release will have no influence on the Lundbeck Group's financial result for 2008.

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About Lundbeck

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of pharmaceuticals for the treatment of psychiatric and neurological disorders. In 2007, the company's revenue was DKK 11 billion (approximately EUR 1.5 billion or USD 2.0 billion). The number of employees is approx. 5,300 globally. For more information, please visit www.lundbeck.com.