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SCHWARZ PHARMA Announces Publication of Rotigotine Data for Advanced Parkinson's Disease in *Neurology*

Phase III trial results for transdermal rotigotine published in *Neurology* demonstrated a statistically significant reduction in "off" time in advanced Parkinson's disease patients.

April 16, 2007 –SCHWARZ PHARMA announced today the publication of an article titled, "Advanced Parkinson Disease Treated with Rotigotine Transdermal System: PREFER Study," in the April 17th issue of the journal *Neurology* (Vol. 68, No. 16, p. 1262). The full article can also be found on *Neurology's* website at <http://www.neurology.org>.

The randomized, double-blind, placebo-controlled trial was designed to assess efficacy and safety with two doses of rotigotine, a dopamine agonist formulated as a patch for once-daily administration, in subjects with advanced Parkinson's disease (PD). The primary efficacy variable was change from baseline in the absolute "off" time or periods where the effectiveness of medications wear off and PD symptoms return.

SCHWARZ PHARMA's Phase III trial PREFER (**P**rospective **R**andomized **E**valuation of a new **F**ormulation: **E**fficacy of **R**otigotine) in advanced-stage PD showed a statistically significant and clinically relevant reduction in "off" time as well as an increase in "on" time without troublesome dyskinesia.

The author and lead investigator of the study, Peter A. LeWitt, MD, Professor of Neurology, Wayne State School of Medicine, Detroit, Michigan, and Head of Clinical Neuroscience Center in Southfield, Michigan, stated, "Many advanced-stage PD patients experience multiple daily increases in

Parkinsonian symptoms between each dose of medication. By providing continuous drug delivery, this study demonstrated that the rotigotine patch can greatly improve the consistency of PD symptom control throughout the day.”

Study Design and Results

This Phase III clinical trial evaluated 351 patients with advanced-stage idiopathic PD at 54 clinical sites in the United States and Canada. Patients were randomized to receive placebo patches (n=120) or rotigotine up to either 8 mg/24 hr (n=120) or 12 mg/24 hr (n=111). A five-week titration phase was followed by a 24-week maintenance phase. Rotigotine transdermal system was added to stable levodopa treatment.

Compared to placebo, both rotigotine 8 mg/24 hr and 12 mg/24 hr significantly reduced “off” time in patients with advanced PD. The average decrease of 2.4 hours in daily “off” time with rotigotine exceeded the 0.9 hour decrease in the placebo group. The differences between both rotigotine dose arms and placebo were statistically significant with p-values of <0.001 and 0.003, respectively. The most commonly reported adverse events that occurred in patients receiving rotigotine were application site reactions, somnolence, nausea and vomiting, and dizziness.

About Rotigotine

Rotigotine is a non-ergolinic dopamine receptor-agonist formulated as a transdermal delivery system, a patch, designed for once-a-day application. Rotigotine is designed to mimic the action of dopamine, a naturally-produced neurotransmitter crucial for proper motor functioning. Rotigotine is currently under review with the U.S. Food and Drug Administration (FDA) for its efficacy and safety as treatment for early-stage PD. In January 2007, the European Commission approved Neupro[®] (rotigotine transdermal patch) for all stages of PD, including the treatment of the signs and symptoms of early-stage idiopathic PD as monotherapy or in combination with levodopa, over the course of the disease through to late stages. Since March 2006, the drug has been available in the European market and has already been launched by SCHWARZ PHARMA in Germany, the UK, Austria, Denmark, Ireland, Norway, Switzerland, Sweden, Greece, Spain, Finland and Poland.

About Parkinson's Disease

Parkinson's disease is a progressive disorder of the central nervous system. The patients - roughly four million worldwide, including approximately 1 million people in the U.S. - suffer primarily from a lack of dopamine, a messenger substance in the central nervous system, which is responsible for the coordination of movement. As a result of this shortage, patients are no longer able to control their movements reliably. Dopamine agonists are drugs that attempt to compensate for this lack of dopamine.

SCHWARZ PHARMA (headquartered in Monheim, Germany) is a pharmaceutical company with approximately 4,400 employees worldwide. The company develops novel medicines in the therapeutic areas of the central nervous system. Furthermore it markets innovative drugs focused to treat cardiovascular and gastro-intestinal diseases. In 2006 the SCHWARZ PHARMA group achieved global sales of € 1 billion. The company has a strong international presence with subsidiaries in Europe, USA and Asia.

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