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Rotigotine Transdermal System Shows Significant Symptom Reduction and Tolerability in Patients with Restless Legs Syndrome

- Data Presented at the 132nd Annual Meeting of the American Neurological Association in Washington, D.C. -

Atlanta - October 8, 2007 – UCB, Inc. presented results from two Phase III pivotal trials and one open-label extension trial of rotigotine transdermal system for the treatment of moderate-to-severe restless legs syndrome (RLS). These rotigotine data showed significant drops in RLS symptoms, including changes of up to 8 points over placebo using the International Restless Legs Syndrome Study Group Rating Scale (IRLS) and a reduction in disease severity over a two-year period.

“Given the strong efficacy and tolerability seen to date, rotigotine, if approved, would provide a new and valuable alternative for many patients negatively impacted by the symptoms of moderate-to-severe RLS,” said Wayne Hening, M.D., a lead study investigator and Assistant Clinical Professor of Neurology at the Robert Wood Johnson Medical School.

In the two six-month, double-blind, placebo-controlled trials, rotigotine produced clinically relevant and statistically significant reductions in RLS symptoms compared to placebo and was generally well-tolerated. An additional presentation highlighted a two-year interim analysis of a long-term, open-label extension of rotigotine for moderate-to-severe RLS, representing some of the longest safety follow-up information for a dopamine agonist in RLS to date.

In these studies, the efficacy of rotigotine was evaluated by monitoring several clinician-administered scales including the IRLS, the Clinical Global Impressions (CGI) and the Restless Leg Syndrome-6 (RLS-6). The IRLS scale measures the severity and frequency of RLS symptoms and the degree to which they affect sleep and daily life (IRLS: 0 = no

symptoms and 40 = very severe symptoms). The CGI scale measures the general severity of an illness, clinical improvement or efficacy of treatment parameters. On the RLS-6 scale, patients rate the severity of their RLS at four periods during the night and day, as well as sleep satisfaction and daytime tiredness.

A synopsis of rotigotine RLS clinical data presented at the meeting follows.

Six-Month Studies in Patients with Moderate-to-Severe Idiopathic RLS

SP 790

- In a multi-center, double-blind, placebo-controlled, Phase III trial, 458 patients were studied in eight European countries
- Rotigotine was studied in doses of 1, 2 and 3 mg/24 hours over a period of six months
- The study showed a statistically significant improvement in the IRLS sum score and a clinically relevant reduction in the CGI Item-1 (severity of illness) score compared to placebo
- The mean baseline scores were: IRLS 28.1 ± 6.1 and CGI 5.0 ± 0.8 reflecting moderate-to-severe symptoms at baseline
- The net effects over placebo after 6 months of treatment were -5.1 ± 1.3 , -7.5 ± 1.3 , and -8.2 ± 1.3 in the IRLS and -0.76 ± 0.19 , -1.07 ± 0.19 and -1.21 ± 0.19 in CGI Item-1 for rotigotine 1, 2, and 3 mg/24 hours respectively ($p < 0.001$ for all comparisons)
- Rotigotine was also shown to be generally well-tolerated
- The most common adverse events that were determined by the investigators to be drug-related were application site reactions, nausea, headache and dizziness

SP 792

- In a multi-center, double-blind, placebo-controlled, Phase III trial, 505 patients were studied in the United States
- Rotigotine was studied at doses of 0.5, 1, 2 and 3 mg/24 hours over a period of six months, with all doses showing improvement over placebo
- Rotigotine, in doses of 2 and 3 mg/24 hours over a period of six months, resulted in a statistically significant improvement in IRLS sum score and a clinically relevant reduction in the CGI Item-1 (severity of illness) score compared to placebo
- The mean baseline scores were: IRLS 23.3 ± 5.0 and CGI 4.7 ± 0.7 , reflecting moderate-to-severe symptoms at baseline
- The net effects over placebo after six months of treatment were -2.2 ± 1.2 , -2.3 ± 1.2 , -4.5 ± 1.2 ($p < 0.001$), -5.2 ± 1.2 ($p < 0.001$) in the IRLS and -0.35 ± 0.19 , -0.32 ± 0.19 , -0.65 ± 0.19 ($p < 0.001$), -0.90 ± 0.19 ($p < 0.001$) in CGI Item-1 for rotigotine 0.5, 1, 2, and 3 mg/24 hours respectively
- Rotigotine was also shown to be generally well-tolerated
- The most common adverse events were application site reactions (27.2%), nausea (21.5%), headache (17.6%) and somnolence (12.6%)

24-Month, Open-Label Extension Trial in RLS

SP 710

- In an open-label extension of a double-blind, placebo-controlled, Phase II dose-finding study conducted at multiple centers in Europe, rotigotine, administered with optimal dose titration, showed long-term therapeutic efficacy in patients with moderate-to-severe idiopathic RLS who were treated for 24 months

- A total of 295 patients entered the open-label extension trial and 191 (65%) completed the two-year maintenance period of this ongoing trial
- After 24 months of open-label rotigotine treatment, 87% of patients were rated as only mildly ill, borderline symptomatic, or normal on the CGI Item-1 scale which rates overall severity of illness
- The "change of condition" CGI Item-2 score showed a sustained improvement from the beginning through to the 24th month of open-label maintenance
- Additionally, the "*severity at bedtime falling asleep*" score (RLS-6 Item 2) improved by 4.0 ± 3.1 points following optimal rotigotine treatment
- Rotigotine treatment led to a 4.3 ± 3.3 point increase in "*sleep satisfaction*" (RLS-6 Item 1) and a 4.9 ± 3.0 point reduction of symptom severity "*during the night*" (RLS-6 Item 3)
- "*Daytime tiredness and sleepiness*" (RLS-6 Items 4 and 6) scores were reduced by 2.4 ± 2.7 points
- All effects were first observed during the titration period and were sustained over 24 months of open-label treatment
- The most common adverse events were application and instillation site reactions (50%), nasopharyngitis (12%), back pain (11%) and nausea (11%)

"We are pleased to report these promising findings, which show that rotigotine has potential as an important therapy in the management and treatment of RLS," said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB. "Clinical data strongly support the development of rotigotine for RLS, and we will work closely with regulatory authorities in both the United States and Europe in order to bring this important medication to market."

Neupro[®] (Rotigotine Transdermal System) is currently approved in the United States for the treatment of early-stage idiopathic Parkinson's disease and in Europe for the treatment of patients with early-stage Parkinson's disease and in combination with levodopa for advanced-stage Parkinson's disease. Applications for the use of rotigotine transdermal system in patients with moderate-to-severe RLS are currently being prepared for submission to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

About Neupro[®] (Rotigotine Transdermal System)

Rotigotine transdermal system 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. The system is applied to the skin once daily and provides rotigotine continuously to the body for 24 hours.

About Restless Legs Syndrome

Restless legs syndrome (RLS) is a chronic and progressive neurological disorder that affects up to 10 percent of the population. It is characterized by unpleasant feelings in the legs and an irresistible urge to move in order to relieve the discomfort. RLS sensations are frequently

described as tingling, burning, tugging, creepy-crawly, gnawing and pulling. Symptoms typically appear during periods of rest and inactivity, particularly in the evenings and at night. This can make it difficult to fall asleep and stay asleep, thus preventing recuperative sleep and often leading to daytime fatigue and reduced alertness.

About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialisation of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology - UCB focuses on securing a leading position in severe disease categories. Employing more than 10,000 people in over 40 countries, UCB achieved revenue of 3.5 billion euro in 2006 on a pro forma basis. UCB is listed on the Euronext Brussels Exchange and owns approximately 88% of the shares of SCHWARZ PHARMA AG. SCHWARZ PHARMA AG (Monheim, Germany) is a member of UCB Group.

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