CT Registry ID#: *NCT00263068 (ClinicalTrials.gov Identifier number)*
Study No.: SP793

These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.

Proprietary Drug Name	**INN**	**Therapeutic area and indication(s)**
Neupro® transdermal patch	Rotigotine	Restless legs syndrome

Name of Sponsor/Company: SCHWARZ BIOSCIENCES, INC. A member of the UCB group

Title of Study:
An open-label extension trial to investigate the safety and tolerability of long-term treatment with transdermal rotigotine in subjects with idiopathic Restless Legs Syndrome (RLS)

Investigator(s) (number only): 54

Study Center(s) (number only): 48

Length of Study:	Maximum ~14 months	Phase of Development: 3
Date first subject enrolled:	15 Dec 2005	
Date last subject completed:	18 Dec 2007	

Abstract:
SP793 was a multicenter, open-label (OL) extension trial to assess safety and tolerability of rotigotine in subjects with idiopathic RLS, administered at an optimal dose for up to 1 year in subjects who previously participated in SP792 (6-month pivotal trial).

The following safety variables were measured: adverse events (AEs) reported spontaneously by the subject or observed by the investigator, changes in laboratory tests, changes in vital signs, physical and neurological examination findings, changes in 12-lead electrocardiograms (ECGs), changes in menstrual and sexual function, subject's rating of daytime sleepiness as measured by the Epworth Sleepiness Scale, Global Subject Rating of Tolerability, Clinical Global Impressions (CGI) Item 4, the Jay Modified Minnesota Impulsive Disorder Interview, changes in the Augmentation Severity Rating Scale, changes in the Self-Rating Depression Scale, and assessments of application sites and patch adhesiveness.

Subjects who had completed the Maintenance and Taper Period of SP792 and who had given their written informed consent were included in this trial. Subjects were excluded if they had an ongoing serious adverse event (SAE) from SP792 that was assessed as related to trial medication by the investigator.

The treatment duration of this trial was approximately 14 months and consisted of a Titration Period of up to 28 days (±3 days), a 12-month Maintenance Period, a Taper Period of up to 4 days, and a Safety Follow-Up Period of 30 days.

Number of Subjects:	
Planned, N:	450
Enrolled, N:	279 (100.0)
Completed, n (%):	174 (62.4)
Number of Subjects Withdrawn, n (%):	105 (37.6)
Withdrawn due to Adverse Events, n (%):	51 (48.6)
Withdrawn for Other Reasons, n (%):	54 (51.4)
Demography:	
Gender (Females/Males):	151/128
Age (years), mean (SD):	54.2 (11.8)
Race	
White, n (%):	266 (95.3)
Black, n (%):	3 (1.1)
Asian, n (%):	1 (0.4)
Other, n (%):	9 (3.2)

Safety Outcomes:
Overall, rotigotine was well tolerated during the trial. Most AEs were consistent with stimulation of dopamine receptors and the use of a transdermal patch. The majority of AEs were mild or moderate in intensity. The most common AEs were application site reactions, nausea, somnolence, and headache. A total of 18% of subjects discontinued trial medication due to an AE, the most common AEs being application site reactions. A total of 4% of subjects experienced an SAE during treatment; these SAEs occurred across multiple System Organ Classes with no obvious grouping. No death was reported during the trial. There were no trends observed in laboratory parameters that were of clinical relevance. There was no indication for rotigotine to cause any ECG abnormalities or changes in this trial. No clinically relevant changes in vital signs or physical and neurological examinations were noted. Most subjects reported no changes in menstrual and sexual function.

A summary of AEs is provided below:

Treatment Emergent AEs (TEAE):

TEAEs occurring in ≥5% of subjects:

Preferred Term	N=279 *n (%)*
Any AE	230 (82.4)
Application and instillation site reactions[a]	68 (24.4)
Nausea	43 (15.4)
Somnolence	33 (11.8)
Headache	32 (11.5)
Upper respiratory tract infection	21 (7.5)
Fatigue	18 (6.5)
Dizziness	16 (5.7)
Sinusitis	14 (5.0)

[a] MedDRA High Level Term

Drug-related TEAEs (as assessed by the Investigator):	
Drug-related TEAEs occurring in ≥5% of subjects:	
Preferred Term	N=279 *n (%)*
Any AE	160 (57.3)
Application and instillation site reactions[a]	68 (24.4)
Nausea	33 (11.8)
Somnolence	23 (8.2)
Headache	19 (6.8)
Fatigue	16 (5.7)
[a] MedDRA High Level Term	
Death, SAEs, and Other SAEs:	
Death, n (%):	0
Subjects with treatment-emergent SAEs, Preferred Terms, n (%):	12 (4.3)
Chest discomfort	1 (0.4) [0]
Chest pain	1 (0.4) [0]
Appendicitis	1 (0.4) [0]
Ankle fracture	1 (0.4) [0]
Fibula fracture	1 (0.4) [0]
Lower limb fracture	1 (0.4) [0]
Postoperative ileus	1 (0.4) [0]
Breast cancer	1 (0.4) [0]
Breast cancer in situ	1 (0.4) [0]
Colon cancer	1 (0.4) [0]
Neuroendocrine carcinoma of the skin	1 (0.4) [0]
Balance disorder	1 (0.4) [1]
Somnolence	1 (0.4) [2]
Brain stem syndrome	1 (0.4) [0]
Dizziness	1 (0.4) [1]
Dysarthria	1 (0.4) [1]
Confusional state	1 (0.4) [1]
Renal colic	1 (0.4) [0]
Primary & Secondary Efficacy Outcomes: This was an open-label exploratory trial with no specified primary or secondary efficacy endpoints.	
Publication Reference(s) based on the study: None at this time	
Date of report: 05-Dec-2008	