Approved by UCB 10-Jun-2008

Clinical Study Summary (CSS) Template

CT Registry ID#: *NCT00238511*
Study No.: SP690

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)**
Vimpat™	Lacosamide	Postherpetic Neuralgia

Name of Sponsor/Company: UCB

Title of Study:
An open-label follow-on trial to assess the long-term safety and efficacy of oral SPM 927 in subjects with postherpetic neuralgia (PHN)

Investigator(s) (number only): 7

Study Center(s) (number only): 7

Length of Study:
Date first patient enrolled: 26-Nov-2002
Date last patient completed: 06-Jan-2005

Phase of Development: 2

Abstract:
This was an open-label, follow-on trial of lacosamide in subjects with PHN. Following a 1-week Baseline Run-In Phase, subject had their dose escalated from 50mg twice daily (100mg/day) up to a maximum dose of 300mg twice daily (600mg/day), increasing by 100mg at weekly intervals based on subject's pain relief, safety assessments, and drug tolerance. Once the optimal dose was reached, subjects were maintained on that dose. Up- and down-titration was allowed throughout the trial.

The primary objective of the trial was to assess the tolerability and safety of long-term lacosamide administration in subjects with PHN. The secondary objective was to gather further information on the efficacy of lacosamide in this indication.

Of the 17 enrolled subjects, 13 were treated for up to 6 months and 4 subjects remained in the trial for longer periods of time up to a maximum of 743 days. At Baseline, the average Likert pain score for all subjects combined was 4.86. Across the period of the trial, the average pain score decreased beginning in the Titration Phase. The overall reduction in Likert pain score throughout the entire Treatment Phase was 0.85. In all, 1 serious adverse event (SAE) (inguinal hernia) occurred during this study and was considered to be not related to trial medication by the investigator. Three subjects experienced adverse events (AEs) classified as "other significant AEs" ("rash," "QTc interval increased," and "GGT increased"). All 17 subjects experienced at least 1 treatment-emergent AE. Among all subjects, treatment-emergent AEs were most common in the nervous system and gastrointestinal system. The most frequently reported AEs were vertigo (29% of subjects), tremor (24%), and dizziness, nasopharyngitis, and nausea (18% each). No subject had an AE that was severe in intensity. Four subjects discontinued from the trial due to AEs; all resolved subsequently.

Number of Patients:

Planned, N:	
Enrolled, N:	**17**
Completed, n(%):	**2 (11.8)**
Number of Patients Withdrawn, n(%):	**15 (88.2)**
Withdrawn due to Adverse Events, n(%):	**4 (23.5)**
Withdrawn for Other Reasons, n(%):	**0**

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Demography:

Gender (Females/Males):	**9/8**
Age (years), mean(SD):	**69.2 (9.41)**
Race, n(%): White	**17 (100.0)**

Safety Outcomes:
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:

Treatment Emergent AEs (TEAE):

Patients with at least one TEAE, n(%):	**17 (100.0)**
Patients with TEAEs (by Primary System Organ Class)	*n(%) [n considered drug-related by the Investigator]*
Ear and labyrinth disorders	*5 (29) [4]*
Eye disorders	*1 (6) [1]*
Gastrointestinal disorders	*7 (41) [3]*
General disorders and administration site conditions	*3 (18) [3]*
Infections and infestations	*3 (18) [1]*
Injury, poisoning and procedural complications	*2(12)[0]*
Investigations	*4 (24) [3]*
Metabolism and nutritional disorders	*2 (12) [0]*
Musculoskeletal and connective tissue disorders	*3 (18) [0)*
Nervous system disorders	*9 (53) [8]*
Psychiatric disorders	*2 (12) [0]*
Reproductive system and breast disorders	*2 (12) [1]*
Skin and subcutaneous tissue disorders	*2 (12) [1]*
Vascular disorders	*3 (18) [2]*

Death, SAEs, and Other SAEs (if applicable):

Death, n (%):	**0**
Patients with SAEs, n(%):	**1 (5.9)**
Patients with SAEs (by Primary System Organ Class)	*n(%) [n considered drug-related by the Investigator]*
Gastrointestinal disorders	*1 (6) [0]*

Primary & Secondary Outcomes:

Results of safety variables show Lacosamide was generally well tolerated.

In all, 1 SAE occurred and was considered to be not related to trial medication by the investigator. Three subjects experienced AEs classified as “other significant AEs” (“rash,” “QTc interval increased,” and “GGT increased”). Four subjects discontinued from the trial due to AEs; all resolved subsequently. No subject had an AE that was severe in intensity. The most frequently reported AEs were vertigo (29% of subjects), tremor (24%), and dizziness, nasopharyngitis, and nausea (18% each).

There were no apparent trends in shifts of hematology parameters, clinical chemistry parameters including liver function tests, or urinalysis parameters that were considered to be clinically relevant. No clinically

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important changes from Baseline were observed for BP or pulse rate. One AE of elevated pulse rate was reported leading to withdrawal.

At Baseline, the average Likert pain score for all subjects combined was 4.86. Across the period of the trial, the average pain score decreased beginning in the Titration Phase. The overall reduction in Likert pain score throughout the entire Treatment Phase was 0.85. Improvements in pain interference with sleep and general activity and overall pain (assessed using VAS) were consistent with the results from the Likert pain scale.

Changes in efficacy variables show that a limited number of subjects on lacosamide in this open-label extension trial showed some improvement in pain over time.

Publication Reference(s) based on the study:
None

Date of report: 10-Jun-2008