UCB reference No.: RXCE06E1678

Approved by UCB 06-Mar-2008

Clinical Study Summary (CSS)

DEV/CCM/03460.2007

CT Registry ID#: NCT00610454 **Study No.: N01166**		
These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.		
Based on Clinical Study Report document reference code: RRCE04F1401		
Proprietary Drug Name Keppra® Concentrate Solution for Infusion	**INN** Levetiracetam	**Therapeutic area and indication(s)** epilepsy
Name of Sponsor/Company: UCB Pharma SA		
Title of Study: A multicenter, open-label, single arm, exploratory trial evaluating the safety and tolerability of levetiracetam intravenous (500 mg/5 mL ampoules) 15-minute infusion at doses ranging from 1000 mg to 3000 mg/day, administered in b.i.d. regimen as an adjunctive antiepileptic treatment in subjects from 16 to 65 years suffering from partial onset seizures.		
Investigator(s) (number only): 4		
Study Center(s) (number only): 4		
Length of Study: Date first patient enrolled: 09-Jun-2004 Date last patient completed: 20-Aug-2004	Phase of Development: Phase II (therapeutic exploratory safety trial)	

Abstract:
The objective of this trial was to evaluate the safety and tolerability of levetiracetam (LEV) 1000 mg/day to 3000 mg/day intravenous (IV), after switching from the same oral dose administration to 15-minute IV infusion during repeated dosing (4 days b.i.d.). Safety assessments included the recording of adverse events (AEs), vital signs, 12-lead electrocardiogram (ECG), safety laboratory tests, physical and neurological examinations, and plasma level concentrations of LEV and AEDs. Subjects were to be 16 to 65 years old, suffering from partial onset seizures (according to the International League Against Epilepsy [ILAE] classification of epileptic seizures), and receiving LEV as an adjunctive antiepileptic oral treatment in addition to 1 or 2 antiepileptic drugs (AED) at a stable dose for at least 4 weeks. The trial consisted of 1 treatment period of 4 days with LEV b.i.d. IV administration.

Number of Subjects:	**LEV**
Planned, N:	25
Enrolled, N:	25
Completed, n (%):	25 (100)
Demography:	**LEV (N=25)**
Gender (Females/Males):	13/12
Age (years), mean (SD):	40.84 (10.64)
Race, n (%):	
Caucasian	25 (100)

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Safety Outcomes:

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

Overall, 44% of the subjects reported treatment-emergent (TE) AEs during the trial. The most commonly reported TEAEs during the trial were nervous system disorders (28% of the subjects), and general disorders and administration site conditions (16% of the subjects). A total of 5 (20%) subjects experienced TEAEs considered by the Investigator as related to the study drug. No deaths or other serious AEs were reported and none of the subjects discontinued the study due to an AE.

No clinically relevant changes in vital signs were observed except for one intermittent diastolic blood pressure decrease that was reported as AE and considered as related to the study drug by the Investigator. No clinically relevant changes in clinical laboratory parameters, ECG, and physical and neurological examinations were reported.

Treatment Emergent AEs (TEAE):	**LEV (N=25)**
Subjects with at least one TEAE, n (%):	11 (44.0)
MedDRA Primary System Organ Class	*n (%) [n considered drug-related by the Investigator]*
Nervous system disorders	7 (28) [1]
General disorders and administration site conditions	4 (16) [0]
Eye disorders	1 (4) [1]
Ear and labyrinth disorders	1 (4) [1]
Renal and urinary disorders	1 (4) [1]
Investigations	1 (4) [1]
Death, and Other SAEs:	
Death, n (%):	0
Subjects with SAEs, n (%):	0

Primary Outcomes:

Safety was the primary objective of this trial.

Publication Reference(s) based on the study: Baulac et al. – Epilepsia 2007; 48: 589-592

Date of report: 06-Mar-2008