UCB reference No.: RXCE06E1664

Approved by UCB 28-Jan-2008

Clinical Study Summary (CSS)

DEV/SGE/00233.2008

CT Registry ID#: NCT00730357
Study No.: N01037

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: RRCE05H3101

Proprietary Drug Name	**INN**	**Therapeutic area and indication(s)**
Keppra® Tablets	Levetiracetam	Epilepsy

Name of Sponsor/Company: UCB Pharma SA

Title of Study:
A phase IV, open-label, multi-center trial to evaluate the safety and efficacy of Keppra® after conversion to mono-therapy in adult, subjects with partial epilepsy.

Investigator(s) (number only): 3

Study Center(s) (number only): 3

Length of Study:
Date first patient enrolled: 27-Mar-2003
Date last patient completed: 12-Jul-2004

Phase of Development: Phase IV

Abstract:
The objective of this study was to investigate whether and for how long seizure freedom with levetiracetam (LEV) flexible dosing (within a range of 1000-3000 mg/day) was achieved after conversion to mono-therapy. The primary efficacy variable was the time to the occurrence of the first seizure after the beginning of the mono-therapy period. Safety assessments included monitoring of adverse events (AEs), clinical laboratory tests, vital signs, body weight, and physical and neurological examinations. Subjects were to be male or female aged ≥ 16 years, with a diagnosis of partial epilepsy, were to be seizure-free, were to have taken LEV 1000 to 3000 mg daily, were treated with a single concomitant antiepileptic drug (AED) for ≥ 3 months prior to inclusion, were on a stable dose of LEV and AED during the last 4 weeks prior to inclusion, and were considered suitable for progressive conversion to LEV mono-therapy. The trial consisted of an 8-week conversion to mono-therapy and a mono-therapy period with LEV b.i.d. for 6 months. As the trial was stopped prematurely due to slow recruitment, no statistical analysis was performed and only data listings were provided.

Number of Patients:	**LEV**
Planned, N:	50
Enrolled, N:	14
Completed, n:	7
Number of Patients Withdrawn, n:	7
Withdrawn due to Adverse Events, n:	0
Withdrawn for Lack of Efficacy, n:	7
Demography:	**LEV (N=14)**
Gender (Females/Males):	11/3
Age (years), mean:	45.3
Race, n:	
White/Caucasian	13
Asian/Pacific Islander	1

CT Registry ID#: NCT00730357
Study No.: N01037

Safety Outcomes:

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

Overall, 9 subjects reported treatment-emergent (TE) AEs during the trial. The most common reported TEAEs were infections and infestations (4 subjects), musculoskeletal and connective tissue disorders (3 subjects), nervous system disorders and gastrointestinal disorders (3 subjects, each). None of these TEAEs were considered to be related to the study drug by the Investigator.

There were no serious AE (SAE) or AEs leading to discontinuation reported during the trial.

No clinically relevant changes were observed for the other safety parameters.

Treatment Emergent AEs (TEAE):	**LEV (N=14)**
Patients with at least one TEAE, n (%):	9
Primary system organ Class with an incidence of ≥ 10%	*n (%) [n considered drug-related by the Investigator]*
Infections and infestations	4 [0]
Musculoskeletal and connective tissue disorders	3 [0]
Nervous system disorders	3 [0]
Gastrointestinal disorders	2 [0]

Primary Outcomes:

Of the 13 subjects who successfully completed the conversion to LEV monotherapy, 7 subjects were still seizure-free when reaching 6 months of mono-therapy. One subject reported seizures after 6 months of mono-therapy. Seizures observed during the mono-therapy phase occurred between 12 and 212 days after the start of the LEV mono-therapy.

Publication Reference(s) based on the study: None

Date of report: 28-Jan-2008