UCB reference No.: RXCE06E1672

Approved by UCB 26-Jul-2007

Clinical Study Summary

DEV/CCM/03127.2007

CT Registry ID#: NCT00150787 **Study No.: N01093**		
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: RRCE05L2109		
Proprietary Drug Name Keppra® Tablets	**INN** levetiracetam	**Therapeutic area and indication(s)** Epilepsy
Name of Sponsor/Company: UCB Pharma SA		
Title of Study: A multicenter, double-blind, follow-up trial evaluating the long-term safety of levetiracetam (1000 to 3000 mg/day b.i.d.) and carbamazepine (400 to 1200 mg/day oral b.i.d.), used as monotherapy in subjects (≥ 16 years) coming from the N01061 trial.		
Investigator(s) (number only): 74		
Study Center(s) (number only): 72		
Length of Study: Date first patient enrolled: 23-Jul-2003 Date last patient completed: 10-Nov-2005		**Phase of Development:** Phase III (long-term follow-up)

Abstract:
The objectives of this study were: to allow subjects who had benefited from levetiracetam (LEV) or carbamazepine (CBZ) monotherapy in study N01061 to stay on the same investigational product; to ensure blindness of N01061 treatment identity until N01061 database lock; and to continue to assess the safety of LEV as per adverse event (AE) reporting. Male or female subjects (≥ 16 years) were required to have had a previous diagnosis of epilepsy characterized by partial-onset seizures or generalized tonic-clonic seizures without clear focal origin. Subjects had to fulfill all the conditions for switching from Study N01061 to Study N01093. Subjects who needed the addition of another AED, and had developed any clinical or electroencephalogram (EEG) findings suggestive of idiopathic generalized epilepsy were excluded. No efficacy data were collected in this study. Safety was assessed through the extent of exposure, the reporting of AEs, vital signs, medical procedures, physical and neurological examinations. All baseline, demographic and safety parameters were analyzed by treatment group using descriptive statistics.

Number of Subjects:	**CBZ**	**LEV**
Enrolled, N:	164	171
Completed, n (%):	126 (76.8)	148 (86.5)
Number of Subjects Withdrawn, n (%):	38 (23.2)	23 (13.5)
Withdrawn due to Adverse Events, n (%):	7 (4.3)*	4 (2.3)*
Withdrawn for Other Reasons**, n (%):	31 (18.9)	19 (11.1)

* Including 1 subject with a pre-treatment AE.
** Withdrawn because of lack or loss of efficacy, lost to follow-up, withdrawal of consent, remission or other reasons.

Demography:	**CBZ (N=164)**	**LEV (N=171)**
Gender (Females/Males):	56/108	76/95
Age (years), mean (SD):	40.4 (15.8)	41.6 (17.4)
Race, n (%)		
Caucasian	153 (93.3)	165 (96.5)
African/American	6 (3.7)	2 (1.2)
Asian/Pacific Islander	1 (0.6)	0
Other	4 (2.4)	4 (2.3)

CT Registry ID#: NCT00150787
Study No.: N01093

Safety Outcomes:
- Summary of treatment-emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:
Overall, 65 subjects (38.0%) in the LEV group and 63 subjects (38.4%) in the CBZ group experienced ≥ 1 treatment-emergent (TE)AE. The most frequent TEAEs were infections and infestations (15.8% LEV subjects and 14.6% CBZ subjects) and nervous system disorders (11.1% LEV subjects and 12.8% CBZ subjects). TEAEs leading to discontinuation occurred in 3 subjects (1.8%) in the LEV group and 6 subjects (3.7%) in the CBZ group.
No deaths occurred during this study. Serious AEs (SAEs) were experienced by 4 subjects (2.3%) in the LEV group and 13 subjects (7.9%) in the CBZ group. No treatment-emergent SAEs were considered treatment-related.

Treatment-Emergent AEs:	**CBZ (N=164)**	**LEV (N=171)**
Subjects with at least 1 TEAE, n (%):	63 (38.4)	65 (38.0)
UCB System Organ Class with an incidence ≥ 4%	*n (%) [n considered drug-related by the Investigator]*	
Gastrointestinal disorders	8 (4.9) [2]	10 (5.8) [1]
General disorders and administration site conditions	4 (2.4) [2]	9 (5.3) [2]
Infections and infestations	24 (14.6) [2]	27 (15.8) [2]
Injury, poisoning and procedural complications	8 (4.9) [0]	2 (1.2) [0]
Metabolism and nutrition disorders	12 (7.3) [5]	4 (2.3) [1]
Musculoskeletal and connective tissue disorders	6 (3.7) [0]	13 (7.6) [1]
Nervous system disorders	21 (12.8) [6]	19 (11.1) [6]
Psychiatric disorders	5 (3.0) [0]	7 (4.1) [4]
Respiratory, thoracic and mediastinal disorders	7 (4.3) [0]	3 (1.8) [0]
Death, other SAEs:	**CBZ (N=164)**	**LEV (N=171)**
Death, n (%):	0	0
Subjects with SAEs, n (%):	13 (7.9)	4 (2.3)
Subjects with SAEs (by UCB System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Cardiac disorders	1 (0.6) [0]	0
Ear and labyrinth disorders	1 (0.6) [0]	0
Gastrointestinal disorders	1 (0.6) [0]	1 (0.6) [0]
Infections and infestations	2 (1.2) [0]	0
Injury, poisoning and procedural complications	4 (2.4) [0]	0
Musculoskeletal and connective tissue disorders	1 (0.6) [0]	0
Neoplasms benign, malignant & unspecified, including cysts and polyps	1 (0.6) [0]	0
Nervous system disorders	4 (2.4) [0]	2 (1.2) [0]
Renal and urinary disorders	0	1 (0.6) [0]
Reproductive system and breast disorders	1 (0.6) [0]	1 (0.6) [0]
Respiratory, thoracic and mediastinal disorders	2 (1.2) [0]	0

Primary Outcomes:
Not applicable – no efficacy data was collected.

Publication Reference(s) based on the study: None

Date of report: 27-Jul-2007