Clinical Study Summary

DEV/CCM/03380.2007

CT Registry ID#: NCT00545012
Study No.: N164

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: RRCE03H0603

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

Name of Sponsor/Company: UCB Pharma SA

Title of Study:
A 30-month safety and efficacy open multicenter follow-up study, add-on or monotherapy, with 83, 125, 166, 250 and 500 mg levetiracetam oral tablets in b.i.d. administration (at individualized optimal dose with a maximum of 60 mg/kg/day or 3 g/day) in children (4 to 17 years old at inclusion) suffering from typical absences in Childhood Absence Epilepsy (CAE) or Juvenile Absence Epilepsy (JAE).

Investigator(s) (number only): 3

Study Center(s) (number only): 3

Length of Study:
Date first patient enrolled: 26-May-2000
Date last patient completed: 28-May-2003

Phase of Development: Phase II (therapeutic exploratory – long-term follow-up)

Abstract:
The primary objective of this study was to give pediatric subjects with epilepsy the opportunity to continue levetiracetam (LEV) treatment after participating in a pilot study. The study was also performed to determine the safety profile, and long-term efficacy, of LEV at individualized doses in pediatric subjects with typical absence seizures in CAE or JAE. The primary efficacy objective was the evaluation of the spike and wave (SW) responder status defined for a subject as staying responder or becoming responder from the evaluation visit of the pilot study. A SW responder was a subject with a ≥ 50% reduction of the 3 Hz spike and wave discharges number at 24-hour electroencephalogram (EEG) recording during wakefulness per wakeful hour as recorded at the 6 months, 1 year, 18 months or 2 year evaluation visit in comparison with baseline of the pilot study. Subjects were to be male and female between 4 and 17 years of age, and had completed the evaluation visit of the pilot study. Safety assessments included: adverse events (AEs); vital signs; body weight and height; physical and neurological examinations; electrocardiogram (ECG) and safety laboratory tests.

Number of Subjects:	**LEV**			
Enrolled, N:	4			
Subject number	**001/001**	**001/002**	**001/003**	**002/001**
Completed:	Yes	Yes	Yes	No
Withdrawn	No	No	No	Yes
Withdrawn due to Adverse Events:	No	No	No	No
Withdrawn for Other Reasons:	No	No	No	Yes
Demography:				
Gender:	Female	Male	Female	Male
Age (years):	6.1	4.0	7.9	7.1
Race	Caucasian	Caucasian	Caucasian	Caucasian

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Safety Outcomes:
– Summary of treatment-emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:
Overall, the 4 subjects experienced 39 treatment emergent (TE)AEs during the study. The most frequently reported TEAEs were in the system organ classes: 'infections and infestations' and 'respiratory disorders'. Only 3 TEAEs, experienced by 1 subject (001/002), were considered drug-related: hyperkinesia, aggressiveness and nervousness. There were no deaths. One subject (002/001) experienced a serious (S)AE of appendicitis which was not considered drug-related and lead to temporary discontinuation of the study drug. None of the changes in hematology or biochemistry laboratory parameters were considered clinically significant. No clinically relevant changes in vital signs or ECGs were noted.

Treatment-Emergent AEs:	**LEV**			
Subject number	**001/001**	**001/002**	**001/003**	**002/001**
TEAEs (by Primary System Organ Class)	*n [n considered drug-related by the Investigator]*			
Gastrointestinal disorders	0	0	1 [0]	1 [0]
General disorders and administration site conditions	0	2 [0]	0	0
Infections and infestations	1 [0]	3 [0]	3 [0]	5 [0]
Nervous system disorders	0	1 [1]	0	1 [0]
Psychiatric disorders	0	2 [2]	0	0
Renal and urinary disorders	0	1 [0]	0	0
Reproductive system and breast disorders	0	1 [0]	0	1 [0]
Respiratory thoracic and mediastinal disorders	3 [0]	2 [0]	2 [0]	1 [0]
Death, other SAEs:				
Deaths:	0	0	0	0
Subjects with SAEs:	0	0	0	1
Subjects with SAEs (by Primary System Organ Class)	*n [n considered drug-related by the Investigator]*			
Infections and infestations	0	0	0	1 [0]

Primary Outcomes:
It was not possible to draw any overall conclusions on the therapeutic benefit of LEV add-on therapy in CAE or in JAE due to the small number of subjects in this long-term follow-up study. In this study, 3/4 subjects were SW responders compared to baseline of the pilot study.
The safety profile observed was in line with previous studies, which have shown very good tolerability of LEV in adult and pediatric populations.

Publication Reference(s) based on the study: None

Date of report: 26-Jul-2007