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Clinical Study Summary (CSS)

DEV/SGE/00968.2008

CT Registry ID#: NCT00160654		
Study No.: N01036		
<i>These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.</i>		
Based on Clinical Study Report document reference code: RRCE06E0301		
Proprietary Drug Name Keppra® Tablets	INN Levetiracetam	Therapeutic area and indication(s) Uncontrolled partial epilepsy
Name of Sponsor/Company: UCB Pharma SA		
Title of Study: A phase IV, open-label, multi-center, community-based trial in Asia studying the safety and efficacy of Keppra® as adjunctive therapy in adult subjects with uncontrolled partial epilepsy. S.K.A.T.E. II: Safety of Keppra® as Adjunctive Therapy in Epilepsy		
Investigator(s) (number only): 29		
Study Center(s) (number only): 29		
Length of Study: Date first patient enrolled: 24-Nov-2003 Date last patient completed: 12-Dec-2006		Phase of Development: Phase IV (Therapeutic use)
Abstract: The primary objective of the study was to further evaluate the safety and tolerability of levetiracetam (LEV) in a broad population of subjects and confirm the favorable safety of the drug found during clinical development. Safety assessments included the reporting of adverse events (AEs). Subjects were to be at least 16 years old, had epilepsy with partial seizures secondarily generalized or not, classifiable according to the International Classification of Epileptic Seizures, experienced between 3 and 42 partial seizures over the 3 months prior to the selection visit, and used 1 or 2 concomitant anti-epileptic drugs at study entry at a stable dose for at least 4 weeks prior to the first visit. The study period lasted between 16 and 22 weeks. LEV was taken b.i.d. The starting dose of LEV was 500 to 1000 mg/day. For subjects on LEV 500 mg/day, the dose was up-titrated to 1000 mg/day after Week 1. From Week 2 to 16, the LEV dose could be up-titrated by increments of 1000 mg to a maximum of 3000 mg/day in case of lack of efficacy. In case of tolerability problems, the dose could be down-titrated by steps of 500 or 1000 mg/day. At Week 16, the subjects had the opportunity to continue on LEV on the investigator's prescription or to enter a 2 to 4 week down-titration period. No interferential analysis was performed. The analysis was restricted to a description of the data by means of adequately descriptive statistics.		
Number of Subjects:	LEV	
Planned, N:	1000	
Enrolled, N:	251	
Completed, n (%):	218 (86.9)	
Number of Subjects Withdrawn, n (%):	33 (13.1)	
Withdrawn due to Adverse Events, n (%):	14 (5.6)	
Withdrawn for Other Reasons, n (%):	19 (7.6)	



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Demography:	LEV (N=251)
Gender (Females/Males):	137/114
Age (years), mean (SD):	34.42 (11.21)
Race, n (%):	
Asian/Pacific Islander:	249 (99.2)
Indian/Pakistani:	1 (0.4)
Other/mixed race:	1 (0.4)
Safety Outcomes:	
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:	
Overall, 73.3% of the subjects reported at least one treatment-emergent (TE) AE. The most commonly reported TEAEs were nervous system disorders (55.4% of the subjects), gastrointestinal disorders, and general disorders and administration site conditions (13.5% of the subjects, each). Drug-related AEs were reported for 62.9% of the subjects.	
Serious AEs (SAEs) were reported for 15 (6.0%) subjects, of which 5 subjects reported a drug-related SAE. Eighteen (7.2%) subjects reported a TEAE leading to permanent drug discontinuation.	
Treatment Emergent AEs (TEAE):	LEV (N=251)
Subjects with at least one TEAE, n (%):	184 (73.3)
<i>Primary System Organ Class with an incidence of ≥ 5%</i>	<i>n (%) [n considered drug-related by the Investigator]</i>
Nervous system disorders	139 (55.4) [122]
Gastrointestinal disorders	34 (13.5) [19]
General disorders and administration site conditions	34 (13.5) [26]
Psychiatric disorders	25 (10.0) [22]
Skin and subcutaneous tissue disorders	16 (6.4) [7]
Infections and infestations	13 (5.2) [0]
Death and Other SAEs:	LEV (N=251)
Death, n (%):	0
Subjects with SAEs, n (%):	15 (6.0)
<i>Primary System Organ Class with an incidence of ≥ 0.5%</i>	<i>n (%) [n considered drug-related by the Investigator]</i>
Nervous system disorders	9 (3.6) [2]
Skin and subcutaneous tissue disorders	3 (1.2) [2]
Psychiatric disorders	2 (0.8) [1]
Primary Outcomes:	
Safety was the primary outcome.	
Publication Reference(s) based on the study: None	
Date of report: 03-Apr-2008	