UCB reference No.: RXCE06A2616

Approved by UCB: 06-Feb-2006

Clinical Study Summary

DEV/BBU/cco/00476.2006

CT Registry ID#: Not applicable *(for Reg Ops use only)*
Study No: N01099

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: RRCE05B2803

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

Name of Sponsor/Company: UCB

Title of Study:
A Korean open-label, multi-center, community-based trial assessing the efficacy and safety of levetiracetam as adjunctive therapy in adult subjects with uncontrolled partial epilepsy for bridging purpose with a similar study on Caucasian epileptic subjects.

Investigator(s) (number only): 10

Study Center(s) (number only): 9

Length of Study:		**Phase of Development:**
Date first patient enrolled:	05-Mar-2004	Phase III (bridging study)
Date last patient completed:	06-Oct-2004	

Abstract:
Study objectives were to evaluate the efficacy of levetiracetam (1000 up to 3000 mg/day in two equally divided doses for 16 weeks) in a community-based population with partial onset seizures and to gain further information about optimal dose in daily practice (primary); to further evaluate the safety and tolerability of levetiracetam in a broad population of epileptic subjects (secondary); to assess similarity of levetiracetam efficacy and safety in Korean subjects with epilepsy with those of a similar study conducted in mainly Caucasian subjects with epilepsy in Europe (exploratory). Main criteria for efficacy were the percentage reduction from historical baseline in partial (Type I) and total (Type I+II+III) seizure frequency per week over the treatment period, and the responder rates. Safety was assessed through the reporting of AEs, vital signs, laboratory data, ECG, and physical and neurological examinations. Were eligible for the study females/males subjects above 18 years old with epilepsy experiencing partial seizures, whether or not secondary generalized, and classifiable according to the International Classification of Epileptic Seizures; subjects had also to have at least three and no more than 42 partial seizures over a 3-month historical baseline, and to take at least one and no more than two concomitant marketed antiepileptic drugs at stable dose. Efficacy and safety parameters were analyzed descriptively.

Number of Subjects	**Levetiracetam**
Planned, N	100
Enrolled, N	100
Completed, n(%)	92 (92.0)
Number of Subjects Withdrawn, n(%)	8 (8.0)
Withdrawn due to Adverse Events, n(%)	4 (4.0)
Withdrawn due to Lack of Efficacy, n(%)	1(1.0)
Withdrawn for Other Reasons, n(%)	3 (3.0)

Demography	**Levetiracetam (N=100)**
Females: Males	48:52
Age (years), mean(SD)	35.3 (11.7)
Race, n(%)	Korean, 100 (100.0)

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Efficacy Results	**Levetiracetam (N=97)** (No seizure data for 3 subjects)
Percentage reduction from historical baseline in total (Type I+II+III) seizure frequency per week over the 16-week treatment period: median (Q1-Q3) (Note: only Type I seizures were present)	43.2 (0.4- 84.8)
Responder rate in total (Type I+II+III) seizure frequency over the 16-week treatment period: 50%, n(%) 75%, n(% 100%, n(%) (Note: only Type I seizures were present)	44 (45.4) 35 (36.1) 18 (18.6)
Mean daily dose over the last 8 weeks of treatment (for completers only) (mg/day): mean (SD)	2236.1 (679.2)
Safety Results	**Levetiracetam (N=100)**
Treatment emergent AEs	
Subjects with at least one AE, n(%)	59 (59.0)
Description of the AEs *(by Primary System Organ Class)*	*n(%) [n considered drug-related by the Investigator]*
Cardiac Disorders	1 (1.0) [0]
Eye Disorders	2 (2.0) [2]
Gastrointestinal Disorders	10 (10.0) [7]
General Disorders and Administration Site Conditions	10 (10.0) [9]
Infections and Infestations	4 (4.0) [0]
Investigations	1 (1.0) [1]
Metabolism and Nutrition Disorders	4 (4.0) [2]
Musculoskeletal and Connective Tissue Disorders	1 (1.0) [0]
Neoplasm Benign, Malignant and Unspecified (incl. Cysts and Polyps)	1 (1.0) [0]
Nervous System Disorders	48 (48.0) [45]
Psychiatric Disorders	5 (5.0) [2]
Skin and Subcutaneous Tissue Disorders	1 (1.0) [0]
Death, SAEs, and Other SAEs	
Death, n (%)	0 (0.0)
Subjects with SAEs, n(%)	4 (4.0)
Subjects with SAEs *(by Primary System Organ Class)*	*n(%) [n considered drug-related by the Investigator]*
Gastrointestinal Disorders	1 (1.0) [0]
Musculoskeletal and Connective Tissue Disorders	1 (1.0) [0]
Neoplasm Benign, Malignant and Unspecified (incl. Cysts and Polyps)	1 (1.0) [0]
Psychiatric Disorders	1 (1.0) [1]
Subjects with AEs leading to permanent drug discontinuation, n(%)	4 (4.0)

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Subjects with AEs leading to permanent drug discontinuation (by Primary System Organ Class)	*n(%)[n considered drug-related by the Investigator]*
Gastrointestinal Disorders	1 (1.0) [1]
Neoplasm Benign, Malignant and Unspecified (incl. Cysts and Polyps)	1 (1.0) [0]
Nervous System Disorders	4 (4.0) [3]

Laboratory data, vital signs, physical findings, and other observations related to safety:
Some changes in laboratory data, vital signs, physical and neurological findings, and in ECG were observed but were not considered clinically relevant by the Investigators.

Publication Reference(s) based on the study:
None.