

Approved by UCB: 06-Feb-2006

Clinical Study Summary

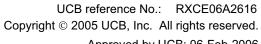
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BE 17BBC7666700 176.2000		
CT Registry ID#: Not applicable (i Study No: N01099	for Reg Ops us	e only)
These results are supplied for it		urposes only. Prescribing decisions should
be made ba	ased on the ap	proved package insert.
Based on Clinical Study Report	document refe	erence code: RRCE05B2803
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Proprietary Drug Name	INN	Therapeutic area and
Keppra [®]		indication(s)
		Epilepsy
Name of Sponsor/Company: UC	В	
Title of Study:		
A Korean open-label, multi-center,	community-ba	sed trial assessing the efficacy and safety of
levetiracetam as adjunctive therap	y in adult subje	cts with uncontrolled partial epilepsy for
bridging purpose with a similar stu	dy on Caucasia	an 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)







Efficacy Results 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) Responder rate in total (Type I+II+III) seizure frequency over the 16-week treatment period: 50%, n(%) 75%, n(%) 35 (36.1) 100%, n(%) 44 (45.4) 75%, n(%) 35 (36.1) 100%, n(%) (Note: only Type I seizures were present) Mean daily dose over the last 8 weeks of treatment (for completers only) (mg/day): mean (SD) Safety Results Levetiracetam (N=100) Treatment emergent AES Subjects with at least one AE, n(%) 59 (59.0) Description of the AES (hor primary System Organ Class) Cardiac Disorders 1 (1.0) [0] Eye Disorders 2 (2.0) [2] Gastrointestinal Disorders 10 (10.0) [7] General Disorders and Administration Site Conditions Infections and Infestations 4 (4.0) [0] Investigations 1 (1.0) [0] Metabolism and Nutrition Disorders 1 (1.0) [0] Metabolism and Nutrition Disorders 4 (4.0) [2] Musculoskeletal and Connective Tissue Disorders Disorders 5 (5.0) [2] Skin and Subcutaneous Tissue Disorders 1 (1.0) [0] Peschy, SAES Death, n (%) 0 (0.0) Subjects with SAES (by Primary System Organ Class) Investigator) Cardiac Disorders 1 (1.0) [0] Peath, SAES (by Primary System Organ Class) Investigator) Reconsidered drug-related by the Investigator of the Conditions 1 (1.0) [0] Death, SAES (by Primary System Organ Class) Investigator) Reconsidered drug-related by the Investigator of the Conditions 1 (1.0) [0] Peath, SAES (by Primary System Organ Class) Investigator of the Considered drug-related by the Investigator of the Consi	CT Registry ID#: Not applicable (for Reg Ops use only) Study No: N01099		
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Neoplasm Benign, Malignant and Unspecified (incl. Cysts and Polyps) Psychiatric Disorders 1 (1.0) [0] Subjects with AEs leading to permanent drug	Musculoskeletal and Connective Tissue		
(incl. Cysts and Polyps)1 (1.0) [0]Psychiatric Disorders1 (1.0) [1]Subjects with AEs leading to permanent drug		1 (1.0) [0]	
Psychiatric Disorders 1 (1.0) [1] Subjects with AEs leading to permanent drug	Neoplasm Benign, Malignant and Unspecified		
Subjects with AEs leading to permanent drug		1 (1.0) [0]	
		1 (1.0) [1]	
		4 (4.0)	



Approved by UCB: 06-Feb-2006

CT Registry ID#: Not applicable (for Reg Ops use only)		
Study No: N01099		
Subjects with AEs leading to permanent drug	n(%)[n considered drug-related by the	
discontinuation	Investigator]	
(by Primary System Organ Class)		
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 finding	se and other observations related to safety:	

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.