

## **Clinical Study Summary**

CT Registry ID#: NCT00612859   Study No.: N01086   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: RRCE06F0115   Proprietary Drug Name INN   Levetiracetam Social anxiety disorder (generalized type)   Name of Sponsor/Company: UCB Pharma SA Therapeutic area and indication(s) Social anxiety disorder (generalized type)   Investigator(s) (number only): Not stated   Study Center(s) (number only): Not stated   Study Center(s) (number only): Not stated   Study Center(s) (number only): Phase of Development: II   Che of generalized type) (GSAD) during a 12-week treatment and evaluation period. Subjects were to ave had a diagnosis of clinically predominant GSAD according to the Diagnostic and Statistical Manual of Mental Disorders – 4 <sup>th</sup> Edition (DSM-IV) criteria, a score of at least 60 on the Liebowitz Social Anxiety Seale (LSAS) at Visist 1 and 2, and a Clinical Global Impression of Change (CGIC) score of >2 at Visit 2. The trial consisted of a single-blind 1-week PBO lead-in period followed by a 12-week double-slind evaluation perio	DEV/SGE/04125.2007					
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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: RRCE06F0115   Proprietary Drug Name Keppra <sup>®</sup> Tablets INN Levetiracetam Therapeutic area and indication(s) Social anxiety disorder (generalized type)   Name of Sponsor/Company: UCB Pharma SA Therapeutic area and indication(s) Evetiracetam versus PBO for the treatment of social anxiety disorder generalized type)   Investigator(s) (number only): Not stated   Study Center(s) (number only): 20   Length of Study: In-applicate of the treatment of social anxiety disorder generalized type)   Date first patient enrolled: 05-Sep-2003   Ats patient completed: 15-Jun-2004   Phase of Development: II   Date first patient completed: 15-Jun-2004   Abstract: Itherapeutic of this study were to assess the efficacy and safety of levetiracetam (LEV) in social anxiety disorder (generalized type) (GSAD) during a 12-week treatment and evaluation period. Subjects were to ave had a diagnosis of clinically predominant GSAD according to the Diagnostic and Statistical Manual of Mental Disorders – 4 <sup>th</sup> Edition (DSM-IV) criteria, a score of at least 60 on the Liebowitz Social Anxiety Scale (LSAS) at Visits 1 and 2, and a Clinical Global Impression of Change (CGIC) score of >2 tt Visit 2. The trial consisted of a single-blind 1-week PBO lead-in period followed by a 12-week double- blind evaluation period visit 2 to	Study No.: N01086					
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CT Registry ID#: NCT00612859		
Study No.: N01086		
Number of Patients:	PBO	LEV
Planned, N:	95	95
Enrolled, N:	106	111
Single-blind, 1-week PBO lead-in	2	265
Double-blind, 12-week Evaluation period	106	111
Completed, n (%):	71 (67)	77 (70)
Number of Patients Withdrawn, n (%):	35 (33)	33 (30)
Withdrawn due to Adverse Events, n (%):	6 (6)	11 (10)
Withdrawn for Other Reasons*, n (%):	29 (27)	22 (20)
*Withdrawn because of lack of efficacy, loss of efficacy, lost to reasons not related to AEs or lack of efficacy, other reasons, or o	follow-up, protocol violation, with ther (change of residence)	drawal of consent for personal
Demography:	PBO	LEV
Gender (Females/Males):	38/68	45/65
Age (years), mean(SD):	35.77 (11.89)	35.81 (11.56)
Race Caucasian n (%):	74 (69.8)	81 (73.6)

## **Safety Outcomes:**

No deaths occurred during the study. One LEV subjects experienced a serious AE (SAE) during the treatment period: gastroenteritis resulting in hospitalization. No subjects in the LEV or PBO groups experienced SAEs that were considered related to treatment. Discontinuation of treatment due to AEs occurred more frequently in the LEV group (9%) than in the PBO group (5%). The most frequently occurring AEs in the dose up-titration period were nervous system disorders (headache was reported by 24.5% [LEV] and 20.8% [PBO] of subjects; somnolence was reported by 9.1% [LEV] and 8.5% [PBO] of subjects) and psychiatric disorders (insomnia and irritability were both reported by 7.3% [LEV] and 5.7% [PBO] of subjects. Nervous system disorders were also the most frequently reported AEs during the stable dose period, the most frequent individual AE being headache (10.9% [LEV] and 8.5% [PBO] of subjects). Similar percentages of subjects overall experienced non-psychotic mood and anxiety symptoms (17% PBO; 18.2% LEV) and sleep symptoms (8.5% PBO; 11.8% LEV). Few subjects experienced self-aggressive symptoms (0 PBO; 1.8% LEV). No clinically important differences were observed in the frequency of drug-related TEAEs: 59% (PBO) and 66% (LEV).

Treatment Emergent AEs: if applicable					
Patients with at least one TEAE, n (%):	PBO		LEV		
	(N=106) (N=110)		110)		
Total number of TEAEs reported	367 481		81		
Subjects with at least one TEAE, n (%)	89 (84)		93 (8	93 (84.5)	
Patients with TEAEs ( $\geq$ 5% of patients)	N (%) [n considered drug-related by the				
(by Primary System Organ Class)	Investigator]				
Up-titration period/stable dose period	PBO LEV (N=106) (N=110)		EV		
			(N=110)		
	Up-titration	Stable dose	Up-titration	Stable dose	
Blood and lymphatic system disorders	1 (0.9)	1 (0.9)	0	1 (0.9)	
Cardiac disorders	1 (0.9)	0	1 (0.9)	0	
Congenital, familial and genetic disorders	0	1 (0.9)	0	0	
Ear and labyrinth disorders	1 (0.9)	0	0	0	
Eye disorders	2 (1.9)	1 (0.9)	6 (5.5)	1 (0.9)	
Gastrointestinal disorders	15 (14.2)	5 (4.7)	14 (12.7)	8 (7.3)	
General disorders and administration site conditions	14 (13.2)	4 (3.8)	17 (15.5)	1 (0.9)	
Immune system disorders	1 (0.9)	0	6 (5.5)	1 (0.9)	
Infections and infestations	18 (17.0)	15 (14.2)	19 (17.3)	10 (9.1)	
Injury, poisoning and procedural complications	2 (1.9)	2 (1.9)	0	1 (0.9)	



1 (0.9) [0]

CT Registry ID#: NCT00612859				
Study No.: N01086				
Investigations	3 (2.8)	2 (1.9)	2 (1.8)	6 (5.5)
Metabolism and nutrition disorders	4 (3.8)	0	5 (4.5)	0
Musculoskeletal and connective tissue disorders	4 (3.8)	5 (4.7)	6 (5.5)	6 (5.5)
Nervous system disorders	35 (33.0)	13 (12.3)	48 (43.6)	19 (17.3)
Psychiatric disorders	22 (20.8)	8 (7.5)	29 (26.4)	13 (11.8)
Renal and urinary disorders	1 (0.9)	1 (0.9)	0	0
Reproductive system and breast disorders	4 (3.8)	3 (2.8)	6 (5.5)	2 (1.8)
Respiratory, thoracic and mediastinal disorders	15 (14.2)	2 (1.9)	11 (10.0)	3 (2.7)
Skin and subcutaneous tissue disorders	7 (6.6)	1 (0.9)	3 (2.7)	3 (2.7)
Vascular disorders	0	1 (0.9)	0	0
Death, SAEs, and Other SAEs: if applicable	•			
Death, n (%):	0		0	
Patients with SAEs, n (%):	0		1 (0.9)	
Patients with SAEs	N (%)	N (%) [n considered drug-related by the		
(by Primary System Organ Class)	Investigator			

Gastroenteritis

## **Primary & Secondary Outcomes:**

Substantial improvements in mean LSAS scores from Visit 2 to Visit 11 were observed in both treatment groups. Mean LSAS scores at Visit 2 and Visit 11 (LOCF) for the PBO group were 93.2 and 62.4; corresponding scores for the LEV group were 91.0 and 65.7. Adjusted mean changes (Visit 2 to Visit 11 [LOCF] for the PBO and LEV groups were -28.71 and -24.44. The difference between these adjusted change scores, showing a trend in favor of PBO treatment, was below the pre-determined 10-point limit signifying clinical importance and was not statistically significant (ANCOVA for treatment effect p=0.282). A non-parametric test of change from Visit 2 to Visit 11 (LOCF) using the Wilcoxon Signed Rank test showed no difference between PBO and LEV groups (p=0.103). The ANCOVA treatment effect was the prospectively determined primary outcome measure and did not achieve the required statistical  $\alpha$  value of 0.05.

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**Publication Reference(s) based on the study:** None **Date of report:** 6-Nov-2006