UCB reference No.: *RXCE08K2103*

Approved by UCB 17-NOv-2008

Clinical Study Summary

CT Registry ID#: NCT00160615
Study No.: N01020

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: RRCE07D0207

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

Name of Sponsor/Company: UCB Japan Co., Ltd.

Title of Study:
Follow-up Study of L059 (Levetiracetam) in Epileptic Patients with Partial Onset Seizures by Open Label Method

Investigator(s) (number only): 96

Study Center(s) (number only): 71

Length of Study:		Phase of Development:
Date first patient enrolled:	12-September-2001	Phase 3/ Open label study
Date last patient completed:	17-January-2007	

Abstract:
The purpose of the study was to evaluate the safety and efficacy of L059 in patients who completed "N165 Clinical Trial of L059". The safety outcome variables were the frequency of adverse events and adverse drug reactions. The efficacy variable was a weekly frequency of partial seizures. Analyses were conducted by descriptive methods by duration of exposure to LEV categories on the FAS population that was defined as all subjects who took at least one dose of Levetiracetam and excluding subjects with major protocol deviations.

Subjects received a daily dose of oral Levetiracetam b.i.d. ranged from 1000 mg to 3000 mg as an add-on therapy to the standard anti-epileptic drugs (AEDs) concurrently administered.

Number of Patients:	**Overall**
Planned, N:	154
Enrolled, N:	154
Number of Patients included in FAS	151*
Number of Patients partially excluded from FAS	12 (7.9)**
Completed, n (%):	76 (50.3)
Number of Patients Withdrawn, n (%):	63 (41.7)
Withdrawn due to Adverse Events, n (%):	17 (11.3)
Withdrawn due to lack of efficacy (%):	34 (22.5)
Withdrawal of consent (%):	2 (1.3)
Withdrawn for Other Reasons, n(%):	10 (6.6)

*Three subjects were excluded from the FAS population due to major protocol deviations.
** Data for 12 subjects from 1 August 2004 were excluded from the FAS population.

Demography:	**Overall**
Gender (Females/Males):	74/77
Age (years), mean(SD):	32.79 (10.11)
Race, n(%): Asian (Japanese)	151 (100.0)

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Primary Outcome(safety): Frequency of AE/ADR

Of the 151 subjects, 150 (99.3%) subjects reported at least one Adverse Event (AE), and 139 (92.1%) subjects reported at least one Adverse Drug Reaction (ADR). Sixteen subjects (10.6%) had reported AEs that led to permanent discontinuation and 2 (1.3%) had AEs leading to temporary discontinuation. Of the 151 subjects, 34 (22.5%) reported 50 Serious Adverse Events. All events resolved except one fatal event that was the death related to a drowning and its causal relationship to the study drug was determined as "not related". The subjects with Study-Emergent AEs at least 10% incidence or with Serious AEs by primary system organ class are shown below.

Study Emergent AEs

Patients with at least one TEAE, by Primary SOC at least 10% incidence, n (%):

Patients with TEAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*
Eye Disorders	28 (18.5) [24]
Gastrointestinal disorders	93 (61.6) [82]
General disorders and administration site conditions	43 (28.5) [34]
Infections and infestations	127 (84.1) [99]
Injury, poisoning and procedural complications	82 (54.3) [34]
Investigations	76 (50.3) [65]
Musculoskeletal and connective tissue disorders	54 (35.8) [38]
Nervous system disorders	106 (70.2) [99]
Psychiatric disorders	37 (24.5) [30]
Reproductive system and breast disorders	19 (12.6) [15]
Respiratory, thoracic and mediastinal disorders	64 (42.4) [49]
Skin and subcutaneous tissue disorders	55 (36.4) [40]

Death, SAEs, and Other SAEs

Death, n (%):	1 (0.7)
Patients with SAEs, n(%):	34 (22.5)

Patients with SAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*
Blood and lymphatic system disorders	1 (0.7) [1]
Gastrointestinal disorders	3 (2.0) [2]
General disorders and administration site conditions	3 (2.0) [2]
Hepatobiliary disorders	1 (0.7) [1]
Infections and infestations	6 (4.0) [3]
Injury, poisoning and procedural complications	7 (4.6) [4]
Neoplasms benign, malignant and unspecified	1 (0.7) [1]
Nervous system disorders	14 (9.3) [10]
Pregnancy, puerperium and perinatal conditions	1 (0.7) [0]
Psychiatric disorders	2 (1.3) [1]
Respiratory, thoracic and mediastinal disorders	2 (1.3) [2]
Surgical and medical procedures	2 (1.3) [0]

Secondary Outcome(efficacy): Seizure frequency per week

The efficacy analysis was performed on the FAS population and split by duration of exposure to LEV categories in the study.

Median Partial (Type I) Seizure Frequency per Week by Analysis Visit and Duration of Exposure – FAS Population

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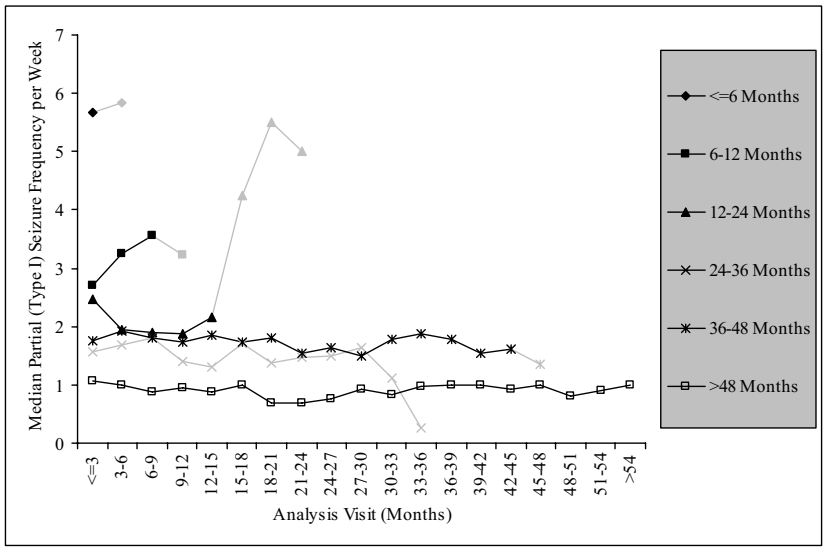

Note: Points shown in grey are based on 10 or fewer subjects

The median partial (type I) seizure frequency per week remained constant over the course of the study within each of the duration of exposure to LEV groups suggesting that the efficacy in terms of frequency of partial (type I) seizures was maintained with long-term treatment with LEV.

Publication Reference(s) based on the study: None

Date of report: 15 Nov-2008