UCB reference No.: RXCE07D2330

Approved by UCB 16-Jul-2007

Clinical Study Summary

DEV/CCM/03014.2007

CT Registry ID#: NCT00160680
Study No.: A00392

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: RRCE06G0405

Proprietary Drug Name	**INN**	**Therapeutic area and indication(s)**
Xyzal® Tablets	Levocetirizine dihydrochloride	Persistent allergic rhinitis

Name of Sponsor/Company: UCB Pharma SA

Title of Study: A pilot, open, monocenter, randomized two parallel groups, clinical efficacy trial: Comparison continuous versus on demand regimen of treatment with levocetirizine 5 mg oral tablets, once a day, in adults suffering from PErsistent allergic Rhinitis (PER) over six months.

Investigator(s) (number only): 1

Study Center(s) (number only): 1

Length of Study:
Date first patient enrolled: 11-Mar-2005
Date last patient completed: 21-Jun-2006

Phase of Development: Phase IV (Therapeutic use)

Abstract:
The primary objective of this study was to investigate and compare in adults suffering from PER continuous vs. on demand regimen of treatment with levocetirizine 5 mg (LCTZ) during 6 months as measured by the evolution of the mean weekly sum of the individual symptom scores for sneezing, rhinorrhea, nasal pruritus, and ocular pruritus (T4SS), evaluated on a 4-point scale over the past 24 hours. Subjects were ≥ 18 years old, had a clinical history of PER, a positive skin prick test, and a mean T4SS of ≥ over the 7 days baseline period. LCTZ was administered once daily in the morning for 24 weeks under the continuous regimen or once daily as needed under the on demand regimen. The primary efficacy variable was analyzed by means of repeated measures analysis of variance controlled for the factors treatment, week, and treatment by week interaction, and with the baseline values as covariate. Safety assessments were based upon physical examination and the recording of adverse events (AE).

Number of Subjects:	**LCTZ continuous**	**LCTZ on demand**
Planned, N:	50	50
Enrolled, N:	31	31
Completed, n (%):	22 (71.0)	18 (58.1)
Number of Subjects Withdrawn, n (%):	9 (29.0)	13 (41.9)
Withdrawn due to Adverse Events, n (%):	0	1 (3.2)
Withdrawn due to withdrawal of consent, n (%)	4 (12.9)	9 (29.0)
Withdrawn for Other Reasons, n (%):	5 (16.1)	3 (9.7)

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Demography:	**LCTZ continuous N=31**	**LCTZ on demand N=31**
Gender (Females/Males):	19/12	24/7
Age (years), mean (SD):	34.74 (12.33)	35.20 (10.71)
Race, n (%):		
Caucasian	26 (83.9)	27 (87.1)
Black	0	1 (3.2)
Asian/Pacific islander	1 (3.2)	0
Other	4 (12.9)	3 (9.7)

Safety Outcomes:

- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:

Four subjects (13.3%) reported treatment-emergent (TE) AEs under the continuous regimen and ten subjects (31.3%) under the on demand regimen. The most common reported TEAEs during the treatment period were nervous system disorders (3.3% and 15.6% of the subjects under the continuous and on demand regimen, respectively) and infections and infestations (3.3% of the subjects under the continuous regimen and 12.5% of the subjects under the on demand regimen). Three subjects (9.4%) had a drug-related TEAE under the on demand regimen and one subject (3.3%) under the continuous regimen.

There were no deaths or serious AE during the trial. Only one subject (3.1%), under the on demand regimen, had a TEAE leading to permanent study drug discontinuation.

Treatment Emergent AEs (TEAE)	**LCTZ continuous N=30***	**LCTZ on demand N=32***
Subjects with at least one TEAE, n (%):	4 (13.3)	10 (31.3)
Subjects with TEAEs with an incidence of ≥ 5% (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Infections and infestations	1 (3.3) [0]	4 (12.5) [0]
Nervous system disorders	1 (3.3) [1]	5 (15.6) [3]
Respiratory, thoracic and mediastinal disorders	1 (3.3) [0]	3 (9.4) [0]

* One subject (Subject 001/0011) took the treatment under on demand regimen instead of continuous regimen. For the safety analyses, this subject was analyzed according to actual regimen received.

Primary & Secondary Outcomes:

The mean T4SS over the total treatment period was similar under the continuous regimen (adjusted mean ± SE: 2.89 ± 0.43) and under the on demand regimen (adjusted mean ± SE: 3.15 ± 0.44), with the difference between the two regimens not being statistically significant (p = 0.667). Nevertheless, it is noticeable from the curve profiles that the treatment period is divided into two phases: an early phase (up to 3 or 4 months) with no significant difference between the two regimens, followed by a later phase (after 3 or 4 months) when the efficiency of a long-term therapy under a continuous regiment becomes evident. The median percentages of study drug intake ranged from 96 to 100% for the continuous regimen and from 53 to 70% for the on-demand regimen.

Publication Reference(s) based on the study: None

Date of report: 13-Jul-2007