Clinical Study Summary

DEV/CCM/03160.2007

CT Registry ID#: NCT00524836
Study No.: A00349

These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert.

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Based on Clinical Study Report document reference code: RRCE04L1603

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

Name of Sponsor/Company: UCB Pharma SA

Title of Study:
A multicentre, randomised, investigator blinded, active-control, parallel-group study evaluating the efficacy and safety of 5 mg levocetirizine oral tablets, once daily versus 10 mg loratadine oral tablets, once daily for the treatment of perennial allergic rhinitis (PAR)

Investigator(s) (number only): 2

Study Center(s) (number only): 2

Length of Study:
Date first patient enrolled: 12-Sep-2003
Date last patient completed: 24-Feb-2004

Phase of Development: III (therapeutic confirmatory study)

Abstract:
The primary objective of this study was to confirm the effect of levocetirizine (LCTZ 5 mg) compared to loratadine (LRTD 10 mg), in subjects suffering from PAR, in improving rhinitis symptoms measured by the Total 5 Symptom Score (T5SS) over a 14-day treatment period. Subjects were male and female, aged 18 to 60 years and were clinically diagnosed with PAR. Descriptive statistics were used to perform analysis on the change of investigator assessed T5SS from baseline to end of treatment. Additionally, ANCOVA (with treatment and centre as factors, and baseline values as covariate) was used to test the differences of change from baseline between the LCTZ 5 mg and LRTD 10 mg treatment groups. Safety was assessed by changes from predose to postdose for vital signs, electrocardiogram (ECG), laboratory parameters and physical examination results, as well as by the incidence of adverse events (AE).

Number of Subjects:	**LCTZ 5 mg**	**LRTD 10 mg**
Planned, N:	36	36
Enrolled, N:	35	36
Completed, n (%):	32 (91.4)	34 (94.4)
Number of Subjects Withdrawn, n (%):	3 (8.6)	2 (5.6)
Withdrawn due to Adverse Events, n (%):	0	0
Withdrawn for Other Reasons, n (%):	3 (8.6)	2 (5.6)
Demography:	**LCTZ 5 mg (N=35)**	**LRTD 10 mg (N=36)**
Gender (Females/Males):	21/14	22/14
Age (years), mean (SD):	37.1 (11.7)	37.5 (11.7)
Race, n (%):		
Asian/Mongolian	35 (100.0)	36 (100.0)

Safety Outcomes:
- Summary of treatment-emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:
During the treatment period, 7 subjects (20.0%) in the LCTZ 5 mg group and 5 subjects (13.9%) in the LRTD 10 mg group, experienced at least 1 treatment-emergent (TE)AE. The most frequently occurring AEs during the treatment period were nervous system disorders, which were experienced by 4 subjects (11.4%) in the LCTZ 5 mg group and 2 subjects (5.6%) in the LRTD 10 mg group. Drug-related AEs were experienced

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by 4 subjects (11.4%) in the LCTZ 5 mg group and 1 subject (2.8%) in the LRTD 10 mg group.
No deaths or serious AEs were reported during the study. No subjects experienced AEs that led to permanent discontinuation of the study drug. There was no evidence that LCTZ 5 mg was associated with any consistent or clinically important changes in postdose physical examination findings, vital signs, ECGs and laboratory measurements.

Treatment-Emergent AEs:	**LCTZ 5 mg (N=35)**	**LRTD 10 mg (N=36)**
Subjects with at least 1 TEAE, n (%):	7 (20.0%)	5 (13.9%)
Subjects with TEAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Gastrointestinal disorders	0	1 (2.8) [0]
General disorders and administration site conditions	2 (5.7) [1]	0
Infections and infestations	0	2 (5.6) [0]
Nervous system disorders	4 (11.4) [3]	2 (5.6) [1]
Respiratory, thoracic and mediastinal disorders	0	1 (2.8) [0]
Skin and subcutaneous tissue disorders	1 (2.9) [0]	0

Primary Outcomes:
The Least Square mean changes from baseline of T5SS was –4.54 for LCTZ group and –3.83 for LRTD group, the difference between the two treatment groups was not statistically significant (p=0.3552).

Publication Reference(s) based on the study: none

Date of report: 20-Jul-2007