Clinical Study Summary

DEV/CCM/03159.2007

CT Registry ID#: NCT00525278
Study No.: A00348

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Based on Clinical Study Report document reference code: RRCE04L1602

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

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 seasonal allergic rhinitis (SAR)

Investigator(s) (number only): 2

Study Center(s) (number only): 2

Length of Study:
Date first patient enrolled: 29-Aug-2003
Date last patient completed: 22-Oct-2003

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 SAR, in improving rhinitis symptoms measured by the Total 5 Symptom Score (T5SS) over a 14-day treatment period, as recorded by the investigator. Subjects were male and female, aged 18 to 60 years, clinically diagnosed with SAR, with a mean T5SS of ≥ 5 evaluated the last 24 hours of the selection week and the day before the randomization visit. 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 incidence of adverse events (AE).

Number of Subjects:	**LCTZ 5 mg**	**LRTD 10 mg**
Planned, N:	36	36
Enrolled, N:	34	33
Completed, n (%):	33 (97.1)	33 (100)
Number of Subjects Withdrawn, n (%):	1 (2.9)	0
Withdrawn due to Adverse Events, n (%):	1 (2.9)	0
Withdrawn for Other Reasons, n (%):	0	0
Demography:	**LCTZ 5 mg (N=34)**	**LRTD 10 mg (N=33)**
Gender (Females/Males):	14/20	13/20
Age (years), mean (SD):	37.5 (10.4)	37.3 (9.7)
Race, n (%):		
Asian/Mongolian	34 (100.0)	33 (100.0)

Safety Outcomes:
- Summary of treatment-emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:
No deaths or serious (S)AEs were reported during the study. Over the treatment period, 7 subjects (20.6%) in the LCTZ 5 mg group and 2 subjects (6.1%) in the LRTD 10 mg group experienced at least 1 treatment emergent (TE)AE. The most frequently occurring AEs were nervous system disorders, which were

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experienced by 3 subjects (8.8%) in the LCTZ 5 mg group and 1 subject (3.0%) in the LRTD 10 mg group. Drug-related AEs were reported in 3 subjects (8.8%) in the LCTZ 5 mg group and 1 subject (3.0%) in the LRTD 10 mg group.
In the LCTZ 5 mg group, 1 subject permanently discontinued study medication due to pregnancy. There were no clinically significant changes in vital signs, physical examinations, laboratory measurements and ECGs.

Treatment-Emergent AEs:	**LCTZ 5 mg (N=34)**	**LRTD 10 mg (N=33)**
Subjects with at least 1 TEAE, n (%):	7 (20.6%)	2 (6.1%)
Subjects with TEAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Gastrointestinal disorders	2 (5.9) [1]	1 (3.0) [0]
Infections and infestations	2 (5.9) [0]	0
Nervous system disorders	3 (8.8) [2]	1 (3.0) [1]
Pregnancy, puerperium and perinatal condition	1 (2.9) [0]	0
Renal and urinary disorders	1 (2.9) [0]	0
Respiratory, thoracic and mediastinal disorders	0	2 (6.1) [0]
Skin and subcutaneous tissue disorders	1 (2.9) [1]	0

Primary Outcomes:
The Least Square (LS) mean changes from baseline of T5SS was –5.54 for LCTZ group and –5.99 for LRTD group, the difference between the two treatment groups was not statistically significant (p=0.4798).

Publication Reference(s) based on the study: none

Date of report: 20-Jul-2007