UCB reference No.: RXCE06E1648

Approved by UCB 20-Jul-2007

Clinical Study Summary

DEV/CCM/03158.2007

CT Registry ID#: NCT00525382
Study No.: A00334

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**:** RRCE04L1601

Proprietary Drug Name	**INN**	**Therapeutic area and indication(s)**
Xyzal® Tablets	Levocetirizine dihydrochloride	Chronic idiopathic urticaria

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 chronic idiopathic urticaria (CIU).

Investigator(s) (number only): 2

Study Center(s) (number only): 2

Length of Study:
Date first patient enrolled: 21-Aug-2003
Date last patient completed: 03-Mar-2004

Phase of Development: III (therapeutic confirmatory study)

Abstract:
The primary objective of the study was to confirm the efficacy of levocetirizine 5 mg (LCTZ 5 mg) compared to loratadine 10 mg (LRTD 10 mg) on pruritus severity, assessed by the investigator (based on the daily record card) over 2 weeks of treatment in subjects suffering from CIU. Subjects were males and females aged 18 to 60 years, clinically diagnosed with CIU and with moderate to severe CIU defined as pruritus score ≥ 2, number of wheals ≥ 2, and total symptoms CIU score ≥ 2 at randomization.
Statistical analysis was performed on the change of pruritus score, from baseline to end of treatment, using descriptive statistics. Additionally, ANCOVA, with treatment and center as factors, and baseline values as covariates, 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, electrocardiograms (ECG), laboratory parameters and physical examination results, as well as by incidence of adverse event (AE).

Number of Subjects:	**LCTZ 5 mg**	**LRTD 10 mg**
Planned, N:	72	72
Enrolled, N:	67	67
Completed, n (%):	61 (91.0)	63 (94.0)
Number of Subjects Withdrawn, n (%):	6 (9.0)	4 (6.0)
Withdrawn due to Adverse Events, n (%):	1 (1.5)	0
Withdrawn for Other Reasons, n (%):	5 (7.5)	4 (6.0)
Demography:	**LCTZ 5 mg (N=67)**	**LRTD 10 mg (N=67)**
Gender (Females/Males):	45/22	42/25
Age (years), mean (SD):	36.7 (11.0)	38.0 (11.4)
Race, n (%):		
Asian/Mongolian	67 (100.0)	67 (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, 12 subjects (17.9%) in the LCTZ 5 mg group and 5 subjects (7.5%) in the LRTD 10 mg group experienced a treatment-emergent (TE) AE. The most frequently occurring AEs during the treatment period were nervous system disorders (4.5%) which were experienced by 4 subjects (6.0%) in

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the LCTZ 5 mg group and 2 subjects (3.0%) in the LRTD 10 mg group.
Drug-related AEs were experienced by 9 subjects (13.4%) in the LCTZ 5 mg group and 3 subjects (4.5%) in the LRTD 10 mg group. No deaths or serious (S)AEs were reported during the study. In the LCTZ 5 mg group, 1 subject (1.5%) had an AE that led to permanent discontinuation of the drug. Changes from baseline in physical examinations included 1 subject in the LCTZ 5 mg group who had had erythema and vesicles on their right upper limb at baseline, which normalised by the end of treatment. There were no other clinically significant changes in vital signs, physical examinations, laboratory measurements and ECGs.

Treatment-Emergent AEs:	**LCTZ 5 mg (N=67)**	**LRTD 10 mg (N=67)**
Subjects with at least 1 TEAE, n (%):	**12 (17.9)**	**5 (7.5)**
Subjects with TEAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Cardiac disorders	1 (1.5) [1]	1 (1.5) [1]
Ear and labyrinth disorders	1 (1.5) [1]	0
Gastrointestinal disorders	4 (6.0) [2]	1 (1.5) [0]
General disorders and administration site conditions	4 (6.0) [3]	0
Infections and infestations	1 (1.5) [0]	1 (1.5) [0]
Investigations	3 (4.5) [2]	0
Nervous system disorders	4 (6.0) [4]	2 (3.0) [2]
Skin and subcutaneous tissue disorders	1 (1.5) [0]	0

Primary Outcomes:
The Least Square mean changes of pruritus severity score by investigator from baseline was -1.85 for LCTZ group and -1.68 for LRTD group. The difference between the two treatment groups was not statistically significant (p=0.2580).

Publication Reference(s) based on the study: none

Date of report: 20-Jul-2007