Clinical Study Summary Template

DEV/CCM/02881.2007

CT Registry ID#: NCT 00160537
Study No.: A00391

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: RRCE05F2312

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

Name of Sponsor/Company: UCB Pharma SA

Title of Study:
A monocenter, double-blind, randomized trial, with two parallel groups comparing the clinical efficacy of levocetirizine 5 mg capsules and desloratadine 5 mg capsules taken once a day over 3 weeks of treatment in adult subjects suffering from seasonal allergic rhinitis (SAR) due to grass pollen

Investigator(s) (number only): 1

Study Center(s) (number only): 1

Length of Study:		Phase of Development:	IV (therapeutic exploratory)
Date first patient enrolled:	11-May-2005		
Date last patient completed:	11-Jul-2005		

Abstract:
The primary study objective was to compare the clinical efficacy of levocetirizine (LCTZ) 5 mg and desloratadine (DESL) 5 mg as measured by the subjects' satisfaction/dissatisfaction after the first week of treatment (subject's choice to continue with the administered treatment or to switch to alternative treatment). Secondary objectives included analyzing the correlation between switch and various aspects of the T5SS (sum of individual symptom scores for sneezing, rhinorrhea, nasal pruritus, ocular pruritus, and nasal congestion evaluated on a 4-point scale retrospectively over the past 24 hours); subject satisfaction/dissatisfaction; and safety (adverse events [AEs] reported by the subjects during the study, physical examination, and vital signs). Subjects were to have at least a 2-year history of SAR that became symptomatic and required treatment during the grass pollen season. For each subject, the trial lasted a maximum of 4 weeks: 3 to 7 days' baseline and 3 weeks' treatment. After 1 week's treatment, subjects had the choice to continue or to switch to alternative treatment. Efficacy was assessed by a daily record card filled in by the subject during baseline and treatment periods; an assessment of subject's dissatisfaction of treatment, if the subject made the choice to switch to alternative treatment after 1 week; assessment of the T5SS daily during baseline and treatment periods; a global assessment of disease evolution (subject Global Evaluation Scale) after 1 week's treatment (Visit 3); visual analog scale (VAS) to assess how quickly the symptoms were relieved and how quickly the blocked nose was relieved after 1 week's treatment; VAS at randomization (Visit 2) and at Visit 3 to assess how much the nose was blocked; VAS at Visit 3 to assess impact of treatment on quality of sleep and quality of daily activities during the last week; and subject's satisfaction/dissatisfaction of choice to switch or not to switch. The primary efficacy variable was analyzed using the Fisher's exact test. Logistic regressions were used to investigate correlation between the switch and symptom scores or Global Evaluation Scale. The Global Evaluation Scale was compared between treatment groups using a Cochran Mantel-Haenszel test. Number, nature, and duration of AEs were analyzed descriptively.

Publication Reference(s) based on the study:
None

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Number of Patients:	**DESL 5 mg**	**LCTZ 5 mg**
Planned, N:	100	100
Enrolled, N:	100	100
Completed, n (%):	98 (98)	98 (98)
Number of Patients Withdrawn, n(%):	2 (2)	2 (2)
Withdrawn due to Adverse Events, n(%):	0	0
Withdrawn for Other Reasons[a], n(%):	2 (2)	2 (2)
[a] Withdrawal of consent, lack of efficacy, mandatory intake of forbidden medication		
Demography:		
Gender (Females/Males):	57/43	40/60
Age (years), mean (SD):	34.9 (10.2)	34.0 (9.8)
Caucasian, n (%):	99 (99)	100 (100)

Safety Outcomes:
Safety data fully support the safety profile of LCTZ 5 mg and DESL 5 mg. There were no unexpected findings during the course of the study. Adverse events, which might be expected during treatment with an H1-receptor antagonist, were observed in both treatment groups.

No relevant changes in vital signs and no relevant abnormalities in physical examination were observed.

Treatment Emergent AEs (2 periods combined):	**DESL 5 mg (N=155)**	**LCTZ 5 mg (N=154)**
Patients with TEAEs (by Primary System Organ Class)	*n (%) [n considered drug-related by the Investigator]*	
Cardiac disorders	1 (0.6) *[0]*	1 (0.6) *[1]*
Eye disorders	1 (0.6) *[0]*	0
Gastrointestinal disorders	8 (5.2) *[2]*	9 (5.8) *[4]*
General disorders and administration site conditions	13 (8.4) *[10]*	16 (10.4) *[15]*
Infections and infestations	3 (1.9) *[0]*	6 (3.9) *[0]*
Investigations	2 (1.3) *[0]*	3 (1.9) *[0]*
Metabolism and nutrition disorders	1 (0.6) *[0]*	0
Musculoskeletal and connective tissue disorders	1 (0.6) *[0]*	2 (1.3) *[0]*
Nervous system disorders	31 (20.0) *[6]*	32 (20.8) *[3]*
Psychiatric disorders	2 (1.3) *[0]*	0
Renal and urinary disorders	0	1 (0.6) *[0]*
Reproductive system and breast disorders	1 (0.6) *[0]*	2 (1.3) *[0]*
Respiratory, thoracic, and mediastinal disorders	3 (1.9) *[0]*	12 (7.8) *[4]*
Skin and subcutaneous tissue disorders	4 (2.6) *[0]*	2 (1.3) *[0]*
Vascular disorders	1 (0.6) *[0]*	1 (0.6) *[1]*
Death, SAEs, and Other SAEs: if applicable		
Death, n (%):	0	0
Patients with SAEs, n(%):	0	0

Primary & Secondary Outcomes:
There was no difference between the LCTZ 5 mg and DESL 5 mg treatment groups in the percentage of subjects who switched to alternative treatment during the study. The study was not powered to detect statistically significant differences between groups for variables other than the primary endpoint variable. However, examination of trends indicated :

- a more pronounced improvement of T5SS, during 1 week, in subjects treated with LCTZ 5 mg compared to subjects treated with DESL 5 mg (the improvement was not

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reflected in subjects who switched to alternative treatment in spite of a significant correlation to symptom score; thus, the primary endpoint did not appear to be sufficiently discriminative to be useful in clinical trials, and the decision to switch treatments may have been confounded by unreported curiosity);

- subjects who decided to switch to alternative treatment (LCTZ 5 mg or DESL 5 mg) were significantly less relieved by their first treatment than subjects who did not switch (the subjects did not have the opportunity to compare the 2 treatments before making the decision to switch to alternative treatment or to pursue the same treatment; switch decisions were based on individual expectations, rather than experience with the 2 drugs);
- higher satisfaction with LCTZ 5 mg than with DESL 5 mg (the percentage of subjects dissatisfied with the switch from LCTZ 5 mg to DESL 5 mg was nearly twice the percentage of subjects dissatisfied with the switch from DESL 5 mg to LCTZ 5 mg);
- faster overall symptom relief, faster blocked nose relief, higher satisfaction with quality of sleep and daily activities, and better blocked nose relief in subjects treated with LCTZ 5 mg;
- the incidences of a “feeling of no improvement” in the DESL 5 mg group were about twice those in the LCTZ 5 mg group;
- the first “feeling of sufficient improvement” occurred earlier in subjects treated with LCTZ 5 mg than in subjects treated with DESL 5 mg.