

## Late-Breaking Abstracts

SESSION TITLE: Late Breaking Abstracts

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### A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PHASE III STUDY TO EVALUATE THE EFFICACY AND SAFETY OF A COMBINATION THERAPY OF MONTELUKAST AND LEVOCETIRIZINE IN PATIENTS WITH ASTHMA AND ALLERGIC RHINITIS

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**PURPOSE:** The aim of this study was to evaluate the efficacy and safety of a fixed-dose combination of montelukast and levocetirizine in subjects with perennial allergic rhinitis with mild-to-moderate asthma compared to montelukast alone

**METHODS:** This was a 4-week, randomized, multicenter, double-blind, phase III study. Following a 1-week placebo run-in period, the subjects were randomized to receive montelukast (10 mg/day, n = 112) or montelukast (10 mg/day)/levocetirizine (5 mg/day, n = 116) treatment for 4 weeks. The primary efficacy endpoint was mean daytime nasal symptom score (MDNSS). Other efficacy endpoints included mean nighttime nasal symptom score (MNSS), mean composite symptom score (MCSS), overall assessment of allergic rhinitis by both subjects and physicians, forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), FEV1/FVC, asthma control test (ACT) score, and the frequency of rescue medication used during the treatment period.

**RESULTS:** Of 333 patients screened for this study, 228 eligible patients were randomized to treatment. The mean (SD) age of patients was 43.32 (15.02) years, and two-thirds of them were women (66.67%). The demographic characteristics were similar between the treatment groups. Compared to that of the montelukast group, the montelukast/levocetirizine group showed significant reduction in MDNSS (least squares mean  $\pm$  standard error of combination vs. montelukast,  $-0.98 \pm 0.06$  vs.  $-0.81 \pm 0.06$ ,  $p = 0.045$ ). For all the other allergic rhinitis efficacy endpoints, the montelukast/levocetirizine group showed greater improvement than the montelukast group did. Similar results were observed in overall assessment scores and in FEV1, FVC, FEV1/FVC, and ACT score changes from baseline for the two treatment groups. Montelukast/levocetirizine was well-tolerated, and the safety profile was similar to that observed in the montelukast group.

**CONCLUSIONS:** The fixed-dose combination of montelukast and levocetirizine is effective and safe in treating perennial allergic rhinitis patients with asthma compared to montelukast alone.

**CLINICAL IMPLICATIONS:** The fixed-dose combination of montelukast and levocetirizine is effective and safe in treating perennial allergic rhinitis patients with asthma.

**DISCLOSURES:** No relevant relationships by Young Joo Cho, source=Web Response no disclosure on file for Byoung Whui Choi;

No relevant relationships by Jong Sook Park, source=Web Response

No relevant relationships by Choon-Sik Park, source=Web Response

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