Mepolizumab Reduces Disease Symptoms for Chronic Rhinosinusitis With Nasal Polyps: Data From the SYNAPSE Study

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Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) is characterized by mucosal inflammation, often by type 2 cytokines such as IL-4, CRTh2-mediated inflammmatory diseases also include rhinosinusitis. Significant loss of quality of life and function is often associated with CRSwNP.

Determinants of symptom severity in the patient population is key to improving treatment efficacy. Our study focused on the role of eosinophils in patients with CRSwNP.

Mepolizumab, a monoclonal antibody to IL-5, was studied in a Phase 3, double-blind, placebo-controlled, multicenter study (EPOS) to evaluate the efficacy of mepolizumab on CRSwNP in adult patients with eosinophilic CRSwNP (EPOS-33). The primary endpoint was an improvement from baseline on the nasal polyps obstruction visual analog score (VAS) score >5.

Methods

The primary endpoint was the proportion of subjects with a ≥2-point improvement from baseline on the nasal polyps obstruction VAS score >5. Efficacy assessments were conducted using ANOVA models with treatment group, geographic region, baseline score, and log(e) baseline blood eosinophil count as covariates.

Results

Baseline demographics

1234 patients included in the study, 200 received mepolizumab and 201 received placebo. Mild (N=366) patients were male with a median (IQR) age of 51 (42, 60) years. A total of 170 men and 164 women were included.

Overall, the median (IQR) age was 51 (42, 60) years. Median (IQR) age was significantly lower in the placebo group than in the mepolizumab group (50 (43, 60) vs. 51 (43, 60) years; p = 0.03).

Efficacy analyses

There was a significant difference in the proportion of patients who achieved ≥2-point improvement from baseline (p = 0.0065).

At Week 52, 36.9% (95% CI: 28.7, 45.3) of patients in the mepolizumab group achieved ≥2-point improvement from baseline in the nasal polyps obstruction VAS score >5 compared to 26.3% (95% CI: 18.5, 35.2) in the placebo group. The median (IQR) change in the nasal polyps obstruction VAS score was 1.1 (−1.0, 2.0) in the mepolizumab group and 0.0 (−1.0, 1.0) in the placebo group. The difference in medians was −1.1 (−2.1, 0.0) (p = 0.0028).

In the placebo group, the median (IQR) change in the nasal polyps obstruction VAS score was −0.4 (−2.4, 0.0) at Week 52. The difference in medians was −1.5 (−2.5, 0.0) (p = 0.0028).

Conclusions

In conclusion, mepolizumab was associated with significant and meaningful improvements in symptoms compared with placebo in patients with CRSwNP. Mepolizumab treatment should be considered for patients with CRSwNP who are intolerant or do not respond to antibiotics or anti-infective treatments.