Impact of Lebrikizumab on Patient-Reported Outcomes in Atopic Dermatitis: Prospective and Post Hoc Analyses of a Phase 2b Clinical Trial Demonstrate Clinically Meaningful Improvements

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SYNOPSIS

• Atopic dermatitis (AD) is associated with higher rates of anxiety and depression, likely due to a number of contributing factors such as intense itching, disrupted sleep, stigma, increased healthcare costs, and a lower quality of life.
• Lebrikizumab (LEB) is a high affinity, fully human monoclonal antibody targeting IL-13 that selectively prevents formation of the IL-13Rα1/IL-4Rα heterodimer receptor signaling complex while leaving endogenous regulation of IL-4 receptor signaling intact.
• This randomized, double-blind, placebo-controlled, dose-ranging trial was designed to investigate the impact of LEB on patient-reported outcomes, including those for anxiety and depression, among adults with moderate-to-severe AD.

RESULTS

• A total of 73, 80, 75, and 52 patients were randomized to LEB 125 mg Q4W, 250 mg Q4W, 250 mg Q2W, and placebo, respectively.
• Week 16 completion rates were similar across all LEB groups (77.7%–80.6%) and greater than placebo (64.4%).
• LEB 125 mg Q4W was found to have a greater impact than placebo on depression and anxiety-related endpoints, as measured by the Hopkins Anxiety and Depression Scales (HADS), respectively, vs. placebo.
• At Week 16, LEB arms vs. placebo showed improvements in anxiety (HADS A: -8.9% ± 2.5% vs. -2.1% ± 1.7%, p < 0.001) and depression (HADS D: -6.8% ± 2.2% vs. -1.3% ± 1.7%, p < 0.05), consistent with dose-dependent changes across a range of AD-specific and other measures.

Efficacy and Patient-Reported Outcomes Assessments

• The primary endpoint was percent change in Eczema Area and Severity Index (EASI) from baseline to Week 16.
• Secondary endpoints included changes in patients’ Dermatology Life Quality Index (DLQI), Patient-Evaluated Eczema Severity (POEM),不止于AD症状和患者报告的结局

Patient-Reported Outcomes

• LEB-treated patients showed a numerically greater reduction in pruritus NRS by Day 2 vs. placebo-treated patients with further improvement across LEB arms vs. placebo at Week 16 as assessed by joint point analysis or baseline from Placebo
• Differences in the proportions of patients achieving pruritus NRS change ≥4 points at Day 42 (56–60%) vs. 35% of placebo-treated patients, respectively.

CONCLUSIONS

• This trial demonstrated statistically and clinically meaningful improvements in AD symptoms and patient-reported outcomes with LEB, especially those related to anxiety and depression.

REFERENCES


Poster presented virtually at the Fall Clinical Dermatology Conference • October 29 – November 1, 2020