Efficacy And Safety of Lebrikizumab in Moderate-to-Severe Atopic Dermatitis: Results from Two Phase 3, Randomized, Double-Blinded, Placebo-Controlled Trials

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Introduction: Lebrikizumab, a high-affinity IgG-4 monoclonal antibody targeting interleukin 13, selectively prevents the formation of IL-13Ra1/IL-4Ra heterodimer receptor signalling complex. Lebrikizumab demonstrated rapid, dose-dependent efficacy and acceptable safety profile in moderate-to-severe atopic dermatitis (AD) patients in a Phase 2b trial (NCT03443024). Here, we report 16-week efficacy and safety outcomes of lebrikizumab monotherapy in AD patients from two ongoing 52-week, randomized, double-blinded, placebo-controlled Phase 3 trials, ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967).

Methods: Eligible moderate-to-severe AD patients (adults and adolescents [12-17 years, weighing ≥ 40 kg]) were randomized 2:1 to subcutaneous lebrikizumab 250 mg or placebo every 2 weeks. Efficacy analyses included proportions of patients achieving IGA 0/1, EASI-75 and Pruritus NRS ≥4-point improvement from baseline (P≥4) at Week 16. Non-efficacy related missing data were imputed by multiple imputation.

Results: In ADvocate1, proportions of patients treated with lebrikizumab 250 mg (N=283) and placebo (N=141) achieving IGA 0/1 at Week 16 were 43.0% and 12.8% (p<0.001); EASI-75 responses were 59.3% and 16.4% (p<0.001); P≥4 proportions were 46.3% and 12.7% (p<0.001), respectively. In ADvocate2 (lebrikizumab, N=281, placebo, N=146), corresponding proportions for IGA 0/1 were 33.1% and 10.9% (p<0.001); EASI-75 responses were 50.8% and 18.2% (p<0.001); P≥4 proportions were 38.3% and 11.3% (p<0.001), respectively. The percentage of patients reporting ≥1 TEAE was comparable in ADvocate1 (lebrikizumab, 45.4%; placebo, 51.1%) and ADvocate2 (lebrikizumab 53.0%; placebo, 66.2%).

Conclusion: Data from two ongoing pivotal Phase 3 trials suggest that lebrikizumab 250 mg Q2W provides an efficacious treatment option with an acceptable safety profile for patients with moderate-to-severe AD.
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