Safety and efficacy of lebrikizumab in adolescent patients with moderate-to-severe atopic dermatitis: an open-label study

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Background: Atopic dermatitis (AD) can greatly impact quality of life in adolescents and improved management is needed. Lebrikizumab, a high-affinity monoclonal antibody targeting interleukin (IL)-13, demonstrated clinical benefit in Phase 3 trials; ADvocate1 and ADvocate2 and ADhere.

Objective: To report 52-week safety and efficacy outcomes from ADore (NCT04250350), a Phase 3, open label study of lebrikizumab in adolescent patients with moderate-to-severe AD.

Methods: Eligible adolescents (N=206) (≥12 to <18 years; weighing ≥40 kg) received 500mg loading doses at baseline and Week-2, and 250mg lebrikizumab subcutaneous injections every 2-weeks (Q2W) for 52-weeks. Safety was monitored using adverse events (AEs), AEs leading to treatment discontinuation, vital signs, and laboratory testing. Efficacy analyses included Investigator Global Assessment (IGA) and Eczema Area and Severity Index (EASI).

Results: A total of 172 patients completed the treatment period. Low frequencies of AEs leading to treatment discontinuation (2.4%) and SAEs (2.4%) were reported.
Overall, 134 (65.0%) patients reported at least 1 TEAE, most being mild or moderate in severity, including 14 (6.8%) conjunctivitis events. Efficacy was rapid, with 14.4% achieving IGA (0,1) at Week-4, increasing to 46.3% at Week-16 and 62.6% at Week-52. EASI-75 was 28.6% at Week-4, 73.2% at Week-16, and 81.9% at Week-52. The mean percent improvement from baseline to Week-52 in EASI was 86.0%.

**Conclusion:** Lebrikizumab open-label 250mg Q2W had a safety profile in adolescents with moderate-to-severe AD which was consistent with previous trials, with 2.4% treatment discontinuation due to AEs. Lebrikizumab demonstrated efficacy, with 81.9% of patients achieving EASI-75 and 62.6% achieving IGA (0,1) at Week-52.

**Keywords:** Lebrikizumab, efficacy, atopic dermatitis

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