Lebrikizumab is an effective treatment for moderate-to-severe atopic dermatitis in patients ≥60 years of age

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Introduction: Historically, atopic dermatitis (AD) was believed to affect primarily children. However, a recent meta-analysis of 17 studies reporting age of AD onset as >16 years found that the pooled proportion of adult-onset AD was 26.1%, and that AD onset can occur at all ages. Lebrikizumab (LEB) is a high-affinity monoclonal antibody which targets IL-13, the key cytokine implicated in AD.

Objectives: This analysis investigated the efficacy and safety of lebrikizumab in adults ≥60 years with moderate-to-severe AD.

Methods: Data for patients aged ≥60 years from two Phase 3 trials, ADvocate1 and ADvocate2, were pooled. A total of 98 patients ≥ 60 years participated in the ADvocate trials (N=28 placebo (PBO), N=70 LEB). Patients were treated with lebrikizumab
250mg every 2 weeks or PBO, for 16 Weeks. Baseline demographics and characteristics were recorded. Efficacy was assessed in the pooled modified intent to treat population at Week 16 with Investigator's Global Assessment (IGA) (0,1) with ≥2-point improvement, ≥75% improvement in Eczema Area and Severity Index (EASI 75), EASI percentage change from baseline (CFB), and Pruritus Numeric Rating Scale (NRS) ≥4-point improvement. Categorical outcomes were evaluated by Cochran Mantel Haenszel tests to compare treatment groups. Continuous outcomes were analyzed using the analysis of covariance model. Data collected after use of rescue medication or discontinuation due to lack of efficacy were imputed with non-responder imputation (NRI) for categorical endpoints, or baseline values for continuous endpoints. Data collected after discontinuation for other reasons were set to missing and missing data were imputed with multiple imputation. Safety was also assessed in the integrated modified safety population.

**Results:** The baseline mean age was 67.2 years (standard deviation [SD] 6.7, range 60-93) in LEB- treated patients and 69 years ([6.2], range 60-85) in PBO. The LEB- treated population was 62.9% male (n=44/70) vs PBO 46.4% (n=13/28). Race was comparable between groups. At baseline 67.1% LEB (n=47/70) and 57.1% PBO (n=16/28) patients had IGA 3, while 32.9% LEB (n=23/70) and 42.9% PBO (n=12/28) had IGA 4. Other baseline characteristics were comparable: EASI: LEB 26.1, [10.6] vs PBO 27.1, [8.1]; BSA: LEB 38.3, [19.8] vs. PBO 40.9, [18.1]; and Pruritus NRS: LEB 7.5, [2.0] vs PBO 7.4, [1.7].

At Week 16, IGA (0,1) was achieved by 34.5% LEB-treated patients vs 11% PBO (P=0.022). EASI 75 was achieved by 48.9% and 16.3% of LEB- and PBO-treated patients, respectively (P=0.004). Pruritus NRS with ≥4-point improvement was reported by 45.5% and 12.2% of LEB vs PBO, respectively (P=0.004). The mean
percent CFB EASI was LEB -58.5% (SE 8.5) and PBO -29.4% (SE 11.1) (P=0.002). Safety results in the older adult population were consistent with the overall modified safety population.

Conclusions: At Week 16, efficacy and patient reported outcome endpoints were met in the older adult population. These results indicate that lebrikizumab is an effective treatment for moderate-to-severe AD in the adult population ≥60 years of age and has a consistent safety profile.

Keywords: Atopic dermatitis, Adults, Eczema Area and Severity Index, Lebrikizumab, Treatment

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