

## Long-term safety and efficacy of tralokinumab in more than 1400 patients with moderate-to-severe atopic dermatitis treated for up to 42 months: an interim analysis of ECZTEND

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**Introduction.** Atopic dermatitis (AD), a chronic inflammatory skin disease, negatively impacts quality of life and often persists throughout a patient's lifespan. Few long-term treatments are currently available for patients with moderate-to-severe disease, presenting a need for options with a positive risk-benefit profile. Three Phase 3 trials have shown that tralokinumab, a fully human monoclonal antibody that specifically targets interleukin-13, provided significant improvements in the severity of AD and was well tolerated up to 52 weeks (Wollenberg A, et al. *Br J Dermatol.* 2021;184:437-449; Silverberg JI, et al. *Br J Dermatol.* 2021;184:450-463). An ongoing, open-label, 5-year extension trial, ECZTEND (NCT03587805), is evaluating the safety and efficacy of treatment with subcutaneous tralokinumab 300 mg every 2 weeks (plus optional corticosteroids) after a 600-mg loading dose in adult patients with moderate-to-severe AD who completed previous tralokinumab parent trials.

**Methods.** We performed an interim analysis of ECZTEND to assess the safety and efficacy of tralokinumab for up to 42 months of total tralokinumab treatment ( $\leq 2.5$  years of which was in the open-label extension ECZTEND and  $\leq 1$  year in parent trials). The primary endpoint is the number of adverse events (AEs) during the treatment period from baseline to Week 268. Secondary endpoints were defined as Investigator's Global Assessment (IGA) score of 0/1 (clear/almost clear) and  $>75\%$  improvement in Eczema Area and Severity Index (EASI-75) at prespecified weeks.

**Results.** This interim safety analysis included 1442 patients from the parent trials who had received  $\geq 1$  dose of tralokinumab as of data cut-off, April 30, 2021. 57.6% of patients were male, median age was 38.0 years, and median age of onset of AD was 3.0 years. Median duration of AD was 27.0 years, and median body surface area affected at parent-trial baseline was 46.0%. Median time from last dose of study drug in parent trial to first dose in ECZTEND was 34.0 days. Overall, 1127 patients (78.2%) reported experiencing an AE, with 101 patients (7.0%) reporting serious AEs (SAEs). The most frequent AEs ( $\geq 5\%$  by MedDRA preferred term) were viral upper respiratory tract infection, AD, upper respiratory tract infection, headache, and conjunctivitis. In addition, 2.5% of patients reported injection-site reaction, 2 patients (0.1%) reported eosinophilia, 38 (2.6%) reported herpes simplex, and 30 (2.1%) reported herpes zoster. Most AEs (66.3%) were of mild severity. AEs led to withdrawal from ECZTEND in 34 patients (of these 2 were conjunctivitis and 2 were allergic conjunctivitis). No

conjunctivitis events were SAEs. No deaths were reported. In patients who reached the 2-year time point (Week 104), or would have reached that time point had they not discontinued earlier (prior to data cutoff April 30, 2021), EASI-75 was achieved by 77.6% of patients and IGA 0/1 was achieved by 46.4% of patients. Worst weekly pruritus numeric rating scale (NRS)  $\leq 3$  was achieved by 54.4% of patients, and Dermatology Life Quality Index  $\leq 5$  was achieved by 68.8% of patients, by modified NRI.

**Conclusion.** This interim analysis of ECZTEND demonstrates that long-term use of tralokinumab 300 mg Q2W was well-tolerated, and no new safety signals were identified with up to 42 months of treatment

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