Tralokinumab improves signs and symptoms of moderate-to-severe atopic dermatitis in patients aged 12 years and older with and without atopic comorbidities

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Introduction/Background: Atopic dermatitis (AD) is an inflammatory skin disease associated with atopic comorbidities, including asthma, food allergy, hay fever, and allergic conjunctivitis. Tralokinumab, a high-affinity monoclonal antibody that specifically targets IL-13, is indicated for the treatment of moderate-to-severe AD.

Objectives: To assess the impact of atopic comorbidities on the efficacy and safety of tralokinumab vs. placebo for moderate-to-severe AD in patients age ≥12 years.

Methods: This post-hoc analysis presents data from the adult trials ECZTRA 1 and 2 (NCT03131648 and NCT03160885 pooled; 300 mg tralokinumab every 2 weeks [Q2W] vs. placebo) and ECZTRA 3 (NCT03363854; 300 mg tralokinumab Q2W vs. placebo, both plus TCS as needed), and the ECZTRA 6 adolescent trial (NCT03526861; pooled 150 mg and 300 mg tralokinumab Q2W vs. placebo). Tralokinumab-treated patients received a loading dose.
Proportion of patients achieving IGA 0/1 and EASI-75 at Week 16 according to patient-reported current or past atopic comorbidity are presented as observed regardless of rescue medication use; missing data were imputed as non-responders.

**Results:** In total 2,223 patients were included across four trials. Among patients in ECZTRA 1 and 2, 50.5% reported history of asthma, 38.5% food allergy, 53.8% hay fever, and 33.5% allergic conjunctivitis, while 19.8% reported no atopic comorbidities and 79.3% reported ≥1 atopic comorbidity. Proportions of patients in ECZTRA 3 and 6 reporting history of atopic comorbidities were largely similar, although more adolescent patients reported food allergy. In all subgroups at Week 16, higher proportions of patients receiving tralokinumab vs. placebo achieved EASI-75. In ECZTRA 1 and 2, response rates among patients in each subgroup were asthma: 35.3% vs. 12.8%, food allergy: 33.2% vs. 14.7%, hay fever: 36.8% vs. 16.5%, allergic conjunctivitis: 34.8% vs. 12.7%, none: 34.6% vs. 20.5%; and ≥1 atopic comorbidity: 35.5% vs. 15.2% ($P<0.05$ for all). A similar pattern of response was observed in ECZTRA 3 and 6, and for IGA 0/1 across trials. EASI-75 response rates for tralokinumab-treated patients were consistent across patients with different numbers of atopic comorbidities. Safety across subgroups was consistent with the safety profile of tralokinumab observed overall in adults and adolescents.

**Conclusions:** 16 weeks of tralokinumab treatment improved AD signs and symptoms in adult and adolescent patients with and without atopic comorbidities, regardless of type or number of atopic comorbidities. The safety profile of tralokinumab was consistent between patients with and without atopic comorbidities.

**Keywords:** tralokinumab, moderate-to-severe, comorbidities, efficacy, safety
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