Tralokinumab treatment substantially improves patient-reported outcomes in adolescents with moderate-to-severe atopic dermatitis at 16 weeks

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Introduction. Atopic dermatitis (AD) is a chronic inflammatory skin disease that negatively impacts quality of life (QoL) at any age. Tralokinumab, a high-affinity monoclonal antibody, specifically neutralizes interleukin (IL)-13 activity. In the phase 3 ECZTRA 6 trial (NCT03526861), tralokinumab demonstrated substantial efficacy and was well-tolerated in adolescents with moderate-to-severe AD. We evaluated the impact of tralokinumab on patient-reported outcomes (PROs) through Week 16 in ECZTRA 6.
Methods. Adolescents (12-17 years) were randomized to subcutaneous tralokinumab 150 mg (n=100) or 300 mg (n=101), or placebo (n=100), every 2 weeks. Patients recorded itch (adolescent worst pruritus Numeric Rating Scale (NRS)) and sleep interference (eczema-related sleep NRS) daily via eDiary. Assessments for Children's Dermatology Life Quality Index (CDLQI), Patient Oriented Eczema Measure (POEM), and Hospital Anxiety and Depression Scale (HADS) were recorded during scheduled visits. Patients receiving rescue therapy or with missing data were considered non-responders.
Results. At Week 16, significantly greater proportions of patients receiving tralokinumab (150 mg/300 mg vs. placebo) achieved ≥4-point improvement in adolescent worst pruritus NRS (23.2%/25.0% vs. 3.3%; $P<0.001$/$P<0.001$), ≥6-point improvement in CDLQI (31.0%/39.5% vs. 15.9%; $P=0.029$/$P<0.001$), and ≥6-point improvement in POEM (38.7%/46.8% vs. 10.5%; $P<0.001$/$P<0.001$). Tralokinumab was associated with greater improvement than placebo in eczema-related sleep NRS (adjusted mean change±SE –2.9±0.3/–3.1±0.3 vs. –1.8±0.4; $P=0.015$/$P=0.005$). Tralokinumab vs. placebo adjusted mean change±SE for HADS was –1.8±0.7/–4.4±0.6 vs. –2.1±0.8 ($P=0.81$/$P=0.023$).
Conclusions. Tralokinumab significantly improved symptomatic and psychosocial impacts of moderate-to-severe AD in adolescents utilizing clinically relevant PROs at Week 16, including itch, sleep interference, anxiety/depression, and overall QoL.
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Andrew Blauvelt is a scientific adviser and clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, EcoR1, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron Pharmaceuticals, Inc., Sanofi Genzyme, Sun Pharma, UCB Pharma, and Vibliome.

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