

Efficacy and safety of tildrakizumab for the treatment of moderate-to-severe plaque psoriasis of the scalp: Week 52 results of a multicenter, randomized, double-blind, placebo-controlled clinical study

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Objective 1: To assess the long-term efficacy of tildrakizumab in patients with moderate-to-severe plaque psoriasis of the scalp from Week 16 to Week 52 of treatment

Objective 2: To assess the safety of tildrakizumab in patients with moderate-to-severe plaque psoriasis of the scalp during 52 weeks of treatment

Background: Tildrakizumab, an anti-interleukin-23 p19 antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis, was investigated for the treatment of scalp psoriasis in a Phase 3b, randomized, double-blind, placebo-controlled study (NCT03897088). The primary endpoint, Investigator's Global Assessment (IGA) modified 2011 (scalp) response ("clear [0]" or "almost clear [1]" with ≥ 2 -point reduction from baseline) at Week (W)16, was met. Results through W52 are reported.

Methods: Patients originally randomized to tildrakizumab 100 mg continued dosing at W16 and every 12 weeks thereafter; patients randomized to placebo switched to receive tildrakizumab 100 mg at W16, W20, W32, and W44. Efficacy assessments included IGA modified 2011 (scalp), Psoriasis Scalp Severity Index (PSSI), scalp surface area (SSA; % affected), scalp Itch-Numeric Rating Scale (Itch-NRS), and Dermatology Life Quality Index (DLQI). Safety was assessed in all treated patients.

Results: Of the 44/89 (49.4%) and 54/89 (60.7%) IGA mod 2011 (scalp) and PSSI 90 responders to tildrakizumab at W16, 36/44 (81.8%) and 44/54 (81.5%), respectively, sustained response at W52 (modified intention-to-treat [mITT] population). From W16 to W52 in patients originally randomized to tildrakizumab/placebo (ITT population), mean (standard deviation) scalp Itch-NRS score decreased from 3.4 (2.8)/6.8 (2.8) to 2.3 (2.6)/2.3 (2.6), SSA involvement from 13.5% (22.3%)/48.0% (25.0%) to 6.1% (15.5%)/8.3% (16.0%), PSSI score from 5.9 (9.2)/25.3 (16.3) to 2.9 (6.9)/3.9 (8.3), and DLQI score from 4.8 (5.6)/12.6 (8.3) to 2.9 (4.4)/2.8 (4.4). No new safety signals were detected.

Conclusion: Efficacy and safety of tildrakizumab in patients with scalp psoriasis were maintained through W52.

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Disclosures

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