Efficacy and safety of tildrakizumab for the treatment of moderate-to-severe plaque psoriasis of the scalp: A multicenter, randomized, double-blind, placebo-controlled, Phase 3b study

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Background: Tildrakizumab is an anti–interleukin-23 p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis. Efficacy and safety of tildrakizumab for the treatment of scalp psoriasis were investigated in a Phase 3b, randomized, double-blind study (NCT03897088).

Methods: Patients with moderate-to-severe plaque psoriasis of the scalp (Investigator's Global Assessment [IGA] mod 2011 [scalp] ≥3, Psoriasis Scalp Severity Index [PSSI] ≥12, ≥30% scalp surface area affected) were randomized 1:1 to receive tildrakizumab 100 mg or placebo at Week (W)0 and W4. The primary efficacy endpoint was IGA mod 2011 (scalp) response, defined as "clear (0)" or "almost clear (1)" with ≥2-point reduction from baseline, at W16 (modified intention-to-treat [mITT] population); key secondary endpoints were PSSI 90 response at W16 and W12 and IGA mod 2011 (scalp) response at W12 (all mITT). Missing data were imputed as nonresponse. Safety was assessed in all patients as treated.

Results: The safety population included 231 patients (58.0% male, mean age 45.2 years; mITT, 171 patients). The primary endpoint of IGA mod 2011 (scalp) response at W16 was achieved in significantly more patients receiving tildrakizumab vs placebo (49.4% vs 7.3%; P <0.00001). Tildrakizumab was superior to placebo for all key secondary endpoints (PSSI 90 response, 60.7% vs 4.9% at W16, 48.3% vs 2.4% at W12; W12 IGA mod 2011 [scalp] response, 46.1% vs 4.9%; all P <0.00001). No serious treatment-related adverse events occurred.

Conclusion: Tildrakizumab was efficacious vs placebo for the treatment of moderate-to-severe plaque psoriasis of the scalp. No new safety signals were detected.

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