Real-world effectiveness and safety in a Phase 4 study of tildrakizumab in patients with moderate-to-severe plaque psoriasis

Neal Bhatia[1], J Gabriel Vasquez[2], Brad Schenkel[3], Ranga Gogineni[3], Jayme Heim[2]

[1]Therapeutics Clinical Research, San Diego, CA, USA; [2]West Michigan Dermatology, Grandville, MI, USA; [3]Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA

Background: Tildrakizumab is an anti–interleukin-23p19 monoclonal antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis. This analysis assesses the effectiveness and safety of tildrakizumab from a real-world study of patients with moderate-to-severe plaque psoriasis.

Methods: In this real-world Phase 4 study (NCT03718299), adults with moderate-to-severe plaque psoriasis received tildrakizumab 100 mg at Week 0 (baseline), Week 4, and every 12 weeks thereafter through Week 52. Effectiveness was assessed from Psoriasis Area and Severity Index (PASI) score through Week 52 and from the percentage of body surface area (BSA) affected and static Physician Global Assessment (sPGA) through Week 64. Safety was assessed from adverse events (AEs) through Week 64. Missing data were not imputed.

Results: Of 55 patients enrolled, 45 completed the study. The mean (standard deviation [SD]) PASI score was 11.6 (7.1) at baseline and decreased significantly (P <0.001) to 6.5 (5.1; mean percentage improvement, 45.3%) at Week 4 and 1.6 (2.6; mean percentage improvement, 84.7%) at Week 52; Week 52 PASI 75, PASI 90, and PASI 100 response rates were 87.0%, 56.5%, and 32.6%, respectively. Mean (SD) BSA decreased significantly from 14.5% (11.5%) at baseline to 11.6% (10.6%) at Week 4 and 2.1% (3.6%) at Week 64, mean (SD) sPGA from 3.2 (0.6) at baseline to 2.1 (0.7) at Week 4 and 1.0 (1.0) at Week 64, and mean (SD) BSA x sPGA from 47.0 (41.5) at baseline to 26.0 (26.2) at Week 4 and 4.6 (9.4) at Week 64 (all P <0.001 at Week 4 and Week 64). Serious AEs were infrequent. No treatment-emergent AEs were considered related to tildrakizumab.

Conclusion: These real-world data demonstrated the significant effectiveness of tildrakizumab beginning as early as Week 4 and showed a favorable safety profile in patients with moderate-to-severe plaque psoriasis.

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