Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose, Phase 2b Study to Demonstrate the Safety and Efficacy of Tildrakizumab, a High-Affinity Anti–Interleukin-23P19 Monomeric Antibody, in Patients with Active Psoriatic Arthritis

BACKGROUND

There is an unmet need for therapeutics that address all of the manifestations of PsA, and have an acceptable safety profile for long-term use.

MATERIALS AND METHODS

Patients ≥18 years old with a diagnosis of PsA (Classification of Psoriatic Arthritis [CASPAR] criteria) for ≥6 months and active disease according to PASI ≥10 and swollen joint count ≥6 were randomized to weekly or every 12-week tildrakizumab doses (100 mg Q4W, 200 mg Q4W, 100 mg Q12W, 200 mg Q12W, and placebo Q12W) for 24 weeks. Safety assessments and laboratory assessments were performed throughout the study. ACR, American College of Rheumatology response criteria; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

RESULTS

The proportion of patients at week 24 with ≥20%, ≥50% and ≥70% improvement in American College of Rheumatology response criteria (ACR20, ACR50, ACR70) was significantly greater among all tildrakizumab treatment arms vs placebo except for tildrakizumab 20 mg Q12W for ACR70 (Table 1). At week 24, there was a significantly greater proportion of ACR20, ACR50, and ACR70 responders among all tildrakizumab treatment arms vs placebo except for tildrakizumab 20 mg Q12W for ACR70 (Figure 3).

Efficiency of pain relief

Mean change in patient pain from baseline was significantly decreased in all tildrakizumab treatment arms vs placebo except for tildrakizumab 20 mg Q12W for ACR70 (Table 2). At week 22, patients with ≥50% improvement in ACR20 and ACR50 had significantly reduced tender joint counts vs placebo (Figure 5). In all tildrakizumab arms, patients with ≥70% improvement in ACR20 also had significantly reduced tender joint counts vs placebo (Figure 6).

CONCLUSIONS

Tildrakizumab was well tolerated with low rates of TEAEs reported. There were no reports of candidiasis, inflammatory bowel disease, major adverse cardiac events, or nonserious TEAEs leading to death. The most commonly reported TEAEs were nasopharyngitis (17% vs 6%), headache (15% vs 2%), and hypertension (11% vs 5%). There were no significant differences in laboratory parameters that led to a serious TEAE or discontinuation of the study drug. The incidence of serious TEAEs was low. Tildrakizumab was well tolerated with low rates of TEAEs reported.

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