Efficacy and safety of tildrakizumab, a high-affinity anti–interleukin-23p19 monoclonal antibody, in patients with active psoriatic arthritis

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BACKGROUND

Psoriatic arthritis (PsA), a chronic inflammatory arthritis of the seronegative spondyloarthropathy type, is characterized by arthritis, skin plaques, enthesitis, and dactyliitis and occurs in 1% to 3% of patients with psoriasis (Ps). PsA is a progressive disease linked to increased disability, diminished health-related quality of life, and comorbidities, including cardiovascular disease, metabolic syndrome, and psoriatic skin disease. The pathogenesis of PsA is complex, involving both genetic and environmental factors, and is characterized by T-cell-mediated inflammation, with a role of Th17 cells. 

METHODS

Patients were randomized to receive tildrakizumab (TIL) 100 mg Q12W or TIL 200 mg Q12W or placebo (PBO). Patients with at least 10% improvement from baseline in swollen joint count and at least 20% improvement from baseline in tender joint count were considered to have achieved ACR20 response. The primary endpoint was ACR20 response at week 12.

RESULTS

At week 52, more patients in the TIL 200 mg Q12W arm achieved ACR20 response (59.5%) compared with the TIL 100 mg Q12W arm (59.0%; P = 0.65) and the PBO arm (53.8%; P < 0.0001 vs PBO). A significantly greater proportion of patients in the TIL 200 mg Q12W arm achieved ACR50 (44.0%) and ACR70 (32.1%) responses compared with those in the PBO arm (both P < 0.0001). By week 52, 44.0% of patients in the TIL 200 mg Q12W arm achieved PASI 75, 28.6% achieved PASI 90, and 15.0% achieved PASI 100 (all P < 0.0001 vs PBO). During the 52-week treatment period, the incidence rates for serious infections were 7.5/100 patient-years in the TIL 200 mg Q12W arm, 8.7/100 patient-years in the TIL 100 mg Q12W arm, and 5.6/100 patient-years in the PBO arm. Common adverse events (AEs) included upper respiratory tract infection, influenza, and neutropenia.

CONCLUSIONS

Tildrakizumab was well tolerated and resulted in sustained clinical response and improvement in skin disease in patients with active PsA over 52 weeks. Further studies are needed to assess the long-term safety and efficacy of tildrakizumab in patients with PsA.

REFERENCES


