Tofacitinib in Patients with Psoriatic Arthritis: Analysis of Dermatologic Endpoints from 2 Phase 3 Studies

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Background: Psoriatic arthritis (PsA) is a chronic, systemic inflammatory disease; the onset of dermatologic symptoms often precedes rheumatic manifestations. Tofacitinib is an oral Janus kinase inhibitor for the treatment of PsA. It has been shown that tofacitinib can improve dermatologic symptoms in patients (pts) with PsA.1,2

Objectives: To investigate the efficacy of tofacitinib in improving additional dermatologic endpoints in adult pts with active PsA.

Methods: This analysis included data from 2 placebo (PBO)-controlled, double-blind, Phase 3 studies in pts with active PsA and an inadequate response to ≥1 conventional synthetic disease-modifying antirheumatic drug (csDMARD) who were tumour necrosis factor inhibitor (TNFi)-naïve (OPAL Broaden [12 months; NCT01877668]; N=4225) or had an IR to ≥1 TNFi (OPAL Beyond [6 months; NCT01882439]; N=3945). Pts must have had active plaque psoriasis screening only and were required to receive a stable dose of 1 csDMARD. Pts were randomized to tofacitinib 5 mg twice daily (BID), 10 mg BID, adalimumab 40 mg subcutaneous injection every 2 weeks (OPAL Broaden only) or PBO (advanced to tofacitinib 5 or 10 mg at Month [M]3). Percentage (% change) from baseline (BL) (%) in Psoriasis Area and Severity Index (PASI) total score, % of pts achieving ≥75% PASI improvement from BL (PASI75) stratified by BL PASI severity (>0 to ≤10, >10 to ≤30, >30 to ≤50, >50 to ≤75, >75 to ≤100, >100) and Pts’ Global Joint and Skin Assessment-Visual Analogue Scale Psoriasis question (PGJS–VAS Psoriasis) were measured at M1, 3, 6, and at M9 and 12 (OPAL Broaden only). % ΔPASI total score and PASI75 were measured only in pts with BL affected body surface area (BSA) >3% and PASI >0. Safety endpoints were also analyzed. Results: BL demographics were similar between treatment groups and studies. BL median PASI scores (pts with BL BSA >3% and PASI >0) ranged from 5.6 to 7.8 (OPAL Broaden) and 7.1 to 8.8 (OPAL Beyond). BL mean PGJS–VAS Psoriasis ranged from 5.0 to 5.4 (OPAL Broaden) and 53.5 to 58.9 (OPAL Beyond). At M1 and 3, % ΔPASI total score, PASI75 response rates in pts with mild or moderate/severe dermatologic symptoms at BL, and %ΔPGJS–VAS Psoriasis were improved vs PBO in tofacitinib-treated pts; these improvements were maintained to M12 in OPAL Broaden and M6 in OPAL Beyond (Table). Similar effects were observed in adalimumab-treated pts vs PBO in OPAL Broaden across these endpoints. Serious adverse events (AEs) and discontinuations due to AEs were similar across treatment groups up to M6 in these studies. BL median PASI scores (pts with BL BSA >3% and PASI >0) ranged from 5.6 to 7.8 (OPAL Broaden) and 7.1 to 8.8 (OPAL Beyond).

Conclusion: In pts with PsA (TNFi-naïve or TNFi-IR), tofacitinib improved dermatologic endpoints, and responses were maintained to the end of each study. Tofacitinib may provide a treatment option for pts with active PsA, including the dermatologic symptoms of PsA.

REFERENCES:

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