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POS1025

TOFACITINIB TREATMENT IN PATIENTS WITH PSORIATIC ARTHRITIS AND PROBABLE DEPRESSION AND/OR ANXIETY: A POST HOC ANALYSIS OF TWO PHASE 3 CLINICAL TRIALS

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Background: Depression and anxiety are highly prevalent in patients (pts) with psoriatic arthritis (PsA),¹ with inflammation a key pathogenic feature of depression in these pts.² Tofacitinib is an oral Janus kinase inhibitor for the treatment of PsA. It acts by modulating immune and inflammatory responses. The link between major depressive disorder/generalised anxiety disorder (MDD/GAD), inflammation and tofacitinib effectiveness has not been fully explored.

Objectives: Analyse the prevalence of probable MDD/GAD in pts with PsA initiating tofacitinib treatment and the impact of baseline (BL) probable MDD/GAD status on tofacitinib efficacy in these pts.

Methods: This was a post hoc analysis of data from pts who received tofacitinib 5 or 10 mg twice daily (BID), or placebo (PBO), pooled from two Phase 3 trials (12-month OPAL Broaden [NCT01877668];³ 6-month OPAL Beyond [NCT01882439]).⁴ Pts with BL probable MDD and/or GAD were identified by a Short Form-36 Health Survey (SF-36) Mental Component Summary score (MCS) ≤ 38 . Pt demographics/BL characteristics and outcomes were stratified by the presence (SF-36 MCS ≤ 38) or absence (SF-36 MCS > 38) of BL probable MDD/GAD. At Months (M)3/6/9/12, changes from BL in SF-36 MCS were evaluated, and efficacy assessed by the proportions of pts who achieved: Psoriatic Arthritis Disease Activity Score (PASDAS) ≤ 3.2 , Health Assessment Questionnaire-Disability Index (HAQ-DI) improvement ≥ 0.35 and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) improvement ≥ 4 . BL global pain was measured via visual analogue scale.

Results: Of the 706 pts included in this analysis, BL probable MDD/GAD was identified in 46.2%, 44.9% and 46.2% of pts in the tofacitinib 5 mg BID (108/234), tofacitinib 10 mg BID (106/236) and PBO (109/236) groups, respectively. BL disease activity was similar across the three treatment groups, independent of probable MDD/GAD status (mean PASDAS: 6.1–6.4 in pts with vs 5.8–6.1 in pts without probable MDD/GAD). In the tofacitinib 5 mg BID group, mean BL scores for HAQ-DI (1.4 vs 1.0), FACIT-F total score (20.5 vs 32.4) and global pain (61.3 vs 51.5) indicated worse disability, fatigue and pain, respectively, for pts with vs without BL probable MDD/GAD. Similar findings were seen in the tofacitinib 10 mg BID and PBO groups. At M3, improvements from BL in SF-36 MCS in pts with probable MDD/GAD were numerically, but not significantly, greater with tofacitinib 5 and 10 mg BID vs PBO, and these changes were largely sustained to M12 (Figure 1a). At M3, numerically greater proportions of pts achieved improvements in PASDAS, HAQ-DI and FACIT-F with tofacitinib 5 or 10 mg BID vs PBO, regardless of BL probable MDD/GAD status (Figure 1b–d). Through M3–12, the proportions of pts who achieved PASDAS ≤ 3.2 with tofacitinib 5 or 10 mg BID were generally significantly greater in pts without vs with probable MDD/GAD (Figure 1b). At all timepoints, rates of improvement in HAQ-DI with tofacitinib 5 mg BID were numerically greater in pts with vs without probable MDD/GAD, whereas the opposite was true for tofacitinib 10 mg BID (Figure 1c). FACIT-F improvement rates with tofacitinib 10 mg BID were consistently numerically greater in pts with vs without probable MDD/GAD, while findings were mixed for tofacitinib 5 mg BID (Figure 1d).

Figure. Efficacy measures at M3/6/9/12, (pooled data from OPAL Broaden and Beyond): a) change from BL in SF-36 MCS in pts with BL probable MDD/GAD (SF-36 MCS ≤ 38); b) proportion of pts achieving b) PASDAS ≤ 3.2 ; c) HAQ-DI ≥ 0.35 ; d) FACIT-F ≥ 4 , stratified by presence (SF-36 MCS ≤ 38) or absence (SF-36 MCS > 38) of BL probable MDD/GAD

Missing data were not imputed.
*p<0.05, **p<0.005 for SF-36 MCS ≤ 38 vs > 38 strata.
†Statistical comparisons between tofacitinib and PBO at M3 were via t-test.
‡Statistical comparisons between SF-36 MCS ≤ 38 vs > 38 strata were via chi-squared test.
N, number of evaluable patients; SE, standard error.

Conclusion: Around 46% of pts with PsA treated with tofacitinib had BL probable MDD/GAD (SF-36 MCS ≤ 38). Pts with BL probable MDD/GAD treated with tofacitinib had sustained changes in SF-36 MCS. Rates of clinical improvement with tofacitinib were generally greater in pts without vs with probable MDD/GAD, whereas findings for disability and fatigue improvements varied between tofacitinib doses. Further research is required to evaluate the relationship between PsA and depression, to improve treatment targets and the quality of life of pts with PsA.

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POS1026

GUSELKUMAB PROVIDES SUSTAINED IMPROVEMENTS IN WORK PRODUCTIVITY AND NON-WORK ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS THROUGH 1 YEAR OF A PHASE 3 TRIAL

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