patients were at significantly higher (p<0.001) odds of attaining therapeutic response thresholds compared to DMARD-treated patients, specifically: DAS-28 LDA/remission [OR (95%CI): 4.5 (2.8-7.3)] or remission [OR (95% CI): 4.1 (2.7-6.0)] vs RZB [OR (95% CI): 3.0 (2.0-4.4)]; ACR20 [OR (95% CI): 3.0 (2.0-4.4)]; ACR70 [OR (95% CI): 5.1 (2.0-4.9)]. mMDA [OR (95% CI): 2.4 (1.6-3.6)], and PsO BSA <3% [OR (95% CI): 2.2 (1.2-3.7)].

Overall, 32 (10.7%) of adalimumab-treated patients reported 86 AEs, the most common related to infections [16 events in 10 (3.3%) patients].

Conclusion: Real-world treatment with adalimumab was more effective in improving disease activity and psoriasis severity, over 24 months when compared to nbDMARDs and was associated with significantly greater likelihood of achieving minimal disease activity. Observed AEs were consistent with the established safety profile of adalimumab.

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AB0559

EFFICACY AND SAFETY OF RISANKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AFTER INADEQUATE RESPONSE OR INTOLERANCE TO DMARDS: 24-WEEK RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND KEEPSAKE 1 TRIAL

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Background: Risankizumab (RZB) is a humanized immunoglobulin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding to its p19 subunit. RZB is being investigated as a treatment for adults with psoriatic arthritis (PsA).

Objectives: To compare the efficacy and safety of RZB vs placebo (PBO) for the treatment of active PsA in patients who have had inadequate response or intolerance to ≥ 1 conventional synthetic disease modifying antirheumatic drug (csDMARD-IR).

Methods: In KEEPSAKE 1 (NCT03675308), eligible adults (csDMARD-IR with ≥ 5 swollen joints [SJc] and ≥ 5 tender joints [TJC]) were randomized (1:1) to receive blinded subcutaneous RZB 150 mg or PBO at weeks 0, 4, and 16. The primary endpoint was the proportion of patients achieving 20% improvement in American College of Rheumatology score (ACR20) at week 24. Ranked secondary and other secondary endpoints are shown in the Table 1. Safety was assessed throughout the study. Results reported here are from the 24-week double-blind period; the open-label period with all patients receiving RZB is assessed throughout the study. Results reported here are from the 24-week double-blind period; the open-label period with all patients receiving RZB is assessed throughout the study. Results reported here are from the 24-week double-blind period; the open-label period with all patients receiving RZB is assessed throughout the study. 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EFFECT OF DEUCRAVACITINIB ON THE PSORIATIC ARTHRITIS IMPACT OF DISEASE (PsAID) QUESTIONNAIRES 12 AND 9: ANALYSIS OF A PHASE 2 STUDY OF ACTIVE PSORIATIC ARTHRITIS

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Background: Tyrosine kinase 2 (TYK2) is an intracellular kinase that mediates IL-23, IL-12, and IFN(γ) signaling. Deucravacitinib is a novel, oral selective inhibitor of TYK2 via the TYK2 regulatory domain. Phase 2 results of this study (identiﬁed as “Clinical R&D, Phase 2 deucravacitinib for active psoriatic arthritis”) were presented in the 2021 American College of Rheumatology Annual Meeting. The present analysis was to compare the effects of deucravacitinib vs placebo (PBO) on PsAID-12 and PsAID-9 and related outcomes. Patients: Patients who achieved PRO or clinical response to deucravacitinib in the Phase 2 study were eligible for the Phase 2b study (NCT03881059). Results: Of the 203 patients randomized and baseline characteristics were similar across groups. Adjusted mean changes from BL in PsAID-12 and PsAID-9 scores at Wk 16 were significantly greater in the deucravacitinib groups vs PBO. Spearman correlations were also assessed. Results: 203 pts were randomized and BL characteristics were similar across groups. Adjusted mean changes from BL in PsAID-12 and PsAID-9 scores at Wk 16 were significantly greater in the deucravacitinib groups vs PBO (Figure 1). Adjusted mean changes from BL in PsAID-12 and PsAID-9 scores at Wk 16 were significantly improved with deucravacitinib vs PBO in pts who achieved response for PROs, as well as PASDAS low disease activity and PASI 75 response (Table 1). Adjusted mean changes from BL were generally similar with deucravacitinib vs PBO in nonresponders. Spearman correlation analysis revealed signiﬁcant correlations at BL and Wk 16 between PsAID-12 and PsAID-9 scores and clinical and PRO measures (P<0.0001).

Conclusion: With deucravacitinib vs PBO, PsAID-12 and PsAID-9 scores were signiﬁcantly improved vs BL at Wk 16. PsAID detected additional improvements among pts achieving response for multiple other PROs and select clinical outcome measures.

REFERENCES:

Figure. Adjusted mean change from baseline in PsAID-12 and PsAID-9 total scores at Wk 16

Table 1. Adjusted mean change from BL in PsAID-12 total score at Wk 16 in patients who achieved PRO or clinical response

Response Definition | PBO n=66 | Deucravacitinib Δ value vs PBO n=70 | Deucravacitinib Δ value vs PBO n=67
--- | --- | --- | ---
Patient global VAS | -1.6 (n=40) | -2.8 (n=54) | 0.0008 -2.9 (n=48) 0.003
Patient pain VAS | -2.3 (n=32) | -3.4 (n=44) | 0.004 -3.3 (n=45) 0.004
HAQ-DI (≥ 0.30) | -2.8 (n=10) | -3.8 (n=27) | 0.09 -3.8 (n=27) 0.11
FACIT-Fatigue (≥ 4.0) | -2.4 (n=27) | -3.3 (n=36) | 0.02 -3.6 (n=41) 0.002
SF-36 PCS (≥ 2.5) | -1.7 (n=35) | -2.7 (n=44) | 0.02 -3.1 (n=43) 0.001
SF-36 MCS (≥ 2.5) | -2.1 (n=21) | -3.5 (n=33) | 0.005 -3.8 (n=31) 0.0009
Clinician assessments | | | |
PASI75 (≥ 0.2) | -3.1 (n=6) | -4.2 (n=14) | 0.004 -4.5 (n=15) 0.0006
PASI90 (≥ 0.75) | -2.4 (n=11) | -3.7 (n=25) | 0.05 -3.9 (n=31) 0.02

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**Table 1. Adjusted mean change from BL in PsAID-12 total scores at Wk 16 in patients who achieved PRO or clinical response**