Risankizumab demonstrated durable long-term efficacy in patients with active psoriatic arthritis

Among those patients who achieved a risankizumab treatment response in measures of psoriatic arthritis symptom improvement, disease activity, skin involvement, 24% and/or 52% treatment response were maintained through week 148.

**RESULTS**

- Most patients who achieved clinical responses at weeks 24 or 52 for ACRR20/70, PASI 90, and/or clinically meaningful reduction in pain maintained those responses through weeks 52, 100, and 148–in KEEPsAKE 1 (Figures 2–5) and KEEPsAKE 2 (Table)
- Responses were generally consistent between NRI-MI and AO analyses (Figures 2–5; Table)

**INTRODUCTION**

- Risankizumab (RZB), a humanized immunoglobulin G1 monoclonal antibody, specifically inhibits the p75 subunit of human interleukin-23 (IL-23)
- RZB has shown efficacy compared with placebo (PBO) at week 24 for treating active PsA in the ongoing phase 3 trials, KEEPsAKE 1 (NCT03775588) and KEEPsAKE 2 (NCT03731467)
- To confirm durable maintenance of responses with long-term RZB treatment in patients with PsA, we report results from a post hoc analysis evaluating maintenance of clinical response through 3 years (148 weeks) of RZB treatment using data from KEEPsAKE 1 and KEEPsAKE 2 clinical trials

**METHODS**

**Study Design and Treatment**

- KEEPsAKE 1 and 2 are ongoing phase 3 trials evaluating the efficacy and safety of RZB vs PBO in 2 patient populations
  - KEEPsAKE 1 enrolled adults with active PsA who had a history of inadequate response or intolerance to ≥1 biologic therapy
  - KEEPsAKE 2 enrolled adults with active PsA who had a history of inadequate response or intolerance to ≥1 non-biologic therapy
- Patients included in this analysis received continuous subcutaneous RZB 150 mg from week 0, including double-blind doses at weeks 0, 4, and 16 and open-label RZB 150 mg every 12 weeks thereafter (Figure 1)

**Assessments**

- PASI responses were assessed by achieving an improvement from baseline ≥20%, ≥50%, and ≥70% using the American College of Rheumatology criteria (ACR20, ACR50, and ACR70, respectively)
- The ACR criteria is based on improvements in 5 domains: joint count (JUC), tender joint count (TJC), physician global assessment of disease activity (PGA-D), patient global assessment of disease activity (PGA-D), patient assessment of pain, Health Assessment Questionnaire–Disability Index (HAQ-DI), and high-sensitivity C-reactive protein
- Skin improvement was evaluated as a ≥20% improvement from baseline in Psoriasis Area and Severity Index (PASI 90) in patients who had ≥20% body surface area affected by psoriasis at baseline
- The proportion of patients who achieved Minimal Disease Activity (MDA) was based on meeting ≥5 of the following criteria: JUC ≤1, TJC ≤1, PASI ≤1 and/or body surface area affected by psoriasis ≤10%, patient assessment of pain on visual analog scale (VAS) ≤10 mm, patient global assessment of disease activity on VASI ≤20 mm, HAQ-DI ≤0.3, and/or tender and/or swollen joint counts ≤3
- Clinically meaningful reduction from baseline in pain was also assessed (≥10 mm on a VAS)

**Analyses**

- Analyses populations were based on treatment responders for each endpoint at weeks 24 or 52 and were evaluated as the proportion of:
  - Week 24 responders who maintained responses at week 52, week 100, and week 148
  - Week 52 responders who maintained responses at week 100 and week 148

**Statistical Analysis**

- Analyses included patients who received continuous RZB (those who were originally randomized to and received ≥1 dose of RZB)
- Missing data were handled with responder imputation incorporating multiple imputation (NRI-MI) for data missing due to COVID-19 (KEEPsAKE 1 and KEEPsAKE 2 clinical trials only)
- As observed (AO) results are also reported

**RESULTS**

- Most patients who achieved clinical responses at weeks 24 or 52 for ACRR20/70, PASI 90, and/or clinically meaningful reduction in pain maintained those responses through weeks 52, 100, and 148–in KEEPsAKE 1 (Figures 2–5) and KEEPsAKE 2 (Table)
- Responses were generally consistent between NRI-MI and AO analyses (Figures 2–5; Table)