Maintenance of Response to Risankizumab in Patients With Psoriatic Arthritis: A 5-Year Analysis of the KEEPsAKE 1 and 2 Trials

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OBJECTIVE

To assess the maintenance of response to risankizumab in patients with active psoriatic arthritis from week 24 through week 244 in the KEEPsAKE 1 and KEEPsAKE 2 trials

CONCLUSIONS

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

Among risankizumab-treated psoriatic arthritis patients who acheived a treatment response in measures of peripheral arthritis, disease activity, skin involvement, pain, and/or axial symptoms at week 24, treatment responses were maintained through week 244

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INTRODUCTION

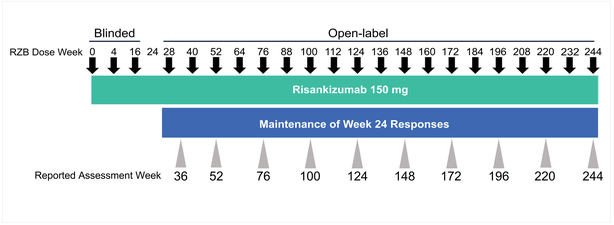
- Risankizumab (RZB) is a humanized immunoglobulin G1 monoclonal antibody that inhibits interleukin-23 (IL-23) by targeting its p19 subunit
  - IL-23 inhibition may result in longer treatment durability as IL-23 promotes the expansion and maintenance of Th17 cells, a key driver of inflammatory autoimmune diseases[1]
- RZB has demonstrated efficacy and safety at weeks 24[2,3] and 196[4,5] for treating active psoriatic arthritis (PsA) in the ongoing, global, multicenter KEEPsAKE 1 (NCT03675308) and KEEPsAKE 2 (NCT03671148) phase 3 trials
  - Among patients who achieved clinical responses at week 24, responses to RZB were maintained through week 196[6]
- To examine 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 ~5 years (244 weeks) of RZB treatment using data from the 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 placebo in 2 patient populations
  - KEEPsAKE 1 enrolled adults with active PsA who had a history of inadequate response or intolerance to ≥ 1 conventional synthetic DMARD (csDMARD)
  - KEEPsAKE 2 enrolled adults with active PsA who had a history of inadequate response or intolerance to 1 or 2 biologic therapies (bDMARDs) and/or ≥ 1 csDMARDs
- Patients included in this analysis received subcutaneous RZB 150 mg from week 0, including double-blind doses at weeks 0, 4, 16, and 24. At week 28, all patients received open-label RZB 150 mg and every 12 weeks thereafter **(Figure 1)**

Figure 1. Treatment and Assessment Schedule in KEEPsAKE 1 and KEEPsAKE 2 for Patients Receiving Continuous Risankizumab



RZB, risankizumab.

Assessments

- PsA symptoms were assessed by achieving an improvement from baseline ≥ 20%, ≥ 50%, and ≥ 70% using the American College of Rheumatology criteria (ACR20, ACR50, and ACR70, respectively)
  - ACR criteria are based on ≥ 20%, ≥ 50%, and ≥ 70% improvement in TJC, SJC, and ≥ 3 of the following parameters: Physician global assessment of disease activity, patient global assessment of disease activity, patient assessment of pain, Health Assessment Questionnaire–Disability Index (HAQ-DI), and high-sensitivity C-reactive protein
- Skin improvement was evaluated as a ≥ 90% improvement from baseline in Psoriasis Area and Severity Index (PASI90) in patients who had ≥ 3% 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: TJC ≤ 1, SJC ≤ 1, PASI ≤ 1, or body surface area affected by psoriasis ≤ 3%, patient assessment of pain on visual analog scale (VAS) ≤ 15 mm, patient global assessment of disease activity on VAS ≤ 20 mm, HAQ-DI ≤ 0.5, and/or tender entheseal points ≤ 1
- Two patient pain endpoints were assessed via:
  - Clinically meaningful reduction in pain (≥ 10 mm decrease) in patients with VAS > 10 mm at baseline
  - Proportion of patients with VAS > 15 mm at baseline who achieved the MDA patient pain criteria (≤ 15 mm)
- Axial improvement was evaluated as clinically meaningful reduction in modified Bath Ankylosing Spondylitis Disease Activity Index (mBASDAI; ≥ 1.1 decrease) in patients with > 1.1 at baseline; mBASDAI assesses the following 4 criteria: Patient fatigue; neck, back, and hip pain; areas tender to touch or pressure; severity of morning stiffness; duration of morning stiffness

Analyses

- Analysis populations (N) comprise week 24 treatment responders (defined by as observed [AO] analysis) for each endpoint
- Proportions of responders (n/N) are reported for each time point through week 244

Statistical Analysis

- Nonresponder imputation incorporating multiple imputation (NRI-MI) is used with data missing due to COVID-19 or geopolitical conflict; all other missing data are imputed as nonresponders
- AO data are also reported

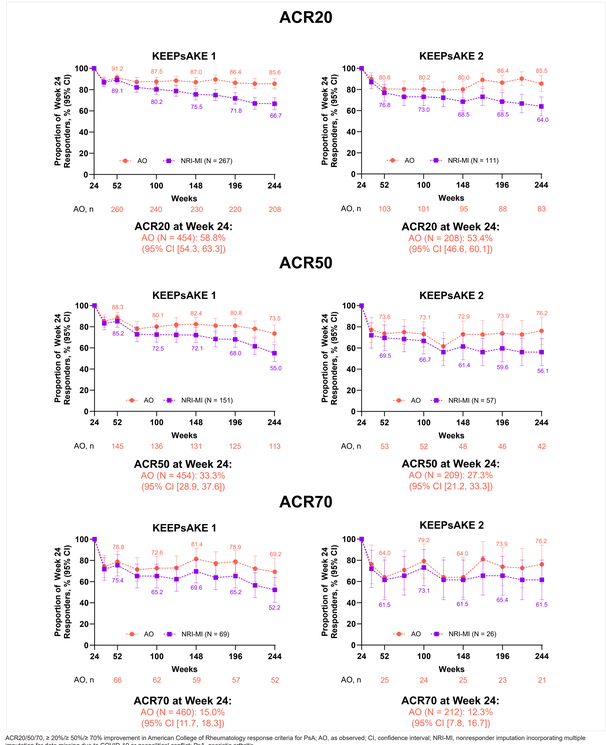
RESULTS

- Of the patients enrolled in the KEEPsAKE 1 (N = 483) and KEEPsAKE 2 (N = 224) studies:
  - 2.1% (n = 10) of patients in KEEPsAKE 1 and 4.0% (n = 9) of patients in KEEPsAKE 2 discontinued the study by week 24
  - 25.1% (n = 121) of patients in KEEPsAKE 1 and 32.1% (n = 72) of patients in KEEPsAKE 2 discontinued the study by week 244

By Week 244:

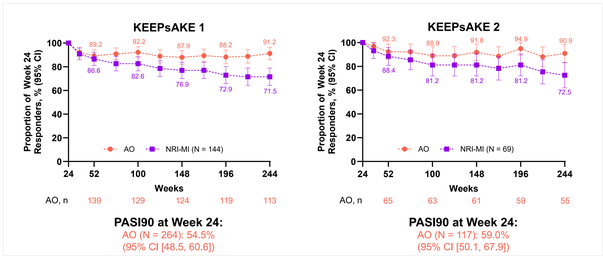
- Most patients enrolled in KEEPsAKE 1 and 2 who achieved ACR20, ACR50, ACR70, PASI90, and MDA at week 24 also maintained these responses at week 244 (**Figures 2-4**)
- Week 24 responders also maintained clinically meaningful reductions in pain, with nearly half maintaining the MDA patient pain criteria (**Figures 5-6**), and mostly maintained clinically meaningful reductions in axial symptoms (**Figure 7**)

Figure 2. Long-Term Maintenance of ACR Responses Among Those Who Achieved Week 24 Response



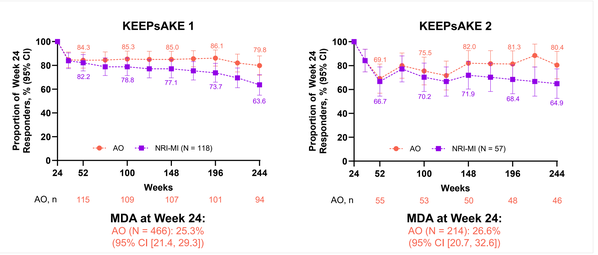
ACR20/50/70, ≥ 20%/≥ 50%/≥ 70% improvement in American College of Rheumatology response criteria for PsA; AO, as observed; CI, confidence interval; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict; PsA, psoriatic arthritis.

Figure 3. Long-Term Maintenance of PASI90 Responses Among Those Who Achieved Week 24 Response



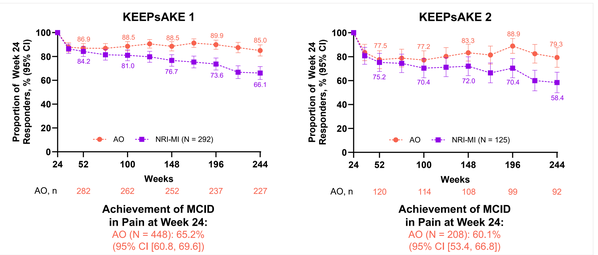
AO, as observed; CI, confidence interval; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict; PASI90, ≥ 90% improvement from baseline in Psoriasis Area and Severity Index (in patients who had ≥ 3% body surface area affected by psoriasis at baseline.

Figure 4. Long-Term Maintenance of MDA Responses Among Those Who Achieved Week 24 Response



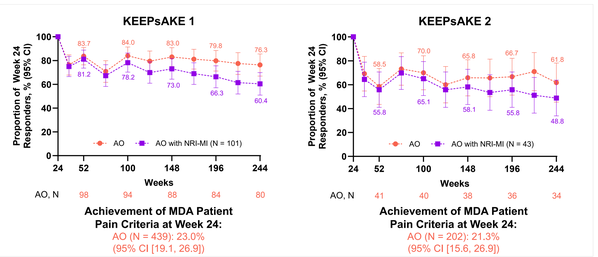
AO, as observed; CI, confidence interval; MDA, minimal disease activity; NRI-MI, nonresponder imputation incorporating multiple imputation for missing data due to COVID-19 or geopolitical conflict.

Figure 5. Long-Term Maintenance of Clinically Meaningful Reduction in Pain (VAS ≥ 10 mm Decrease) Among Those Who Achieved Week 24 Response



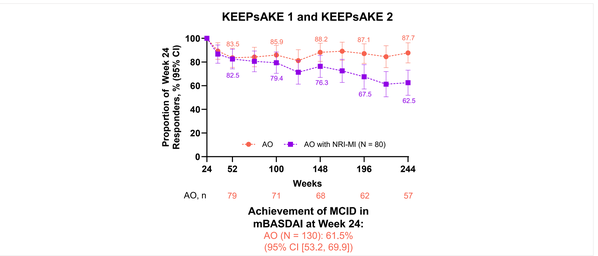
AO, as observed; CI, confidence interval; MCID, minimal clinically important difference; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict.

Figure 6. Long-Term Maintenance of MDA Patient Pain Criteria (VAS ≤ 15 mm) Among Those Who Achieved Week 24 Response



AO, as observed; CI, confidence interval; MDA, minimal disease activity; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict.

Figure 7. Long-Term Maintenance of Clinically Meaningful Reduction in mBASDAI (> 1.1 Decrease) Among Those Who Achieved Week 24 Response



AO, as observed; mBASDAI, modified Bath Ankylosing Spondylitis Disease Activity Index; CI, confidence interval; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict.