Maintenance of Response to Risankizumab in Patients With Psoriatic Arthritis: A 3-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 weeks 24 and 52 through week 148 in the KEEPsAKE 1 and KEEPsAKE 2 trials

CONCLUSIONS

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, or clinically meaningful reduction in pain at weeks 24 and/or 52, treatment responses were maintained through week 148

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References

1. Kristensen LE, et al. *Ann Rheum Dis.* 2021;80:1315–6.
2. Östör A, et al. *Ann Rheum Dis.* 2021;80:138–9.

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INTRODUCTION

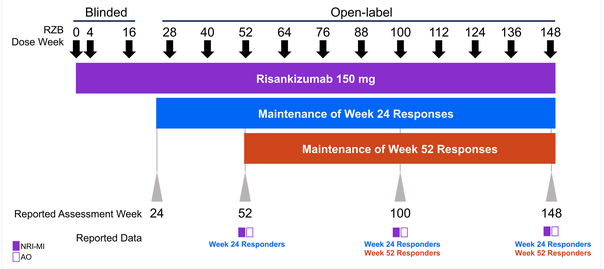
- Risankizumab (RZB), a humanized immunoglobulin G1 monoclonal antibody, specifically inhibits the p19 subunit of human interleukin 23
- RZB has shown efficacy compared with placebo (PBO) at week 24 for treating active PsA in the ongoing phase 3 trials, KEEPsAKE 1 (NCT03675308) and KEEPsAKE 2 (NCT03671148)[1,2]
- 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 conventional synthetic disease-modifying antirheumatic drug (csDMARD)
  - KEEPsAKE 2 enrolled adults with active PsA who had a history of inadequate response or intolerance to 1 or 2 biologic therapies and/or ≥1 csDMARDs 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)**

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



AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; 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). The ACR criteria is based on improvements in swollen joint count (SJC) and tender joint count (TJC), 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 (PASI 90) 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
- Clinically meaningful reduction from baseline in pain was also assessed (≥10 mm on a VAS)

Analyses

- Analysis 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

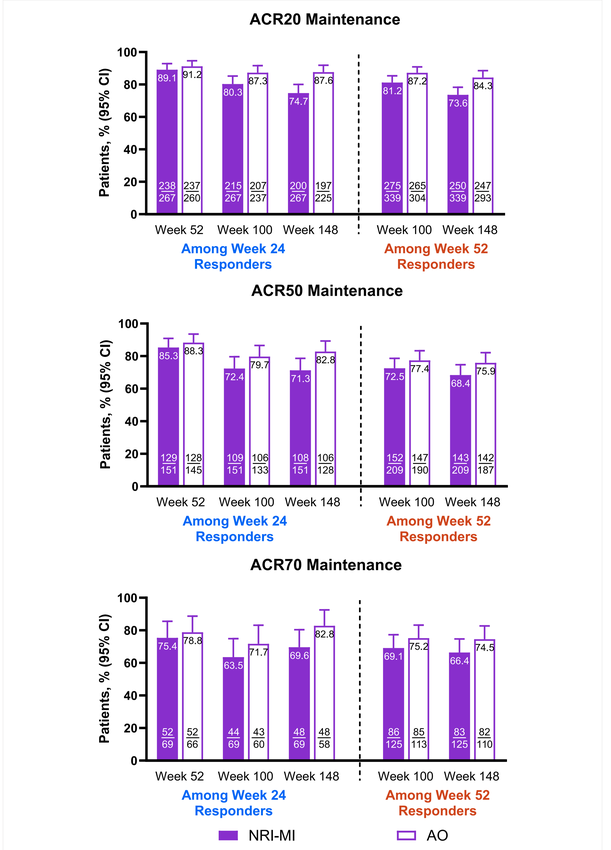
Statistical Analysis

- Analysis included patients who received continuous RZB (those who were originally randomized to and received ≥1 dose of RZB)
- Missing data were handled with nonresponder imputation incorporating multiple imputation (NRI-MI) for data missing due to COVID-19 (KEEPsAKE 1 and KEEPsAKE 2) or geopolitical conflict in Ukraine and Russia (KEEPsAKE 1 only)
- As observed (AO) results are also reported

RESULTS

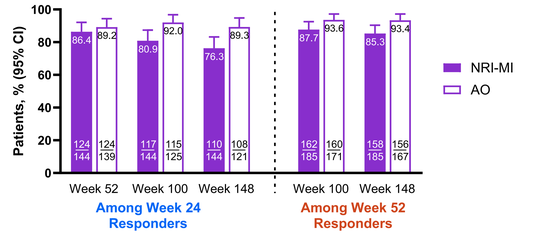
- Most patients who achieved clinical response at weeks 24 or 52 for ACR20/50/70, PASI 90, MDA, and clinically meaningful reduction in pain maintained those responses through weeks 52, 100, and 148 in KEEPsAKE 1 **(Figures 2–5)** and KEEPsAKE 2 **(Table)**
- Responses were generally consistent between NRI-MI and AO analyses **(Figures 2–5; Table)**

Figure 2. Maintenance of ACR Responses in KEEPsAKE 1



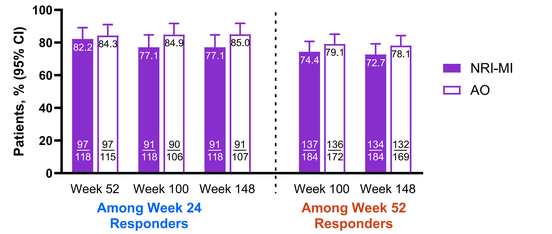
ACR20/50/70, ≥20%/≥50%/≥70% improvement in American College of Rheumatology response criteria for PsA; AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; PsA, psoriatic arthritis. Numbers in bars represent proportion of patients maintaining a week 24 or 52 response (top) and n/N (bottom).

Figure 3. Maintenance of PASI 90 Responses in KEEPsAKE 1



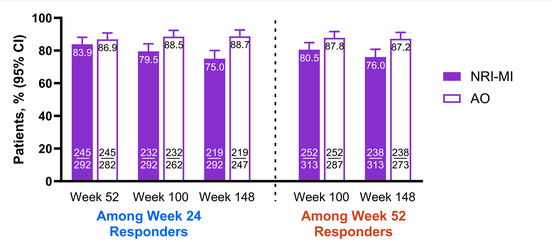
AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; PASI 90, ≥90% improvement from baseline in Psoriasis Area and Severity Index (in patients who had had ≥3% body surface area affected by psoriasis at baseline). Numbers in bars represent proportion of patients maintaining a week 24 or 52 response (top) and n/N (bottom).

Figure 4. Maintenance of MDA Responses in KEEPsAKE 1



AO, as observed; MDA, minimal disease activity; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia. Numbers in bars represent proportion of patients maintaining a week 24 or 52 response (top) and n/N (bottom).

Figure 5. Maintenance of Clinically Meaningful Reductions in Pain VAS in KEEPsAKE 1



AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; VAS, visual analog scale. Numbers in bars represent proportion of patients maintaining a week 24 or 52 response (top) and n/N (bottom).

Table. Maintenance of Clinical Responses in KEEPsAKE 2

		Among Week 24 Responders						Among Week 52 Responders			
		Week 52		Week 100		Week 148		Week 100		Week 148	
Response		NRI-MI	AO	NRI-MI	AO	NRI-MI	AO	NRI-MI	AO	NRI-MI	AO
ACR20	%	77.2	80.6	73.0	80.2	68.5	80.0	74.8	78.4	69.5	79.8
	n/N	86/111	83/103	81/111	81/101	76/111	76/95	98/131	98/125	91/131	91/114
ACR50	%	69.8	73.6	66.7	73.1	61.4	72.9	72.2	75.4	69.4	76.9
	n/N	40/57	39/53	38/57	38/52	35/57	35/48	52/72	52/69	50/72	50/65
ACR70	%	61.5	64.0	73.1	79.2	61.5	64.0	81.1	83.3	75.7	77.8
	n/N	16/26	16/25	19/26	19/24	16/26	16/25	30/37	30/36	28/37	28/36
PASI 90	%	88.4	92.3	81.2	88.9	81.2	91.8	84.8	88.2	82.3	91.5
	n/N	61/69	60/65	56/69	56/63	56/69	56/61	67/79	67/76	65/79	65/71
MDA	%	66.7	69.1	70.2	75.5	71.9	82.0	83.6	85.0	75.4	82.1
	n/N	38/57	38/55	40/57	40/53	41/57	41/50	51/61	51/60	46/61	46/56
Clinically meaningful reduction in pain VAS	%	74.4	77.5	70.4	77.2	72.0	83.3	77.7	81.7	76.0	84.4
	n/N	93/125	93/120	88/125	88/114	90/125	90/108	94/121	94/115	92/121	92/109

ACR20/50/70, ≥20%/≥50%/≥70% improvement in American College of Rheumatology response criteria; AO, as observed; MDA, minimal disease activity; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19; PASI 90, ≥90% improvement from baseline in Psoriasis Area and Severity Index (in patients who had had ≥3% body surface area affected by psoriasis at baseline); VAS, visual analog scale.