Maintenance of Response to Risankizumab in Patients With Psoriatic Arthritis: A 4-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 196 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 or 52, treatment responses were maintained through week 196

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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

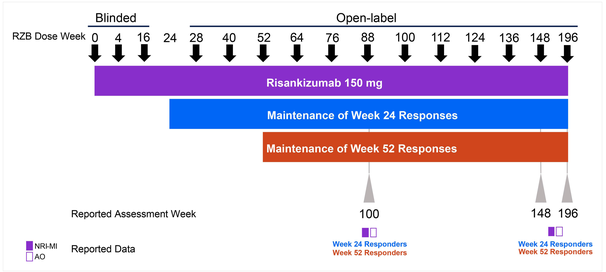
- Risankizumab, a humanized immunoglobulin G1 monoclonal antibody, specifically inhibits the p19 subunit of human interleukin 23
- Risankizumab has shown efficacy compared with placebo at week 24 for treating active PsA in the ongoing phase 3 trials, KEEPsAKE 1 (NCT03675308) and KEEPsAKE 2 (NCT03671148)[1,2]
- To confirm durable maintenance of responses with long-term risankizumab treatment in patients with PsA, we report results from a post hoc analysis evaluating maintenance of clinical response through ~4 years (196 weeks) of risankizumab 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 risankizumab 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 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 risankizumab 150 mg from week 0, including double-blind doses at weeks 0, 4, 16, and 24. At week 28, all patients received open-label risankizumab 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



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 ≥20%, ≥50%, and ≥70% improvement 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 100, week 148, and week 196
  - Week 52 responders who maintained responses at week 100, week 148, and week 196

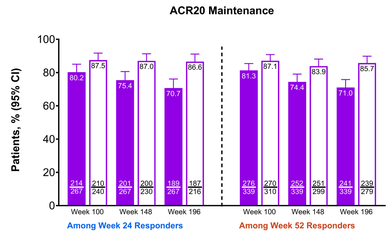
Statistical Analysis

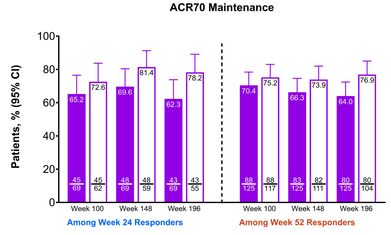
- Analysis included patients who received continuous risankizumab (those who were originally randomized to and received ≥1 dose of risankizumab)
- Missing data were handled with nonresponder imputation incorporating multiple imputation (NRI-MI) for data missing due to COVID-19 (KEEPsAKE 1 and KEEPsAKE 2) or geopolitical conflict in Ukraine and Russia (KEEPsAKE 1 only)
- A mixed-effect model for repeated measures was used to analyze continuous endpoints
- 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 100, 148, and 196 in KEEPsAKE 1 **(Figures 2–5)** and KEEPsAKE 2 **(Table)**

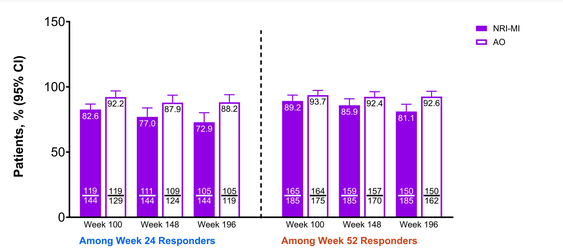
Figure 2. Maintenance of ACR Responses in KEEPsAKE 1





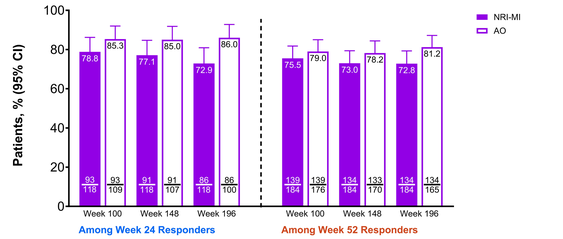
ACR20/50/70, ≥20%/≥50%/≥70% improvement in American College of Rheumatology response criteria for PsA; AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; PsA, psoriatic arthritis. Numbers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



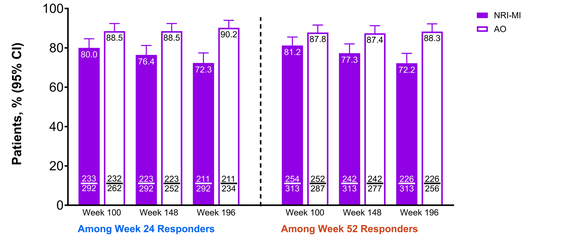
AO, as observed; NRI-MI, nonresponder imputation incorporating multiple imputation for data missing due to COVID-19 or geopolitical conflict in Ukraine and Russia; PASI 90, ≥90% improvement from baseline in Psoriasis Area and Severity Index (in patients who had had ≥3% body surface area affected by psoriasis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

Response		Among Week 24 Responders						Among Week 52 Responders					
		Week 100		Week 148		Week 196		Week 100		Week 148		Week 196	
		NRI-MI	AO	NRI-MI	AO	NRI-MI	AO	NRI-MI	AO	NRI-MI	AO	NRI-MI	AO
ACR20	%	73.0	80.2	68.5	80.0	68.5	86.4	74.8	78.4	69.5	79.8	68.7	83.3
	n/N	81/111	81/101	76/111	76/95	76/111	76/88	98/131	98/125	91/131	91/114	90/131	90/108
ACR50	%	66.7	73.1	61.4	72.9	59.6	73.9	72.2	75.4	69.4	76.9	63.9	76.7
	n/N	38/57	38/52	35/57	35/48	34/57	34/46	52/72	52/69	50/72	50/65	46/72	46/60
ACR70	%	73.1	79.2	61.5	64.0	65.4	73.9	81.1	83.3	75.7	77.8	70.3	74.3
	n/N	19/26	19/24	16/26	16/25	17/26	17/23	30/37	30/36	28/37	28/36	26/37	26/35
PASI 90	%	81.2	88.9	81.2	91.8	81.2	94.9	84.8	88.2	82.3	91.5	84.8	97.1
	n/N	56/69	56/63	56/69	56/61	56/69	56/59	67/79	67/76	65/79	65/71	67/79	67/69
MDA	%	70.2	75.5	71.9	82.0	68.4	81.3	83.6	85.0	75.4	82.1	77.0	85.5
	n/N	40/57	40/53	41/57	41/50	39/57	39/48	51/61	51/60	46/61	46/56	47/61	47/55
Clinically meaningful reduction in pain VAS	%	70.4	77.2	72.0	83.3	70.4	88.9	77.7	81.7	76.0	84.4	75.2	90.1
	n/N	88/125	88/114	90/125	90/108	88/125	88/99	94/121	94/115	92/121	92/109	91/121	91/101

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.