Patient Phenotypes Within the Risankizumab PsA Clinical Program

MEDICAL AFFAIRS + HEALTH IMPACT

INDICATIONS[1]

Risankizumab-rzaa is indicated for the treatment of active psoriatic arthritis in adults.

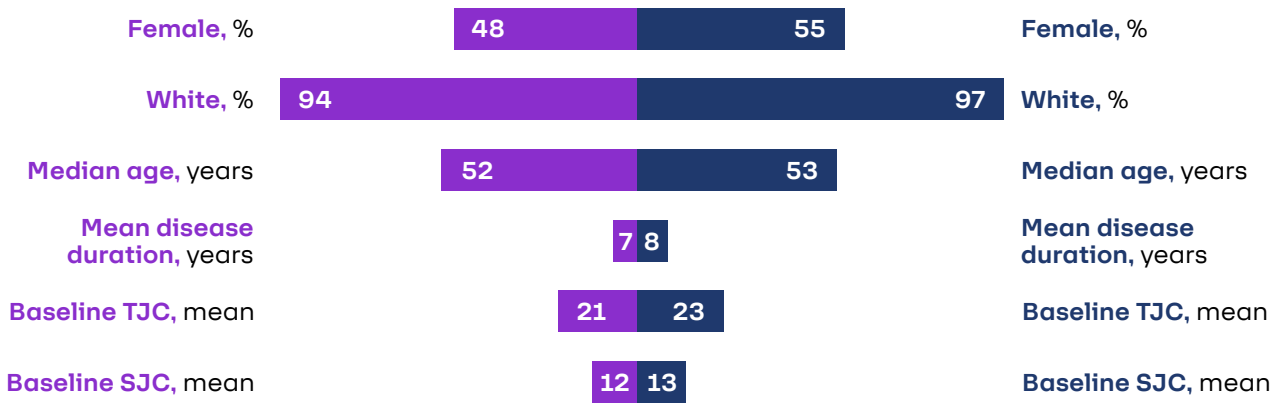
Risankizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

KEEPsAKE 1 and **2** are Phase 3, multicenter, randomized, double-blind, placebo-controlled studies designed to evaluate the safety and efficacy of risankizumab (RZB) in adult patients with active psoriatic arthritis (PsA).

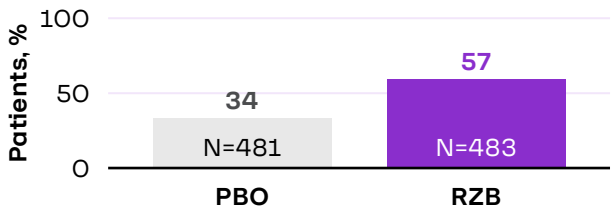
KEEPsAKE 1 Overview[2,a]

Bio-naïve
csDMARD-IR

Mixed Population
53% csDMARD-IR | 47% bDMARD-IR



Primary Endpoint
ACR20 at Week 24 (NRI)



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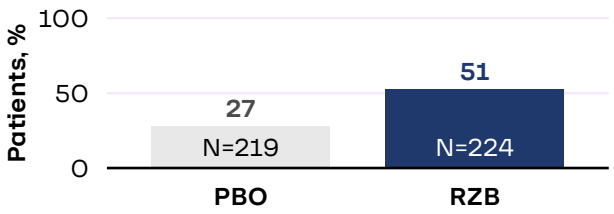

KEEPsAKE 2 Overview[3,a]

Identification and post hoc analysis of patient phenotypes in the KEEPsAKE program[4]

Input

Baseline characteristics of 1,119 **bio-naïve** patients in KEEPsAKE 1 and 2

Phenotype identification

Unsupervised analysis finds 5 distinct phenotypes based on PsA manifestations

Post hoc analysis

Efficacy of risankizumab evaluated in each phenotypic cluster

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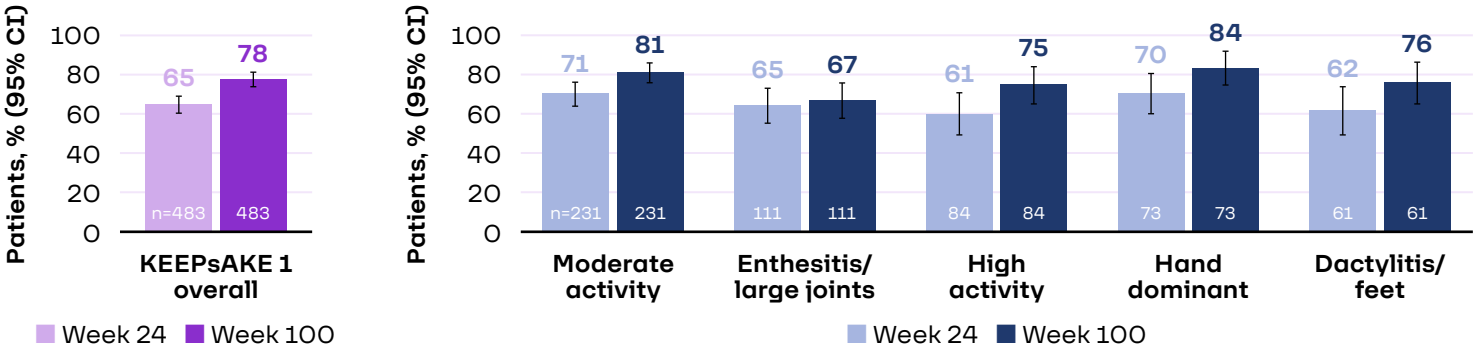
See Important Safety Considerations on Page 4

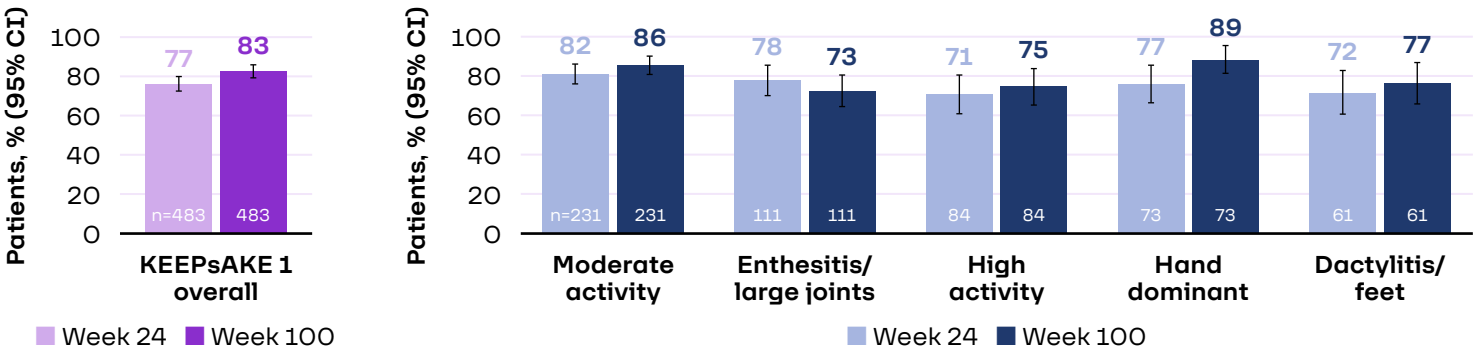
Scan for more information on the KEEPsAKE Program and composite measures for PsA.

Efficacy of RZB in KEEPsAKE 1 overall and 5 phenotypes from bio-naïve patients in the KEEPsAKE program

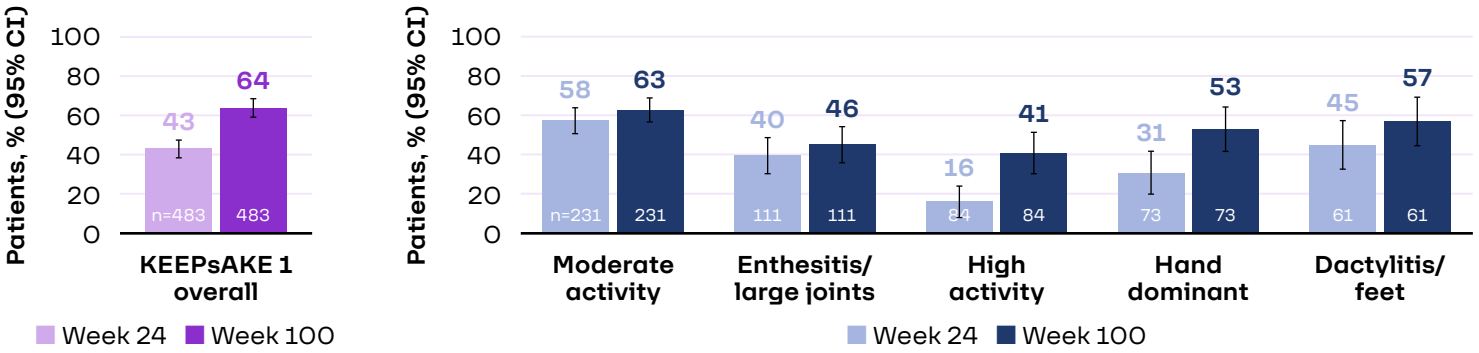
≥50% TJC improvement through Week 100 (NRI-MI)[4,5]



≥50% SJC improvement through Week 100 (NRI-MI)[4,5]



DAPSA LDA through Week 100 (NRI-MI)[4,5]



Information

Patient phenotype data is generated from a post hoc analysis and no comparisons can be made between the patient phenotype data and KEEPsAKE 1

OLE Limitation: There is a potential for enrichment of the long-term data in the remaining patient populations since patients who are unable to tolerate or do not respond to the drug often drop out

DAPSA[6]

Assesses

- TJC/SJC
- PtGA
- Pain
- Acute phase reactants

Disease thresholds

- >28, high
- ≤28 to >14, moderate
- ≤14 to >4, LDA
- ≤4, remission

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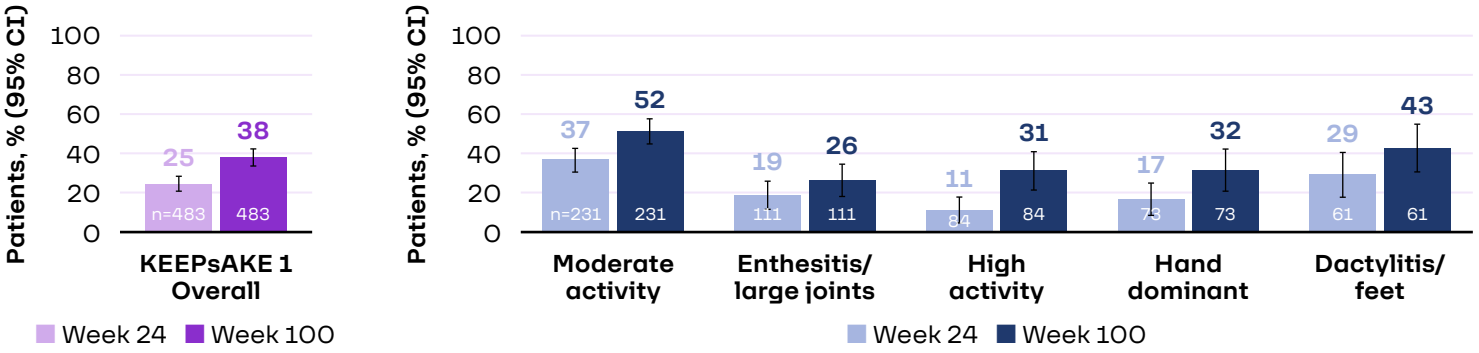
Efficacy of RZB in KEEPsAKE 1 overall and 5 phenotypes from bio-naïve patients in the KEEPsAKE program

MDA through Week 100 (NRI-MI)[2,4,7]



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MDA[6] (≥5 criteria acheived)

- TJC ≤1
- SJC ≤1
- Pain VAS ≤15 mm
- PtGA of disease activity VAS ≤20 mm
- PASI ≤1 or BSA-PsO ≤3%
- HAQ-DI ≤0.5
- Tender entheseal points ≤1

Safety of RZB

PsA

TEAEs of interest through Week 24 in KEEPsAKE 1 and 2[2,3,8–12]

TEAEs, Events (E/100 PY)	KEEPsAKE 1 PBO N=481, PY=223.5	KEEPsAKE 1 RZB N=483, PY=224.3	KEEPsAKE 2 PBO N=219, PY=101.3	KEEPsAKE 2 RZB N=224 PY=104.3
Any TEAE	387 (173.2)	398 (177.6)	292 (288.3)	286 (274.2)
Any hepatic event	32 (14.3)	43 (19.2)	9 (8.9)	11 (10.5)
Serious AE	22 (9.8)	15 (6.7)	15 (14.8)	14 (13.4)
Any hypersensitivity	3 (1.3)	12 (5.4)	8 (7.9)	6 (5.8)
Serious infections	8 (3.6)	6 (2.7)	5 (4.9)	3 (2.9)
Injection site reactions	0	4 (1.8)	1 (1.0)	4 (3.8)
HZ	1 (0.4)	2 (0.9)	1 (1.0)	0
COVID-19–related TEAEs	2 (0.9)	1 (0.4)	0	1 (1.0)
Malignant tumors	2 (0.9)	0	3 (3.0)	1 (1.0)
Malignant tumors, excluding NMSC	2 (0.9)	0	0	0
Death	0	1 (0.4)[b]	0	0
Active TB	0	0	0	0
MACE	0	0	0	1 (1.0)
Opportunistic infection excluding TB and HZ	0	0	0	0

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Safety of RZB

PsA Adverse drug reactions occurring in ≥2% of patients in KEEPsAKE 1 and 2 through Week 24[2,3,11]

	KEEPsAKE 1		KEEPsAKE 2	
AE, n (%)	PBO (N=481)	RZB (N=483)	PBO (N=219)	RZB (N=224)
Nasopharyngitis	14 (2.9)	16 (3.3)	8 (3.7)	9 (4.0)
Upper respiratory tract infection	20 (4.2)	12 (2.5)	12 (5.5)	17 (7.6)
Hypertension	-	-	6 (2.7)	10 (4.5)
Increased ALT	10 (2.1)	13 (2.7)	-	-
Increased AST	7 (1.5)	10 (2.1)	-	-
Headache	8 (1.7)	10 (2.1)	8 (3.7)	5 (2.2)
Any hypersensitivity	3 (0.6)	10 (2.1)	7 (3.2)	6 (2.7)
Arthralgia	-	-	7 (3.2)	7 (3.1)
Nausea	-	-	9 (4.1)	6 (2.7)
Psoriatic arthropathy	-	-	9 (4.1)	6 (2.7)
Bronchitis	-	-	4 (1.8)	5 (2.2)
Diarrhea	-		5 (2.3)	5 (2.2)

PsO Adverse drug reactions occurring in ≥1% of patients treated with RZB in pooled PsO trials though Week 16[1,13,14]

AE, n (%)	PBO (N=300)	RZB (N=1,306)
Any infection	44 (14.7)	288 (22.1)
Upper respiratory tract infection[c]	29 (9.7)	170 (13.0)
Headache[d]	6 (2.0)	46 (3.5)
Fatigued[e]	3 (1.0)	33 (2.5)
Injection site reactions[f]	3 (1.0)	19 (1.5)
Tinea infections[g]	1 (0.3)	15 (1.1)

The overall safety profile observed in subjects with PsA treated with risankizumab is generally consistent with the safety profile in subjects with plaque PsO with the addition of hepatic events and hypersensitivity reactions

IMPORTANT SAFETY CONSIDERATIONS

Risankizumab is contraindicated in patients with a history of **serious hypersensitivity reaction** to risankizumab or any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, may occur. If a serious hypersensitivity reaction occurs, discontinue risankizumab and initiate appropriate therapy immediately. Risankizumab may increase the risk of **infections**. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, discontinue risankizumab until the infection resolves. Evaluate patients for **tuberculosis** infection prior to initiating treatment with risankizumab. Avoid use of **live vaccines** in patients treated with risankizumab. The **most common adverse reactions (≥1%)** are upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

Review accompanying risankizumab-rzaa full Prescribing Information for additional information, visit www.rxabbvie.com or contact AbbVie Medical Information at 1-800-633-9110

[a]At Week 16, subjects classified as nonresponders (defined as not achieving at least a 20% improvement in either or both TJC and SJC at both Week 12 and Week 16 compared with baseline) had the option to add or modify rescue concomitant medications/therapy; [b]1 subject, 81 years of age with dementia, hospitalized for pneumonia, developed urosepsis and complications resulting in death; [c]Includes: respiratory tract infection (viral, bacterial, or unspecified), sinusitis (including acute), rhinitis, nasopharyngitis, pharyngitis (including viral), tonsillitis; [d]Includes: headache, tension headache, sinus headache, cervicogenic headache; [e]Includes: fatigue, asthenia; [f]Includes: injection site bruising, erythema, extravasation, hematoma, hemorrhage, infection, inflammation, irritation, pain, pruritus, reaction, swelling, warmth; [g]Includes: tinea pedis, tinea cruris, body tinea, tinea versicolor, tinea manuum, tinea infection, onychomycosis.

Abbreviations: ACR20, improvement of ≥20% in American College of Rheumatology core criteria; AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; bDMARD-IR, biologic disease-modifying antirheumatic drug inadequate response; BSA, body surface area; CI, confidence interval; COVID-19, coronavirus disease 2019; csDMARD-IR, conventional synthetic disease-modifying antirheumatic drug inadequate response; DAPSA, Disease Activity in Psoriatic Arthritis; E, event; HAQ-DI; Health Assessment Questionnaire Disability Index; HZ, herpes zoster; LDA, low disease activity; MACE, major adverse cardiovascular event; MDA, minimal disease activity; MI, multiple imputations; NMSC, nonmelanoma skin cancer; NRI, nonresponder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; PtGA, patient global assessment; PY, patient-year; RZB, risankizumab; SJC, swollen joint count; TB, tuberculosis; TEAE, treatment-emergent adverse event; TJC, tender joint count; VAS, visual analog scale.

References: 1. SKYRIZI (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc; **2.** Kristensen LE et al. *Ann Rheum Dis*. 2022;81(2):225-231; **3.** Östör A et al. *Ann Rheum Dis*. 2022;81(3):351-358; **4.** Gossec L et al. ACR Convergence 2024. Abstract 2355; **5.** Data on File, AbbVie Inc. ABVRRTI80794; **6.** Mease PJ et al. *Semin Arthritis Rheum*. 2018;47(6):786-796. **7.** Kristensen LE et al. *Rheumatol Ther*. 2024;11(3):617-632; **8.** Kristensen LE et al. ACR Convergence 2022. Abstract 2145; **9.** Data on file, AbbVie Inc. ABVRRTI73417; **10.** Kristensen LE et al. Poster presented at: Fall Clinical Dermatology Conference; October 21–24, 2021; Las Vegas, NV; **11.** AbbVie Data on File, ABVRRTI74973; **12.** Östör A, et al. Poster presented at: Fall Clinical Dermatology Conference; October 21-24, 2021; Las Vegas, NV. **13.** Strober B et al. AAD 2019. Abstract P9876; **14.** Data on file, AbbVie Inc. ABVRRTI68139.

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