Composite Measures to Inform Treatment Choices in Bio-naïve Patients with PsA

US Medical Affairs Rheumatology

INDICATIONS

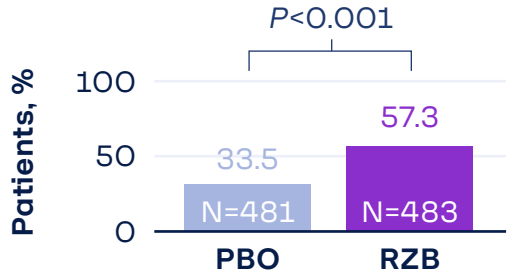
Risankizumab-rzaa is indicated for the treatment of active psoriatic arthritis in adults.[1]

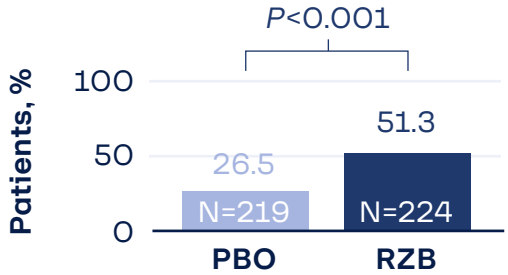
Risankizumab-rzaa is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1]

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]		KEEPsAKE 2 Overview[3]
Bio-naïve Patients csDMARD-IR		**Mixed Patient Population** 53% csDMARD-IR; 47% bDMARD-IR
Female, %	48	55 Female, %
White, %	94	97 White, %
Median Age, years	52	53 Median Age, years
Mean Disease Duration, years	7	8 Mean Disease Duration, years

Primary Endpoint ACR20 at W24 (NRI)	Primary Endpoint ACR20 at W24 (NRI)





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Composite Measures in KEEPsAKE 1

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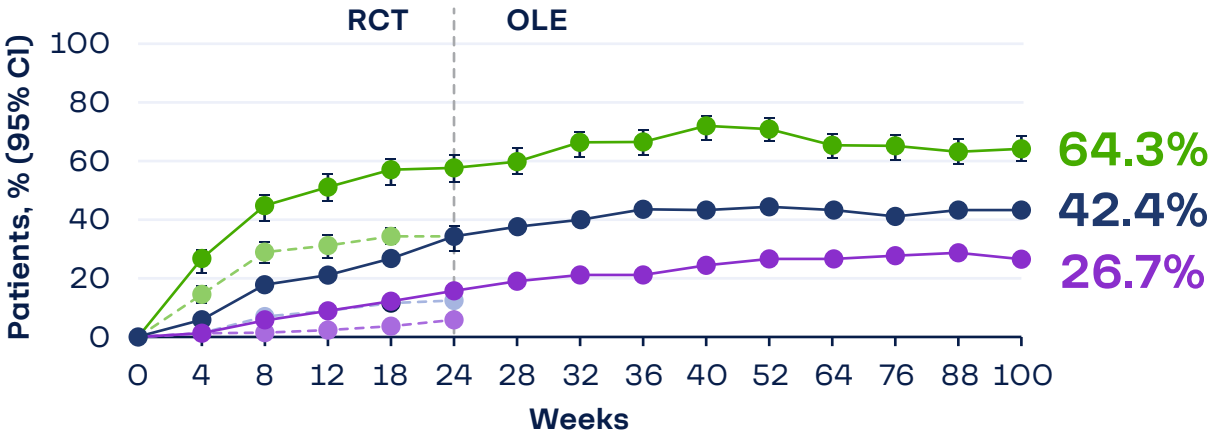
Outcomes for ACR20/50/70 through Wk 100 (NRI)[2,4]



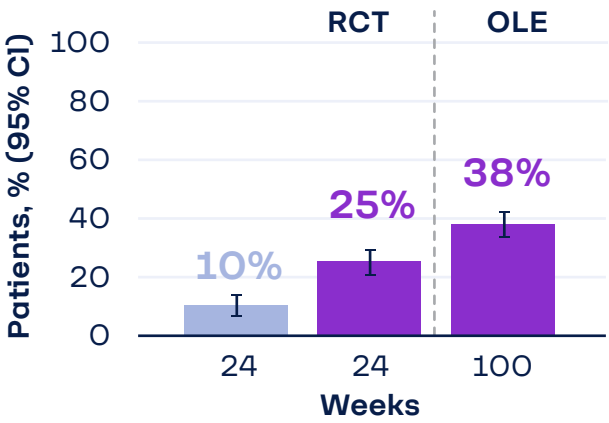
PBO (N=481) RZB (N=483)
ACR20
ACR50
ACR70

ACR

Assesses[5]:

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

RZB outcomes for MDA at Wk 24 and 100 (NRI)[2,4]



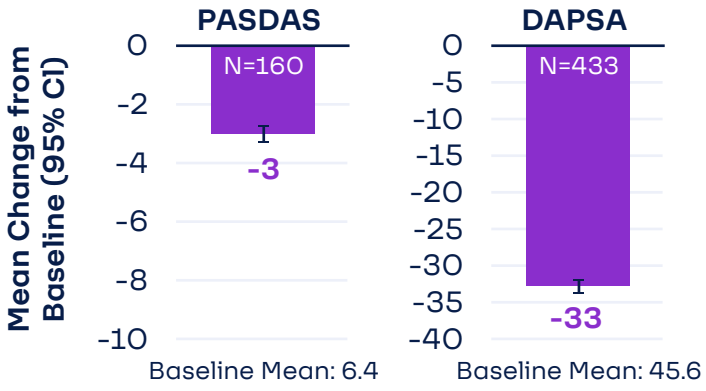
RZB
N=483
PBO
N=481

MDA

≥5 of the following criteria acheived[6]:

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

RZB outcomes for PASDAS and DAPSA at Wk 52 (AO)[7]



Prespecified, but not controlled for multiple comparisons

PASDAS

Assesses[6]:

- Function
- Enthesitis
- Dactylitis
- Acute phase reactants
- TJC/SJC
- PGA
- PtGA

Disease activity cut-offs:
≥5.4, high
<3.2, LDA
≤1.9, very low

DAPSA

Assesses[6]:

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

Disease activity cut-offs:
>28, high
≤28 to >14, moderate
≤14 to >4, LDA
≤4, remission

OLE Limitation:
In an OLE, 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.
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 to baseline) had the option to add or modify rescue concomitant medications/therapy.

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RZB Safety from KEEPsAKE 1 and 2

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TEAEs OF INTEREST THROUGH WEEK 24 IN KEEPsAKE 1 and 2[2–4, 8–11]

TEAEs, Events (E/100 PYs)	KEEPsAKE 1		KEEPsAKE 2	
	PBO N=481, PYs=223.5	RZB N=483, PYs=224.3	PBO N=219, PYs=101.3	RZB N=224, PYs=104.3
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 (3.4)
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)
Herpes zoster	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)*	0	0
Active tuberculosis	0	0	0	0
MACE	0	0	0	1 (1.0)
Opportunistic infection excluding TB and HZ	0	0	0	0

The overall safety profile of RZB observed in subjects with PsA treated with RZB is generally consistent with the safety profile in subjects with plaque psoriasis, with the addition of hepatic events – for example, increased ALT and AST, but no serious hepatic events were reported – and hypersensitivity reactions

Most Common AEs

In patients treated with risankizumab for plaque psoriasis and psoriatic arthritis, the most common AEs (≥1%) include any infection, upper respiratory tract infections, headache, fatigue, injection-site reactions, and tinea infections

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

*1 subject, 81 years of age with dementia, hospitalized for pneumonia, developed urosepsis and complications resulting in death.

ACR20/50/70, improvement of ≥20%/50%/70% in American College of Rheumatology core criteria; AE, adverse event; ALT, alanine aminotransferase; AO, as observed; AST, aspartate aminotransferase; BSA-Ps, body surface area-psoriasis; bDMARD-IR, biologic disease-modifying antirheumatic drug inadequate response; 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, events; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDA, low disease activity; MACE, major adverse cardiovascular event; MDA, minimal disease activity; NMSC, nonmelanoma skin cancer; NRI, nonresponder imputation; OLE, open-label extension; PASDAS, Psoriatic Arthritis Disease Activity Score; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsO, psoriasis; PGA, physician global assessment; PtGA, patient global assessment; PY, person years; RCT, randomized controlled trial; SJC, swollen joint count; TB, tuberculosis; TEAE, treatment-emergent adverse event; TJC, tender joint count; VAS, visual analog scale; W/Wk, week.

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.** Kristensen LE et al. Poster presented at: American College of Rheumatology Convergence; November 10–14, 2022; Philadelphia, PA; **5.** McGagh D, Coates LC. Rheumatology (Oxford). 2020;59(Suppl. 1):i29–i36; **6.** Mease PJ, Coates LC. *Semin Arthritis Rheum*. 2018;47(6):786–796; **7.** Data on File, AbbVie Inc. ABVRRTI76352; **8.** Data on file, AbbVie Inc. ABVRRTI73417; **9.** Kristensen LE et al. Poster presented at: Fall Clinical Dermatology Conference; October 21–24, 2021; Las Vegas, NV; **10.** Östör A, et al. Poster presented at: Fall Clinical Dermatology Conference; October 21–24, 2021; Las Vegas, NV; **11.** Data on file, AbbVie Inc. ABVRRTI74973.

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