Psoriasis for Rheumatologists

What Rheumatologists Can Learn From the IMMpulse Study With Risankizumab in Moderate Plaque Psoriasis

US Medical Affairs Rheumatology

INDICATIONS

Risankizumab-rzaa, a humanized monoclonal antibody to IL-23, is indicated for the treatment of active psoriatic arthritis in adults and for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1]

IMMpulse Study Design[2,3]

IMMpulse was a head-to-head, Phase 4, randomized, open-label, efficacy assessor-blinded, 52-week study comparing **risankizumab vs apremilast** for the treatment of adult patients with moderate plaque psoriasis who were candidates for systemic therapy (n=352).*

In Period A, patients were randomized 1:2 to risankizumab (n=118) or apremilast (n=234) for 16 weeks.[2,†] In Period B, patients treated with apremilast were re-randomized 1:1 to risankizumab (n=102) or apremilast (n=97), stratified by Week 16 PASI 75 response. Results of **Period A** of the IMMpulse study are described in this summary.

PASI 90
at Week 16 (NRI-MI)

Co-primary Endpoint
Period A (ITT)

	RZB 150 mg‡	APR 30 mg bid
	55.9% (n=118)	5.1% (n=234)
95% CI:	47.0–64.9	2.3–8.0

P<0.001

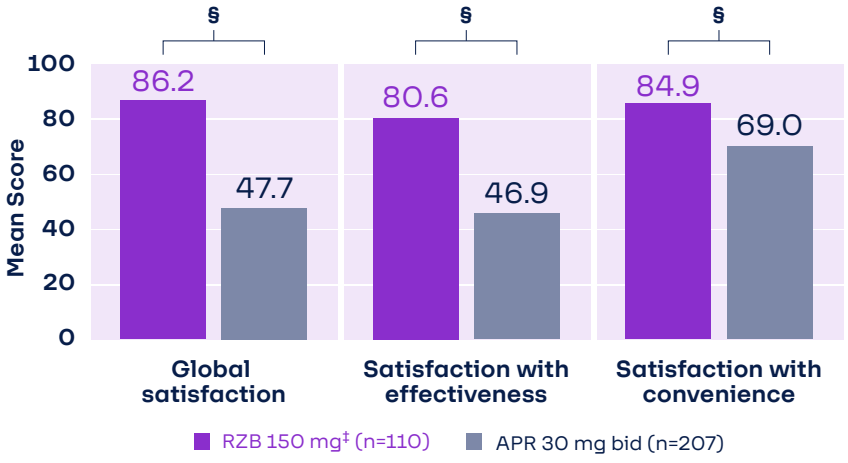
sPGA 0/1
at Week 16 (NRI-MI)

Co-primary Endpoint
Period A (ITT)

	RZB 150 mg‡	APR 30 mg bid
	75.4% (n=118)	18.4% (n=234)
95% CI:	67.7–83.2	13.4–23.3

P<0.001

Exploratory Endpoint
Patient Satisfaction[2]: Mean TSQM-9 scores at Week 16



TSQM-9 is a questionnaire completed by patients in this study to measure patient satisfaction with medication over the previous 2–3 weeks or since it was last used.[3]

It is a scientifically validated, commonly used patient-reported outcome that was prespecified in this open-label H2H clinical trial of RZB vs APR.[3,4]

The objective was to measure patient satisfaction across three domains shown (left).

Scores range from 0 to 100 in each domain; higher scores indicate higher satisfaction.[3]

*Moderate plaque psoriasis defined as sPGA=3, BSA involvement of 10–15%, and PASI ≥12. †Period A ITT population included all patients randomly assigned to receive RZB or APR from baseline until Week 16. ‡RZB is dosed subcutaneously at Weeks 0 and 4, and then every 12 weeks thereafter. §Nominal P<0.001, and not controlled for multiplicity.

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Treatment-Emergent Adverse Events[2]

Period A (Week 16) TEAE, n (%)	RZB 150 mg N=118	APR 30 mg‖ N=234
AE	49 (41.5)	143 (61.1)
Severe AE	1 (0.8)	9 (3.8)
Serious AE	1 (0.8)	4 (1.7)
Any infection	29 (24.6)	39 (16.7)
AE leading to discontinuation of study drug	0	16 (6.8)
AE leading to death	0	0
TEAEs reported in ≥5% of patients		
Diarrhea	1 (0.8)	47 (20.1)
Nausea	0	41 (17.5)
Headache	3 (2.5)	27 (11.5)
COVID-19	13 (11.0)	16 (6.8)

Treatment-Emergent Adverse Events of Interest[3]

Period A (Week 16) TEAE, n (%)	RZB 150 mg N=118	APR 30 mg‖ N=234
Adjudicated MACE	0	1 (0.4)
Extended MACE	0	1 (0.4)
Serious infections	0	1 (0.4)
Opportunistic infections excluding tuberculosis and herpes zoster	0	0
Injection-site reactions	2 (1.7)	0
Malignancies	0	0
NMSC	0	0
Malignant tumor excluding NMSC	0	0
Hypersensitivity	3 (2.5)	1 (0.4)
Serious Hypersensitivity	0	0
Adjudicated anaphylactic reaction	0	0
Hepatic events	0	3 (1.3)

Period B (through 52 weeks) safety rates (E/100 PYs) in the continuous RZB arm were consistent with safety rates from Period A, with the exception of serious AEs (RZB=8.9, APR=4.3), serious infection (RZB=0.8, APR=0), injection site reactions (RZB=5.7, APR=0), and hypersensitivity (RZB=4.1, APR=2.9)

Safety analyses were conducted on all patients receiving ≥1 treatment dose after randomization or re-randomization.

Statistical comparison of the TEAEs could not be determined due to the small sample size.

TEAEs in Period A were defined as any AE with an onset date on or after the first dose of the study drug in Period A and before the first dose of the study drug in Period B. If no study drug was administered in Period B, TEAEs in Period A included any AE with an onset date within 140 days of the last dose of RZB in Period A and within 28 days of the last dose of APR in Period A.

‖According to the US label, the most common adverse reactions (≥5%) for APR in plaque PsO are diarrhea, nausea, upper respiratory tract infection, and headache, including tension headache.

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IMMpulse Study Overview

Key Takeaways From Period A

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Primary and exploratory endpoints in the IMMpulse study[2]

For the **risankizumab group**, compared to the apremilast group, at Week 16

- Significantly more patients in the study achieved co-primary endpoints
- Based on TSQM-9, numerically higher treatment satisfaction scores were reported

No new safety signals were observed for risankizumab[2]

- Tolerability and safety are important considerations when selecting a treatment for patients across the spectrum of psoriatic disease

Can this data in patients with psoriasis help to inform your clinical decision-making in rheumatology?

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.

Please review risankizumab-rzaa full Prescribing Information for additional information by visiting www.rxabbvie.com/pdf/skyrizi _pi.pdf or contact AbbVie Medical Information at 1-800-633-9110.

Abbreviations:
AE, adverse event; APR, apremilast; BSA, body surface area; CI, confidence interval; COVID-19, coronavirus disease 2019; E, event; H2H, head-to-head; IL, interleukin; ITT, intention-to-treat; MACE, major adverse cardiovascular event; MI, multiple imputation; NMSC, nonmelanoma skin cancer; NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index; PsO, psoriasis; PY, patient-year; RZB, risankizumab; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse event; TSQM-9, Treatment Satisfaction Questionnaire for Medication 9-item.

References:
1. SKYRIZI® (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc. **2.** Stein Gold LF et al. [published online ahead of print] *Br J Dermatol*. 2023. doi: 10.1093/bjd/ljad252. **3.** Data on file, AbbVie Inc. ABVRRTI76434. **4.** Bharmal M et al. *Health Qual Life Outcomes*. 2009;7:36. doi:10.1186/1477-7525-7-36.

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