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OP0228

EFFICACY AND SAFETY OF RISANKIZUMAB FOR ACTIVE PSORIATIC ARTHRITIS, INCLUDING PATIENTS WITH INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGIC THERAPIES: 24-WEEK RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, KEEPSAKE 2 TRIAL

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Background: Risankizumab (RZB) is a humanized immunoglobulin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding its p19 subunit. RZB is being investigated as a treatment for adults with psoriatic arthritis (PsA).

Objectives: To compare the efficacy and safety of RZB vs placebo (PBO) for the treatment of active PsA in patients who have had inadequate response or intolerance to 1 or 2 biologic therapies (Bio-IR) or to ≥ 1 conventional synthetic disease modifying antirheumatic drug (csDMARD-IR).

Methods: KEEPSAKE 2 (NCT03671148) enrolled adults with active PsA (≥ 5 swollen joints [SJC] and ≥ 5 tender joints [TJC]) who were Bio-IR or csDMARD-IR. Patients were randomized to receive blinded subcutaneous RZB 150 mg or PBO at weeks 0, 4, and 16. The primary endpoint was the proportion of patients achieving ≥ 20% improvement in American College of Rheumatology score (ACR20) at week 24. Ranked secondary endpoints and other secondary endpoints are shown in the Table. Safety was assessed throughout the study. Results reported here are from the 24-week double-blind period; the open-label period with all patients receiving RZB is ongoing.

Results: A total of 443 patients (RZB, N = 224; PBO, N = 219) were included in the analysis. Demographics and baseline disease characteristics were similar across treatment arms (mean SJC: 13.3; mean TJC: 22.6; mean duration of PsA: 8.2 years; mean body surface area involved with psoriasis [BSA] in patients with BSA ≥ 3%: 12.1%); 206 patients (46.5%) were Bio-IR. Significantly greater proportions of RZB-treated patients vs PBO-treated patients achieved the primary endpoint (51.3% vs 26.5%, respectively; $P < .001$) and all ranked secondary endpoints ($P < .001$ for all except for Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-Fatigue; $P < .009$]; Table). Other secondary outcomes also showed improvement for RZB- vs PBO-treated patients (Table). Serious adverse events were reported for 4.0% and 5.5% of RZB- and PBO-treated patients, respectively; serious infections were reported for 0.9% and 2.3%.

Conclusion: RZB resulted in significantly greater improvements in signs and symptoms of PsA compared with PBO and was well tolerated in patients who were Bio-IR or csDMARD-IR.

Table. Efficacy Results

	RZB 150 mg N = 224	PBO N = 219	Difference (95% CI)	P value*
Primary endpoint				
ACR20, %	51.3	26.5	24.5 (15.9, 33.0)	< .001***
Ranked secondary endpoints				
HAQ-DI score, change	-0.22	-0.05	-0.16 (-0.26, -0.07)	< .001***
PASI 90, %	55.0	10.2	44.3 (33.9, 54.6)	< .001***
ACR20 at week 16, %	48.3	25.3	22.6 (13.9, 31.2)	< .001***
MDA, %	25.6	11.4	14.0 (7.0, 21.0)	< .001***
SF-36 PCS score, change	5.9	2.0	3.9 (2.4, 5.3)	< .001***
FACIT-Fatigue score, change	4.9	2.6	2.2 (0.6, 3.9)	.009**
Other secondary endpoints				
ACR50, %	26.3	9.3	16.6 (9.7, 23.6)	< .001†
ACR70, %	12.0	5.9	6.0 (0.8, 11.3)	.024†
Resolution of enthesitis, %	42.9	30.4	13.8 (3.5, 24.2)	.009†
Resolution of dactylitis, %	72.5	42.1	38.8 (22.9, 54.8)	< .001†

ACR20/ACR50/ACR70, ≥ 20/50/70% improvement in American College of Rheumatology score; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI, Health Assessment Questionnaire-Disability Index; MDA, minimal disease activity; PASI 90, ≥ 90% reduction in Psoriasis Area Severity Index; PBO, placebo; RZB, risankizumab; SF-36 PCS, 36-Item Short Form Health Survey Physical Component Summary. All endpoints assessed at week 24 unless otherwise noted. All changes are mean changes from baseline.

***: statistically significant at 0.001 level, multiplicity controlled.

** Statistically significant at 0.01 level, multiplicity controlled.

†: Nominal P value.

*For patients with involved body surface area ≥ 3% (PASI 90, RZB N = 123; PBO N = 119), enthesitis (RZB N = 147; PBO N = 158), or dactylitis (RZB N = 40; PBO N = 57) at baseline.

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OP0229

THE GROUP FOR RESEARCH AND ASSESSMENT OF PSORIASIS AND PSORIATIC ARTHRITIS (GRAPPA) TREATMENT RECOMMENDATIONS 2021

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Background: Since the 2015 GRAPPA treatment recommendations were published, therapeutic options and management strategies for psoriatic arthritis (PsA) have advanced considerably.

Objectives: The goal of the GRAPPA recommendations update is to develop high quality, evidence-based recommendations for the treatment of PsA, including related conditions and comorbidities.

Methods: GRAPPA rheumatologists, dermatologists and patient research partners (PRPs) updated overarching principles for the management of adults with PsA by consensus. Principles considering use of biosimilars and tapering/discontinuing of therapy were added to this update. Systematic literature searches based on data publicly available from three databases (MEDLINE, EMBASE, and Cochrane CENTRAL) were conducted from the end of the previous recommendations' searches through August 2020. Additional abstract searches were performed for conference presentations in 2017-2020. Searches covered PsA treatments (peripheral arthritis, axial arthritis, enthesitis, dactylitis, skin, and nail disease). Additional searches were performed for related conditions (uveitis and IBD) and comorbidities evaluating their impact on safety and treatment outcomes. Individual groups assessed the risk of bias and applied the GRADE system to generate strong or conditional recommendations for therapies within the domain groups and for the management of comorbidities and related conditions. These recommendations were then incorporated into an overall treatment schema.

Results: Updated, evidence-based treatment recommendations are shown (Table 1). Since 2015, many new medications have been incorporated. Additional results for older medications, such as methotrexate, have been published across PsA domains. Based on the evidence, the treatment recommendations developed by individual groups were incorporated into the overall schema including principles for management of arthritis, spondylitis, enthesitis, dactylitis, skin, and nail disease in PsA, and associated conditions (Figure 1). Choice of therapy for an individual should ideally address all of the domains that impact on that patient, supporting shared decision making with the patient involved. Additional consideration in the recommendations was given to key associated conditions and comorbidities as these often impact on therapy choice.

Conclusion: These GRAPPA treatment recommendations provide up to date, evidence-based guidance to providers who manage and treat adult patients with PsA. These recommendations are based on domain-based strategy for PsA and supplemented by overarching principles developed by consensus of GRAPPA members.

Indication	Strong For	Conditional For	Conditional Against	Strong Against	Insufficient evidence
Peripheral Arthritis	csDMARDs, TNFi, PDE4i, IL-12/23i, IL-17i, IL-23i, JAKi	NSAIDs, oral CS, IA CS,	IL-6i,		
DMARD Naive					
Peripheral Arthritis	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi	PDE4i, other csDMARD, NSAIDs, oral CS, IA CS,	IL-6i,		
DMARD IR		NSAIDs, oral CS, IA CS,			
Peripheral Arthritis	TNFi, IL-17i, IL-23i, JAKi,	CS, IA CS, IL-12/23i, PDE4i, CTLA-4-Ig	IL-6i,		
bDMARD IR		CS SIJ injections, bisphosphonates		cs DMARDs, IL-6i,	IL-12/23i, IL-23i
Axial arthritis, Biologic Naive	NSAIDs, Physiotherapy, simple analgesia, TNFi, IL-17i, JAKi				
Axial PsA, Biologic IR	NSAIDs, Physiotherapy, simple analgesia, TNFi, IL-17i, JAKi			csDMARDs, IL-6i,	IL-12/23i, IL-23i
Enthesitis	TNFi, IL-12/23i, IL-17i, PDE4i, IL-23i, JAKi	NSAIDs, physiotherapy, CS injections, MTX		IL-6i,	Other cs DMARDs
Dactylitis	TNFi IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, CS injections, MTX	Other csDMARDs		
Psoriasis	Topicals, phototherapy, csDMARDs, TNFi, IL-12/23i, IL-17i, IL-23i, PDE4i, JAKi	Acitretin			
Nail psoriasis	TNFi, IL12/23i, IL17i, IL23i, PDE4i	Topical CS, tacrolimus and calcipotriol combination or individual therapies, Pulsed dye laser, csDMARDs, acitretin, JAKi			Topical Cyclosporine / Tazarotene, Fumarate, Fumaric Acid Esters, UVA and UVB Phototherapy, Aitretinoin
IBD	TNFi (not ETN), IL-12/23i, JAKi			IL-17i	
Uveitis	TNFi (not ETN)				