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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 DMARD Naïve	csDMARDs, TNFi, PDE4i, IL-12/23i, IL-17i, IL-23i, JAKi	NSAIDs, oral CS, IA CS,	IL-6i,		
Peripheral Arthritis DMARD IR	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi	PDE4i, other csDMARD, NSAIDs, oral CS, IA CS,	IL-6i,		
Peripheral Arthritis bDMARD IR	TNFi, IL-17i, IL-23i, JAKi,	NSAIDs, oral CS, IA CS, IL-12/23i, PDE4i, CTLA-4-Ig	IL-6i,		
Axial arthritis, Biologic Naïve	NSAIDs, Physiotherapy, simple analgesia, TNFi, IL-17i, JAKi	CS SIJ injections, bisphosphonates		cs DMARDs, IL-6i,	IL-12/23i, IL-23i
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, Alitretinoin
IBD	TNFi (not ETN), IL-12/23i, JAKi			IL-17i	
Uveitis	TNFi (not ETN)				

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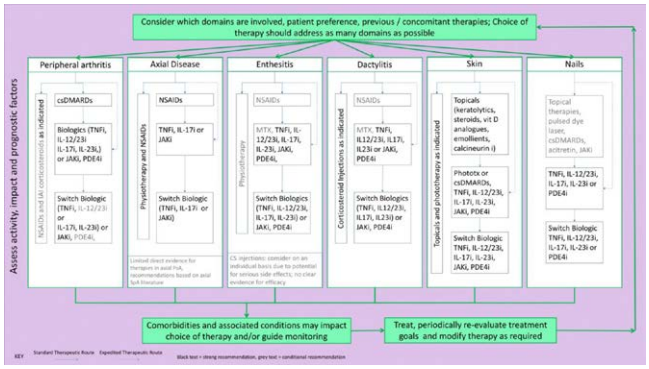

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OP0230

EFFICACY AND SAFETY OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS WHO DEMONSTRATED INADEQUATE RESPONSE TO TUMOR NECROSIS FACTOR INHIBITION: WEEK 24 RESULTS OF A PHASE 3B, RANDOMIZED, CONTROLLED STUDY

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Background: Guselkumab (GUS), a selective monoclonal antibody targeting the interleukin-23p19 subunit, has demonstrated efficacy in 2 pivotal Ph3 psoriatic arthritis (PsA) studies (DISCOVER-1,[1] DISCOVER-2[2]).

Objectives: Evaluate GUS efficacy and safety in PsA patients (pts) with inadequate response (IR) to tumor-necrosis-factor inhibition (TNFi) through Week24 (W24) of the Ph3b COSMOS study.

Methods: In this randomized, double-blind, placebo (PBO)-controlled trial, 285 pts with active PsA (≥3 swollen & ≥3 tender joints) who demonstrated lack of benefit or intolerance to 1-2 TNFi were randomized 2:1 to subcutaneous GUS 100mg (n=189) or PBO (n=96) at W0, W4, then every 8 weeks (Q8W) through W44 (with PBO crossover to GUS at W24). At W16, pts who met early escape (EE) criteria (<5% improvement in both tender & swollen joint counts) also could switch from PBO to GUS. The primary efficacy endpoint was ACR20 response at W24 among randomized, treated pts. Pts missing ACR20 data at W24 or who met treatment failure criteria (including meeting EE criteria at W16) were considered nonresponders (NRs). Subgroup analyses were performed to assess consistency of primary treatment effect based on demographics, disease characteristics, and medication use at baseline. Prespecified sensitivity analyses included 'Per-Protocol' (PP) (excluded pts with major protocol deviations) and 'EE-Correction' (included pts incorrectly routed to EE) analyses. Adverse events (AEs) were summarized by treatment received.

Results: Baseline characteristics were similar across GUS and PBO pts, though a higher proportion of females and more severe joint symptoms were seen in the GUS group. At W24, 44.4% of GUS vs 19.8% of PBO pts achieved ACR20 (p<0.001) (Figure). GUS was superior to PBO for all major secondary endpoints. Efficacy was consistent across subgroups defined by baseline characteristics, including in pts who discontinued prior TNFi use due to inadequate efficacy (84% GUS vs 81% PBO) and safety (16% GUS vs 19% PBO) (Table). 20 pts (12 GUS, 8 PBO) were incorrectly routed to EE. Results of PP (48.8% vs 23.8%) and EE-correction (48.1% vs 19.8%) sensitivity analyses were consistent with the primary analysis (Figure). AEs were similar between GUS- and PBO-treated pts (Table).

Table 1. Baseline characteristics of, and adverse events reported by, randomized and treated COSMOS pts

	GUS 100 mg Q8W (N=189)	PBO (N=96)
Age, y	49	49
Sex, Female	54%	46%
Duration of PsA, y	8.3	8.7
Body mass index, kg/m^2	29	31[a]
Swollen (0-66) / tender (0-68) joint count	10 / 21	9 / 18
Pt pain / Pt global arthritis / Physician global disease, 0-10 cm VAS	6.5 / 6.5 / 6.9	6.0 / 6.2 / 6.4
Health Assessment Questionnaire-Disability Index, 0-3	1.3[b]	1.2
C-reactive protein, mg/dL	1.2[b]	1.2
Methotrexate use at baseline	56%	53%
Psoriatic body surface area, %	17.9	13.4
Number of prior TNFi: 1 / 2	88% / 12%	89% / 11%
Reason for prior TNFi discontinuation: Efficacy / Safety	84% / 16%*	81% / 19%*
Pts with ≥1 AE / SAE	37% / 3%	48% / 3%
Pts with ≥1 infection / serious infection	18% / 0%	20% / 0%
Pts with ≥1 AE leading to study agent discontinuation	2%	2%
Pts with ≥1 malignancy	0.4%	0
Pts with ≥1 injection-site reaction	2%	1%

Data shown are mean or %. [a]N=95; [b]N=188. *Missing for 1 pt. *SAE – serious adverse events*; *VAS – visual analog scale*

Conclusion: In this Ph3b, placebo-controlled study of PsA pts with IR to 1-2 TNFi, GUS 100 mg Q8W elicited a significantly higher ACR20 response rate vs.

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