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AB0753

COMPARING COMPOSITE MEASURES OF DISEASE ACTIVITY IN PSORIATIC ARTHRITIS: RESULTS FROM A RANDOMIZED PHASE 2 TRIAL WITH GUSELKUMAB

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Background: Psoriatic Arthritis Disease Activity Score (PASDAS), GRAppa Composite scoreE (GRACE) Index, modified Composite Psoriatic Disease Activity Index (mCPDAI), and Disease Activity Index for Psoriatic Arthritis (DAPSA) are composite indices recently developed to assess disease activity in psoriatic arthritis (PsA).^{1,2} Guselkumab (GUS) is a monoclonal antibody targeting interleukin-23 that has demonstrated efficacy in a phase 2 PsA trial.³

Objectives: To compare the effect of GUS on disease activity in psoriatic arthritis (PsA) as measured by these composite indices.

Methods: In this Phase-2 trial, patients with active PsA (≥ 3 tender, ≥ 3 swollen joints, C-reactive protein ≥ 3 mg/L, $\geq 3\%$ body surface area) were randomized 2:1 to subcutaneous GUS 100mg (n=100) or placebo (PBO, n=49) at Wk0, Wk4, and every 8 wks through Wk44. At Wk16, patients with $<5\%$ improvement in swollen plus tender joints could early-escape (EE) to open-label ustekinumab. Patients continuing PBO crossed-over to receive GUS 100mg at Wks 24/28/36/44 (PBO to GUS). PsA composite indices PASDAS, GRACE, mCPDAI, and DAPSA were analyzed using last-observation-carried-forward for missing/post-EE data through Week24. Instruments were validated using SF-36 physical component summary (PCS) score as an anchor. Sensitivity was assessed via standardized mean differences (SMDs), effect size (ES) and standardized response means (SRMs).

Figure. Comparative statistics evaluating guselkumab treatment effects detected at Week 24 according to specific composite endpoints: standardized mean difference (d), effect size (d), and standardized response means (C)

Composite index	Low (n=100)	Very low (n=100)	Very low (n=100)	Very low (n=100)
PASDAS	10 (10%)	10 (10%)	10 (10%)	10 (10%)
GRACE	10 (10%)	10 (10%)	10 (10%)	10 (10%)
mCPDAI	10 (10%)	10 (10%)	10 (10%)	10 (10%)
DAPSA	10 (10%)	10 (10%)	10 (10%)	10 (10%)

Results: Changes in SF-36 PCS score were consistent with disease activity states at Wk24 for each PsA composite index in guselkumab-

treated patients. The SMD, ES and SRM indicated that guselkumab elicited a substantial effect in treating the diverse manifestations of PsA compared with placebo, regardless of composite index employed (Figure). PASDAS and GRACE indices appeared to be more sensitive than mCPDAI and DAPSA in detecting changes upon treatment and distinguishing guselkumab treatment effects relative to placebo. Residual disease activities among guselkumab-treated patients who achieved low disease activity at Week24 based on each PsA composite index are summarized in the Table.

Conclusion: Regardless of the PsA-specific composite index employed, GUS significantly improved disease activity and achieved clinically meaningful therapeutic targets such as low/minimal disease activity or remission. PASDAS and GRACE indices were more sensitive than mCPDAI and DAPSA in detecting changes in disease activity by guselkumab treatment.

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AB0754

CLINICALLY MEANINGFUL IMPROVEMENT IN SKIN AND NAIL PSORIASIS IN BIO-NAÏVE ACTIVE PSORIATIC ARTHRITIS PATIENTS TREATED WITH INTRAVENOUS GOLIMUMAB: RESULTS THROUGH WEEK 52 FROM A PHASE-3 STUDY

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Background: GO-VIBRANT is a Phase 3 trial of intravenous (IV) golimumab (GLM) in adult patients (pts) with active psoriatic arthritis (PsA). Clinically meaningful improvements in skin and nail psoriasis (PsO) and in Dermatology Life Quality Index (DLQI) that were significantly greater than placebo (PBO) at weeks (wks) 14 & 24 were previously reported.¹

Objectives: To evaluate improvement in skin and nail PsO and DLQI with IV GLM through wk52.

Methods: Adult bio-naïve PsA pts with active disease (≥ 5 swollen & tender joints, CRP ≥ 0.6 mg/dL, active plaque psoriasis or documented history), despite treatment w/csDMARDs &/or NSAIDs, were randomized to IV GLM 2mg/kg at wks 0/4 & every 8 wks thereafter or PBO at wks 0/4/12/20 with crossover to GLM at wk24. Pts with $\geq 3\%$ body surface area (BSA) psoriasis at baseline (BL) were assessed using Psoriasis Area and Severity Index (PASI, 0-72) of 75/90/100% improvement scale,