Table 1.

	W4	W8	W12	W16	W20	W24
ACR20	20	39	50	56	60	61
HAQ-DI score	36	45	52	54	56	57
SJC66	61	74	84	86	87	88
TJC68	48	65	75	79	80	81
PGA	50	67	74	78	81	81
PtGA	35	48	58	59	62	64
Pt Pain	32	48	55	58	61	63
CRP	56	60	62	63	64	64

Figure. Median time to ACR20 response.

Data shown at W2 were derived solely from DISCOVER-2, as DISCOVER-1 did not include assessments at W2. The intersection of horizontal and vertical dashed lines denotes the time at which 50% of patients in a treatment group achieved ACR20 response.

Figure 1

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AB0526

SUSTAINED GUSELKUMAB RESPONSE IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS REGARDLESS OF BASELINE DEMOGRAPHIC AND DISEASE CHARACTERISTICS: POOLED RESULTS THROUGH WEEK 52 OF TWO PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED STUDIES

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Background: In the Phase 3 DISCOVER-1¹ & DISCOVER-2² trials, guselkumab (GUS), a human monoclonal antibody targeting the IL-23p19-subunit, was effective in psoriatic arthritis (PsA) across joint & skin endpoints. At Week 24 (W24), GUS benefit was consistent regardless of baseline (BL) demographic & disease characteristics.³

Objectives: We assessed whether GUS efficacy was sustained through W52 in pooled DISCOVER-1 & -2 patients (pts) across select BL subgroups.

Methods: Adults with active PsA despite standard therapies were enrolled in DISCOVER-1 (swollen [SJC] ≥3 & tender joint count [TJC] ≥3, C-reactive protein [CRP] ≥0.3 mg/dL) & DISCOVER-2 (SJC ≥5 & TJC ≥5, CRP ≥0.6 mg/dL). 31% of DISCOVER-1 pts had received 1-2 prior tumor necrosis factor inhibitors; DISCOVER-2 pts were biologic naïve. Pts were randomized 1:1:1 to GUS 100 mg every 4 weeks (Q4W); GUS 100 mg at W0, W4, then Q8W; or placebo (PBO). Pts randomized to PBO received GUS 100 mg Q4W starting at W24 & were excluded from these analyses assessing maintenance of effect from W24 to W52. GUS effects on joint (American College of Rheumatology [ACR]20/50/70) & skin (Investigator's Global Assessment [IGA=0/1 + ≥2-grade reduction from W0] in pts with ≥3% body surface area [BSA] with psoriasis & IGA ≥2 at W0) endpoints were evaluated by pt BL SJC, TJC, conventional synthetic disease-modifying antirheumatic drug (csDMARD) use, body mass index (BMI), PsA duration, & % BSA with psoriasis. Missing data were imputed as non-response through W52.

Results: BL pt characteristics in DISCOVER-1 (N=381) & DISCOVER-2 (N=739) were well balanced across randomized groups.^{1,2} Among 1120 pooled pts, mean SJC was 11, mean TJC was 21, & 68% used csDMARDs (primarily methotrexate [MTX]). At W24, 62% (232/373) & 60% (225/375), respectively, of GUS Q4W- & Q8W-treated pts achieved ACR20 vs 29% (109/372) of PBO, with GUS effect consistently observed across pt BL subgroups (Figure 1). ACR20 response rates were sustained or increased at W52 in the GUS Q4W (72%) & Q8W (70%) groups & across SJC (61-79%), TJC (68-76%), & csDMARD use (68-80%) subgroups (Table 1) & pt subgroups defined by BL BMI, PsA duration, & % BSA with psoriasis (data not shown). ACR50 & 70 response patterns were similar to ACR20 (Table 1). In pts with ≥3% BSA psoriasis & IGA ≥2 at BL, 71% (193/273) & 66% (171/258) of GUS Q4W- & Q8W-treated pts, respectively, vs 18% (47/261) of PBO, achieved IGA 0/1 at W24, with GUS effect consistently observed across pt BL subgroups (Figure 1). IGA 0/1 response rates were also sustained or increased at W52 in the GUS Q4W (80%) & Q8W (71%) groups & across % BSA with psoriasis (67-87%) & csDMARD use (68-87%) subgroups (Table 1) & pt subgroups defined by BL BMI and PsA duration (data not shown).

Conclusion: Treatment with GUS 100 mg Q4W & Q8W resulted in sustained improvement in signs & symptoms of active PsA through W52 regardless of pt BL characteristics.

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Figure. ACR & IGA Responses at W24 by Select BL Characteristics

Figure 1

Table 1. ACR & IGA Responses at Weeks 24 & 52 & by Select BL Characteristics

	Guselkumab Q4W		Guselkumab Q8W	
	N=373		N=375	
	Week 24	Week 52	Week 24	Week 52
ACR20, %	62	72	60	70
SJC (<10/10-15/>15)	68/59/53	79/61/67	57/66/60	68/68/76
TJC (<10/10-15/>15)	74/67/56	73/76/69	62/60/60	75/68/68
csDMARD use (none/any/MTX)	66/60/63	80/68/68	62/59/57	73/68/68
ACR50, %	34	49	31	45
SJC (<10/10-15/>15)	41/32/20	58/39/38	34/28/26	46/40/49
TJC (<10/10-15/>15)	51/41/24	58/53/43	40/33/26	52/46/43
csDMARD use (none/any/MTX)	36/33/35	53/46/48	36/29/27	51/42/40
ACR70, %	16	27	16	27
SJC (<10/10-15/>15)	22/10/7	32/20/24	18/10/19	30/23/26
TJC (<10/10-15/>15)	29/19/9	34/32/22	27/15/14	35/28/24
csDMARD use (none/any/MTX)	21/13/14	30/26/27	21/14/14	34/24/23
IGA 0/1, %	71	80	66	71
BSA $\geq 3\%$ with psoriasis	61/71/80	76/87/79	62/64/72	67/72/74
($\geq 3\%$ to $<20\%$ to $\geq 20\%$)				
csDMARD use (none/any/MTX)	84/64/67	87/77/78	72/63/64	77/68/68

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AB0527

CORRELATIONS BETWEEN REDUCTIONS IN FATIGUE SEVERITY AND IMPROVEMENTS IN PHYSICAL FUNCTION AND CLINICAL RESPONSE IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS FROM THE PHASE 3 DISCOVER PROGRAM

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Background: In patients (pts) with psoriatic arthritis (PsA), fatigue is a major driver of perceived impact of disease and has been identified as an important domain to be assessed in clinical trials.^{1,2} The association between fatigue and other PsA domains (eg, physical function) or clinical response is not well understood.

Objectives: Fatigue was measured with the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue questionnaire in the pivotal DISCOVER-1 and DISCOVER-2 Phase 3 studies of guselkumab (GUS) vs placebo (PBO). This post hoc analysis explores the correlation between FACIT-Fatigue and physical function and clinical response in the DISCOVER program.

Methods: This analysis used pooled data from pts (N=1120) treated with GUS or PBO. In DISCOVER-1 and DISCOVER-2, 381 pts with active PsA (swollen joint count [SJC] ≥ 3 , tender joint count [TJC] ≥ 3 , C-reactive protein [CRP] ≥ 0.3 mg/dL) and 739 pts with active PsA (SJC ≥ 5 , TJC ≥ 5 , CRP ≥ 0.6 mg/dL) and inadequate response to standard therapies, respectively, were randomized 1:1 to GUS 100 mg Q4W; GUS 100 mg at W0, W4, then Q8W; or PBO. PBO pts switched to GUS 100 mg Q4W at W24. The FACIT-Fatigue questionnaire has 13 items that assess self-reported fatigue/tiredness over the last 7 days. Items are scored from 0 (very much fatigued) to 4 (not at all fatigued). FACIT-Fatigue response was defined as an increase of ≥ 4 points from baseline. Physical function was evaluated with the Health Assessment Questionnaire-Disability Index (HAQ-DI). HAQ-DI response was defined as a decrease of ≥ 0.35 points from baseline. Clinical response was defined as achievement of $\geq 20\%$