Table. Number of Patients Achieving ACR-20 Response at Week 24 by Treatment Group in Subgroups of Patients Defined by Baseline Demographic/Disease Characteristics and PsA Medication Use			
	Placebo n/N (%)	Guselkumab n/N (%)	Difference (95% CI)
All Patients	9/49 (18.4)	58/100 (58.0)	39.6 (25.2, 54.1)
Gender			
Male	5/24 (20.8)	29/52 (55.8)	33.8 (12.6, 54.9)
Female	4/25 (16.0)	29/48 (60.4)	43.2 (22.8, 63.7)
Age (yrs)			
<65	9/47 (19.1)	48/89 (53.9)	34.7 (19.6, 49.9)
≥65	0/2 (0)	10/11 (90.9)	90.9 (73.9, 100.0)
Weight (kg)			
≤90	8/31 (25.8)	38/67 (56.7)	31.2 (11.9, 50.5)
>90	1/18 (5.6)	20/33 (60.6)	55.2 (35.7, 74.7)
Geographic Region			
USA, Canada, Spain, or Germany	2/11 (18.2)	9/19 (47.4)	29.0 (0.0, 59.7)
Poland, Russia, or Romania	7/38 (18.4)	49/81 (60.5)	42.4 (26.2, 58.5)
PsA duration (yrs)			
<1	1/10 (10.0)	10/15 (66.7)	56.7 (26.4, 86.9)
1 to <3	5/10 (50.0)	16/25 (64.0)	16.7 (-19.6, 52.9)
≥3	3/29 (10.3)	32/60 (53.3)	43.0 (26.4, 59.6)
PsA Subtype			
Arthritis Mutans	0/3 (0)	0	
Asymmetric Peripheral Arthritis	2/14 (14.3)	18/26 (69.2)	52.3 (25.4, 79.2)
Dip Joint Involvement	3/7 (42.9)	8/17 (47.1)	-2.9 (-49.5, 43.6)
Polysynovial Arthritis with Absence of Rheumatoid Nodules	3/20 (15.0)	19/39 (48.7)	32.1 (9.1, 55.0)
Spondylitis with Peripheral Arthritis	1/5 (20.0)	13/18 (72.2)	48.8 (7.0, 90.5)
# Swollen joints			
<5	0/7 (0)	4/10 (40.0)	40.0 (9.6, 70.4)
5-10	5/25 (20.0)	28/44 (63.6)	43.1 (22.0, 64.2)
>10	4/17 (23.5)	26/46 (56.5)	32.1 (7.6, 56.6)
# Tender joints			
<5	0/1 (0)	1/2 (50.0)	50.0 (-19.3, 100.0)
5-10	0/11 (0)	13/20 (65.0)	66.6 (46.5, 86.8)
>10	9/37 (24.3)	44/78 (56.4)	32.1 (14.7, 49.6)
CRP			
<1	5/28 (17.9)	29/53 (54.7)	36.5 (16.9, 56.1)
≥1	4/21 (19.0)	29/47 (61.7)	41.9 (20.1, 63.6)
HAQ-DI			
<1	1/10 (10.0)	11/19 (57.9)	46.8 (16.5, 77.0)
≥1	8/39 (20.5)	47/81 (58.0)	37.5 (21.0, 53.9)
PASI Score			
<12	6/31 (19.4)	30/60 (50.0)	30.9 (12.2, 49.6)
12-20	0/9 (0)	12/17 (70.6)	72.4 (52.7, 92.2)
>20	2/8 (25.0)	15/21 (71.4)	43.4 (6.9, 80.0)
Psoriatic BSA (%)			
3-10	6/29 (20.7)	24/43 (55.8)	34.9 (14.0, 55.9)
10-20	1/6 (16.7)	17/30 (56.7)	40.5 (5.5, 75.5)
>20	2/14 (14.3)	17/27 (63.0)	48.1 (22.3, 73.9)
Enthesitis			
Yes	5/31 (16.1)	46/76 (60.5)	43.9 (27.1, 60.8)
No	4/18 (22.2)	12/24 (50.0)	26.7 (-0.2, 53.5)
Dactylitis			
Yes	6/23 (26.1)	36/58 (62.1)	35.8 (14.1, 57.5)
No	3/26 (11.5)	22/42 (52.4)	40.8 (21.5, 60.2)
Prior PsA Med use:			
Anti-TNF			
Yes	0/4 (0)	6/9 (66.7)	66.7 (35.9, 97.5)
No	9/45 (20.0)	52/91 (57.1)	37.1 (21.7, 52.6)
DMARD			
0	2/8 (25.0)	4/10 (40.0)	15.0 (-27.7, 57.7)
1	5/33 (15.2)	43/71 (60.6)	45.4 (28.8, 62.0)
≥2	2/8 (25.0)	11/19 (57.9)	30.6 (-7.2, 68.3)
Baseline PsA Med use:			
MTX			
Yes	5/19 (26.3)	27/47 (57.4)	30.0 (5.8, 54.2)
No	4/30 (13.3)	31/53 (58.5)	44.4 (26.5, 62.2)
Corticosteroid			
(oral)	2/8 (25.0)	10/12 (83.3)	61.3 (27.3, 95.4)
No	7/41 (17.1)	48/88 (54.5)	37.5 (22.0, 52.9)
NSAID			
Yes	7/36 (19.4)	42/70 (60.0)	40.6 (23.5, 57.8)
No	2/13 (15.4)	16/30 (53.3)	38.3 (12.0, 64.6)

ACR-20 = 20% improvement in American College of Rheumatology criteria; BSA = Body Surface Area; CI = confidence interval; CRP = C-Reactive Protein; HAQ-DI = Health Assessment Questionnaire-Disability Index; MTX = methotrexate; Med=medication; NSAID = non-steroidal anti-inflammatory drug; PASI = Psoriasis Area and Severity Index; PsA = psoriatic arthritis; TNF = tumor necrosis factor. 95% CI's were calculated based on Wald statistics.

Conclusion: In this phase 2 trial of patients with PsA, GUS demonstrated efficacy consistently across subgroups of pts according to baseline demographics, disease characteristics, and PsA-medication use. The relationship between baseline characteristics and clinical outcome will be further explored in phase 3 studies with a larger PsA population.

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SAT0388

CHARACTERIZATION OF PATIENTS WITH PSORIATIC ARTHRITIS AND NAIL PSORIASIS: DATA FROM THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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Background: Nail disease is an important feature of PsA and may even precede the disease by many years.¹ Nail psoriasis is considered one of the 6 disease domains of PsA²; however, there have been limited real-world studies that have examined characteristics of patients with PsA and nail psoriasis, particularly in the United States.

Objectives: To characterize the disease activity, quality of life, and work productivity of patients with PsA with and without nail psoriasis in the US-based Corrona PsA/SpA Registry.

Methods: This study included all patients in the Corrona PsA/SpA registry enrolled between March 2013 and October 2018 with a diagnosis of PsA who had non-missing data on physician-reported nail psoriasis. Patients were stratified by presence vs absence of nail psoriasis at the time of enrollment, defined as a non-zero response on the nail psoriasis visual analog scale (VAS) of 0-100. Descriptive analyses of patient demographics, disease activity, quality of life, and work productivity were assessed at enrollment and compared between nail psoriasis groups using *t*-tests or Wilcoxon rank-sum tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables.

Results: A total of 2841 patients with PsA met the inclusion criteria, including 1152 patients (40.5%) with nail psoriasis and 1689 patients (59.5%) without nail psoriasis at enrollment. Patients with and without nail psoriasis were similar in terms of demographic and clinical characteristics; however, patients with nail psoriasis were slightly younger (53.1 vs 54.4 years) and more likely to be male (51.9% vs 44.1%) and have a higher history of depression (17.8% vs 13.3%) compared with patients without nail psoriasis (all *P* < 0.05). Patients with nail psoriasis had more severe psoriasis and PsA disease activity, as reflected by statistically significantly higher percentage of affected body surface area (BSA), higher tender and swollen joint counts, decreased likelihood of being in minimal disease activity, worse mean Disease Activity in Psoriatic Arthritis (DAPSA) and Psoriatic Arthritis Disease Activity Score (PASDAS) values, and increased likelihood of having enthesitis and dactylitis at enrollment compared with patients without nail psoriasis (Table 1; all *P* < 0.05). Patients with nail psoriasis had worse self-reported physical function (HAQ-DI), pain, fatigue, EQ-5D scores, and work and activity impairment compared with patients without nail psoriasis (Table 2; all *P* < 0.05).

Conclusion: PsA patients with nail psoriasis at the time of registry enrollment had worse disease activity, quality of life, and work productivity compared with those patients without nail involvement. These findings emphasize the importance of identification and management of nail disease in patients with PsA.

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Table 1. Disease Activity Among Patients With PsA at Enrollment Stratified by Presence of Nail Psoriasis

Characteristic*	With Nail PsO (N = 1152)	Without Nail PsO (N = 1689)	P Value†
Nail PsO (VAS 0–100)	18.9 (22.5) [1152]	0 [1689]	—
Tender joint count (0–68)	6.0 (9.9) [1127]	3.5 (7.1) [1639]	< 0.01
Swollen joint count (0–66)	2.4 (4.4) [1125]	1.7 (3.5) [1639]	< 0.01
MDA, n/m (%)‡	359/1027 (35.0)	716/1503 (47.6)	< 0.01
DAPSA	18.1 (15.7) [643]	13.4 (12.4) [994]	< 0.01
DAPSA group, n (%)	n = 643	n = 994	< 0.01
Remission	90 (14.0)	232 (23.3)	
Low	231 (35.9)	402 (40.4)	
Moderate	195 (30.3)	247 (24.8)	
High	127 (19.8)	113 (11.4)	
PASDAS	3.8 (1.6) [619]	3.3 (1.5) [972]	< 0.01
PASDAS group, n (%)	n = 619	n = 972	< 0.01
Inactive	215 (34.7)	465 (47.8)	
Moderate	132 (21.3)	227 (23.4)	
Active	228 (36.8)	239 (24.6)	
Very active	44 (7.1)	41 (4.2)	
Enthesitis, n/m (%)	319/1152 (27.7)	287/1689 (17.0)	< 0.01
SPARCC Enthesitis Index (1–16)	3.8 (2.9) [319]	3.5 (2.8) [287]	0.14
Dactylitis, n/m (%)	140/1152 (12.2)	125/1689 (7.4)	< 0.01
Dactylitis count (1–20)	2.4 (2.3) [140]	2.2 (1.8) [125]	0.50
BSA, % affected	7.9 (14.8) [1125]	3.5 (7.6) [1636]	< 0.01
BSA (categorical), n (%)	n = 1125	n = 1636	< 0.01
No disease (0%)	201 (17.9)	583 (35.6)	
Mild disease (> 0% to ≤ 3%)	469 (41.7)	680 (41.6)	
Moderate disease (> 3% to ≤ 10%)	258 (22.9)	254 (15.5)	
Severe disease (> 10%)	197 (17.5)	119 (7.3)	

BSA, body surface area; DAPSA, Disease Activity in Psoriatic Arthritis; MDA, minimal disease activity; PASDAS, Psoriatic Arthritis Disease Activity Score; PsO, psoriasis; SPARCC, Spondyloarthritis Research Consortium of Canada; VAS, visual analog scale.

* All values were calculated based on available data and are presented as "mean (SD) [n]" unless otherwise stated.

† t-test or Wilcoxon rank-sum test for continuous variables and χ^2 or Fisher's exact test for categorical variables.

‡ MDA is defined as 'yes' if a patient met at least 5 of the 7 following categories: tender joint count ≤ 1 , swollen joint count ≤ 1 , body surface area $\leq 3\%$, patient pain VAS ≤ 15 , patient global activity visual analogue scale ≤ 20 , health assessment questionnaire ≤ 0.5 , and tender entheses points ≤ 1 .

Table 2. Patient-Reported Outcome Measures Among Patients With PsA at Enrollment Stratified by Presence of Nail Psoriasis

Characteristic*	With Nail PsO (N = 1152)	Without Nail PsO (N = 1689)	P Value†
Patient pain (VAS 0–100)	41.7 (30.1) [1081]	36.1 (29.1) [1603]	< 0.01
Patient-reported fatigue (VAS 0–100)	43.9 (29.4) [1135]	39.0 (29.6) [1661]	< 0.01
Patient global assessment of arthritis (VAS 0–100)	41.8 (29.5) [1132]	38.0 (30.1) [1663]	< 0.01
Patient global assessment of arthritis and psoriasis (VAS 0–100)	41.6 (29.0) [1130]	37.4 (30.0) [1659]	< 0.01
Morning stiffness	n = 1118	n = 1644	< 0.01
< 30 minutes	380 (34.0)	600 (36.5)	
≥ 30 minutes	738 (66.0)	1044 (63.5)	
HAQ (0–3)	0.7 (0.7) [1087]	0.6 (0.6) [1613]	< 0.01
EQ-5D (0–1)	0.7 (0.2) [1080]	0.8 (0.2) [1600]	< 0.01
EQ VAS (0–100)	68.6 (21.4) [1127]	72.1 (21.1) [1663]	< 0.01
WPAI domains			
Current employment, n/m (%)	678/1109 (61.1)	1003/1636 (61.3)	0.93
% Work time missed	5.9 (16.9) [575]	4.6 (14.9) [868]	0.26
% Impairment while working	20.3 (23.8) [605]	18.1 (23.1) [929]	0.02
% Overall work impairment	23.2 (26.1) [540]	20.5 (25.3) [839]	0.02
% Activity impairment	32.5 (30.2) [1026]	26.6 (28.0) [1543]	< 0.01

EQ-5D, EuroQol 5 Dimensions questionnaire; HAQ-DI, Health Assessment Questionnaire Disability Index; MDA, minimal disease activity; PsO, psoriasis; VAS, visual analog scale; WPAI, Work Productivity and Activity Impairment questionnaire.

* All values were calculated based on available data and are presented as "mean (SD) [n]" unless otherwise stated.

† t-test or Wilcoxon rank-sum test for continuous variables and χ^2 or Fisher's exact test for categorical variables.

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SAT0389

INHIBITION OF RADIOGRAPHIC PROGRESSION WAS ACHIEVED WITH INTRAVENOUS GOLIMUMAB IN ACTIVE PSA PATIENTS REGARDLESS OF CHANGES IN COMPOSITE INDICES OF DISEASE ACTIVITY IN A PHASE III TRIAL

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Background: GO-VIBRANT is a Phase 3 trial of intravenous (IV) golimumab (GLM), an anti-tumor necrosis factor alpha (TNF α) monoclonal antibody, in adult patients (pts) with active psoriatic arthritis (PsA).

Objectives: To assess if changes in Disease Activity in PsA (DAPSA), PsA Activity Score (PASDAS), Minimal Disease Activity (MDA), Very Low Disease Activity (VLDA), and Clinical Disease Activity Index (CDAI) measures correlate with X-ray progression.

Methods: In this multicenter, randomized, double-blind, placebo (PBO)-controlled trial, 480 bionative PsA pts with active disease (≥ 5 swollen & ≥ 5 tender joints, C-reactive protein ≥ 0.6 mg/dL, active plaque psoriasis or documented history despite treatment w/csDMARDs &/or NSAIDs) received IV GLM 2mg/kg (N=241) at Wks0/4 then q8wks or PBO (N=239) at Wks0/4/12/20 with crossover to GLM at Wk24. In a post-hoc analysis, association of disease activity measures DAPSA, PASDAS, MDA, VLDA, & CDAI with X-ray progression was examined. Total modified van der Heijde-Sharp (vdH-S) score assessed X-ray progression at Wks 0/24/52. Last observation carried forward imputation was used for partially missing data & non-responder imputation for missing data. Nominal p-values are reported without multiplicity adjustment.

Results: Mean changes from baseline in vdH-S scores were lower with GLM than PBO at Wk24 (-0.36 vs 1.95, respectively, p<0.001) and at Wk52 after crossover from PBO to GLM arm (-0.49 vs 0.76). Changes in all disease activity measures appeared to correlate with X-ray progression (Table). GLM-treated pts had less X-ray progression regardless of disease activity measure. GLM treated pts in remission or with low disease activity tended to have less X-ray progression at Wk52 vs pts with moderate or high disease activity (mean change in vdH-S: DAPSA remission or low disease activity -0.88, moderate activity -0.48, high disease activity 0.41). Similar patterns were seen with PASDAS and CDAI (Table). Irrespective of level of disease activity, GLM-treated pts from Wk 0-52 tended to have less X-ray progression vs PBO-treated pts who switched to GLM at Wk24 (mean change in vdH-S 0-52 wk GLM vs PBO→GLM: DAPSA remission or low disease activity -0.88 vs 1.49, moderate activity -0.48 vs 1.38, high disease activity 0.41 vs 1.27).

Interestingly, pts treated with GLM who did not achieve MDA or VLDA by Wk52 also tended to have less X-ray progression vs PBO pts (mean change no MDA GLM 0.03 vs PBO 1.50; p=0.0011 and mean change no VLDA GLM -0.30 vs PBO 1.45; p<0.0001).

Conclusion: In this analysis, all disease activity measures generally correlated with X-ray progression from baseline to Wk24 and to Wk52. Higher disease activity was associated with increased X-ray progression. GLM-treated pts not achieving MDA & VLDA at Wk52 tended to have less X-ray progression vs PBO→GLM pts. GLM's ability to inhibit X-ray progression, despite pts not being in clinical remission or low disease activity, illustrates an example of "disconnect" between clinical outcomes & X-ray progression seen in other studies.

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