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
WPAl 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; WPAl, 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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Table. Mean change from baseline (SD) in total modified vdH-S score stratified by CDAL, DAPSA, PASDAS, MDA, and VLDA in PsA patients from GO-VIBRANT				
	Baseline to Wk24		Baseline to Wk52	
	PBO	GLM 2 mg/kg	PBO→GLM 2*	GLM 2 mg/kg
DAPSA				
Remission-low disease activity (≤14), n	10	107	105	119
Mean change (SD)	-0.05±2.14	-0.64±1.66	1.49±4.96	-0.88±2.34
p-value		0.4422		<0.001
Moderate disease activity (>14–28), n	37	59	66	64
Mean change (SD)	0.29±1.81	-0.32±1.54	1.38±4.16	-0.48±1.82
p-value		0.0268		0.0025
Active disease activity (>28), n	190	71	66	54
Mean change (SD)	1.77±3.56	0.21±1.97	1.27±4.36	0.41±3.30
p-value		0.0007		0.2598
PASDAS				
Inactive disease activity (≤3.2), n	12	101	114	118
Mean change (SD)	-0.17±2.136	-0.64±1.729	1.53±4.850	-1.01±2.384
p-value		0.4305		<0.0001
Moderate disease activity (>3.2 & ≤5.4), n	85	109	83	83
Mean change (SD)	0.73±1.926	-0.16±1.750	1.14±3.727	-0.20±1.965
p-value		0.0003		0.0055
High disease activity (≥5.4), n	125	22	19	17
Mean change (SD)	2.29±4.107	0.47±1.891	3.81±7.052	0.54±3.066
p-value		0.0290		0.1122
MDA				
Yes, n	11	78	80	101
Mean change (SD)	0.91±2.49	-0.83±1.78	1.19±3.86	-1.16±2.46
p-value		0.0232		<0.0001
No, n	226	159	157	136
Mean change (SD)	1.49±3.39	-0.26±1.70	1.50±4.90	0.03±2.44
p-value		<0.0001		0.0011
VLDA				
Yes, n	1	16	24	35
Mean change (SD)	0	-0.91±1.04	0.91±3.32	-1.49±2.22
p-value		0.3749		0.0041
No, n	236	221	213	202
Mean change (SD)	1.47±3.36	-0.26±1.80	1.45±4.69	-0.30±2.52
p-value		<0.0001		<0.0001
CDAL				
Remission (≤2.8), n	5	43	58	63
Mean change (SD)	-0.60±1.34	-0.80±1.76	1.52±5.55	-1.06±2.41
p-value		0.9170		0.0003
Low disease activity (>2.8 & ≤10), n	28	98	78	92
Mean change (SD)	0.77±2.01	-0.41±1.43	1.21±3.59	-0.81±2.12
p-value		0.0011		<0.0001
Moderate disease activity (>10 & ≤22), n	67	66	64	69
Mean change (SD)	0.88±2.73	-0.10±2.04	1.32±4.25	0.20±2.82
p-value		0.0429		0.0905
High disease activity (>22), n	137	30	37	13
Mean change (SD)	1.96±3.79	0.30±1.95	1.75±5.34	1.11±2.65
p-value		0.0079		0.2144

CDAL=Clinical Disease Activity Index; DAPSA=Disease Activity in Psoriatic Arthritis score; GLM=golimumab; MDA=Minimal Disease Activity; PBO=placebo; PASDAS=Psoriatic Arthritis Activity Score; PsA=active psoriatic arthritis; SD=standard deviation; vdH-S=van der Heijde-Sharp; VLDA=Very Low Disease Activity
 *PBO pts crossed over to IV GLM 2 mg/kg at Wk24.
 †P-value is based on ANOVA w/ Van der Waerden rank test

Inc., Janssen, Lilly, Novartis, Pfizer, SUN and UCB, Speakers bureau: AbbVie, Amgen, BMS, Celgene, Genentech, Janssen, Lilly, Novartis, Pfizer and UCB, M Elaine Husni Grant/research support from: Janssen, Shelly Kafka Shareholder of: J&J, Employee of: J&J, Soumya D Chakravarty Shareholder of: Johnson & Johnson, Employee of: Johnson & Johnson, Diane D Harrison Employee of: Janssen Research & Development, LLC, Kim Hung Lo Employee of: Janssen Research & Development, LLC, Stephen Xu Employee of: Employee of Janssen Research & Development, LLC, Elizabeth C Hsia Employee of: Employee of Janssen Research & Development, LLC, Arthur Kavanaugh Grant/research support from: UCB Pharma

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SAT0390

GUSELKUMAB WAS MORE EFFECTIVE THAN SECUKINUMAB IN PATIENTS WITH PLAQUE PSORIASIS AND THE SUBSET OF PATIENTS WITH SELF-REPORTED PSORIATIC ARTHRITIS IN THE RANDOMIZED, DOUBLE-BLIND, HEAD-TO-HEAD COMPARISON STUDY ECLIPSE OVER 1 YEAR

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Background: Guselkumab (GUS, an antibody against IL-23) and secukinumab (SEC, an antibody against IL-17A) are both approved for the treatment of psoriasis (PsO). Up to 30% of patients with PsO may have psoriatic arthritis (PsA).

Objectives: The ECLIPSE study compared efficacy and safety of GUS vs SEC in patients with plaque PsO. Post hoc analyses examined outcomes in the subgroup of patients with self-reported psoriatic arthritis (PsA).

Methods: ECLIPSE was a randomized, double-blind trial of adults with moderate-to-severe plaque PsO who received GUS 100 mg at Weeks 0, 4, then every 8 weeks, or SEC 300 mg at Weeks 0, 1, 2, 3, and 4, then every 4 weeks, both through Week 44. The primary endpoint was

the proportion of patients achieving ≥90% improvement compared to baseline in the Psoriasis Area and Severity Index (PASI) score at Week 48. Cochran-Mantel Haenszel chi-square testing stratified by investigator was used to compare treatment-group responses.

Results: Overall, treatment groups [GUS (n=534), SEC (n=514)] were comparable at baseline: weight 89kg, 24% body surface area PsO, and Investigator Global Assessment (IGA) moderate (76%) or severe (24%). These characteristics were similar to those of subgroups with self-reported PsA [GUS (n=97), SEC (n=79)]. In the overall population, the primary endpoint of PASI 90 response at Week 48 was achieved by 84.5% of GUS vs 70.0% of SEC patients (treatment difference 14.2 [95% CI=9.6%,18.8%], P<0.001). Among patients with PsA, the primary endpoint of PASI 90 response at Week 48 was achieved by 82.5% of GUS vs 63.3% of SEC patients (treatment difference 19.2% [95% CI=5.0%, 33.4%]). Beyond week 20, in both the overall study population and the PsA subpopulation, GUS-treated patients maintained the PASI 90 response while SEC-treated patients had a reduction in response through week 48 (Figure). In the overall population, results of the first major secondary endpoint (proportion of patients with a PASI 75 response at both Week 12 and 48) showed non-inferiority of GUS vs SEC (GUS-84.6% vs SEC-80.2% of patients, p<0.001), but superiority was not demonstrated (p=0.062). Adverse events observed in the overall population and PsA subgroup were generally consistent with the established safety profiles for GUS and SEC.

Conclusion: In the subset of patients with self-reported PsA in the ECLIPSE study, GUS demonstrated better maintenance of response and higher efficacy at approximately one year compared with SEC in the treatment of moderate to severe plaque PsO. These findings were consistent with those for the overall study population of patients with plaque PsO. AEs observed were generally consistent with the established safety profiles for GUS and SEC.

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Figure. Proportion of Patients Achieving PASI 90 Response (95% CI)

Non-responder imputation was used for missing data.
 CI=Confidence interval, PASI 90=90% improvement in the Psoriasis Area and Severity Index (PASI).