fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-F] scale), & 36-item Short Form Health Survey (SF-36) physical & mental component summary (PCS & MCS) scores & weakly correlated with other variables (Figure 1). Based on univariate analyses ($p < 0.20$) & evaluation of collinearity between variables, attributes at W0 & W24 included in the multivariate models were age, sex, CRP, FACIT-F, pain, psoriasis area & severity index (PASI) score, TJC, SJC, enthesitis, & dactylitis. In the final model, CRP, FACIT-F, pain, PASI score, & the presence of dactylitis were significantly associated with EQ-5D-5L index & EQ-VAS scores. A higher TJC was significantly associated with a worse EQ-5D-5L index score. A higher SJC was significantly associated with a worse EQ-VAS score (Table 1). For reference, in the GUS Q4W (N=244), GUS Q8W (N=246), & PBO (N=244) groups, the LS mean changes from baseline at W24 were 0.12, 0.12, & 0.05, respectively, for EQ-5D-5L index & 18.1, 18.4, & 6.8, respectively, for EQ-VAS.

Conclusion: Joint & skin symptoms, dactylitis, fatigue, pain, & elevated levels of CRP were significantly associated with reduced HRQoL (measured by EQ-5D-5L index & EQ-VAS) in bio-naïve pts with active PsA. Treatment of multiple PsA domains may help optimize HRQoL. Improvement across clinical domains¹ & in HRQoL has been observed in GUS-treated pts with PsA.

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Figure. Spearman correlations between BL pt characteristics/clinical features & BL EQ-5D-5L index & EQ-VAS scores at W0

Table 1. Multivariate analysis of pt characteristics/clinical features & EQ-5D-5L index & EQ-VAS scores at W0 & W24

Parameter	EQ-5D-5L Index		EQ-VAS	
	Estimate	p value	Estimate	p value
Age (y)	-0.0001	0.69	0.06	0.12
Female	-0.003	0.53	1.11	0.20
CRP (mg/dL)	-0.005	<0.001	-0.51	0.007
FACIT-F (0-52)	0.007	<0.001	0.57	<0.001
Pain (0-10)	-0.02	<0.001	-3.47	<0.001
PASI (0-72)	-0.001	0.03	-0.17	<0.001
SJC (0-66)	-0.001	0.21	-0.17	0.02
TJC (0-68)	-0.001	0.04	-0.04	0.41
Dactylitis (Y/N)	0.01	0.02	1.74	0.49
Enthesitis (Y/N)	-0.004	0.33	-0.98	0.22

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Research & Development, LLC, May Shawi Shareholder of: Johnson & Johnson, Employee of: Janssen Global Services, LLC, William Tillett Speakers bureau: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Consultant of: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, MSD, Pfizer, and UCB, Grant/research support from: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, Pfizer, SUN, and UCB, Proton Rahman Speakers bureau: AbbVie, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Consultant of: AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, Roche, and UCB, Grant/research support from: Janssen and Novartis.

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POS1029

GUSELKUMAB-TREATED PATIENTS WITH PSORIATIC ARTHRITIS ACHIEVED CLINICALLY MEANINGFUL IMPROVEMENTS IN GENERAL HEALTH OUTCOMES MEASURED WITH PROMIS-29 THROUGH 52 WEEKS: RESULTS FROM THE PHASE 3 DISCOVER-1 TRIAL

A. M. Orbai¹, L. C. Coates², A. Deodhar³, P. Helliwell⁴, C. T. Ritchlin⁵, A. Kollmeier⁶, E. C. Hsia^{6,7}, X. L. Xu⁶, S. Sheng⁸, Y. Jiang⁸, Y. Liu⁶, C. Han⁶.
¹Johns Hopkins University School of Medicine, Psoriatic Arthritis Program, Baltimore, United States of America; ²Oxford University, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom; ³Oregon Health & Science University, Division of Arthritis and Rheumatic Diseases, Portland, United States of America; ⁴University of Leeds, Leeds Institute of Rheumatic and Musculoskeletal Medicine, Leeds, United Kingdom; ⁵University of Rochester Medical Center, Department of Medicine, Allergy/Immunology and Rheumatology, Rochester, United States of America; ⁶Janssen Research & Development, LLC, Immunology, Spring House, United States of America; ⁷University of Pennsylvania School of Medicine, Rheumatology, Philadelphia, United States of America; ⁸Janssen Research & Development, LLC, Biostatistics, Spring House, United States of America

Background: In the DISCOVER-1 study, the interleukin-23 p19 subunit inhibitor guselkumab (GUS) demonstrated robust efficacy across joint and skin clinical manifestations of psoriatic arthritis (PsA).¹ Patients (pts) with PsA also experience a broad range of symptoms that negatively impact health-related quality of life (eg, pain, fatigue, anxiety, depression, sleep disturbance, poor physical function).²

Objectives: Assess the treatment effect of GUS on general health outcomes in pts with PsA in the DISCOVER-1 trial through Week (W) 52 using the Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29) instrument.

Methods: Pts with active PsA (≥ 3 swollen + ≥ 3 tender joints; C-reactive protein ≥ 0.3 mg/dL) and inadequate response to standard conventional therapies were randomized 1:1:1 to GUS 100 mg Q4W; GUS 100 mg at W0, W4, then Q8W; or placebo (PBO). PBO pts switched to GUS 100 mg Q4W at W24. PROMIS-29 contains 4 items for each of 7 domains (anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, social participation) and 1 pain intensity item; 28 items are scored on a 5-point Likert-type scale, and pain intensity is rated from 0-10. The raw score of each domain is converted to a standardized T-score, with norms based on a general population mean score=50 and a standard deviation (SD)=10. Higher scores in anxiety, depression, fatigue, pain interference, and sleep disturbance indicate more severe symptoms; higher physical function and social participation scores indicate better health outcomes. Changes ≥ 5 points (1/2 SD of T-score) are considered clinically meaningful. Analyses were performed using both observed (mean scores/changes, effect sizes) and imputed (clinically meaningful response, whereby change from baseline was set to 0 at W24/52 for pts who had missing data or at W24 for pts who met treatment failure criteria prior to W24).

Results: At baseline, mean PROMIS-29 T-scores for physical function, social participation, sleep disturbance, pain, and fatigue were worse in the 381 PsA pts enrolled in DISCOVER-1 than in the general US population. Across all 7 domains, observed mean PROMIS-29 T-scores showed improvements in GUS-treated pts from baseline to W24 and W52 (Figure 1). Observed mean changes from baseline to W24 and W52, with calculated effect size, are shown (Table 1). In all pts, including those with imputed data, significantly higher percentages of pts in both GUS treatment groups vs PBO had ≥ 5 -point improvements in fatigue, pain interference, physical function, sleep disturbance, social participation, and pain intensity domains at W24 (all nominal $p < 0.05$). Mean improvements in PROMIS-29 domains were maintained through W52.

Conclusion: In pts with active PsA, PROMIS-29 results indicate that GUS treatment was associated with clinically meaningful reductions in fatigue and pain and improvement in physical function and social participation, which were maintained through 1 year.

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Figure. Mean PROMIS-29 T-scores at Baseline, W24, and W52 (Observed Data)* **Table 1. Mean Change and Effect Size of Change From Baseline in PROMIS-29 Domain Scores at W24 and W52 (Observed)**

	Mean Change From Baseline [Effect Size]					
	GUS Q4W		GUS Q8W		PBO W0-24	GUS Q4W W24-52
	W24	W52	W24	W52	W24	W52
Anxiety	-3.1 [-0.3]	-3.1 [-0.3]	-3.7 [-0.4]	-4.3 [-0.5]	-1.5 [-0.2]	-3.6 [-0.4]
Depression	-2.7 [-0.3]	-3.0 [-0.4]	-4.0 [-0.4]	-4.0 [-0.4]	-0.6 [-0.1]	-2.5 [-0.3]
Fatigue	-4.8 [-0.5]	-5.6 [-0.6]	-4.8 [-0.5]	-6.8 [-0.7]	-2.1 [-0.2]	-5.7 [-0.6]
Pain interference	-5.4 [-0.8]	-6.2 [-1.0]	-5.8 [-1.0]	-7.0 [-1.1]	-2.8 [-0.4]	-6.3 [-1.0]
Physical function	5.0 [0.8]	5.9 [0.9]	4.1 [0.6]	5.0 [0.7]	1.7 [0.2]	4.2 [0.6]
Sleep disturbance	-2.5 [-0.4]	-3.9 [-0.6]	-3.8 [-0.6]	-4.4 [-0.6]	-1.5 [-0.2]	-3.3 [-0.5]
Social participation	4.2 [0.5]	5.3 [0.7]	5.3 [0.6]	6.6 [0.8]	1.7 [0.2]	4.9 [0.6]
Pain intensity*	-2.3 [-1.2]	-2.8 [-1.5]	-2.1 [-1.1]	-2.7 [-1.4]	-0.7 [-0.4]	-2.5 [-1.3]

*Raw score; all other domains reported as T-score.

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POS1030

EFFICACY OF UPADACITINIB IN PATIENTS WITH PSORIATIC ARTHRITIS STRATIFIED BY BASELINE SKIN SEVERITY: A SUBGROUP ANALYSIS OF TWO PHASE III TRIALS

J. F. Merola^{1,2}, P. Richette³, E. Lubrano⁴, E. Drescher⁵, L. Soto⁶, C. Lovan⁷, K. Kato⁷, R. Lippe⁸, M. Lane⁷, M. Kishimoto⁹. ¹Brigham and Women's Hospital, Division of Rheumatology, Immunology and Allergy, Boston, United States of America; ²Harvard Medical School, Division of Rheumatology, Boston, United States of America; ³Hopital Lariboisiere Centre Viggo Petersen and Inserm UMR1132 Bioscar, Université Paris Diderot UFR de Médecine, Service de Rhumatologie, Paris, France; ⁴University of Molise, Department of Medicine and Health Sciences Vincenzo Tiberio, Campobasso, Italy; ⁵Veszprém Csoknoky Ferenc County Hospital, Veszprém, Hungary; ⁶Universidad de Chile, Facultad de Medicina, Santiago, Chile; ⁷AbbVie, Immunology, North Chicago, United States of America; ⁸AbbVie Deutschland GmbH & Co. KG, Immunology, Wiesbaden, Germany; ⁹Kyōrin University School of Medicine, Department of Nephrology and Rheumatology, Tokyo, Japan

Background: In the SELECT-PsA 1 and 2 clinical trials, upadacitinib (UPA) demonstrated efficacy and safety in patients (pts) with active psoriatic arthritis (PsA).^{1,2} PsA is associated with varying degrees of psoriatic symptoms; however, the impact of skin severity on treatment outcomes is not well understood.

Objectives: This post-hoc analysis assessed the effects of baseline skin severity on UPA efficacy.

Methods: SELECT-PsA 1 and SELECT-PsA 2 enrolled pts with PsA and prior inadequate response (IR) or intolerance to ≥1 non-biologic disease-modifying antirheumatic drug (DMARD)¹ or ≥1 biologic DMARD², respectively. In both trials, pts received once daily UPA 15 mg or UPA 30 mg or placebo (switched at Wk 24 to either UPA 15 mg or 30 mg); SELECT-PsA 1 also included the active comparator adalimumab (ADA). Only continuous UPA 15 mg and ADA are presented here. In this analysis, pts were divided into subgroups based on the extent of psoriasis at baseline (body surface area [BSA] of ≥3%–<10% or BSA ≥10%); efficacy endpoints were analyzed at Wk 56. Results for binary endpoints are based on non-responder imputation; continuous endpoints are based on mixed model repeated measures analysis with as-observed data.

Results: In the UPA 15 mg and ADA groups, respectively, 32% (138/429) and 31% (132/429) of pts had a BSA ≥3%–<10% at baseline in SELECT-PsA 1; 18% (76/429) in each treatment group had a BSA ≥10%. In SELECT-PsA 2, 38% (80/211) had a BSA ≥3%–<10% and 24% (50/211) had a BSA ≥10% at baseline in the UPA 15 mg group. Across pt populations (non-biologic DMARD-IR and biologic DMARD-IR), generally consistent results were observed between patients in both skin severity subgroups (Figure 1). In non-biologic DMARD-IR pts, a numerically greater proportion of UPA 15 mg pts with lower skin involvement compared with higher skin involvement achieved PASI100 and PASI≤1, two more stringent

Figure. Efficacy Outcomes at Week 56 Stratified by the Severity of Skin Involvement at Baseline

MDA was determined by fulfilling 5 of 7: TJC ≤1; SJC ≤1; PASI ≤1 or BSA-psoriasis ≤3; patient assessment of pain ≤1.5 (0-10 NRS); PGA disease activity ≤2 (0-10 NRS); HAQ-DI score ≤0.5, and LEI ≤1.

ADA, adalimumab; BL, baseline; BSA, body surface area; CI, confidence interval; EOW, every other week; HAQ-DI, Health Assessment Questionnaire-Disability Index; LEI, Leeds Enthesitis Index; MDA, minimal disease activity; NRS, numeric rating scale; PASI75/90/100, ≥75%/90%/100% improvement in Psoriasis Area Severity Index; QD, once daily; SAPS, Self-Assessment of Psoriasis Symptoms; SJC, swollen joint count; TJC, tender joint count; UPA, upadacitinib.