improvement in the American College of Rheumatology (ACR 20) criteria. Relationships between FACIT-Fatigue and HAQ-DI at W8/W16/24 were assessed by Pearson correlation coefficients. Mean changes in HAQ-DI scores at W8/W16/24 were summarized in FACIT-Fatigue responders and nonresponders. A logistic regression model was applied to estimate odds ratios (ORs) for achievement of HAQ-DI and ACR 20 response by FACIT-Fatigue response status at each visit. A multiple linear regression model was used to evaluate the association between FACIT-Fatigue and HAQ-DI at W24 after adjusting for SJC, TJC, CRP, and pt assessment of pain.

Results: FACIT-Fatigue and HAQ-DI scores and changes from baseline were negatively correlated at W8, W16, and W24 (Table 1). Mean changes in HAQ-DI were -0.31, -0.43, and -0.48 at W8, W16, and W24, respectively, in FACIT-Fatigue responders and -0.06, -0.07, and -0.09, respectively, in FACIT-Fatigue nonresponders. FACIT-Fatigue responders were significantly more likely than nonresponders to achieve HAQ-DI and ACR 20 response (OR [95% CI] at W8, 2.8 [2.2-3.7] and 2.4 [1.9-3.1]; at W16, 3.6 [2.8-4.7] and 2.9 [2.3-3.7]; and at W24, 4.4 [3.4-5.7] and 3.2 [2.5-4.2], respectively; Figure 1). Correlations between FACIT-Fatigue and HAQ-DI remained significant after adjusting for SJC, TJC, CRP, and pt assessment of pain.

Conclusion: In pts with PsA, fatigue response is a clinically meaningful predictor of improvements in physical function and achievement of ACR 20 response, reinforcing the importance of assessing fatigue in PsA disease management.

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Table 1. Correlation* of FACIT-Fatigue and HAQ-DI

Visit	HAQ-DI and FACIT Fatigue Scores	Changes From Baseline in HAQ-DI and FACIT-Fatigue Scores
W8	-0.61 (p<0.0001)	-0.42 (p<0.0001)
W16	-0.60 (p<0.0001)	-0.47 (p<0.0001)
W24	-0.62 (p<0.0001)	-0.50 (p<0.0001)

*Determined by Pearson correlation coefficient; p-values derived from hypothesis tests of correlation $\rho=0$ (ie, no correlation).

Figure. HAQ-DI and ACR 20 Responders by FACIT-Fatigue Responder Status (Y/N)

Figure 1

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AB0528

COMPARABLE SAFETY PROFILE OF GUSELKUMAB IN PSORIATIC ARTHRITIS AND PSORIASIS: RESULTS FROM PHASE 3 TRIALS THROUGH 1 YEAR

A. B. Gottlieb¹, J. F. Merola², A. Armstrong³, R. Langley⁴, M. Lebwohl¹, C. E. M. Griffiths⁵, M. Shawi⁶, Y. W. Yang⁶, E. C. Hsia^{7,8}, A. Kollmeier⁹, X. L. Xu⁹, M. Izutsu⁹, P. Ramachandran¹⁰, S. Sheng¹¹, Y. You¹¹, M. Miller¹⁰, C. T. Ritchlin¹², I. McInnes¹³, P. Rahman¹⁴, ¹Icahn Medical School/Mount Sinai, Department of Dermatology, New York, United States of America; ²Brigham and Women's Hospital, Harvard Medical School, Dermatology, Rheumatology, Immunology and Allergy, Boston, United States of America; ³Keck School of Medicine, University of Southern California, Clinical Research, Los Angeles, United States of America; ⁴Dalhousie University, Division of Clinical Dermatology & Cutaneous Science, Halifax, Canada; ⁵The University of Manchester, Manchester Centre for Dermatology Research, Manchester, United Kingdom; ⁶Janssen Global Services, LLC, Immunology, Horsham, United States of America; ⁷University of Pennsylvania School of Medicine, Rheumatology, Philadelphia, United States of America; ⁸Janssen Research & Development, LLC, Immunology, Spring House, United States of America; ⁹Janssen Research & Development, LLC, Immunology, San Diego, United States of America; ¹⁰Janssen Research & Development, LLC, Immunology, Spring House, United States of America; ¹¹Janssen Research & Development, LLC, Biostatistics, Spring House, United States of America; ¹²University of Rochester, Department of Medicine, Allergy/Immunology and Rheumatology, Rochester, United States of America; ¹³University of Glasgow, Institute of Infection Immunology and Inflammation, Glasgow, United Kingdom; ¹⁴Memorial University of Newfoundland, Craig L Dobbin Genetics Research Centre, St. John's, Canada

Background: DISCOVER 1&2 (PsA) and VOYAGE 1&2 (PsO) are Phase 3 trials of guselkumab (GUS).

Objectives: Compare safety results through up to 1yr of GUS in PsA and PsO pts.

Methods: In DISCOVER, 1120 pts with active PsA despite standard therapy were treated. Most pts were biologic-naïve; ~30% in DISCOVER 1 had previous exposure to 1-2 TNFi. Concomitant MTX (57%), oral corticosteroids (17%), and NSAIDs (64%) were permitted. Pts were randomized to SC GUS 100mg at W0, W4, then Q8W; GUS 100mg Q4W; or PBO. At W24, PBO patients were switched to GUS 100mg Q4W. In VOYAGE, in which concomitant MTX use was prohibited, 1245 pts with moderate to severe PsO were treated and randomized to SC GUS 100mg at W0, W4, W12, then Q8W; or PBO at W0, W4, W12, with crossover to GUS at W16, W20, then Q8W. AEs and laboratory parameters, analyzed by National Cancer Institute-Common Terminology Criteria for AEs [NCI-CTCAE] toxicity grades, were summarized through the PBO-controlled periods and 1yr.

Results: Safety profiles were generally consistent across the GUS PsO and PsA clinical programs (Table 1). Time-adjusted incidence rates for numbers of AEs, serious AEs, serious infections, malignancy, MACE and AEs leading to d/c were generally similar between PsO and PsA. No cases of anaphylaxis or opportunistic infections were reported. Proportions of pts with decreased neutrophil counts and elevations in hepatic transaminases were slightly higher in PsA vs PsO. These abnormalities were mostly of NCI-CTCAE Grade 1 or 2 (<LLN-1000/mm³ for neutrophils; <5.0 x ULN for AST/ALT), generally transient, required no medical interventions, resolved spontaneously, and did not lead to interruption or d/c of treatment. Through 1yr, proportions of pts with ALT/AST elevations in PsA trials were slightly higher for GUS Q4W than Q8W and in pts with vs without baseline MTX use.

Conclusion: The GUS safety profile was generally consistent in PsA and PsO GUS-treated pts through 1yr of the DISCOVER and VOYAGE trials.

Table 1. Treatment-Emergent AEs During PBO-controlled Period and Through 1Yr: VOYAGE & DISCOVER Trials

Time Period	Pooled VOYAGE 1&2				Pooled DISCOVER 1&2				
	W0-16	Through 1Yr	W0-24 ^b	Through 1Yr	W0-24 ^b	Through 1Yr	W0-24 ^b	Through 1Yr	W0-24 ^b
(N=)	PBO (422)	GUS Q8W (823)	Combined GUS ^a (1221)	PBO ^c (372)	GUS Q8W (375)	GUS Q4W (373)	GUS Q8W (375)	GUS Q4W (373)	Combined GUS† (1100)
Total pt-yrs of follow-up	128	255	974	173	173	172	384	385	973
Incidence/100 pt-yrs (95% CI) ^d									
AEs	317 (287,349)	330 (308,353)	259 (249, 270)	219 (198,243)	256 (232,281)	221 (200, 245)	218 (203,233)	177 (164,191)	191 (182, 199)
SAEs	5 (2, 10)	6 (4, 10)	6 (5, 8)	9 (5, 15)	4 (2, 8)	5 (2, 10)	6 (4, 9)	4 (2, 7)	6 (4, 7)
AEs leading to study agent d/c	3 (0.9, 8)	4 (2, 8)	2 (2, 4)	4 (2, 8)	3 (1, 7)	7 (4, 12)	2 (1, 4)	4 (2, 6)	3 (2, 5)
Infections	86 (71, 104)	98 (86, 111)	98 (92, 104)	58 (48, 71)	58 (47, 71)	63 (51, 76)	58 (50, 66)	53 (46, 61)	55 (50, 60)
Serious Infections	0.8 (0, 4)	0.4 (0, 2)	1 (0.5, 2)	4 (2, 8)	0.6 (0, 3)	2 (0.4, 5)	2 (0.6, 3)	1 (0, 2)	2 (0.9, 3)
All Malignancy	0 (0, 2)	0.4 (0, 2)	1 (0.4, 2)	0.6 (0, 3)	1 (0, 4)	0 (0, 2)	0.5 (0, 2)	0 (0, 0.8)	0 (0, 1)
MACE	0 (0, 2)	0.4 (0, 2)	0.4 (0, 1)	0.6 (0, 3)	0 (0, 2)	0.6 (0, 3)	0 (0, 0.8)	0.3 (0, 1.4)	0.1 (0, 0.6)
% pts with ≥1 injection site rxn	3.1	4.5	5.0	0.3	1.3	1.1	1.6	2.4	1.7

^aPlacebo crossover pts were included in the combined GUS column after crossover to GUS^bFor all pts who d/c study treatment early with the last dose of PBO/GUS prior to W24 and who did not receive any PBO/GUS at or after Wk24, all data including the final safety follow-up visit collected through 1yr were included^cFor pts in PBO group who switched to GUS due to cross-over or inadvertently, only data prior to first administration of GUS were included.^dCI based on an exact method assuming observed number of events follows a Poisson distribution

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AB0529

CHARACTERIZATION OF REMISSION IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH UPADACITINIB: POST-HOC ANALYSIS FROM TWO PHASE 3 TRIALS

P.J. Mease¹, A. Kavanaugh², D. D. Gladman³, O. Fitzgerald⁴, E. Soriano⁵, P. Nash⁶, D. Feng⁷, A. Lertratanakul⁷, K. Douglas⁷, R. Lippe⁸, L. Gossec⁹.
¹Department of Rheumatology, Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, United States of America;
²University of California San Diego, Rheumatology, San Diego, United States of America;
³Krembil Research Institute, Toronto Western Hospital, University Health Network, Division of Rheumatology, Department of Medicine, and Institute of Medical Science, University of Toronto, Toronto, Canada;
⁴Conway Institute for Biomolecular Research, University College, Dublin, Ireland;
⁵Internal Medicine Services, Hospital Italiano de Buenos Aires and Instituto Universitario Italiano, Buenos Aires, Argentina;
⁶School of Medicine, Griffith University, Brisbane, Australia;
⁷AbbVie Inc, Rheumatology, North Chicago, United States of America;
⁸AbbVie, Deutschland GmbH & Co. KG, Wiesbaden, Germany;
⁹Sorbonne Université and Rheumatology Department, Hôpital Pitié Salpêtrière, Paris, France

Background: For patients (pts) with PsA, several disease activity measures are available including very low/minimal disease activity (VLDA/MDA), cutoffs based on the Disease Activity in PsA (DAPSA) score, and on the Psoriatic Arthritis Disease Activity Score (PASDAS) score.

Objectives: To assess the rates of pts achieving these remission or low disease activity (LDA) criteria at Wk 24 using data from the SELECT-PsA 1 and SELECT-PsA 2 phase 3 studies.^{1,2} Additionally, we assessed the distribution of individual MDA components among pts who did or did not achieve MDA criteria at Wk 24.

Methods: In SELECT-PsA 1 and SELECT-PsA 2, pts with PsA and prior inadequate response (IR) or intolerance to ≥1 non-biologic DMARD (N=1705) or ≥1 biologic DMARD (N=642), respectively, were randomized to once daily upadacitinib (UPA) 15mg, UPA 30mg, adalimumab (ADA) 40mg every other week (SELECT-PsA 1 only), or placebo (PBO). Remission and LDA were assessed using VLDA/MDA, DAPSA scores of ≤4/≤14, and PASDAS scores of ≤1.9/≤3.2, at Wk 24 (Table 1). Non-responder imputation (NRI) was used for handling missing data; pts rescued at Wk 16 were considered non-responders. Pairwise comparisons between UPA doses and PBO or ADA were conducted using the Cochran-Mantel-Haenszel test.

Results: Overall, 2345 pts were analyzed; mean age 51 years, 53% female. In both studies, higher rates of remission and LDA were observed with both UPA doses vs PBO at Wk 24 (nominal P-values <0.05 for both time points; Table 1). Generally, higher rates of remission and LDA were also observed with UPA30 vs ADA in non-biologic DMARD-IR pts (nominal P-values <0.05). Greater rates of MDA/VLDA were observed at Wk 24 with UPA15 and UPA30 vs PBO in both studies and with UPA30 vs ADA in non-biologic DMARD-IR pts (nominal P-values <0.05 for all comparisons). The proportion of responder or non-responder pts receiving UPA15 or UPA30 was similar for each of the MDA components in both studies. At Wk 24, more responder and non-responder pts in both studies achieved Swollen Joint Count (SJC) 66 ≤1, Psoriasis Area and Severity Index (PASI) ≤1 or Body Surface Area-Psoriasis (BSA-Ps) ≤3%, and Leeds Enthesitis Index (LEI) ≤1 (Figure 1). Conversely, the proportion of pts Achieving Tender Joint Count (TJC) 68 ≤1 and Pt's Global Assessment of Pain ≤1.5 tended to be lower.