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BRIEF REPORT

Efficacy of Guselkumab in Treating Nails, Scalp, Hands, and Feet in Patients with Psoriasis and Self-reported Psoriatic Arthritis

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ABSTRACT

Introduction: The aim of this study was to evaluate guselkumab efficacy on regional psoriasis in a subset of psoriasis patients with a self-reported psoriatic arthritis (PsA) diagnosis.
Methods: In the phase 3 VOYAGE-1 and -2 studies, at week (W)0, patients with moderate-to-severe psoriasis were randomized to guselkumab 100 mg, placebo → guselkumab 100 mg at W16 through W44, or adalimumab 80 mg then 40 mg at W1 through W48 (VOYAGE-1) or W24 (VOYAGE-2). Pooled efficacy outcomes, including scalp-specific Investigator's Global Assessment (ss-IGA), hands and/or feet Physician's Global Assessment (hf-PGA), fingernail PGA (f-PGA), Nail Psoriasis Area and Severity Index (NAPSI), and Dermatology Life Quality Index (DLQI), were compared (nominal *p*-values) through W24 in patients with self-reported PsA diagnosis. Response rates/percentage improvement from baseline were determined, employing treatment failure rules and non-response/no improvement data imputation.
Results: A total of 76, 153, and 106 psoriasis patients with self-reported PsA were randomized to the placebo, guselkumab, or adalimumab groups, respectively; the baseline characteristics of patients in all three arms were comparable. At W16, a greater proportion of

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guselkumab- versus placebo-treated patients achieved ss-IGA 0/1 (80.6% vs. 22.7%, $p < 0.001$), hf-PGA 0/1 (68.9% vs. 14.8%, $p < 0.001$), f-PGA 0/1 (47.6% vs. 17.0%, $p < 0.001$), and DLQI 0/1 (45.6% vs. 2.7%, $p < 0.001$) responses; mean percentage NAPSI improvement was also greater with guselkumab (39.5% vs. 6.5%, $p < 0.001$). At W24, patients receiving guselkumab had higher ss-IGA 0/1 (77.5% vs. 58.5%, $p = 0.003$) and DLQI 0/1 (47.7% vs. 34.3%, $p = 0.024$) response rates versus those receiving adalimumab. Response rates/mean percentage improvements at W48 (VOYAGE-1) were numerically greater with guselkumab than adalimumab (e.g., NAPSI improvement: 75.6% vs. 60.9%).

Conclusions: Guselkumab-treated patients with psoriasis and self-reported PsA showed meaningful improvements in nail, scalp, and palmoplantar psoriasis.

Trial Registration: VOYAGE-1 (ClinicalTrials.gov Identifier: NCT02207231) and VOYAGE-2 (ClinicalTrials.gov Identifier: NCT02207244).

Keywords: Guselkumab; Nail psoriasis; Palmoplantar psoriasis; Psoriatic arthritis; Scalp psoriasis

Key Summary Points

Why carry out this study?

Guselkumab has demonstrated efficacy in moderate-to-severe psoriasis and across multiple domains of psoriatic arthritis (PsA), including skin and joint manifestations. Among patients with moderate-to-severe psoriasis, those treated with guselkumab have achieved significantly greater improvements in psoriasis involving difficult-to-treat body regions (nails, scalp, palms and/or soles).

Nail disease is a common manifestation of PsA and is associated with more active disease overall (including more swollen/tender joints, more severe skin disease, and increased pain and fatigue).

This post hoc analysis was performed to evaluate the efficacy of guselkumab in treating psoriasis of the nails, scalp, palms and/or soles in patients with PsA.

What were the study outcomes/conclusions?

In the subset of patients with moderate-to-severe disease and self-reported PsA diagnosis, guselkumab demonstrated meaningful improvements in psoriasis involving the nails, scalp, palms, and/or soles at week 16 of treatment compared with placebo, lessening the impact of psoriasis on health-related quality of life (HRQoL). Greater mean improvements in psoriasis of the nails, scalp, and palms and/or soles were observed with guselkumab through week 24 compared with adalimumab, and response rates were consistent at 1 year.

Guselkumab offers an effective treatment option with durable therapeutic benefits for patients with moderate-to-severe psoriasis and with psoriasis involving the nails, scalp, palms and/or soles, including patients with coexistent PsA. Improvement in psoriasis of these difficult-to-treat body regions is associated with better HRQoL. These findings should be considered when selecting a treatment for regional forms of psoriasis, which commonly affect patients with PsA.

INTRODUCTION

Psoriatic arthritis (PsA) is a heterogeneous chronic inflammatory disease characterized by skin and musculoskeletal involvement. Current treatment recommendations consider the six PsA domains: peripheral arthritis, axial disease,

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enthesitis, dactylitis, and skin and nail psoriasis [1]. Psoriasis of the nails, scalp, palms and/or soles is challenging to treat and has been associated with higher disease activity, poorer health-related quality of life (HRQoL), greater disability, and work impairment [2]. Patients with PsA and nail psoriasis tend to have more active disease overall (including more swollen/tender joints, more severe skin disease, and increased pain and fatigue) than those without nail involvement [3, 4].

Guselkumab, a fully human monoclonal antibody targeting the interleukin (IL)-23p19 subunit, is approved for adults with moderate-to-severe psoriasis and active PsA [5]. In the DISCOVER-1 (1 year) and DISCOVER-2 (2 year) studies, guselkumab demonstrated efficacy across multiple PsA domains (including arthritic joint signs and symptoms, psoriasis, enthesitis, and dactylitis) at week 24 compared with placebo; however, nail and regional psoriasis assessments were not performed [6, 7]. The VOYAGE-1 and VOYAGE-2 studies demonstrated superior efficacy of guselkumab in achieving complete skin clearance compared with placebo and adalimumab in patients with moderate-to-severe plaque psoriasis [8, 9]. Subsequent analyses demonstrated that guselkumab was efficacious in treating psoriasis of the nails, scalp, and palms and/or soles [10]. The present analysis evaluates the efficacy of guselkumab on regional psoriasis in a subgroup of VOYAGE-1 and -2 patients with self-reported PsA.

METHODS

Study Design

Details of the phase 3, randomized, double-blind, placebo- and active-controlled studies, VOYAGE-1, and VOYAGE-2, have been described [8, 9]. Both trials comprised placebo-controlled (weeks 0–16), placebo crossover (weeks 16–28), and active comparator-controlled (VOYAGE-1: weeks 0–48; VOYAGE-2: weeks 0–28) periods (Electronic Supplementary Material [ESM] Fig. S1). Patients were randomized to (1) guselkumab 100 mg at week 0, week 4, then every 8 weeks (Q8W) through week 44; (2) placebo at week 0, week 4, and week 12, followed by guselkumab 100 mg at weeks 16 and 20 then Q8W; or (3) adalimumab 80 mg at week 0, 40 mg at week 1, and Q2W thereafter through week 47 in VOYAGE-1 and week 23 in VOYAGE-2.

Patients

Adults diagnosed with plaque psoriasis for ≥ 6 months (with/without PsA) and Investigator's Global Assessment (IGA) score ≥ 3, Psoriasis Area and Severity Index (PASI) score ≥ 12, and ≥ 10% body surface area affected by psoriasis were eligible for VOYAGE-1 and VOYAGE-2 [8, 9]. Patients were excluded if they had ever received guselkumab or adalimumab or previously used tumor necrosis factor inhibitors other than adalimumab within 3 months or 5 half-lives of the first administration of study drug. Systemic immunosuppressants were permitted with prespecified washout periods [8, 9]. These post hoc analyses included a subgroup of patients from VOYAGE-1 and VOYAGE-2 with self-reported PsA (noted by the investigator via electronic case report form), rather than a confirmed PsA diagnosis by a dermatologist and/or rheumatologist.

These studies were conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practices. The governing ethical bodies for each of the participating sites approved the VOYAGE-1 and -2 study protocols, and all patients provided written informed consent.

Assessments

The co-primary endpoints in both studies were IGA 0/1 and ≥ 90% improvement in PASI (PASI90) at week 16. Nail disease and regional psoriasis were assessed using the fingernail Physician's Global Assessment (f-PGA), Nail Psoriasis Severity Index (NAPSI) [11], scalp-specific Investigator's Global Assessment (ss-IGA), and hand and/or foot PGA (hf-PGA). HRQoL was assessed using the Dermatology Life Quality Index (DLQI) [12]. Adverse event (AE)

reporting occurred throughout the studies [8, 9]. Additional details are reported in the ESM Methods.

Statistical Methods

In these post hoc analyses, data from patients with moderate-to-severe plaque psoriasis and self-reported PsA from VOYAGE-1 and VOYAGE-2 were pooled through week 24. Owing to differences in study design beyond week 28, only VOYAGE-1 week 48 data are reported. Through week 48, treatment failure rules were applied, and any remaining missing data were imputed as previously detailed [8, 9]. All *p*-values reported herein (week 16 and week 24) are nominal; statistical significance has not been established (see ESM Methods for additional details) [10].

Safety analyses included all patients who received ≥ 1 study drug administration and were reported through week 28 for the pooled population and through week 48 in VOYAGE-1.

RESULTS

Baseline Characteristics and Patient Disposition

Among the 1829 patients randomized in VOYAGE-1 and VOYAGE-2 [8, 9], 153, 106, and 76 in the guselkumab, adalimumab, and placebo arms, respectively, self-reported also having PsA (pooled PsA cohort). In this pooled population, baseline characteristics were consistent across treatment groups (ESM Table S1), and with the VOYAGE-1 PsA cohort ($N = 156$) (ESM Table S2). Compared with the overall study populations [8, 9], patients in the pooled PsA cohort had higher PASI and NAPSI scores and were more likely to have moderate or severe regional psoriasis (scores = 3 or 4). In the pooled PsA cohort, 35 patients discontinued study agent through week 28; 16 patients in VOYAGE-1 discontinued through week 48 (see ESM Results for additional details).

Efficacy

In the pooled PsA cohort, response rates for achieving IGA 0/1, PASI90, and IGA 0 were greater in the guselkumab versus the placebo group at week 16 and versus the adalimumab group at week 24 (ESM Fig. S2).

Greater proportions of patients in the guselkumab (47.6%) and adalimumab (46.4%) arms versus the placebo arm (17.0%), respectively, achieved f-PGA 0/1 (both nominal $p < 0.001$) and f-PGA 0 (10.7% and 14.5% vs. 6.4%) at week 16. Consistently, NAPSI 0 was achieved by 18.0%, 20.3%, and 6.0% of patients in the guselkumab, adalimumab, and placebo groups, respectively, and mean percentage improvements in NAPSI were 39.5%, 40.3%, and 6.5%, respectively (both nominal $p < 0.001$). Response rates and mean improvements continued to increase in both the guselkumab and adalimumab groups at week 24. Mean NAPSI nail bed and nail matrix scores were numerically lower in the guselkumab and adalimumab groups than in the placebo group at week 16 and were comparable between the guselkumab and adalimumab groups at week 24 (Fig. 1).

At week 16, 80.6%, 66.0%, and 22.7% of patients in the guselkumab, adalimumab, and placebo groups achieved ss-IGA 0/1 (both nominal $p < 0.001$); at week 24, 77.5% and 58.5% of patients in the guselkumab and adalimumab groups, respectively, achieved this response (nominal $p = 0.003$). An hf-PGA 0/1 response was achieved by 68.9%, 61.3%, and 14.8% of patients in the guselkumab, adalimumab, and placebo groups, respectively, at week 16 (both nominal $p < 0.001$) and by 66.7% and 58.1% of guselkumab and adalimumab patients, respectively, at week 24. Similar trends were observed for achievement of ss-IGA 0 and hf-PGA 0 (Fig. 2).

Greater proportions of guselkumab-treated (45.6%) and adalimumab-treated (30.5%) patients than placebo patients (2.7%) achieved DLQI 0/1 at week 16 (both nominal $p < 0.001$); at week 24, 47.7% and 34.3% of patients in the guselkumab and adalimumab groups, respectively, achieved DLQI 0/1 (nominal $p = 0.024$; Fig. 3).

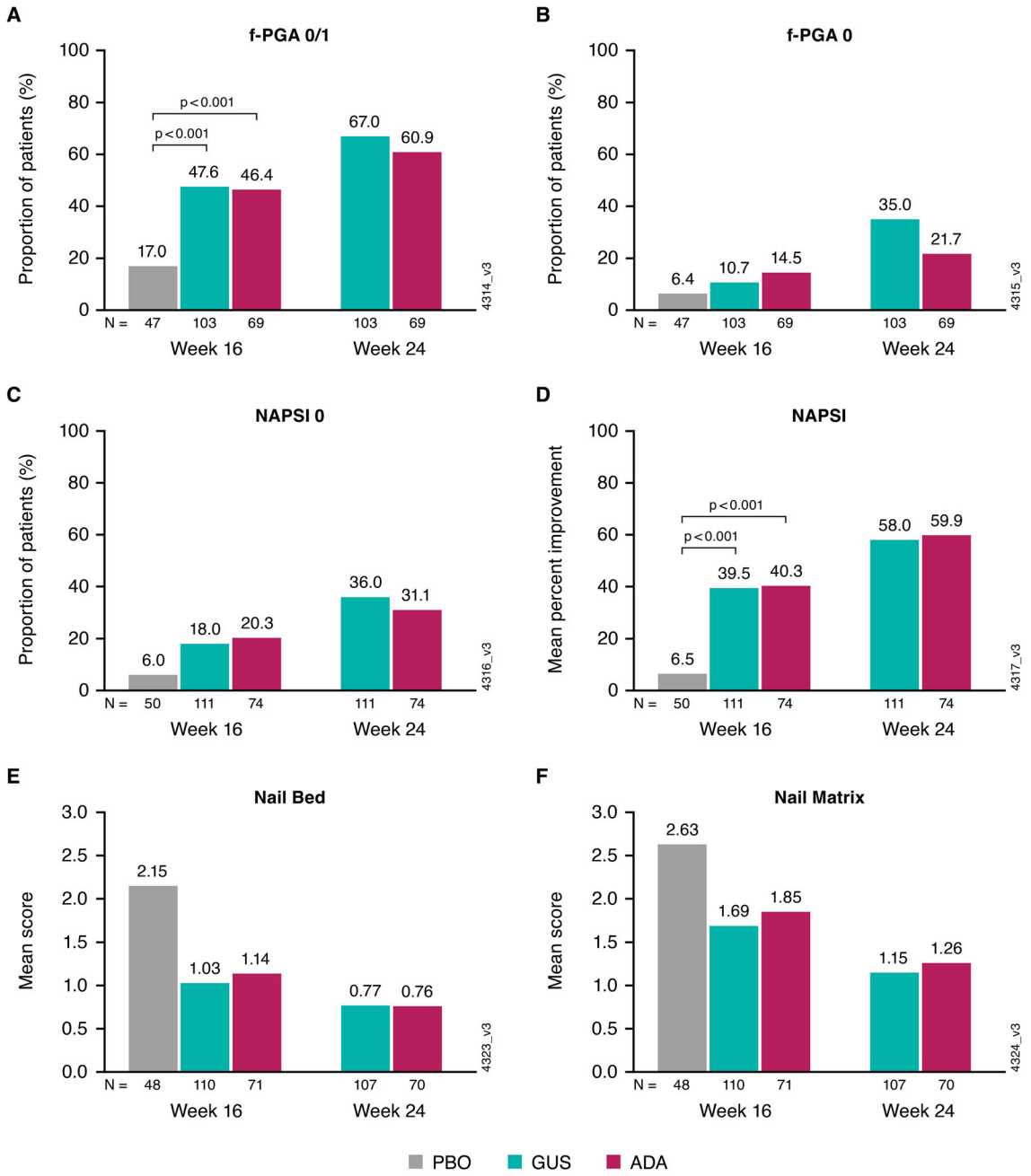

Fig. 1 Nail assessments at weeks 16 and 24 in VOYAGE-1 and -2 patients with self-reported PsA. Proportions of patients achieving an f-PGA score of 0 or 1 (**A**) and a f-PGA score of 0 (**B**) (both among patients with f-PGA ≥ 2). Proportions of patients with NAPSI score of 0 (**C**), and mean percentage improvement from baseline in NAPSI (**D**) (both among patients with baseline NAPSI > 0). Mean NAPSI nail bed psoriasis score (**E**), and nail matrix psoriasis score (**F**). Treatment group comparisons employed the Cochran-Mantel–Haenszel χ^2 test stratified by study for binary endpoints or a nonparametric analysis of variance test with study as a covariate for continuous variables. All *p*-values are nominal. *ADA* adalimumab, *f-PGA* fingernail Physician's Global Assessment, *GUS* guselkumab, *NAPSI* Nail Psoriasis Severity Index, *PBO* placebo, *PsA* psoriatic arthritis

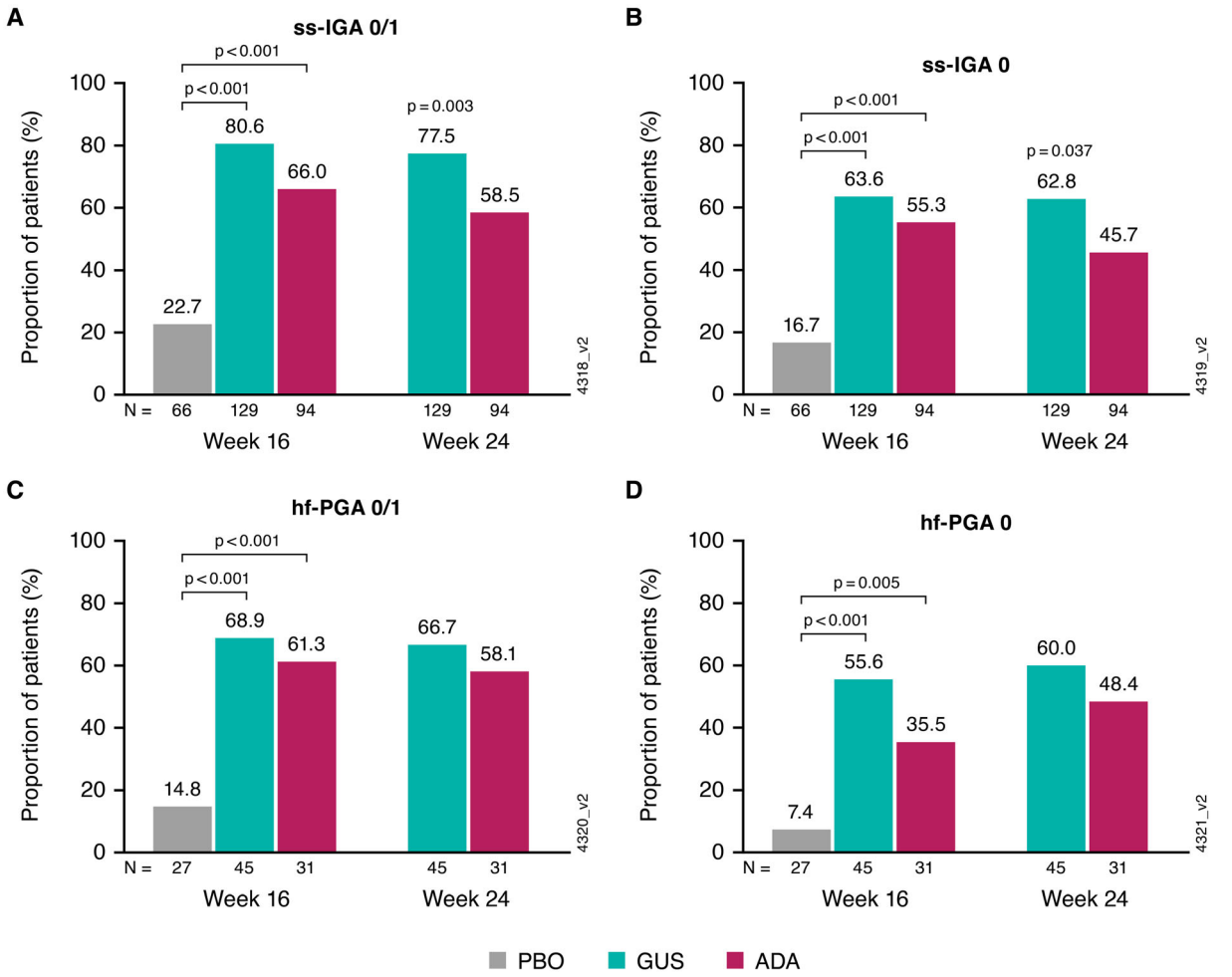

Fig. 2 Proportions of patients achieving an ss-IGA score of 0 (clear) or 1 (very mild) (**A**), ss-IGA score of 0 (**B**), hf-PGA score of 0 or 1 (almost clear) (**C**), and hf-PGA score of 0 (**D**) at weeks 16 and 24 in VOYAGE-1 and -2 patients with self-reported PsA, among those with baseline scores ≥ 2. Treatment group comparisons employed the Cochran-Mantel–Haenszel χ^2 test stratified by study. All *p*-values are nominal. *ADA* adalimumab, *GUS* guselkumab, *hf-PGA* hand and/or foot Physician's Global Assessment, *PBO* placebo, *ss-IGA* scalp-specific Investigator's Global Assessment

Results at week 48 in the VOYAGE-1 PsA cohort were largely consistent with pooled results at week 24 (ESM Figs. S3, S4).

Safety

The types and frequencies of AEs in this PsA cohort were consistent with those reported for the overall studies (ESM Results and Tables S3 and S4).

DISCUSSION

In this post hoc analysis of patients with moderate-to-severe psoriasis and self-reported PsA from the pivotal phase 3 VOYAGE-1 and -2 studies, greater proportions of guselkumab-treated patients demonstrated clinically meaningful improvements in psoriasis of the nails, scalp, palms and/or soles as early as week 16 when compared with placebo. Although modest improvements in nail disease were noted at earlier timepoints, through 1 year, a pattern of enhanced nail responses was observed with

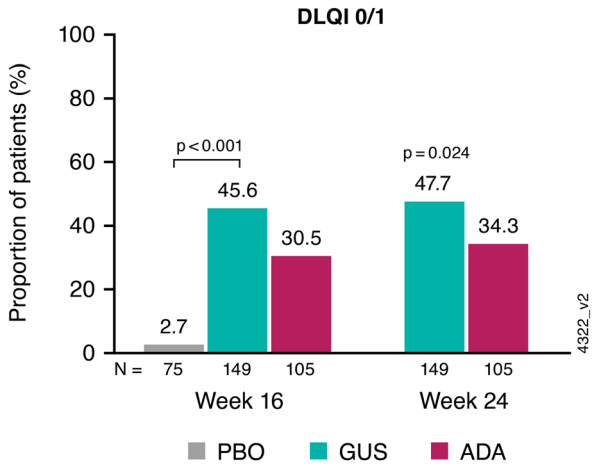

Fig. 3 Proportion of patients achieving a DLQI score of 0 or 1 (no effect on HRQoL) at weeks 16 and 24 in VOYAGE-1 and -2 patients with self-reported PsA, among those with baseline DLQI score > 1. Treatment group comparisons employed the Cochran-Mantel–Haenszel χ^2 test stratified by study. All *p*-values are nominal. *ADA* adalimumab, *DLQI* Dermatology Life Quality Index, *GUS* gusekumab, *HRQoL* health-related quality of life, *PBO* placebo

guselkumab when compared with adalimumab, including numerically higher response rates for achieving clear or minimal nail disease, greater percentage improvements in nail psoriasis, and less severe psoriasis involving the nail matrix and nail bed. Guselkumab also markedly improved psoriasis of the scalp, and palms and/or soles through 1 year of treatment, with numerically higher rates of near and complete clearance of psoriasis of these regions compared with adalimumab. Guselkumab-treated patients were also more likely to report meaningful enhancement of HRQoL, with higher proportions of patients in the guselkumab group experiencing no impact of psoriasis or its treatment on HRQoL, as compared with placebo at week 16 and adalimumab at weeks 24 and 48.

Given the chronic nature of psoriatic skin disease and challenges associated with treating psoriasis of the nails, scalp, palms and/or soles, sustained response to treatment in these body regions is critical for improved patient outcomes [2, 13]. Results of the current analysis of patients with self-reported PsA were consistent with results observed in the overall VOYAGE-1 and -2 populations of patients with psoriasis [10]. Although regional psoriasis assessments were not performed beyond 1 year in either study, robust response rates for achieving complete skin clearance in guselkumab-treated patients through 4 years in the subgroup with self-reported PsA and through 5 years in the overall VOYAGE-1 and -2 study populations [14, 15] suggest guselkumab may provide therapeutic longevity for difficult-to-treat regional forms of psoriasis. Of note, in the VOYAGE-1 and -2 studies, psoriasis responses with adalimumab appeared to wane with longer treatment duration through week 48 based on various measures, and guselkumab was effective at treating adalimumab non-responders after switching treatment at week 28 [8, 9]. The VOYAGE studies excluded patients with non-plaque forms of psoriasis, such as palmoplantar pustulosis (PPP), precluding an evaluation in the present analysis; however, significant improvements in PPP disease activity and HRQoL were demonstrated with both guselkumab dosing regimens through 1 year in a phase 3 study of patients with PPP [16]. These data suggest guselkumab may be an effective and safe treatment option for recalcitrant psoriatic skin disease.

Psoriasis involving visible body regions such as the face, hands, scalp, and nails can have a greater detrimental effect on physical impairment, pain, and HRQoL than lesions on other body areas [2, 17]. Improvements in skin disease-specific HRQoL with guselkumab are consistent with benefits in HRQoL and physical function observed through up to 2 years among patients with active PsA in DISCOVER-1 and DISCOVER-2 [18, 19]. The reduced impact of disease on HRQoL following guselkumab treatment may be partially attributed to alleviation of psychosocial effects associated with lesions in visible body areas [20, 21].

These findings are limited by the post hoc nature of analyses; the VOYAGE studies were not powered to evaluate these assessments in PsA patients. Additionally, findings in this trial population may not be generalizable to the broader population of patients with PsA. Misclassification bias may have occurred as patients self-reported having PsA. Longer-term treatment duration is likely required to discriminate

between therapies for nail disease given the relatively slow growth of this appendage [22]. Week 48 analyses were restricted to VOYAGE-1 data due to differences in design of VOYAGE-1 and -2 beyond week 28, thus limiting the sample size for analysis of longer-term effects. Study strengths include an overall large sample size, use of a placebo- and active-comparator study design, and employment of validated tools for assessing regional psoriasis.

CONCLUSION

In these post hoc analyses of data from VOYAGE-1 and -2, guselkumab was efficacious in treating psoriasis of the nails, scalp, and palms and/or soles and reducing effects of psoriasis on HRQoL among patients with moderate-to-severe psoriasis and self-reported PsA diagnosis. In the context of demonstrated efficacy of guselkumab across multiple PsA domains [6, 7], the findings reported herein suggest guselkumab has the potential to address all key PsA domains, aligning with current treatment recommendations.

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Author Contributions Study conception and design or acquisition of data: Soumya D Chakravarty, Yin You, May Shawi, Ya-Wen Yang. Data analysis: Yin You. Data interpretation: Ana-Maria Orbai, Soumya D Chakravarty, Yin You, May Shawi, Ya-Wen Yang, Joseph F Merola. Drafting the article or revising it critically for important intellectual content: Ana-Maria Orbai, Soumya D Chakravarty, Yin You, May Shawi, Ya-Wen Yang, Joseph F Merola. Final approval of the version to be published: Ana-Maria Orbai, Soumya D Chakravarty, Yin You, May Shawi, Ya-Wen Yang, Joseph F Merola. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: Ana-Maria Orbai, Soumya D Chakravarty, Yin You, May Shawi, Ya-Wen Yang, Joseph F Merola. Soumya D Chakravarty had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Data Availability The data sharing policy of Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at http://yoda.yale.edu.

Declarations

Conflict of Interest. Ana-Maria Orbai has received grant/research support from AbbVie, Amgen, Celgene, Eli Lilly, Horizon, Novartis, and Janssen; and consulting fees from Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. Soumya D Chakravarty is an employee of Janssen Scientific Affairs, LLC and owns stock or stock options in Johnson & Johnson. Yin You is an employee of Janssen Research & Development, LLC. Ya-Wen Yang is an employee of Janssen Pharmaceutical Companies of Johnson & Johnson. May Shawi is an employee of Janssen Research & Development, LLC, and owns stock in Johnson & Johnson. Joseph F Merola is a consultant and/or investigator for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte, Janssen, Leo Pharma, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB.

Ethical Approval. These studies were conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical

Practices. The governing ethical bodies for each of the participating sites approved the VOYAGE-1 and -2 study protocols, and all patients provided written informed consent.

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