ORIGINAL RESEARCH ARTICLE

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Improvement in Patient-Reported Outcomes (Dermatology Life Quality Index and the Psoriasis Symptoms and Signs Diary) with Guselkumab in Moderate-to-Severe Plaque Psoriasis: Results from the Phase III VOYAGE 1 and VOYAGE 2 Studies

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Abstract

Background Health-related quality of life (HRQoL) may be markedly impaired in patients with moderate-to-severe psoriasis.
Objectives Our objectives were to compare improvements in Dermatology Life Quality Index (DLQI) and Psoriasis Symptoms and Signs Diary (PSSD) scores between patients receiving guselkumab compared with placebo or adalimumab and to correlate these improvements with skin clearance.
Methods Pooled phase III VOYAGE 1 and VOYAGE 2 data were evaluated through week 24. At baseline, patients were randomized to guselkumab 100 mg, placebo, or adalimumab 40 mg. At week 16, patients receiving placebo switched to guselkumab. Assessment measures included DLQI percent change from baseline, DLQI 0/1, DLQI minimal clinically important difference (MCID), individual domain scores, PSSD symptoms and signs score = 0, DLQI association with PSSD, Investigator's Global Assessment (IGA), and Psoriasis Area and Severity Index (PASI).
Results Significantly greater improvements from baseline DLQI were observed with guselkumab versus placebo (weeks 8 and 16) and versus adalimumab (week 24; $p < 0.001$). The proportion of patients achieving DLQI 0/1 ("no impact") at week 24 was higher with guselkumab than with adalimumab (58.9 vs. 40.2%; $p < 0.001$), and more patients attained a ≥ 4-point reduction in DLQI (MCID) at this timepoint ($p < 0.001$). Changes in individual DLQI domains were significantly greater for patients receiving guselkumab than for those receiving adalimumab, and among patients with individual baseline domain scores = 3 or 6 (severest impact), more guselkumab recipients than those receiving adalimumab achieved a score = 0 across all domains at week 24. DLQI 0/1 scores were associated with a PSSD symptom or sign score = 0 (no impact) and greater improvement of PASI and IGA (week 24).
Conclusions Pooled VOYAGE 1/VOYAGE 2 data demonstrated that guselkumab was superior to adalimumab in improving HRQoL, which was associated with greater skin clearance.
Clinical Trial Registration NCT02207231 and NCT02207244.

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1 Introduction

Psoriasis is a chronic disease with predominant skin signs and symptoms of erythema, scaling, pruritus, and pain, resulting in psychological impact and reduced quality of life [1–3]. The importance of patient-reported assessments of improvement in health-related quality of life (HRQoL) has been recognized. The Dermatology Life Quality Index (DLQI) was developed to measure a patient's perception of the effect of skin disease on his/her daily life [4]. A DLQI goal of 0 or 1, indicating no impact on quality of life, is a standard measure in clinical studies for skin diseases [5]. Additionally, the minimal clinically important difference (MCID) for the DLQI, the smallest score difference that patients perceive as beneficial [6], has varied, having been previously defined as 6 [7] or 5 [7, 8] but most recently clarified as 4 [9].

Increasingly, greater emphasis has been placed on HRQoL in clinical studies, and multiple new tools to assess HRQoL have been created and validated [10–12]. The Psoriasis Symptoms and Signs Diary (PSSD) [10, 13] is a validated tool that measures psoriasis-specific symptoms and signs and disease severity and was used to evaluate these parameters in the guselkumab psoriasis program. Consistent with the negative impact of psoriasis, patients often desire clear skin [14, 15]. Treatment with biologics that block the interleukin (IL)-23/IL-17 immune pathway has been shown to result in clear or almost clear skin in the majority of patients with psoriasis [16–22]. Data are conflicting as to whether greater improvements in Psoriasis Area and Severity Index (PASI) scores correlate with lower DLQI scores [23–29], which may be partly due to the methodology of the analyses. Therefore, it is important that new psoriasis treatments should not only improve a patient's skin clearance as assessed by the physician but also demonstrate improvement from the patient's perspective, utilizing newer assessment tools, in addition to the DLQI, that focus on patient-reported evaluations of the symptoms and signs of psoriasis [10, 13].

Guselkumab (TREMFYA®; Janssen Research & Development LLC, Spring House, PA, USA) is a fully human monoclonal antibody that binds to the p19 subunit of IL-23 and inhibits the intracellular and downstream signaling of IL-23. Results for efficacy, safety, and patient-reported outcomes of guselkumab compared with adalimumab were previously reported for two pivotal, phase III clinical trials (VOYAGE 1 and VOYAGE 2) [16, 17]. Here, we present the pooled DLQI and PSSD data from VOYAGE 1 and VOYAGE 2 and evaluate the associations between DLQI and improvements in PSSD, PASI, and Investigator's Global Assessment (IGA).

2 Patients and Methods

2.1 Study Design

VOYAGE 1 (NCT02207231) and VOYAGE 2 (NCT02207244) are phase III, multicenter, randomized, double-blinded, placebo- and adalimumab comparator-controlled studies with identical designs through week 24. Patients were randomized at baseline to guselkumab 100 mg at weeks 0, 4, 12, and 20; placebo at weeks 0, 4, and 12 followed by guselkumab 100 mg at weeks 16 and 20; or adalimumab 80 mg at week 0, adalimumab 40 mg at week 1, and adalimumab 40 mg every 2 weeks through week 24. In both studies, patients were >18 years old had a diagnosis of plaque-type psoriasis for ≥ 6 months before the first administration of study agent, had a baseline PASI ≥ 12, IGA score ≥ 3, an involved body surface area of ≥ 10%, and were a candidate for phototherapy/systemic psoriasis treatments. Exclusion criteria and other details of the studies have been reported previously [16, 17]. Informed consent was obtained from all individual participants included in these studies. The analyses in this report were performed using the pooled data from the VOYAGE 1 [16] and VOYAGE 2 [17] studies.

2.2 Assessments

Skin-related HRQoL was assessed using the DLQI and PSSD measures. The DLQI has ten questions related to the effect of skin problems on six aspects of life-labeled individual domains: symptoms and feelings (two questions), daily activities (two questions), leisure (two questions), work and school performance (one question), personal relationships (two questions), and treatment (one question). Each question is scored from 0 (not at all) to 3 (very much), indicating the intensity of impact on individual aspects of life. The total domain score varies from 0 to 3 in domains with one question and from 0 to 6 in domains with two questions. For example, a score of 0 indicates no impact at all of psoriasis on an individual functional domain, and a score of 3 or 6 (depending on the number of questions) indicates the most severe impact.

The overall DLQI score is the sum of the individual questions and ranges from 0 (meaning no impact of skin disease on HRQoL) to 30 (meaning maximum impact on HRQoL) [4]. Overall DLQI measures included percent change from baseline, a score of 0 or 1 (no impact of psoriasis on a patient's HRQoL), and the MCID (the smallest score difference that patients perceive as beneficial), evaluated as a change in score of 4, 5, or 6 points.

The PSSD evaluates symptoms (i.e., itch, pain, stinging, burning, and skin tightness) and signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) of psoriasis, graded individually (0–10 scale) by the patient using electronic capture in a daily diary requiring 24-h recall. A higher score indicates more severe symptoms or signs of psoriasis [10, 13]. The proportions of patients achieving PSSD symptom and sign summary scores of 0 (i.e., free of symptoms and signs) at week 24 were reported.

Clinical disease severity was evaluated by clinicians using two instruments: the IGA (range 0 [cleared] to 4 [severe]) and PASI (range 0–72; a higher score indicates more severe disease) [30]. Pooled data from both studies through week 24 were used to evaluate DLQI improvement and its relationship to PSSD and objectively measured skin improvement.

2.3 Statistical Analyses

DLQI scores were analyzed in patients with a DLQI score evaluated at baseline. Endpoints included the proportion of patients achieving a DLQI score of 0/1 with DLQI baseline score > 1, as well as the change in DLQI score from baseline to weeks 8, 16, and 24. Additionally, the percent improvement in the individual domains and the proportion of patients achieving an individual domain score of 0 (no impact) were assessed among patients who had corresponding scores of 3 (most severe impact) at baseline. Binary endpoints were analyzed using a Cochran-Mantel–Haenszel Chi squared test stratified by study and investigator site, and continuous endpoints were analyzed using an analysis of variance model with study and investigator site as covariates. After treatment failure rules were applied, nonresponder imputation rules were applied for binary endpoints, and last observation carried forward rules were applied for continuous variables, respectively, for the remaining missing data. Nominal p-values were reported for these post hoc analyses.

3 Results

3.1 Baseline Demographics and Disease Characteristics

A total of 1829 patients were analyzed in the pooled VOYAGE 1 [16] and VOYAGE 2 [17] studies: VOYAGE 1 included 837 patients (guselkumab 329; adalimumab 334; placebo 174), and VOYAGE 2 included 992 patients (guselkumab 496; adalimumab 248; placebo 248). Baseline demographics and psoriasis disease characteristics were comparable across the treatment groups of the pooled population (Table 1) and were consistent with those for the treatment groups in the individual studies. The median DLQI score at baseline was 14.0 in each group.

3.2 Efficacy

3.2.1 Changes in Dermatology Life Quality Index (DLQI) Scores from Baseline

A significantly greater reduction (improvement) in DLQI score from baseline was observed in guselkumab-treated patients (-9.6 ± 6.7) compared with placebo-treated patients (-1.7 ± 5.9) ($p < 0.001$) at week 8, the first timepoint of DLQI evaluation after baseline, and at week 16 (-11.3 ± 7.0 vs. -1.8 ± 6.7, respectively; $p < 0.001$) (Table 2).

At week 24, significant improvements were observed in the guselkumab group compared with the adalimumab group (-11.8 ± 7.2 vs. -9.6 ± 7.7, respectively; $p < 0.001$; Table 2). At week 24, improvements in DLQI were similar between the placebo-crossover patients and those originally randomized to guselkumab (data not shown).

Among the patients with a DLQI score > 1 at baseline, significantly greater proportions of guselkumab-treated patients achieved a DLQI score of 0/1 at weeks 8 and 16 compared with placebo-treated patients ($p < 0.001$ for all; Fig. 1). Likewise, a significantly greater proportion of guselkumab-treated patients achieved a DLQI score of 0/1 compared with adalimumab-treated patients at week 24 ($p < 0.001$; Fig. 1).

In addition, significantly greater proportions of guselkumab-treated patients achieved a ≥ 4-point (88.7 vs. 79.0%), ≥ 5-point (88.4 vs. 76.3%), or ≥ 6-point (87.3 vs. 75.2%) reduction in DLQI score at week 24 compared with adalimumab-treated patients ($p < 0.001$ for all; Fig. 2).

At week 24, changes in each of the individual DLQI domains were significantly greater for guselkumab-treated patients than for adalimumab-treated patients ($p < 0.001$). The greatest numerical difference in percent improvement was observed for the "Symptoms and Feelings" domain (74.5 ± 31.8 vs. 57.4 ± 47.9, respectively; Table 3).

At baseline, a substantial proportion of patients in the guselkumab and adalimumab groups experienced a severe impact (score of 3 [one question] or score of 6 [two questions]) of psoriasis on HRQoL. Following treatment, among patients with a baseline average domain score of 3 or 6 (depending on the question), across all domains, greater proportions of guselkumab-treated patients achieved a score of 0 (no impact)

Table 1 Baseline disease characteristics

	Placebo	Guselkumab	Adalimumab	Total
Patients randomized at week 0, N	422	825	582	1829
Psoriasis disease duration, years				
N	422	825	582	1829
Mean $\pm$ SD	17.8 $\pm$ 12.1	17.9 $\pm$ 12.1	17.3 $\pm$ 11.4	17.7 $\pm$ 11.9
Median	15.0	16.0	15.0	15.0
BSA, % involvement				
N	422	825	582	1829
Mean $\pm$ SD	27.1 $\pm$ 16.3	28.4 $\pm$ 16.7	28.8 $\pm$ 16.7	28.2 $\pm$ 16.6
Median	21.0	23.0	24.0	23.0
DLQI score (0–30)				
N	418	817	575	1810
Mean $\pm$ SD	14.3 $\pm$ 7.2	14.4 $\pm$ 7.2	14.6 $\pm$ 7.1	14.5 $\pm$ 7.2
Median	14.0	14.0	14.0	14.0
PASI score (0–72)				
N	422	825	582	1829
Mean $\pm$ SD	21.1 $\pm$ 8.3	22.0 $\pm$ 9.1	22.1 $\pm$ 9.0	21.8 $\pm$ 8.9
Median	18.3	19.0	19.5	19.0
IGA score (0–4), N (%)				
N	422	825	582	1829
Moderate (3)	322 (76.3)	632 (76.6)	436 (74.9)	1390 (76.0)
Severe (4)	100 (23.7)	192 (23.3)	143 (24.6)	435 (23.8)
PSSD symptom score (0–100)				
N	327	660	475	1462
Mean $\pm$ SD	54.5 $\pm$ 24.1	54.2 $\pm$ 25.6	53.8 $\pm$ 25.9	54.2 $\pm$ 25.3
Median	54.0	54.0	56.0	54.0
PSSD sign score (0–100)				
N	327	660	475	1462
Mean $\pm$ SD	58.1 $\pm$ 20.5	56.5 $\pm$ 22.1	57.8 $\pm$ 21.6	57.3 $\pm$ 21.6
Median	58.0	57.5	58.0	58.0

BSA body surface area, *DLQI* Dermatology Life Quality Index, *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area and Severity Index, *PSSD* Patient Symptoms and Signs Diary, *SD* standard deviation

at week 24 compared with adalimumab-treated patients (Table 4). Overall, in the pooled analysis of all patients at week 24, change from baseline in PASI score was significantly correlated with change in DLQI total score ($r = 0.375$; $p < 0.001$; data not shown).

3.2.2 Changes in Psoriasis Symptoms and Signs Diary (PSSD) Scores from Baseline

A significantly greater proportion of patients achieved a PSSD symptom score of 0 at week 24 with guselkumab versus adalimumab treatment (35.6 vs. 22.0%; $p < 0.001$). Similar results were observed for the proportion of patients achieving a PSSD sign score of 0 at week 24 (guselkumab: 28.4% vs. adalimumab: 15.6%; $p < 0.001$). Overall, in the pooled analysis of all patients at week 24, changes from

baseline in PASI score significantly correlated with changes in PSSD symptom score ($r = 0.307$; $p < 0.001$) and changes in PSSD sign score ($r = 0.301$; $p < 0.001$) (data not shown).

3.2.3 DLQI 0/1 Response by Psoriasis Area and Severity Index (PASI), Investigator's Global Assessment (IGA), and PSSD Responses

Stratified by the improvement in PASI, IGA, and PSSD scores, our analysis showed a clear trend indicating that greater improvement in psoriasis severity was associated with greater improvement in DLQI 0/1. Additionally, regardless of the level of clinical response assessed by PASI or IGA, there was a trend showing that a greater proportion of guselkumab-treated patients achieved a DLQI score of 0/1 compared with adalimumab-treated patients (Table 5).

Table 2 Change in Dermatology Life Quality Index scores from baseline through week 24

	Placebo	Guselkumab	Adalimumab
Patients randomized at week 0, N	422	825	582
Week 8			
N	418	817	575
Mean ± SD	− 1.7 ± 5.9	− 9.6 ± 6.7	− 8.8 ± 6.8
Median	− 2.0	− 9.0	− 8.0
p value vs. placebo		< 0.001	< 0.001
Week 16			
N	418	817	575
Mean ± SD	− 1.8 ± 6.7	− 11.3 ± 7.0	− 9.5 ± 7.4
Median	− 1.0	− 11.0	− 9.0
p value vs. placebo		< 0.001	< 0.001
Week 24			
N	NA	817	575
Mean ± SD	NA	− 11.8 ± 7.2	− 9.6 ± 7.7
Median	NA	− 12.0	− 9.0
p value vs. adalimumab		< 0.001	

NA not applicable, *SD* standard deviation

4 Discussion

In pooled data from the two pivotal phase III VOYAGE 1 [16] and VOYAGE 2 [17] studies, guselkumab was superior to adalimumab in improving HRQoL, which was assessed across multiple endpoints of the DLQI and PSSD measures. At week 24, patients treated with guselkumab had a significantly greater improvement in DLQI score from baseline than patients treated with adalimumab. In addition, a significantly greater proportion of guselkumab-treated patients achieved a DLQI 0/1 and an MCID of 4, 5, or 6 compared with adalimumab-treated patients. Changes in each of the individual DLQI domains were significantly greater among guselkumab-treated patients than among adalimumab-treated patients at week 24. A greater proportion of patients receiving guselkumab versus adalimumab achieved a PSSD score of 0 for both symptoms and signs at week 24. Improvements in HRQoL, defined as a DLQI 0/1, correlated with skin improvement, measured by both PASI and IGA. Achieving a DLQI of 0/1 also correlated with achieving PSSD symptoms and signs scores of 0. The totality of the data confirmed that, from both the physician and the patient perspective, guselkumab will be an effective
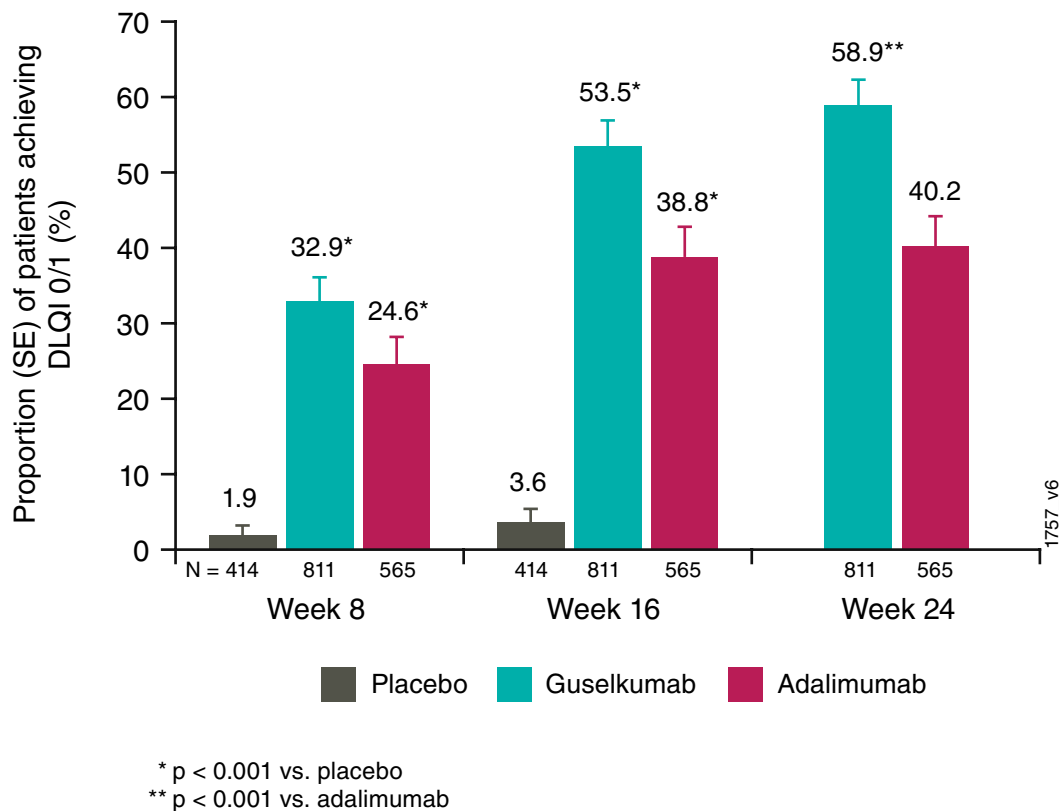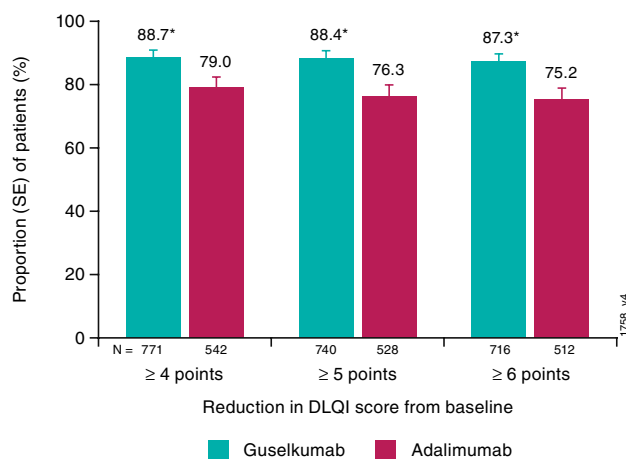

Fig. 1 Proportion of patients achieving a Dermatology Life Quality Index (DLQI) score of 0/1 at weeks 8, 16, and 24 in patients with baseline DLQI score > 1. *SE* standard error

Fig. 2 Proportion of patients with a reduction of 4/5/6 or more points in Dermatology Life Quality Index (DLQI) score from baseline to week 24 in patients with baseline DLQI scores of ≥ 4, 5, or 6. *SE* standard error

treatment for patients with moderate-to-severe psoriasis, particularly those desiring a high degree of efficacy.

Clinically meaningful improvement in the DLQI, a validated, 10-item, dermatology patient-reported outcome [9, 23, 24], is defined as the smallest difference in score that a patient perceives as beneficial, commonly accepted to be 4 [9]. Failure to achieve this level of response would suggest, in the absence of adverse events or other precipitating factors, a need for change in the patient's management [6, 31]. Using this criterion and two higher MCID cutoffs of 5 and 6, guselkumab was superior to adalimumab. Further, using the most rigorous assessment, a significantly greater proportion of guselkumab-treated than adalimumab-treated patients achieved DLQI 0/1 at week 24. For each of the individual domains, the percent improvement was significantly greater in the guselkumab group than in the adalimumab group. Additionally, among patients who were most severely affected in each domain (baseline scores of 3 or 6), a greater number of guselkumab-treated patients than adalimumab-treated patients achieved a score of 0 across all six domains. This is particularly notable because comparative patient-reported outcomes are increasingly recognized as important in psoriasis. This study demonstrated, using two different instruments, that patients assess guselkumab as superior to adalimumab, one of the most widely used biologics to treat psoriasis, in improving all aspects of their HRQoL. Other biologics targeting the IL-23 pathway, specifically IL-17, have also demonstrated superiority in improving HRQoL using the DLQI compared with established agents such as etanercept and ustekinumab [19–21, 32–34].

High levels of physician-assessed improvements in psoriasis in these studies, as assessed by the PASI and IGA

Table 3 Summary of change in Dermatology Life Quality Index (DLQI) domain scores from baseline to week 24

	Guselkumab	Adalimumab
Patients randomized at week 0, *N*	825	582
DLQI domain scores		
Symptoms and feelings		
N	817	575
Mean change ± SD	− 3.1 ± 1.7	− 2.4 ± 1.8
Median change	− 3.0	− 2.0
p value vs. adalimumab	< 0.001	
N	813	570
Mean % improvement ± SD	74.5 ± 31.8	57.4 ± 47.9
Median % improvement	80.0	66.7
p value vs. adalimumab	< 0.001	
Daily activities		
N	817	575
Mean change ± SD	− 2.6 ± 1.8	− 2.1 ± 1.8
Median change	− 3.0	− 2.0
p value vs. adalimumab	< 0.001	
N	751	530
Mean % improvement ± SD	84.0 ± 34.8	66.4 ± 52.4
Median % improvement	100.0	100.0
p value vs. adalimumab	< 0.001	
Leisure		
N	817	575
Mean change ± SD	− 2.2 ± 1.9	− 1.9 ± 2.0
Median change	− 2.0	− 2.0
p value vs. adalimumab	0.017	
N	688	487
Mean % improvement ± SD	83.6 ± 37.9	69.3 ± 56.0
Median % improvement	100.0	100.0
p value vs. adalimumab	< 0.001	
Work and school		
N	817	575
Mean change ± SD	− 1.0 ± 1.2	− 0.8 ± 1.2
Median change	− 1.0	− 1.0
p value vs. adalimumab	0.016	
N	520	365
Mean % improvement ± SD	87.2 ± 40.4	72.9 ± 51.2
Median % improvement	100.0	100.0
p value vs. adalimumab	< 0.001	
Personal relationships		
N	817	575
Mean change ± SD	− 1.8 ± 1.9	− 1.4 ± 1.8
Median change	− 1.0	− 1.0
p value vs. adalimumab	0.001	
N	587	427
Mean % improvement ± SD	84.2 ± 37.2	66.4 ± 63.2
Median % improvement	100.0	100.0
p value vs. adalimumab	< 0.001	

Table 3 (continued)

	Guselkumab	Adalimumab
Treatment		
N	817	575
Mean change ± SD	− 1.1 ± 1.0	− 0.9 ± 1.1
Median change	− 1.0	− 1.0
p value vs. adalimumab	< 0.001	
N	607	423
Mean % improvement ± SD	86.2 ± 33.5	70.7 ± 46.6
Median % improvement	100.0	100.0
p value vs. adalimumab	< 0.001	

SD standard deviation

Table 4 Proportion of patients achieving scores of 0 at week 24 among patients with baseline Dermatology Life Quality Index (DLQI) individual domain scores of 3 or 6 (severe)

	Guselkumab	Adalimumab
Patients randomized at week 0, *N*	825	582
Individual DLQI domain scores		
Symptoms and feelings		
Patients with baseline score = 6, *N*	171	111
Patients with score = 0 at week 24	67 (39.2)	20 (18.0)
p value vs. adalimumab	< 0.001	
Daily activities		
Patients with baseline score = 6, *N*	78	58
Patients with score = 0 at week 24	45 (57.7)	16 (27.6)
p value vs. adalimumab	0.053	
Leisure		
Patients with baseline score = 6, *N*	89	70
Patients with score = 0 at week 24	48 (53.9)	31 (44.3)
p value vs. adalimumab	0.501	
Work and school		
Patients with baseline score = 3, *N*	176	134
Patients with score = 0 at week 24	144 (81.8)	76 (56.7)
p value vs. adalimumab	< 0.001	
Personal relationships		
Patients with baseline score = 6, *N*	68	44
Patients with score = 0 at week 24	45 (66.2)	15 (34.1)
p value vs. adalimumab	0.073	
Treatment		
Patients with baseline score = 3, *N*	124	94
Patients with score = 0 at week 24	89 (71.8)	54 (57.4)
p value vs. adalimumab	0.030	

All values are *n* (%) unless noted otherwise

Domains with one question have a total maximum score (most severe) of 3; domains with two questions have a total maximum score (most severe) of 6

measures, were associated with improved patient HRQoL. The proportion of guselkumab-treated patients who achieved a DLQI of 0/1 increased with PASI improvement. The same trend was observed for IGA responses. Likewise, the correlation between greater skin clearance and better HRQoL was also observed with adalimumab treatment. These findings support the relationship between skin clearance and better HRQoL [25, 35] and further validate the increasing emphasis on patient-reported outcomes in evaluating clinical responses to treatment. It is notable that, among patients who achieved either PASI 100 or IGA 0, higher proportions of guselkumab-treated patients than adalimumab-treated patients achieved a DLQI of 0/1, suggesting that factors other than complete skin clearance may also drive impact on HRQoL and that patient-reported outcomes may capture additional treatment benefits beyond PASI or IGA. Further investigation and validation is required to better understand this finding.

The major limitations of the study include a limited follow-up of 24 weeks, the restricted experience to date with the PSSD, and the limitations of the DLQI. While the DLQI is a validated instrument, it is not psoriasis-specific and does not assess the impact of signs and symptoms of psoriasis on HRQoL. The DLQI has limitations in some other aspects of psychometric performance, particularly unidimensionality and item bias [36–38], as well as the biases related to "not relevant" responses and issues with content validity [39–41]. As a result, multiple psoriasis-specific patient-reported outcome instruments have been developed and validated in recent years to assess newer biologics [10–12]. Strengths of the study include the substantial database from the pooled study, the comparison against adalimumab, and the use of the validated, psoriasis-specific PSSD. Notably, greater improvements in patient-reported outcomes were demonstrated with guselkumab treatment compared with adalimumab treatment in the VOYAGE 1 and VOYAGE 2 primary studies using the PSSD [16, 17], and in the analysis of pooled data in this report likely due in part to greater skin clearance with guselkumab. Further, we demonstrated that improvements in HRQoL, as measured by achieving a DLQI 0/1, correlated with improvements in patient-reported symptoms and signs as assessed by achieving PSSD scores of 0.

5 Conclusion

Pooled data from the phase III VOYAGE 1 and VOYAGE 2 studies demonstrated that guselkumab was superior to adalimumab in improving HRQoL through 24 weeks of treatment as assessed by multiple DLQI endpoints and patient-assessed symptoms and signs evaluated by the PSSD. The comparative data between guselkumab and adalimumab in a substantial cohort are novel and useful in treatment decisions, particularly with inclusion of the PSSD, which is a psoriasis-specific validated patient assessment. In addition, a distinct association between

Table 5 Proportion of patients with Dermatology Life Quality Index (DLQI) scores of 0/1 at week 24[a] by Psoriasis Area and Severity Index responses, Investigator's Global Assessment scores, and Patient Symptoms and Signs Diary scores

	Placebo→guselkumab	Guselkumab	Adalimumab	Total
Patients randomized at week 0, N	422	825	582	1829
Patients with baseline DLQI score > 1, N	390	811	565	1766
Psoriasis Area and Severity Index (PASI)				
Patients achieving PASI 100, N	73	360	146	579
Achieved DLQI 0/1	52 (71.2)	286 (79.4)	96 (65.8)	434 (75.0)
Patients achieving PASI 90 to < PASI 100, N	112	263	158	533
Achieved DLQI 0/1	46 (41.1)	145 (55.1)	85 (53.8)	276 (51.8)
Patients achieving PASI 75 to < PASI 90, N	124	105	101	330
Achieved DLQI 0/1	47 (37.9)	40 (38.1)	36 (35.6)	123 (37.3)
Patients achieving < PASI 75, N	81	83	160	324
Achieved DLQI 0/1	16 (19.8)	7 (8.4)	10 (6.3)	33 (10.2)
Investigator's Global Assessment (IGA)				
Patients achieving IGA of cleared (0), N	107	422	171	700
Achieved DLQI 0/1	69 (64.5)	320 (75.8)	114 (66.7)	503 (71.9)
Patients achieving IGA of minimal (1), N	192	255	184	631
Achieved DLQI 0/1	69 (35.9)	127 (49.8)	80 (43.5)	276 (43.7)
Patients achieving IGA ≥ 2, N	91	134	210	435
Achieved DLQI 0/1	23 (25.3)	31 (23.1)	33 (15.7)	87 (20.0)
Patient Symptoms and Signs Diary (PSSD)				
PSSD symptom score = 0 and baseline > 0, N	39	232	102	373
Achieved DLQI 0/1	31 (79.5)	219 (94.4)	85 (83.3)	335 (89.8)
PSSD symptom score > 0 and baseline > 0, N	268	421	364	1053
Achieved DLQI of 0/1	86 (32.1)	162 (38.5)	97 (26.6)	345 (32.8)
PSSD sign score = 0 and baseline > 0, N	25	186	72	283
Achieved DLQI 0/1	21 (84.0)	176 (94.6)	64 (88.9)	261 (92.2)
PSSD sign score > 0 and baseline > 0, N	282	468	396	1146
Achieved DLQI 0/1	96 (34.0)	206 (44.0)	120 (30.3)	422 (36.8)

All values are n (%) unless noted otherwise

[a]In patients randomized to placebo, after week 16 the data includes only those patients who crossed-over to guselkumab at or after week 16

HRQoL improvement and greater skin clearance (PASI and IGA) was identified, with a trend for guselkumab to provide greater patient-perceived benefit than adalimumab in those with clear skin. This suggestion that patient-reported outcomes capture greater benefit than standard physician measurement of psoriasis is intriguing and requires further investigation. Finally, the correlation between the well-established DLQI and the novel PSSD is reassuring.

Compliance with Ethical Standards

investigator and/or scientific officer and/or speaker for AbbVie, Akros, Allergan, Amgen, Anacor, Arcutis, Astrellas, AstraZeneca, Baxalta, Baxter, Boehringer Ingelheim, BMS, CanFite, Celgene, Coherus, Demira, Dow Pharma, Eli Lilly, Forward Pharam, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, Leo Pharma, Medimmune, Meiji Seiki Pharma, Merck Sharp & Dohme, Merck-Serono, Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis/Genzyme, Takeda, UCB, and Valeant. C. Han, M. Song, Y.-K. Shen, and Y. You are employees of Janssen Research & Development, LLC. and own stock in Johnson & Johnson, of which Janssen is a subsidiary.

Ethical approval/informed consent All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All patients provided written informed consent prior to any study-related procedures.

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