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RESEARCH ARTICLE

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Real-world effectiveness and safety of guselkumab in adult patients with facial and/or genital psoriasis: a 52-week analysis from the Italian multicentric GULLIVER study

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ABSTRACT

Objectives: Facial and genital plaques are common manifestations of psoriasis, are challenging to treat, and significantly impact patients' quality of life (QoL).

Methods: GULLIVER is a prospective, non-interventional study conducted in 2020–2023 in Italy, aimed at examining the effectiveness, safety and QoL impact of guselkumab through 52 weeks of treatment in patients with facial and/or genital psoriasis. The primary endpoint was the percentage of patients achieving a static Physician Global Assessment (sPGA) score of ≤1 and a minimum 2-grade improvement in sPGA score at Week 52.

Results: Of 351 enrolled patients, 88.6% remained on guselkumab treatment at Week 52. The proportions of patients achieving the sPGA targets in the facial and genital groups, respectively, were 83.3% and 76.5% at week 12, increasing to 93.8% and 97.9% at Week 52. Mean Dermatology Life Quality Index score improved from 12.0±7.5 at baseline to 1.1±2.0 at Week 52 for patients with facial psoriasis (p-value <0.001) and from 12.0±6.9 to 1.6±3.5 for those with genital psoriasis (p-value <0.001). Guselkumab was well-tolerated and no new safety signals were identified.

Conclusions: This Italian real-world study demonstrated the high effectiveness and a good safety profile of guselkumab in treating facial and genital psoriasis.

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KEYWORDS

Effectiveness; facial psoriasis; genital psoriasis; Real-World studies; safety

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Main text introduction

Plaque psoriasis is a chronic inflammatory, immune-mediated, disease that affects between 1.5% and 2.0% of the adult population in most high-income countries (1). Psoriasis can occur in various body regions, with sensitive areas being more challenging to manage and treat (2). Among these, the face and genital region are two relatively common sites of psoriasis involvement, manifesting at some point during the course of the disease in more than one-third of patients (3,4). The real burden of genital psoriasis is especially difficult to assess, as it is often under-reported by patients and overlooked by health care providers (2,5).

The impact of facial and genital psoriasis on quality of life (QoL) is particularly high (6–9). In addition to the common physical burden of psoriasis (10–12), the visibility of lesions in facial psoriasis and the stigma associated with genital psoriasis have a significant emotional and social impact. Patients often experience shame, depression and impaired sexual health, and may adopt coping strategies that involve avoiding personal relationships (13,14).

Treatment of psoriasis has improved considerably over the last few decades, and several effective and safe systemic therapeutic options are now available for moderate-to-severe disease (12,15). However, data on the treatment of psoriasis involving high impact body areas both from clinical trials and real-world studies remain limited (16–19), and significant challenges persist. According to a Delphi consensus of experts, patients with psoriasis of high impact areas – including the face and genital region – are candidates for systemic therapies commonly used for moderate or severe psoriasis (20).

Guselkumab is a biologic therapeutic monoclonal antibody that targets the interleukin (IL)-23-p19 subunit. The efficacy, safety and favorable impact on QoL of guselkumab in treating moderate-to-severe psoriasis have been demonstrated in various clinical trials (21–24) and real-world studies (25–28). However, information regarding the use of guselkumab in patients with psoriasis on the face and genital region is scarce.

In a previous interim analysis from the Italian GULLIVER study, we reported findings on the short-term effectiveness of guselkumab in patients with facial and genital psoriasis (29). The aim of this extended analysis is to provide additional real-world data on the effectiveness and safety of guselkumab from the GULLIVER study through 52 weeks.

Methods

GULLIVER is a real-world, prospective, non-interventional study conducted between July 2020 and November 2023 at 36 dermatology centers spanning Italy. The study aims to examine the effectiveness, safety, and impact on disease burden of guselkumab treatment in patients with psoriasis involving the face and/or genital region. The study was conducted in accordance with the principles of the Declaration of Helsinki, was approved by the Ethics Committee of the coordinating center, with acknowledgement by the other participating centers. All patients enrolled provided written informed consent before the initiation of any study procedure. The GULLIVER study was registered on ClinicalTrials.gov (NCT04439526).

The study design has been detailed in a previous publication (29). In brief, patients were eligible to participate if they met the following inclusion criteria: i) Were an outpatient male or female ≥18 years of age; ii) Had a confirmed diagnosis of psoriasis, with significant involvement of the face and/or genital region (i.e., defined as a static Physician Global Assessment [sPGA] score ≥3), and requiring systemic treatment; iii) Had started treatment with guselkumab for psoriasis according to the approved indications in Italy; iv) Had signed an informed consent. Note that having a Psoriasis Area and Severity Index (PASI) score of >10 was not an inclusion criterion. According to the Italian Medicines Agency (AIFA, Determina DG/523/2022, 11th November 2022, https://www.gazzettaufficiale.it/eli/gu/2022/11/16/268/sg/pdf), biologics for the treatment of psoriasis may be reimbursed after therapeutic failure of a prior synthetic conventional disease-modifying antirheumatic drug in patients with either PASI >10 or body surface area (BSA) >10%, or with PASI <10 or BSA <10% when psoriatic lesions are present in high impact body areas, such as the face, genital region, palms, soles or nails (29). The sPGA is commonly used to assess the severity of facial and genital psoriasis and the response to treatment (30). Exclusion criteria included: i) Having a contraindication to guselkumab use; ii) Use of treatment or an investigational drug or vaccine, or medical device for psoriasis within the 30 days preceding the initiation of guselkumab; iii) Concurrent participation in another clinical trial or investigational study; iv) Inability to read, write or understand and sign the informed consent. Patients with an sPGA scores ≥3 for psoriasis involving both the face and genital region were assigned to the body region group with the highest degree of severity.

In line with common clinical practice and the summary of product characteristics, guselkumab 100 mg was administered by subcutaneous injection at Week 0, Week 4, and then every 8 weeks until Week 52. Patients were allowed to enroll at any time between Week 0 (i.e., at the time of the first guselkumab injection) and Week 4 or Week 12 (i.e., at a subsequent visit, based on clinical practice standards for patient follow up). Information retrieved for the first study visit (i.e., at Week 0) was collected retrospectively, whereas data for subsequent visits were collected prospectively.

The primary effectiveness endpoint for both facial and genital psoriasis was the percentage of patients achieving a sPGA score of 0 (i.e., clear) or 1 (i.e., almost clear) with at least a 2-grade improvement at week 52. The regional sPGA scores were based on the qualitative degree of erythema, thickness and scaling of lesions, with each rated using a 6-point scale, (i.e., ranging from 0 [clear] to 5 [severe]) (31,32). Secondary endpoints included: i) the percentage of patients achieving the sPGA targets at Weeks 12 and 28; ii) the percentages of patients achieving PASI 75, PASI 90 and PASI 100 responses (among participants with a PASI score >10 at baseline); iii) the change from baseline in PASI and BSA scores; iv) safety; and v) the change from baseline in Dermatology Life Quality Index (DLQI) and selected visual analogue scales (VAS) related to QoL. Stratified analysis of the main results according to age, body mass index (BMI) and duration of psoriasis was also performed. The safety of guselkumab treatment was evaluated through the tabulation of the frequency and severity of adverse events (AE), serious adverse events (SAE), treatment-emergent adverse events (TEAE), AEs leading to treatment discontinuation, and patients' vital status.

Statistical analyses

Descriptive analyses were conducted by tabulating frequencies and percentages for categorical variables, and mean and median values, standard deviations (SD), and ranges for continuous variables. For categorical endpoints for which no formal statistical hypothesis was formulated, 95% confidence intervals (CI) were

computed using Wilson's method (33). Comparisons between subgroups (i.e., strata of age, BMI and duration of psoriasis) were conducted using contingency table analysis with the Chi-square test. Mean change from baseline to Weeks 12, 28 and 52, along with the corresponding 95% CIs, were computed for continuous effectiveness endpoints and examined using analysis of variance (ANOVA) for repeated measures. Tests were two-sided, and a p-value of less than 0.05 was considered statistically significant. Data analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA) statistical software.

Results

A total of 351 patients were enrolled, with 147 (41.9%) having primarily facial psoriasis and 204 (58.1%) having primarily genital psoriasis. For 139 patients (39.6%), psoriasis was localized in both face and genital region. Mean duration of follow-up (± SD) was 49.8 ± 9.7 weeks, with 309 patients (88.0%) completing the entire study through 52 weeks.

Baseline characteristics of patients enrolled in the GULLIVER study are shown in Table 1. Mean age for the overall study population was 45.1 ± 15.5 years. The corresponding age was 41.9 ± 14.9 years for the group of patients with facial psoriasis and 47.4 ± 15.7 years for the group with genital psoriasis. A total of 204 patients (58.1%) were male. Regarding lifestyle habits at baseline, 42.2% of patients were current smokers and 13.1% were former smokers. Mean body mass index (BMI) was 27.1 ± 5.9 kg/m^2. The first site of psoriasis presentation was the head for more than half (57.5%) of facial psoriasis patients, whereas among genital psoriasis patients, 29.9% reported the upper extremities and 27.9% reported the head as the first site presenting with the disease. Median duration of psoriasis at enrollment was 13 years, with an interquartile range of 6 to 22 years. Most patients (92.9%) reported at least one previous treatment for psoriasis, with only a minimal difference between facial (93.9%) and genital (92.2%) patients, whereas 15.1% of patients reported one or more concomitant treatment for psoriasis. Comorbidities were present in 56.1% of overall patients, with 59.2% of facial and 53.9% of genital psoriasis patients manifesting comorbidities.

Table 2 provides details regarding guselkumab treatment for the 351 psoriasis patients enrolled in the GULLIVER study. Mean numbers (± SD) of guselkumab administrations during the study were 7.6 ± 1.2 for the overall study population, and 7.5 ± 1.4 for the facial psoriasis group and 7.7 ± 1.0 for the genital psoriasis group. A total of 84.6% of all patients, 80.3% of facial psoriasis patients and 87.7% of genital psoriasis patients received 8 administrations of guselkumab. The mean duration of treatment was 350.4 ± 62.5 days, and 88.6% of patients were reported to still be receiving treatment at Week 52.

Achievement of sPGA score 0 or 1 and at least 2-grade improvement compared to baseline at Week 52, i.e., the primary endpoint, and at various time-points, as well as by body site of psoriasis involvement is shown in Figure 1. The proportions of patients achieving the target sPGA endpoint in the facial and genital groups, respectively, were 83.3% and 76.5% at Week 12, increasing to 93.8% and 97.9% at Week 52. Combining the two groups, the percentage of overall patients achieving the sPGA primary endpoint at Week 52 was 96.2% (95% CI, 93.5%-97.8%).

Results for select clinical and QoL outcome measures at 12, 28 and 52 weeks are presented in Table 3. Mean values for all indexes considered, including PASI, BSA and DLQI, improved significantly over the follow-up period in both the facial and genital psoriasis groups. At Week 52, mean PASI scores (± SD) were 0.5 ± 1.4 for the facial psoriasis group and 0.6 ± 1.6 for the genital psoriasis group, as compared to 13.7 ± 9.3 and 12.8 ± 8.8, respectively, at baseline (p-value < 0.001 for both groups). Additional findings regarding the proportions of overall patients achieving PASI 75, PASI 90, and PASI 100 responses are shown in Supplementary Figure 1. PASI 100 was achieved by 46.7% of patients at Week 12, 64.4% at Week 28, and 76.1% at Week 52. The corresponding proportions of patients achieving PASI 90 at

Table 1. Baseline characteristics of patients with facial and genital psoriasis enrolled in the GULLIVER study.

	All patients (*n* = 351)	FP patients (*n* = 147)	GP patients (*n* = 204)
Age (years), n (%)			
≤65	311 (88.6%)	137 (93.3%)	174 (85.3%)
>65	40 (11.4%)	10 (6.8%)	30 (14.7%)
Age (years), mean (SD)	45.1 (15.5)	41.9 (14.9)	47.4 (15.7)
Age (years), median (IQ range)	44.0 (33.0–57.0)	39.0 (31.0–54.0)	47.0 (35.0–59.5)
Gender, n (%)			
Females	147 (41.9%)	64 (43.5%)	83 (40.7%)
Males	204 (58.1%)	83 (56.5%)	121 (59.3%)
Smoking status, n (%)[a]			
Never smoked	154 (44.8%)	71 (50.4%)	83 (40.9%)
Current smoker	145 (42.2%)	55 (39.0%)	90 (44.3%)
Former smoker	45 (13.1%)	15 (10.6%)	30 (14.8%)
Body mass index, kg/m^2			
Mean (SD)	27.1 (5.9)	27.6 (6.8)	26.8 (5.2)
Median (IQ range)	26.1 (23.0–30.2)	26.2 (22.4–31.2)	26.0 (23.2–29.4)
First localization of psoriasis, n (%)[a]			
Head	141 (40.3%)	84 (57.5%)	57 (27.9%)
Trunk	65 (18.6%)	20 (13.7%)	45 (22.1%)
Upper extremities	87 (24.9%)	26 (17.8%)	61 (29.9%)
Lower extremities	57 (16.3%)	16 (11.0%)	41 (20.1%)
Duration of psoriasis (years)			
Mean (SD)	15.8 (12.3)	17.0 (13.0)	15.0 (11.7)
Median (IQ range)	13.0 (6.0–22.0)	15.0 (6.0–23.0)	12.0 (6.0–21.0)
At least 1 previous psoriasis therapy, n (%)	326 (92.9%)	138 (93.9%)	188 (92.2%)
At least 1 concomitant psoriasis therapy, n (%)	53 (15.1%)	25 (17.0%)	28 (13.7%)
At least 1 concomitant disease, n (%)	197 (56.1%)	87 (59.2%)	110 (53.9%)

FP: facial psoriasis; GP: genital psoriasis; IQ: interquartile; SD: standard deviation.
[a]The sums may not reflect the total number of patients due to some cases of missing data.

Table 2. Information on the number of injections and duration of treatment with guselkumab in the GULLIVER study.

	All patients (*n* = 351)	FP patients (*n* = 147)	GP patients (*n* = 204)
No. of guselkumab administrations, n (%)			
≤6	33 (9.4%)	19 (12.9%)	14 (6.9%)
7	21 (6.0%)	10 (6.8%)	11 (5.4%)
8	297 (84.6%)	118 (80.3%)	179 (87.7%)
No. of administrations, mean (SD)	7.6 (1.2)	7.5 (1.4)	7.7 (1.0)
Duration of treatment (days), mean (SD)	350.4 (62.5)	342.0 (73.8)	356.5 (52.2)
Patients on treatment at week 52, n (%)	311 (88.6%)	123 (83.7%)	188 (92.2%)

FP: facial psoriasis; GP: genital psoriasis; IQ: interquartile; SD: standard deviation.
[a]The sums may not reflect the total number of patients due to some cases of missing data.

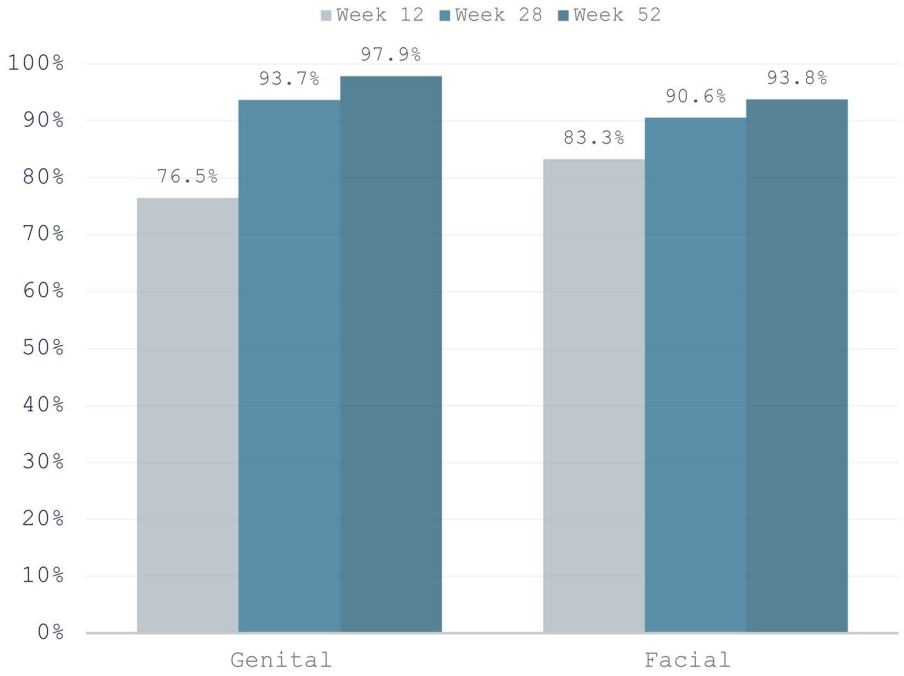

Figure 1. Achievement of sPGA 0 or 1 and at least 2-grade improvement compared to baseline during study follow-up.
sPGA: static Physicians Global Assessment

Table 3. Summary of the main clinical and quality of life outcomes at designated timepoints, according to body site affected with psoriasis.

	FP patients	GP patients
Achieving sPGA score 0 or 1 and at least 2-grade improvement vs baseline		
At 12 weeks, n (%)	120 (83.3%)	153 (76.5%)
At 28 weeks, n (%)	126 (90.6%)	178 (93.7%)
At 52 weeks, n (%)	120 (93.8%)	185 (97.9%)
PASI		
At baseline	13.7 (9.3)	12.8 (8.8)
At 12 weeks, mean (SD)	1.4 (2.7)	1.9 (4.3)
At 28 weeks, mean (SD)	0.6 (1.3)	0.8 (1.8)
At 52 weeks, mean (SD)	0.5 (1.4)	0.6 (1.6)
PASI change from baseline[a]		
At 12 weeks, mean (95% CI)	−12.3 (−13.8, −10.8)*	−11.1 (−12.4, −9.8)*
At 28 weeks, mean (95% CI)	−13.1 (−14.7, −11.5)*	−12.2 (−13.5, −11.0)*
At 52 weeks, mean (95% CI)	−13.3 (−14.9, −11.7)*	−12.4 (−13.7, −11.2)*
BSA[b]		
At baseline	26.9 (19.0)	27.5 (18.0)
At 12 weeks, mean (SD)	3.4 (6.6)	5.0 (10.5)
At 28 weeks, mean (SD)	1.4 (2.7)	1.6 (3.6)
At 52 weeks, mean (SD)	0.9 (3.0)	0.6 (1.9)
BSA change from baseline[ab]		
At 12 weeks, mean (95% CI)	−23.5 (−27.2, −19.8)*	−22.6 (−26.1 − 19.3)*
At 28 weeks, mean (95% CI)	−25.0 (−28.9, −21.0)*	−26.2 (−29.8, −22.6)*
At 52 weeks, mean (95% CI)	−27.3 (−31.7, −22.9)*	−27.4 (−31.1, −23.7)*
DLQI		
At baseline	12.0 (7.5)	12.0 (6.9)
At 12 weeks, mean (SD)	2.4 (3.6)	3.5 (5.5)
At 28 weeks, mean (SD)	1.5 (2.3)	2.1 (3.8)
At 52 weeks, mean (SD)	1.1 (2.0)	1.6 (3.5)
DLQI change from baseline[a]		
At 12 weeks, mean (95% CI)	−10.3 (−12.8, −7.8)*	−7.6 (−9.6, −5.5)*
At 28 weeks, mean (95% CI)	−11.1 (−13.3, −8.8)*	−9.8 (−11.6, −8.1)*
At 52 weeks, mean (95% CI)	−11.1 (−13.4, −8.8)*	−10.3 (−12.0, −8.5)*

BSA: body surface area; CI: confidence interval; DLQI: Dermatology Quality of life Index; FP: facial psoriasis; GP: genital psoriasis; PASI: Psoriasis Area Severity Index; SD: standard deviation; sPGA: static Physicians Global Assessment.
[a]Change from baseline analyses included only patients with both a baseline value and a value at the designated timepoint.
[b]Only patients with a BSA score ≥10 at baseline were included in the analysis.
*p-value < 0.001, ANOVA for change from baseline.

each timepoint were 67.8%, 84.4%, and 88.3%, respectively. Among patients with BSA ≥10% at baseline, mean BSA decreased from 26.9% ± 19.0% at Week 0 to 0.9% ± 3.0% at Week 52 among patients with facial psoriasis (p-value < 0.001) and from 27.5% ± 18.0% to 0.6% ± 1.9% among those with genital psoriasis (p-value < 0.001). Mean DLQI scores decreased

Table 4. Proportions of patients with facial and genital psoriasis achieving sPGA 0 or 1 and at least 2-grade improvement at week 52, stratified by selected variables.

	FP patients	GP patients
Age		
≤ 60 years	105 (94.6%)	142 (97.3%)
> 60 years	15 (88.2%)	43 (100.0%)
p-value[a]	0.32	0.27
BMI		
< 30 kg/m^2	91 (95.8%)	150 (97.4%)
≥ 30 kg/m^2	29 (87.9%)	35 (100.0%)
p-value[a]	0.11	0.34
Duration of psoriasis		
< 5 years	22 (95.7%)	36 (94.7%)
≥ 5 years	98 (93.3%)	149 (98.7%)
p-value[a]	0.68	0.13

BMI: body mass index; FP: facial psoriasis; GP: genital psoriasis; sPGA: static Physicians Global Assessment; VAS: Visual Analogue Scale.
[a]p-value from chi-square test, for comparison of achievement of sPGA across subgroups stratified by age, BMI and duration of psoriasis.

Table 5. Adverse events reported during the study for all patients receiving at least one administration of study agent.

	n (%)	Total number of AE
At least one TEAE	77 (21.9%)	142
At least one treatment-related TEAE	7 (2.0%)	8
Gastrointestinal disorders	*1 (0.3%)*	*1*
General disorders and administration site conditions	*2 (0.6%)*	*2*
Infections and infestations	*2 (0.6%)*	*2*
Musculoskeletal and connective tissue disorders	*1 (0.3%)*	*1*
Skin and subcutaneous tissue disorders	*2 (0.6%)*	*2*
At least one severe TEAE	6 (1.7%)	9
At least one TESAE	8 (2.3%)	10
At least one treatment-related TESAE	0 (0.0%)	0
Study drug withdrawal due to TEAE	8 (2.3%)	13
At least one TEAE leading to death	0 (0.0%)	0

TEAEs: treatment-emergent adverse events; TESAEs: treatment-emergent serious adverse events.

from 12.0 ± 7.5 at baseline to 1.1 ± 2.0 at week 52 in the facial psoriasis group (p-value < 0.001) and from 12.0 ± 6.9 to 1.6 ± 3.5 in the genital psoriasis group (p-value < 0.001). For all VAS outcomes examined, including those for pain, itch, discomfort, redness, scaling and thickness, significant improvements at Week 52 were observed in both the facial and genital psoriasis groups, as shown in Supplementary Table 1 (all p-values < 0.001).

Results of stratified analyses (according to age, BMI and duration of psoriasis) regarding the proportions of patients achieving an sPGA score of 0 or 1 and at least 2-grade improvement at Week 52 are shown in Table 4. High response rates were observed in all subgroups, with proportions of patients achieving the target sPGA endpoint always above 85% and no significant difference across any of the strata examined (all p-values were > 0.05).

Safety findings are shown in Table 5. A total of 142 AEs occurred during the study, with 21.9% of patients reporting at least one AE. Eight treatment-related AEs occurred in 7 of 351 patients (2.0%). Eight patients (2.3%) reported at least one SAE, none of which were treatment-related. Guselkumab therapy was discontinued in 8 patients (2.3%) due to the occurrence of AEs. No AEs leading to death were recorded. Additional safety details are given in the supplementary materials. Supplementary Table 2 reports the distribution of AEs according to severity and system organ class. Supplementary Table 3 shows the distribution of TEAEs leading to study drug withdrawal according to system organ class.

Discussion

Results of the GULLIVER study, conducted in a real-world setting in Italy over a 1 year period of observation, demonstrate a high level of effectiveness with guselkumab treatment for patients with facial and/or genital psoriasis, and safety findings consistent with the well-established guselkumab safety profile. In particular, almost all patients with genital psoriasis and over 90% of those with facial psoriasis achieved an sPGA score of 0 or 1 at 1 year, and all clinical and QoL outcomes showed dramatic improvements over the study period for both high impact body sites. Complete resolution of psoriatic lesions, based on PASI 100 response, was achieved by more than three-fourths of patients. Furthermore, most patients completed the full 1-year treatment schedule.

Clinical findings of the GULLIVER study, including sPGA, PASI 75, PASI 90, PASI 100 and BSA outcomes, were comparable to those obtained in patients with more generalized moderate-to-severe plaque psoriasis derived from randomized controlled trials (21,24) and real-life studies (26,27, 34,35) for guselkumab. Thus, results from GULLIVER support the high effectiveness of guselkumab for psoriasis involving the less well-studied facial and genital body sites.

Evidence-based information derived from a real-life setting to help guide management of psoriasis involving these difficult-to-treat body areas is sparse. In a recent study of ixekizumab, which included 26 patients with genital psoriasis, 95% of cases achieved an sPGA score of ≤1 at Week 52 (19). A high effect of ixekizumab, with substantial improvements in PASI scores, was also reported in the short term (i.e., at 12 weeks) in a Chinese observational study considering various high impact areas with psoriasis involvement (17). Further, a long-term real-world study from Greece examined the role of secukinumab in difficult-to-treat manifestations of psoriasis (16). The study included 99 bio-naïve patients, 27 of whom had genital psoriasis. By Week 52, 86% of patients achieved PASI 75, 78% achieved PASI 90, and 43% achieved PASI 100. In the German PERSIST study, 153 psoriasis patients with anogenital involvement were treated with guselkumab; marked improvement was noted, with 84% of patients achieving an area-specific PGA score of ≤1 at Week 28 (27). Similar proportions of patients achieved equivalent site-specific responses for scalp and palmoplantar psoriasis in the same study. Results from the large cohort of patients in the GULLIVER study are consistent with those for guselkumab in the PERSIST study. Further research is needed, however, to fill additional knowledge gaps in the management of difficult-to-treat body areas with psoriasis involvement.

The impact of facial and genital psoriasis on patients' QoL is strong and well-recognized (6,9). In our study, mean DLQI scores improved from 12 points at baseline – a score indicating a very large effect of psoriasis on QoL (36) – to 1.1 and 1.6 points (i.e., no effect of psoriasis on QoL), respectively, in patients with facial and genital psoriasis after 1 year of guselkumab treatment. Comparable improvements were also recorded for several QoL-domains related to symptoms of psoriasis, including pruritus, pain and discomfort. Availability of data on patients' QoL

response in high impact body areas are even more limited. In the PERSIST real-world study of guselkumab therapy, 83% of patients with anogenital involvement had a DLQI score of ≤5 at week 28 (i.e., no or small effect of psoriasis on QoL), compared to just 7% at baseline (27). Another recent German observational psoriasis study (G-EPOSS) reported a decrease in patients' perception of stigma from 51% to 8%, and of sexual impairment from 54% to 12%, alongside an overall improvement in health-related QoL, after 28 weeks of guselkumab therapy (37). The GULLIVER study, in turn, provides additional data to augment the limited body of evidence on the favorable impact of biologic treatment, namely guselkumab, on the impairment of QoL associated with facial and genital psoriasis.

Guselkumab demonstrated an excellent safety profile in the GULLIVER study, consistent with previous findings from both clinical trials and observational studies (27,38). The percentage of patients reporting severe AEs during the 52 weeks of study follow-up was below 2%, and none were associated with infections or infestations nor were treatment-related. A similarly low proportion of patients (i.e., 2.3%) withdrew from the GULLIVER study due to the occurrence of an AE, consistent with drug tolerability findings from other guselkumab studies.

Limitations of this study are those typical of observational real-world analyses in general. These include, among others, the risk of information bias, the lack of a comparison group, and a likely higher frequency of missing data compared to clinical trials. On the other hand, real-world studies generate findings in a context that closely reflects everyday clinical practice, without the strict inclusion criteria of RCTs, which often exclude patients with psoriasis involving high impact areas. The multicenter, nationwide study design, the large numbers of facial and genital psoriasis patients enrolled (which also allows for some subgroup analyses), and the low proportion of patients lost to follow-up are among the main strengths of this investigation.

In conclusion, we provide information regarding the high effectiveness of guselkumab in real-life treatment of facial and genital psoriasis. The significance of these findings derives from the overall paucity of available real-world evidence on patients suffering with facial and genital psoriasis, the high unmet need for addressing their disease burden and psychophysical wellbeing. Increasing awareness of the availability of effective therapies for genital psoriasis, in particular, may also encourage more patients to report, and physicians to consider this largely under-reported and under-treated disease manifestation.

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Data availability statement

The datasets generated and/or analyzed during the current study are not publicly available due to legal/commercial restrictions. Requests to access the datasets should be directed to fsaibenei@its.jnj.com. Access to anonymized individual participant-level data will not be provided for this study as it meets one or more of the exceptions described on https://yoda.yale.edu/ under 'Data Use Agreement - Janssen Pharmaceuticals DUA.'

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