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BRIEF REPORT

Real-World Effectiveness of 9–12 Months of Guselkumab Therapy among Patients with Moderate-to-Severe Plaque Psoriasis in the CorEvitas Psoriasis Registry

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ABSTRACT

Introduction: Guselkumab, an anti-interleukin-23 biologic therapy, has been shown to significantly reduce disease activity and improve patient-reported outcome measures (PROMs) among patients with moderate-to-severe plaque psoriasis in clinical trials. However, characterization of the real-world effectiveness of guselkumab among patients living in the USA and Canada is warranted.

Methods: Patients who participated in the CorEvitas Psoriasis Registry between 18 July 2017 and 10 March 2020 were included if they met the following criteria: Investigator's Global Assessment (IGA) score ≥ 3 and body surface area (BSA) ≥ 10% (moderate-to-severe psoriasis), initiated guselkumab at a registry (index) visit, and had a registry follow-up visit after 9–12 months of persistent guselkumab therapy. Data were retrieved for baseline patient demographics and disease characteristics, treatment history, disease activity, and PROMs. Outcomes were assessed at index and follow-up visits; response rates and mean changes were calculated.

Results: Among 113 patients, mean age was 49.7 years, mean psoriasis duration was 17.5 years, and 65.5% of patients were biologic experienced. At baseline, mean IGA score was 3.3, Psoriasis Area Severity Index (PASI) score was 13.6, and Dermatology Life Quality Index (DLQI) score was 9.6. At follow-up, IGA 0/1, PASI 90, and DLQI 0/1 were achieved by 62.2%, 56.8%, and 54.7% of patients, respectively. Statistically significant improvements were observed in all disease activity scores and PROMs, including the EuroQoL Visual Analogue Scale, Work Productivity and Activity Impairment, Patient Global Assessment, fatigue, skin pain, and itch ($p < 0.05$).

Conclusions: This real-world study showed that patients with moderate-to-severe psoriasis who received 9–12 months of persistent guselkumab therapy experienced improvements in disease severity and PROMs.

Keywords: CorEvitas Psoriasis Registry; Guselkumab; Psoriasis; Moderate to severe; Real world; Effectiveness; USA; Canada

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Key Summary Points

Why carry out this study?

Guselkumab is a fully human monoclonal antibody that targets the p19 subunit of the cytokine interleukin-23 and has shown improvements in disease severity and patient-reported outcome measures in randomized clinical trials of patients with moderate-to-severe psoriasis.

Several real-world studies have shown the effectiveness of guselkumab in the moderate-to-severe population in everyday clinical practice; however, these analyses have typically focused on relatively short durations of therapy, evaluated small patient populations, analyzed few outcomes, and/or did not focus on patients living in the USA and Canada.

The objective of this study was to evaluate the effectiveness of persistent guselkumab use for 9–12 months among patients with moderate-to-severe plaque psoriasis who initiated treatment in the CorEvitas Psoriasis Registry and were living in the USA or Canada.

What was learned from this study?

At follow-up, guselkumab-treated patients showed statistically significant improvements in all disease activity endpoints and patient-reported outcome measures related to health-related quality of life, work productivity, symptoms, and daily functioning compared with the index visit.

This study is among the first to show the benefits of 9–12 months of persistent guselkumab therapy across a wide range of disease activity scores and patient-reported outcome measures among patients with moderate-to-severe psoriasis living in the USA and Canada.

INTRODUCTION

Guselkumab is a fully-human immunoglobulin G1λ antibody that selectively binds to the p19 subunit of interleukin-23 (IL-23), inhibiting its interaction with the IL-23 receptor [1]. In the pivotal phase III VOYAGE 1 (NCT02207231) and VOYAGE 2 (NCT02207244) clinical trials, the therapy was shown to significantly improve several disease activity endpoints and patient-reported outcome measures (PROMs) compared with placebo and adalimumab among patients with moderate-to-severe plaque psoriasis [2, 3]. On the basis of these studies, the Food and Drug Administration (FDA) and Health Canada approved guselkumab in 2017 for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy [1, 4]. Guidelines from the American Academy of Dermatology and the National Psoriasis Foundation (NPF) recommend guselkumab monotherapy for this indication [5].

Although randomized-controlled trials remain the gold standard for evaluation of the safety and efficacy of new therapies, study protocols may not include the entire spectrum of patients seen in clinical practice [6]. The current study therefore sought to assess the real-world effectiveness of 9–12 months of guselkumab therapy among patients with moderate-to-severe psoriasis (defined as IGA [Investigator's Global Assessment] $\geq$ 3 and body surface area [BSA] $\geq$ 10%) enrolled in the CorEvitas Psoriasis Registry. This work builds on a recently conducted analysis of patients with a broader range of psoriasis severities (IGA score $\geq$ 2, indicating mild or greater disease) followed in the registry, which showed that up to 1 year of persistent guselkumab therapy led to statistically significant improvements from baseline across several disease activity outcomes and PROMs [7]. It was hypothesized that similar to the previous analysis, treatment with guselkumab would improve these outcomes among patients with moderate-to-severe psoriasis.

METHODS

Data Source

Patient data were obtained from the CorEvitas Psoriasis Registry, an independent, non-interventional, multicenter registry that was launched in April 2015 in collaboration with the NPF. As detailed elsewhere [7, 8], this observational registry prospectively collects data from US and Canadian sites for patients who are ≥ 18 years of age, have dermatologist-diagnosed psoriasis, are willing and able to provide written informed consent for registry participation, and started on or switched to an eligible psoriasis treatment (FDA-approved biologics and non-biologic systemics) at enrollment or ≤ 12 months before enrollment. Effectiveness data and PROMs are collected from dermatologists and patients at enrollment and during subsequent outpatient clinical encounters, which occur at approximately 6-month intervals.

Study Population

Data were collected from patients with CorEvitas Psoriasis Registry visits that occurred between 18 July 2017 (the approval date of guselkumab) and 10 March 2020 (the latest registry data cut at the time of the analysis). Patients were included for analysis if they met the following criteria: diagnosis of plaque psoriasis, initiated guselkumab at or after registry enrollment during a registry visit (the index date), received persistent treatment with guselkumab for ≥ 9 months after the index date, had a follow-up registry visit between 9 and 12 months after the index date, and had an IGA score ≥ 3 and BSA ≥ 10% at initiation of guselkumab. Patients could have attended ≥ 1 registry visit within the 9–12-month follow-up window; in such cases, data were used from the visit closest to 12 months to consider the longest follow-up possible.

Study Outcomes and Other Variables

The primary outcome of interest was the proportion of patients who achieved IGA 0/1 (clear/almost clear skin) at their follow-up visit. Secondary outcomes included the proportion of patients who achieved improvement milestones on other measures of disease activity (IGA 0; PASI 75, 90, 100) at follow-up, mean changes in IGA, PASI, and BSA, and the following PROMs: Dermatology Life Quality Index (DLQI) 0/1 (maintained or achieved, as well as achieved among patients with DLQI > 1 at the index visit), Work Productivity and Activity Impairment (WPAI), EuroQoL visual analog scale (EQ-VAS), and fatigue, skin pain, overall itch, and Patient Global Assessment (PGA) on the VAS-100 scale. These measures have been detailed previously [7, 9–17]. Demographics, socioeconomic characteristics, and disease characteristics were also assessed at the index visit.

Data Analysis

Descriptive statistics were calculated for variables captured at the index visit. Counts (*n*) and frequencies (%) were calculated for categorical variables and means and standard deviations (SD) were calculated for continuous variables. For the primary and secondary dichotomous response outcomes, the proportion of patients who achieved a response at follow-up was calculated with a 95% confidence interval (CI). For the secondary mean change outcomes, mean values were calculated for all patients at both the index and follow-up visits; differences between these values were then calculated for individual patients and mean differences and 95% CIs (confidence intervals) were reported. Paired Student's *t*-tests were used to estimate the mean difference in these outcomes and calculate *p*-values, testing a null hypothesis of no change ($\alpha = 0.05$). Stata Release 15 (StataCorp LLC, College Station, Texas, USA) was used to perform all analyses.

Compliance with Ethics Guidelines

The CorEvitas registry and its investigators were reviewed and approved by a central institutional review board (IRB; IntegReview, Corrona-PSO-500). For academic investigative sites that did not receive a waiver to use the central IRB, full board approval was obtained from the respective governing IRBs. All registry participants were required to provide written informed consent and authorization prior to participating. The study was performed in accordance with the Declaration of Helsinki of 1964 and its later amendments.

RESULTS

Between 18 July 2017, and 10 March 2020, a total of 1301 patients were identified who had initiated guselkumab at or after the time of enrollment in the CorEvitas Psoriasis Registry (Fig. 1). Of these patients, 825 had at least one follow-up visit and 547 had persistent use of guselkumab for at least 9 months; 240 of these patients had initiated guselkumab at a registry visit and had a follow-up visit that occurred between 9 and 12 months after the index date. Among these patients, 235 had plaque psoriasis, and 113 had an IGA score ≥ 3 and BSA $\geq 10\%$ at the index visit. These 113 patients represented the population for analysis.

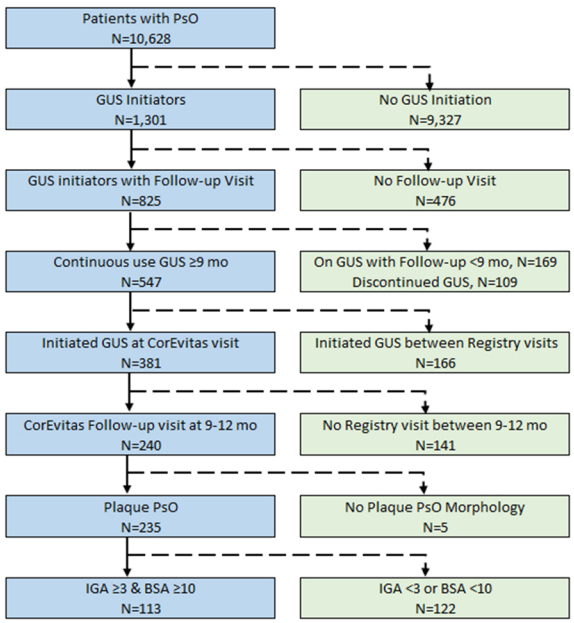

Fig. 1 Flowchart for identification of patients included from the CorEvitas Psoriasis Registry. *BSA* body surface area, *GUS* guselkumab, *IGA* Investigator's Global Assessment, *mo* months, *PsO* psoriasis

Baseline Demographics and Disease Characteristics

At baseline, the mean (SD) age of included patients was 49.7 (14.5) years; 39.8% were female and 80.0% were white (Table 1). Mean BMI was 32.9 kg/m^2 (7.9) and half of patients with data were current or former smokers. The most frequent comorbidities were hypertension (34.5%) and infection (any; 33.6%) and the mean number of comorbidities was 0.3 (0.6).

For psoriasis morphology history, 46.9% of patients had scalp psoriasis, 18.6% had nail, 11.5% had palmoplantar, 8.9% had inverse/intertriginous, and 4.4% each had guttate and/or erythrodermic disease (Table 1). The mean (SD) duration of psoriasis since diagnosis was 17.5 (13.5) years. Among the 110 of 113 patients with data, 30.9% had been diagnosed with psoriatic arthritis (PsA) by a dermatologist; 30.6% had a Psoriasis Epidemiology Testing Tool (PEST) score ≥ 3. A total of 66% patients had received at least one prior biologic therapy and half had received at least one prior non-biologic oral systemic agent at any time before initiation of guselkumab.

At the index visit, mean (SD) scores were 3.3 (0.5) for IGA, 20.5% (13.3) for BSA, 13.6 (8.2) for PASI, and 9.6 (6.2) for DLQI (Table 1). The WPAI results showed that 68.1% of patients were currently employed; among these individuals, the mean percent of work hours missed was 5.4% (16.8), impairment while working was 21.9% (26.3), and work hours affected was 19.9% (24.1) (all related to psoriasis). Among all patients, the mean percent daily activities affected was 29.6% (29.4). Mean scores for fatigue, skin pain, and itch on the VAS-100 were 38.9 (30.3), 41.9 (34.0), and 59.8 (29.2), respectively; mean EQ-VAS and PGA scores were 68.0 (20.7) and 55.9 (28.2), respectively.

Table 1 Patient demographics and disease characteristics at the index visit

Patient characteristics	*N* = 113 unless otherwise specified
Demographic characteristics	
Age (years), mean (SD)	49.7 (14.5)
Gender (female), *n* (%)	45 (39.8%)
Race, white, *n* (%)	90 (80.0%)
Ethnicity, Hispanic, *n* (%)	N = 110
	14 (12.7%)
Work status, full time, *n* (%)	72 (63.7%)
Lifestyle characteristics	
Smoking history, *n* (%)	N = 87
Never	44 (50.6%)
Former	26 (29.9%)
Current	17 (19.5%)
BMI (kg/m^2)	N = 112
Mean (SD)	32.9 (7.9)
Categorical, *n* (%)	
BMI < 25 (underweight/normal)	16 (14.3%)
BMI 25 to < 30 (overweight)	30 (26.8%)
BMI ≥ 30 (obese)	66 (58.9%)
Comorbidities	
History of selected comorbidities, *n* (%)	
Hypertension	39 (34.5%)
Any infection[a]	38 (33.6%)
Any serious infection	4 (3.5%)
Depression	26 (23.0%)
Hyperlipidemia	23 (20.4%)
Anxiety	22 (19.5%)
Diabetes mellitus	21 (18.6%)
Cardiovascular disease[b]	11 (10.0%)
Cancer	9 (8.0%)
Crohn's disease	1 (0.9%)
Ulcerative colitis	0 (0.0%)
Number of comorbidities[c]	
Mean (SD)	0.3 (0.6)

Table 1 continued

Patient characteristics	*N* = 113unless otherwise specified
Psoriasis presentation and duration	
History of psoriasis morphology[d], n (%)	
Guttate	5 (4.4%)
Erythrodermic	5 (4.4%)
Pustular (localized)	0 (0.0%)
Pustular (generalized)	0 (0.0%)
Inverse/intertriginous	10 (8.9%)
Scalp	53 (46.9%)
Nail	21 (18.6%)
Palmoplantar	13 (11.5%)
Psoriasis duration (years), mean (SD)	*N* = 112
	17.5 (13.5)
Psoriasis patients with PsA	
PSA, Dermatologist diagnosed, *n* (%)	*N* = 110
	34 (30.9%)
PsA, Diagnosis confirmed by rheumatologist, *n* (%)	20 (17.7%)
PsA duration (years)[e], mean (SD)	*N* = 34
	11.6 (12.7)
PEST Score of 3+ , *n* (%)	*N* = 111
	34 (30.6%)
Psoriasis treatment characteristics	
Concomitant psoriasis therapy[f], *n* (%)	
GUS + systemic therapy	7 (6.2%)
GUS + topical agents	55 (48.7%)
GUS + phototherapy	5 (4.4%)
No. of prior biologic therapies used[e,g], *n* (%)	
0	39 (34.5%)
1	18 (15.9%)
≥ 2	56 (50.0%)
No. of prior non-biologic systemic therapies used,[f,h] *n* (%)	
0	57 (50.4%)

Table 1 continued

Patient characteristics	*N* = 113unless otherwise specified
1	34 (30.1%)
≥ 2	22 (19.5%)
Disease activity	
BSA (% involvement)	
Mean (SD)	20.5 (13.3)
Categorical, *n* (%)	
3–10% (moderate disease)	24 (21.2%)
> 10% (severe disease)	89 (78.8%)
PASI score	
Mean (SD), (range: 0–72)	13.6 (8.2)
IGA score	
Mean (SD), (range: 0–4)	3.3 (0.5)
Patient-reported outcome measures	
DLQI Score (range 0–30)	*N* = 112
Mean (SD)	9.6 (6.2)
WPAI summary scores, (range 0–100%)	*N* = 113
Currently employed, *n* (%)	77 (68.1%)
% Work hours missed due to PsO[i], *n*	*N* = 70
Mean (SD)	5.4 (16.8)
% Impairment while working due to PsO[i], *n*	*N* = 69
Mean (SD)	21.9 (26.3)
% Work hours affected by PsO[i], *n*	*N* = 71
Mean (SD)	19.9 (24.1)
% Daily activities affected by PsO, *n*	*N* = 113
Mean (SD)	29.6 (29.4)
EQ-VAS (0–100)	
Mean (SD)	68.0 (20.7)
Patient Global Assessment (VAS: 0–100)	
Mean (SD)	55.9 (28.2)
Patient Fatigue Assessment (VAS: 0–100)	*N* = 112
Mean (SD)	38.9 (30.3)
Patient Skin Pain Assessment (VAS: 0–100)	
Mean (SD)	41.9 (34.0)
Patient Overall Itch Assessment (VAS: 0–100)	
Mean (SD)	59.8 (29.2)

AIDs acquired immunodeficiency syndrome, *BMI* body mass index, *BSA* body surface area, *DLQI* Dermatology Life Quality Index, *EQ-VAS* European Quality of Life Visual Analog Scale, *GUS* guselkumab, *IGA* Investigator's Global Assessment, *IV* intravenous, *No.* number, *PASI* Psoriasis Area Severity Index, *PEST* Psoriasis Epidemiology Screening Tool, *PsA* psoriatic arthritis, *PsO* psoriasis, *SD* standard deviation, *TB* tuberculosis, *TIA* transient ischemic attack, *VAS* Visual Analog Scale, *WPAI* Work Productivity and Activity Impairment

[a] Infections included joint/bursa, cellulitis/skin, sinusitis, Candida, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, meningitis/encephalitis, urinary tract, upper respiratory, TB, and other. Infections resulting in hospitalization or administration of IV antibiotics indicated serious infection

[b] Cardiovascular disease includes baseline history of any of the following: cardiac revascularization procedure, ventricular arrhythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, coronary artery disease, congestive heart failure; cerebrovascular disease includes baseline history of any of the following: stroke, TIA, peripheral vascular disease, peripheral arterial disease

[c] Includes the following comorbidities: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease (stroke or transient ischemic attack), chronic obstructive pulmonary disease, history of peptic and/or gastrointestinal bleeding ulcer, diabetes mellitus, leukemia, lymphoma, solid tumor cancer (excluding non-melanoma skin cancer), and liver disease

[d] All included patients had a diagnosis of plaque psoriasis. Additional morphologies present in this population are summarized in this section

[e] Restricted to patients with dermatologist-diagnosed PsA

[f] Not mutually exclusive; percentages may not sum to 100

[g] Prior biologic count does not include patients' current biologic

[h] Prior non-biologic systemic use count does not include the current non-biologic systemic therapy, if applicable. Non-biologic users are biologic naïve

[i] Evaluated among currently employed patients

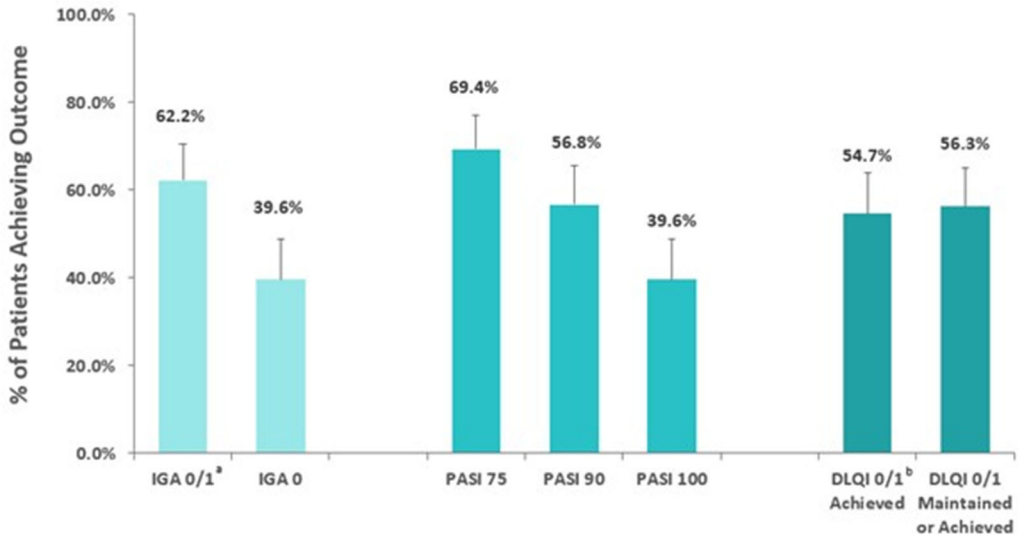

Fig. 2 Proportion of patients achieving IGA, PASI, and DLQI outcomes after 9–12 months of persistent use of guselkumab. [a]Primary endpoint; [b]DLQI 0/1 achieved among patients with a DLQI score > 1 at the index visit. $N = 111$ for all outcomes except DLQI 0/1 achieved among those with DLQI > 1 at baseline ($N = 106$) and DLQI 0/1 maintained or achieved ($N = 112$). Vertical bars represent 95% CIs. *CI* confidence interval, *DLQI* Dermatology Life Quality Index, *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area Severity Index

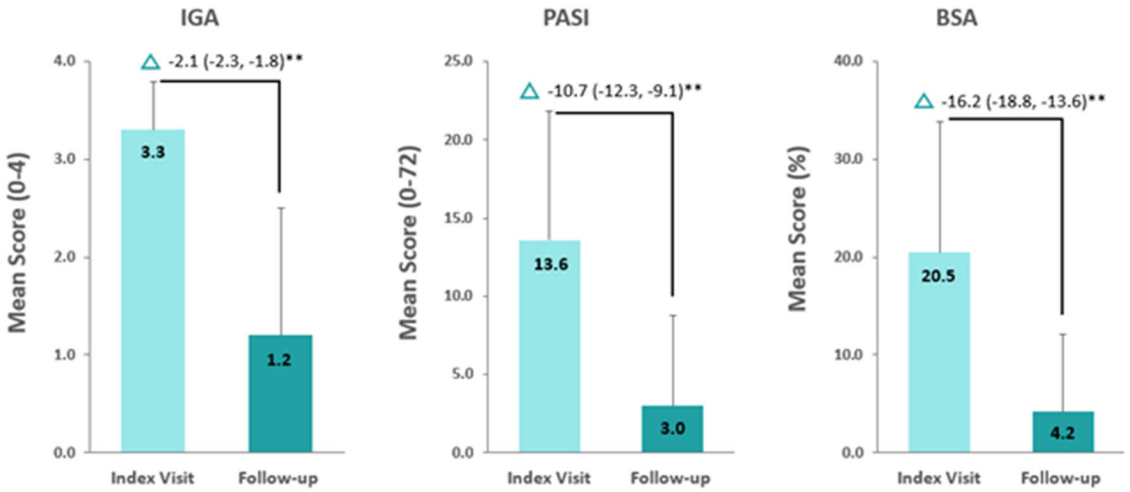

Fig. 3 Mean changes in disease activity outcomes between index and follow-up visits after 9–12 months of persistent use of guselkumab. $^{**}p < 0.001$. $N = 111$ for all outcomes. Vertical bars represent standard deviations; Δ indicates the mean change (95% CI) in values between the index and follow-up visits. Improvements are indicated by negative values. *BSA* body surface area, *CI* confidence interval, *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area Severity Index

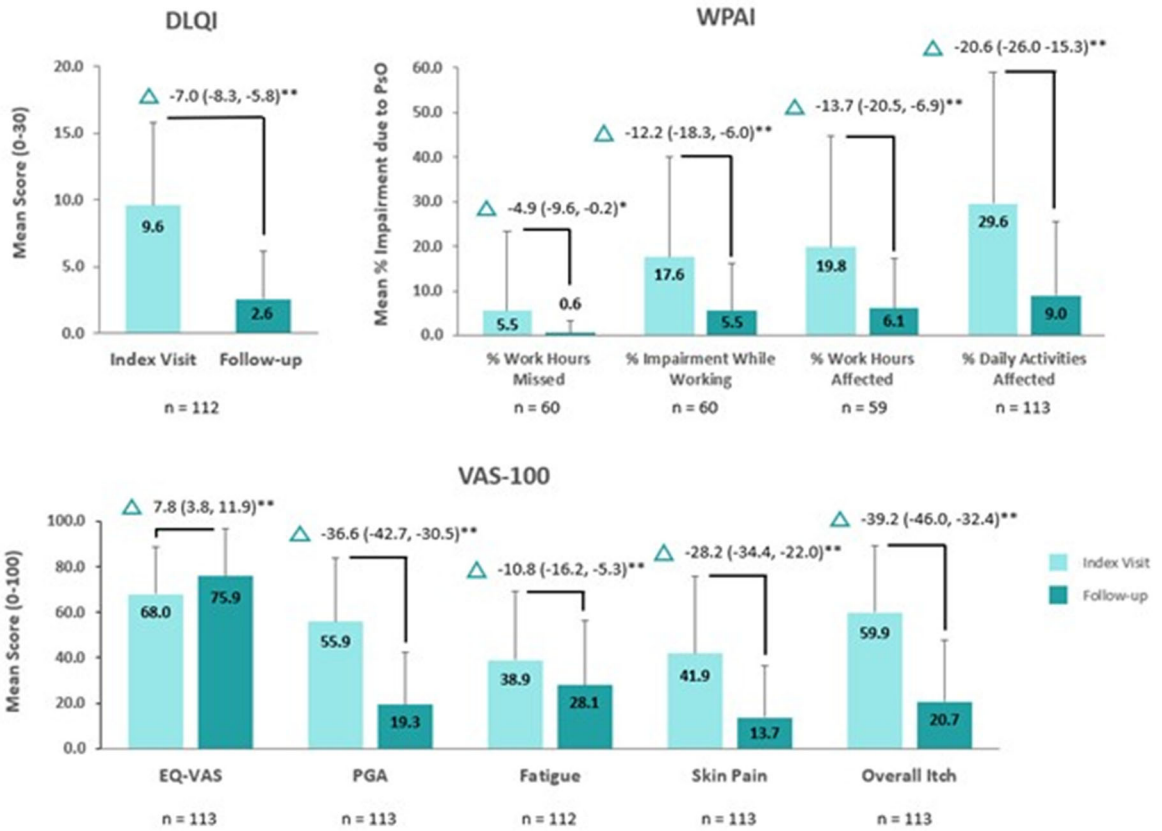

Fig. 4 Mean changes in PROMs between index and follow-up visits after 9–12 months of persistent use of guselkumab. $^{*}p < 0.05$; $^{**}p < 0.001$. Vertical bars represent standard deviations; Δ indicates the mean change (95% CI) in values between the index and follow-up visits. Improvements are reflected by negative values for all outcomes except the EQ-VAS. Data are only presented for patients with values at both index and follow-up visits. *CI* confidence interval, *DLQI* Dermatology Life Quality Index, *EQ-VAS* EuroQoL 5 Dimensions Visual Analog Scale, *PROMs* patient-reported outcomes measures, *VAS* Visual Analog Scale, *WPAI* Work Productivity and Activity Impairment

Primary and Secondary Outcomes

Among the 113 included patients, 62.2% achieved an IGA score of 0/1 at their follow-up visit (primary outcome), indicating their skin was clear or almost clear (Fig. 2). An IGA score of 0 (clear) was achieved by 39.6% of patients and PASI 75, 90, and 100 were achieved by 69.4%, 56.8%, and 39.6% of patients, respectively. Among the 106 patients with a DLQI score > 1 at baseline, 58 (54.7%) achieved a DLQI score of 0/1; 63 of 112 patients (56.3%) maintained or achieved this outcome. From the index visit to follow-up, mean improvements were observed across all disease activity scores (Fig. 3) and PROMs (Fig. 4) ($p < 0.05$).

DISCUSSION

This study prospectively analyzed real-world data from 113 patients with moderate-to-severe psoriasis who had received persistent treatment with guselkumab for 9–12 months in the USA and Canada and were enrolled in the CorEvitas Psoriasis Registry. The findings show that, similar to our analysis of patients with baseline IGA severities of mild, moderate, or severe (IGA $\geq$ 2) [7], guselkumab-treated patients experienced

significant improvements from baseline in psoriasis activity, the ability to work, overall HRQoL, symptom burden, and daily functioning. With the exception of IGA 0/1 and WPAI work hours affected, the magnitude of improvement in all outcomes was higher in the current study than in our prior analysis. This finding is not unexpected, given differences in baseline characteristics (e.g., biologic exposure) between the study cohorts.

Real-world evaluations of drug therapies are important to inform clinical practice, given that differences commonly exist between the characteristics of patients receiving therapy in everyday care versus those enrolled in randomized clinical trials. Several other real-world studies of guselkumab have been conducted that also included varying definitions of moderate-to-severe psoriasis. Most of these evaluations were retrospective in design, included smaller patient populations, had shorter follow-up durations, and/or evaluated fewer outcomes than the current study [7, 18–32]. Furthermore, although guselkumab has been commercially available in the USA and Canada since 2017 [1, 4], only two previous real-world studies included patients living in these countries [7, 22]. Regardless, similar to the findings of the current analysis, these investigations showed that guselkumab therapy was associated with improvements in disease severity outcomes (e.g., PASI, BSA) and a limited number of PROMs (e.g., DLQI, PGA). The magnitude of these improvements varied across the other real-world studies and the current analysis, likely resulting from differences in baseline patient characteristics. As highlighted above, evidence from other investigations suggests that an increased response to guselkumab therapy may be achieved among patients who are biologic naïve, as well as those without comorbidities and potentially those with lower BMIs [18, 20, 23–25]. As such, additional analysis of the CorEvitas population is warranted to understand outcomes among these patient subgroups and others, such as those with concomitant PsA.

Strengths and Limitations

Several strengths can be noted for this study. Patients were included across multiple sites located in the USA and Canada and numerous disease activity outcomes and PROMs were assessed, thereby providing a comprehensive evaluation of the impact of guselkumab. Additionally, the study had a prospective design and included a larger patient population and a longer treatment duration than most other real-world studies of guselkumab. However, some limitations should be considered. Patients were only included if they had received persistent treatment with guselkumab, thus the findings may not be generalizable to all patients who receive guselkumab. Furthermore, patients with persistent guselkumab therapy who did not have a follow-up registry visit at 9–12 months were excluded. Finally, the CorEvitas Psoriasis Registry only includes patients residing in the USA and Canada, limiting generalizability, and participation by patients and dermatologists is voluntary, which may introduce selection bias if, for example, healthier or sicker patients are more likely to be enrolled.

CONCLUSIONS

In this real-world study of patients with moderate-to-severe plaque psoriasis in the CorEvitas Psoriasis Registry, 9–12 months of persistent treatment with guselkumab was associated with statistically significant improvements in all evaluated disease activity outcomes and PROMs. These benefits extend beyond the reductions in disease activity that have been reported in previous real-world studies of guselkumab, showing improvement of overall HRQoL, symptoms, the ability to work, and daily functioning, and provide additional support for the label indication for guselkumab. Evaluation of longer-term treatment with guselkumab, as well as its use in other subpopulations that may experience variations in response, is warranted to fully understand the effectiveness of therapy.

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Author Contributions. Robert R McLean, Timothy Ftizgerald, Katelyn Rowland, and Amanda Teeple were responsible for study conception and design. Robert R McLean, Ying Shan, and Lin Gao were responsible for acquisition, analysis, and interpretation of data. Access to study data was limited to CorEvitas, and CorEvitas statisticians completed all analyses. All authors were responsible for drafting the manuscript, contributing to the interpretation of the results, critically revising/reviewing the manuscript, and providing final approval.

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Compliance with Ethics Guidelines. The study was performed in accordance with the Declaration of Helsinki and the Guidelines for Good Pharmacoepidemiology Practice (GPP). All participating investigators were required to obtain full board approval for conducting non-interventional research involving human subjects with a limited dataset. Sponsor approval and continuing review was obtained through a central Institutional Review Board (IRB), the New England Independent Review Board (NEIRB; no. 120160610). For academic investigative sites that did not receive authorization to use the central IRB, full board approval was obtained from their respective governing IRBs and documentation of approval was submitted to CorEvitas, LLC before the site's participation and initiation of any study procedures. All patients in the registry were required to provide written informed consent and authorization before participating.

Data Availability. Data are available from CorEvitas, LLC through a commercial subscription agreement and are not publicly available. No additional data are available from the authors.

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