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The Disease Burden of Generalized Pustular Psoriasis: Real-World Evidence From CorEvitas' Psoriasis Registry

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Abstract

Background: Generalized pustular psoriasis (GPP) is a rare, systemic disease characterized by persistent or recurrent flares of painful neutrophilic pustules. There is limited real-world evidence characterizing patients with GPP. **Objectives:** To establish the distinguishing characteristics of GPP relative to plaque psoriasis, and help inform future treatment decisions and improve patient outcomes. **Methods:** North American adults with GPP or plaque psoriasis (without pustules) identified from CorEvitas' Psoriasis Registry were included in this dataset. Registry enrollment data, including patient sociodemographics, disease characteristics, medication use, and patient-reported outcome measures were compared for patients with GPP vs those with plaque psoriasis. This study was descriptive, and no hypothesis tests were performed. **Results:** In this sample, patients with GPP (N = 60) reported greater median (interquartile range) pain (20 [3-62] vs 5 [0-35]), fatigue (44 [15-73] vs 20 [4-50]), and itch (59 [10-85] vs 22 [5-70]) than those with plaque psoriasis (N = 4894). Descriptively, patients with GPP also reported more anxiety and depression (EQ-5D-3L: 38% vs 26%) and had more treatment experience (≥2 previous systemics: 15% vs 7%). **Conclusions:** A greater degree of symptom severity and impact on quality of life was reported by patients with GPP compared with plaque psoriasis in this sample. Importantly, patients with GPP had more treatment experience, suggesting that current treatment options do not adequately resolve the disease—highlighting the need to develop more effective GPP treatments.

Keywords

Psoriasis, generalized pustular psoriasis, Plaque psoriasis, dermatology, registry

Introduction

Generalized pustular psoriasis (GPP) is a potentially life-threatening, rare, systemic, chronic autoinflammatory disease.[1-4] It is classically characterized by recurrent acute flares that can persist and that comprise widespread diffuse dermatitis with accompanying neutrophil-filled, sterile pustules.[2-5] With or without therapies currently approved in psoriatic disease, acute flares may persist and/or reoccur, leading to serious complications, and most patients experience residual disease post flare despite treatment.[3,6] Although GPP occurs both independently and in association with plaque psoriasis, clinical and genetic evidence suggests that they are distinct entities;[2,4] plaque psoriasis is an immune disease associated with deregulation of the innate and/or adaptive immune systems,[7-9] whereas GPP is typically linked to uncontrolled activation of the interleukin (IL)-36 pathway.[4,10,11]

Generalized pustular psoriasis is a rare disease, with a reported prevalence of between 0.01 and 0.02/10,000 in France to 5/10,000 in Germany.[12,13] Accordingly, there is limited information available in scientific literature about patients with GPP and their clinical characteristics. Understanding GPP is further complicated by the number of different disease forms with varying natural histories and symptoms that have been grouped under "GPP," either with or without systemic symptoms—from the classic and acute "von

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Zumbusch" type to the "annular" form.[3,5,14] GPP causes significant extracutaneous and systemic morbidity, and can lead to death in certain cases,[2,3] with metabolic, cardiac, liver, respiratory, and neurologic comorbidities reported.[6] Mortality rates as a direct result of GPP range from 3% to 25%.[6,15,16] Due to limited information and varying guidelines, the standard of care for patients with GPP varies by region.[5,17,18] Globally, very few countries have any treatments specifically approved for GPP. In countries with approved treatments, approval is based on open-label trials, case studies, or the very few cases found in general psoriasis trials.[19] The lack of approved treatments specifically for GPP means that patients are often treated similarly to those with plaque psoriasis; although these treatments help manage GPP symptoms to some degree, they do not address the multifactorial underlying drivers of inflammation in GPP.[10,20] While retinoids are a systemic treatment for psoriasis and are known to be effective for the treatment of palmoplantar pustulosis,[21] they are teratogenic and therefore contraindicated for women of childbearing age.[22] Furthermore, they regularly cause mucocutaneous adverse events including hair loss, cheilitis, pyogenic granulomas, and retinoid dermatitis. Additional treatments, including tumor necrosis factor inhibitors (TNFi; eg, infliximab) and IL inhibitors such as IL-12/23i (ustekinumab), IL-23 (eg, risankizumab and guselkumab), and IL-17 (eg, ixekizumab and secukinumab) are indicated in plaque psoriasis and may be used to manage the symptoms of pustular psoriasis; however, the prospective, open-label studies of these treatments for GPP used non–disease-specific endpoints (eg, Clinical Global Impression index) that were assessed at 12–16 weeks, so clinically meaningful aspects (such as the rapid or spontaneous resolution of painful pustules) could not be adequately assessed.[23-26] Furthermore, they are not specific to the IL-36 pathway and so may not provide sufficiently targeted long-term treatment for GPP. Treatment success in many trials of therapies for GPP is defined as any improvement. Importantly, the withdrawal and/or use of topical or systemic treatments, including steroids, TNFi therapies, and some IL inhibitors, has even precipitated GPP flares.[11,18,27-29] Therefore, there is a great need for approved, safe, highly effective treatments for patients with GPP.

Establishing the distinguishing characteristics and unique disease burden of GPP compared to psoriasis without pustules could help to inform treatment decisions and facilitate the development of specific treatments for GPP, improving patient outcomes. Delineating the specific needs of patients with GPP may guide treatment development and aims, while characterizing GPP may help to structure clinical trials around this rare, relapsing/remitting disease.

Using data from CorEvitas' Psoriasis Registry, this real-world study aims to define, describe, and compare the clinical characteristics and patient-reported symptoms that differentiate GPP from plaque psoriasis among patients based in the USA who are experiencing current treatments for psoriasis, and how they are related to disease severity.

Materials and Methods

To address the need for more substantial and cohesive data on psoriasis, CorEvitas developed the Psoriasis Registry in collaboration with the National Psoriasis Foundation and collects real-world clinical data on patients with psoriasis. The Registry is a prospective, multicenter, observational, disease-based registry containing clinical data on patients with a diagnosis of psoriasis who are under the care of a dermatologist, including patients with GPP. To join the Registry, patients must have a dermatologist-confirmed diagnosis of psoriasis, be at least 18 years of age, provide written informed consent, and have started or switched to an eligible systemic psoriasis treatment within the past 12 months or at the time of enrollment. CorEvitas' Psoriasis Registry captures a breadth of randomized controlled trial-equivalent outcome measures for these patients, from clinical and patient-reported outcomes (PROs) to safety. As of the data cut-off (January 10, 2020), a total of 10,026 patients with psoriasis were enrolled in the Registry.

In this study, patients were classified as having GPP if they had a dermatologist-confirmed diagnosis of generalized pustules (0.6% of the registry); patients were classified as having plaque psoriasis if they had a dermatologist-confirmed diagnosis of plaque psoriasis but no other form of psoriasis (48.8% of the registry). Given the rarity of GPP, and the fact that GPP can coexist with plaque psoriasis, the GPP population included patients with concomitant plaque psoriasis.

Data collected upon enrollment in CorEvitas' Psoriasis Registry included patient demographics, medication history, medical history, clinical assessments, and lifestyle factors. Patient sociodemographics, disease characteristics, comorbidities, medications, and PROs were assessed as variables in this study. All comparisons were conducted using data collected at the time of enrollment into the registry. Due to the small GPP sample size and the exploratory nature/large number of potential outcomes, no hypothesis testing was performed in this study. As such, all results reported here are descriptive, and apply to this sample only; no inferences can be made about the population from which this sample was drawn.

The first study objective aimed to describe the characteristics of patients with GPP and plaque psoriasis. The second study objective aimed to descriptively compare the characteristics and PROs of patients with GPP and with those with plaque psoriasis. To facilitate these objectives, categorical variables from the Registry were summarized using frequencies and percentages, while continuous variables were described using mean, standard deviation, and median, interquartile range.

The third study objective aimed to compare the characteristics and PROs of patients with GPP with those with plaque psoriasis, stratified by disease severity. Using either body surface area (BSA; range 0-100%) or the Psoriasis Area Severity Index (PASI; range 0-72), patients were classified as having either mild or moderate-to-severe disease. Mild disease was defined as <3% BSA affected and moderate-to-severe

Table 1. Sociodemographics of Patients in This Study With GPP and Plaque Psoriasis.

Characteristic	GPP	GPP sample size	Plaque psoriasis	Plaque psoriasis sample size
Age, years, mean (SD)	50.9 (14.3)	60	50.6 (14.3)	4894
Sex, female, n (%)	36 (60.0)	60	2174 (44.4)	4894
Health insurance type, n (%)		55		4662
Private	33 (60.0)		3480 (74.6)	
Medicare	16 (29.1)		811 (17.4)	
Medicaid			546 (11.7)	
No insurance			153 (3.3)	
Education, n (%)		59		4882
High school graduate/GED	23 (39.0)		1189 (24.4)	
College graduate or higher	21 (35.6)		1841 (37.7)	
Work status, n (%)		60		4886
Full-time	31 (51.7)		2926 (59.9)	
Part-time	—		399 (8.2)	
Retired	9 (15.0)		781 (16.0)	
Disabled	12 (20.0)		369 (7.6)	
Other	—		411 (8.4)	
Smoking status, current, n (%)	12 (20.3)	59	822 (17.0)	4844
BMI (kg/m^2), n (%)		59		4826
Normal/underweight (≤24.9)	9 (15.3)		929 (19.2)	
Overweight (25–29.9)	15 (25.4)		1489 (30.9)	
Obese (≥30)	35 (59.3)		2408 (49.9)	

Abbreviation: BMI, body mass index; GED, General Education Development; GPP, generalized pustular psoriasis; SD, standard deviation. Categories are not an exhaustive list due to the small sample size.

disease as ≥3%. A PASI score of ≤5 was defined as mild disease and a score >5 as moderate-to-severe disease. Comparisons were conducted for severity-stratified samples between patients with GPP and with those with plaque psoriasis, in line with the first and second objectives.

Results

In total, 60 patients with GPP and 4894 patients with plaque psoriasis were identified and included in the analyses. Patients enrolled in this study were similar in terms of age, with small differences in educational status, sex, and body mass index (Table 1).

Although patients with GPP and those with plaque psoriasis in this sample were generally similar in sociodemographic and disease characteristics, there appears to be some differences between the two groups (Tables 1 and 2). Patients with GPP scored higher on the Psoriasis Epidemiology Screening Tool (PEST), with 38.3% scoring 3+ vs 27.3% of patients with plaque psoriasis, indicating that in this sample, patients with GPP reported a high degree of joint, heel, and nail discomfort. Patients with GPP also had a higher prevalence of psoriatic arthritis versus those with plaque psoriasis (45.0% vs 35.2%, respectively) as diagnosed by their treating dermatologist; however, caution should be taken when interpreting this result as this diagnosis was not confirmed by a rheumatologist. In addition, in the CorEvitas Psoriasis Registry (formerly known as Corrona), more patients with GPP versus plaque psoriasis reported that their current work status was disabled (20.0% vs 7.6%, respectively). Some comorbidity history also differed between patients with GPP and those with plaque psoriasis (Table 2). A higher proportion of patients with GPP had a history of hypertension (46.7% vs 36.8%), asthma (11.7% vs 5.8%), clinician-reported anxiety (28.3% vs 17.1%), and clinician-reported depression (31.7% vs 17.1%) compared with those with plaque psoriasis in this sample.

Descriptively, a higher proportion of patients with GPP had experience with biologic and non-biologic systemic therapies, with 60.0% of patients with GPP receiving prior biologic therapies compared to 45.6% with plaque psoriasis (Table 2). Likewise, 56.7% of patients with GPP had experience with non-biologic systemic therapies compared to 39.5% with plaque psoriasis. In addition, a higher proportion of these patients with GPP had received ≥2 previous non-biologic systemic therapies compared with patients with plaque psoriasis (15.0% vs 6.7%, respectively).

In this sample, patients with GPP reported a greater degree of symptom severity and impact on quality of life (QoL) than patients with plaque psoriasis (Table 3). Patient Global Assessment score (a PRO measure of global disease impact from 0 to 100, for which a higher number indicates greater impact) was greater in patients with GPP compared with those with plaque psoriasis (mean 45.6 vs 35.9 and median 50.0 vs 30.0, respectively). Patient-reported overall pain (mean 33.1 vs 21.5; median 20.0 vs 5.0), itch (mean 47.7 vs 35.4; median 59.0 vs 22.0), and fatigue (mean 42.6 vs 29.5; median 44.0 vs

Table 2. Disease Characteristics, Comorbidities, and Prior Treatment Regimens of Patients with GPP and Plaque Psoriasis.

Characteristic	GPP	GPP sample size	Plaque psoriasis	Plaque psoriasis sample size
Psoriasis duration, years		60		4848
Mean (SD)	12.1 (12.2)		14.6 (13.5)	
Median (IQR)	8.0 (2.0-22.0)		11.0 (4.0-22.0)	
Psoriatic arthritis, n (%)	27 (45.0)	60	1674 (35.2)	4762
Psoriatic arthritis duration, years		27		1674
Mean (SD)	7.8 (8.5)		7.3 (8.3)	
Median (IQR)	5.0 (0.0-14.0)		4.0 (1.0-11.0)	
PEST, n (%)		60		4842
3+	23 (38.3)		1337 (27.6)	
BSA, n (%)		60		4881
Mild disease (<3%)	20 (33.3)		1774 (36.3)	
Moderate-to-severe disease (≥3%)	40 (66.7)		3107 (63.7)	
PASI (range 0–72), n (%)		60		4886
≤10	50 (83.3)		4006 (82.0)	
>10	10 (16.7)		880 (18.0)	
IGA, n (%)		60		4883
0: Clear	6 (10.0)		701 (14.4)	
1: Almost clear	9 (15.0)		813 (16.6)	
2: Mild	18 (30.0)		1129 (23.1)	
3: Moderate	22 (36.7)		1778 (36.4)	
4: Severe	5 (8.3)		462 (9.5)	
History of comorbidities, n (%)				
Malignancies other than skin cancer	5 (8.3)	60	165 (3.4)	4894
Infections		60		4893
All	29 (48.3)		1339 (27.4)	
Serious	8 (13.3)		194 (4.0)	
Due to select pathogens	9 (15.0)		262 (5.4)	
Hypertension	28 (46.7)	60	1801 (36.8)	4889
Other CVD (eg stroke)	7 (11.7)	60	298 (6.1)	4894
Hyperlipidemia	16 (26.7)	60	1230 (25.2)	4889
Diabetes mellitus	13 (21.7)	60	708 (14.5)	4889
Asthma	7 (11.7)	60	285 (5.8)	4889
Depression	19 (31.7)	60	835 (17.1)	4889
Anxiety	17 (28.3)	60	838 (17.1)	4889
Treatment experience, n (%)				
Biologic exposure		60		4894
Biologic naïve	24 (40.0)		2662 (54.4)	
1 previous biologic	21 (35.0)		1167 (23.8)	
≥2 previous biologics	15 (25.0)		1065 (21.8)	
Non-biologic systemic exposure		60		4894
Systemic naïve	26 (43.3)		2963 (60.5)	
1 previous systemic	25 (41.7)		1603 (32.8)	
≥2 previous systemics	9 (15.0)		328 (6.7)	
Phototherapy	26 (43.3)	60	1958 (40.0)	4893
Current therapy		44		3301
TNFi	13 (29.5)		879 (26.6)	
Non-TNFi biologic	26 (59.1)		2035 (61.6)	
Systemic non-biologic	5 (11.4)		387 (11.7)	

Abbreviation: BSA, body surface area; CVD, cardiovascular disease; GPP, generalized pustular psoriasis; IGA, Investigator Global Assessment; IQR, interquartile range; PASI, Psoriasis Area Severity Index; PEST, Psoriasis Epidemiology Screening Tool; SD, standard deviation; TNFi, tumor necrosis factor inhibitor. Categories are not an exhaustive list due to the small sample size.

Table 3. Patient-Reported Symptom and QoL Measures for Those With GPP and Plaque Psoriasis.

Characteristic	GPP	GPP sample size	Plaque psoriasis	Plaque psoriasis sample size
Itch VAS (range 0-100)		60		4887
Mean (SD)	47.7 (36.8)		35.4 (34.3)	
Median (IQR)	59.0 (10.0-85.0)		22.0 (5.0-70.0)	
Fatigue VAS (range 0-100)		60		4885
Mean (SD)	42.6 (31.2)		29.5 (28.4)	
Median (IQR)	44.0 (15.0-73.0)		20.0 (4.0-50.0)	
Pain VAS (range 0-100)		60		4883
Mean (SD)	33.1 (34.2)		21.5 (29.0)	
Median (IQR)	20.0 (2.5-62.0)		5.0 (0.0-35.0)	
Patient global assessment		60		4882
Mean (SD)	45.6 (31.2)		35.9 (30.1)	
Median (IQR)	50.0 (15.0-74.0)		30.0 (10.0-60.0)	
Currently employed, n (%)	35 (58.3)	60	3336 (68.2)	4893
Percent work hours missed		29		3001
Mean (SD)	8.3 (12.9)		3.3 (13.7)	
Median (IQR)	0.0 (0.0-10.0)		0.0 (0.0-0.0)	
Percent work impairment		29		2958
Mean (SD)	28.6 (26.2)		12.5 (21.3)	
Median (IQR)	24.0 (3.0-50.0)		0.0 (0.0-15.0)	
Overall percent work hours affected		29		2968
Mean (SD)	23.6 (23.1)		11.3 (20.0)	
Median (IQR)	20.0 (0.0-35.0)		0.0 (0.0-13.0)	
Percent daily activity impairment		60		4849
Mean (SD)	31.9 (32.9)		17.1 (25.5)	
Median (IQR)	20.0 (0.5-55.0)		3.0 (0.0-25.0)	
DLQI score (range 0-30)				
Mean (SD)	7.8 (6.8)		6.5 (6.1)	
Median (IQR)	5.0 (2.0-14.0)		5.0 (2.0-10.0)	
DLQI "Effect on life," n (%)		60		4882
0: None	10 (16.7)		1202 (24.6)	
1: Small	23 (38.3)		1483 (30.4)	
2: Moderate	—		1012 (20.7)	
3: Very large	18 (30.0)		1014 (20.8)	
4: Extremely large	—		171 (3.5)	
Patient health state		60		4877
EQ-5D VAS (range 0-100)				
Mean (SD)	63.4 (23.8)		73.9 (20.9)	
Median (IQR)	70.0 (50.0-85.0)		80.0 (65.0-90.0)	
EQ-5D-3L, n (%)		60		4833
Walking	21 (35.0)		1106 (22.9)	
Self-care	13 (21.7)		289 (6.0)	
Usual activities	26 (43.3)		1252 (25.9)	
Pain and discomfort	42 (70.0)		2298 (47.5)	
Anxiety and depression	23 (38.3)		1245 (25.8)	

Abbreviation: DLQI, Dermatology Life Quality Index; EQ-5D-3L, EuroQol 5-Dimensions 3-Levels; GPP, generalized pustular psoriasis; IQR, interquartile range; QoL, quality of life; SD, standard deviation; VAS, visual analog scale. Categories are not an exhaustive list due to the small sample size.

20.0) were all higher in patients with GPP compared with those with plaque psoriasis in this sample (all reported on a scale of 0 to 100). Furthermore, 70.0% of patients with GPP had self-reported overall pain and discomfort on the EQ-5D-3L, compared with only 47.5% of patients with plaque psoriasis; patients with GPP also reported more anxiety and depression than patients with plaque psoriasis (38.3% vs 25.8%; Table 3).

The reported percentage of impairment while working was higher for patients with GPP than those with plaque psoriasis (Work Productivity and Activity Impairment [WPAI], mean 28.6 vs 12.5; median 24.0 vs 0), with more than double the

mean percentage of working hours missed (WPAI, mean 8.3 vs 3.3, median both 0). In addition, patients with GPP were more impaired in their daily activities than patients with plaque psoriasis (WPAI, mean 31.9% vs 17.1%; median 20.0% vs 3.0%) (Table 3).

Patient data were also stratified by disease severity, as assessed by BSA and PASI. Overall, more patients in each group were classified as having "mild" disease according to PASI, while more patients were classified as "moderate-to-severe" according to BSA. As GPP typically does not involve plaque thickness or hyperkeratosis, which are the primary rating characteristics of psoriasis severity using PASI, PASI-based severity ratings may not have accurately captured the severity of GPP. That said, regardless of severity classification, patients with GPP reported greater symptom severity and resulting QoL impairment relative to those with plaque psoriasis (Supplementary Tables S1 and S2).

Discussion/Conclusion

In this real-world evidence study of patients within CorEvitas' Psoriasis Registry, sociodemographic factors were similar between patients with GPP and plaque psoriasis, with some distinct differences in disease characteristics, comorbidities, and PROs. Patients in the GPP population reported a greater degree of symptom severity, with their disease resulting in greater impact on QoL and more severe symptoms of pain, fatigue, and itch than in the plaque psoriasis population. This may be due in part to the lack of highly effective treatments currently available for GPP. Patients with GPP had higher PEST scores and incidence of psoriatic arthritis, and were less able to attend work and carry out work tasks and daily activities than patients with plaque psoriasis. Furthermore, a higher proportion of patients with GPP had clinically reported anxiety and depression. These differences (worse QoL for patients with GPP than those with plaque psoriasis) were observed even at the same level of disease severity categorized by BSA or PASI. It is possible that GPP categorized as "mild" by BSA or PASI might have a disproportionate effect on patients, and that patients with "mild" GPP may require a more aggressive treatment strategy than patients with plaque psoriasis with similar disease severity. Ongoing studies into IL-36 pathway inhibitors, building on promising proof-of-concept results in GPP, may lead to a future treatment option that can rapidly and effectively alleviate the clinical symptoms of GPP.[30,31]

As a result of the CorEvitas' Psoriasis Registry enrollment criteria, all patients (regardless of whether they had GPP or plague psoriasis) had to be on advanced therapy. This may explain why patients with GPP in this sample typically received similar treatments to those with plaque psoriasis. Such treatment decisions may derive from the lack of GPP-specific therapies available or may be driven by the requirement to treat other concomitant diseases. This highlights the clear need for treatments that directly address the unmet needs of patients with GPP.

However, there are some notable limitations to this study. Consistent with the rarity of GPP, the sample size of the GPP cohort was relatively small. The resulting size discrepancy between the GPP and plaque psoriasis cohorts means that no statistical tests were performed. As such, this study is purely descriptive, and no statistical inferences can be made. The results herein only apply to this registry sample rather than the population in general, and caution should be taken when interpreting any differences.

Furthermore, patients within CorEvitas' Psoriasis Registry may not represent typical patients with recurring GPP flares. Patients were classified into the GPP cohort based on each patient's full history of psoriasis subtypes, determined at the discretion of their dermatologist. GPP has been reported as a disease with phenotypic heterogeneity and may include the presence of chronic as well as acute lesions in a subset of patients.[11] Thus, it is not clear whether a "GPP patient" had pustules at the time of enrollment (when outcome measures were collected). In addition, several subtypes of GPP have been described that vary in severity. Classic GPP, also known as the highly acute "von Zumbusch" type, is associated with very severe symptoms,[12,14] but milder systemic pustules may also be classified as GPP, albeit controversially.[3] Finally, given that GPP was not available as a formal diagnosis for patients within CorEvitas' Psoriasis Registry, patients were classified in this study as having GPP if they had a history of generalized pustules; as such, it is possible that some patients included in this group did not have GPP. The possible inclusion of subacute cases, and exclusion of acute cases, may have resulted in an underestimation of some differences between patients with GPP and those with plaque psoriasis.

Finally, dermatologist ratings of PASI, BSA, and IGA for patients with GPP within CorEvitas' Psoriasis Registry are likely to have been based on concomitant plaque psoriasis, rather than GPP. These non-GPP-specific measures do not account for the pustular component of psoriasis, and induration (a key measure of severity in PASI) is rarely found in GPP. This means that one cannot state that the classifications of disease severity for the GPP cohort accurately reflect differences in severity of GPP. The use of BSA or PASI to stratify GPP by disease severity may not be appropriate. Patients with GPP typically experience recurrent flares with intermittent residual disease, and these measures only characterize a specific timepoint in that patient's disease course, rather than capturing their long-term experience.

Overall, this report has delineated descriptive differences between patients with GPP (defined in this study as patients with a history of generalized pustules) and those with plaque psoriasis. Outcomes for patients with GPP and their experience of the disease were more severe compared with patients with plaque psoriasis without pustules. This report highlights a clear need to develop therapeutic approaches specifically for patients with GPP, and special considerations for their management to improve patient outcomes in this rare disease.

Conflict of Interest Statement

This study design and conduct were the result of a collaborative effort between CorEvitas, LLC and Boehringer Ingelheim. Dr Strober reports being an investigator for AbbVie, Dermavant, CorEvitas, Dermira; speaker for AbbVie, Janssen, Ortho Dermatologics; consultant for AbbVie, Almirall, Amgen, Arena, Aristea Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Janssen, LEO Pharma, Eli Lilly, Kyowa Hakko Kirin, Meiji Seika Pharma, Novartis, Pfizer, GlaxoSmithKline, UCB, Sun Pharma, Ortho Dermatologics, Regeneron, Sanofi-Genzyme; Co-Scientific Director for CorEvitas. Dr Lebwohl reports paid consulting activities for Aditum Bio, Almirall, AltruBio Inc. AnaptysBio, Arcutis, Inc. Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, CorEvitas, Dermavant Sciences, Dr Reddy's Laboratories, Evelo Biosciences, Evommune, Inc. Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica; and research funds from AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen Research & Development, LLC, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB. Dr Kotowsky, Dr Valdecantos, and Dr Flack are full-time employees of Boehringer Ingelheim. Dr Golembesky reports being employed by Boehringer Ingelheim at the time of the study being conducted, but is currently employed by GSK. Dr Mackey was an employee of CorEvitas, LLC at the time of the study being conducted, but is currently employed by Premier, Inc. Dr Medeiros reports being an of employee of CorEvitas, LLC at the time of the study being conducted, but is currently employed by R.A. Medeiros Statistical Consulting, Columbus, Ohio. LR Harrold is a shareholder and an employee of CorEvitas, LLC, has received funding from Pfizer, and has been a consultant to AbbVie, Bristol Myers Squibb and Roche.

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Ethical approval

All participating investigators were required to obtain full board approval for conducting non-interventional research involving human subjects. Sponsor approval and continuing review was obtained through a central Institutional Review Board (IRB) (IntegReview, Protocol # 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 and documentation of approval was submitted to CorEvitas prior to initiating any study procedures. All registry patients were required to provide written informed consent and authorization prior to participating.

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Supplemental Material

Supplemental material for this article is available online

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