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 ORIGINAL ARTICLE

Tildrakizumab Real-World Effectiveness and Safety Over 64 Weeks in Patients With Moderate-to-Severe Plaque Psoriasis

Jayme Heim MSN FNP-BC,[a] J. Gabriel Vasquez MD,[a] Tina Bhutani MD MAS FAAD,[b] John Koo MD,[b] Jacob Mathew PharmD MBA,[c] Ranga Gogineni PhD,[c] Thomas Ferro MD,[c] Neal Bhatia MD FAAD[d]

[a]West Michigan Dermatology, Grandville, MI
[b]University of California San Francisco Health, San Francisco, CA
[c]Sun Pharmaceutical Industries, Inc., Princeton, NJ
[d]Therapeutics Clinical Research, San Diego, CA

ABSTRACT

Background: Tildrakizumab is a humanized anti–interleukin-23 p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis. This report describes real-world effectiveness and safety of tildrakizumab through 64 weeks of treatment.
Methods: In this Phase 4, multicenter, uncontrolled, open-label trial (NCT03718299), adults with moderate-to-severe plaque psoriasis received tildrakizumab 100 mg at weeks 0 and 4 and every 12 weeks thereafter through week 52. Effectiveness was assessed from body surface area (BSA) affected and static Physician Global Assessment (sPGA) through week 64 and Psoriasis Area and Severity Index (PASI) through week 52. Adverse events are reported.
Results: Of 55 patients enrolled, 45 completed the study and 36 received all doses of tildrakizumab. From baseline to week 64, mean ± standard deviation BSA decreased by 83.1% (from 14.5 ± 11.5 to 2.1 ± 3.6) and sPGA by 67.6% (from 3.2 ± 0.6 to 1.0 ± 1.0); sPGA x BSA decreased by 89.6% (from 47.0 ± 41.5 to 4.6 ± 9.4; all $P<0.001$). PASI scores decreased compared to baseline at weeks 4, 16, 28, and 52 ($P<0.001$). For PASI responses at week 52 compared with baseline, 87.0% achieved ≥75% improvement, 56.5% achieved ≥90% improvement, and 32.6% achieved 100% improvement. Of 85 treatment-emergent adverse events in 34/55 patients, none were considered related to tildrakizumab treatment.
Conclusions: Tildrakizumab treatment was effective in adult patients with moderate-to-severe plaque psoriasis in real-world settings, with no new safety signals.

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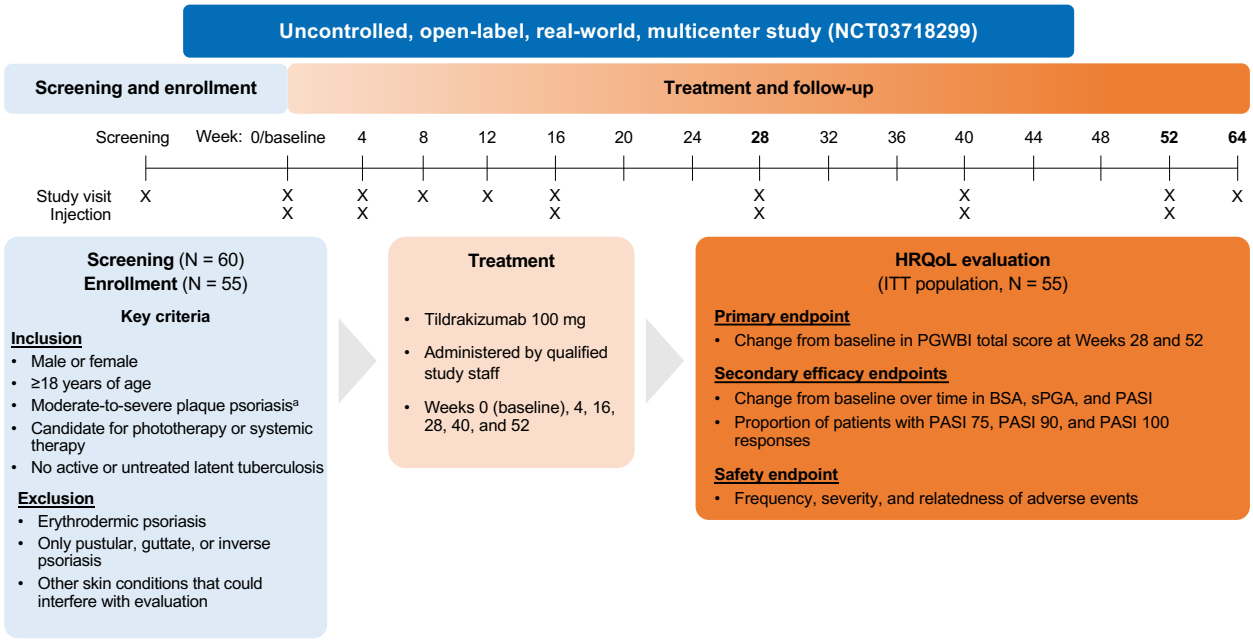
INTRODUCTION

Plaque psoriasis, the most common type of psoriasis, is a chronic, inflammatory skin disorder that requires life-long management.[1-3] This multisystem disease is associated with a range of medical and psychological comorbidities, including cardiovascular disease, obesity, type 2 diabetes, psoriatic arthritis, inflammatory bowel disease, and depression.[1,3] Moderate-to-severe plaque psoriasis typically requires systemic treatment, although topical treatments and phototherapy are also available.[3]

Tildrakizumab is a humanized anti–interleukin-23 p19 monoclonal antibody therapy approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic or phototherapy.[4-6] The safety and efficacy of tildrakizumab in patients with moderate-to-severe plaque psoriasis were established in two Phase 3 randomized, double-blind clinical trials (reSURFACE 1 [NCT01722331] and reSURFACE 2 [NCT01729754]).[7-9] Patients receiving tildrakizumab who completed the 64-week reSURFACE 1 or 52-week reSURFACE 2 study with at least a ≥50% improvement from baseline Psoriasis Area and Severity Index (PASI) score could enroll in optional extension studies continuing the same dose for an additional 4 years.[10,11] Pooled analysis of data from reSURFACE 1 and reSURFACE 2 and corresponding extension studies demonstrated sustained disease control and a favorable safety profile for up to 5 years of treatment in patients who achieved a ≥75% improvement from baseline PASI score (PASI 75 response) at week 28.[11]

The long-term efficacy and safety of tildrakizumab are well established in randomized, blinded clinical trial settings, but real-world evidence is limited.[3] To address this gap, we performed a Phase 4 study to assess the effect of tildrakizumab treatment on health-related quality of life in patients with moderate-to-severe plaque psoriasis over 64 weeks of treatment under real-world conditions.[12,13] Effectiveness and safety were also assessed as secondary endpoints, and interim analysis results demonstrated sustained clinical improvement through week 28, with no new reported safety concerns.[14] Here, we report the effectiveness and safety results through week 64 of the Phase 4 study.

FIGURE 1. Study design.



[a]BSA ≥3%. BSA, body surface area; HRQoL, health-related quality of life; ITT, intention-to-treat; PASI, Psoriasis Area and Severity Index; PASI 75/90/100 responses, proportion of patients achieving ≥75%/≥90%/100% improvement from baseline in PASI score; PGWBI, Psychological General Well-Being Index; sPGA, static Physician Global Assessment.

MATERIALS AND METHODS

Study Design and Patients

This Phase 4, 64-week, multicenter, uncontrolled, open-label, real-world study was conducted at 2 study sites in the US (NCT03718299; Figure 1).[12] The study design has been described in detail elsewhere. Briefly, eligible patients were immunocompetent adults ≥18 years of age with moderate-to-severe plaque psoriasis affecting ≥3% of total body surface area (BSA) who were diagnosed ≥6 months before study entry and were candidates for phototherapy or systemic therapy. Exclusion criteria included a diagnosis of erythrodermic psoriasis; only pustular, guttate, or inverse psoriasis; evidence of skin conditions other than psoriasis that would interfere with study-related psoriasis evaluations; treatment with any biological drug other than tildrakizumab within 1 week prior to baseline; or use of any investigational agent or device within 12 weeks of baseline. Patients were administered subcutaneous injections of tildrakizumab 100 mg at week 0, week 4, and every 12 weeks thereafter through week 52. Postbaseline study visits occurred at weeks 4, 8, 12, 16, 28, 40, 52, and 64.

The study protocol and all amendments were approved by a central institutional review board in compliance with pertinent sections of the Code of Federal Regulations prior to study initiation. The study was conducted in accordance with the principles of the Declaration of Helsinki and current guidelines for Good Clinical Practice. All patients provided written informed consent before any study-related procedures were performed.

Assessments

Effectiveness

On all study visits, investigators assessed the percentage of BSA affected using the estimate that 1% BSA is equivalent to the area of the patient's closed hand (palm with fingers held together). For the static Physician Global Assessment (sPGA), the investigator first rated the severity of induration, erythema, and scaling of the psoriatic plaques on individual 6-point scales from 0 (no evidence) to 5 (severe).[15] The scores for each attribute were averaged over the entire body. The final sPGA score was obtained using a scale from 0 (clear, except for residual discoloration) to 5 (severe, lesions have individual scores for induration, erythema, and scaling of at least 5). The sPGA was assessed at all study visits. The PASI score, which captures the severity (erythema, induration, and desquamation) and extent of psoriasis plaques on the head, trunk, upper limbs, and lower limbs on a scale of 0 (no psoriasis) to 72 (most severe), was assessed at baseline and weeks 4, 16, 28, and 52.

Safety

Adverse events (AEs) were recorded throughout the study and classified according to severity and relationship to treatment.

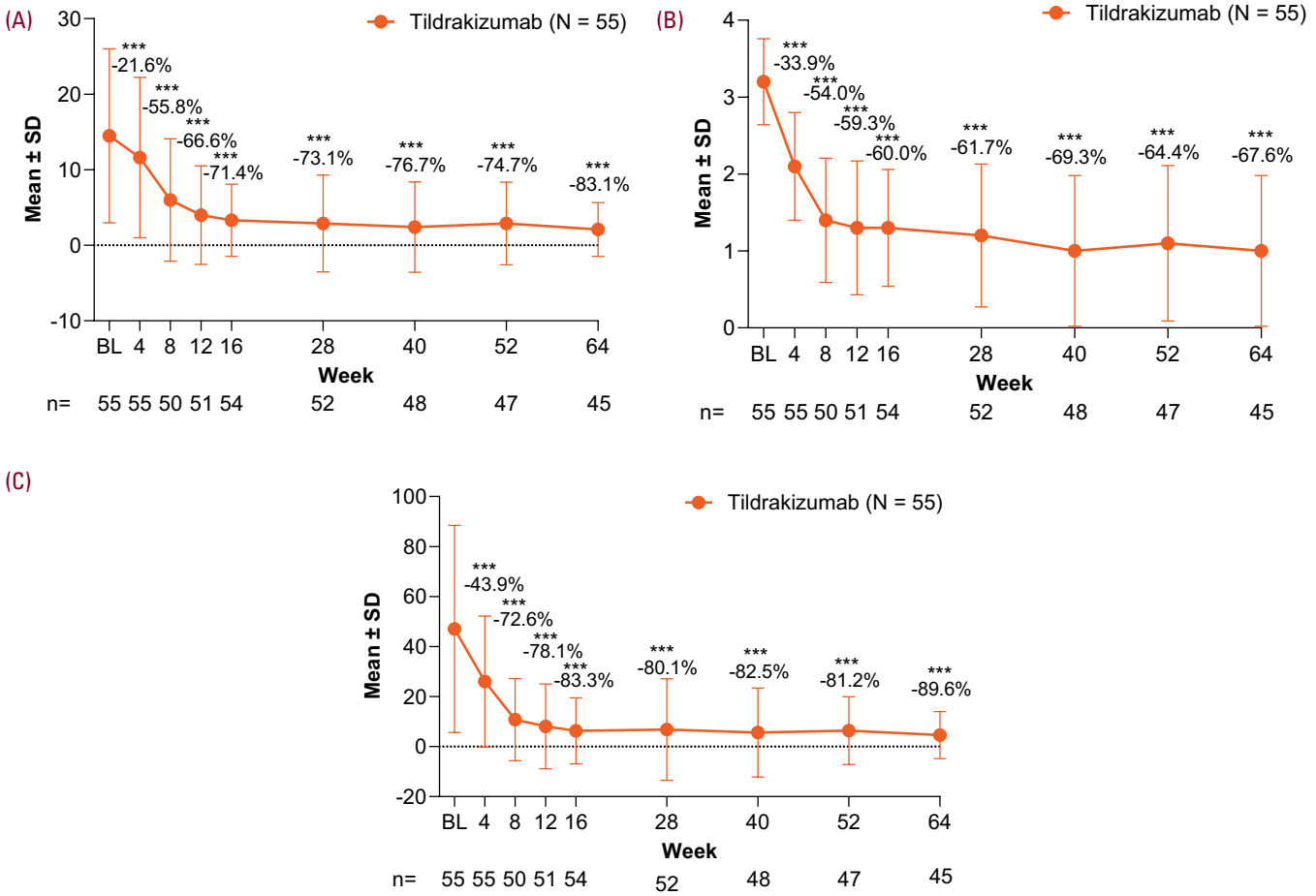
Endpoints

The primary endpoint was change in quality of life defined as the improvement from baseline in the total Psychological General Well-Being Index score at weeks 28 and 52; results are reported elsewhere.[12,13] Secondary effectiveness endpoints reported here include the change in disease activity, based on the percentage of BSA affected, sPGA, and the product of BSA and sPGA (BSA x sPGA) over time through week 64, and clinical improvement through week 52, based on change in PASI score from baseline and proportions of patients achieving PASI 75, PASI 90 (≥90% improvement from baseline in PASI score), and PASI 100 (100% improvement from baseline in PASI score) responses at weeks 4, 16, 28, and 52. Safety endpoints included the incidence, severity, and relationship to treatment of treatment-emergent AEs (TEAEs) and treatment-emergent serious AEs through week 64.

Statistical Analysis

No formal power analysis was performed. A sample size of 60 patients screened was expected to provide adequate estimates of probable events in the population. Effectiveness was analyzed in the intention-to-treat population, consisting of all patients who enrolled and were assigned to receive tildrakizumab. Hypothesis testing of the difference from baseline of the BSA, sPGA, BSA x sPGA, and PASI scores was performed using Student's t-tests. The PASI 75, PASI 90, and PASI 100 response rates are presented as the number and proportion of patients with each level of response. Missing data were not imputed for most time points; however, for all efficacy by visit analyses, an additional end-of-treatment (EOT) value is reported for the final assessment time point using last-observation-carried-forward imputation from each patient's final evaluation for each endpoint. Safety analysis was performed in all enrolled patients who received at least 1

FIGURE 2. Mean change from baseline in (A) BSA, (B) sPGA, and (C) the product of BSA and sPGA (BSA x sPGA) over time through week 64. Data are graphed as the absolute score with the percent change from baseline over each time point.



***P<0.001. BL, baseline; BSA, body surface area; SD, standard deviation; sPGA, static Physician Global Assessment.

dose of tildrakizumab. Reported TEAEs were classified by Medical Dictionary for Regulatory Activities System Organ Class and Preferred Term and summarized by frequency, severity, and relationship to treatment. Analyses were performed using SAS® Version 9.4 or higher. Results are presented as mean ± standard deviation (SD) unless otherwise noted.

RESULTS

Study Population

Of the 60 patients screened, 55 enrolled and 45 (81.8%) of these completed the study and were assessed at week 64; 36 (65.5%) received all doses of tildrakizumab through week 52. The 10 patients who discontinued the study did so due to withdrawal by patient (n = 6), physician decision (n = 2), loss to follow-up (n = 1), and an AE (n = 1). The majority of patients were male (28/55; 50.9%) and White (52/55; 94.5%), with a mean ± SD age of 48.6 ± 15.3 years (Table 1).

Effectiveness

Disease severity improved in tildrakizumab-treated patients through week 64. Affected BSA significantly decreased from a mean of 14.5 ± 11.5 at baseline to 2.1 ± 3.6 at week 64 (95% confidence interval [CI] of change, –16.3 to –9.1; *P*<0.001; mean percent change from baseline, –83.1%; Figure 2A); the week 64/EOT value was 3.1 ± 5.9 (95% CI of change, –14.4 to –8.3; *P*<0.001; mean percent change from baseline, –78.1%). Mean sPGA scores significantly decreased from 3.2 ± 0.6 at baseline to 1.0 ± 1.0 at week 64 (95% CI of change, –2.5 to –1.9; *P*<0.001; mean percent change from baseline, –67.6%; Figure 2B); the week 64/EOT value was 1.1 ± 1.1 (95% CI of change, –2.4 to –1.8; *P*<0.001; mean percent change from baseline, –64.8%). The product of BSA and sPGA, which captures both the severity and extent of plaques, decreased from 47.0 ± 41.5 at baseline to 4.6 ± 9.4 at week 64 (95% CI of change, –55.8 to –30.7; *P*<0.001;

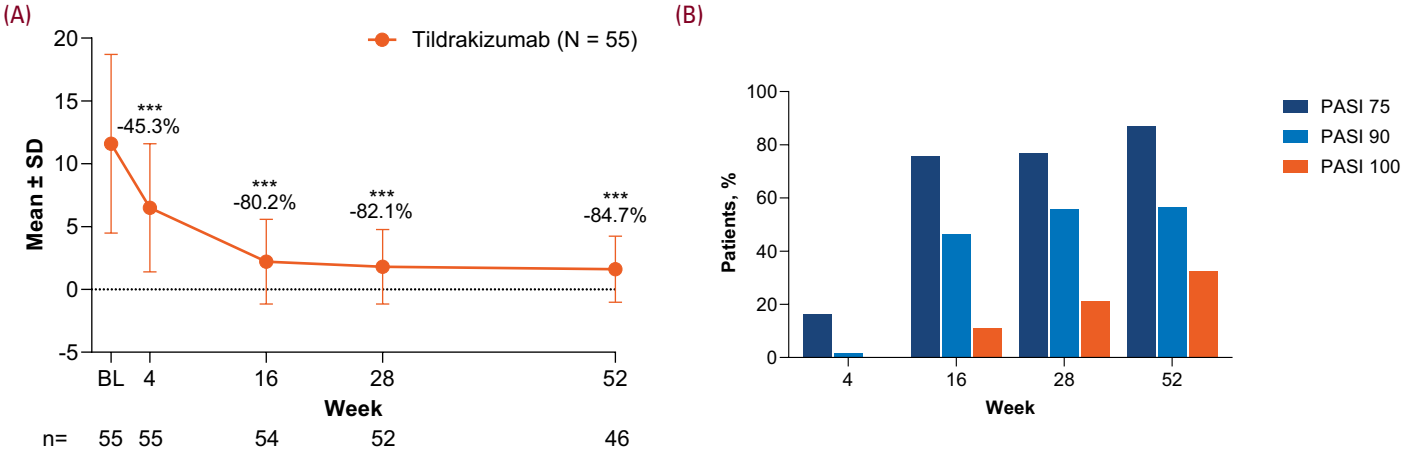
TABLE 1.

Demographics and Baseline Characteristics of the ITT Population

Characteristic	Tildrakizumab N = 55
Sex	
Female	27 (49.1)
Male	28 (50.9)
Age, years, mean ± SD	48.6 ± 15.3
Race	
White	52 (94.5)
Black or African American	2 (3.6)
Asian	1 (1.8)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
BSA, %, mean ± SD	14.5 ± 11.5
sPGA	
0	0
1	0
2	4 (7.3)
3	36 (65.5)
4	15 (27.3)
5	0
PASI, mean ± SD	11.6 ± 7.1

Data presented as n (%) unless otherwise noted.
BSA, body surface area; ITT, intention-to-treat; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static Physician Global Assessment.

FIGURE 3. (A) Disease activity and (B) clinical improvement based on PASI score through week 52. Data are graphed as the absolute score with the percent change from baseline over each time point.



***P<0.001. BL, baseline; PASI, Psoriasis Area and Severity Index; PASI 75/90/100 response, ≥75%/≥90%/100% improvement from baseline in PASI score; SD, standard deviation.

TABLE 2.

TEAEs (Safety Population)	
Evaluation	**Tildrakizumab N = 55**
Number of TEAEs	85
Patients with ≥1 TEAE	34 (61.8)
Treatment-related TEAEs	0
Serious TEAEs	4 (7.3)
Ischemic stroke	1 (1.8)
Transitional cell carcinoma	1 (1.8)
IgA nephropathy	1 (1.8)
COVID-19 pneumonia	1 (1.8)
TEAEs leading to treatment discontinuation	2 (3.6)
Transitional cell carcinoma	1 (1.8)
COVID-19 pneumonia	1 (1.8)
Deaths	0
Most frequent TEAEs (>3% of patients)	
Psoriasis	7 (12.7)
Hypertension	5 (9.1)
Dermatitis	3 (5.5)
Arthralgia	2 (3.6)
Eczema	2 (3.6)
Hematuria	2 (3.6)
Large intestine polyp	2 (3.6)
Nasopharyngitis	2 (3.6)
Skin papilloma	2 (3.6)
Upper respiratory tract infection	2 (3.6)

Data presented as n (%) of patients with event in the safety population and reported using MedDRA preferred terms.
COVID-19, coronavirus disease 2019; IgA, immunoglobulin A; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

mean percent change from baseline, –89.6%; Figure 2C) and to 7.1 ± 15.1 (95% CI of change, –50.9 to –29.0; *P*<0.001; mean percent change from baseline, –84.6%) at week 64/EOT. Clinical improvement of psoriasis as indicated by statistically significant decrease in PASI scores from baseline (11.6 ± 7.1) was observed at weeks 4 (6.5 ± 5.1; 95% CI of change, –6.3 to –3.8), 16 (2.2 ± 3.4; 95% CI of change, –11.2 to –7.4), 28 (1.8 ± 3.0; 95% CI of change, –11.3 to –7.4), and 52 (1.6 ± 2.6; 95% CI of change, –12.2 to –7.8; *P*<0.001 for all; mean percent change from baseline of –45.3%, –80.2%, –82.1%, and –84.7%, respectively; Figure 3A). The week 52/EOT PASI score was 2.1 ± 3.6 (95% CI of change, –11.4 to –7.6; *P*<0.001; mean percent change from baseline, –82.5%). At week 52, 87.0%, 56.5%, and 32.6% of patients achieved PASI 75, PASI 90, and PASI 100 responses, respectively (Figure 3B); the corresponding values for week 52/EOT were 81.8%, 54.5%, and 30.9% of patients achieving PASI 75, PASI 90, and PASI 100 responses, respectively.

Safety

Among the 55 patients who enrolled and received at least 1 dose of tildrakizumab (safety population), 34 (61.8%) patients experienced a total of 85 TEAEs during the study (Table 2). No TEAEs were considered related to tildrakizumab treatment by the investigators. Psoriasis (n = 7 patients), hypertension (n = 5 patients), and dermatitis (n = 3 patients) were the most common TEAEs; all other TEAEs occurred in ≤2 patients each. The majority of TEAEs were reported as mild in severity (n = 63, 74.1%), 18 (21.2%) were reported as moderate, and 4 (4.7%) were reported as severe. A total of 4 serious TEAEs occurred in 4 (7.3%) patients, including coronavirus disease 2019 (COVID-19)–related pneumonia, transitional cell carcinoma, ischemic stroke, and immunoglobulin A nephropathy reported in 1 patient each. Two (3.6%) patients experienced TEAEs, moderate transitional cell carcinoma and severe COVID-19–related pneumonia, that led to treatment discontinuation. There were no deaths during the study.

DISCUSSION

Tildrakizumab was effective at improving multiple measures of disease severity in patients with moderate-to-severe plaque psoriasis in the real-world setting of this open-label, Phase 4 clinical trial. Improvement was noted as early as week 4 (ie, after 1 dose) and maintained through week 64. Patients had significant decreases from baseline in BSA, sPGA, and BSA x sPGA through week 64 and significantly improved PASI scores from baseline through week 52. The real-world safety profile of tildrakizumab was consistent with observations in the clinical trials; >95% of TEAEs were mild or moderate in severity, and none were considered to be related to treatment.

The results of this study show that the efficacy and safety observed in the pivotal Phase 3 clinical trials of tildrakizumab in moderate-to-severe plaque psoriasis translate to real-world effectiveness. The PASI response rates observed here (PASI 75, 87.0%; PASI 90, 56.5%; PASI 100, 32.6%), for example, are consistent with the values observed at week 52 in patients in the reSURFACE 1 and reSURFACE 2 trials who were PASI 75 responders to tildrakizumab 100 mg at week 28 and continued receiving the same dose (observed cases analysis: PASI 75, 91.2%; PASI 90, 73.2%; PASI 100, 34.4%).[7,10]

The patients enrolled in this real-world study differed from the reSURFACE trial patients in several respects, suggesting that the effectiveness and safety of tildrakizumab are stable across differing subgroups of patients with moderate-to-severe plaque psoriasis in the US. The reSURFACE patients generally had more severe disease at baseline, with a mean percentage BSA affected of 29.7% to 34.2% compared with 14.5% in the Phase 4 study and a mean PASI score of 20.0 to 20.5 vs 11.6 in the current study.[7] The distribution of patients by sex and race also differed between this trial and the Phase 3 trials, likely due in part to this

study being conducted at 2 sites in the US compared with the large, multinational reSURFACE trials.

Other prospective real-world studies have demonstrated rapid and sustained improvement of disease severity with tildrakizumab treatment based on PASI, BSA, or PGA scores.[16-19] Results of an interim analysis of the TILOT study, an ongoing 3-year, prospective, multicenter study of tildrakizumab for the treatment of moderate-to-severe psoriasis in Germany, were similar to the current study, with 78.7% and 57.7% of patients achieving PASI 75 and 90 responses, respectively, at week 52.[19] Results of previously published prospective real-world studies were also comparable to the overall safety and tolerability profile of tildrakizumab observed in the reSURFACE 1 and reSURFACE 2 clinical trials.[16-19] The consistency of the Phase 4 effectiveness and safety results with other real-world studies and the Phase 3 trials support the use of tildrakizumab to treat patients with moderate-to-severe plaque psoriasis.

This study has several limitations that may affect the applicability and interpretation of the results. First, the small sample size (N=55) may restrict the identification of uncommon AEs. Additionally, given the open-label and single-arm design of this study, the interpretation of improvement in disease severity under treatment may have been confounded by the natural history of the underlying plaque psoriasis. The prolonged nature of improved disease severity measured by multiple assessments, however, argues against this scenario. Finally, as no data imputation took place in this study, and results were based only on observed data, our results may be biased toward either greater or lesser treatment effectiveness than would be seen with a more rigorous analysis.

CONCLUSION

Tildrakizumab treatment resulted in improvement across multiple measures of disease severity in adult patients with moderate-to-severe plaque psoriasis in the real-world setting. The reported AEs were consistent with the previously established safety profile of tildrakizumab.

DISCLOSURES

JH has been a speaker, adviser, and consultant for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, and Novartis; an adviser for Galderma, Mayne Pharma, Regeneron Pharmaceuticals, and Sanofi; an adviser and consultant for Ortho Dermatologics; and a speaker and adviser for Sun Pharma, Incyte, LEO Pharma, and Beiersdorf. JGV reports nothing to disclose. TB has received research funding from AbbVie, Celgene, Galderma, Janssen, Eli Lilly, Pfizer, Regeneron Pharmaceuticals, and Sun Pharma and has served as an adviser for AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Pfizer, LEO Pharma, and Novartis. JK has served as an adviser for AbbVie, Amgen, Celgene, EPI Health, Janssen, LEO Pharma, Eli Lilly, Novartis, Ortho Dermatologics, Pfizer, Regeneron Pharmaceuticals, Sanofi, Sun Pharma, and UCB. JM, RG, and TF are employees of Sun Pharmaceutical Industries, Inc. NB is an adviser, consultant, and investigator for AbbVie, Almirall, Arcutis Biotherapeutics, Advanced Derm Solutions, Amytrx, Beiersdorf, Biofrontera, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle, Dermavant Sciences, Eli Lilly, Ferndale, Foamix, Galderma, Incyte, ISDIN, Johnson & Johnson, La Roche-Posay, LEO Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Procter & Gamble, Regeneron Pharmaceuticals, Sanofi, Sun Pharma, Skinfix, Soligenix, Verrica Pharmaceuticals, and Zerigo Health.

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Data Availability Statement

Data and other documents will be made available after publication, with no end date, to anyone who submits a reasonable request to the study sponsor.

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AUTHOR CORRESPONDENCE

Jayme Heim MSN FNP-BC
E-mail:..... heim.jayme@gmail.com