Patients' quality of life and satisfaction with treatment in a Phase 4 real-world study of tildrakizumab in moderate-to-severe plaque psoriasis

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INTRODUCTION

- Psoriasis is a chronic, immune-mediated skin disease characterized by scaly, erythematous plaques that can significantly impact patients' emotional and psychological well-being[1]
- Tildrakizumab is an anti–interleukin-23 p19 monoclonal antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy[1,2]
- Efficacy of tildrakizumab was associated with better skin-related quality of life in the Phase 3 reSURFACE 1 and reSURFACE 2 trials,[3] but there is limited available real-world evidence regarding overall health-related quality of life and treatment satisfaction with tildrakizumab in patients with moderate-to-severe plaque psoriasis

OBJECTIVE

- To evaluate the change in health-related quality of life and satisfaction with treatment in patients with moderate-to-severe plaque psoriasis treated with tildrakizumab in real-world practice for up to 64 weeks

METHODS

Study design and population

- This was a Phase 4, 64-week, uncontrolled, open-label, real-world study (NCT03718299)
- Immunocompetent patients ≥18 years of age with moderate-to-severe plaque psoriasis affecting ≥3% of total body surface area who were candidates for phototherapy or systemic therapy were eligible
- Patients with erythrodermic or only pustular, guttate, or inverse psoriasis, or evidence of skin conditions other than psoriasis that would interfere with study-related evaluations of psoriasis, were excluded from the study

Treatment and assessments

- All patients received tildrakizumab 100 mg at Week 0, Week 4, and every 12 weeks thereafter up to Week 52
- The primary endpoint was improvement from baseline in Psychological General Well-Being Index (PGWBI) total score
  - — Assessed by questionnaire at baseline and Weeks 4, 8, 12, and 16, and every 12 weeks thereafter through Week 64
  - — Higher PGWBI scores indicate improvement
- Secondary endpoints included improvement from baseline in the Dermatology Life Quality Index (DLQI) score
  - — Assessed by questionnaire at baseline and Weeks 4, 8, 12, and 16, and every 12 weeks thereafter through Week 64
  - — Higher DLQI scores indicate greater impairment
- Patient satisfaction was evaluated using the Treatment Satisfaction Questionnaire for Medication (TSQM), including the Global Satisfaction domain
  - — Assessed by questionnaire at Weeks 4, 8, 12, and 16, and every 12 weeks thereafter through Week 64
  - — Higher scores indicate greater satisfaction

Statistical analysis

- The intention-to-treat population was used for quality-of-life and satisfaction analyses and included all patients who enrolled and were assigned to receive tildrakizumab
- The change from baseline in PGWBI and DLQI scores was analyzed using paired t-tests; the TSQM-Global Satisfaction domain score is presented descriptively
  - — Missing data were not imputed

RESULTS

Patient demographics

- Of 55 patients enrolled, 45 were assessed at Week 64 (end of study)
- The majority of patients were male (28/55; 50.9%) and White (52/55; 94.5%), with a mean ± standard deviation (SD) age of 48.6 ± 15.3 years (**Table 1**)

Table 1. Patients' demographic and baseline characteristics

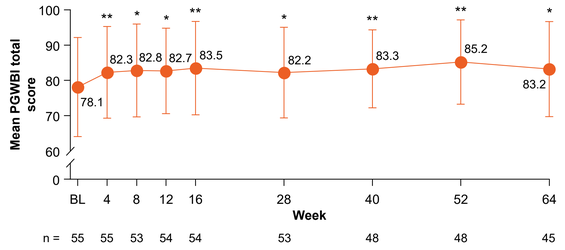
	Tildrakizumab (N = 55)
Sex	
Female	27 (49.1)
Male	28 (50.9)
Race	
White	52 (94.5)
Black or African American	2 (3.6)
Asian	1 (1.8)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
Age, years, mean ± SD	48.6 ± 15.29
Baseline PGWBI, mean ± SD	
Total score	78.1 ± 14.1
Positive Well-Being domain	12.6 ± 3.3
General Health domain	9.9 ± 2.5
Anxiety domain	16.9 ± 4.0
Depressed Mood domain	12.5 ± 2.1
Self-Control domain	12.9 ± 2.1
Vitality domain	13.3 ± 3.2
Baseline DLQI, mean ± SD	9.4 ± 5.2

Intention-to-treat population.
Data shown as n (%) unless otherwise noted.
DLQI, Dermatology Life Quality Index; PGWBI, Psychological General Well-Being Index; SD, standard deviation.

Change in PGWBI

- The PGWBI total score improved significantly from baseline to Week 64, with mean ± SD score increasing from 78.1 ± 14.1 at baseline to 83.2 ± 13.5 at Week 64 ($P = 0.01$; **Figure 1**)

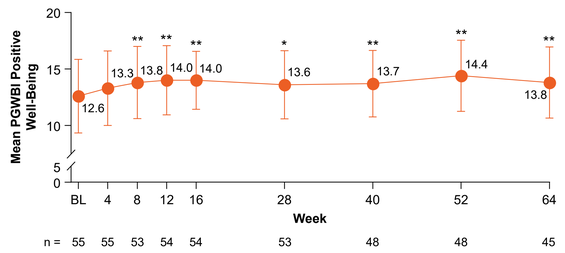
Figure 1. Mean ± SD PGWBI total score through Week 64



Intention-to-treat population.
Error bars represent the SD.
*P <0.05; **P <0.01. Statistically significant change from baseline based on t-test.
BL, baseline; PGWBI, Psychological General Well-Being Index; SD, standard deviation.

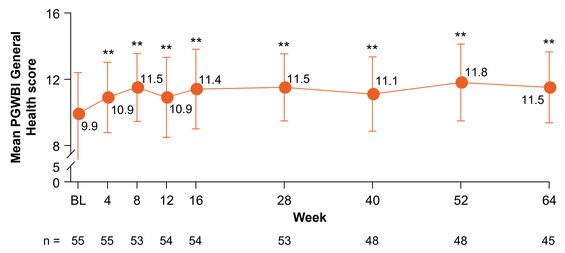
- The PGWBI domains with significant improvements from baseline to Week 64 included Positive Well-Being (**Figure 2**) and General Health (**Figure 3**)
- From baseline to Week 64, other PGWBI domain scores (mean ± SD) changed from 16.9 ± 4.0 to 18.0 ± 3.9 for Anxiety (change, $P = 0.08$), 12.5 ± 2.1 to 12.7 ± 1.9 for Depressed Mood (change, $P = 0.3$), 12.9 ± 2.1 to 13.2 ± 1.8 for Self-Control (change, $P = 0.5$), and 13.3 ± 3.2 to 14.0 ± 3.5 for Vitality (change, $P = 0.06$)

Figure 2. Mean ± SD PGWBI Positive Well-Being score through Week 64



Intention-to-treat population.
Error bars represent the SD.
*P <0.05; **P <0.01. Statistically significant change from baseline based on t-test.
BL, baseline; PGWBI, Psychological General Well-Being Index; SD, standard deviation.

Figure 3. Mean ± SD PGWBI General Health score through Week 64

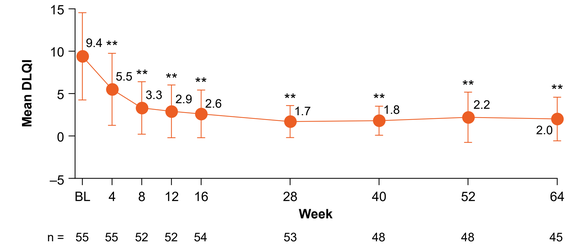


Intention-to-treat population.
Error bars represent the SD.
**P <0.01. Statistically significant change from baseline based on t-test.
BL, baseline; PGWBI, Psychological General Well-Being Index; SD, standard deviation.

Change in DLQI

- There were statistically significant improvements from baseline in DLQI score at all visits beginning as early as Week 4, with sustained improvement through Week 64 (**Figure 4**)

Figure 4. Mean ± SD DLQI score through Week 64

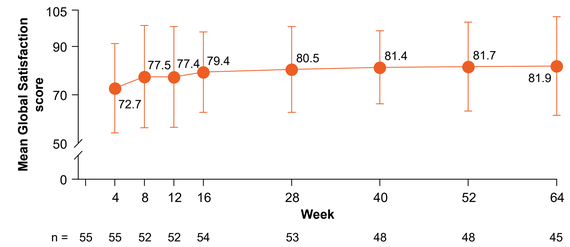


Intention-to-treat population.
Error bars represent the SD.
**P <0.01. Statistically significant change from baseline based on t-test.
BL, baseline; DLQI, Dermatology Life Quality Index; SD, standard deviation.

Global satisfaction with treatment

- The change in the TSQM-Global Satisfaction domain score was positive at each visit and increased over time, peaking at Week 64 with a mean ± SD of 81.9 ± 20.5 (**Figure 5**)

Figure 5. Mean ± SD TSQM-Global Satisfaction score through Week 64



Intention-to-treat population.
Error bars represent the SD.
BL, baseline; TSQM, Treatment Satisfaction Questionnaire for Medication; SD, standard deviation.

CONCLUSIONS

- Treatment with tildrakizumab in patients with psoriasis in a real-world setting significantly improved quality of life as measured by the PGWBI and DLQI
- Patient satisfaction as measured by the TSQM-Global Satisfaction domain improved throughout the study and peaked at Week 64

REFERENCES

1) Reich K, et al. *Lancet.* 2017;390(10091):276-88. **2)** ILUMYA® (tildrakizumab injection). Full prescribing information. Sun Pharmaceutical Industries, Inc. 2021. **3)** Blauvelt A, et al. *J Eur Acad Dermatol Venereol.* 2019;33(12):2305-12.

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DISCLOSURES

JH has been a speaker, advisor, and consultant for Amgen, AbbVie, Celgene, Eli Lilly, Janssen, and Novartis; an advisor for Galderma, Mayne, and Sanofi Regeneron; an advisor and consultant for Ortho Dermatologic; and a speaker and advisor for Sun Pharma. **JGV** reports nothing to disclose. **RG** and **BS** are employees of Sun Pharmaceutical Industries, Inc. **NB** is an advisor, consultant, and investigator for Abbvie, Almirall, Arcutis, Beiersdorf, Biofrontera, BMS, BI, Cara, Dermavant, EPI Health, Ferndale, Galderma, InCyte, ISDIN, J&J, LaRoche-Posay, Leo, Lilly, Ortho, Pfizer, Regeneron, Sanofi, Sun Pharma, and Verrica.