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

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INTRODUCTION

- Psoriasis is a chronic, systemic, inflammatory disorder characterized by scaly, erythematous plaques on the skin 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 for clinical improvement 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 (HRQoL) in patients with moderate-to-severe plaque psoriasis

OBJECTIVE

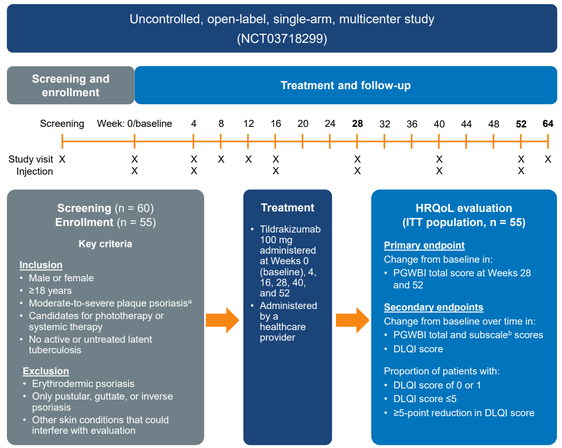
- To evaluate improvement in general and skin-specific HRQoL in patients with moderate-to-severe plaque psoriasis after 64 weeks of treatment with tildrakizumab under real-world conditions

METHODS

Study design and population

- This was a Phase 4, 64-week, uncontrolled, open-label, real-world study (**Figure 1**)

Figure 1. Study design



Time points (Weeks) shown in bold indicate when the primary efficacy endpoint was assessed (at Weeks 28 and 52) and the end of the study (at Week 64).
[a]BSA ≥3%. [b]Subscales of Anxiety, Depressed Mood, Positive Well-Being, Self-Control, General Health, and Vitality.
BSA, body surface area; DLQI, Dermatology Life Quality Index; HRQoL, health-related quality of life; ITT, intention-to-treat; PGWBI, Psychological General Well-Being Index.

Assessments

- Quality of life was evaluated using
  - The Psychological General Well-Being Index (PGWBI), administered at baseline and all postbaseline visits
    - Total score is the sum of 6 subscale scores
    - Higher PGWBI scores indicate improvement
  - The Dermatology Life Quality Index (DLQI), administered at baseline and all postbaseline visits
    - Higher DLQI scores indicate greater impairment

Statistical analysis

- The intention-to-treat population was used for quality-of-life analyses and included all patients who enrolled and were assigned to receive tildrakizumab
- Changes from baseline in PGWBI and DLQI scores were analyzed using Student's t-tests
  - 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. Demographics and baseline characteristics

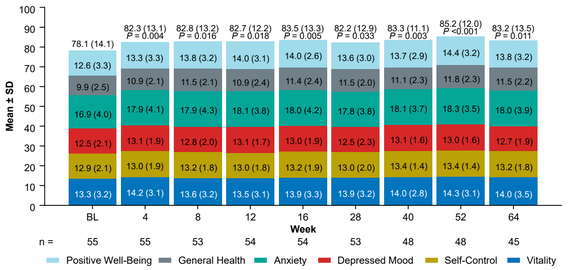
Characteristic	Tildrakizumab (N = 55)
Sex	
Female	27 (49.1)
Male	28 (50.9)
Race	
White	52 (94.5)
Black or African American	2 (3.6)
Asian	1 (1.8)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
Age, years, mean ± SD	48.6 ± 15.3
PGWBI score, mean ± SD	
Total score	78.1 ± 14.1
Positive Well-Being	12.6 ± 3.3
General Health	9.9 ± 2.5
Anxiety	16.9 ± 4.0
Depressed Mood	12.5 ± 2.1
Self-Control	12.9 ± 2.1
Vitality	13.3 ± 3.2
DLQI score, mean ± SD	9.4 ± 5.2

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

Improvement in PGWBI

- The total PGWBI score improved significantly from baseline to Week 64, with a mean ± SD change from baseline of 5.6 ± 14.1 (P = 0.01); the change from baseline was significant at both of the primary endpoint time points at Week 28 (P = 0.033) and Week 52 (P <0.001; **Figure 2**)

Figure 2. Mean PGWBI total and subscale scores through Week 64



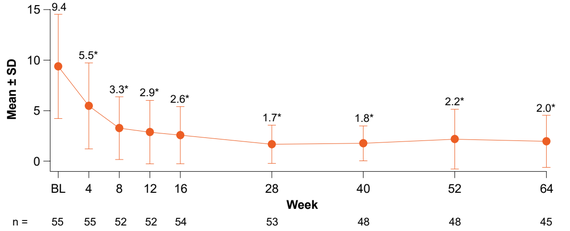
ITT population. Data labels report the mean (SD).
P-values are for change from baseline based on Student's t-test.
BL, baseline; ITT, intention-to-treat; PGWBI, Psychological General Well-Being Index; SD, standard deviation.

- The PGWBI components with significant improvement from baseline to Week 64 were Positive Well-Being (mean ± SD change, 1.4 ± 3.3; P = 0.008) and General Health (mean ± SD change, 1.7 ± 2.3; P <0.001)
- The mean ± SD change from baseline to Week 64 for other PGWBI component scores was 1.1 ± 4.0 (P = 0.08) for Anxiety, 0.4 ± 2.5 (P = 0.3) for Depressed Mood, 0.2 ± 2.1 (P = 0.5) for Self-Control, and 0.9 ± 3.2 (P = 0.06) for Vitality

Improvement 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
- The DLQI score (mean ± SD) improved from 9.4 ± 5.2 at baseline to 2.0 ± 2.6 at Week 64 (P <0.001; **Figure 3**)

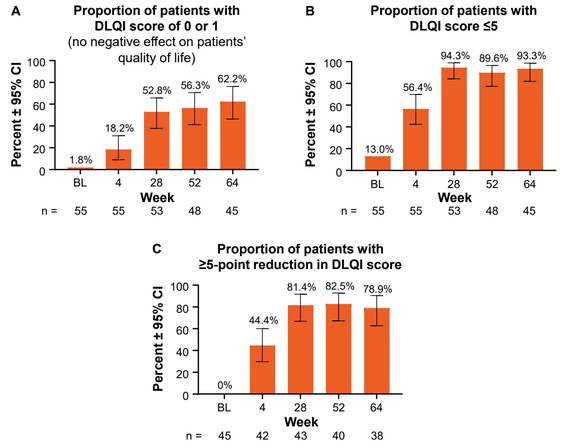
Figure 3. Mean DLQI score through Week 64



ITT population.
Error bars represent the SD.
*P <0.01. Statistically significant change from baseline based on Student's t-test.
BL, baseline; DLQI, Dermatology Life Quality Index; ITT, intention-to-treat; SD, standard deviation.

- Proportions of patients meeting prespecified DLQI response thresholds at Week 64 included
  - DLQI score of 0 or 1 signifying no negative impact on patients' quality of life: 62.2% of patients (95% confidence interval [CI], 46.5%−76.2%; **Figure 4A**)
  - DLQI score ≤5: 93.3% of patients (95% CI, 81.7%−98.6%; **Figure 4B**)
  - ≥5-point reduction in DLQI score: 78.9% of patients (95% CI, 62.7%−90.4%; **Figure 4C**)

Figure 4. Prespecified DLQI responses through Week 64



ITT population. Data are shown as percent ± 95% CI.
BL, baseline; CI, confidence interval; DLQI, Dermatology Life Quality Index; ITT, intention-to-treat.

CONCLUSIONS

- Treatment with tildrakizumab in patients with moderate-to-severe plaque psoriasis in a real-world setting significantly improved HRQoL as measured by the PGWBI and DLQI

REFERENCES

1) Reich K, et al. *Lancet.* 2017;390(10091):276–88. **2)** ILUMYA® (tildrakizumab-asmn) Injection 100 mg/mL. Full prescribing information. Cranbury, NJ; Sun Pharmaceutical Industries, Inc., 2022. **3)** Blauvelt A, et al. *J Eur Acad Dermatol Venereol.* 2019;33(12):2305–12.

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DISCLOSURES

JH is 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. **BS** is an employee of Sun Pharmaceutical Industries, Inc. **NB** is an advisor, consultant, and investigator for AbbVie, Almirall, Arcutis, Biofrontera, BMS, Brickell, Dermavant, EPI Health, Ferndale, Galderma, Genentech, InCyte, ISDIN, J&J, LaRoche-Posay, Leo, Lilly, Novartis, Ortho, Pfizer, P&G, Regeneron, Sanofi, Stemline, Sun Pharma, and Verrica.