Patient-reported symptom relief in a Phase 4 real-world study of tildrakizumab in patients with moderate-to-severe plaque psoriasis

J Gabriel Vasquez[1], Neal Bhatia[2], Brad Schenkel[3], Ranga Gogineni[3], Jayme Heim[1]

[1]West Michigan Dermatology, Grandville, MI, USA; [2]Therapeutics Clinical Research, San Diego, CA, USA; [3]Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA

INTRODUCTION

- Psoriasis is a chronic, immune-mediated skin disease characterized by scaly, erythematous plaques that can itch and bleed[1,2]
- Among psoriasis-related symptoms, itch and pain are among the most important contributors to patients' diminished health-related quality of life[2]
- The effectiveness of biologic agents in reducing itch, pain, and scaling severity in patients with moderate-to-severe plaque psoriasis has not been well evaluated in real-world settings[3]
- 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[4]

OBJECTIVE

- To evaluate improvement in health-related quality of life, including patient-reported relief from itch, pain, and scaling, through 64 weeks in a real-world study of tildrakizumab in patients with moderate-to-severe plaque psoriasis

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 psoriasis 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 through Week 52
- Patient-reported severity of itch, pain, and scaling were assessed using numeric rating scales (NRSs)
  - Itch-, Pain-, and Scaling-NRS scores were collected and reported at baseline and Weeks 4, 8, 12, 16, 28, 40, 52, and 64
    - The NRSs are simple, self-administered 11-point scales with scores ranging from 0 (no itch, pain, or scaling) to 10 (worst imaginable itch, pain, or scaling)

Statistical analysis

- The intention-to-treat population was used for analyses of patient-reported symptoms and included all patients who enrolled and were assigned to receive tildrakizumab
- Changes from baseline in Itch-, Pain-, and Scaling-NRS scores were analyzed using paired t-tests
- Missing data were not imputed

RESULTS

Patient demographics

- Of the 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 ± 15.3
Itch-NRS score, mean ± SD	6.6 ± 2.6
Pain-NRS score, mean ± SD	3.8 ± 3.2
Scaling-NRS score, mean ± SD	7.0 ± 2.3

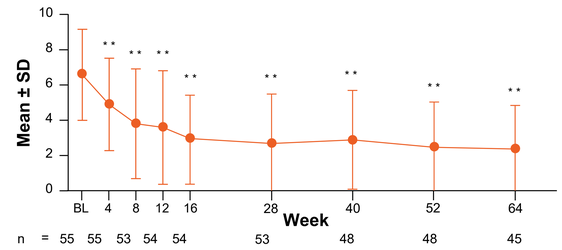
Intention-to-treat population.
Data shown as n (%) unless otherwise noted.
NRS, numeric rating scale; SD, standard deviation.

Improvement in patient-reported symptoms

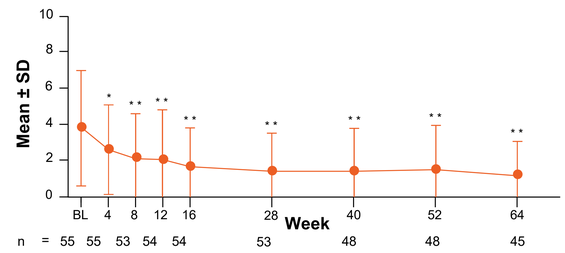
- Patients receiving tildrakizumab had significant improvements in patient-reported symptoms beginning as early as Week 4; improvements were sustained through Week 64
  - The mean ± SD Itch-NRS score improved from 6.6 ± 2.6 at baseline to 4.9 ± 2.6 at Week 4 and 2.4 ± 2.4 at Week 64 (both significant at P <0.001; **Figure 1A**)
  - The mean ± SD Pain-NRS score decreased from 3.8 ± 3.2 at baseline to 2.6 ± 2.5 at Week 4 (P = 0.001) and 1.1 ± 1.9 at Week 64 (P <0.001; **Figure 1B**)
  - Mean ± SD Scaling-NRS score improved from 7.0 ± 2.3 at baseline to 4.4 ± 2.5 at Week 4 and 2.4 ± 2.6 at Week 64 (both significant at P <0.001; **Figure 1C**)

Figure 1. Patient-reported symptoms through Week 64

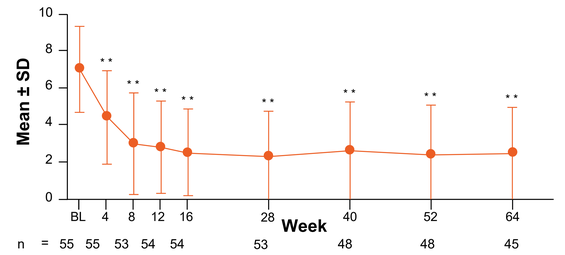
A) Mean ± SD Itch-NRS



B) Mean ± SD Pain-NRS



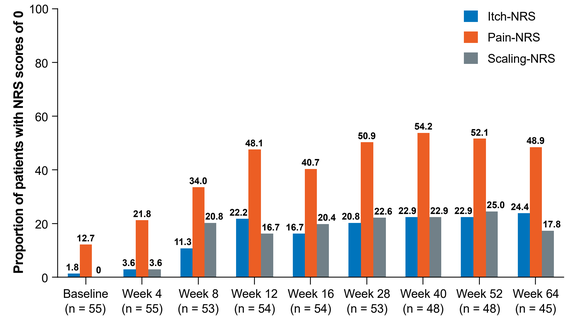
C) Mean ± SD Scaling-NRS



Intention-to-treat population.
Error bars represent the SD.
*P = 0.001, **P <0.001. Statistically significant change from baseline based on t-test.
BL, baseline; NRS, numeric rating scale; SD, standard deviation.

- The proportion of patients with an Itch-, Pain-, and Scaling-NRS score of zero (no itch, pain, or scaling) increased from baseline through Week 64
  - At Week 64, the percentage of patients with an NRS score of zero was 24.4% for itch, 48.9% for pain, and 17.8% for scaling (**Figure 2**)

Figure 2. Proportion of patients with an Itch-, Pain-, or Scaling-NRS score of zero through Week 64



Intention-to-treat population.
NRS, numeric rating scale.

CONCLUSIONS

- Tildrakizumab rapidly and significantly improved patient-reported itch, pain, and scaling in patients with moderate-to-severe plaque psoriasis in a real-world setting, with meaningful effects observed after one dose
- Improvements were observed at each visit and maintained for up to 64 weeks

REFERENCES

1) Menter A, et al. *J Am Acad Dermatol*. 2011;65:137–74. **2)** Globe D, et al. *Health Qual Life Outcomes*. 2009;7:62. **3)** Kimball AB, et al. *Acta Derm Venereol*. 2018;98:98–102. **4)** ILUMYA® (tildrakizumab). Full prescribing information. 2021.

ACKNOWLEDGMENTS

We thank the patients for their participation and Drs. Tina Bhutani, John Koo, and Stephen J Rozzo for contributions to the study. The study and analyses were funded by Sun Pharma. Medical writing support was provided by Elisabetta Lauretti, PhD, of AlphaBioCom, a Red Nucleus company, and funded by Sun Pharma.

DISCLOSURES

JGV reports nothing to disclose. **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 Pharma, Lilly, Ortho, Pfizer, Regeneron, Sanofi, Sun Pharma, and Verrica. **BS** and **RG** are employees of Sun Pharmaceutical Industries, Inc. **JH** has been a speaker, advisor, and consultant for Amgen, AbbVie, Celgene, 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.