Patient-reported symptom relief from the Week 28 interim analysis of a Phase 4 real-world study of tildrakizumab in patients with moderate-to-severe psoriasis

J Gabriel Vasquez,[1] Neal Bhatia,[2] Paulita Beute,[1] Monique Torres,[2] Brad Schenkel,[3] Stephen J Rozzo,[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]
- Among psoriasis-related symptoms, itch and pain are among the most important contributors to patients' diminished health-related quality of life[2]
- Tildrakizumab, an anti–interleukin-23p19 monoclonal antibody, is approved for treatment of moderate-to-severe plaque psoriasis[3]
- This is an interim analysis of an ongoing Phase 4 study assessing the effectiveness and safety of tildrakizumab, including patient-reported outcomes, in real-world practice

OBJECTIVE

- To evaluate improvements in patient-reported relief from itching, skin pain, and scaling at the Week 28 interim analysis of a Phase 4 real-world study of tildrakizumab in patients with moderate-to-severe psoriasis

METHODS

Study design and population

- This was a Phase 4 multicenter, 64-week, uncontrolled, open-label, real-world study (NCT03718299)
- Nonimmunocompromised patients aged ≥18 years 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 were excluded from the study

Assessments

- All patients received tildrakizumab 100 mg at Week 0, Week 4, and every 12 weeks thereafter through Week 52; assessments through the Week 28 interim analysis are reported here
- Patient-reported severity of itch, pain, and scaling were assessed using Numerical Rating Scales (NRSs)
  - 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

- Descriptive statistics were calculated for the absolute and percentage change from baseline in the itch, pain, and scaling NRS scores in the intent-to-treat (ITT) population
- Missing data were not imputed

RESULTS

Patient demographics

- Of the 55 patients enrolled, 28/55 (50.9%) were male and 52/55 (94.5%) were white, with a mean ± SD age of 48.6 ± 15.3 years (**Table 1**)

Table 1. Demographics and baseline characteristics

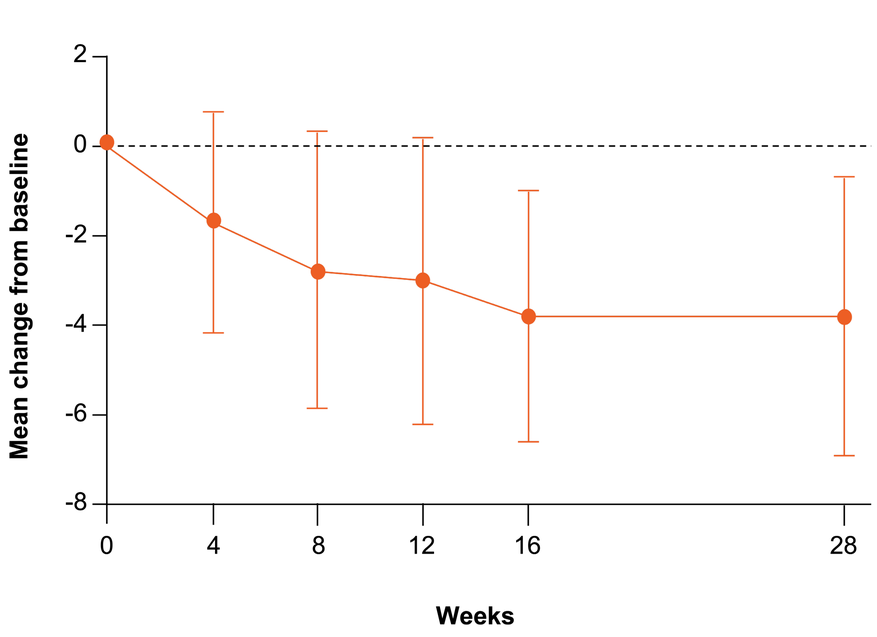
	(N = 55)
Sex, male	28 (50.9)
Age, years, mean ± SD	48.6 ± 15.3
Race	
Asian	1 (1.8)
Black or African American	2 (3.6)
White	52 (94.5)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
BSA, mean ± SD	14.5 ± 11.5
PASI, mean ± SD	11.6 ± 7.1
Itch NRS, mean ± SD	6.6 ± 2.6
Pain NRS, mean ± SD	3.8 ± 3.2
Scaling NRS, mean ± SD	7.0 ± 2.3

All data are n (%) unless otherwise noted.
BSA, body surface area; NRS, Numerical Rating Scale; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

Efficacy

- Patients receiving tildrakizumab had significant and consistent improvements in patient-reported itch, pain, and scaling
- The mean ± SD Itch-NRS score improved from 6.6 ± 2.6 at baseline to 4.9 ± 2.6 at Week 4 and 2.7 ± 2.8 at Week 28
  - The mean ± SD change from baseline was −1.7 ± 2.5 (−19.8%) at Week 4 and −3.8 ± 3.1 (−57.4%) at Week 28 (both *P* <0.001) (**Figure 1**)

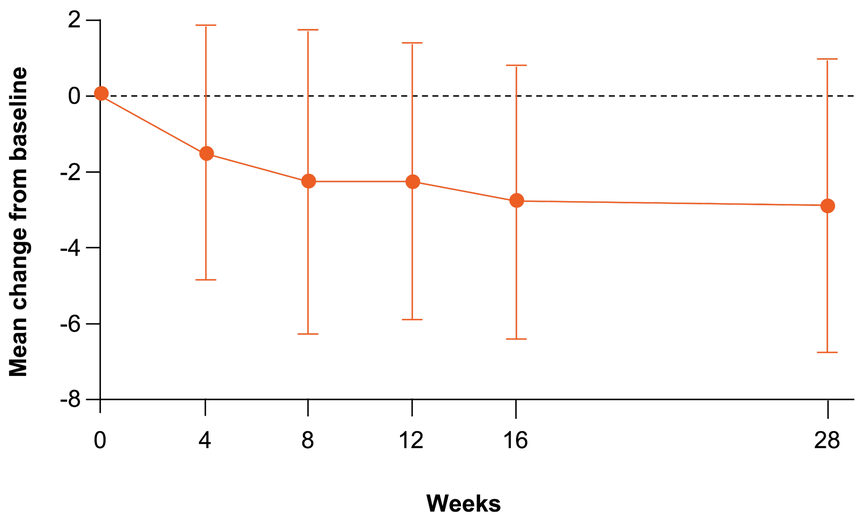
Figure 1. Itch NRS change from baseline



ITT population; missing data were not imputed; error bars represent the SD.
ITT, intent-to-treat; NRS, Numerical Rating Scale; SD, standard deviation.

- The Pain-NRS score (mean ± SD) improved from 3.8 ± 3.2 at baseline to 2.6 ± 2.5 at Week 4 and 1.4 ± 2.1 at Week 28
  - The mean ± SD change from baseline was −1.2 ± 2.6 (−10.0%) (*P* = 0.001) at Week 4 and −2.3 ± 3.0 (−44.8%) (*P* <0.001) at Week 28 (**Figure 2**)

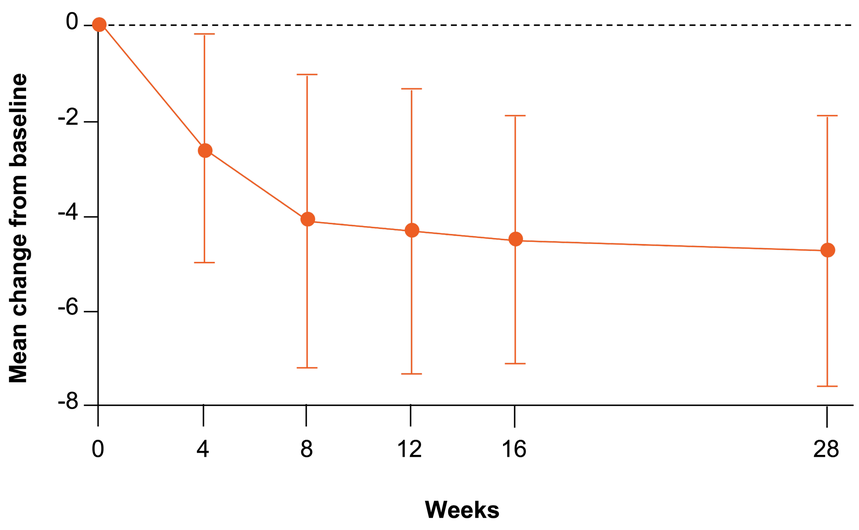
Figure 2. Pain NRS change from baseline



ITT population; missing data were not imputed; error bars represent the SD.
ITT, intent-to-treat; NRS, Numerical Rating Scale; SD, standard deviation.

- Mean ± SD Scaling-NRS score improved from 7.0 ± 2.3 at baseline to 4.4 ± 2.5 at Week 4 and 2.3 ± 2.5 at Week 28
  - Mean ± SD change was −2.6 ± 2.4 (−36.7%) at Week 4 and −4.7 ± 2.8 (−66.8%) at Week 28 (both *P* <0.001) (**Figure 3**)

Figure 3. Scaling NRS change from baseline



ITT population; missing data were not imputed; error bars represent the SD.
ITT, intent-to-treat; NRS, Numerical Rating Scale; SD, standard deviation.

CONCLUSIONS

- Based on this interim analysis, tildrakizumab treatment rapidly and significantly improved patient-reported itching, pain, and scaling in patients with moderate-to-severe plaque psoriasis in a real-world setting
- Improvements in scores were noted as early as Week 4 and maintained through Week 28

REFERENCES

1) Menter A, et al. *J Am Acad Dermatol*. 2011;65(1):137–74; **2)** Globe D, et al. *Health Qual Life Outcomes*. 2009;7:62; **3)** ILUMYA® (tildrakizumab). Full prescribing information; July 2020.

ACKNOWLEDGMENTS

We thank the patients for their participation and Dr. Alan Mendelsohn for his contributions to the study. The study was funded by Sun Pharma Global FZE. Analyses were funded by Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA. Medical writing support was provided by Prachi Patil, MS, of AlphaBioCom, LLC, and funded by Sun Pharmaceutical Industries, Inc., Princeton, NJ, USA.

DISCLOSURES

NB is an advisor, consultant, and investigator for Abbvie, Almirall, Arcutis, Arena, Biofrontera, BMS, BI, Brickell, Dermavant, EPI Health, Ferndale, Galderma, Genentech, InCyte, ISDIN, J&J, LaRoche-Posay, Leo, Lilly, Mayne, Novartis, Ortho, Patagonia, Pfizer, P&G, Regeneron, Sanofi, Stemline, SunPharma, Verrica, and Vyne. **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 Pharmaceutical Industries, Inc. **MT** is a sub-investigator for Sun Pharmaceutical Industries, Inc. **PB** and **JGV** report nothing to disclose. **SJR** and **BS** are employees of Sun Pharmaceutical Industries, Inc.