Patient satisfaction with tildrakizumab treatment in the Week 28 interim analysis of a Phase 4 real-world study of tildrakizumab in patients with moderate-to-severe psoriasis

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INTRODUCTION

- Psoriasis is a chronic, systemic, inflammatory disorder of the skin that significantly impacts patients' physical health and quality of life[1]
- Treatment satisfaction is an important element in disease management, with implications for health care delivery, treatment adherence, and effectiveness in real-world clinical practice[1]
- Treatment dissatisfaction among patients with moderate-to-severe psoriasis is a concern in clinical settings[1,2]
- Tildrakizumab is an anti–interleukin-23p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis[3]
- Limited data are available on patient satisfaction with tildrakizumab treatment in real-world settings

OBJECTIVE

- To report patient satisfaction overall and with specific aspects of treatment at the Week 28 interim analysis of a 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

- Patients received tildrakizumab 100 mg at Weeks 0, 4, and every 12 weeks thereafter through Week 52; assessments through the Week 28 interim analysis are reported here
- Patient satisfaction was evaluated using:
  - The Effectiveness, Convenience, and Global Satisfaction domains of the Treatment Satisfaction Questionnaire for Medication (TSQM),[4] administered at all post treatment visits
  - The Tildrakizumab Overall Satisfaction Numerical Rating Scale (NRS), which includes domains for Improvement in Symptoms, Speed of Improvement, Frequency of Dosing, and Side Effects, administered at all post treatment visits
  - The Patient Happiness with Psoriasis Control NRS administered at baseline and all post treatment visits
- For all measures, higher scores indicate greater patient satisfaction

Statistical analysis

- Patient satisfaction was analyzed in the intent-to-treat population
- Changes from baseline in Happiness with Psoriasis Control were analyzed using paired t-tests
- 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 ± standard deviation (SD) age of 48.6 ± 15.3 years (**Table 1**)

Table 1. Demographics and baseline characteristics

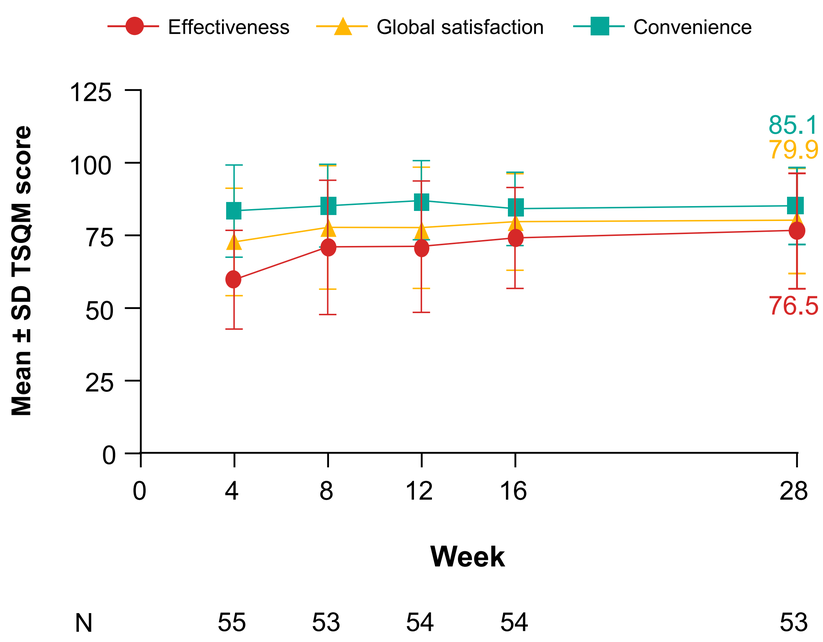
	(N = 55)
Sex, male	28 (50.9)
Age, years, mean ± SD	48.6 ± 15.3
Race	
Asian	1 (1.8)
Black or African American	2 (3.6)
White	52 (94.5)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
BSA, mean ± SD	14.5 ± 11.5
PASI, mean ± SD	11.6 ± 7.1

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

Efficacy

- Patients reported improvement in satisfaction across all of the domains in each instrument used in this study through Week 28
- From Week 4 to Week 28, the mean ± SD TSQM score increased from 59.5 ± 17.0 to 76.5 ± 19.9 for Effectiveness, from 83.3 ± 15.9 to 85.1 ± 13.4 for Convenience, and from 72.7 ± 18.6 to 79.9 ± 18.1 for Global Satisfaction (**Figure 1**)

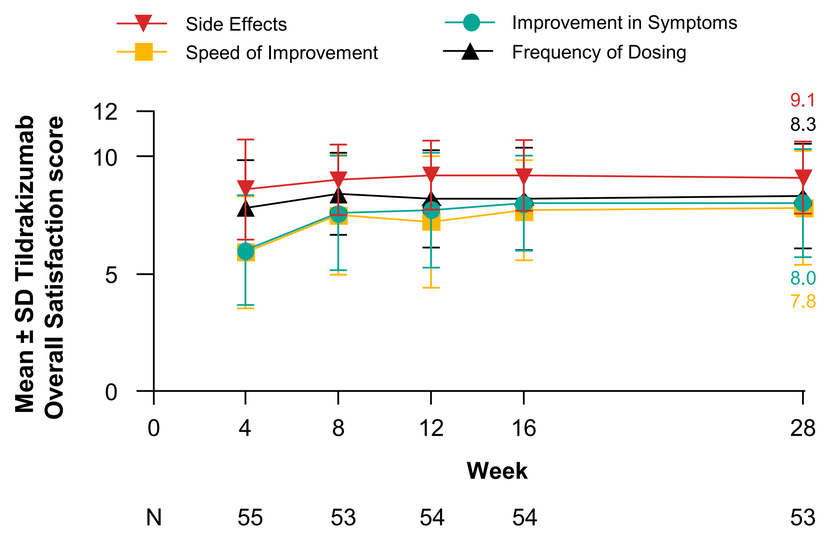
Figure 1: Mean TSQM scores for the Effectiveness, Convenience, and Global Satisfaction domains through Week 28



ITT population. Data shown as mean ± SD. n = 52 for the "Convenience" and "Global Satisfaction" domains at Week 8.
ITT, intention-to-treat; SD, standard deviation; TSQM, Treatment Satisfaction Questionnaire for Medication.

- The mean ± SD score for Tildrakizumab Overall Satisfaction domains increased from 6.0 ± 2.4 at Week 4 to 8.0 ± 2.3 at Week 28 for Improvement in Symptoms, from 5.9 ± 2.4 at Week 4 to 7.8 ± 2.4 at Week 28 for Speed of Improvement, from 7.8 ± 2.1 at Week 4 to 8.3 ± 2.2 at Week 28 for Frequency of Dosing, and from 8.6 ± 2.1 at Week 4 to 9.1 ± 1.5 at Week 28 for Side Effects (**Figure 2**)

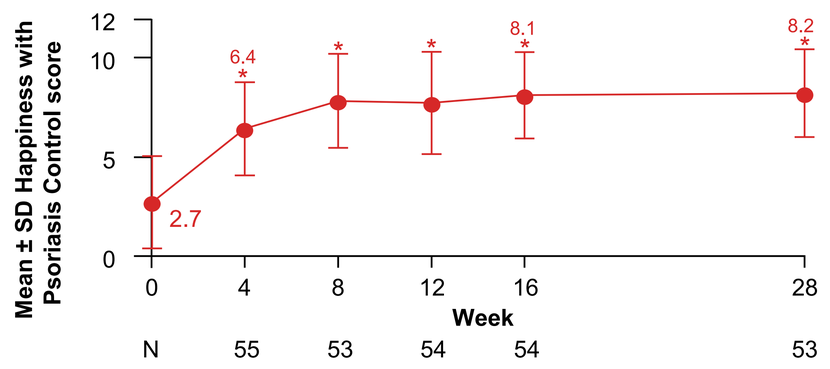
Figure 2: Mean Tildrakizumab Overall Satisfaction scores for the Improvement in Symptoms, Speed of Improvement, Frequency of Dosing, and Side Effects domains through Week 28



ITT population Data shown as mean ± SD. Data were available for all 4 domains for the patients shown (N).
ITT, intent-to-treat population; SD, standard deviation.

- For the Happiness with Psoriasis Control instrument, the mean ± SD score increased from 2.7 ± 2.3 at baseline to 6.4 ± 2.3 at Week 4 and 8.2 ± 2.2 at Week 28, corresponding to "extremely happy" (**Figure 3**)

Figure 3: Mean Happiness with Psoriasis Control score from baseline through Week 28



ITT population. Data shown as mean ± SD. *Statistically significant change from baseline ([based on t- test] P <0.001).
ITT, intention-to-treat; SD, standard deviation.

CONCLUSIONS

- In this interim analysis, patients with moderate-to-severe psoriasis treated with tildrakizumab in a real-world setting reported improvements in satisfaction overall and across all domains assessed

REFERENCES

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DISCLOSURES

JH has been a speaker, advisor, and consultant for AbbVie, Amgen, 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. **NB** is an advisor, consultant, and investigator for AbbVie; Almirall; Arcutis; Arena; Biofrontera; BMS; BI; Brickell; Dermavant; Eli Lilly; EPI Health; Ferndale; Galderma; Genentech; InCyte; ISDIN; J&J; LaRoche-Posay; LEO; Mayne; Novartis; Ortho Dermatologic; Patagonia; Pfizer; P&G; Regeneron; Sanofi; Stemline; Sun Pharmaceutical Industries, Inc.; Verrica; and Vyne