

# 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<sup>1</sup>
- Treatment satisfaction is an important element in disease management, with implications for health care delivery, treatment adherence, and effectiveness in real-world clinical practice<sup>1</sup>
- Treatment dissatisfaction among patients with moderate-to-severe psoriasis is a concern in clinical settings<sup>1,2</sup>
- Tildrakizumab is an anti-interleukin-23p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis<sup>3</sup>
- 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),<sup>4</sup> 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

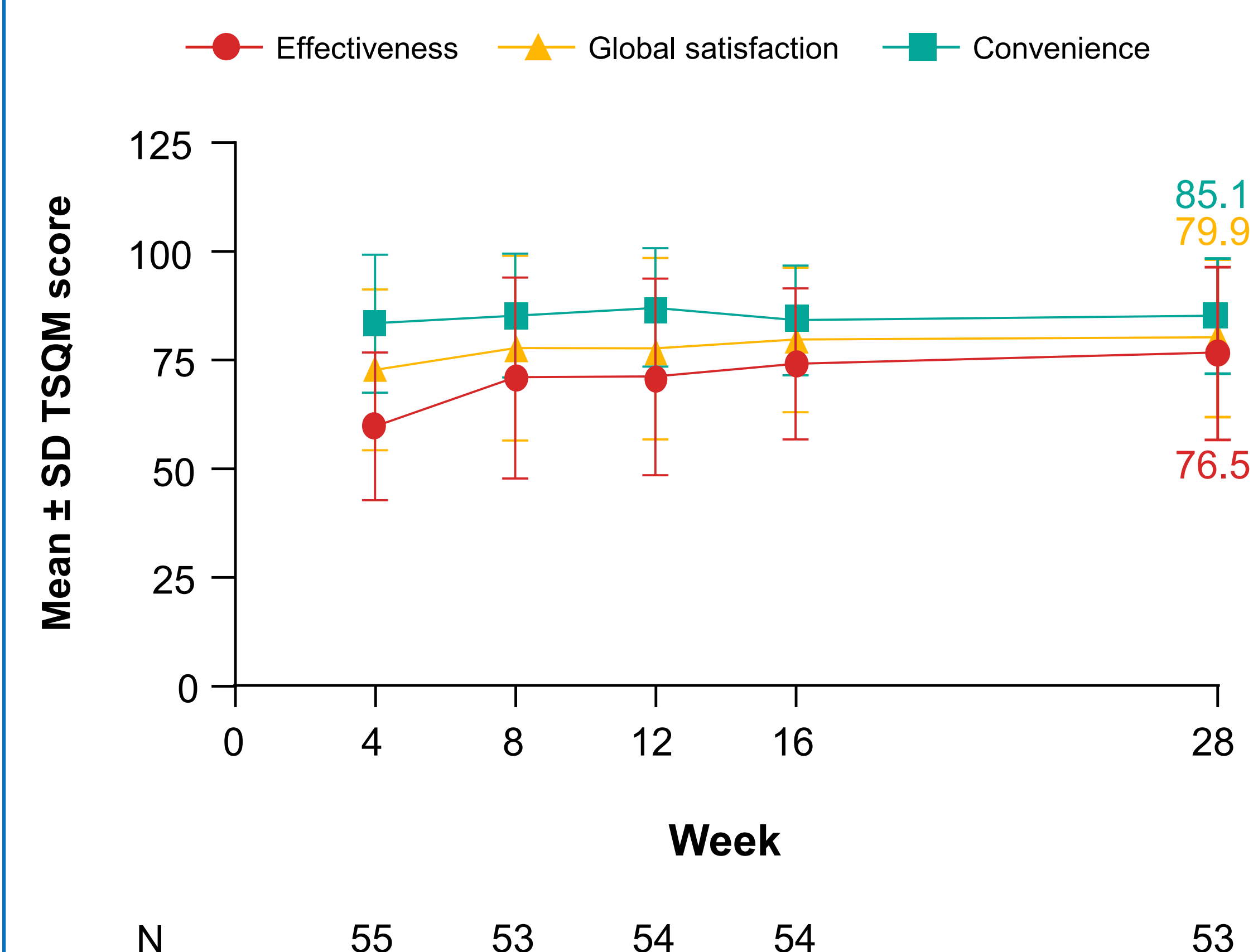
	(N = 55)
Sex, male	28 (50.9)
Age, years, mean ± SD	48.6 ± 15.3
Race	
Asian	1 (1.8)
Black or African American	2 (3.6)
White	52 (94.5)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
BSA, mean ± SD	14.5 ± 11.5
PASI, mean ± SD	11.6 ± 7.1

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)

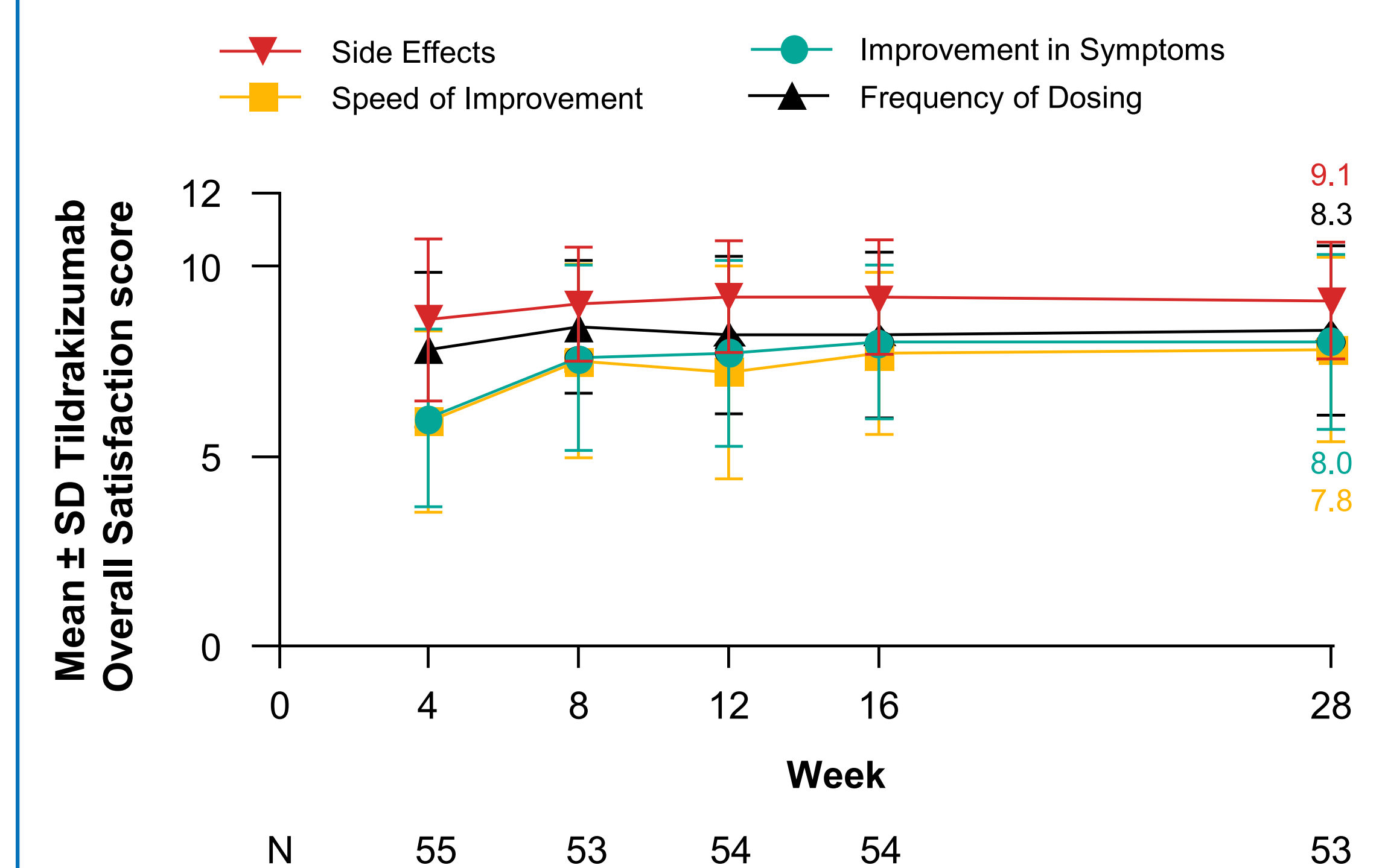
Figure 1: Mean TSQM scores for the Effectiveness, Convenience, and Global Satisfaction domains through Week 28



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)

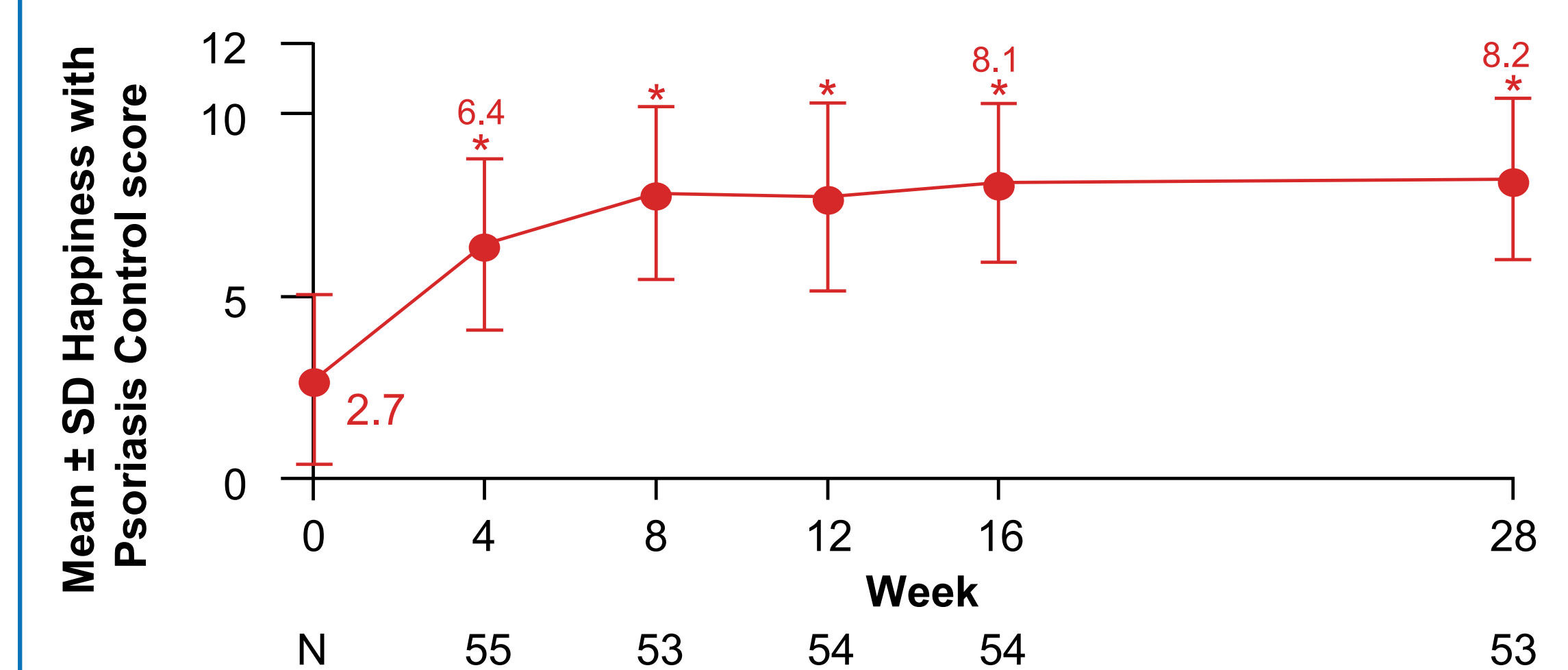
Figure 2: Mean Tildrakizumab Overall Satisfaction scores for the Improvement in Symptoms, Speed of Improvement, Frequency of Dosing, and Side Effects domains through Week 28



ITT population. Data shown as mean ± SD. Data were available for all 4 domains for the patients shown (N). ITT, intention-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

1) Duffin KC, et al. *Br J Dermatol*. 2014;170(3):672–80; 2) Armstrong AW, et al. *JAMA Dermatol*. 2013;149(10):1180–85; 3) Reich K, et al. *Br J Dermatol*. 2020;182(3):605–17; 4) Atkinson MJ, et al. *Health Qual Life Outcomes*. 2004;2:12.

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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