Psoriasis-related work productivity improvement from a Phase 4 real-world study of tildrakizumab in patients with moderate-to-severe plaque psoriasis

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INTRODUCTION

- Psoriasis is a chronic, inflammatory skin disorder that negatively impacts patients' physical health, quality of life, and work productivity, posing a substantial economic burden on the healthcare system and patients[1,2]
- Tildrakizumab is an anti–interleukin-23 p19 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy[3]
- The effect of tildrakizumab treatment on patients' work productivity in the Phase 3 clinical trials, reSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754), was not evaluated[4]

OBJECTIVE

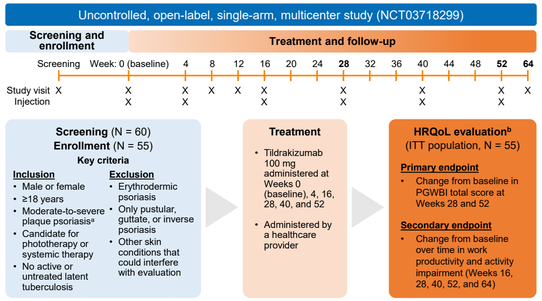
- This analysis assessed improvement in work productivity and reduction in activity impairment from a Phase 4 real-world study of patients with moderate-to-severe plaque psoriasis treated with tildrakizumab for up to 64 weeks

METHODS

Study design and population

- This was a Phase 4, multicenter, 64-week, uncontrolled, open-label, real-world study of tildrakizumab in patients with moderate-to-severe plaque psoriasis (NCT03718299; 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]HRQoL endpoints included in this analysis.
BSA, body surface area; HRQoL, health-related quality of life; ITT, intention-to-treat; PGWBI, Psychological General Well-Being Index.

Assessments

- Work productivity was evaluated using the Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI:PSO)
  - The WPAI:PSO is a validated, self-reported assessment that determines the amount of absenteeism, presenteeism, and daily activity impairment attributed to a patient's psoriasis
  - The following WPAI:PSO domains are reported:
    - Absenteeism: Percentage of time missed from work due to psoriasis
    - Presenteeism: Percentage reduction of productivity at work due to psoriasis
    - Total activity impairment: Percentage impairment in activities other than work due to psoriasis
    - Total work productivity impairment: Total percentage of work impairment from both absenteeism and presenteeism due to psoriasis
  - Each WPAI:PSO domain score is expressed as percentage impairment (0–100), with lower scores representing lesser impairment and higher scores representing greater impairment or worse outcome

Statistical analysis

- The WPAI:PSO domain scores were analyzed in the intention-to-treat population
- Differences between baseline and posttreatment values were analyzed using paired Student's t-tests
- Missing data were not imputed

RESULTS

Demographics and baseline characteristics

- Of the 55 patients enrolled, 31 completed all domains of the WPAI:PSO at Week 64
- 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. Baseline demographics and clinical characteristics

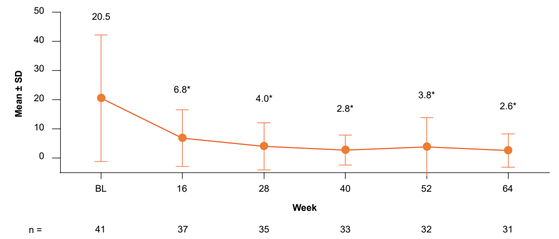
Characteristic	Tildrakizumab N = 55
Sex, male	28 (50.9)
Age, years, mean ± SD	48.6 ± 15.3
Race	
Asian	1 (1.8)
Black or African American	2 (3.6)
White	52 (94.5)
Ethnicity	
Hispanic or Latino	5 (9.1)
Not Hispanic or Latino	50 (90.9)
BSA, mean ± SD	14.5 ± 11.5
PASI, mean ± SD	11.6 ± 7.12
WPAI:PSO, mean ± SD	
Presenteeism domain	20.5 ± 21.7
Total activity impairment domain	29.5 ± 26.6
Total work productivity impairment domain	20.9 ± 22.2
Absenteeism domain	1.1 ± 5.7

ITT population.
Data shown as n (%) unless otherwise noted.
BSA, body surface area; ITT, intention-to-treat; PASI, Psoriasis Area and Severity Index; SD, standard deviation; WPAI:PSO, Work Productivity and Activity Impairment Questionnaire: Psoriasis.

Effectiveness

- Statistically significant improvements in work productivity compared to baseline were observed starting at Week 16 for all WPAI:PSO domains except absenteeism
  - The mean ± SD presenteeism domain score decreased significantly (P <0.001) from baseline (20.5 ± 21.7) to Week 64 (2.6 ± 5.8) of tildrakizumab treatment (change from baseline, −89.7%; **Figure 2**)

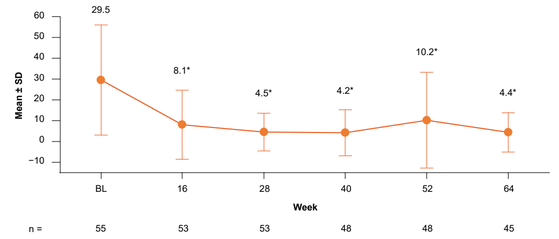
Figure 2. Presenteeism domain score through Week 64



ITT population. Error bars represent the SD. *All scores shown after baseline represent a statistically significant change from baseline based on Student's t-test (P <0.001).
BL, baseline; ITT, intention-to-treat; SD, standard deviation.

  - The mean ± SD total activity impairment domain score decreased significantly (P <0.001) from baseline (29.5 ± 26.6) to Week 64 (4.4 ± 9.4) of tildrakizumab treatment (change from baseline, −87.0%; **Figure 3**)

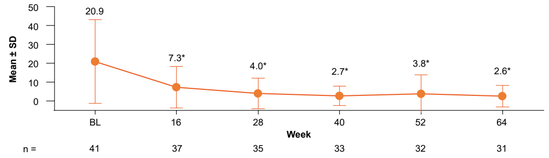
Figure 3. Total activity impairment domain score through Week 64



ITT population. Error bars represent the SD. *All scores shown after baseline represent a statistically significant change from baseline based on Student's t-test (P <0.001).
BL, baseline; ITT, intention-to-treat; SD, standard deviation.

  - The mean ± SD total work productivity impairment domain score decreased significantly (P <0.001) from baseline (20.9 ± 22.2) to Week 64 (2.6 ± 5.8) of tildrakizumab treatment (change from baseline, −89.7%; **Figure 4**)

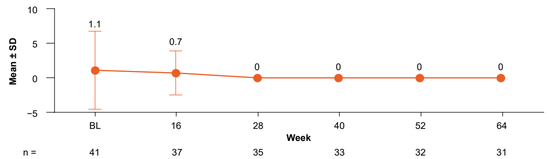
Figure 4. Total work productivity impairment domain score through Week 64



ITT population. Error bars represent the SD. *All scores shown after baseline represent a statistically significant change from baseline based on Student's t-test (P <0.001).
BL, baseline; ITT, intention-to-treat; SD, standard deviation.

  - The mean ± SD absenteeism domain score decreased from baseline (1.1 ± 5.7) to Week 64 (0.0 ± 0.0), but this change did not reach statistical significance (**Figure 5**)

Figure 5. Absenteeism domain score through Week 64



ITT population. Error bars represent the SD.
BL, baseline; ITT, intention-to-treat; SD, standard deviation.

CONCLUSIONS

- Tildrakizumab treatment significantly improved work productivity and decreased work activity impairment in patients with moderate-to-severe plaque psoriasis treated in a real-world clinical setting
- Although the reduction in absenteeism from baseline was not statistically significant, this was likely due to the near-zero baseline value for absenteeism

REFERENCES

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DISCLOSURES

NB is an advisor, consultant, and investigator for AbbVie, Almirall, Arcutis, Beiersdorf, Biofrontera, Boehringer Ingelheim, Bristol Myers Squibb, Cara, Dermavant, EPI Health, Ferndale, Galderma, InCyte, ISDIN, Johnson & Johnson, La Roche-Posay, LEO Pharma, Eli Lilly, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and Verrica Pharmaceuticals, Inc. **JH** has been a speaker, advisor, and consultant for AbbVie, Amgen, Celgene, Eli Lilly, Janssen, and Novartis; an advisor for Galderma, Mayne, Regeneron, and Sanofi; an advisor and consultant for Ortho Dermatologics; and a speaker and advisor for Sun Pharma. **BS** and **RG** are employees of Sun Pharmaceutical Industries, Inc. **JGV** reports nothing to disclose.