IMPROVING PATIENTS' WELL-BEING AND PSORIASIS-RELATED WORK PRODUCTIVITY WITH TILDRAKIZUMAB: 52-WEEK INTERIM RESULTS FROM THE PHASE IV REAL-WORLD POSITIVE STUDY IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

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INTRODUCTION

- Chronic diseases, such as psoriasis, profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being, which in turn can affect work productivity.[1]
- Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.[2,3]
- The objective of this analysis was to assess the effect of tildrakizumab treatment on the overall well-being and work productivity of moderate-to-severe psoriasis patients in the real-world setting.

METHODS

- POSITIVE is an ongoing 24-month, phase IV, observational, multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab 100 or 200 mg in a real-world setting.[4]
- Effectiveness assessments included Psoriasis Area and Severity Index (PASI): assessment of the severity of lesions and the area affected (range from 0 to 72, where 0=no psoriasis and 72=maximal disease).
- The well-being was assessed through the 5-item World Health Organization Well-being Index (WHO-5), a generic validated tool to assess subjective well-being:
  - ✓ The overall score ranges from 0 to 100, where 0=absence of well-being and 100=maximal well-being.[5]
  - ✓ As a reference, the mean WHO-5 score in the general population of the countries participating in the POSITIVE study was calculated to be 64.9, and was 52.2 among women with breast cancer or 51.4 among patients with diabetes with distress.[6-8]
  - ✓ The threshold for a clinically relevant change is 10 points.[5]
- The work productivity was assessed through the Work Productivity and Activity Impairment: Psoriasis (WPAI:PSO) questionnaire, which yields 4 scores (%): work time missed (absenteeism), impairment while working (presenteeism), overall work impairment (work productivity loss), and activity impairment.[9]
- Here, we report 52-week interim data using an observed cases approach.

RESULTS

- A total of 400 patients were included. Baseline characteristics are shown in **Table 1**.

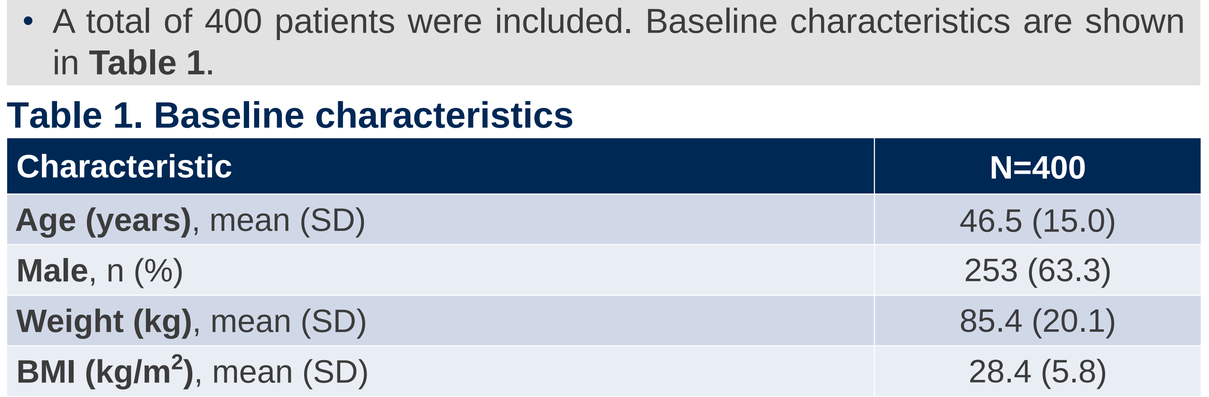
Table 1. Baseline characteristics

Characteristic	N=400
Age (years), mean (SD)	46.5 (15.0)
Male, n (%)	253 (63.3)
Weight (kg), mean (SD)	85.4 (20.1)
BMI (kg/m^2), mean (SD)	28.4 (5.8)
Current smoker, n (%)	147 (36.8)
Time since psoriasis diagnosis (years), mean (SD)	15.1 (13.0)
Biologic-naïve patients, n (%)	290 (72.5)

BMI, body mass index; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

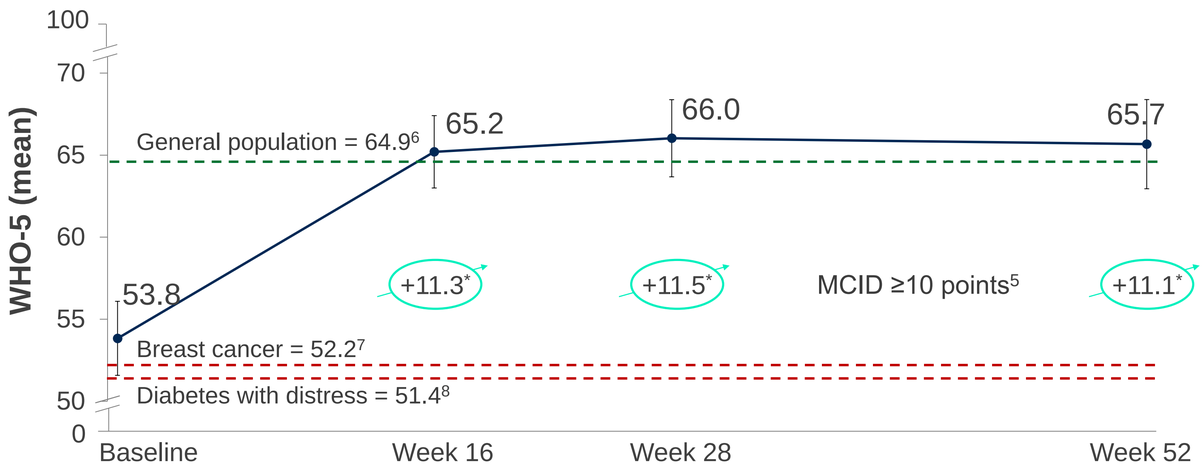
- The mean (95% CI) PASI decreased from 13.1 (12.3-13.8) at baseline to 2.4 (2.1, 2.7) at week 16 and to 1.5 (1.2-1.7) at week 52 (p<0.0001, both) (**Figure 1**).
- The mean (95% CI) WHO-5 score increased from 53.8 (51.6-56.1) at baseline to 65.2 (63.0-67.4) at week 16 and to 65.7 (63.0-68.4) at week 52 (p<0.0001, both) (**Figure 2**).

Figure 1. PASI up to week 52



*Mean change from baseline (p<0.0001). Error bars show the 95% confidence intervals of the means. PASI, Psoriasis Area and Severity Index (range 0-72, no disease to maximal disease).

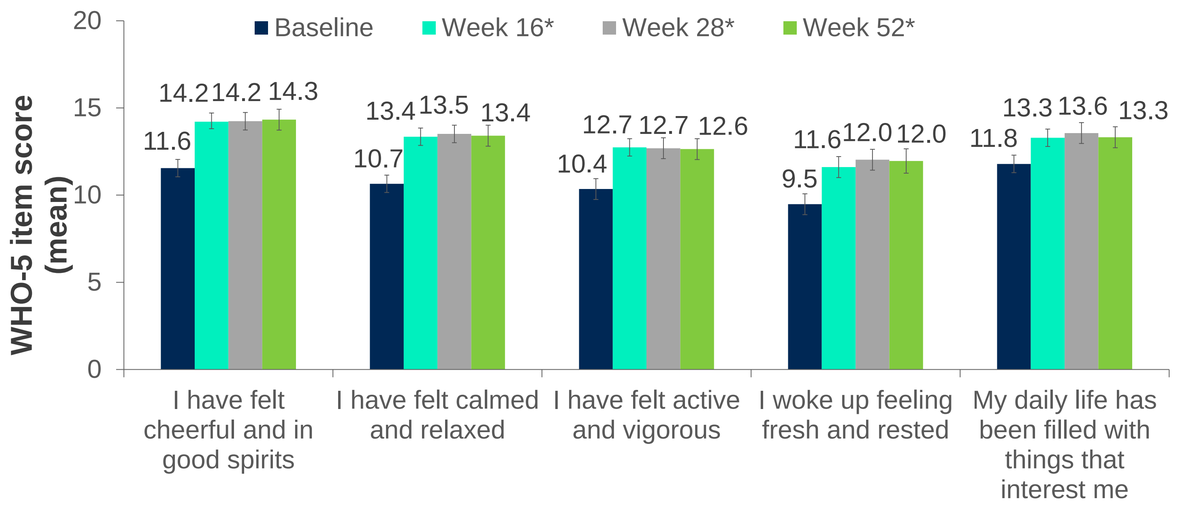
Figure 2. WHO-5 score up to week 52



*Mean change from baseline (p<0.0001). Error bars show the 95% confidence intervals of the means. WHO-5, WHO Well-Being Index (range 0-100, where 0=absence of well-being and 100=maximal well-being). As a reference, the mean WHO-5 score in the general population of the countries participating in the POSITIVE study was calculated to be 64.9, and was 52.2 among women with breast cancer or 51.4 among patients with diabetes with distress.[6-8] The threshold for a minimal clinically important difference (MCID) was considered to be 10 points.[5]

- The evolution of mean scores of individual WHO-5 items is shown in **Figure 3**.

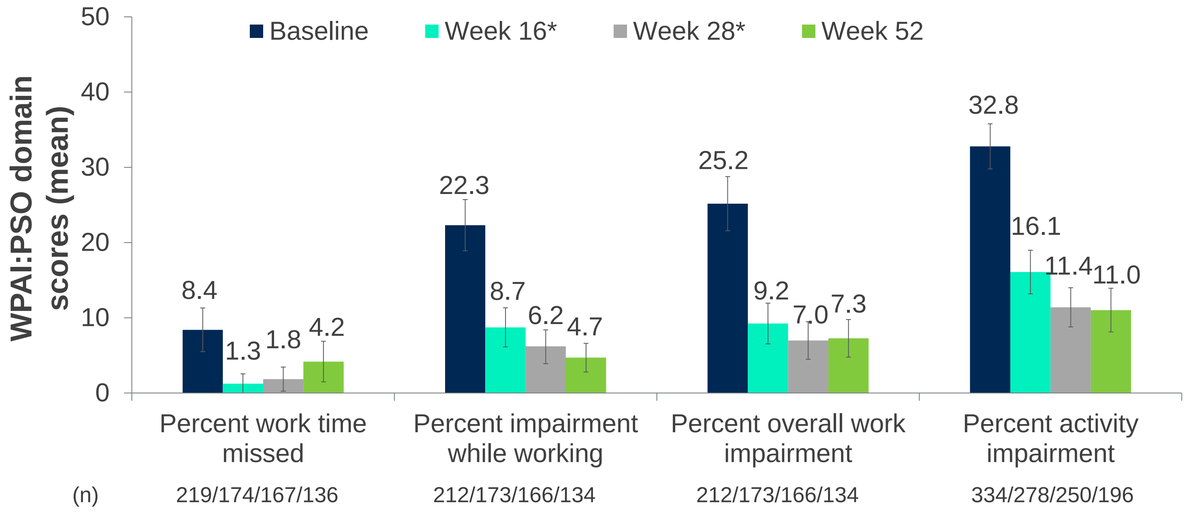
Figure 3. WHO-5 item scores up to week 52



*p<0.001 for all comparisons vs baseline. Error bars show the 95% confidence intervals of the means. WHO-5, WHO Well-Being Index (range of each item 0-20). Baseline: n=359; Week 16: n=317; Week 28: n=284; Week 52: n=218.

- All WPAI:PSO domain scores improved after 16/52 weeks (**Figure 4**). For instance, the mean (95% CI) percent absenteeism decreased from 8.4 (5.5-11.3) at baseline to 1.3 (-0.1-2.6) at week 16 (p<0.0001) and to 4.2 (1.5-6.9) at week 52, and the mean percent work productivity loss decreased from 25.2 (21.6-28.8) at baseline to 9.2 (6.5-12.0) at week 16 and to 7.3 (4.8-9.8) at week 52 (p<0.0001, both).

Figure 4. WPAI:PSO domain scores up to week 52



*p<0.001 for all comparisons vs baseline. Error bars show the 95% confidence intervals of the means. WPAI:PSO, Work Productivity and Activity Impairment Questionnaire: Psoriasis.

CONCLUSIONS

- In a real-world setting, tildrakizumab significantly improved patients' well-being and psoriasis-related work productivity in moderate-to-severe psoriasis patients after 16 weeks, and the improvement was maintained through week 52.

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ACKNOWLEDGEMENTS

- Writing support was provided by TFS HealthScience.
- This study was funded by Almirall.