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Patient Reported Outcomes in the Phase 3 THRIVE-AA1 Trial With CTP-543 (Deuruxolitinib) in Adult Patients With Moderate-to-Severe Alopecia Areata

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Background and Methods

Background

- AA is an autoimmune disorder causing partial or complete loss of hair, leading to reduced quality of life and considerable psychosocial impact for patients[1]
- JAK inhibitors have been shown to reverse hair loss in AA patients[2]
- Deuruxolitinib is an inhibitor of JAK1 and JAK2 that resulted in significant improvements in hair regrowth compared with placebo in the Phase 2 dose-ranging trial (NCT03137381)[3]
- Key safety and efficacy data from the THRIVE-AA1 study (NCT04518995) will be shown in presentations 42736, 41701 and 42752

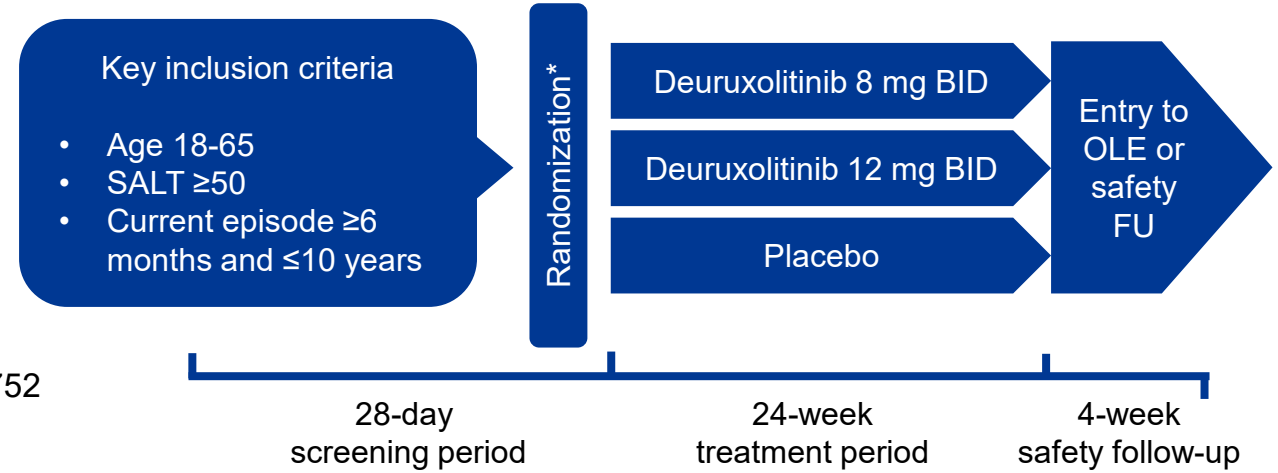
Materials and methods

- A key secondary endpoint was the percentage of responders who reported satisfaction on the hair satisfaction patient-reported outcome (SPRO) scale (5-point scale, ranging from 'very dissatisfied [5]' to 'very satisfied [1]') at Week 24
- A hair quality patient-reported outcome scale (QPRO) assessing satisfaction and a patient global impression of severity (PGI-S) or improvement (PGI-I) were also employed

Objective

- To present the SPRO improvements over time up to Week 24 from the Phase 3 THRIVE-AA1 trial (NCT04518995)

THRIVE-AA1 Study Design



Primary endpoint
- SALT score ≤20 at Wk 24

Key secondary endpoint
- SPROs (% responders) at Wk 24

Secondary endpoints
- QPRO (change from baseline)
- PGI-S (change from baseline)

*Randomization 3:5:2 to deuruxolitinib 12 mg BID, 8 mg BID or placebo. AA, alopecia areata; BID, twice daily; FU, follow-up; OLE, open-label extension; PGI-I, patient global impression of improvement; PGI-S, patient global impression of severity; QPRO, Quality of Hair Patient-Reported Outcome; SALT, severity of alopecia tool; SPRO, hair satisfaction patient-reported outcome; Wk, week.

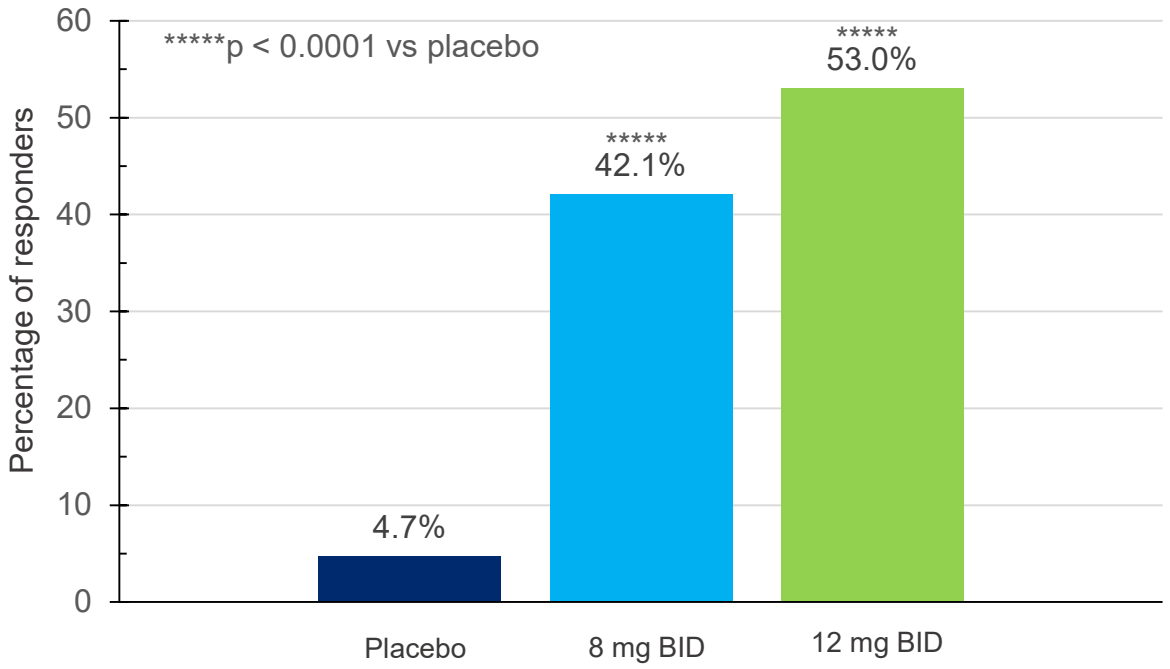
1. Lintzeri DA, et al. *J Dtsch Dermatol Ges.* 2022;20(1):59-90; 2. Dillon KL, et al. *Clin Cosmet Investig Dermatol.* 2021;14:691-714; 3. King B, et al. *J Am Acad Dermatol.* 2022;87(2):306-313.

Baseline Characteristics and Results

Patient Demographics and Baseline Characteristics

	Placebo (n = 140)	Deuruxolitinib 8 mg BID (n = 351)	Deuruxolitinib 12 mg BID (n = 215)	Total (n = 706)
Age, mean (SD), years	38.7 (13.81)	38.9 (13.32)	38.2 (12.80)	38.6 (13.25)
Gender, n (%)				
Female	89 (63.6)	217 (61.8)	131 (60.9)	437 (61.9)
Race: n (%)				
White	98 (70.0)	241 (68.7)	145 (67.4)	484 (68.6)
Baseline total SALT score, mean (SD)	88.1 (15.10)	85.5 (18.35)	85.2 (18.41)	85.9 (17.78)
Duration of current episode, mean (SD), years	3.9 (2.88)	3.6 (2.63)	3.6 (2.86)	3.7 (2.75)
Alopecia areata classification, n (%)				
Partial scalp hair loss (SALT ≥50 and <95)	62 (44.3)	155 (44.2)	95 (44.2)	312 (44.2)
Complete or near-complete scalp loss (SALT ≥95)	78 (55.7)	196 (55.8)	120 (55.8)	394 (55.8)

Hair Patient-Reported Outcome (SPRO) at Week 24

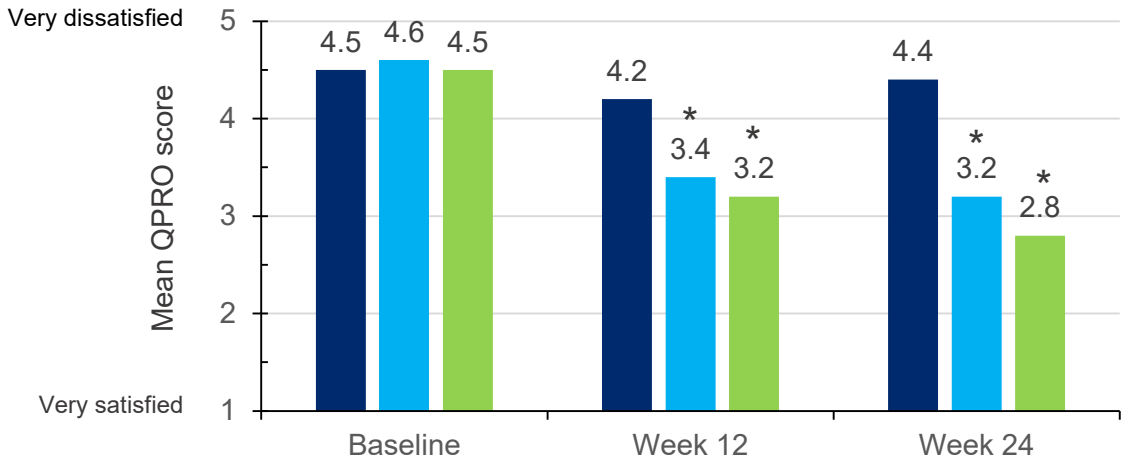


In both the 8 mg BID and 12 mg BID groups, significantly more patients reported being ‘satisfied’ or ‘very satisfied’ with their scalp hair at Week 24 compared with placebo

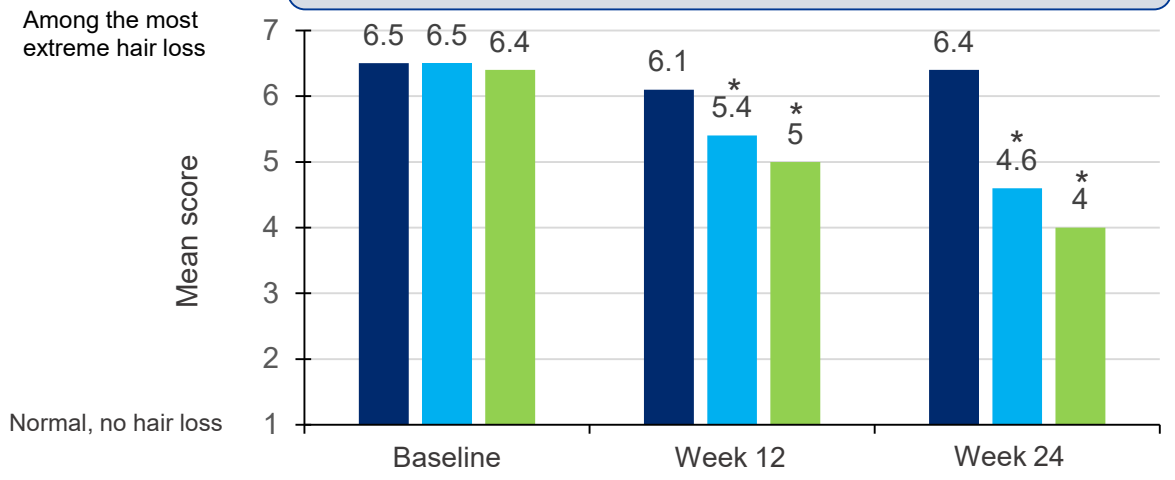
Data are mean (SD) unless stated otherwise.
BID, twice daily; SALT, severity of alopecia tool; SD, standard deviation.

Results

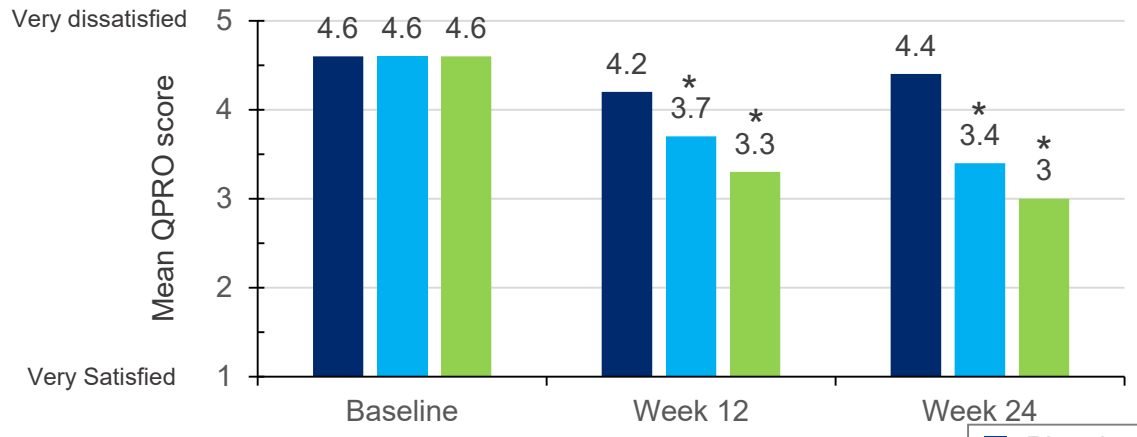
Quality of Hair Patient-Reported Outcome (QPRO): Satisfaction in 'Thickness of Hair Coverage'



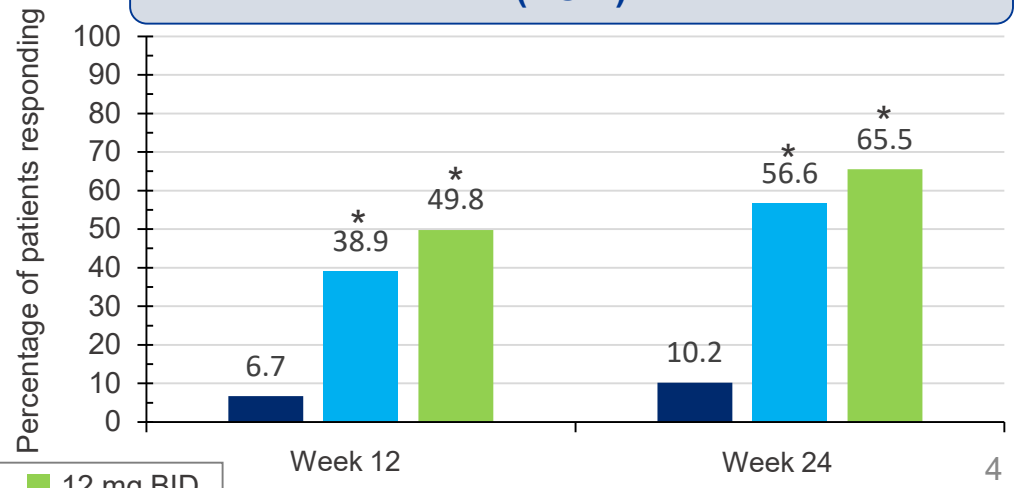
Patient Global Impression of Severity (PGI-S) by Treatment Group and Visit



Quality of Hair Patient-Reported Outcome (QPRO): Satisfaction in 'Evenness of Hair Coverage'



Patient Global Impression of Improvement (PGI-I)



Placebo | 8 mg BID | 12 mg BID

*p < 0.001 vs Placebo. BID, twice daily.

Conclusions

In the Phase 3 THRIVE-AA1 study, patient satisfaction with their scalp hair was significantly higher in patients receiving 8 mg or 12 mg deuruxolitinib at Week 24 compared with placebo

- Significantly more patients with moderate-to-severe AA receiving 8 mg and 12 mg deuruxolitinib BID, respectively, reported feeling ‘satisfied’ or ‘very satisfied’ with their scalp hair on SPRO after 24 weeks compared with the placebo group
- Improvement in patient-reported outcome measures was observed for the 8 mg and 12 mg deuruxolitinib BID dose groups compared with placebo, with a significant increase in the percentage of patients assessing their AA at Week 24 as ‘much improved’ or ‘very much improved’
- Significantly more patients receiving deuruxolitinib 8 mg or 12 mg BID considered their AA to be less severe at Weeks 12, 16, 20 and 24 compared with baseline than patients receiving placebo, according to the PGI-S scale
- Treatment with deuruxolitinib 8 mg or 12 mg BID resulted in significant improvements in individual items of the hair QPRO scale from baseline to Week 24, with patients receiving deuruxolitinib reporting significant improvements in satisfaction with scalp hair thickness and evenness compared with placebo

BID, twice daily; PGI-S, patient global impression of severity; QPRO, Quality of Hair Patient-Reported Outcome; SPRO, hair satisfaction patient-reported outcome.