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Efficacy of the Oral JAK1/JAK2 Inhibitor CTP-543 (Deuruxolitinib) in Adult Patients With Moderate to Severe Alopecia Areata: Results From the Multinational Double-Blind, Placebo-Controlled THRIVE-AA1 Phase 3 Trial

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Background, Methods and Baseline Characteristics

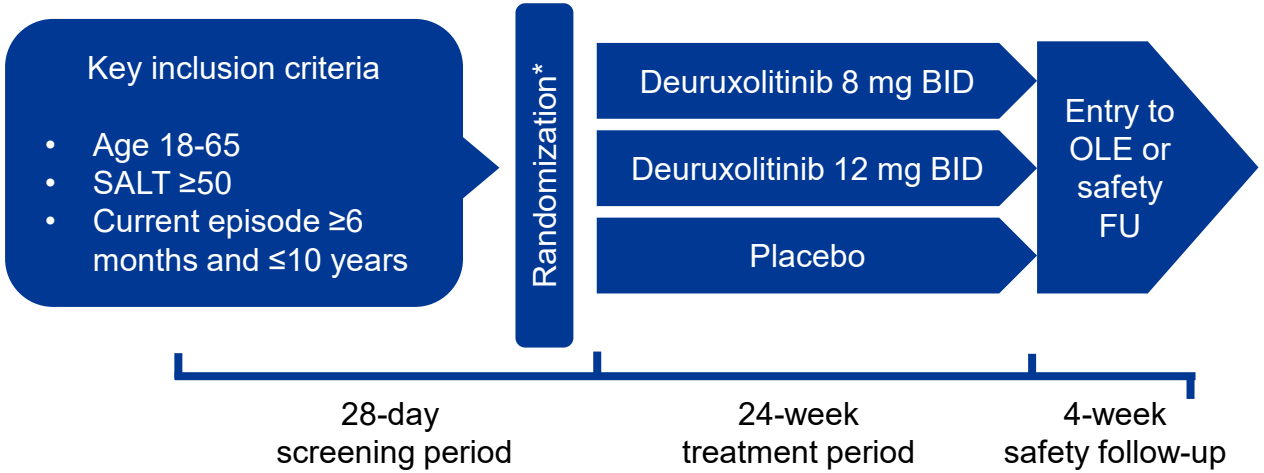
Background

- 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, 42746 and 42752

Objective

- To present key efficacy outcomes from the randomized, controlled, Phase 3 THRIVE-AA1 trial in patients with moderate-to-severe AA (NCT04518995)

THRIVE-AA1 Study Design



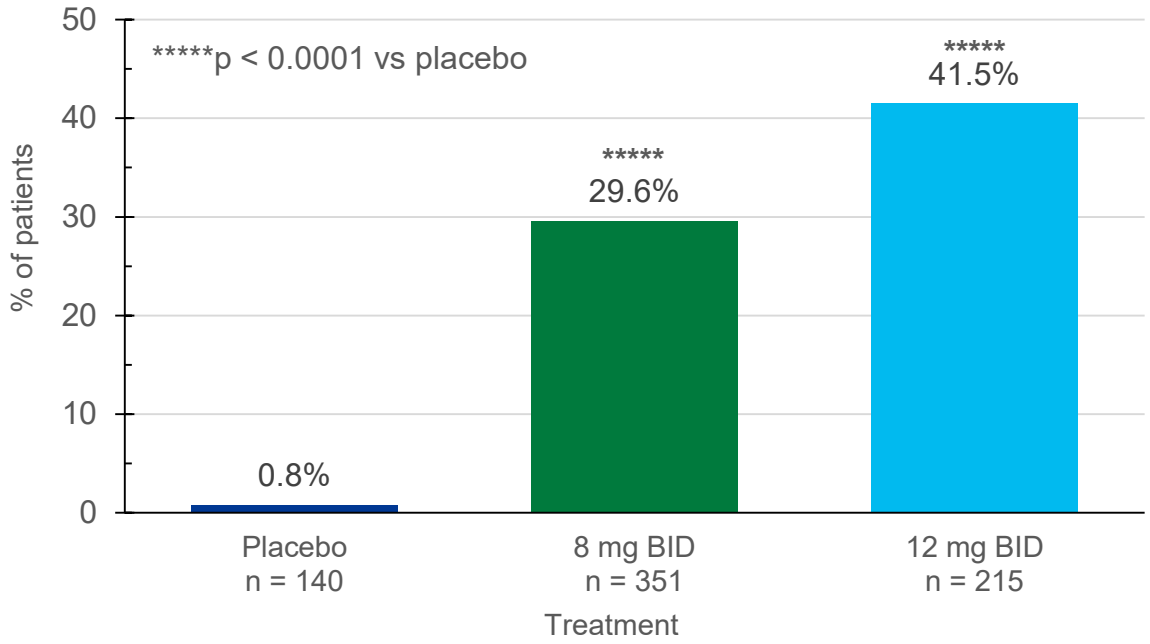
Primary efficacy endpoint: SALT score ≤20 at Wk 24; **Secondary efficacy endpoints:** SALT score ≤20 at Wk 20, 16, 12 and 8; 75% reduction in SALT score; 90% reduction in SALT score; SALT score ≤10 at Wk 24

Baseline characteristics	Placebo (n = 140)	Deuruxolitinib 8 mg BID (n = 351)	Deuruxolitinib 12 mg BID (n = 215)	Total (n = 706)
Duration of current episode (years), mean (SD)	3.9 (2.88)	3.6 (2.63)	3.6 (2.86)	3.7 (2.75)
Baseline total SALT score, mean (SD)	88.1 (15.10)	85.5 (18.35)	85.2 (18.41)	85.9 (17.78)
Partial scalp hair loss (SALT ≥50 and <95), n (%)	62 (44.3)	155 (44.2)	95 (44.2)	312 (44.2)
Complete/near-complete hair loss (SALT ≥95), n (%)	78 (55.7)	196 (55.8)	120 (55.8)	394 (55.8)

*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; SALT, severity of alopecia tool; SD, standard deviation; 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.

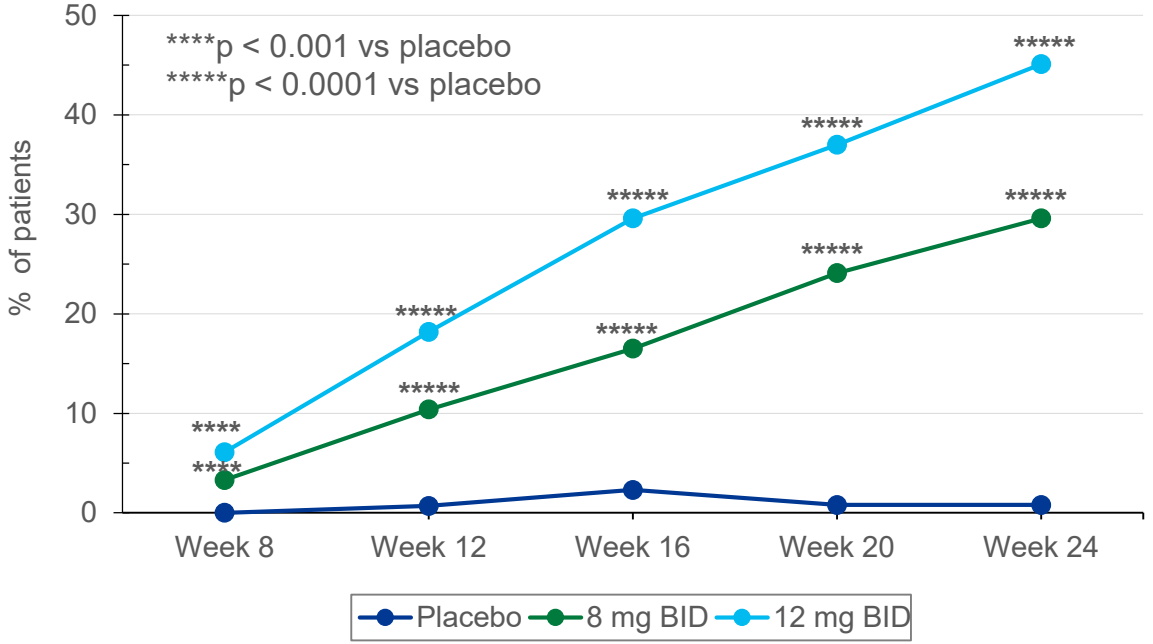
Results: Primary and Key Secondary Endpoint

Primary Efficacy Endpoint: Proportion of Patients Achieving SALT Score ≤20 at Week 24



- Both doses of deuruxolitinib met the primary efficacy endpoint (SALT score ≤20 at Week 24)
- For 8 mg BID and 12 mg BID, 29.6% and 41.5% of patients achieved a SALT score ≤20 at Week 24 compared with 0.8% for placebo

Key Secondary Endpoint: Patients Achieving Absolute SALT Score ≤20 by Weeks on Treatment

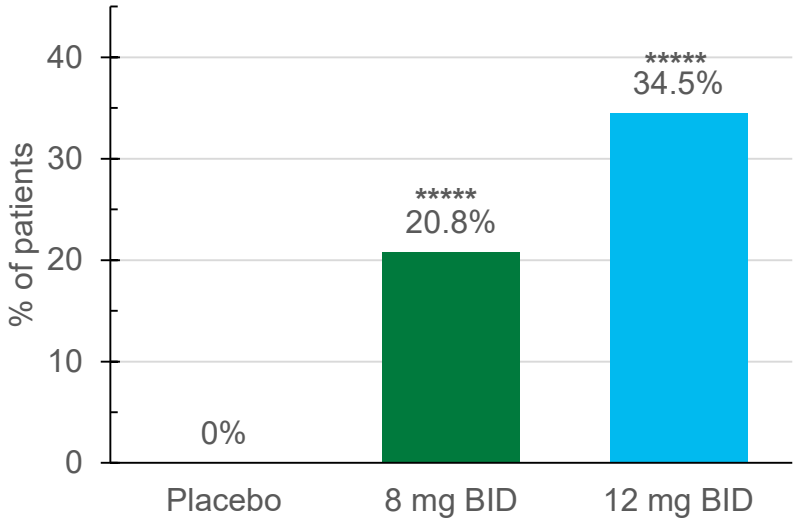


- Significant differences from placebo for both doses of deuruxolitinib were seen as early as Week 8

BID, twice daily; SALT, severity of alopecia tool.

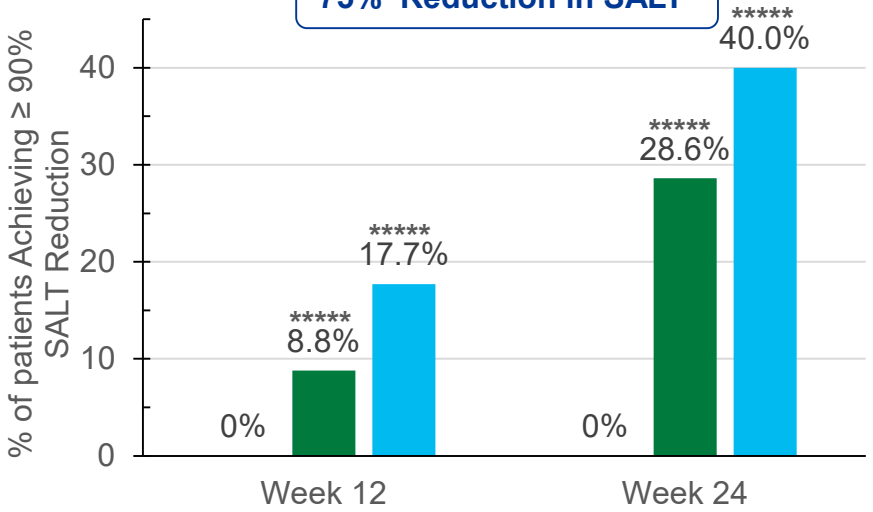
Results: Secondary Endpoints

Proportion of Patients Achieving SALT Score ≤10 at Week 24

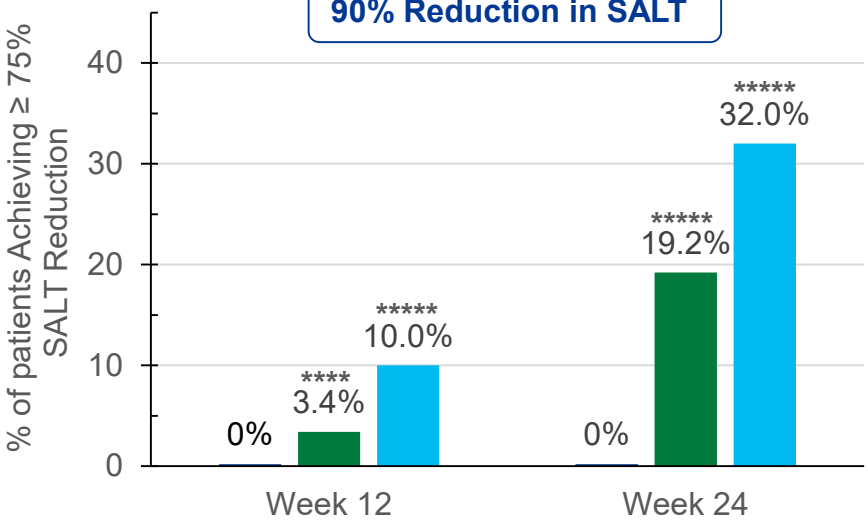


Percentage of Patients Achieving at Least a 75% or 90% Relative Reduction in SALT Score From Baseline at Week 12 and 24

75% Reduction in SALT



90% Reduction in SALT



****p < 0.001 vs placebo
*****p < 0.0001 vs placebo

- Both the 8 mg BID and 12 mg BID groups achieved a SALT score ≤10 at Week 24 compared with placebo
- Patients achieved a 75% and 90% relative improvement from baseline as early as Week 12 for both doses with significant differences versus placebo

BID, twice daily; SALT, severity of alopecia tool.

Conclusions

- Both the 8 mg BID and 12 mg BID doses of deuruxolitinib met the primary efficacy endpoint (SALT score ≤20 at Week 24)
  - A SALT score ≤20 has been shown to be clinically meaningful for patients and hair experts[1]
- Both doses of deuruxolitinib resulted in significant regrowth of scalp hair, starting as early as 8 weeks and continuing throughout the 24-week study period
  - The deuruxolitinib 12 mg BID group was numerically superior to the deuruxolitinib 8 mg BID group
- The efficacy of deuruxolitinib in the treatment of moderate-to-severe alopecia areata is encouraging

BID, twice daily; SALT, severity of alopecia tool.

1. Wyrwich KW, et al. *Br J Dermatol.* 2020;183(4):702-709.