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

• AA is an autoimmune disorder causing partial or complete loss of hair, leading to reduced quality of life and considerable psychosocial impact for patients.
• JAK inhibitors have been shown to reverse hair loss in AA patients.
• 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).
• 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).

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

*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.

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

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BID, twice daily; SALT, severity of alopecia tool.
Results: Secondary Endpoints

- 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.