

Abstract N°: 2534

Patient satisfaction and impressions of severity of moderate to severe alopecia areata are improved by deuruxolitinib (CTP-543): Patient-reported outcomes from the multinational, double-blind, placebo-controlled THRIVE-AA2 Phase 3 trial

Thierry Passeron^{1, 2}, Ulrike Blume-Peytavi³, Athanasios Tsianakas⁴, Oscar Muñoz Moreno-Arrones⁵, Adriána Evelin Csernus⁶, Colleen Hamilton⁷, James Cassella⁷

¹Côte d'Azur University, University Hospital of Nice, Nice, France, ²INSERM U1065, C3M, Nice, France, ³Charité – Universitätsmedizin Berlin, Berlin, Germany, ⁴Fachklinik Bad Bentheim, Bad Bentheim, Germany, ⁵Ramón y Cajal Hospital, Madrid, Spain, ⁶University of Pécs, Pécs, Hungary, ⁷Sun Pharmaceutical Industries, Inc., Lexington, United States

Introduction & Objectives:

Alopecia areata (AA) is an autoimmune disease that causes partial or complete loss of hair, leading to reduced quality of life (QoL) and considerable psychosocial impact on patients. Without effective treatment, many individuals with chronic AA will have persistent multifocal recurrent disease, and some may progress to more severe forms. Deuruxolitinib (CTP-543), an inhibitor of Janus kinase (JAK)1 and JAK2, has demonstrated significant improvements in hair regrowth compared with placebo in both a Phase 2 dose-ranging trial (NCT03137381) and in the Phase 3 THRIVE-AA1 trial (NCT04518995). Here, patient-reported outcomes (PROs) from the second Phase 3 clinical trial of deuruxolitinib (THRIVE-AA2; NCT04797650) in adult patients with moderate to severe AA are reported.

Materials & Methods: Patients aged 18–65 years with AA, $\geq 50\%$ scalp hair loss (as measured by the Severity of Alopecia Tool score) and a current AA episode lasting >6 months to <10 years were eligible. Participants were treated with deuruxolitinib 8 mg twice daily (BID), deuruxolitinib 12 mg BID or placebo for 24 weeks. A key secondary endpoint was percentage of responders 'satisfied' or 'very satisfied' on the Hair Satisfaction Patient-Reported Outcome (SPRO) 5-point rating scale at Week 24. Other secondary endpoints included percentage of responders 'much improved' or 'very much improved' on the Patient Global Impression of Improvement (PGI-I), and change from baseline on the Patient Global Impression of Severity (PGI-S) and Hair Quality Patient-Reported Outcome (QPRO) scales.

Results: Overall, 517 patients were enrolled (mean age 39 years; 67.5% female; 79.7% White; 61.3% SALT score ≥ 95). In the PRO population, 503 patients were randomized 2:1:1 to deuruxolitinib 8 mg ($n = 249$), 12 mg ($n = 127$) or placebo ($n = 127$). On the SPRO, 46.5% and 51.7% of the 8 mg and 12 mg groups, respectively, reported being 'satisfied' or 'very satisfied' with their hair at Week 24 vs 1.7% for placebo ($p < 0.0001$). On the PGI-I, 50.9% and 68.3% of the 8 mg and 12 mg groups, respectively, reported their hair being 'much improved' or 'very much improved' at Week 24 vs 1.7% for placebo ($p < 0.0001$). At Week 24, both deuruxolitinib doses showed significant differences vs placebo when evaluated on the PGI-S ($p < 0.0001$) and PGI-I ($p < 0.0001$). Patients on both deuruxolitinib doses also reported significant differences vs placebo at Week 24 for satisfaction with *thickness* ($p < 0.0001$) and *evenness* ($p < 0.0001$) of scalp hair coverage (QPRO).

Conclusion: Consistent with data from THRIVE-AA1, patient satisfaction and impressions of severity and improvement of scalp hair were significantly higher with both doses of deuruxolitinib vs placebo, demonstrating that significant improvements in patient satisfaction are achieved alongside the efficacy of deuruxolitinib.

