

**Title:** Safety, Tolerability and Efficacy of a Topical Treatment (SM04554) for Androgenetic Alopecia (AGA): Results from a Phase 2 Trial

**Introduction:** The safety, tolerability, and efficacy of SM04554, a novel, small molecule, topical scalp treatment for AGA, was assessed in a multicenter, randomized, double-blind, vehicle-controlled trial.

**Methods:** Male subjects were treated topically once daily for 90 days with 0.15% or 0.25% SM04554 or vehicle, returning 45 days post-treatment for final evaluation. Study objectives included quantifying non-vellus hair by scalp macrophotography, assessing subject-reported outcomes, and further characterizing SM04554 safety and tolerability (ECGs, laboratory measures, vital signs and investigator scalp assessment).

**Results:** 302 subjects (0.15% n=102, 0.25% n=102, vehicle n=98) were enrolled. 77 related adverse events (AEs) were reported by 55 (18%) subjects [21 (21%) vehicle; 21 (21%) 0.15%; 13 (13%) 0.25% group]. The most common related AEs were administration site erythema, paraesthesia, pruritis, and hypersensitivity. One serious AE (small bowel obstruction) was reported in the vehicle group. Changes in ECGs, laboratory measures, vital signs and investigator scalp assessments were unremarkable. Following 90 days of daily treatment, the 0.15% group exhibited a significant improvement in hair count ( $P=0.0249$ ) and density ( $P=0.011$ ) at Day 135 compared to vehicle adjusting for age, Norwood-Hamilton grade, compliance and Day 90 assessment in the intention-to-treat analysis set.

**Conclusions:** SM04554 appears to be safe, well-tolerated, and potentially efficacious.

**Authors:** Yusuf Yazici, MD<sup>1</sup>, Christopher J. Swearingen, PhD<sup>1</sup>, Ismail Simsek, MD<sup>1</sup>, Anita DiFrancesco<sup>1</sup>, John D. Hood, PhD<sup>1</sup>.

<sup>1</sup> Samumed LLC, San Diego, CA, USA