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**Safety and Efficacy of a Topical Treatment (SM04554) for Androgenetic Alopecia (AGA): Results from a Phase 1 Trial**

**Biography:**

Dr. Yazici is the Chief Medical Officer of Samumed, LLC. Additionally, Dr. Yazici is an Assistant Professor at New York University School of Medicine Department of Rheumatology, where he serves as Director of the Seligman Center for Advanced Therapeutics and Director of the Behcet's Syndrome Center, the largest US center for Behcet's Disease. Recognized nationally and internationally, Dr. Yazici has more than 250 publications. After receiving his medical degree from Istanbul University, his Rheumatology Fellowship was completed at the Weill Medical College Hospital for Special Surgery of Cornell University and his Internal Medicine Residency at Creighton University in Nebraska.

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**Abstract:**

AGA is a common form of hair loss with only two approved drugs in the US. A randomized, double-blind, placebo-controlled, single-center trial for AGA assessing safety and efficacy of SM04554, a novel small molecule modulating the Wnt pathway, was conducted.

The trial treated male subjects topically once daily for 14 days with either 0.05%, 0.15% or 0.45% SM04554 or vehicle; subjects returned 14 days post-treatment for final evaluation. Safety data, including pharmacokinetics (PK), electrocardiogram (ECG), laboratory parameters, application site assessments and vital signs, were collected throughout treatment, with subject-reported efficacy outcomes collected at end of study.

29 subjects (7-0.05%, 8-0.15%, 8-0.25%, 6-vehicle, average age 44.6) were enrolled; 13 (45%) were Norwood-Hamilton score 5 (range 4-7). 15 treatment-emergent adverse events (TEAEs) were reported by 11 (38%) subjects. The most frequently reported TEAE was eye irritation / hyperaemia (N=2 [7%]). ECGs, labs and vital signs were unremarkable. One vehicle subject presented with minimal scalp erythema; no other subject reported application site irritation. Systemic exposure was dose-dependent. In the 0.15% group, 6 (75%) subjects reported slowing of hair loss and 3 (37%) reported increased hair growth compared to zero (P=0.01) and 1 (17%, P=0.58) of vehicle subjects, respectively, at end of study.

SM04554 appears to be safe, well-tolerated, and potentially efficacious. These results will help guide future AGA trials using this treatment.

**Learning Objective:**

To evaluate the safety and efficacy of a topical treatment for androgenetic alopecia (AGA) in a phase 1 clinical trial

**Author Disclosure Information:** **Y. Yazici:** Salary, Contractual Services; Samumed, LLC. **S.R. Smith:** Consultant; Samumed, LLC. **C.J. Swearingen:** Salary, Contractual Services; Samumed, LLC. **I. Simsek:** Salary, Contractual Services; Samumed, LLC. **A. DiFrancesco:** Salary, Contractual Services; Samumed, LLC. **J.D. Hood:** Salary, Contractual Services; Samumed, LLC.

**Category (Complete):** Clinical Trials

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