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SAMUMED PRESENTED DATA ON INCREASES IN HAIR FOLLICLES OBSERVED IN ITS PHASE 2 BIOPSY STUDY FOR A POTENTIAL TREATMENT OF ANDROGENETIC ALOPECIA (AGA) AT ANNUAL MEETING OF THE AMERICAN ACADEMY OF DERMATOLOGY (AAD)

- SM04554 may be the first treatment leading to follicular neogenesis
- Both treatment groups exhibited statistically significantly higher total follicle counts compared to vehicle
- The safety profile emerging from prior trials of SM04554 was further supported with data from this biopsy study, including no serious adverse events reported

San Diego, CA—March 6, 2017— Samumed, LLC, presented safety and efficacy results from a Phase 2 scalp biopsy study for its AGA program during the 75th AAD Annual Meeting in Orlando, FL.

The results suggested that Samumed's investigational drug, a topical solution of the novel small molecule compound SM04554, may be the first treatment causing follicular neogenesis.

The 49-subject, multi-center, randomized (1:1:1), double-blind, vehicle-controlled trial involved 90 days of once-daily therapy and included a 4mm scalp biopsy at baseline (Day -26), Day 91 and Day 135 to assess the safety and efficacy of two different concentrations (0.15% and 0.25%) of SM04554 versus vehicle in male subjects with AGA between the ages of 18 and 65 with Norwood-Hamilton Classification scores of 4, 5, 5A, 5V, or 6.

"Follicle count data from observations at the tissue level in this biopsy study, together with non-vellus hair count increases we observed in past studies, are very exciting for the future prospects of SM04554 as a potential hair regeneration drug," said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. "We are also very encouraged that the safety profile emerging from our prior trials is further supported with a biopsy study."

In the ITT analysis, both treatment groups exhibited significantly higher total follicle counts compared to vehicle: the 0.25% group exhibited significantly higher total follicle counts at Days 91 ($P<0.0001$) and 135 ($P=0.0002$); the 0.15% group exhibited significantly higher total follicle counts at Day 135 ($P=0.0002$).

Different types of follicles (vellus [<30 µm diameter], indeterminate [30-60 µm diameter], terminal [>60 µm diameter]) were counted and categorized by hair-cycle phase. Statistically significantly higher numbers of hair follicles, compared with the vehicle group, were observed as follows:

- The 0.25% group exhibited significantly higher counts at Days 91 and 135 for vellus ($P=0.003$; $P=0.002$), and total anagen ($P<0.0001$; $P=0.004$) follicles. Significantly higher counts were also

seen at Day 91 for indeterminate (P<0.001) and terminal anagen (P=0.01) follicles, and at Day 135 for terminal catagen/telogen (P=0.006) follicles.

- The 0.15% group exhibited significantly higher counts at Day 135 for vellus (P=0.007), terminal (P=0.01), total anagen (P=0.004), and terminal catagen/telogen (P=0.025) follicles.

Nuclear expression of Ki-67, a protein strictly associated with cell proliferation, was also measured in hair bulbs. A higher Ki-67 signal within the hair bulb was observed in both the 0.15% and 0.25% groups from Baseline to Day 91 compared with the vehicle group, suggesting a more robust proliferation of hair bulb epithelial cells. Further, a higher Ki-67 signal within the hair bulb was observed in the 0.25% group from Baseline to Day 135 compared with the vehicle group.

Increased follicle counts and hair bulb Ki-67 signals suggested treatment with SM04554 may have promoted follicular neogenesis and therefore may be a potential treatment for AGA.

In this Phase 2 biopsy study, SM04554 appeared safe and well-tolerated. There were no serious adverse events reported, and no significant differences were observed between 0.15% or 0.25% SM04554 and vehicle in epidermal β-catenin and Ki-67, indicating no abnormal proliferative signal. Adverse events (AE) considered related to treatment with SM04554 were application site erythema (1 patient), application site burning and/or stinging (1 patient), application site pruritus (2 patients), and skin exfoliation (2 patients). Most AEs were mild (grade 1) or moderate (grade 2) in severity per Common Terminology Criteria for Adverse Events (CTCAE) v4.0 (1-5 scale), and no trends or imbalances were noted between all treatment and vehicle groups.

The poster presentation is available at www.samumed.com.

ABOUT SAMUMED, LLC

Based in San Diego, CA, Samumed (www.samumed.com) is a pharmaceutical platform company focused on advancing regenerative medicine and oncology applications through research and innovation. Samumed has discovered new targets and biological processes in the Wnt pathway, allowing the team to develop small molecule drugs that potentially address numerous degenerative conditions as well as many forms of cancer.

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