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PRESS RELEASE

Samumed Doses First Subject in Phase 2/3 Trial of SM04554 for the Treatment of Androgenetic Alopecia

Top-line Data Expected in Second Half of 2020

SAN DIEGO – Nov. 19, 2018 – Samumed, LLC, announced today that it has dosed the first subject in its phase 2/3 trial of SM04554, a topical small molecule Wnt pathway activator, for the treatment of androgenetic alopecia (AGA), the most common type of hair loss in men and women. This trial is being conducted as a pivotal study in Turkey and is expected to enroll approximately 625 patients across 11 study sites. This study is conducted under an IND with the FDA. In addition, the Ministry of Health of Turkey has confirmed that the study, if successful, would support submission of a marketing application for SM04554 in Turkey.

"We have shown in phase 2 trials that daily treatment with SM04554 appeared safe and increased follicle counts and non-vellus hair counts compared to vehicle in males with AGA after 90 days of exposure" said Yusuf Yazici, M.D., Chief Medical Officer of Samumed. "In order to build upon these results, this study will evaluate the effect of treatment with topical SM04554 applied daily for 48 weeks on males with AGA. We anticipate top-line results in the second half of 2020."

This trial is a multi-center, randomized, double-blind, placebo-controlled, parallel group study of two doses of topical SM04554 solution (0.15% & 0.25%) applied daily to the scalp of male AGA subjects. The trial is a 54-week study, with 48 weeks of treatment followed by 6 weeks of follow-up. The primary endpoint of the study is the baseline-adjusted absolute non-vellus hair count in the target area by phototrichogram analysis at Week 48 compared to vehicle.

Prof. Server Serdaroglu, M.D., principal investigator in this study, said, "The negative psychological effects of androgenetic alopecia are well documented. Currently available treatments have limited efficacy and patients need access to better options. We look forward to contributing to this important clinical study which will examine the effects of SM04554 over the course of one year."

Samumed has completed two phase 2 studies examining the safety, tolerability, and efficacy of SM04554 for the treatment of AGA. These studies demonstrated that treatment with SM04554 appeared to be well-tolerated and safe. Key clinical results have shown that treatment with SM04554 applied daily (90 days) to the scalp resulted in:

- Significantly increased non-vellus hair counts and non-vellus hair density with treatment (0.15% SM04554) compared to vehicle (NCT02275351).
- Significantly increased follicle counts in both treatment groups (0.15% and 0.25% SM04554) compared to vehicle (NCT02503137).

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About Androgenetic Alopecia
Androgenetic alopecia (AGA) is the most common type of hair loss in men and women, affecting an estimated 50 million men and 30 million women in the US. It is characterized by varying degrees of hair thinning that occurs as terminal (mature) hairs are gradually "miniaturized" to vellus (fine/wispy) and dormant hairs. AGA generally presents in a characteristic pattern and varies by age and race. It is most prevalent among Caucasians, with approximately half of men developing hair loss by age 50 and one third of women developing some form of loss as age increases.

About SM04554
SM04554 is a topical small molecule Wnt pathway activator being developed for the treatment of androgenetic alopecia (AGA). Additional information on Samumed's SM04554 AGA program can be found here: https://www.samumed.com/pipeline/detail.aspx?id=16

About Samumed
Samumed's small-molecule drug platform is harnessing the innate restorative power of the Wnt pathway to reverse the course of severe and prevalent diseases. Learn more about Samumed's potential regenerative drug candidates and broad clinical pipeline at: https://www.samumed.com/pipeline/default.aspx

Corporate Contact:
Erich Horsley
Samumed, LLC
erich@samumed.com
858-365-0200

Investor Contact:
Ashley Robinson
LifeSci Advisors
arr@lifesciadvisors.com
617-535-7742

Media Contact:
Matt Middleman, M.D.
LifeSci Public Relations
matt@lifescipublicrelations.com
646-627-8384