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SAMUMED ANNOUNCES INCREASES IN BOTH HAIR COUNT AND HAIR DENSITY OBSERVED IN ITS PHASE II STUDY FOR A POTENTIAL TREATMENT OF ANDROGENETIC ALOPECIA (AGA)

SAN DIEGO—December 4, 2015— Samumed, LLC, a leader in tissue regeneration, announced today preliminary analysis of efficacy data from its Phase II AGA trial, in which one of the dosage arms, compared to vehicle, showed statistically significant increases for both objective outcome measures: non-vellus hair count (a primary outcome measures) and hair density (a secondary outcome measures), using the pre-specified statistical model.

Samumed’s investigational drug is a topical solution of its novel small molecule compound SM04554. The 300-subject, multi-center, randomized (1:1:1), double-blind, vehicle-controlled trial studied the safety, tolerability and efficacy of two different doses of SM04554 in male subjects with AGA between the ages of 18 and 55 with Norwood-Hamilton hair loss classification scales of 4, 5, 5A, 5V, or 6. The study involved a 90-day once-a-day treatment period and a 45-day post-treatment follow up. The primary endpoints were the objective quantification by macrophotography of non-vellus hair count, and the subjective assessment of hair quality by subject-completed Men’s Hair Growth Questionnaire.

The findings are consistent with preclinical *in vivo* animal models, in which SM04554 has been shown to generate new hair follicles and increase hair count. The safety results from its Phase II study, as well as results from a previously completed Phase I study, were presented at the 9th World Congress for Hair Research (WCHR) in Miami, Florida on November 21, 2015. As the company previously announced, in the Phase II study, there were no serious adverse events observed in any treated patient, and the incidence of adverse events was similar between treatment and vehicle groups.

“The Phase II safety and efficacy data so far are very promising and support moving this program into pivotal studies. We are analyzing the efficacy data further and plan to present results of both preclinical and clinical studies at upcoming medical conferences,” said Yusuf Yazici, M.D., Chief Medical Officer of Samumed.

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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