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Follicum AB reports top-line data from First-in-Man Scalp Study with FOL-005 against hair loss

Follicum AB ("Follicum" or "Company"), a biotech company that develops new drugs in two areas, hair loss and diabetes, today reports top-line data from the first phase IIa study with FOL-005 for the treatment of hair loss on scalp in patients. The phase IIa study examined the safety and therapeutic effect of different doses of the drug candidate FOL-005, administered as injections into the scalp 3 times per week. The results confirmed that the treatment was safe with minimal side effects reported. Furthermore, increased hair growth was measured at the highest dose. Follicum will now follow up with a clinical efficacy study using a topical formulation of FOL-005.

In the study, hair growth (primary endpoint) increased on average by 7 hairs per cm² and the increase was borderline statistically significant compared to baseline ($p = 0.078$). There was no statistically significant difference for placebo when compared to baseline. The study was designed to measure the effect after treatment vs. baseline (the individual's starting value) and not vs. placebo. A clear positive effect was also shown in the number of hairs in growth phase, another very important parameter for hair growth. At the highest dose, a marked, 11% (median) increase in the number of hair follicles in growth phase was observed. Furthermore, the ratio between the number of hair in the growth phase to those in the dormant phase increased by 18% (median), while the corresponding number for placebo was minus 16% (median). This difference reinforces the other results, which taken together indicate that FOL-005 is a promising treatment for alopecia (hair loss), although the dose and treatment length will probably need to be optimized to obtain maximum effect. In the case of the placebo, the majority of the parameters showed changes in the opposite direction, i.e. weakened hair growth. The next step for the company is to prepare for a clinical study evaluating the effect of a topical formulation of FOL-005, where dose, dosing frequency and treatment duration will be optimized. In parallel, the company will focus on finding a suitable partner for further development of FOL-005.

CEO Jan Alenfall comments

"We are very pleased to have completed this phase IIa clinical study that has shown that the treatment is safe and despite the limited number of patients, also shows a good effect on hair growth. The highest dose showed that the treatment resulted in both increased hair growth and a substantial increase in the number of hair follicles in growth phase. This is of great importance for alopecia patients who have a reduced hair growth period. The clear effect we saw in the growth phase supports the hypothesis that FOL-005 can "awaken" dormant hair follicles. In the placebo group, the proportion of hair follicles in growth phase decreased. Overall, the results provide very important guidance for planning the new efficacy study with a topical formulation where dosage and dosing frequency will be studied. We are now looking forward to starting a new study on the scalp with a larger number of patients to overcome the issues with large, individual variations in a small patient cohort. "

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This information is information that Follicum is obliged to make public according to the EU Market Abuse Regulation. The information was provided through the agency of the contact persons above, for publication on the 31th of October 2018.

About Follicum AB

Follicum is a biotech company focused on the discovery and development of peptide-based drugs. The primary focus is in hair growth stimulation, where Follicum has obtained very promising results with FOL-005 in a recently completed clinical trial. In diabetes, Follicum's research has resulted in a new peptide class which significantly increases the release of insulin in pre-clinical models. The company was founded in 2011, and is based in Lund, Sweden. Follicum is listed on the Swedish small cap exchange Spotlight since 2014. www.follicum.com.