



Press release October 8, 2020

All patients included in Follicum's Phase II study with FOL-005 for stimulation of hair growth

Follicum AB today announced that all patients have been included in the company's ongoing Phase IIa clinical study with its lead drug candidate FOL-005. The study involves more than 200 male patients with hair loss who are being treated with a newly developed topical formulation of FOL-005. No noteworthy adverse reactions have been reported so far and to date none of the patients included have discontinued their participation in the study. The results are expected to be presented in spring 2021.

The ongoing double-blind and placebo-controlled Phase II study examines the safety and efficacy of FOL-005 in a new, cream-like formulation. Patients themselves apply one of three different strengths of FOL-005 or placebo to the scalp once a day. To evaluate the safety and efficacy of treatment, patients visit their respective clinic regularly during the four months study. The study is being conducted at three different clinics in Germany: The Clinical Research Center for Hair and Skin Science ("CRC") in Berlin, proDERM in Hamburg and CentroDerm in Wuppertal. The last patient is scheduled to complete his treatment by the end of January 2021. Two previous clinical studies with FOL-005 have shown that intradermal injection of the drug candidate is an effective and safe treatment for stimulation of hair growth.

CEO Jan Alenfall comments:

"The fact that all patients have initiated treatment is a significant step forward and we are pleased that no patient has stopped their participation so far. So-called "drop-outs" are common in clinical drug trials and may make it difficult to interpret the results. We now look forward to completing the study, with a view to reporting the results in spring 2021."

About FOL-005

FOL-005 is a modified, short version of the endogenous protein, osteopontin. In two completed clinical studies, treatment with FOL-005 has been shown to be effective and safe. The first study was done in healthy volunteers while the other one was conducted in alopecia patients, i.e. in men with incipient baldness. In both studies, patients were treated at the clinic with intradermal injections, 2 or 3 times a week.

About Alopeci

Unwanted hair loss (alopecia), which is commonly referred to as "baldness", affects about a third of all men between the ages of 20 and 50 in the Western world. For men over 50 years of age, the proportion with hair loss is even higher, about 50%. A significant proportion of women also suffer from unwanted hair loss. All in all, this translates to a huge market for an effective and safe hair-stimulating drug. Today, there are principally only two medicinal substances used for treatment. Sales of these drugs amount to more than USD 3 billion annually. Compared to existing preparations, FOL-005 is likely to offer several benefits, such as fewer side effects, easier dosage and higher proportion of responders.

For further information, please contact:

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This information is information that Follicum is obliged to make public under the EU Market Abuse Regulation. The information was submitted, through the agency of the above contact person, for publication on 8 October 2020.

About the Clinical Research Center for Hair and Skin Science (CRC), Berlin, Germany

The Clinical Research Center for Hair and Skin Science ("CRC") is part of the skin clinic at the Charité - University Hospital in Berlin. CRC conducts experimental research and offers specialist expertise in the area of skin and hair research. CRC has conducted several clinical studies in various hair indications and has solid qualifications with specialization in Phase I and II clinical studies.

About proDERM

proDERM is a full-service contract research organization in Hamburg, Germany, specializing in conducting clinical studies in the areas of skin, mucosa, hair, eyes and mouth. proDERM carry out studies on medicinal products, medical devices, cosmetics, nutritional supplements and consumer goods alike, and competently comply with the various regulatory and legal requirements. proDERM is a competent, full-service partner, supervising clinical projects in all phases.

About CentroDerm

Since CentroDerm® was founded in 2000, more than 150 clinical studies (GCP / ICH studies) in Phase II-IV as well as studies under the Medical Devices Act (MPG) within dermatology, oncology, allergy and aesthetic medicine have been conducted by the CentroDerm GmbH team. They have vast experience in hair studies.

About Follicum AB

Follicum AB (Spotlight: FOLLI) develops drugs based on tissue repairing peptides with potential use in a number of disease areas. The company's most advanced drug candidate, FOL-005 for hair loss, is currently being evaluated in a Phase IIa study in collaboration with internationally renowned specialist clinics. In the field of diabetes, a project is being run aimed at protecting insulin-producing cells from damage and thus reducing the risk of complications. Based on promising preclinical results, preparations are underway for a Phase I study. Both projects have the potential to become so-called first-in-class drugs. For more information, visit www.follicum.com.