

## Follicum AB reports that all patients have completed treatment with FOL-005 in the Phase II study against hair loss

**Follicum AB today announced that all patients in the ongoing Phase IIa study with FOL-005 for the treatment of hair loss have completed treatment and made their final visits to the clinic. The study examines the safety and treatment effect of different doses of the drug candidate FOL-005 in just over 200 male patients. Top line results are expected to be presented during spring 2021.**

The ongoing double-blind and placebo-controlled Phase IIa study examines the safety and efficacy of FOL-005 in a new, cream-like formulation. The patients themselves have applied one of three different strengths of FOL-005 or placebo to the scalp once a day and have undergone follow-up at regular visits to the study clinics during the four months of the study. The study was conducted at three clinics in Germany: the Clinical Research Center for Hair and Skin Science ("CRC") in Berlin, proDERM in Hamburg and CentroDerm in Wuppertal. Two previous clinical studies with FOL-005 have shown that treatment with intradermal injections of the drug candidate is effective and safe for stimulation of hair growth.

### **CEO Jan Alenfall comments:**

*"It is very gratifying that all of the more than 200 patients have now completed treatment and made their final follow-up visits to the clinics. Now, a comprehensive review of the data will be undertaken before the study can be un-blinded and analyzed. No relevant adverse reactions have been reported and in only one patient was participation discontinued, a result of the covid-19 pandemic. As previously communicated, we look forward to presenting the results of the study during spring."*

### **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:**

Jan Alenfall – CEO, Follicum AB

Telephone: +46 (0)709 31 51 15

Email: [info@follicum.com](mailto:info@follicum.com)

*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 January 28, 2021.*

### **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](http://www.follicum.com).