



Press release August 18, 2020

## More than 50% of patients enrolled in Follicum's Phase II study of FOL-005 for stimulation of hair growth

**Follicum AB ("Follicum" or the "company") today announced that more than 50% of the patients have been recruited in the ongoing, clinical phase IIa study with FOL-005. The study involves 200 male patients with hair loss who are treated daily for four months with a newly developed topical formulation of FOL-005 or placebo. The study is being conducted at the Clinical Research Center for Hair and Skin Science ("CRC") in Berlin, at proDERM in Hamburg and at CentroDerm® in Wuppertal.**

Two previous clinical studies have shown that intradermal injections of FOL-005 are an effective and safe treatment for stimulation of hair growth. The current Phase II study aims to investigate the safety, efficacy and response of the drug candidate FOL-005 in a topical formulation. Patients themselves will apply one of three different strengths of FOL-005 or placebo to the scalp, once a day during the evening. The results of the study are expected to be communicated in spring 2021.

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

*"The fact that more than half of patients are now recruited is an important milestone for Follicum. We are very relieved that we are one of few pharmaceutical companies have not suffered significant delays in an ongoing study due to the Covid-19-pandemic. We are following the planned recruitment rate after a temporary break and we are working intensively to achieve the recruitment goal so that patients can undergo final treatment before the end of the year. The current study is intended to confirm the interesting results we have seen in previous studies, now in a larger patient group and with the cream-like formulation developed and tested over the past year."*

### **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 Alopecia**

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 according to the EU Market Abuse Regulation. The information was provided through the agency of the contact persons above, for publication on the 18<sup>th</sup> of August, 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 from 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 2a 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).