



Press release January 30, 2020

## Follicum's Phase II study with FOL-005 for treatment of Alopecia approved by the German Medicines Agency

**Follicum AB ("Follicum" or "the Company") today announces that it has received approval from the German Medicines Agency (BfArM) and the German Ethics Committee to start a Phase IIa clinical study with a topical formulation of FOL-005 on patients with alopecia (hair loss). The trial will comprise about 200 patients who will be treated with FOL-005 or placebo daily for 4 months. The study is conducted in collaboration with the Charité Clinical Research Center for Hair and Skin Science ("CRC") in Berlin and proDERM, Hamburg, Germany.**

In two previous clinical studies, FOL-005 has been shown to be an effective and safe treatment for stimulation of hair growth. The upcoming phase IIa study aims to investigate the safety, efficacy of and response to the drug candidate FOL-005 applied as a topical formulation. Once daily in the evening, the patients will themselves apply one of three different strengths of FOL-005 or placebo to the scalp. The study is expected to be completed and the results communicated in Q4, 2020.

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

- We are very pleased that we have now received the "green light" from both the German Medicines Agency and the Ethics Committee to start the new study with FOL-005. Other preparations are also in place and we expect patient recruitment to begin soon. In this study, patients apply the topical formulation of FOL-005 or placebo once daily, thus both simple and practical for repeated long-term treatment. We now look forward to conducting the study together with CRC and proDERM and we look forward to results at the end of the 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**

Alopecia means hair loss. This may be due to a number of causes. The most common form is called Androgenic Alopecia or male hair loss and affects the majority of all men but also a very large proportion of women. It is by far the most common form of hair loss. It is known that high levels of and high sensitivity to a sex hormone called dihydrotestosterone (DHT) leads to an increased risk of hair loss in men and women. Simply put, it can be said that the hormone causes the hair follicles to shrink and no longer produce a pigmented hair.

### **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 30th of January, 2020.*

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