

Follicum reports top-line results from Phase IIa study of FOL-005 for treatment of hair loss (alopecia)

Follicum AB (publ) today reports top-line data from a Phase IIa study of the tissue repairing peptide FOL-005 for treatment of hair loss (alopecia). The study examined safety and therapeutic efficacy after daily treatment with the product for four months. The results confirmed that the treatment was safe and only a few mild side effects were reported. Hair growth increased significantly in the group of patients receiving FOL-005 treatment at the highest dose studied, but no significantly better efficacy compared to the placebo group could be demonstrated. Follicum will conduct further analyses of the study results and also explore the possibilities to further develop FOL-005 for other medical conditions where the drug candidate in preclinical studies has shown good tissue repair effects. The development of the company's preclinical drug project in the diabetes field is not affected by the phase II results for FOL-005.

The study – conducted in collaboration with three reputable specialist clinics in Germany - looked at the safety and efficacy of treatment with a cream-like formulation of the drug candidate FOL-005 that was applied by the patients every night for four months. The study involved 210 male patients, a quarter of whom received placebo. In those treated with the highest dose of FOL-005 studied, hair growth increased by 6.6 hair/cm² (p=0.04), compared to 5.6 hair/cm² in the placebo group (p=0.01). The difference between active treatment with FOL-005 and placebo was not significant (p=0.83). However, positive signs were noted for a number of secondary parameters that may be of importance and a more accurate analysis of these data will take place shortly.

In addition, the company will continue to investigate the tissue repair potential of the peptide in other indications with great medical and commercial potential. Concomitantly, the use of Follicum's unique formulation technology will be evaluated for other applications.

"Compared to the results achieved in previous preclinical and clinical studies of FOL-005, the outcome of the Phase IIa study is disappointing. However, our confidence in the concept of tissue repair peptides remains high and we will now carefully analyze the results to draw conclusions on how we can optimize the development plans for FOL-005 and the company's other projects", says Follicum's CEO, Kim Arvid Nielsen.

After the results of the Phase IIa study have been fully analysed, Follicum will decide how to allocate its resources for the continued development of FOL-005 in different indication areas where tissue repair properties are important. The company's preclinical projects in the field of diabetes are not affected by these results and are making progress at an unabated pace.

For further information, please contact:

Kim Arvid Nielsen – CEO, Follicum AB
Phone: + 46 (0)70 392 1331
Email: kim.nielsen@follicum.com

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 person above, for publication on the 6th of May 2021.

About Follicum AB

Follicum AB (Spotlight: FOLLI) develops drugs based on tissue repair peptides with potential use in a range of disease areas. The company's most advanced drug candidate, FOL-005, is administered using a unique formulation technology found safe and well-tolerated in a comprehensive Phase II study conducted in collaboration with internationally renowned specialist clinics. In the field of diabetes, a project is being conducted that aims to protect insulin-producing cells from damage, thus reducing the risk for complications. The projects have the potential to become so-called first-in-class medicines. For more information, visit www.follicum.com.