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Press release | Umeå February 7, 2024

The Swedish Medical Products Agency approves Lipigon's phase II study with Lipisense[®]

Lipigon Pharmaceuticals AB ("Lipigon") announces today that the Swedish Medical Products Agency and the Swedish Ethical Review Authority, via the European application system CTIS, have approved Lipigon's application to conduct a phase II study. With this approval, Lipigon can now start the phase II study with Lipisense® in patients with severe hypertriglyceridemia.

The study will be conducted entirely in Sweden at three to four different trial clinics and will include up to 26 patients with severely elevated blood fats of the triglyceride type and underlying type 2 diabetes. The patients are treated for one month with four doses of Lipisense® and then followed for six months where safety parameters, blood lipids and other important metabolic factors are studied.

Lipigon will begin screening patients for inclusion in the study as soon as possible. The goal is to administrate the last dosage in the second half of 2024.

"We are extremely happy about the speedy approval from CTIS. The fact that the positive news came so early can only be interpreted as our clinical team together with our CRO Link Medical performing an outstanding job. Their thorough preparations have contributed to a smooth application process, " says Dr. Stefan K. Nilsson, CEO and co-founder.

The phase I study showed that Lipisense® can effectively lower the levels of the target protein ANGPTL4 in plasma, which is believed to significantly contribute to the etiology of metabolic disorders. Focusing on patients with high ANGPTL4 levels, Lipisense® is not only a potential blood lipid lowering agent but may also have a positive effect on blood glucose homeostasis. With the potential to affect several metabolic parameters, Lipisense® is an attractive candidate in a competitive pharmaceutical segment.

"By demonstrating a treatment effect not only on blood lipids but also on blood glucose and other important metabolic parameters in a very challenged patient group, the upcoming phase II study has good prospects for further strengthening the Lipisense® rationale," continues Dr. Stefan K. Nilsson.



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Lipigon's phase II study aims to evaluate the safety of Lipisense® in patients, while providing the opportunity to measure important indicators of the drug candidate's effect. The study has been designed in collaboration with leading clinical experts, which strengthens the positioning of Lipisense®.

About Lipisense®

Lipisense® is an RNA therapeutics drug candidate that prevents the cells from producing the disease-promoting target protein ANGPTL4 in the liver by destroying the protein-coding RNA before the target protein has been formed. Genetic data demonstrate that ANGPTL4 is an independent risk factor for both cardiovascular disease and type 2 diabetes.

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This is information that Lipigon Pharmaceuticals AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 16:00 CET, on 7 February 2024.

About Lipigon

Lipigon Pharmaceuticals AB is a clinical-stage pharmaceutical company developing drugs with new, unique mechanisms of action (first-in-class) for diseases caused by disorders in the body's handling of fats. The company's operations are based on over 50 years of lipid research at Umeå University, Sweden. Lipigon's initial focus is on orphan drugs and niche indications, but in the long term, the company has the possibility to target broader indications, such as diabetes and cardiovascular disease. Lipigon's pipeline includes three active projects: the RNA drug Lipisense® targeting elevated triglycerides, with Phase II studies planned for Q1 2024, an RNA drug for the treatment of acute respiratory distress syndrome, and a small molecule program for the treatment of dyslipidemia in collaboration with HitGen (Inc). Read more at www.lipigon.se.

The company's share (LPGO) is traded on the Nasdaq First North Growth Market. Certified Adviser is G&W Fondkommission.

