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Press release | Umeå November 10, 2023

Lipigon applies for clinical trial Phase II for Lipisense®

Lipigon Pharmaceuticals AB (Lipigon) announces that the company has submitted an application for a Phase II clinical trial for its blood lipid-lowering drug candidate, Lipisense®.

The application has been submitted via CTIS (Clinical Trial Information System), which means that a joint application for approval is sent to the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten) through the electronic EU portal, CTIS.

Lipigon is now awaiting the response from the authorities before recruiting the first patient for the study. Typically, the approval process takes 60-106 days under normal circumstances.

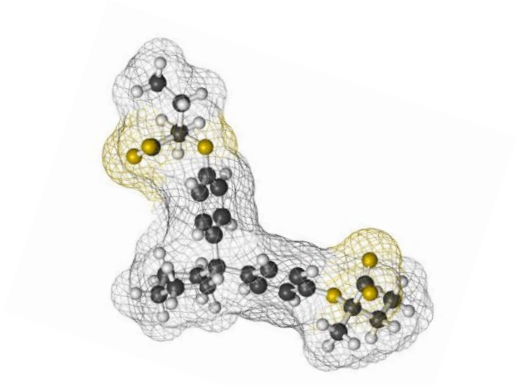
The purpose of the study is to document the safety profile of Lipisense® in patients with severe hypertriglyceridemia (sHTG) and type 2 diabetes. Additionally, secondary and exploratory objectives include the investigation of various biomarkers, such as blood lipid levels and insulin sensitivity. The Phase II study is conducted in collaboration with the contract research organization Link Biomedical at three trial sites in Sweden: Karolinska University Hospital Huddinge, Västerås Hospital, and the Clinical Trial Consultants (CTC) trial unit in Uppsala.

"We are now expanding our efforts to provide data from patients with sHTG and underlying diabetes issues. The patient group with high triglyceride levels has a significantly elevated risk for several serious diseases, primarily acute pancreatitis and atherosclerosis. There is an urgent demand for new treatments for these patients. Through the planned Phase II study, we intend to explore their medical conditions comprehensively. The study design has been well-coordinated with clinical experts in the field and potential future licensees of Lipisense®," says Stefan K. Nilsson, CEO of Lipigon.

The company is adjusting its future timelines based on the submitted application.

"As a result of positive Phase I outcomes, which led to certain modifications in the study protocol and consequently a delay in the application submission, the original timeline for the study start has been slightly adjusted. As it stands now, we aim to commence the study in the first quarter of 2024 and complete it within one year from the start," says Stefan K. Nilsson.

"Furthermore, we are working intensively with our Chinese collaborative partner, Leaderna Therapeutics, to continue the development, which should result in significant savings through cost-



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sharing. Overall, my assessment is that we are well-equipped and prepared for the upcoming developmental stages," says Stefan K. Nilsson.

The clinical development plan focuses on the protein ANGPTL4 and its unique properties that can provide patients with lipid disorders with the potential for a new and effective treatment. "Switching off" the production of the ANGPTL4 protein, specifically in the liver, using the RNA-based drug candidate Lipisense® may also have other valuable effects, such as improved control of blood glucose levels.

"The study we are planning is highly cost-effective and has the potential to address many of the questions that we and others in the research field have. Finally, having the opportunity to investigate the effects of the Lipisense® treatment in patients is incredibly exciting and yet another significant milestone in Lipigon's development," says Stefan K. Nilsson.

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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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. Lipigons pipeline includes four active projects: the RNA-drug Lipisense® for the treatment of hypertriglyceridemia, an RNA drug for the treatment of acute respiratory distress syndrome, a gene therapy treatment for the rare disease lipodystrophy in collaboration with Combigene AB (publ), 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.