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Press release | Umeå May 31, 2022

First-in-human phase I trial with Lipigon's lipid-lowering candidate Lipisense

Lipigon Pharmaceuticals AB ("Lipigon") has announced that their drug candidate Lipisense has been given to humans for the first time. The phase I clinical trial began on Tuesday.

Lipisense is a drug candidate developed to lower blood lipid triglycerides in patients with severely elevated levels by preventing the production of the protein ANGPTL4 in the liver. The primary purpose of the phase I study is to document the candidate's safety, tolerability and pharmacokinetic profile while also evaluating efficacy on relevant biomarkers.

"It is a solemn and exhilarating feeling taking the most important step so far in the company's history. Today we start the first clinical study with Lipisense and give it to a human for the first time. We are anticipating the autumn because we have good hopes to receive the first value-adding results by then," says CEO Stefan K. Nilsson.

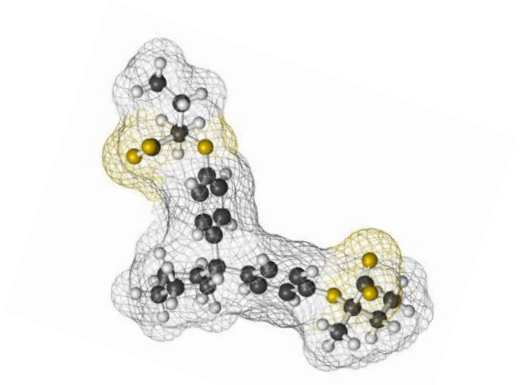
The preclinical studies of Lipisense were completed in 2021. Overall, they showed that Lipisense has a good safety profile. The drug candidate is now entering the clinical phase to be tested on humans.

"Normally, in a phase I study you can only expect to determine the dose and examine how well humans tolerate the drug candidate. But with Lipisense, we also believe that we will be able to see treatment effects, for example on blood lipids, which generally cannot be done until a later phase. This means major de-risking for the continued development", says Stefan K. Nilsson.

Preliminary summary data are expected during the first half of 2023.

The trial is a randomized, double-blind, placebo-controlled study of single ascending doses (SAD) and multiple ascending doses (MAD).

The SAD part includes 20 healthy study participants, divided into four groups, and the primary goal is to evaluate safety and tolerability after an injection of Lipisense or placebo. Four different dose levels of Lipisense will be tested to begin with.



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The MAD part includes 24 healthy study participants. The primary goal is to evaluate safety and tolerability after four doses of Lipisense at three different dose levels or placebo. The secondary objective is to assess the triglyceride-lowering effect.

About Lipisense
The drug candidate is an RNA therapeutic that prevents the cells from producing the disease-promoting target protein ANGPTL4 by destroying the protein-coding RNA before the target protein has been formed. The target gene has a strong genetic association with plasma lipid levels and related diseases, such as type 2 diabetes and cardiovascular disease.

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About Lipigon
Lipigon develops novel therapeutics for patients with lipid metabolism disorders. The company is 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 will have the opportunity to target broader indications in the area, such as diabetes and cardiovascular disease. Lipigon's pipeline includes four active projects: the RNA-drug Lipisense for treatment of hypertriglyceridemia; an RNA-drug for treatment of acute respiratory distress syndrome; a gene therapy treatment for the rare disease lipodystrophy, together with Combigene AB (publ); and a small molecule program for the treatment of dyslipidemia in collaboration with HitGen (Inc).

The company's share (LPGO) is traded on the Nasdaq First North Growth Market. Certified Adviser is G&W Fondkommission, email: ca@gwkapital.se, phone: +46 8 503 000 50.