

Press release | Umeå 2023-07-12

Lipigon announces positive safety results and encouraging target engagement data from the Phase I Lipisense® Trial

Lipigon Pharmaceuticals AB ("Lipigon"), today announced the complete safety results from the lipid lowering investigational ANGPTL4 inhibitory drug Lipisense® Phase I trial. Throughout the treatment groups, a favorable safety and pharmacokinetic profile was observed. Analyses also revealed decreasing plasma ANGPTL4 levels with repeated doses in the multiple ascending dose (MAD) groups.

The Phase I study included 54 healthy study participants, and the primary goal was to evaluate safety and tolerability after single och multiple subcutaneous injections of Lipisense® at different dose levels or placebo. No serious adverse events have occurred, and adverse events possibly or probably related to treatment were mild resolving injection site reactions (89% of treated, 0% of placebo). In this study there were no signs for elevations of markers of toxicity in liver or kidney. In the MAD cohorts a dose dependent trend for decreased plasma ANGPTL4 protein levels was detected, clearly suggesting that Lipisense® has target engagement. Protein levels in plasma were decreased with up to 24 %, 90 days after last dose, corrected for the placebo effect. Decreasing levels compared to placebo were observed throughout the dosing period.

"This is yet a great leap forward for Lipigon and I am especially proud of our clinical team that has taken us this far. We have previously reported about the safety profile and the good tolerability of the compound in healthy volunteers. We can now conclude that Lipisense® has target engagement and decrease plasma ANGPTL4 levels," says CEO and co-founder Dr. Stefan K. Nilsson.

"This is the first drug candidate to ever target ANGPTL4 in humans, thus we did not really know what to expect. Healthy volunteers display low levels of circulating ANGPTL4 so even the most efficacious compound could have had problems showing significant treatment effects in a study with this few study subjects. We are absolutely thrilled to commence with the Phase II trial on patients with elevated plasma lipid levels that are also likely to display 5-10-fold higher levels of ANGPTL4. Before that we will also dig deeper into the Phase I material and perform in-depth lipid analyses and other advanced target related investigations. But as for now, we are really encouraged by the results announced today," Nilsson continues.





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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 22:00 CET, on 12 July 2023.

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. Lipigons 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.

