PRESS RELEASE
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Lipum Announces Successful Completion of Phase I Trial for SOL-116 - Supporting Continued Clinical Development

Lipum AB (publ) announces the completion and publication of the Clinical Study Report (CSR) for its First-in-Human (FIH) Phase I trial evaluating SOL-116. The study investigated single ascending doses (SAD) and multiple doses (MD) of SOL-116 in healthy volunteers, as well as a single dose in patients with mild rheumatoid arthritis (RA), and the findings support further clinical development for potential rheumatoid arthritis therapy.

Key Findings from the Final CSR

- **Favorable safety profile:** SOL-116 was well tolerated across all dose levels, with no serious adverse events deemed related to the investigational drug.
- **Predictable pharmacokinetics (PK):** Dose-proportional increases in exposure and an average terminal half-life of about 16–21 days support a once-monthly dosing regimen.
- **Low immunogenicity:** Anti-drug antibodies (ADA) were detected in only one participant (RA cohort), and the patient reverted to ADA-negative at the subsequent measurement.
- **Confirmed target engagement:** Exploratory results demonstrated reduced levels of bile salt-stimulated lipase (BSSL) in participants receiving SOL-116, suggesting direct on-target activity.

About the Phase I Trial

The randomized, double-blind, placebo-controlled trial included:

- Five Single Ascending Dose (SAD) cohorts of healthy volunteers receiving doses ranging from 0.075 to 6.075 mg/kg of SOL-116.
- A single dose cohort of RA patients (2.025 mg/kg) on stable methotrexate therapy.
- A cohort of healthy volunteers receiving four doses of 3.0 mg/kg at 28-day intervals.

All participants were followed for 90 days after final dosing, allowing for a robust assessment of safety and PK.

Next Steps

Results from this trial support the continued clinical development of SOL-116, including larger Phase II trials in RA. Lipum aims to further explore efficacy, refine dosing strategies, and deepen understanding of the drug's mechanism of action in patients with active, moderate to severe rheumatoid arthritis.

Comment from Lipum Management

"The completion of this First-in-Human CSR marks a significant milestone in our effort to develop a new therapeutic option for inflammatory diseases," said Peter Hovstadius, Chief Medical Officer of Lipum AB. "We are encouraged by the robust safety and PK data, as well as the low immunogenicity profile. We look forward to the next phase of clinical evaluation, focusing on efficacy and broader patient populations."

"We have now reached a key milestone, with two important pillars in place – a successful Phase I read-out and GMP manufacturing underway," said Ola Sandborgh, CEO. "I am pleased with our progress and confident as we prepare for the initiation of our Phase II study."

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About Us
Lipum AB (publ) is a clinical stage biopharmaceutical company specialized in discovery and development of a novel treatment for chronic inflammatory diseases. The lead candidate SOL-116 is a humanized antibody designed to provide efficacious therapy by blocking a previously overlooked target molecule of the immune system (BSSL). SOL-116 is in clinical stage supported by solid data for rheumatoid arthritis. Lipum also explores other inflammatory diseases with a high unmet medical need. The company is based in Umeå, an excellent life science cluster in Sweden. Lipum's unique approach has attracted international attention, including a major European Commission Horizon 2020 grant. The company's share (LIPUM) is traded on the Nasdaq First North Growth Market. Certified Adviser is G&W Fondkommission.

This information is information that Lipum 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 2025-04-11 11:28 CEST.

Attachments
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