PRESS RELEASE
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LIPUM REPORTS FURTHER PROGRESS WHERE THE MULTIPLE DOSE PART OF THE PHASE I CLINICAL STUDY IS COMPLETED

Lipum AB (publ) announces that the multiple dose part of the phase I clinical study is completed. Eight healthy subjects have received four doses 28 days apart of SOL-116 or placebo with 90 days follow up period after last dose.

The drug candidate SOL-116 evaluated in the clinical study is a humanised antibody that shall provide safer and more effective treatment of inflammatory diseases by blocking a previously overlooked target protein Bile Salt-Stimulated Lipase (BSSL) in the immune system.

The study is a double-blind, randomised and placebo-controlled first in human study of SOL-116 evaluating safety, pharmacokinetics and exploratory endpoints including circulating levels of free BSSL and inflammatory biomarkers. It is performed in the Netherlands and is divided in three parts: a single dose escalation part (SAD) with 40 healthy subjects divided in five groups, one multiple-dose group in eight healthy subjects and a single dose group of eight patients with rheumatoid arthritis (RA). Two out of three parts are now completed and recruitment of patients with RA is ongoing.

Interim analysis of the multiple dose part show that subjects had few adverse events and there was no serious adverse event in subjects administered SOL-116. No subject was found to have anti-drug antibodies (ADAs) during the entire study. The pharmacokinetic (PK) parameters of the multiple dose part were in accordance with those from the single dose part with a half-life of about 20 days. The exposure (AUC) and maximum serum concentration observed during the last dose were in line with predictions made in the protocol, thus confirming robust and predictable PK.

“This provides valuable data which strongly supports the continued clinical development of SOL-116 when we move on preparing for the planned proof of concept study. The finding that no subject developed ADAs is very encouraging”, says Ola Sandborgh, CEO of Lipum.

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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.

Attachments
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