PRESS RELEASE
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Lipum reports positive interim results from clinical phase 1 study showing that SOL-116 reduces plasma BSSL levels in healthy subjects

Lipum AB (publ) announces that the first part of the clinical phase 1 study, where healthy subjects received a single dose of the drug candidate SOL-116, has been completed with positive results. These confirm an expected pharmacokinetic profile, consistently good safety profile and that SOL-116 interacts with its target protein BSSL (bile salt-stimulated lipase).

The drug candidate SOL-116 is a humanized antibody that shall provide safer and more effective treatment of inflammatory diseases by blocking a previously overlooked target protein (BSSL) in the immune system.

The study is a double-blind, randomized and placebo-controlled first in human study in three parts and includes in total 48 healthy subjects in five single-dose groups with dose escalation (SAD) and one multiple-dose group (MD). In addition to these, a group of eight patients with rheumatoid arthritis will be included in the study during the spring.

In summary, the results of the first part of the phase 1 study (SAD) show that SOL-116 is well tolerated with few and no serious side effects observed in the subjects at the different dose levels. No subject was found to have anti-drug antibodies (immunogenicity) after dosing. The results show an expected and preferred pharmacokinetic profile with SOL-116 being well absorbed in the body and having a half-life of 20 days. SOL-116 reduces the amount of the target protein BSSL in plasma to undetectable levels from day 3 after administration, which was maintained until day 90 post-dose. The results suggest that SOL-116 is a potent BSSL-binding antibody that can effectively eliminate freely circulating BSSL in humans after a single dose of SOL-116.

The multiple-dose part of the study (MD) commenced in September and all healthy subjects have received their planned four doses of SOL-116 and are now being followed-up.

The phase 1 study is conducted in the Netherlands.

"It is exciting to see the positive interim results from the phase 1 study. This is a very important milestone for Lipum. Data generated on safety, pharmacokinetics, and SOL-116's interaction with the target protein BSSL confirm our expectations and provide important knowledge for the design of a phase 2 program. We really look forward to the next steps in the clinical development of SOL-116", 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.

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 2024-01-29 18:30 CET.

Attachments
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