

# Lipum reports that the last patient has been enrolled in the ongoing phase 1 study with SOL-116

Lipum AB (publ) announces that the eighth and thus final patient with rheumatoid arthritis (RA) has been recruited and dosed with SOL-116 or placebo in the ongoing clinical phase 1 study.

The drug candidate SOL-116 is a humanized antibody that will 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, randomized and placebo-controlled First In Human (FIH) study of SOL-116 evaluating safety, pharmacokinetics and exploratory endpoints including plasma BSSL and inflammatory biomarkers. It is conducted in the Netherlands and is divided into three parts: a dose escalation (SAD) part with 40 healthy subjects divided into five groups, a multi-dose group (MD) with eight healthy subjects, and a single-dose group consisting of eight patients with rheumatoid arthritis (RA). Two out of three parts have already been completed and now 90 days remain to follow up the patients in the final part.

Lipum has previously reported positive interim data from the first two parts of the Phase 1 study (SAD and MD) showing that SOL-116 was well tolerated with few, and no serious adverse events in the subjects at the different dose levels. The results showed an expected pharmacokinetic profile where SOL-116 is well absorbed in the body and has a half-life of 20 days. Additional interim data from the SAD part showed that SOL-116 in healthy subjects reduced the amount of the target protein BSSL in plasma to undetectable levels from day 3 post-administration, which was maintained until day 90 post-dose. Data from the MD part also showed that no subject was shown to have anti-drug antibodies (ADA, immunogenicity) during the entire study period.

"It is very satisfying that all healthy subjects and patients are now included in the phase 1 study. It is an important milestone and I look forward to the final report that will provide us with valuable information for the next step in clinical development," says Lipum's CEO Ola Sandborgh.

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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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