PRESS RELEASE
25 February 2025 10:07:00 CET

Lipum has successfully completed the phase I study with SOL-116

Lipum AB (publ) announces the completion of its phase I clinical trial (LPM-116-001) evaluating SOL-116, with positive results. The study confirmed SOL-116's favourable safety, tolerability, and predictable pharmacokinetics, supporting a once-monthly dosing regimen. Furthermore, exploratory analyses confirmed that SOL-116 effectively suppressed BSSL in both healthy volunteers and rheumatoid arthritis (RA) patients.

These findings mark a key milestone in the development of SOL-116 as a potential treatment for inflammatory diseases with a novel mode of action.

These are top-line results, and a full Clinical Study Report is expected to be available by the end of March 2025.

Study Overview

The study, conducted in the Netherlands, was a randomized, double-blind, placebo-controlled First-In-Human (FIH) trial consisting of three parts:

- Single ascending dose (SAD): 40 healthy volunteers in five dose groups
- Multiple-dose (MD) cohort: Eight healthy volunteers
- Single-dose in RA patients: Eight patients with rheumatoid arthritis (RA)

Objectives

- **Primary:** Assess the safety and tolerability of single and multiple subcutaneous (SC) doses of SOL-116 in healthy volunteers and single-dose administration in RA patients.
- **Secondary:** Evaluate pharmacokinetics (PK) and immunogenicity across all dosing regimens.
- **Exploratory:** Measure the impact of SOL-116 on BSSL (bile salt-stimulated lipase) concentrations in blood in single and multiple subcutaneous (SC) doses of SOL-116 in healthy volunteers, and single-dose administration in RA patients.

Key top-line results:

- **Baseline characteristics:** Total number of subjects: 56 (SOL-116: 42, Placebo: 14), Age range: 20-69 years, 41% of the subjects were women. All RA patients met the 2010 ACR/EULAR classification criteria for RA and had mild disease. They were well-controlled on methotrexate for at least 12 weeks prior to treatment start and remained so until the end of the study.
- **Safety and tolerability:** SOL-116 was well tolerated at all dose levels tested. No Treatment-Emergent Serious Adverse Events (TESAE) were observed in subjects who received SOL-116.

- There were no apparent differences between active and placebo in Treatment-Emergent Adverse Events (TEAEs). All but two TEAEs in subjects administered SOL-116 were classified as mild, the remaining two were reported as moderate. There were no clinically significant abnormalities noted on laboratory tests, vital signs, ECG, physical examinations or telemetry assessments.
- **Immunogenicity:** Anti-drug antibodies (ADA) were detected in only one of 336 post-dose samples from 56 subjects. This occurred in an RA patient treated with SOL-116 on Day 49, but the subject tested negative at the next timepoint (Day 90).
- **Pharmacokinetics:** The PK analysis showed favourable results that support the possibility of a monthly dosing. SOL-116 had a half-life of approximately 20 days and median Tmax values ranging from 5.1 to 7.2 days across different dose levels. SOL-116 systemic exposures as well as peak exposures (Cmax) demonstrated a dose-proportional increase across the single SC injection dose range of 0.075 to 6.075 mg/kg in healthy subjects.
    - PK profiles were comparable between healthy subjects and RA patients after a subcutaneous injection of 2.025 mg/kg.
    - In the multiple dose cohort, SOL-116 reached close to steady state by approximately Day 85 (pre-dose of the fourth SC injection), indicating a predictable PK profile with low accumulation.
- **Exploratory analysis confirmed BSSL suppression.**
  Healthy volunteers: A single dose eliminated BSSL from Day 4 to 90. Multiple doses prolonged the effect of SOL-116 from Day 29 to 169, except for one case on Day 95.
  RA patients: 50% had detectable BSSL at baseline, but all showed absent BSSL levels from Day 22 to 90, except one outlier.

The next step in development

Following the successful completion of the phase I study, further analysis of the complete dataset, including exploratory endpoints such as inflammatory biomarkers, will be conducted to support the continued clinical development of SOL-116. In parallel, discussions with regulatory authorities and stakeholders will be initiated to prepare for the next clinical trial.

"*We are very pleased with the results from our phase 1 study, which confirm that SOL-116 has a favourable safety and pharmacokinetic profile in both healthy subjects and patients with RA*," said Dr. Peter Hovstadius, MD, PhD, Chief Medical Officer at Lipum. "*These results support the continued development of SOL-116, and we look forward to advancing to the next clinical phase*."

"*It is gratifying to take part of the positive results from the phase 1 study. This is a very significant milestone for Lipum. Data on safety, pharmacokinetics and SOL-116's interaction with the target protein BSSL confirms our expectations. I am really looking forward to the next step in the clinical development of SOL-116*", says Ola Sandborgh, CEO of Lipum.

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Ola Sandborgh and Peter Hovstadius will comment on the study results during the presentation of the Q4 Interim Report and Year-End Report 2024 in a **live webcast on 26 February 2025, 9 am CET** (in Swedish only).

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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 2025-02-25 10:07 CET.

Attachments
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