

Lipidor announces today negative results from the company's Phase III clinical study of AKP02G2 for psoriasis

STOCKHOLM, Sweden, 24th May 2025 – (Nasdaq First North: LIPI) reports negative results from a Phase III clinical study of the AKP02G2 cutaneous spray for mild to moderate plaque psoriasis. The study, including 294 randomized patients, did not achieve its primary treatment objective of demonstrating at least equivalent therapeutic effect (“non-inferiority”) in the treatment of psoriasis compared to the reference product, measured as reduction in PASI score (Psoriasis Area and Severity Index).

The main purpose of the study was to compare the therapeutic effect of AKP02G2 for mild to moderate psoriasis with the market-leading product Enstilar, with the intention to provide a basis for a marketing authorization in Europe as a first step. However, the results show that the goal is not achieved.

The study was conducted by Clianza Research, a well-renowned CRO (Clinical Research Organization) with solid experience in dermatological research.

The Phase III study of AKP02G2 is a multicenter, randomized, blinded and placebo-controlled clinical study in which 294 patients were treated at 15 different clinics in India. The study compared AKP02G2 with Enstilar cutaneous foam (Leo Pharma) and with placebo, in patients with mild to moderate plaque psoriasis.

The primary evaluation of effect was based on the percentage change in PASI score from baseline to the end of treatment. PASI (Psoriasis Area and Severity Index) is an established scale providing an overall assessment of the severity of psoriasis symptoms by combining scores for redness, plaque thickness and scaling, in relation to the affected body surface area.

The study design included 4 weeks of treatment, 3 mg/cm² dosage once daily, men and non-pregnant women, three groups of which 126 patients were in the AKP02G2 group, 126 patients in the Enstilar group and 42 in the placebo group. Inclusion criteria at baseline included, among others, mild to moderate plaque psoriasis, stable for six months, with Psoriasis Area and Severity Index (PASI) up to 10, with 5–10% of skin area on arms, legs, trunk and scalp affected. Evaluations were performed at randomization, week 2, and week 4 (end of treatment), and at a follow-up visit in week 6.

The average change in PASI was -47% for AKP02G2, -3% for placebo and -63% for Enstilar after four weeks of treatment. The primary statistical analysis shows that AKP02G2 is superior to placebo but did not achieve a non-inferiority compared to Enstilar.

The frequency of adverse events was low in all groups. No serious adverse events were reported.

Lipidor's continued business plan assumed good results in the clinical study and the board is now being convened for dialogue about the impact of the results on the company's future.

Publication

The information was provided by Lipidor's CEO for publication on 24th May at 12.40 pm (CEST).

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About Lipidor AB

Lipidor AB (Nasdaq First North Growth Market: LIPI) (www.lipidor.se) is a pharmaceutical development company with a pipeline of pharmaceutical development projects in preclinical and clinical phases. The company can develop topical medical products for the treatment of diseases such as psoriasis, acne vulgaris, bacterial skin infections and atopic dermatitis by reformulation of proven pharmaceutical substances. Lipidor's priority project is AKP02G2, which focusses on psoriasis.

This information is information that Lipidor AB 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 2025-05-24 12:40 CEST.

Attachments

[Lipidor announces today negative results from the company's Phase III clinical study of AKP02G2 for psoriasis](#)