



Stockholm, 24 January 2020

**PRESS RELEASE**

## **Lipidor announces positive topline results of AKP01 Phase III clinical study using calcipotriol spray against psoriasis**

**Lipidor AB (Nasdaq First North: LIPI)** today reports positive topline results of its AKP01 Phase III clinical study, using calcipotriol spray against mild to moderate plaque psoriasis. The randomised 277-patient study achieved its primary endpoint demonstrating therapeutic equivalence to comparator measured as reduction of PASI score. Both Lipidor's AKP01 and the comparator had a statistically significantly better efficacy compared to the placebo.

Lipidor has developed a sprayable calcipotriol product, Calcipotriol/AKVANO 50 µg/g cutaneous solution (AKP01), formulated with the company's patented lipid-based AKVANO® technology which provides more precise dosing and increased patient comfort.

"Lipidor's ambition with the AKP01 project is to use our lipid-based technology AKVANO® to improve the quality of life for patients with psoriasis. We're pleased and proud of these very positive results, and will now intensify discussions with partners to determine the best way forward," says Lipidor's CEO, Ola Holmlund.

Holmlund adds: "For Lipidor, these positive study results mean a validation of our platform technology, and with this we can accelerate the pace of development in several other areas."

The AKP01 Phase III clinical study is a multicenter, randomized, observer-blind and placebo-controlled clinical study with 277 patients treated at 14 clinics across India. The purpose of the study was to evaluate the efficacy and safety of AKP01. The study compared the therapeutic equivalence of AKP01 against Calcipotriol ointment 50 micrograms/g (Sandoz) and against placebo, in patients with mild to moderate plaque psoriasis.

The study design consisted of 8 weeks treatment, applied twice daily, 3 mg/cm<sup>2</sup> dosing, males and non-pregnant females, three arms with 119 patients in the AKP01 group, 119 patients in the Calcipotriol ointment group and 39 in the placebo group. Baseline inclusion criteria were mild to moderate plaque type of psoriasis, stable for six months, with Psoriasis Area and Severity Index (PASI) greater than 5, involving 5-10% of body surface area on arms, legs and trunk. Assessments were made at baseline, week 2, 4 and 8.

PASI is a well-established scale (0-72) that gives an overall assessment of the severity of the psoriasis symptoms by combining scores for redness, plaque thickness and scaling of the lesions, taking into account the body surface area affected.

The primary endpoint was percentage change in PASI from baseline to the end of completed treatment. Therapeutic equivalence to comparator was measured by comparing the 95 % confidence interval with the equivalence interval of -10, 10%.



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Topline results of the analysis of the study demonstrated therapeutic equivalence to comparator in reducing psoriasis symptoms according to the PASI scale.

AKP01 was well tolerated through 8 weeks of study drug administration. The incidence of adverse events was low in all treatment groups. All adverse events were mild or moderate, with no serious adverse events reported. Evaluation of secondary endpoints as well as more detailed analysis of the study results will now be started.

The study was conducted in collaboration with Cerbios-Pharma SA, specialized in the development and manufacturing of chemical and biological APIs, and Cadila Pharmaceuticals Ltd of India, which is responsible for the study.

Psoriasis is a chronic disease in which the immune system plays a central part. The disease affects between 2 and 3 percent of the world's population.

### **Information**

*This information above was provided by Lipidor according to EU Market Abuse Regulations. The information was provided, through the below contact person, for publication on 24 January 2020 at 3.20 pm (CET).*

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### **About Lipidor AB**

Lipidor AB (<http://www.lipidor.se>) is a Swedish, Stockholm-based research and development company with a pipeline of pharmaceutical development projects in preclinical and clinical phases. The Company develops topical medical products for the treatment of diseases such as psoriasis, bacterial skin infections and atopic dermatitis by reformulation of proven pharmaceutical substances.