



**PRESS RELEASE**

## **Lipidor Announces Enrolment of First Patients in a Phase III Study on AKP02 for Treatment of Psoriasis**

**STOCKHOLM, Sweden, 26<sup>th</sup> January 2022** – Lipidor AB (publ) (Nasdaq First North Growth Market: LIPI) today reports that the first patients have been enrolled in a Phase III clinical study using AKP02 cutaneous spray (calcipotriol + betamethasone dipropionate 0.005 %/0.05 %) against mild to moderate psoriasis. Results from the study are expected to be presented in Q2 2022.

The observer-blind and placebo-controlled Phase III clinical study with AKP02 comprises a total of 294 patients and is being conducted at 13 clinics in India. The trial is fully funded with existing funds and is conducted by Cadila Pharmaceuticals. Cadila Pharmaceuticals has demonstrated through the successful Phase III study with the predecessor AKP01 that they can effectively recruit patients, administer a clinical trial, and report clinical study results. The aim with AKP02 is to offer a patient-friendly, spray-based treatment for mild to moderate psoriasis.

The drug candidate AKP02 combines calcipotriol and betamethasone and is based on Lipidor's patented AKVANO<sup>®</sup> technology. Positive results from the Phase III study with the drug candidate AKP01, based solely on calcipotriol, show that Lipidor's AKVANO<sup>®</sup> technology is well suited for drugs intended for the treatment of psoriasis, and preclinical studies carried out by Lipidor on AKP02 also show promising results.

The purpose of the Phase III study is to demonstrate good therapeutic efficacy for the treatment of mild to moderate psoriasis on both the body and scalp. Lipidor has chosen to compare the sprayable drug candidate AKP02 with Enstilar which is a commonly prescribed preparation in foam form for topical treatment of this indication, and which contains the same combination of active substances as AKP02.

Most psoriasis patients experience involvement on the scalp and therefore treatment on the scalp is also included in the study. This is expected to result in more efficient recruitment for the study. The study will also measure quality of life and patient satisfaction to demonstrate associated benefits of AKP02.

The first two of the planned 294 patients are now included into the Phase III clinical study.

Lipidor and the company's commercial partner RELIFE, part of the Menarini Group, are collaborating to make available the two topical drug candidates, AKP01 and AKP02, for the treatment of mild to moderate psoriasis. Aurena Laboratories, one of the company's two large industrial owners, will be responsible for the commercial production of the products.

"It's gratifying that the study has started and that the clinics are ready to include patients. We are looking forward to presenting high level study results in Q2 2022. In time, we hope that our work will lead to new user-friendly, spray-based treatments that offer patient-relevant benefits in the treatment of psoriasis," says Ola Holmlund, CEO of Lipidor.

Considering the outbreak of the coronavirus and Covid-19, Lipidor is closely monitoring developments and taking measures to minimize or eliminate the impact on the company's operations. To date, the Covid-19 pandemic has had limited effect on Lipidor's operations, but the company may need to revise its schedules if national conditions affect the execution of the above study.

**Information**



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The information was provided for publication through the office of Lipidor's CEO on 26<sup>th</sup> January 2022 at 2.30pm (CET).

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### **About AKVANO®**

AKVANO® is an innovative water-free and sprayable technology for the formulation of drugs and is particularly suitable for local application to, for example, the skin. AKVANO® is made up of carefully selected lipids which, together with a volatile solvent, constitute carriers of selected active substances. By combining different lipids, AKVANO® can be optimized to achieve the desired function of active components in the formulation. When applied to the skin, the solvent evaporates, and a thin lipid layer is formed on the skin surface for effective release of the active substance.

### **About psoriasis**

Psoriasis is a common, hereditary, chronic, non-contagious skin disease with no clear cause or cure. The negative impact of the disease on people's lives can be enormous. Psoriasis affects people of all ages and countries. In Sweden, it is estimated that approximately 250,000 to 300,000 individuals have psoriasis. Commonly reported prevalence of psoriasis ranges from 1% to 5%, making psoriasis a serious global problem with at least 100 million individuals affected worldwide. The disease can occur at any age and is most common in the 50-69 age group. Psoriasis has an unpredictable course of symptoms, a number of external triggering causes and significant comorbidity such as arthritis, cardiovascular diseases, metabolic syndrome, inflammatory bowel disease and depression.

### **About Lipidor**

Lipidor AB ([www.lipidor.se](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, acne vulgaris, bacterial skin infections and atopic dermatitis by reformulation of proven pharmaceutical substances.