



PRESS RELEASE

Lipidor announces approval to start Phase III clinical study of drug candidate AKP02 for treatment of psoriasis

STOCKHOLM, Sweden, September 27, 2021: Lipidor AB (publ) (Nasdaq First North Growth Market: LIPI) announced today that the company's Phase III clinical study of its drug candidate AKP02 for the treatment of psoriasis has been approved by the Indian Medical Products Agency and is ready to start. The main purpose of the study is to compare the therapeutic efficacy of AKP02 with Enstilar, the current market leader, for mild to moderate psoriasis. As Lipidor previously announced, results from the study are expected in the first half of 2022.

The registration-based Phase III clinical study with AKP02 comprises a total of 294 patients and is being conducted at twelve clinics in India. The trial is fully funded with existing cash and is conducted by Cadila Pharmaceuticals, a leading Indian pharmaceutical company with extensive CRO capacity. 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[®] technology. Positive results from the Phase III study with the drug candidate AKP01, based solely on calcipotriol, show that Lipidor's AKVANO[®] technology works well for the treatment of psoriasis. The preclinical studies carried out by Lipidor also show that betamethasone works well with AKVANO[®] – a positive requirement for the second drug candidate, which combines calcipotriol and betamethasone.

The purpose of the Phase III study with AKP02 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. In order to reach a larger patient population, the scalp has also been included in the study. Psoriasis on the scalp, which often is affected, can consist of anything from weak to severe scale formation and cause varying degrees of itching.

The study will also measure quality of life and patient satisfaction in order to demonstrate associated benefits of AKP02. The observer-blind and placebo-controlled Phase III study is expected to have the first patient in-treatment during this fall with reporting in the first half of 2022.

On [July 1, 2021](#) Lipidor announced that the company had signed a license agreement under which Lipidor grants RELIFE S.r.l., part of leading international pharmaceutical company, Menarini Group, exclusive rights to register, promote, distribute, and market the drug candidates AKP01 and AKP02 for the treatment of psoriasis in EU, Turkey, UK, Switzerland, CIS, and Balkan countries. Lipidor and RELIFE collaborate to make the two topical drug candidates available for the treatment of mild to moderate psoriasis.

Lipidor's partner Aurena Laboratories, one of the company's two large industrial owners, will be responsible for the commercial production of the products.



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"We have high hopes for a successful Phase III clinical study with the psoriasis candidate AKP02 and we are looking forward to the study results," says Ola Holmlund, CEO of Lipidor. "We are pleased to have recently signed an exclusive license agreement with RELIFE, a company in the Menarini Group which has a strong European and global presence. Altogether, this strengthens our quest to make these innovative new drug candidates AKP01 and AKP02 available to psoriasis patients in the hope that they may improve the treatment of their condition and their quality of life."

In light of 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 a limited effect on Lipidor's operations, but the company may need to revise its schedules if the pandemic is prolonged.

This disclosure contains information that Lipidor AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on September 27, 2021 10:55 CET.

For more information, please contact:

Ola Holmlund, CEO
Telephone: +46 (0)72 50 70 369
Email: ola.holmlund@lipidor.se

Certified Adviser

Erik Penser Bank AB
Telephone: +46 (0)8 463 80 00
E-mail: certifiedadviser@penser.se

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 (publ) (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.