



PRESS RELEASE

Lipidor – update on the company’s phase III clinical trial of drug candidate AKP02 for treatment of psoriasis

Stockholm, Sweden, 22 April 2021 – Lipidor AB (publ) (Nasdaq First North: LIPI) today provides an update on the planned Phase III study of the company's drug candidate AKP02 for the treatment of psoriasis. During the first quarter of 2021, Lipidor submitted an application to the Indian Medical Products Agency for commencement of the Phase III study. As Lipidor has previously announced, the main purpose of the study is to compare the therapeutic efficacy of AKP02 with existing medicines for mild to moderate psoriasis. Results from the study are expected in the first half of 2022.

AKP02 is a drug candidate for psoriasis that combines calcipotriol and betamethasone and is based on Lipidor's patented AKVANO® technology. The aim with AKP02 is to offer a patient-friendly, spray-based treatment for mild to moderate plaque psoriasis.

Positive results from the Phase III study with its predecessor AKP01, based solely on calcipotriol, show that Lipidor's AKVANO® technology works well for the treatment of psoriasis. The company's preclinical studies show that betamethasone also works well in AKVANO®, which is a good prerequisite for the combination preparation AKP02.

The registration-based Phase III study with AKP02 is planned to involve 294 patients and is being conducted at circa ten clinics in India by Cadila Pharmaceuticals, a leading Indian pharmaceutical company with extensive CRO capacity. Cadila Pharmaceuticals has demonstrated through the successful Phase III study with AKP01 that they can effectively recruit patients, administer dosage and report clinical study results.

The purpose of the Phase III study with AKP02 is to demonstrate good therapeutic efficacy for the treatment of mild to moderate plaque psoriasis on both the body and scalp, compared to Enstilar. Lipidor has chosen to compare its 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 can consist of anything from weak to severe scale formation and cause varying degrees of itching. According to the Swedish Psoriasis Association, it is estimated that circa 60-70 percent of people who have psoriasis also get it on their scalp. In some cases, psoriasis is found only on the scalp.

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 the summer with reporting in the first half of 2022.

"The experience from AKP01 means that we also have high hopes for a successful study with our other psoriasis candidate, AKP02. It is gratifying that the market has shown a great interest in AKP02, and by financing the implementation of the Phase III study, Lipidor retains a larger upside of any outlicensing," says Ola Holmlund, CEO of Lipidor. "We continue to see great potential in our first drug candidate AKP01 and we consider the opportunity to outlicense AKP01 and AKP02 in a single package to be an advantage for the licensee in registration, manufacture and commercialization."

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



PRESS RELEASE

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.

The information was submitted for publication, through the office of the contact person, on 22 April 2021, at 9.30am CEST.

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. The reported incidence of psoriasis in all countries ranges from 0.09% to 11.43%, making psoriasis a serious global problem with at least 100 million individuals affected worldwide. Skin 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, ethnic diseases, inflammatory bowel disease and depression. Sources: Swedish Psoriasis Association, WHO Global Report on Psoriasis 2016.

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.