



Stockholm, 7 May 2020

**PRESS RELEASE**

## **Lipidor presents updated project plan – initiates Phase III study of AKP02 in-house**

In light of the company's successful Phase III study of calcipotriol spray (AKP01) against mild to moderate plaque psoriasis and subsequent discussions with pharmaceutical companies, the Board of Lipidor submits an updated project plan together with prioritization of the company's project portfolio.

In January 2020, Lipidor announced positive results from the completed Phase III study of calcipotriol spray (AKP01) against mild to moderate plaque psoriasis. Discussions with medium and large pharmaceutical companies regarding the licensing, marketing and sale of a product based on AKP01 have been conducted with generally positive feedback and also clear guidance for the company's prioritization going forward (see below).

AKP01 is a so-called "monoproduct", defined by the active substance calcipotriol formulated with Lipidor's unique and patented AKVANO® technology. AKP01 is designed to provide an improved version ("supergeneric") of the market-leading product Daivonex®. AKP02, developed for the treatment of the same medical condition (mild to moderate psoriasis), is defined by a combination of two active substances (calcipotriol and betamethasone) formulated in AKVANO®. The market potential of this "combo product" is estimated to be around 3 times greater (USD 580m in 2017\*) than that of the monoproduct and also showing significantly higher growth numbers.

\*Data from Datamonitor

### **AKP02 Phase III to be carried out in-house**

Lipidor previously announced the intention to conduct a Phase III study of the combo product (AKP02) in collaboration with a licensee. In light of the positive response to the reported Phase III study of AKP01 in particular, and AKVANO technology in general, Lipidor's Board of Directors has decided to carry out this study on its own, fully-funded by available liquid funds and with a planned start of study at the end of 2020/2021. The Board is of the opinion that AKP02 has excellent prospects for taking significant market share in a large and growing market. With data from a self-financed Phase III study, a large portion of risk is eliminated from the project, implying a significantly higher value for out-licensing at the next stage.

AKP01 continues to be an interesting out-licensing project and partner talks to date have indicated a clear interest in licensing AKP02 in combination with AKP01, with the aim of maximizing penetration of both products in the market. It is also the Board's opinion and the company's objective that commercial agreements regarding a combination license for AKP01 and AKP02 will be concluded within the next 12 months, which would provide further clarity on the products' path to market and future revenue potential for Lipidor.

A general timetable for the planned Phase III study would be as follows:

- Q2 2020 – Agreement on start of study
- Q3 2020 – Manufacture of clinical trial material
- Q1 2021 – First patient in
- Q1 2022 – Results of study



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### **Updates concerning AKP03 and AKP07**

With the listing of Lipidor's share on Nasdaq First North Growth Market in October 2019, the company announced its aim of entering into a partnership regarding Lipidor's project AKP03, with the active pharmaceutical component of fusidic acid. Lipidor has discussed the project with several potential licensees without being able to conclude an agreement before the outbreak of Covid-19. It remains Lipidor's ambition to identify and enter into a partnership for the project without conducting further clinical studies.

Also in connection with the October 2019 listing, the company announced its objective of initiating a Phase II study of AKP07 (Tacrolimus) for the treatment of atopic dermatitis in the first half of 2020. The project continues according to plan in many aspects, with a focus on formulation optimization and product stability. However, in the light of the reprioritisation made in AKP02, the liquid funds that need to be allocated to the planned Phase III study and minor delays based on the Covid-19 outbreak the timetable for the start of the planned Phase II study for AKP07 is being shifted. The company will return with an updated timetable for the project.

### **Upcoming projects - collaboration with Cannasure plus OTC products in collaboration with Aurena**

In addition to the above projects, Lipidor initiated two strategic partnerships during Q4 2019 and Q1 2020.

In December 2019, Lipidor announced that it had entered into an agreement with the Israeli company Cannasure for a feasibility study with a licensing option, for the development and sale of topical medicinal cannabis products. The project is proceeding according to plan with the aim of being evaluated in Q3 2020.

In the first months of the year, Lipidor has also deepened its cooperation with Aurena Laboratories AB, which is also one of the company's largest shareholders. This latest initiative was prompted by the need for new disinfectant products in the wake of the Covid-19 pandemic. A first product has been launched and is now available for purchase on the Swedish market, while talks are taking place with additional retailers internationally. Discussions are being held with Aurena Laboratories AB about further potential products aimed directly at consumers (so-called "OTC" products). It is the ambition of the companies to return with updates on these discussions later in the year.

### **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 7 May 2020.*

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**About Lipidor AB**

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, bacterial skin infections and atopic dermatitis by reformulation of proven pharmaceutical substances.