

Lipidor, Cadila to conduct Ph III study of anti-psoriasis candidate

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Swedish firm Lipidor AB has announced an agreement with Cadila Pharmaceuticals, a leading Indian pharmaceutical company with extensive CRO capacity, to conduct a Phase III study for Lipidor's drug candidate AKP-02. The study is expected to commence in Q1 2021 with final reporting in Q1 2022.

AKP-02 is an antipsoriasis medicine that combines the active substances calcipotriol and betamethasone with Lipidor's spray-based AKVANO technology. The market for "combo products" reached USD \$580 million per year in 2017*, and Lipidor expects to be able to claim a significant market share when the drug reaches the market. Lipidor has previously announced the intention to conduct a fully self-funded Phase III study with the drug candidate AKP-02 in 2020 (see previous press release of 7 May 2020). An agreement has now been concluded with Cadila Pharmaceuticals for the implementation of the study.

"We're very pleased to announce that we have entered into an agreement to carry out a registration-based Phase III study for AKP-02, Lipidor's combination drug candidate against psoriasis. Through the successful Phase III study for AKP-01, Cadila has shown that they can effectively recruit patients, administer dosing and report clinical study results. The experience of AKP-01 means that we have high hopes for effective cooperation and a successful study", says Ola Holmlund, Lipidor CEO.

The Phase III study is expected to involve 270 patients and will be conducted in India on patients with various skin types. The intention is to demonstrate equivalent therapeutic efficacy with existing medicines for mild to moderate psoriasis. The observer-blind and placebo-controlled trial is expected to be completed in Q4 2021 with reporting in Q1 2022. Lipidor has already collaborated with Cadila regarding the drug candidate AKP-01 and this new agreement now strengthens that cooperation.

"The market has shown great interest in AKP-02 and by self-funding the implementation of the Phase III study, we will maximize the benefits of later out-licensing. We continue to see great potential in our first drug candidate AKP-01, and the

opportunity to now discuss AKP-01 and AKP-02 in a package makes us an even more attractive partner for pharmaceutical companies that can take our products through registration for sale," concludes Ola Holmlund.

The cost of the Phase III study is covered by Lipidor's existing funds. Discussions with clinical trial material manufacturers are ongoing and an agreement is expected to be in place in Q3 2020.