

Lipidor updates on development of AKP02

STOCKHOLM, Sweden, 26th May 2023 – Lipidor AB (publ) (Nasdaq First North Growth Market: LIPI) is targeting a new Phase III study of the drug candidate AKP02 in 2024. Data from the earlier completed clinical study with AKP02 has been analyzed, and a way forward is clear.

On 28th October 2022, Lipidor announced that the combination product AKP02 for the treatment of psoriasis did not fully meet the Phase III study's primary endpoint of non-inferiority compared to the reference product. The study compared AKP02 with Enstilar, the market-leading product for topical treatment of mild to moderate psoriasis. The products contain the same active ingredients, calcipotriol and betamethasone dipropionate.

Work on the formulation

AKP02 was very close to achieving equivalent therapeutic efficacy with the reference product. An in-depth analysis, examining why the compared preparations differed in efficacy, has produced an explanatory model that is now undergoing a verification program. The model is based on the interaction of the formulation with the different skin layers, and how this affects the deposition and efficacy of the active substances.

An updated AKP02 formulation with optimized properties is now being externally verified, together with a number of reference formulations. The partial results extracted so far in the preclinical work clearly indicate that the proposed corrections provide the desired effect.

Work continues to provide further support for the change in formulation and thus increase the chances of success in a new study.

"The AKVANO® technology has been developed to provide a flexible platform that can be adapted to the needs of the specific application," says Jan Holmbäck, CSO of Lipidor. "At the same time, we can maintain the basic advantages of the formulations such as solubility, sprayability, no need to touch, and quick drying. The experiments of the last few months have strengthened our confidence in the potential of the technology and also given us new insights."

A great need

Psoriasis is a chronic autoimmune disease that affects, among other things, the process of skin cell formation. The disease is characterized by a vigorous formation of new skin cells and can vary in severity (mild/moderate/severe). Psoriasis is one of the most common public diseases. In Sweden alone, about 300,000 people are estimated to have some form of psoriasis (Source: Psoriasis Association) and the prevalence is 2-3% globally in a market that grows by 6.5% annually.

Living with psoriasis can involve different types of challenges and Lipidor sees great opportunities to contribute to an improved everyday life for patients through AKP02, a treatment that can be delivered in spray format via Lipidor's patented AKVANO® platform.

Key milestones and timeline ahead

It is with confidence that the company is working on a plan to conduct a new Phase III study for AKP02. Already in June, a scientific advisory meeting with the Swedish Medical Products Agency will be held to confirm the continued development plan.

In parallel, commercial dialogues, procurement work, and exploratory talks on financing are ongoing. After the summer, the plan is to start a process for a larger financing round, with the goal of conducting a new Phase III study in 2024. The company is still in positive dialogues with RELIFE about the future.

Publication

The information was provided for publication by Lipidor's CEO on 26 May 2023 at 1.15pm (CEST).

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About Lipidor AB

Lipidor AB (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.

Attachments

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