

Lipidor announces approval for start of Phase III clinical trial of psoriasis candidate AKP02G2

STOCKHOLM, Sweden, 21st March 2024 – Lipidor AB (publ) (Nasdaq First North Growth Market: LIPI) today announced that the company's planned Phase III clinical trial with the drug candidate AKP02G2 for the treatment of psoriasis has been cleared to start by the Indian Medical Products Agency (DCGI). The main objective of the study is to compare the therapeutic efficacy of AKP02G2 against mild to moderate psoriasis with a market-leading product.

The application to start the clinical study was submitted to the Indian Medical Products Agency in December. After a meeting with the agency's Subject Expert Committee, the go-ahead to start the study has now been obtained.

The main objective of the study is to compare the therapeutic efficacy of AKPO2G2 in mild to moderate psoriasis with the market-leading product Enstilar, with the intention of providing a basis for market approval in Europe in the first stage. The Phase III study will include 294 patients and is to be conducted by Cliantha Research, a well-reputed CRO (Clinical Research Organisation) with extensive experience in dermatological research.

The clinical trial material in the study will be manufactured by Oy MedFiles Ltd in Finland.

Lipidor has previously signed a license agreement in which Lipidor grants RELIFE S.r.l. in Italy exclusive rights to register, market, distribute and sell AKPO2G2 for the treatment of psoriasis in Europe, the CIS countries, the Asia-Pacific region and Turkey, following a successful study.

A prerequisite for the Phase III study to be able to start according to plan is still that Lipidor will have supplementary financing in place.

"It is gratifying news that DCGI has approved the study protocol," says Vibhu Rinwa, Program Manager at Lipidor. "And that therefore we, together with Cliantha, have passed the first milestone in our project plan where the goal is study results in early 2025. The next planned milestone is the production of clinical trial material and shortly thereafter the start of the study."

Publication

The information was provided for publication by Lipidor's CEO on 21st March 2024 at 4.00pm (CET).

For more information, please contact:

Ola Holmlund, CEO

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

The company's Certified Adviser is Carnegie Investment Bank AB (publ).





About Lipidor AB

Lipidor AB (www.lipidor.se) is a pharmaceutical development company with a pipeline of pharmaceutical development projects in preclinical and clinical phases. The company can develop 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. Lipidor's priority project is AKPO2G2, which focusses on psoriasis.

About AKVANO®

AKVANO® is an innovative water-free and sprayable technology for formulating medicines and is particularly suitable for local application on, for example, the skin. AKVANO® is made up of carefully selected lipids which, together with a volatile solvent, form the carrier 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.

Attachments

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