

Lipidor – Swedish Medical Products Agency confirms clinical plan for new version of AKP02

STOCKHOLM, Sweden, 22nd June 2023 – Lipidor AB (publ) (Nasdaq First North Growth Market: LIPI) announced today that the Swedish Medical Products Agency (“MPA”) considers that AKP02G2, a modified version of the company’s drug candidate AKP02 for the treatment of psoriasis, can be used in a new Phase III clinical study. This means that no further clinical studies with AKP02G2 will be needed before a new Phase III study can be initiated.

The company has conducted a scientific advisory meeting with preclinical, clinical and quality experts at the MPA. The changes in the composition of AKP02 presented are not considered by the MPA to require further clinical studies before initiating a Phase III study.

The main purpose of the planned study is to compare the therapeutic effect of AKP02G2 for mild to moderate psoriasis with the market-leading product Enstilar, with the intention of providing a basis for a first-stage market authorization in Europe.

According to the MPA, if the study can demonstrate comparable efficacy to Enstilar after 4 weeks in this study, the results can be extrapolated so that AKP02G2, like Enstilar, can be prescribed for maintenance treatment for 52 weeks (treatment twice a week).

"We are of course very pleased with the MPA's announcement," says Ola Holmlund, Lipidor CEO. "Planning for the upcoming Phase III study with AKP02G2 is therefore entering a new phase. The announcement also means we can continue the completion of preclinical documentation and proceed directly to the new Phase III study, starting in Q2 2024."

The planning of the clinical study also includes a process for selecting the clinical trial material manufacturer (CMO) and the clinical trial organization (CRO).

Publication

The information was provided for publication by Lipidor’s CEO on 22 June 2023 at 8.30am (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.

About AKP02G2

The drug candidate AKP02G2, which is a modified version of AKP02, combines calcipotriol and betamethasone and is based on Lipidor's patented AKVANO®-technology. The purpose of a new Phase III study with AKP02 in the form of AKP02G2 is to show good therapeutic effect for the treatment of mild to moderate psoriasis on both body and scalp. Lipidor has chosen to compare the sprayable drug candidate AKP02G2 with Enstilar, which is a commonly prescribed preparation in foam form for topical treatment in this indication, and which contains the same combination of active substances as AKP02G2. To reach a larger patient population, the scalp, which is often affected, has also been included in the study. Psoriasis on the scalp can range from mild to severe scaling and cause varying degrees of itching.

About the Swedish Medical Products Agency's scientific advice

The Swedish Medical Products Agency provides scientific advice to the pharmaceutical industry and other parties, to facilitate an open dialogue concerning the development of new medicines. The advice given is non-binding, neither for the MPA nor for the company.

Attachments

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