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Coegin Pharma reports positive top-line results from the COAK study, a clinical Phase I/II trial with AVX001 in actinic keratosis

Coegin Pharma, a Nordic biotechnology company that, with unique technologies and competencies, develops novel treatments in cancer and inflammatory-driven diseases today reports positive top-line data from its COAK study — a clinical Phase I/II trial in which the safety and tolerability of AVX001 was evaluated in 60 patients with actinic keratosis. The findings demonstrated that two different doses of AVX001 (1% and 3%) are safe and well tolerated in treatment of patients with actinic keratosis. While the study was not designed to draw definite conclusions on efficacy, the findings indicate a clear tendency to efficacy and a potential for AVX001 to become a future treatment option for patients with actinic keratosis. Based on these results, additional in-depth analyses of the findings from the study are ongoing in parallel with the evaluation and planning of the continued clinical development of AVX001.

The COAK study

The COAK study was a double-blind, placebo-controlled, combined Phase I/II clinical study, which was carried out with a decentralized approach based on digital tools designed to be patient-centric. The patients were given remote guidance and support and were able to report to the hospital from home, thus reducing the number of physical visits to the hospital. The study was carried out in collaboration with Studies&Me, a CRO specializing in decentralized clinical trials.

The study included 60 patients divided into three groups treated with a cosmetically attractive gel formulation of two different doses of AVX001 (1% and 3%) and placebo, respectively. Patients self-administered the treatment once daily for four weeks. To evaluate safety and tolerability, patients were monitored eight weeks after finishing treatment. The primary objectives of the study were to evaluate safety and tolerability, and important secondary objectives were efficacy and quality of life.

Primary study objectives — safety and tolerability

The primary objective of the COAK study was to examine local skin reactions during treatment with AVX001, and the findings demonstrated that AVX001 treatment is safe and well tolerated. None of the 60 patients included in the study experienced any adverse events. Two patients out

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of 60 experienced mild to moderate local skin reactions that resolved after treatment. The majority of patients (44 out of 60) received facial treatment, and these patients did not experience any local skin reactions. The two patients who experienced transient local skin reactions were treated with 3% AVX001 on the chest.

Secondary study objective — efficacy
The design and statistical power of the COAK study do not allow any definite conclusions about efficacy. Nevertheless, the secondary endpoints indicate that 15 percent of patients treated with active doses achieved clearance (that is, a reduction in actinic keratosis lesions of more than 50 percent). Due to the low number of patients, these results are not statistically significant. In addition, 74 percent of patients treated with 3% AVX001 saw their AK lesions improve. The findings thus show a clear tendency to efficacy.

Exploratory study objectives
The COAK study evaluated a number of exploratory study endpoints, including Optical Coherence Tomography (OCT), which is a non-invasive optical imaging technology that employs low-power infrared laser light to image the skin surface. This allows the clinician to obtain real-time images of the skin's architecture without having to do a skin biopsy. OCT has proven to be a useful diagnostic tool for detecting skin cancer at an early stage. In the COAK study, OCT was used to evaluate changes in the skin over time. The analysis of these results is ongoing and is expected to be communicated separately once the analysis is completed.

Comment from Professor Merete Hædersdal, Principal Investigator of the COAK study
"We saw almost no local skin reactions in the COAK study, which shows that AVX001 is well tolerated. This is in contrast to many other existing treatments, where patients find the skin reactions difficult to tolerate. We hope that further studies with AVX001 will bring us closer to the goal: a product that shows efficacy that can be of benefit to patients.

The digitalization of both the patient recruitment and the implementation of the study made it possible for us at Bispebjerg Hospital to significantly increase capacity. The active involvement of patients by means of digital solutions was instrumental in the completion of the study in just 5 months. The collaboration with Coegin Pharma was inspiring and efficient, with scientific merit," says Merete Hædersdal, Professor at Bispebjerg Hospital in Copenhagen.

Preliminary conclusions and analysis
The COAK study findings clearly demonstrate that treatment with AVX001 is both safe and well tolerated. Thus, the study has achieved its primary objectives. Although the study was not designed to draw definite conclusions on efficacy, the secondary endpoints indicate that AVX001 has a clear tendency to efficacy and potential to become a future treatment option for patients with actinic keratosis. Further in-depth analyses of the findings from the study are ongoing, in parallel with the evaluation and preparations relating to the continued clinical development of AVX001.

CEO comments
"It is gratifying that the COAK study clearly shows AVX001 to be both safe and well tolerated, and we are pleased that we saw a clear tendency to efficacy. Most of the current treatments for actinic keratosis cause significant discomfort to patients in the form of severe local skin reactions sustained over an extended period of time. There is a clear and well-defined market for a safe and well-tolerated treatment for actinic keratosis, provided that the clinical efficacy is sufficient. We look forward to the further analyses of the findings and the evaluation and planning of the continued clinical development of AVX001 in actinic keratosis, basal cell carcinoma, or both, where the aim is to establish a product that demonstrates efficacy of benefit to patients. We plan

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to disclose more information on the remaining data as soon as the study analysis is complete," says Tore Duvold, CEO of Coegin Pharma.

This information is information that Coegin Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out below, at 2:55 p.m. CET on March 31, 2022.

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Also visit the company's website for additional information: **www.coeginpharma.com**.
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About Coegin Pharma AB
Coegin Pharma is a biotechnology company that, with unique technologies and competencies, develops pioneering treatments in cancer and inflammation. The focus is on diseases with a large unmet medical need and is based on solid research through new biological approaches with both small molecules and peptide-based drug candidates. Coegin Pharma creates value by effectively bringing innovative concepts with great therapeutic potential to clinical studies and proof-of-concept.

About AVX001
AVX001 is a cPLA$_2$α inhibitor in a gel formulation for application to the skin. Inhibition of cPLA$_2$α is predicted to have a therapeutic effect on cancer and inflammatory diseases via a new therapeutic intervention point. AVX001 is a both potent and selective inhibitor of cPLA$_2$α and has demonstrated proof-of-efficacy in multiple pre-clinical disease indications. AVX001 has also previously demonstrated clinical efficacy in psoriasis patients in an exploratory Phase Ib study. With its anti-proliferative and anti-inflammatory properties, there is a strong biological rationale for AVX001 to be a potentially effective new drug candidate for the treatment of actinic keratosis and basal cell carcinoma.

About actinic keratosis
Actinic keratosis is superficial sun damage to the outer layer of the skin, caused by excessive sun exposure during the course of life. It is the most common precursor to skin cancer, and it is estimated that approximately 60 million people in the United States alone suffer from actinic keratosis — a number that is expected to increase moving forward.

There is a great unmet need for better therapeutic options for actinical keratosis with regard to treatment effect, side effects and treatment duration. The disease is mainly treated repeatedly with cryotherapy, photodynamic therapy or topical pharmaceuticals. Cryotherapy may cause cosmetic damage to the skin and is perceived by many as painful, while photodynamic treatment is expensive and time-consuming. It is considered that a safer, more effective, shorter, and more convenient treatment would appeal to patients. Coegin Pharma's aim is to demonstrate a treatment at least as effective as existing treatments, but with reduced treatment time for the patient and fewer side effects.

About basal cell carcinoma
Basal cell carcinoma is the most common form of skin cancer and the most common of all cancers. In the United States alone, 4 million patients annually are diagnosed with basal cell carcinoma. Basal cell carcinoma manifests in many forms ranging from superficial to more invasive. Similar to actinic keratosis, the most common cause is exposure to sunlight and involves abnormal and uncontrolled cell growth.

Although basal cell carcinoma rarely develops into melanoma, it is a great inconvenience to patients as it sometimes develops into large lesions in the form of open wounds, red spots or larger spheres in the skin. Basal cell carcinoma is mainly treated with surgery, but topical drugs are also used in cases where the lesion is superficial.

About Phase I/II studies
A Phase I/II clinical trial is the first time a new treatment is given to patients. The aim of the initial clinical trials is to determine if patients tolerate the drug and whether it affects the body in the way that animal studies and other preclinical research would indicate. Although the study is not designed or statistically prepared to that end, other secondary endpoints such as efficacy, cosmetic acceptability, and quality of life are evaluated.

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