

## **Studies&Me A/S engages in a collaboration with Coegin Pharma AB to execute innovative clinical studies on novel treatments of different stages of skin cancer**

*Studies&Me has initiated a collaboration with the listed, Swedish biotech company, Coegin Pharma AB to conduct innovative clinical studies within their portfolio of novel investigational drugs. An upcoming clinical study will investigate the safety and efficacy of Coegin Pharma's topical AVX001 in the treatment of early stages of skin cancer, Actinic Keratosis (AK).*

*"AK is a common condition that could benefit from new and better treatment", says CEO of Coegin Pharma AB Tore Duvold. He elaborates "Studies&Me seeks to complete an innovative combined phase 1/2a interventional study that allows us to conduct the study safely and fast. The patient-centric approach is attractive for the patients and physicians involved, and is very much in line with our company ambitions".*

The study is led by Principal Investigator, professor Merete Hædersdal at Bispebjerg Hospital of Copenhagen, Denmark.

Studies&Me will be recruiting patients with early stages of skin cancer (AK) for topical treatment with AVX001 gel in different doses, with the purpose of investigating the safety and efficacy. The end goal is to develop a new topical treatment that satisfies the patients' needs for a safe, efficient and practical treatment of their condition. The study results are expected in 2022.

Tore Duvold is optimistic about the collaboration with Studies&Me: *"I am very enthusiastic that we have reached a point in the development of our product that hopefully will provide patients suffering from AK with a new, safer and better treatment of their condition. We have great expectations for our collaboration with Studies&Me and we truly appreciate the company's patient-centric and innovative approach to clinical studies. The concept of decentralized studies makes it easier for patients to engage and easier for the clinics to monitor the treatment, since patients are continually supported and monitored digitally at the comfort of their own homes".*

John Zibert, CEO of Studies&Me echoes Tore Duvold's enthusiasm:

*"We are pleased to have initiated this exciting, strategic cooperation with Coegin Pharma AB and we look forward to contributing with an innovative approach to Coegin Pharma's clinical study of AK. At Studies&Me we strive towards digitizing clinical trials to personalize the study experience for the participants. In a decentralized clinical trial like this one, participants monitor their condition from*

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*home via digital devices and an App developed for the specific study that is downloaded to the participants' own smartphones. The digital approach to clinical studies minimizes the number of visits at the clinic compared to the number of physical consultations in a traditional clinical study. This makes it easier to fit the study into a busy schedule and for patients to contribute to research and development of new treatments despite the restrictions of COVID-19. Our innovative approach to clinical studies fits very well with Coegin Pharma's innovative treatment of AK."*

This study is the first clinical trial to investigate AVX001 in patients with AK, and the second trial in humans to use AVX001 in a gel formulation.

*"There is no clear recommendation on current guidelines for a preferred treatment approach for AK lesions, and treatment is often decided on an individual basis with varied outcomes. As a result there is a need for new topical treatments for use in the treatment of patients with AK."*, Tore Duvold, CEO Coegin Pharma says.

[Click here to see Coegin Pharma's press release](#) about the collaboration with Studies&Me.

### **About Actinic Keratosis (AK)**

AK is a common skin condition that is caused by long-term sun exposure. AK lesions are presented as small, red, rough, scaly flat spots, which feel like patches of dry skin and are a common precursor to skin cancer.

AK is considered a chronic condition as most patients experience that the lesions return over time. AKs increase the risk of developing skin cancer since it can likely develop into Squamous Cell Carcinoma (SCC), which is a common and invasive type of skin cancer.

The occurrence of AK is caused by the skin's exposure to the ultraviolet radiation of the sun over a lifetime. The condition may occur in young adult patients, it is more common with elderly patients who have spent more time in the sun.

There is no clear recommendation on current guidelines for a preferred treatment approach for AK lesions. The condition is mainly treated with cold therapy, photodynamic therapy or topical treatment. As a result there is an unmet medical need for new treatments for use in the treatment of patients with AK.

### **About Coegin Pharma AB**

Coegin Pharma is a biotech company focusing on development of small molecule-based drug candidates for treatment of cancer. The therapeutic platform is based on selective inhibition of the key enzyme cPLA that attenuates inflammations and uncontrolled cell growth. The enzyme has

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passed through preclinical and clinical validation and is a relevant therapeutic target of a series of cancers and inflammatory diseases. The company drives the development from identifying a promising drug candidate to phase 2a clinical studies indicating a “proof of concept”. Upon proof of concept, the drug candidates are sold to international operators/pharmaceutical companies.

## About Studies&Me®

Studies&Me is a virtual contract research organisation established to set new standards for clinical research. We believe the future of treatment development is patient- and data-driven. With a legacy in pharma and health technologies, Studies&Me is working to digitize treatment development across all stages; from recruitment to trial completion.

Studies&Me was initially conceived in 2016 as a platform to facilitate online patient recruitment and qualification for clinical trials at LEO Innovation Lab, LEO Pharma's independent digital innovation unit. Since then, we have explored, tested, and validated new methods for conducting smarter, faster, and more accessible clinical trials by tapping into the unmet potential of emerging technologies and ever-expanding volumes of digital data within treatment development.

Today, Studies&Me has become an independent company and Europe's first virtual contract research organisation, specialising in delivering state of the art end-to-end solutions for conducting decentralized trials.

We collaborate with partners across the globe to advance human health and achieve our mission:

## To personalize treatment development

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