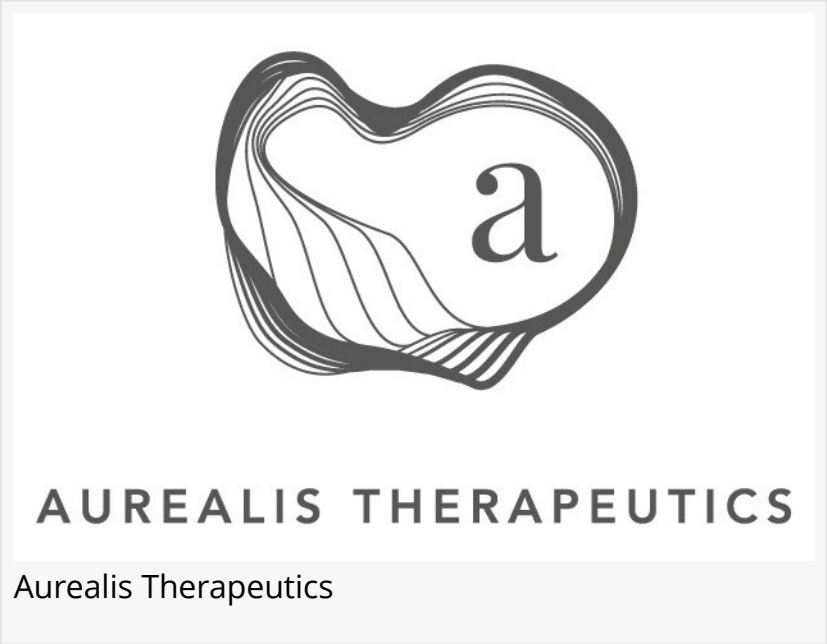
Aurealis Therapeutics receives CTA approval for AUP-16 Phase 2 RCT in Diabetic Foot Ulcer patients

Multi-center, randomized, placebo-controlled diabetic foot ulcer (DFU) Phase 2 study to start May 2023 in Italy, Germany, and Poland



Aurealis Therapeutics

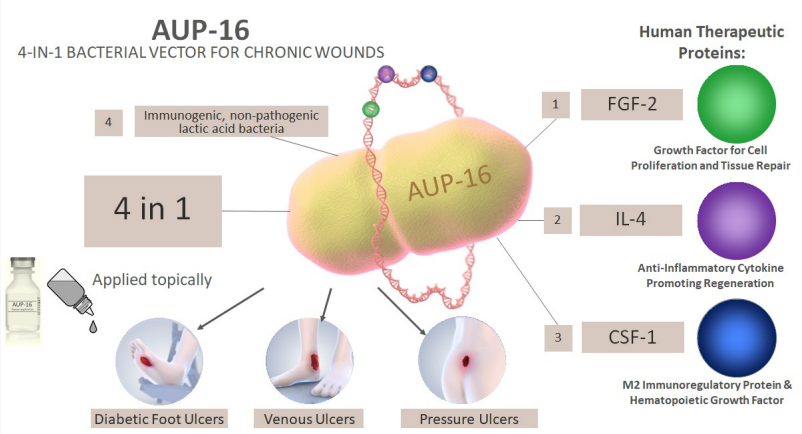
BASEL, SWITZERLAND, May 9, 2023 /EINPresswire.com/ -- Aurealis Therapeutics, a Swiss-Finnish private clinical-stage synthetic biology company focusing on the development of lactic acid bacteria -based GMO cell and gene therapies, announces clinical trial application (CTA) approval of a multi-country, randomized, placebo-controlled diabetic foot ulcer (DFU) Phase 2 study to start this month in Italy, Germany, and Poland. The Global Coordinating Investigator of this clinical study is Professor Alberto Piaggesi. The company plans to enroll the first patient to the Phase 2 DFU patient trial between the end of May and beginning of June.

> After completing 12 months follow-up of our DFU Phase 1 study, and 10M CHF Series A financing round to accelerate our clinical program, these are fantastic news for the company"
>
> *Juha Yrjänheikki, CEO*

"Following previously announced completion of last patient – last visit (LPLV) for the 12-month follow-up of our DFU Phase 1 study, and completion of 10M CHF Series A financing round allowing us to accelerate our clinical program, these are fantastic news for the company. I would like to warmly thank the whole Aurealis Team who has worked night and day to make this happen, and the scientific advisors and investigators for their trust and support" declared Juha Yrjänheikki, CEO of Aurealis Therapeutics.

"We are extremely happy to announce Aurealis Therapeutics Phase 2 clinical trial to investigate

the safety and efficacy of its lead clinical candidate AUP1602-C in patients with non-healing diabetic foot ulcers received regulatory approval. Getting one step closer in providing the much-needed novel treatments to our patients" said Haritha Samaranayake, CMO of Aurealis Therapeutics.



AUP-16 4-in-1 Bacterial Vector for Chronic Wounds

"I'm proud and honored to be part of the team that made this happen by working together for a common goal. The submission and evaluation processes went smoothly via the new harmonized system and I'm excited we can now concentrate on the initiation of the clinical sites and the start of patient recruitment" continued Hanna-Riikka Kärkkäinen, Head of Quality and Regulatory Affairs at Aurealis Therapeutics.

About AUP-16 Phase 2 Clinical Plan

Study AT-W-CLI-2022-04 (EudraCT number: 2022-502048-10-00) is a Phase 2 multi-country, open-label, randomized, standard-of-care plus placebo-controlled clinical study of AUP-16 in humans. The aim of this clinical trial is to evaluate the safety, tolerability, and efficacy of the recommended Phase 2 dose of AUP-16 in two dosing frequencies as a topical treatment for non-healing neuro-ischemic DFUs.

About AUP-16

AUP-16 is a genetically engineered Lactococcus Cremoris, a non-pathogenic, probiotic bacteria, expressing human basic fibroblast growth factor (FGF2, bFGF), interleukin-4 (IL4) and macrophage colony stimulating factor (CSF1, mCSF) – all in one product and accepted as one active pharmaceutical ingredient from regulatory perspective. AUP-16 is topically applied on chronic wounds and covered by wound dressing (e.g. in diabetic foot ulcers, venous leg ulcers and pressure ulcers). In the wound AUP-16 acts as millions of bioreactors producing the therapeutic proteins, which are designed to i) halt chronic inflammation in the wound, ii) induce growth of new blood vessels, and iii) promote granulation tissue formation and skin re-epithelization – all in one product.

About Aurealis Therapeutics

Aurealis Therapeutics AG is a Swiss-Finnish private clinical-stage synthetic biology company focusing on the development of lactic acid bacteria -based GMO cell and gene therapies. The company's lead clinical assets are the first-in-class four-in-one cell and gene therapies AUP-16 for chronic wounds and AUP-55 for cancers. Aurealis therapies are based on proprietary technology

involving genetically engineered Lactococcus Cremoris acting as millions of small immune-activating bioreactors producing multiple human therapeutic proteins (cytokines, growth factors, antibody fragments) to effectively and safely re-educate the distorted host immune microenvironment to a proper state.

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