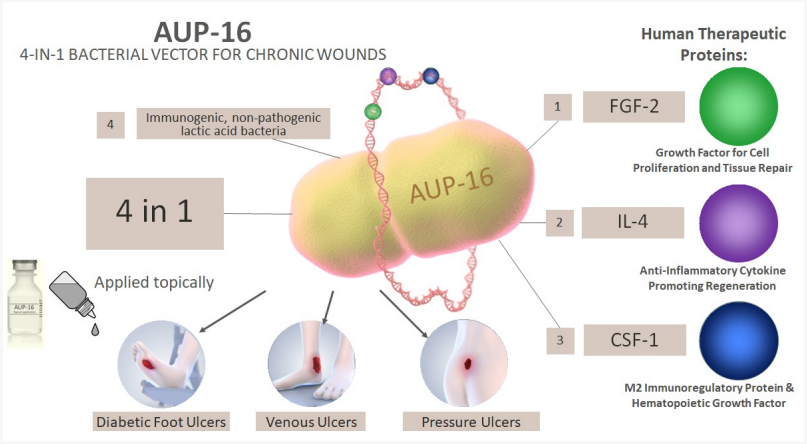
Aurealis Therapeutics Announces First Patient Dosed in DIAMEND Phase 2 Diabetic Foot Ulcer Clinical Trial of AUP-16

BASEL, BASEL-STADT, SWITZERLAND, August 8, 2023 /EINPresswire.com/ -- Aurealis Therapeutics, a Swiss-Finnish clinical-stage synthetic biology company developing bacteria-based multi-target cell and gene therapies for chronic wounds and cancer, announced today that the first diabetic foot ulcer (DFU) patient has been successfully dosed in its DIAMEND phase 2 clinical study of AUP-16. This is a multi-center, single-blinded, randomized, standard-of-care plus placebo-controlled clinical trial that aims to evaluate the safety, tolerability, and efficacy of the recommended phase 2 dose of AUP-16 as a topical treatment for non-healing neuroischemic diabetic foot ulcers (DFUs).

Aurealis Therapeutics



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

"We are excited to launch the DIAMEND trial so quickly after the approval. Dosing the first patient is a very important milestone and a demonstration of the excellence of the team and all stakeholders involved. We look forward to share more as the trial progresses" stated Juha Yrjänheikki, CEO of Aurealis Therapeutics.

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"DFUs afflict millions of people around the world. The ramifications of this disease span from constant discomfort to an overall reduced quality of life. In the worst cases, non-healing DFUs can lead to foot amputation, immobility, and even death. Aurealis Therapeutics 4-in-1 technology

offers a promising alternative to counter this disease. We together with our world-leading clinical collaborators and centers are eager to maximally enroll patients to evaluate the potential of AUP-16" continued Haritha Samaranayake, CMO of Aurealis Therapeutics.

"It has been rewarding to witness first-hand the clinical progress and results of AUP-16 in non-healing DFUs. The promising outcome of our phase 1 clinical study, phase 2 approval, site initiations, and now, first patients dosed are achievements that build excitement internally and externally. Looking forward to continuing the excellent cooperation with the investigators, sites, and service providers in Italy, Germany, and Poland" said Mirka Tikkanen, Senior Clinical Project Manager.

About AUP-16 Phase 2 Clinical Plan
Study AT-W-CLI-2022-04 (EudraCT number: 2022-502048-10-00) is a Phase 2 multi-center, single-blinded, 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 clinical-stage synthetic biology company creating bacteria-based multi-targeting cell and gene therapies for chronic wounds and cancer. 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 nanoscale 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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