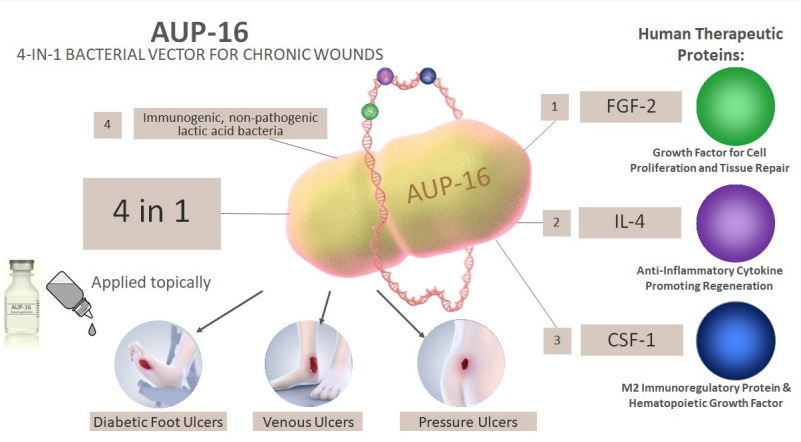
Aurealis Therapeutics completes 50% patient recruitment for DIAMEND Phase-2 study in Diabetic Foot Ulcers

Half of the patients expected to participate DIAMEND Phase-2 study with AUP-16 in Diabetic Foot Ulcers (DFUs) have now been recruited and randomized.

Aurealis Therapeutics



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

ZUG, SWITZERLAND, March 11, 2024 /EINPresswire.com/ -- Aurealis Therapeutics, a Swiss-Nordic clinical-stage company developing scalable and low COGS multi-target cell and gene therapies, announced today the successful recruitment and randomization of half of the patients expected to participate in its DIAMEND AUP-16 Phase-2 clinical trial on Diabetic Foot Ulcers (DFUs).

AUP-16 is Aurealis Therapeutics' lead product candidate for the treatment of chronic wounds. The DIAMEND study (NCT06111183) is a multi-site, randomized, placebo-controlled clinical trial currently ongoing in Italy, Germany, and Poland. The primary goal of this study 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.

DFUs represent a major global health challenge, affecting millions of people worldwide. These chronic wounds can lead to severe complications, including infection, hospitalization, and in severe cases, amputation, or even death. DFUs significantly impact patients' quality of life, from

reduced mobility to increased pain and emotional distress.

“Just a few days after the European Medicines Agency has granted AUP-16 with PRIME (Priority Medicines) status for the treatment of non-healing DFUs, we are proud to communicate the successful recruitment and randomization of half of the patients of our DIAMEND study. These 30 patients are expected to complete the 12-week treatment in May 2024. We look forward to see the data derived from this study” said Haritha Samaranayake, MD, PhD, CMO of Aurealis Therapeutics.

“Achieving the recruitment and randomization of half of the study patients results from the high professionalism, commitment, and work of investigators, clinical sites and service providers, and most importantly the patients and their families. We are very grateful for efforts of everyone involved in the realisation and progression of this study and look forward to seeing what the preliminary results reveal” added Mirka Sanio, Senior Clinical Project Manager of Aurealis Therapeutics.

About AUP-16:
AUP-16 (AUP1602-C) is a genetically engineered Lactococcus Cremoris, a non-pathogenic, probiotic bacteria, expressing human basic fibroblast growth factor (FGF-2, bFGF), interleukin-4 (IL-4) and macrophage colony stimulating factor (CSF-1, 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 multi-target bacteria-based cell and gene therapies allowing to modulate tissue microenvironment and tackle complex multi-factorial diseases such as chronic wounds, cancers, and inflammation. The company’s lead clinical asset is AUP-16, the first-in-class four-in-one cell and gene therapy drug for chronic wounds and other inflammatory degenerative diseases. The product is based on proprietary technology involving genetically engineered lactic acid bacteria acting as millions of small immune activating bioreactors in the human tissue and producing multiple human therapeutic proteins into target tissue to effectively and safely re-educate the distorted host immune microenvironment to proper state.

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