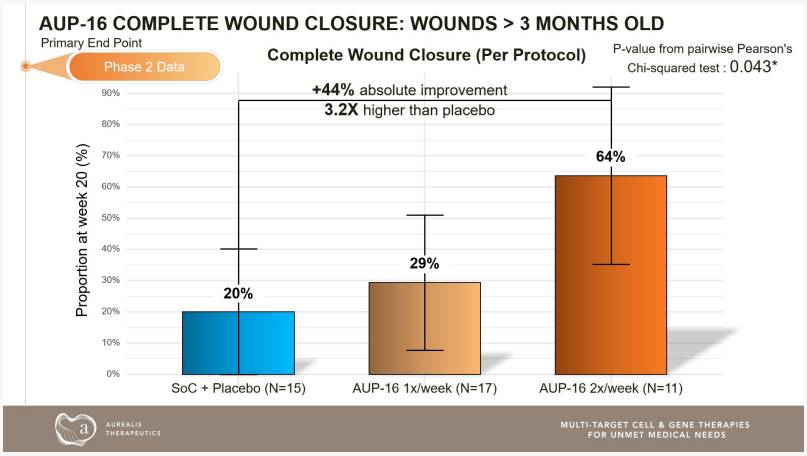
Aurealis Therapeutics DIAMEND Phase-2 RCT: AUP-16 Tripling Complete Wound Closure Rate in Patients with Chronic DFU

Positive Blinded Evaluator Efficacy Results of Aurealis "DIAMEND" Phase-2 RCT, AUP-16 Tripling Complete Wound Closure Rate in Chronic Diabetic Foot Ulcers



Complete Wound Closure Rate - Wounds >3 Months Old - AUP-16 DIAMEND Phase-2 RCT

ZUG, SWITZERLAND, December 4, 2025 /EINPresswire.com/ -- Aurealis Therapeutics, a clinical-stage company developing scalable and low COGS multi-target cell and gene therapies for chronic wounds and cancer, today announced positive blinded evaluator efficacy results and completion of the Database Lock (DBL) in its DIAMEND Phase 2 clinical trial of AUP-16, the company's lead asset for the treatment of non-healing neuro-ischemic Diabetic Foot Ulcers (DFUs). AUP-16 received Priority Medicines (PRIME) designation from the European Medicines Agency (EMA) in February 2024 for its potential to address the significant unmet medical need of chronic DFUs.

The DIAMEND study (NCT06111183 / EU CT 2022-502048-10-00) is a multi-center, patient- and observer-blinded, randomized, standard-of-care plus placebo-controlled trial designed to evaluate the safety, tolerability and efficacy of AUP-16 as a topical therapy for DFUs across two dosing frequencies. The study was conducted at 10 clinical sites across Italy, Germany and Poland. In total, 64 patients were randomized for treatment.

Final Blinded Evaluator data showed 3.2-fold increase in complete wound closure rate between placebo (20%) and AUP-16 administered twice weekly (64%), demonstrating a clinically and statistically significant advantage (+44% absolute increase, p value < 0.05) in chronic DFUs with prior wound duration of more than three months (Per Protocol – PP - Population). In Intention-to-Treat (ITT) population, complete wound closure rate was 2.5-fold increased by AUP-16 (+36% absolute increase, p value < 0.05). Wound Area Remaining at 20 weeks was 7.8 times lower in PP population (6.1% vs 47.4% in AUP-16 vs placebo, respectively) and 7.2 times lower in ITT population (6.2% vs 44.4% in AUP-16 vs placebo, respectively).

“We are pleased to announce the successful completion of our DIAMEND Phase 2 trial. The efficacy results observed in patients with chronic ulcers are exciting and demonstrate the potential of AUP-16 to address the unmet medical need of chronic DFUs. We have started the preparation of a global pivotal study in this target patient population,” said Haritha Samaranayake, Chief Medical Officer at Aurealis Therapeutics.

“Today marks a major milestone for our company and the DFU community. Our study delivered exceptional results in patients with long-standing, non-healing DFUs, reinforcing the promise of our therapy. This success drives us confidently toward the pivotal trial and global partnership discussions. We extend our deepest thanks to the patients, families, investigators, partners and our internal teams who made this possible. Together, we move closer to offering a meaningful new option for people living with chronic wounds”, continued Juha Yrjänheikki, CEO of Aurealis Therapeutics.

DFUs represent a serious global health burden, affecting millions of people worldwide and leading to pain, immobility, emotional distress, and, in severe cases, infection, amputation, or death.

At Aurealis Therapeutics, patient safety and meaningful innovation are at the heart of everything we do. The completion of DBL in the DIAMEND study marks an important milestone in our mission to bring a multi-target, cell and gene therapy solution to patients suffering from chronic wounds such as DFUs.

About AUP-16

AUP-16 (AUP1602-C, INN Rememulgene arelactibac) 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 (e.g. in diabetic foot ulcers, venous leg ulcers or other ulcer types) and covered by wound dressing. 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 Biotechnology company developing scalable and low COGS multi-target cell and gene therapies allowing to modulate tissue microenvironment and tackle complex multi-factorial diseases such as chronic wounds, cancers, inflammatory diseases. Aurealis modular gene therapy platform consists of non-pathogenic food-grade lactic acid bacterium Lactococcus Cremoris, genetically engineered to produce and

release multiple human therapeutic proteins in the body: cytokines, chemokines, growth factors, antibody fragments. These living bacterium act as millions of nanoscale bioreactors at the site of the disease, allowing multi-targeting as one product, to treat multifactorial diseases. Aurealis pipeline includes Chronic Wounds (AUP-16, completed Phase 2), Oncology (AUP-55, pre-clinical stage), Inflammation (AUP-60, discovery stage).

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