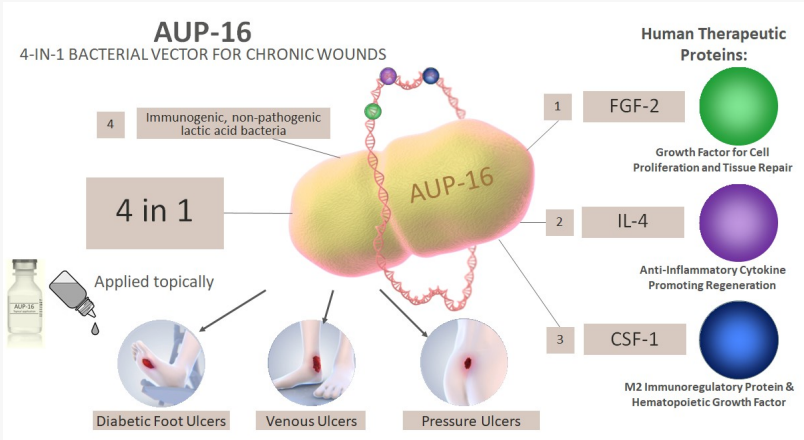
Aurealis Therapeutics’ lead candidate AUP-16 for chronic wounds receives PRIME status from EMA

Aurealis Therapeutics receives PRIME status from EMA for Enhanced Regulatory Support and Accelerated Assessment of AUP-16 in Non-healing Diabetic Foot Ulcers



AUP-16 multi-target cell & gene therapy for Chronic Wounds

ZUG, SWITZERLAND, February 27, 2024 /EINPresswire.com/ -- • Priority medicines (PRIME) is a scheme run by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. The scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier

• EMA CHMP acknowledges that non-healing Diabetic Foot Ulcers (nhDFU) are a potentially life-threatening condition with unmet need for novel therapies

• First Aurealis Therapeutics product candidate to receive PRIME designation by EMA for enhanced regulatory support facilitating the clinical development of multi-target cell and gene therapy candidate AUP-16 in the treatment of nhDFU

• Designation follows positive data for 16 patients from Phase-1 first-in-human study showing a dose-dependent improvement in wound closure, 67% and 83% wound closure at 3 and 6 months respectively, demonstrating the potential to address the unmet medical need in nhDFU

• AUP-16 muti-target gene therapy consists of Lactococcus Cremoris bacterium, genetically

engineered to produce and release three human therapeutic proteins in the wounds (FGF-2, IL-4 and CSF-1), allowing to modulate the wound micro-environment and target all key components of wound healing

Zug, Switzerland and Kuopio, Finland, February 26, 2024. Aurealis Therapeutics today announced that that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) designation to Aurealis Therapeutics' lead product candidate AUP-16 (AUP1602-C) for the treatment of non-healing Diabetic Foot Ulcers (nhDFU).

EMA acknowledges that nhDFU is a serious, debilitating and potentially life-threatening condition, with an unmet need for therapies that improve healing outcomes compared to available options. EMA also recognizes that the high rate of wound closure observed with AUP-16 sufficiently demonstrates the potential to address the unmet medical need in nhDFU to a significant extent.

AUP-16 multi-target gene therapy is a potential first-in-class therapeutic approach which comprises a synergistic combination of four therapeutic components in one pharmaceutical ingredient (API). AUP-16 consists of Lactococcus Cremoris bacterium, genetically engineered to produce, and release three human therapeutic proteins in the wounds: fibroblast growth factor 2 (FGF-2), interleukin 4 (IL-4) and colony stimulating factor 1 (CSF-1). AUP-16 bacterium act as millions of nanoscale bioreactors in the wound, allowing to re-start and accelerate the healing of chronic wounds by 1) awakening the immune microenvironment, 2) driving macrophage conversion from pro-inflammatory M1 to anti-inflammatory and regenerative M2 phenotype, 3) granulation tissue formation by increasing fibroblast proliferation and promoting angiogenesis, and 4) supporting epithelialization.

The product candidate is currently being investigated in an ongoing international, randomized, placebo-controlled Phase-2 study (NCT06111183; EU CT No.: 2022-502048-10-00) that aims to evaluate the safety, tolerability, and efficacy AUP-16 in non-healing neuro-ischemic diabetic foot ulcers.

"Patients suffering from non-healing Diabetic Foot Ulcers experience a poor quality of life, with reduced mobility, increased pain, risk of infections, hospitalization, amputation or even death. DFUs account for more than 60% of all non-traumatic lower limb amputations, and lead to higher 5-year mortality than most cancer types. Increasing the awareness of this silent killer is one of our key missions, so the recognition by CHMP and EMA that nhDFU represent a potentially life-threatening condition with unmet need for therapies was an essential step. And we're extremely proud that AUP-16 has been granted PRIME status, recognizing its potential to address the unmet medical need in nhDFU" said Haritha Samaranayake, MD, PhD, CMO of Aurealis Therapeutics.

"With the PRIME status and support by EMA, we aim to expedite the further development of AUP-16 program to bring a novel therapeutic option for patients suffering from nhDFU, and

bring Aurealis multi-target gene therapies faster to market. This is the result of a fantastic cross-functional collaboration" added Hanna-Riikka Kärkkäinen, Head of Quality and Regulatory Affairs of Aurealis Therapeutics.

The designation is based on positive data from completed Phase-1 study (NCT04281992; EudraCT No.: 2018-003415-22) that was presented at the European Wound Management Association conference in May 2023. The results showed a dose-dependent improvement in wound closure, with the highest dose achieving 67% and 83% wound closure at 3 and 6 months respectively. According to EMA, the high rate of wound closure sufficiently demonstrates the potential of AUP-16 to address the unmet medical need in nhDFU to a significant extent.

The PRIME scheme is a regulatory mechanism introduced by the EMA that provides early and proactive support to developers of promising medicines, to optimize development plans and speed up evaluations so these medicines can reach patients faster. The goal is to help patients benefit as early as possible from innovative new therapies that have demonstrated the potential to significantly address an unmet medical need.

About AUP-16:
AUP-16 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 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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