

Final Results of Phase-2 Randomized Controlled « DIAMEND » Study In Chronic Diabetic Foot Ulcer With Topical Multi-Target Cell & Gene Therapy AUP1602-C

Alberto Piaggese¹, J Mikosiński², E Iacopi¹, D Lammers³, C Kosch⁴, K Pańczak⁵, M Grobelna⁶, M Monami⁷, A Scatena⁸, M Malka⁹, M Meloni¹⁰, C Schindler¹¹, M Sanio¹², J Kurkipuro¹², H-R Kärkkäinen¹², M Piironen¹², I Mierau¹², L Décory¹², J Yrjänheikki¹², H Samaranyake¹²

¹Diabetic Foot Section, Department of Endocrinology and Metabolism, University of Pisa, Italy, ²NZOZ Mikomed, Poland, ³Institut für Diabetesforschung Muenster GmbH, Germany, ⁴Hausärztliche und Diabetologische Praxis, Germany, ⁵Lecran Centrum Opieki Nad Ranami, Poland, ⁶Med-Polonia SP. Z O.O., Poland, ⁷Azienda Ospedaliero Universitaria Careggi, Italy, ⁸Azienda Usl Toscana Sud Est, Italy, ⁹PODOS Klinika, Poland, ¹⁰University of Rome Tor Vergata, Italy, ¹¹Hannover Medical School, Germany, ¹²Aurealis Therapeutics, Switzerland

Aim

To evaluate the safety and efficacy of AUP1602-C, a Gene-Therapy Medicinal Product for non-healing diabetic foot ulcers (DFUs), in a multi-center randomized, controlled (RCT) Phase-2 study.

Methods

AUP1602-C (Rememulgene arelactibac) consists of living Lactococcus cremoris bacteria genetically engineered to secrete human FGF-2, IL-4 and CSF-1, and promote wound healing by microenvironment modulation¹.

In “DIAMEND”, a 64-patient, SoC plus placebo-controlled, patient- and central-evaluator blinded Phase-2 study (NCT06111183), IMP was administered topically once- or twice-a-week to non-healing, neuro-ischemic DFUs for up to 12-weeks.

Efficacy endpoints included completed healing and wound area reduction at 20-weeks, with post-hoc focus on chronic ulcers over 3-months old.

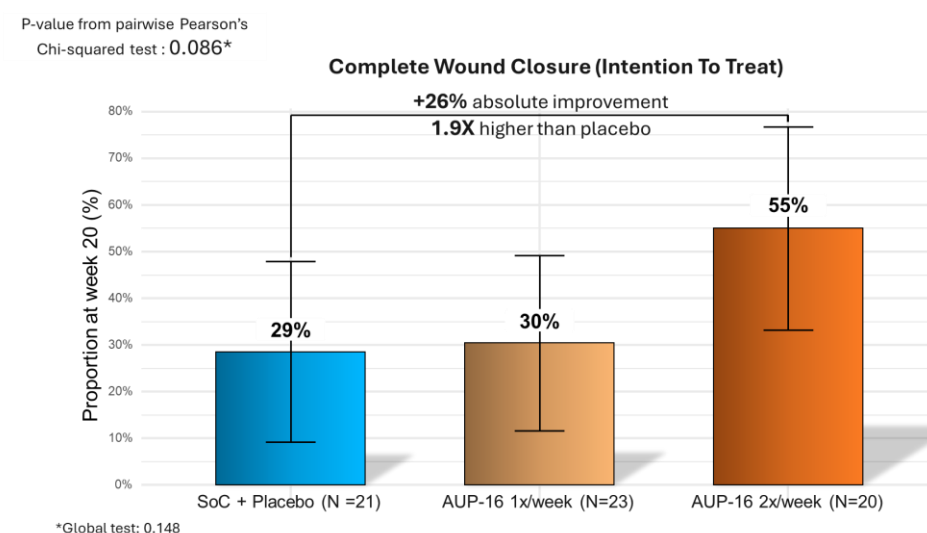
Conclusion

In first-ever Phase-2 study with a topical gene therapy, AUP1602-C demonstrated the potential to be superior to SoC in treating non-healing, neuro-ischemic DFUs in patients with chronic ulcers over 3-months old. Preparation for a global Phase 3 study in this population is underway.

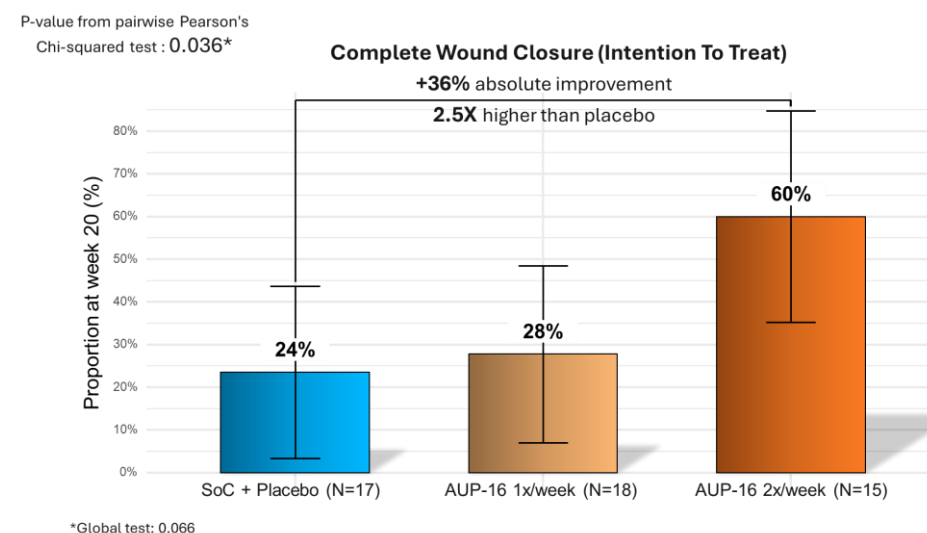
Results

In ITT population, complete wound closure rate was 55% and 30% in AUP1602-C twice-a-week and once-a-week groups resp., 29% in the placebo group (+26% between placebo and AUP1602-C 2x/week, n.s.). In PP Population, complete closure rates were 56%, 32% and 26% resp. (+30%, n.s.). Focusing on chronic ulcers above 3 months old, complete closure rates were 60%, 28% and 24% (+36%, p<0.05) in ITT Population, and 64%, 29%, 20% (+44%, p<0.05) in PP Population. WAR (IIT) at 20 wks showed >5-fold reduction in the 2x/week treated group compared to placebo (7.9% vs 42.4% of remaining area, respectively; n.s.). No serious adverse reactions or safety concerns were observed.

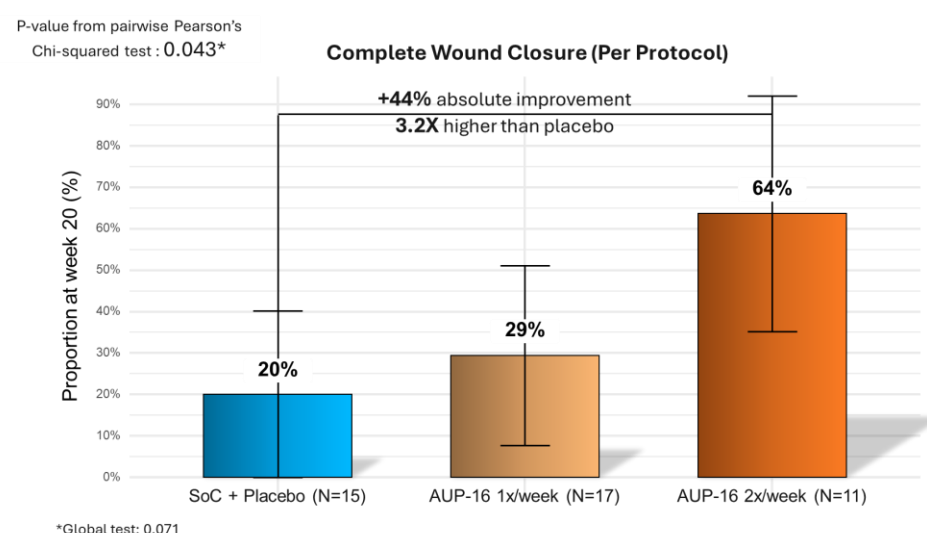
Complete Wound Closure: all patients



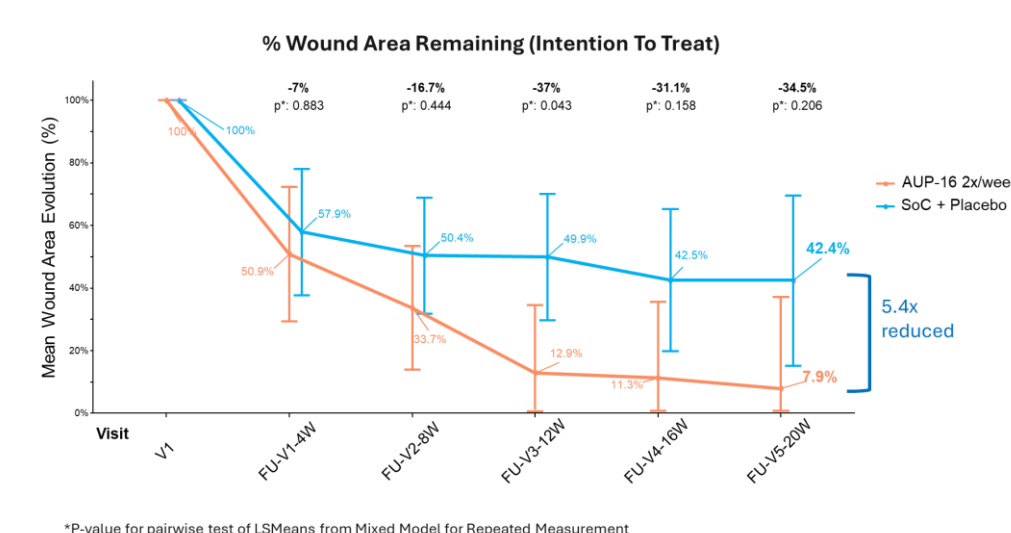
Complete Wound Closure: DFUs > 3 months



Complete Wound Closure: DFUs > 3 months



Wound Area Reduction: DFU >3 months



References:

- Kurkipuro J, Mierau I, Wirth T, Samaranyake H, Smith W, Kärkkäinen HR, Tikkanen M, Yrjänheikki J. Four in one-Combination therapy using live Lactococcus lactis expressing three therapeutic proteins for the treatment of chronic non-healing wounds. PLoS One. 2022 Feb 28;17(2):e0264775. doi: 10.1371/journal.pone.0264775. PMID: 35226700; PMCID: PMC8884502.
 - Schindler C, Mikosiński J, Mikosiński P, et al. Multi-target gene therapy AUP1602-C to improve healing and quality of life for diabetic foot ulcer patients: a phase I, open-label, dose-finding study. Therapeutic Advances in Endocrinology and Metabolism. 2024;15. doi:10.1177/20420188241294134
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