IJTR
The International Journal of Tissue Repair

TRES
Tissue Repair Evidence Summit

ABSTRACT

Evaluation of multiple cellular, acellular, and matrix-like products (CAMPs) and standard of care versus standard of care alone in the treatment of nonhealing diabetic foot ulcers: an interim analysis of the CAMPFIRE clinical trial

Thomas Serena[1] MD | **Brianna Tramelli**[1] | **Stephanie Wilkins**[1] | **Zwelithini Tunyiswa**[2]

[1]SerenaGroup, Inc., Cambridge, MA | [2]Open Wound Research, Puyallup, WA

Correspondence: Brianna Tramelli (btramelli@serenagroups.com)

Received: 30 October 2025 | **Accepted:** 30 October 2025

Funding: The CAMPFIRE trial was conducted under a grant from Samaritan Biologics, LLC

Keywords: Interim analysis | diabetic foot ulcer | chronic wounds | tissue regeneration | cellular, acellular, matrix-like products | clinical trial design

Abstract

Background: Characterized by chronic duration and impaired healing, diabetic foot ulcers (DFUs) impose significant burdens in terms of morbidity, mortality, and economic cost. The limited effectiveness of current standard of care (SOC) approaches highlights the need for novel and cost-effective therapeutic strategies.

Methods: An interim analysis of this multicenter, prospective, randomized controlled modified platform trial evaluated efficacy of multiple cellular, acellular, and matrix-like products (CAMPs) plus SOC versus SOC alone in achieving complete closure of hard-to-heal DFUs in 12-weeks.

Results: Due to the early stage of this trial, percent area reduction at four weeks was used as a measure of success. For the dual layer matrix (Complete AA, Samaritan Biologics, LLC, Cordova, TN, USA) the PAR at 4 weeks was -15.3% compared to SOC at -11.1%. For the perforated tri-layer graft (MOST, Samaritan Biologics, LLC, Cordova, TN, USA) the PAR at 4 weeks was -32.5% compared to the -11.1% for SOC.

Conclusion: This interim analysis demonstrates favorable treatment effect for CAMPs compared to SOC alone.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data is proprietary but is available on request to the corre-sponding author.

Conflicts of Interest: The authors declare no conflicts of interest.

Author Contributions: Conceptualization, T.S.; methodology, T.S., B.T., and Z.T.; data curation, Z.T.; writing—original draft preparation, T.S., B.T. and Z.T.; writing—review and editing, T.S, B.T. and Z.T.; visualization, T.S. and Z.T.; project administration, S.W. All authors have read and agreed to the published version of the manuscript