Interim Analysis from CAMPSTIM – A Multicenter, Prospective, Randomized Controlled Modified Platform Trial Assessing the Efficacy of Multiple Human Placental-Based Skin Substitutes and Standard of Care versus Standard of Care Alone in the Treatment of Hard-to-Heal Diabetic Foot Ulcers

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INTRODUCTION

- Diabetic foot ulcers (DFUs) are chronic wounds with high morbidity, mortality, and economic burden.
- Cellular, acellular, and matrix-like products (CAMPs) are a broad category of biomaterials, synthetic materials, and biosynthetic matrices that support the repair and/or regeneration of injured tissues.
- Here we present an interim analysis of CAMPSTIM (NCT06449638), a multicenter, prospective, randomized clinical trial utilizing a modified platform design. Patients with non-healing DFUs are randomized into two groups: SOC alone or SOC plus a dehydrated complete human placental membrane (dCHPM) allograft product.
- Relese® is a fenestrated dCHPM allograft product (Q4257) – **Figure 1**.

Figure 1: Image of Relese®.

GOAL

To evaluate the efficacy of dCHPM allograft products compared to SOC alone in the treatment of non-healing diabetic foot ulcers (DFUs).

METHODOLOGY

- Eligible subjects: 18 years old, type 1 or 2 diabetes mellitus, target ulcer area 1.0cm^2 to <25.0cm^2; wound age >4 weeks and <52 weeks, Wagner grade 1&2. All patients had <20% wound size reduction in 2-week historical run-in and 2-week screening run-in.
- July 2024 to April 2025, 113 patients at 15 wound care centers across the U.S. were randomized into dCHPM+SOC vs SOC alone with n=82 meeting the Per-Protocol criteria (PP) for the interim analysis – **Figure 2**.

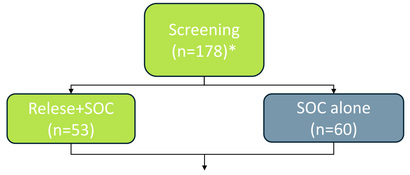


Figure 2: Consort flow diagram (*28% screen fail rate, n=15 subjects enrolled in Revita® arm of trial).

- Treatment included weekly applications for up to 12 weeks and 2-week healing confirmation (HCV).
- Primary objective is percent of ulcers achieving complete closure in 12 weeks
- Secondary objectives include time-to-closure, percent area reduction (PAR), and safety.
- Data analysis also employed a Bayesian Mixed Model for Repeated Measures (MMRM) using Hurdle-Gamma likelihood to further analyze the primary endpoint.

Table 1: Baseline wound characteristics.

Group	Wound size at TV1				Wagner Grade		Age of Wound	
	Min (cm^2)	Max (cm^2)	Median (cm^2)	Mean (SD) (cm^2)	No. Grade 1	No. Grade 2	Median (weeks)	Mean (SD) (weeks)
Relese (n=53)	1.00	24.58	2.08	4.16 (5.34)	33 (62%)	20 (38%)	12	18 (16)
SOC (n=60)	1.00	22.17	1.98	4.06 (4.75)	39 (65%)	21 (35%)	12	20 (24)

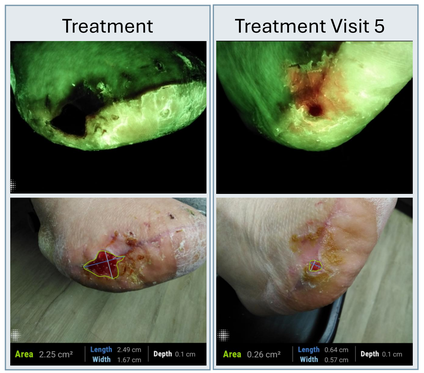
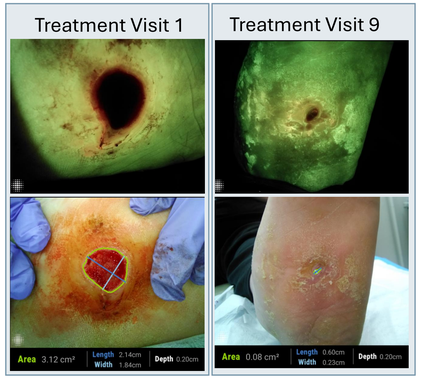


Figure 3: MolecuLight fluorescent images and photographs of wound healing progression from the first and last treatment visit and HCV for Subject 007-013 treated with Relese+SOC.



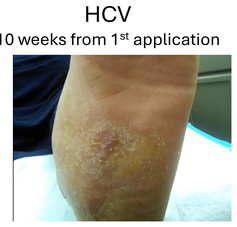


Figure 4: MolecuLight fluorescent images and photographs of wound healing progression from the first and final treatment visit and HCV for Subject 005-014 treated with Relese+SOC.

RESULTS

- Baseline patient demographics were well-balanced between groups. Mean wound size was 4.2±5.3cm^2 – dCHPM+SOC and 4.1±4.8cm^2 – SOC – **Table 1.**
- Wound healing progression with dCHPM+SOC is demonstrated in **Figure 3** and **Figure 4**.
- Interim analyses shows 17% would healing Treatment Effect for dCHPM+SOC (RR = 1.74) at 12 weeks versus SOC alone for the PP population (95% CI 0.89-3.40, p=0.10). Intent-to-Treat (ITT) shows 12% Treatment effect for dCHPM+SOC (RR = 1.70, 95% CI 0.84-3.45, p=0.14).
- Median PAR (ITT) trended better for Relese+SOC versus SOC alone out to 12 weeks (71% vs 47%) – **Figure 5**.
- Utilizing Bayesian statistical methods, posterior mean risk ratio for wound closure when comparing the dCHPM+SOC arm (n=53) to SOC only arm (n=60) was 1.6 (94% HDI 0.88-2.5). The posterior probability that the dCHPM+SOC increased wound closure compared with SOC only (RR > 1) was 96.2% – **Figure 6**.
- Safety was comparable between groups, with no product-related adverse events reported.

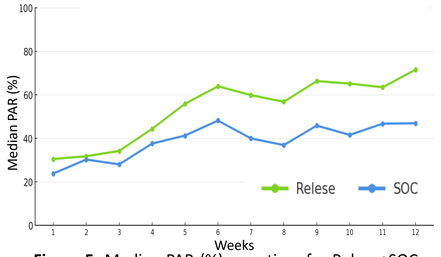


Figure 5: Median PAR (%) over time for Relese+SOC and SOC alone over 12-week treatment (PP).

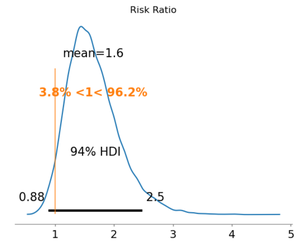


Figure 6: Posterior mean risk ratio for wound closure comparing dCHPM+SOC to SOC alone.

CONCLUSIONS

The interim analysis demonstrates a favorable trend in treatment effect for the fenestrated dCHPM product (Relese) with a high posterior probability of 96.2% supporting that dCHPM+SOC improves wound closure compared with SOC alone. Continued enrollment and follow-up are necessary to refine effect estimates and determine whether the observed probability of benefit is confirmed with full trial completion.

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