INTERIM ANALYSIS OF CELLULAR, ACELLULAR, AND MATRIX-LIKE PRODUCTS FOR THE MANAGEMENT OF CHRONIC LOWER EXTREMITY ULCERS IN THE STABLECAMP TRIAL

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INTRODUCTION

- Diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) are chronic wounds with high morbidity, mortality, and economic burden.
- Standard of care (SOC) includes sharp debridement, offloading (DFU), compression (VLU) reducing bacterial load and maintaining moisture balance .
- 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 through various mechanisms of action.

METHODS

- RCT(clinicaltrials.gov NCT06560502) conducted at SerenaGroup, Inc. & affiliated sites in United States; Oct 2024 start.
- 245 subjects w/ nonhealing DFUs from 19 sites; 137 subjects w/ nonhealing VLUs from 15 sites.
- Intent to Treat (ITT) and Per Protocol (PP) population reported at interim.
- Subjects randomized to one of CAMP + SOC or SOC alone; Stratification by wound area >2cm^2 , 2cm^2 - 3cm^2 , and < 3cm^2 & wound age >60 vs <60 days old.
- Wounds measured weekly with digital photographic planimetry and physical examination.

Table 1: Key Inclusion and Exclusion Criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
• At least 21 years of age • Diagnosis of type 1 or 2 Diabetes mellitus (DFU) • Must be Wagner grade 1 or 2 (DFU) • Surface area between 1.0cm^2 and 5.0cm^2 (DFU) / 20.0cm^2 (VLU) • Present between 4 and 52 weeks, treated with SOC • Has adequate perfusion	• Life expectancy <6 months • Ulcer has infection, cellulitis, or osteomyelitis • Use of systemic antibiotics, immunosuppressants, or cytotoxic chemotherapy • Partial amputation that impedes proper offloading (DFU) • Surface area has reduced in size by >20% in 2 weeks prior to SV or by >20% from SV to TV-1 • Previously treated with HBOT or CAMP

Table 2: Endpoints

PRIMARY ENDPOINT	SECONDARY ENDPOINT
• The percentage of target ulcers achieving complete wound closure in 12 weeks.	• Percentage wound area reduction from TV-1 to TV-13

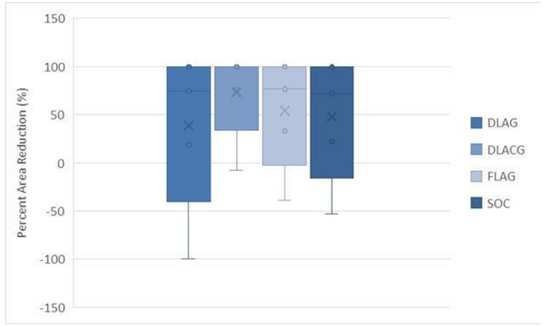
RESULTS

Table 3: Wound Closure Rates (ITT)

TREATMENT ARM	N	100% CLOSURE	RATE (%)
DFU			
SOC	75	16	21.3
DLAG	93	28	30.1
DLACG	13	6	46.2
FLAG	64	19	29.7
VLU			
SOC	40	7	17.5
DLAG	44	14	31.8
DLACG	11	2	18.2
FLAG	42	17	40.5

Table 4: Wound Closure Rates (PP)

TREATMENT ARM	N	100% CLOSURE	RATE (%)
DFU			
SOC	40	12	30
DLAG	48	17	35.4
DLACG	10	5	50
FLAG	26	11	42.3
VLU			
SOC	19	6	31.6
DLAG	24	11	45.8
DLACG	4	2	50
FLAG	25	10	40



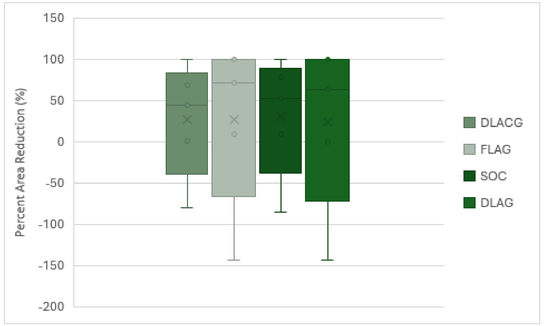


Figure 1: Percent Area Reduction (PAR) for ITT Population without Outliers, DFU (left) and VLU (right)

Results reflect interim ITT analysis with outliers excluded. Median PAR at 12 weeks for DFU was 75% for DLAG + SOC; 100% for DLACG + SOC; and 77% for FLAG + SOC; vs 72% for SOC alone. Median PAR at 12 weeks for VLU was 63% for DLAG + SOC; 44% for DLACG + SOC; and 72% for FLAG + SOC; vs 52% for SOC alone.

CONCLUSIONS

- **For this interim analyses, wounds managed with CAMP products trended toward superiority over those managed with SOC.**
- **These results confirm that the trial design is viable. Enrollment will continue until target for statistical power (at α = 0.05) is achieved.**

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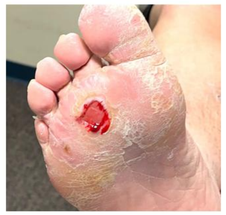
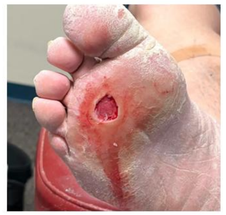




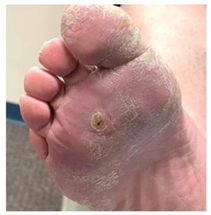
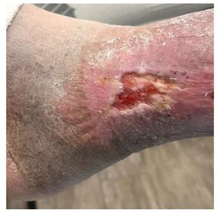
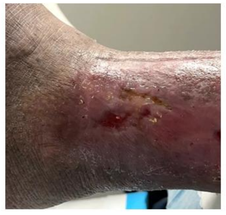


Figure 2: Digital Images from SV-1, TV-1, and HCV (Left to Right), FLAG + SOC Treatment Arm





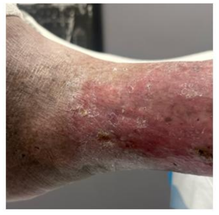


Figure 3: Digital Images from SV-1, TV-1, and HCV (Left to Right), DLAG + SOC Treatment Arm

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