INTERIM ANALYSIS OF SINGLE LAYER AMNIOTIC MEMBRANE WOUND COVER FOR THE MANAGEMENT OF CHRONIC DIABETIC FOOT ULCERS IN THE CAMPX TRIAL

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INTRODUCTION

- Diabetic foot ulcers (DFUs) are chronic wounds with high morbidity, mortality, and economic burden.
- Standard of care (SOC) for DFUs include sharp debridement, offloading, reducing bacterial load and maintaining moisture balance .
- Advanced wound management incorporates cellular, acellular, and matrix-like products (CAMPs) - 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 NCT06564831) conducted across 23 SerenaGroup, Inc. & affiliated sites in the United States.
- 160 eligible subjects w/ nonhealing DFUs Apr 2024 start (**Table 1**).
- Intent to Treat (ITT) and Per Protocol (PP) population reported at interim (**Table 2**).
- Subjects were randomized to SOC alone or SLAM + SOC; Stratification by wound area >2cm^2 vs < 2cm^2 & wound age >60 vs <60 days old.
- Wounds are measured weekly with digital photographic planimetry and physical examination (**Figures 1, 2**).

Table 1: Inclusion and Exclusion Criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
• At least 18 years of age • Diagnosis of type 1 or 2 Diabetes mellitus • Surface area between 0.7cm^2 and 20.0cm^2 • Present between 4 and 52 weeks, treated with SOC • Must be Wagner grade 1 or 2 • 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 • 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 (%)
Standard of Care	76	9	11.8
SLAM	83	16	19.3

Table 4: Wound Closure Rates (PP)

TREATMENT ARM	N	100% CLOSURE	RATE (%)
Standard of Care	38	8	21.1
SLAM	48	16	33.3

- **ITT:** SLAM + SOC arm achieved a 19.3% closure rate versus 11.8% with SOC alone. **(Table 3)**
- **PP:** SLAM + SOC arm achieved a 33.3% closure rate versus 21.1% with SOC alone. **(Table 4)**

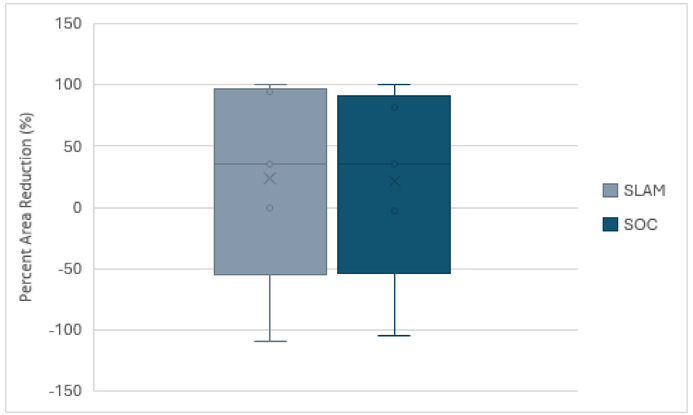

Figure 1: Percent Area Reduction (PAR) for ITT Population without Outliers

Results reflect interim ITT analysis with outliers excluded. Median PAR at 12 weeks was 35% for SLAM + SOC vs 35% for SOC alone.

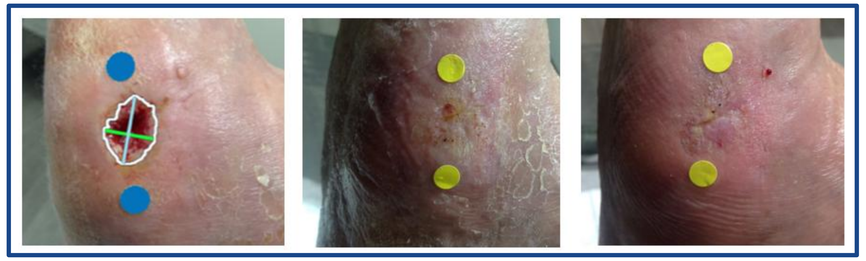

Figure 2: Digital Images from SV-1, TV-1, and HCV (Left to Right), SLAM + SOC Treatment Arm

CONCLUSIONS

- **For this interim analyses, wounds managed with SLAM 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.**

Funding statement: This study was funded by Applied Biologics™.

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