

A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis

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Introduction

- Diabetic foot ulcers (DFUs) are a common type of chronic wound among patients with diabetes and are associated with an increased risk of amputation^{1,2}
- A novel, proprietary combination therapy (Omeza LLC, Sarasota, FL) has been developed in accordance with the clinical perspective that effective wound care should mimic the effects of wound healing in a healthy body
- The combination therapy is composed of:
 - A wound therapy formulation (OCM™)
 - A wound preparation formulation
 - A skin protectant formulation
- OCM is a drug/device that contains peptides, omega fatty acids, and anabolic metabolites that support synthesis of new tissue
- One of the goals of this ongoing study is to demonstrate that the combination therapy plus standard of care (SOC) moves chronic DFUs from a stalled state to a healing state in a 4-week period (NCT05417425)

Objectives and Endpoints

- Primary objectives were to evaluate safety of combination therapy plus SOC (off-loading) and the impact of treatment on chronicity of wound healing after 4 weeks in the management of chronic DFUs
- The key primary endpoint was change in percent area reduction (PAR) after 4 weeks of treatment versus baseline; PAR after 12 weeks of treatment was also assessed
- Safety was evaluated throughout the study
- Secondary objectives were to evaluate healing of DFUs over 4 weeks of combination therapy plus SOC and time to complete wound closure

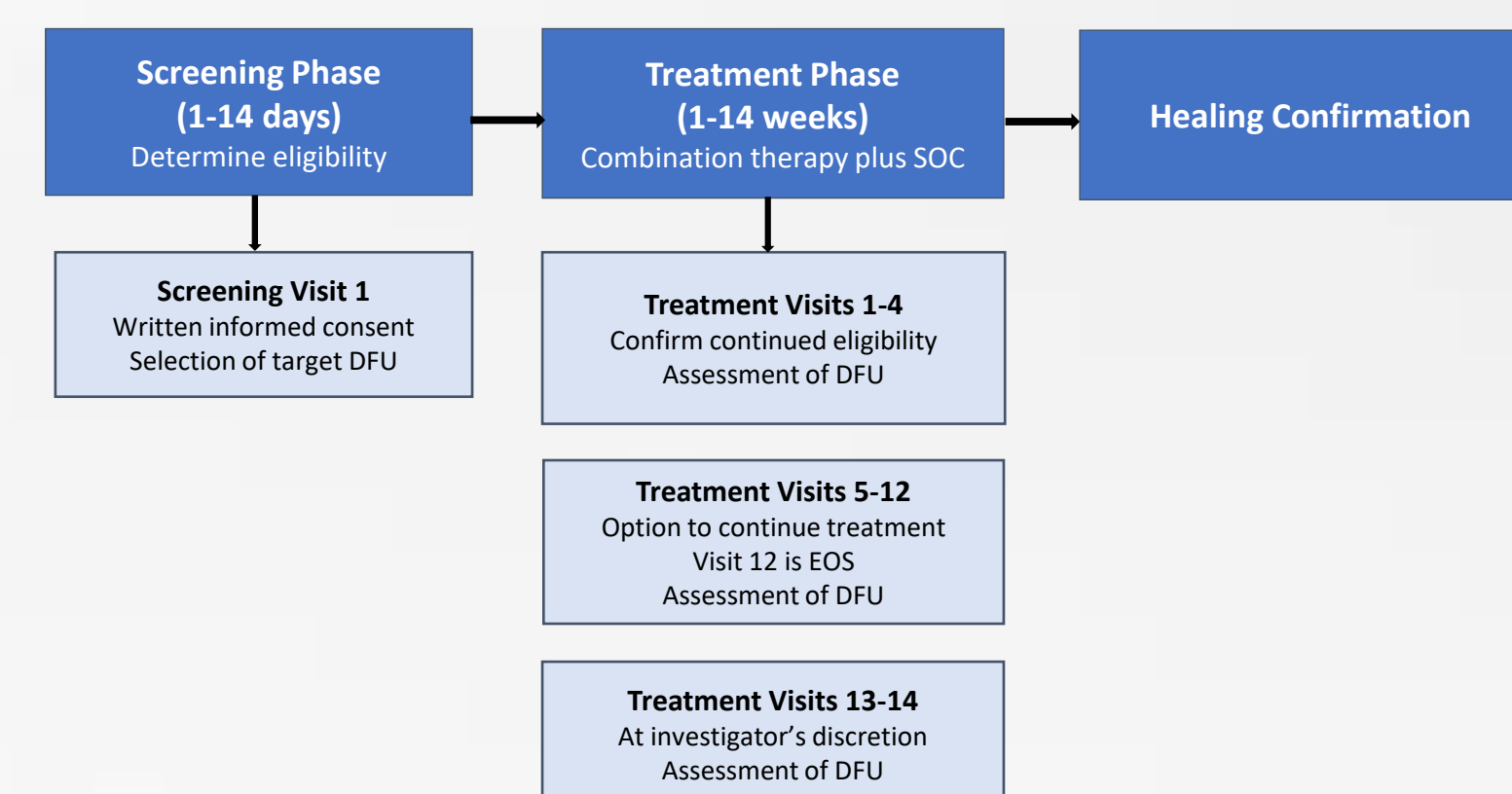
Methods

Study Design and Patients

- The study was conducted in 3 phases: screening, treatment, and healing confirmation (Figure 1)
- During the treatment phase, patients' DFUs were managed with combination therapy plus SOC (off-loading)

- At the end of 4 weeks of treatment visits, patients whose DFUs had not healed had the option of continuing therapy for up to 8 additional weeks; if needed, patients could receive 2 additional weeks of therapy at the investigator's discretion
- Complete healing of the study ulcer was defined as 100% re-epithelialization

Figure 1. Study design.



Abbreviations: EOS, end of study; DFU, diabetic foot ulcer; SOC, standard of care.

- Key inclusion criteria
 - Adult (≥21 years) patients with Type 1 or Type 2 diabetes
 - Presence of a DFU (Wagner grade 1 or 2) extending at least through the dermis
 - Target DFU was located on foot or ankle and, if 2 or more are present, was the largest
 - Study ulcer must have been present for at least 1 month at date of signed consent
 - Study ulcer size between 0.5 cm² and 100 cm²
- Key exclusion criteria
 - Study ulcer with signs and symptoms of infection
 - Patients with a BMI >65 or who were active smokers, were undergoing dialysis, or had active cancer
 - Patients with a history of immunodeficiency or any illness that could interfere with wound healing, untreated osteomyelitis or bone infection, hepatitis, acute deep vein thrombosis, or unstable Charcot foot
- Data were analyzed using descriptive statistics
- Results of an interim analysis are presented

Results

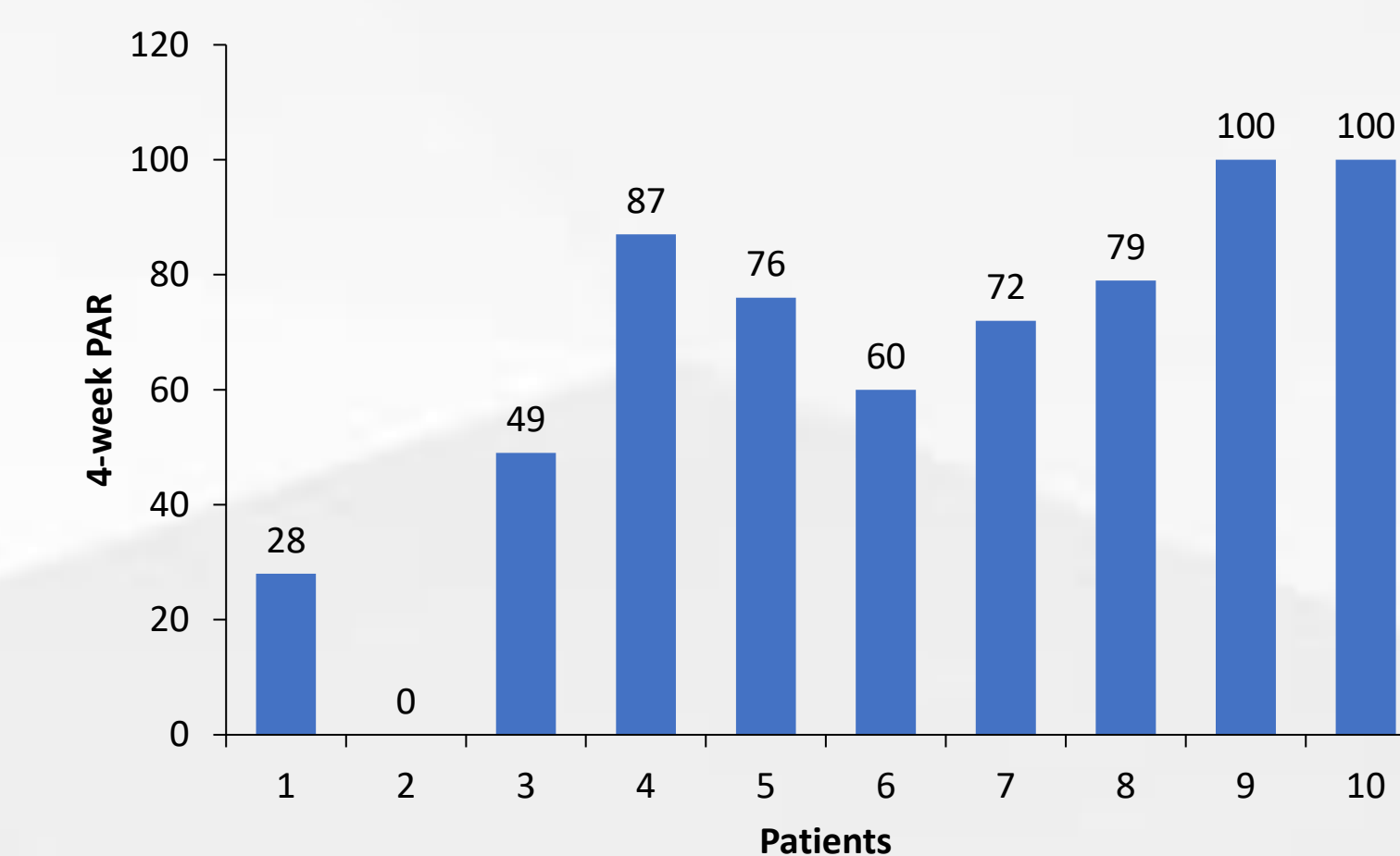
Patients

- Twelve patients were included in this interim analysis
- One patient died as a result of comorbidities before completing the study
- Median age was 55 years (range, 44 to 67), and median wound duration was 40 weeks (range, 4-72)

Efficacy and Safety

- Average 4-week PAR was 63%
 - At treatment visit 1, median wound size was 1.3 cm² (range, 0.37-25.0)
 - At treatment visit 5, median wound size was reduced to 0.57 cm² (range, 0-10.06)
 - Two patients experienced complete closure of their DFUs at week 4 (Figure 2)
 - One patient who had a DFU of 48 weeks duration prior to treatment had a PAR of 45% but did not pursue the continued treatment option

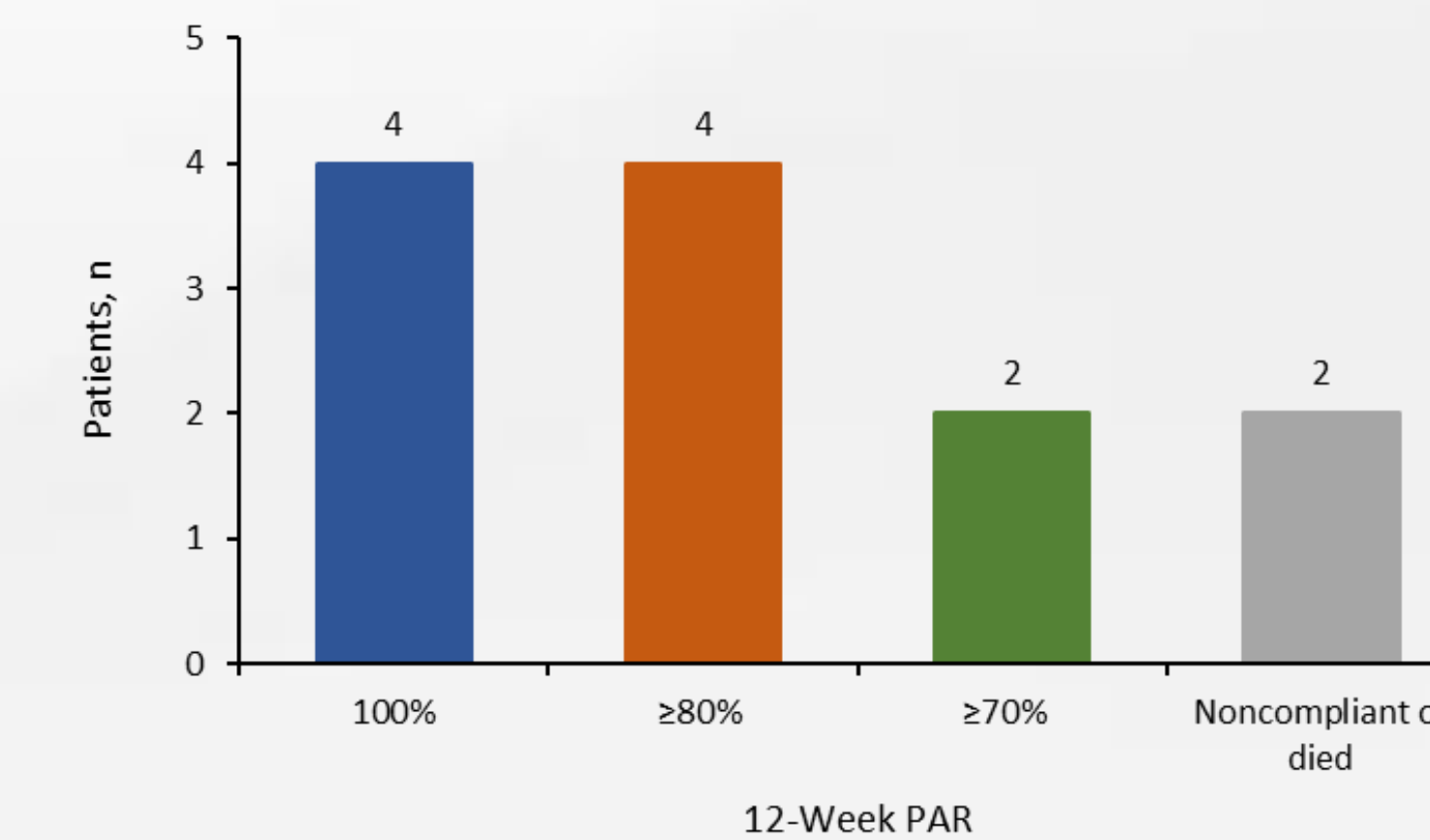
Figure 2. Percentage closure of patients' DFUs after 4 weeks of treatment (4-week PAR).



Abbreviation: PAR, percent area reduction.

- Average 12-week PAR was 91%
 - At treatment visit 12, median wound size was further reduced to 0.13 cm² (range, 0-2.59)
 - 2 additional patients had complete closure of their DFUs; both of these cases were of ≥1 year duration prior to combination therapy and SOC (Figure 3)

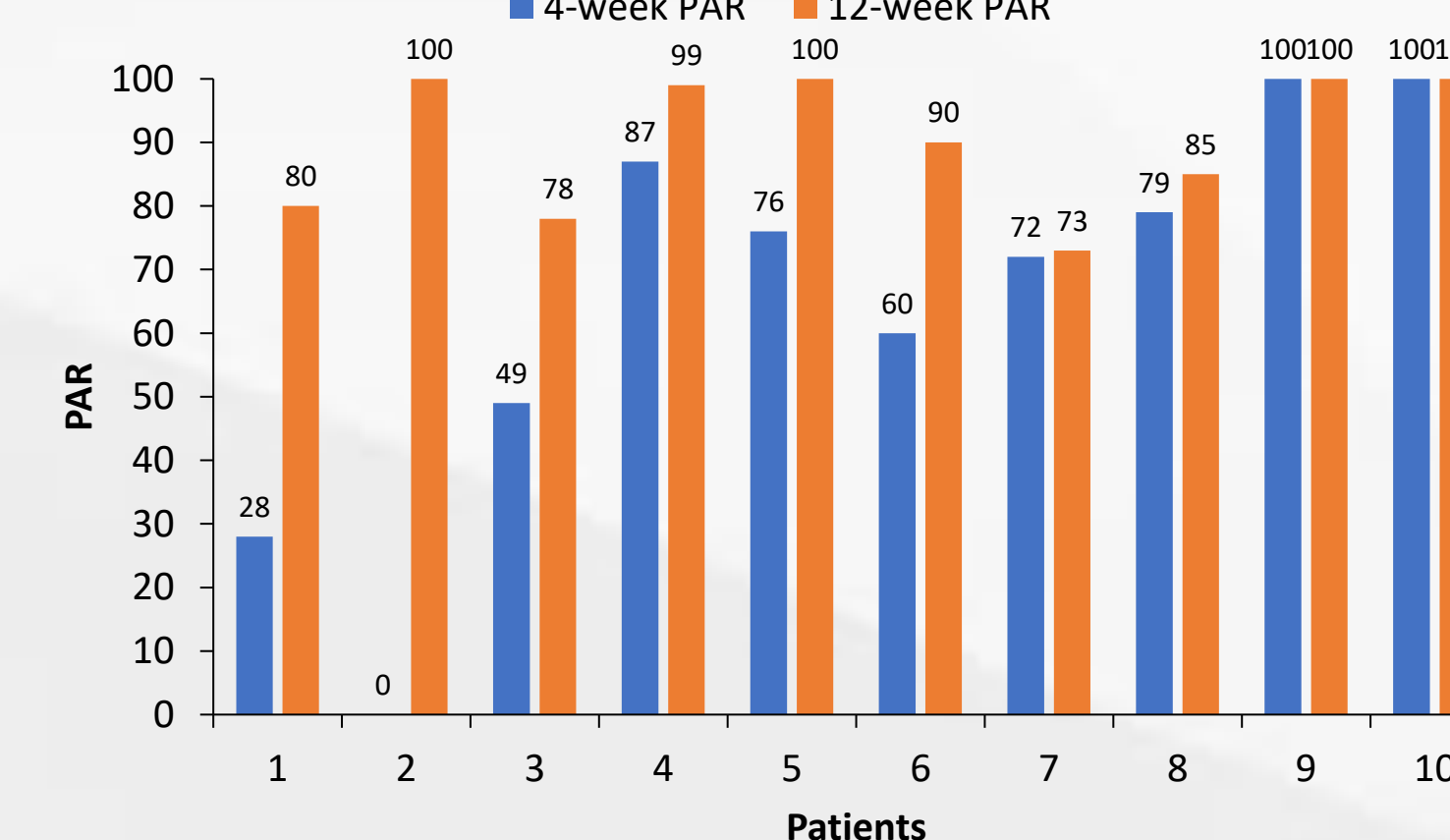
Figure 3. Summary of the percentage closure of patients' DFUs at end of the study (12-week PARs).



Abbreviation: PAR, percent area reduction.

- A total of 10 patients had PAR measurements at week 4 and week 12 (Figure 4)
 - 10 of 12 patients' wounds improved throughout the study
 - One patient's wound healed after week 12 (12-week PAR of 90%)
 - One patient with a 12-week PAR of 73% continued to improve through week 14
 - Three patients' wounds had not healed at the time of analysis (12-week PARs of 78%, 80%, and 85%)

Figure 4. PAR of patients with wound measurements at week 4 and week 12.



Abbreviation: PAR, percent area reduction.

Conclusions

- Results of this interim analysis of a clinical trial show encouraging healing rates (average PAR of 63% at 4 weeks and 91% at 12 weeks) of DFUs that were managed with a novel combination therapy and SOC
- Some patients included in the analysis had comorbid conditions that negatively affected their innate healing abilities
- No adverse events related to treatment were reported during the study
- Final results of this study are forthcoming
- Additional clinical trials evaluating the combination therapy for the treatment of VLUs (NCT05291169) and wounds/ulcers of multiple etiologies (NCT05921292) are underway
- Studies assessing the combination therapy in real-world settings are also underway, and those results will expand and enhance the current evidence supporting use of the combination therapy in multiple types of chronic or refractory wounds

REFERENCES

- Edmonds M, et al. *J Clin Orthop Trauma*. 2021;17:88.
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DISCLOSURES

DB: Employee, Omeza, LLC.
 SS: Research support, Omeza, LLC.
 MC: Research support, Omeza, LLC.
 RS: Research support, Omeza, LLC.

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