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

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.1-3
- 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:
  1. A wound preparation formulation (SCW)
  2. A skin protection formulation (SCB)
  3. DCM or 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 (NCT04574245).

Objectives and Endpoints

- Primary objectives were to evaluate safety of combination therapy plus SOC (off-label) 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 12 weeks of treatment (Figure 1).
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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-label).
- 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.

- The study was sponsored by Omeza LLC (Sarasota, FL, US). Medical writing and editorial assistance were provided by Mediscience Information Services, LLC (Pittsburgh, NS, USA), and were funded by Omeza, LLC.

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 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 93% but did not pursue the continued treatment option.

- Twelve patients were included in this interim analysis.
- Average PAR was 91%.
  - At treatment visit 12, median wound size was further reduced to 0.13 cm² (range, 0-2.59).
  - Two additional patients had complete closure of their DFUs; both of these cases were of 51 year duration prior to combination therapy and SOC (Figure 3).

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 (NCT07592129) are underway.
- Studies assessing the combination therapy in real-world settings are also underway, and these results will expand and enhance the current evidence supporting use of the combination therapy in multiple types of chronic or refractory wounds.

REFERENCES

DISCLOSURES
- DM is an employee, Omeza, LLC.
- ES is a consultant, Omeza, LLC.
- JX is a consultant, Omeza, LLC.
- BG is an employee, Omeza, LLC.

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