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An Open-Label Study of Allogeneic Fibroblasts in the Treatment of Chronic Neuropathic Diabetic Foot Ulcers

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Aim: This open-label study was designed to evaluate the safety and efficacy of allogeneic human dermal fibroblasts (HDFs) in subjects with chronic neuropathic diabetic foot ulcers (DFUs). It was anticipated that HDFs would actively contribute to wound healing when used in association with existing standard of care. **Methods:** Nine subjects with non-ischaemic neuropathic DFUs measuring <20cm^2 and of ≥4 weeks duration and which had not responded to conventional therapy were given up to eight applications of HDFs over a 20 week period. The HDFs, presented in a fibrin–based matrix gel, were applied topically to selected DFUs and were administered in association with standard of care including sharp surgical debridement, maintenance of a clean moist ulcer environment, assessment of ulcer progress, pressure relief by off-loading and infection management. Adverse events were monitored throughout the 24 week study period and efficacy was assessed by monitoring the selected ulcers for complete ulcer closure, the overall rate of ulcer area reduction, the time to first closure and any change in the ulcer area during the study. **Results:** No related serious adverse events have been reported to date. Of the nine subjects enrolled, two (22%) withdrew voluntarily. Of the remainder, two (22%) showed complete wound closure by 12 and 16 weeks respectively, two (22%) showed almost complete closure by 24 weeks (in one of these subjects complete closure was observed at 26 weeks) and two (22%) have shown no significant improvement. One subject has yet to be evaluated. **Conclusion:** Preliminary data are encouraging with four (44%) subjects showing either complete or almost complete wound closure by 24 weeks. These results merit further clinical evaluation of the use of topically-applied HDFs in the management of chronic neuropathic DFUs.