A PHASE I/IIA OPEN-LABEL CLINICAL TRIAL EVALUATING THE SAFETY AND PRELIMINARY EFFICACY OF ELU42, A SMALL-MOLECULE WNT-SIGNALING MODULATOR, IN THE TREATMENT OF DIABETIC FOOT ULCERS

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26-WEEK PROTOCOL TIMELINE: PRELIMINARY DATA FOR THE FIRST FIVE SUBJECTS TREATED WITH ELU42

2-week Screening: Standard of Care including off-loading (SOC only)

ELU42 Spray-on Treatment Period: ≤6 weeks; ≤18 doses; 3x weekly (SOC + IP)

DFU Follow-up Period: Post-IP/Closure ≤4.5 months (SOC only)

ABSTRACT

Background: Chronic diabetic foot ulcers (DFUs) are responsible for substantial morbidity and healthcare costs. ELU42 is a first-in-class topical small-molecule Wnt-signaling modulator formulated as a clinic-ready spray intended to accelerate re-epithelialization and improve durable wound closure. This actively enrolling Phase I/IIA study evaluates safety, systemic exposure, and preliminary efficacy of ELU42 [1mg/ml sterile solution, administered topically] in adults with Wagner Grade 1 and 2 DFUs.

Methods: This single-arm, open-label trial will enroll up to 27 subjects ages 18–75 with chronic Wagner Grade 1 and 2 DFUs that failed standard of care (SOC) with offloading. Key entry criteria: post-debridement index ulcer 1.0–8.0 cm² and HbA1c ≤ 11%. ELU42 is applied three times weekly for up to six weeks; re-treatment is permitted (with maximum of 18 doses) if the index ulcer reopens after initial closure. Safety monitoring includes CBC, CMP, albumin/pre-albumin,12-lead ECGs at Screening, Week 3, and Week 6; and monthly urine pregnancy testing for women of childbearing potential. PK sampling occurs at Weeks 1, 3, and 6 of the Treatment Period (SOC + IP). Efficacy is assessed by validated planimetry (Tissue Analytics) with percent surface area reduction (PAR) as a co-primary endpoint and complete wound closure (100% re-epithelialization + absence of drainage) as an exploratory endpoint through study Week 14.

Preliminary Results (first 5 treated subjects): (Table 1) The first five subjects completed the 2-week Screening Period (SOC) and subsequent ≤6 week Treatment Period (SOC + IP, three times weekly) with ELU42 until complete wound closure or reaching the maximum of 18 doses. Baseline (post-SOC) mean PAR = 1.114% (SD 23.73). After one week (three doses) mean PAR = 40.88% (SD 5.86). After four weeks (12 doses) mean PAR = 85.96% (SD 14.75), [see Figures 1, 2]. **No treatment-related adverse events, no clinically significant laboratory findings, and no ECG abnormalities attributable to ELU42 were observed.** Plasma parent compound levels were below the assay limit of quantification (<0.2 ng/mL) at all sampled timepoints with no evidence of accumulation.

Conclusion: In this early cohort, topical ELU42 demonstrated a favorable safety profile, negligible systemic exposure, and rapid, clinically meaningful reductions in wound area (mean PAR of 85.96% at four weeks). These preliminary results support continued enrollment in this trial, as well as a future pivotal clinical study to confirm the safety and efficacy of the use of topical ELU42 for accelerated durable DFU closure.

UNIQUE FEATURES OF ELU42

1) First-in-class, topical, bacteriostatic, small-molecule therapeutic spray targeting tankyrase (PARP5) to dynamically modulate Wnt signaling and promote regenerative healing in chronic diabetic foot ulcers (Wagner Grade 1 and 2).
2) Portable, sterile, clinic-ready format: A simple spray-on application is compatible with routine outpatient clinic workflows and intra-operative use for point-of-care benefit.
3) Stable at room temperature for over six months or frozen for more than one year, which eliminates cold-chain concerns.
4) Clinically well-tolerated and safe in the initial five subject cohort. No treatment-related serious adverse events or IP related adversities have been observed to date.
5) No systemic exposure: Active Principle Ingredient (API) not detected in plasma pharmacokinetic (PK) samples after one, seven, and 16 doses of ELU42 in any subjects to date.

SuperHealer™ TRIAL: FIRST 5 SUBJECTS EXCEED 4-WEEK EFFICACY ENDPOINT

Mean Age Years	Sex M/F	Mean Area (cm ²) at Screening	Mean Area (cm²) at onset of ELU42	Mean Area (cm²) on Day 7 of ELU42	Mean Area (cm²) on Day 28 of ELU42	Area Δ Day 7: after 3 doses	Area Δ Day 28: after 12 doses
69.4	4/1	1.55 cm²	1.48 cm²	0.89 cm²	0.19 cm²	-40.88%	-85.96%

Table 1: Summary of mean age, DFU surface area at Screening and at ELU42 Treatment Day 0, 7, and 28 | Mean PAR after one and four weeks of ELU42 application: **4 WEEK PAR = 85.96%**

Note: An area Δ of -85.96% is equivalent to a percent surface area reduction (PAR) of 85.96%.

ELU42 ACCELERATES DFU CLOSURE AT 4-WEEKS (FDA BENCHMARK)

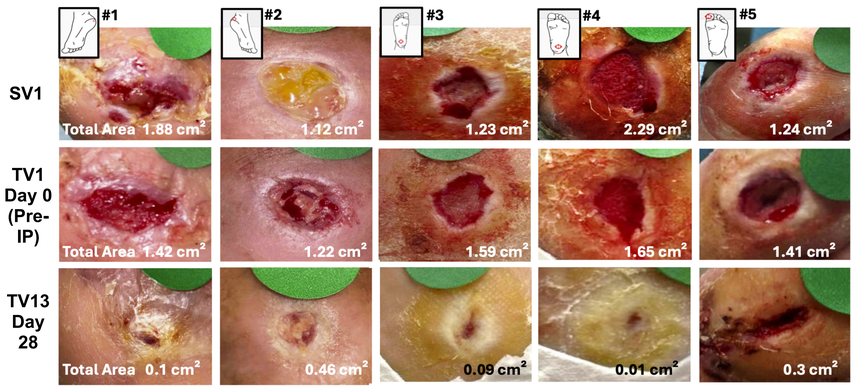

Figure 1: Initial five subjects' wound images at Screening Visit 1, Initiation of IP on Day 0, and on Day 28 after 12 treatments of IP (spray-on ELU42 IP, three times weekly) to Wagner 1 and 2 DFUs). **Primary benchmark at 4 weeks >50% PAR achieved in all five subjects.**

ELU42 - BREAKTHROUGH CANDIDATE: >50% PAR IN FIRST 5 ENROLLED SUBJECTS

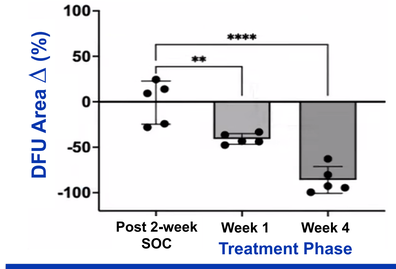

Figure 2: This graph displays the percent change (Δ) in surface area in DFU Wagner 1 and 2 from TV1 to TV13 in the first five subjects. The PAR after 2-week Screening (SOC) was not clinically significant. In the Treatment Phase (SOC + IP) [one week (three doses)] there was a significant decrease in DFU area ($p<0.001$); and, after four weeks (12 doses), there was a clinically significant mean percent surface area reduction (PAR) of 85.96% in DFU ($p<0.0001$) relative to the beginning of ELU42 administration.

ACKNOWLEDGMENTS

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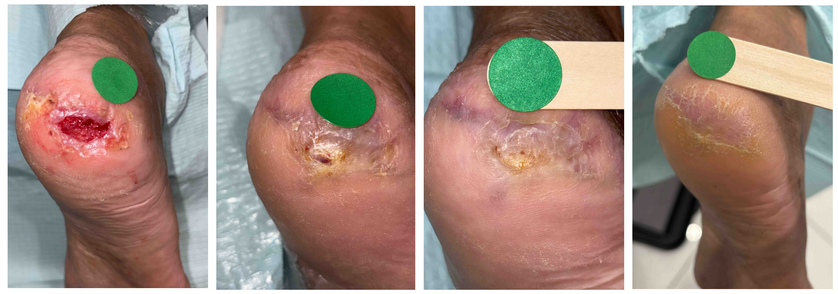
Clinical Trial CRO: Total Diversity, Dallas, TX.

Image capture: Net Health® Tissue Analytics, Pittsburgh, PA.

PATIENT REPORTED OUTCOMES

Preliminary Wound-Q results in the first five subject shows improved social impact, wound characteristics, and daily functioning. Pain scale (NPRS) scores also improved.

DURABLE DFU HEALING WITH ELU42



TV1: Day 0 Initial IP Application | **TV13: Day 28 After 12 Applications (PAR 92.65%)** | **TV17: Day 38 Wound Closure After 17 Applications** | **12-week Follow-Up: Confirmed Durable Wound Healing**

Figure 3: The first subject reached complete healing with 17 doses of ELU42 and has remained healed at 12 weeks post-IP dosing, without recurrence, demonstrating durable DFU closure.

MECHANISM OF ACTION

Target: Wnt pathway; small molecule ELU42 promotes regenerative tissue repair via stem cell recruitment and Wnt pathway dynamic modulation.

Impact: Early Wnt dynamic modulation followed by local reparative signaling promoting organized granulation, neo-vascularization, dermal appendage restoration, basket-weave pattern of collagen and reduced fibrosis.

SAFETY AND PHARMACOLOGY

Local tolerability: Excellent; no unexpected local reactions in first cohort.
Systemic Safety: No treatment-related SAEs; routine labs and ECGs without clinically meaningful abnormalities.
PK: Parent compound below assay lower limit of quantification (LLOQ) in scheduled samples; thus, metabolite testing not clinically indicated.
Safety: No treatment-related serious adverse events were observed in the first evaluable cohort.

CONCLUSION

1) ELU42 (1mg/ml) sterile topical spray has demonstrated a favorable safety and efficacy profile (co-primary endpoint) in the first five subjects treated.
2) ELU42 has yielded significant, clinically meaningful reductions in wound surface areas, with **a mean PAR of 85.96% at four weeks** (exceeding co-primary endpoint).
3) Early Breakthrough status reached in healing of DFU by four weeks (>50% PAR).

REFERENCES

SuperHealer™ Clinical Trial: "Protocol ELU42-01-01: Phase I/IIA, Open Label, Single Arm Evaluation of Topical ELU42 (XAV939 in DHA77) for Wagner Grade 1-2 Diabetic Foot Ulcers"; ClinicalTrials.gov ID: NCT07396376; IND169928.
Standard of Care/Protocol: Lead Consultant-Vicki Driver DPM, MS, FACFAS
FDA Perspective Article: Verma KD, et al. Advancing product development for non-healing chronic wounds. Wound Repair Regen. 2022 May;30(3):299-302. doi: 10.1111/wrr.13008.
Patent: Compositions and methods for wound treatment; Daniel Holsworth; US12059469B2.
2026 WHS Poster: "ELU42 Mechanism of Action" by Sarika Saraswati

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