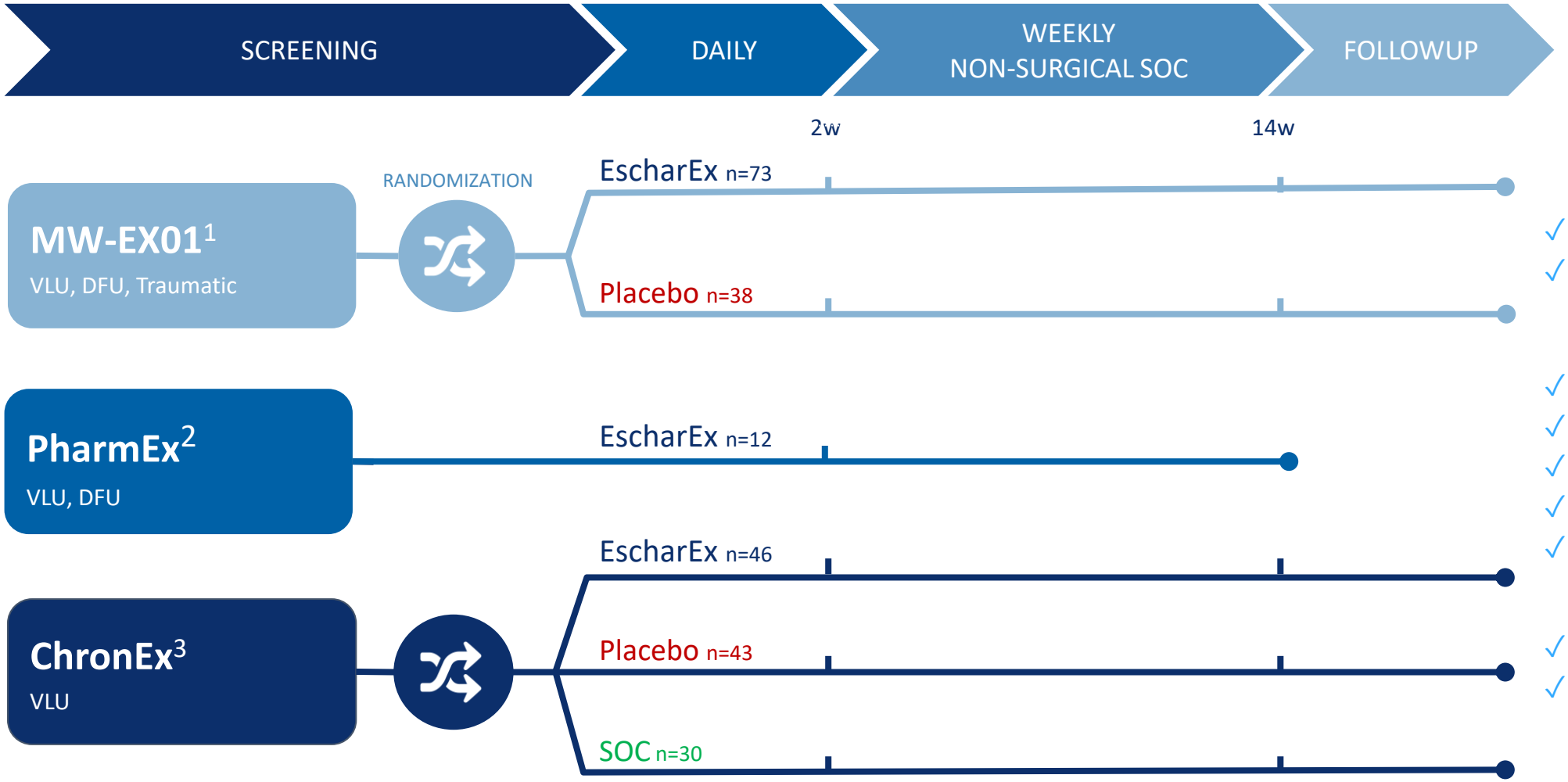
VALUE

EscharEx® VLU Phase III

SAWC Symposium

April 10th, 2025

Robust and Consistent Results in Three Phase 2 Studies

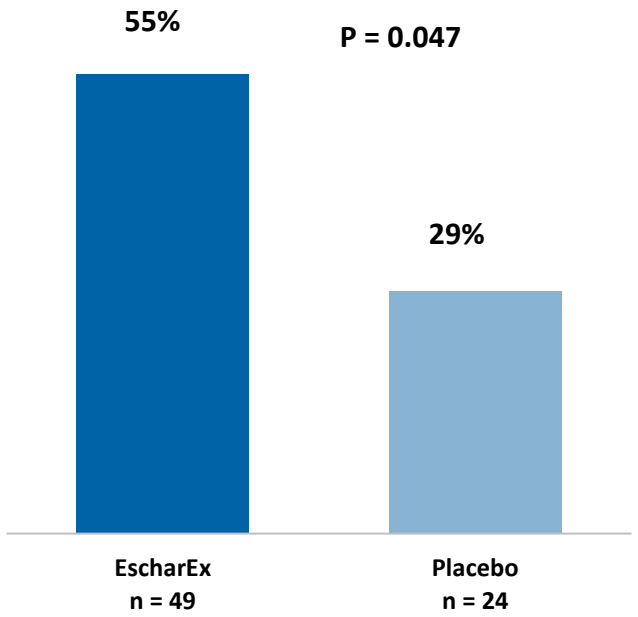


1. Shoham et al. 2021; Wound Rep Reg **2.** Snyder et al. 2023; Wounds Journal **3.** Shoham et al. 2024; LANCET's eClinicalMedicine

MW-EX01: Primary Endpoint Significantly Met

Incidence of complete debridement

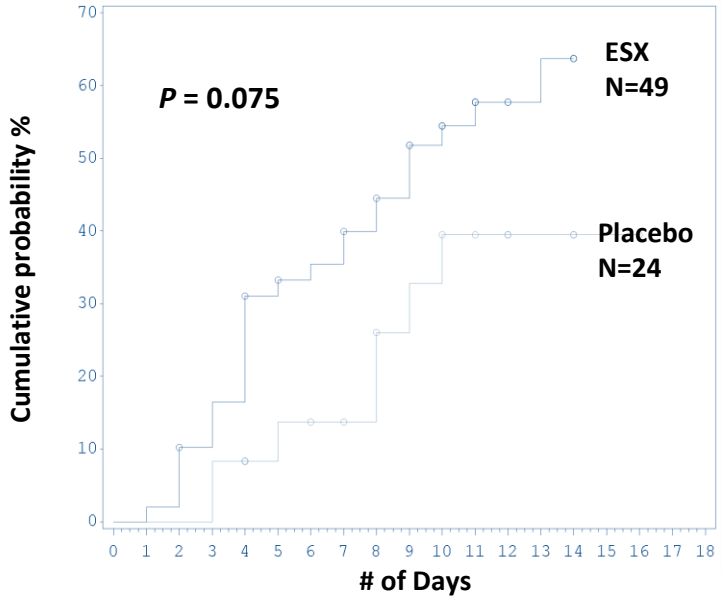
(VLU, DFU, Traumatic ulcers)



Significantly higher incidence of complete debridement

Time to complete debridement

(VLU, DFU, Traumatic ulcers)



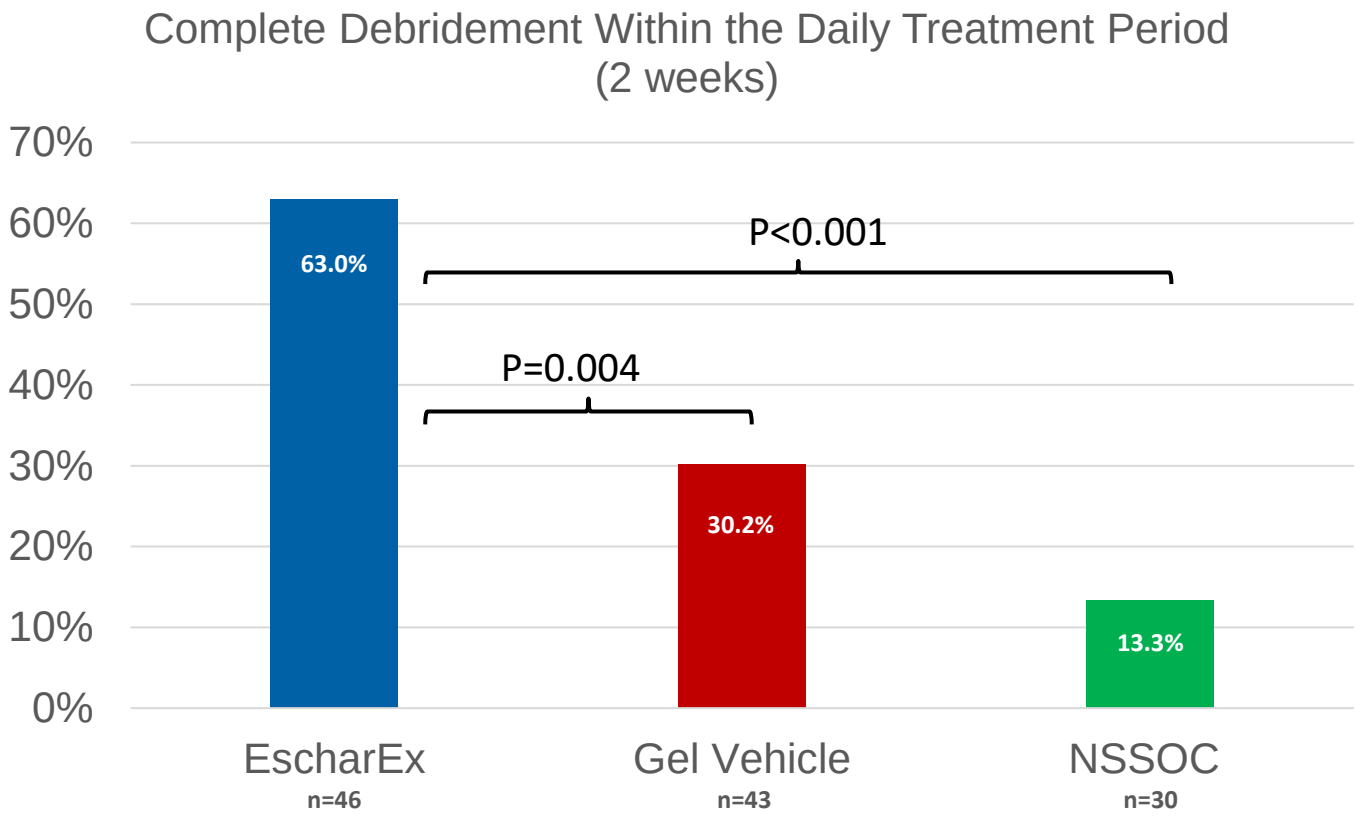
Shorter time to achieve complete debridement

Over 90% of the patients who completed debridement with EscharEx® were debrided within 7 days (4-5 daily applications)

MediWound

Shoham et al. 2021; Wound Rep Reg

ChronEx: Incidence of Complete Debridement



EscharEx® achieved a significantly higher incidence of complete debridement compared to both placebo (primary end point) and NSSOC

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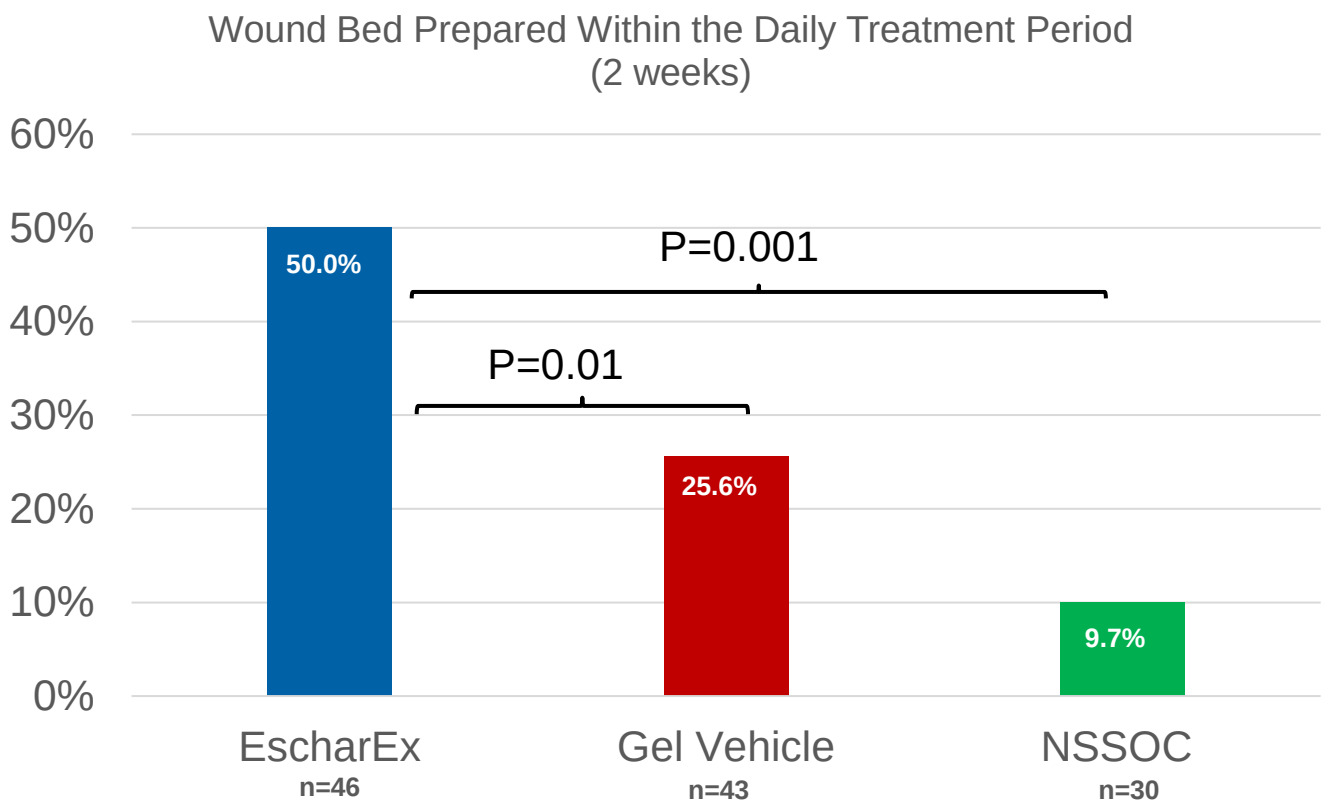
Shoham et al. 2024; LANCET's eClinicalMedicine

ChronEx: Incidence of Wound Bed Prepared

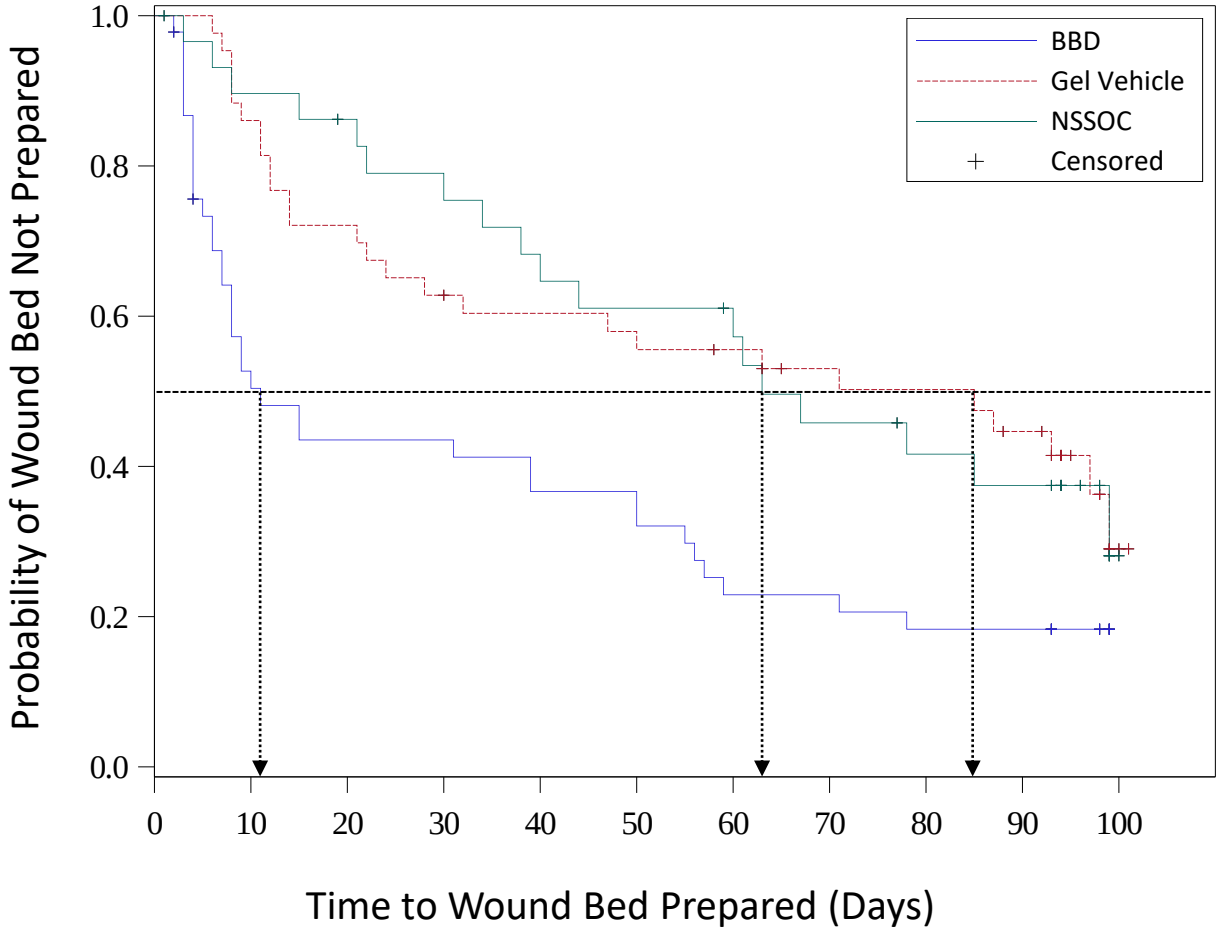


Wound Bed Prepared (WBP)

Complete debridement and complete cover of the wound bed with granulation tissue

The incidence of WBP on EscharEx was significantly higher vs. the Gel Vehicle and NSSOC within the daily visits period (2 weeks)

ChronEx: Faster Time to Wound Bed Preparation



Estimated median time to WBP

EscharEx®: 11 days vs.

- NSSOC: 63 days (P=0.01)
- Gel Vehicle: 85 days (P=0.004)

EscharEx achieved wound bed prepared significantly faster than Gel Vehicle and NSSOC

Shoham et al. 2024; LANCET's eClinicalMedicine

EscharEx® Planned VALUE Phase 3 Study in VLU Patients

STUDY OBJECTIVES

To assess safety and efficacy of EscharEx compared to placebo in VLU patients

STUDY DESIGN

A global (US, EU, ROW), randomized, double blind, adaptive design study in VLU patients

Two arms: EscharEx vs. placebo, 1:1 ratio

Sample size: 216 VLU patients

Study design:

- Daily treatment: Up to 8 applications over 2 weeks, followed by 10 weeks of standardized wound management
- Active wound closure (CTP/ autograft) for patients reaching WBP
- 12 weeks durability follow-up for patients that reached wound closure

Pre-defined interim assessment: Conducted after 65% of patients completed the initial 12-week period

ENDPOINTS

Co-primary:

Incidence of complete debridement

Incidence of complete wound closure

Secondary:

Incidence of 100% granulation tissue

Time to complete debridement

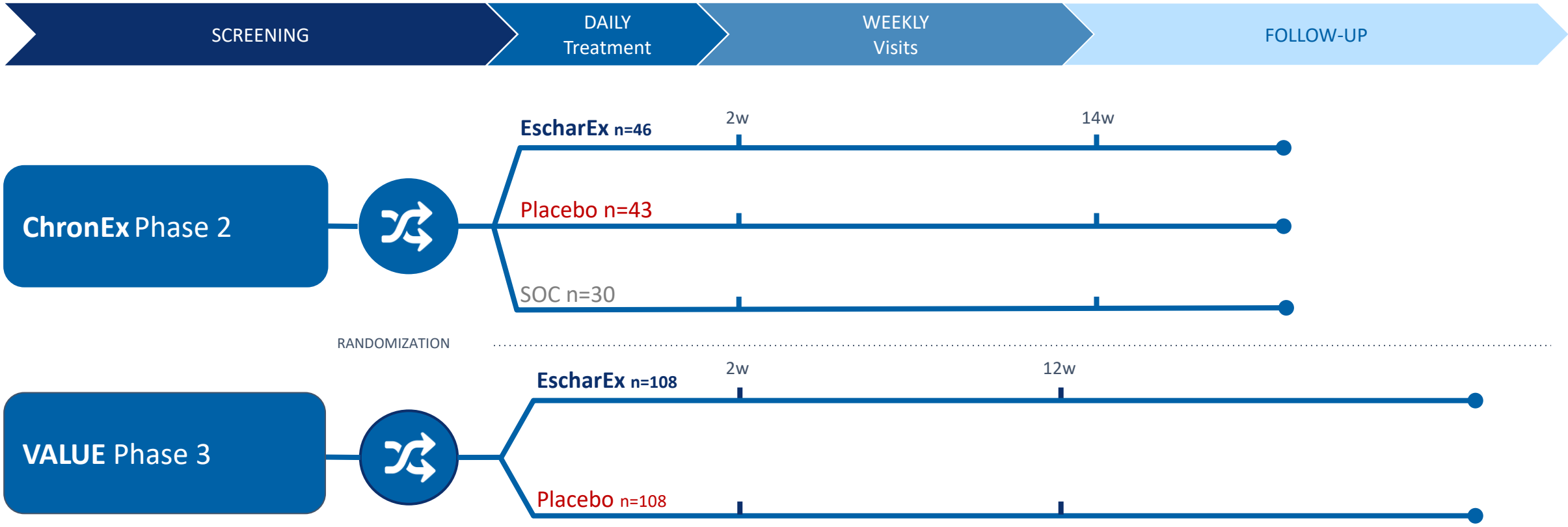
Time to complete wound closure

Change in wound area

Safety:

Safety & tolerability | ECG | Change in pain | Wound infection rates | Immunogenicity

VALUE Study: Based on successful Phase 2 with Key Enhancements

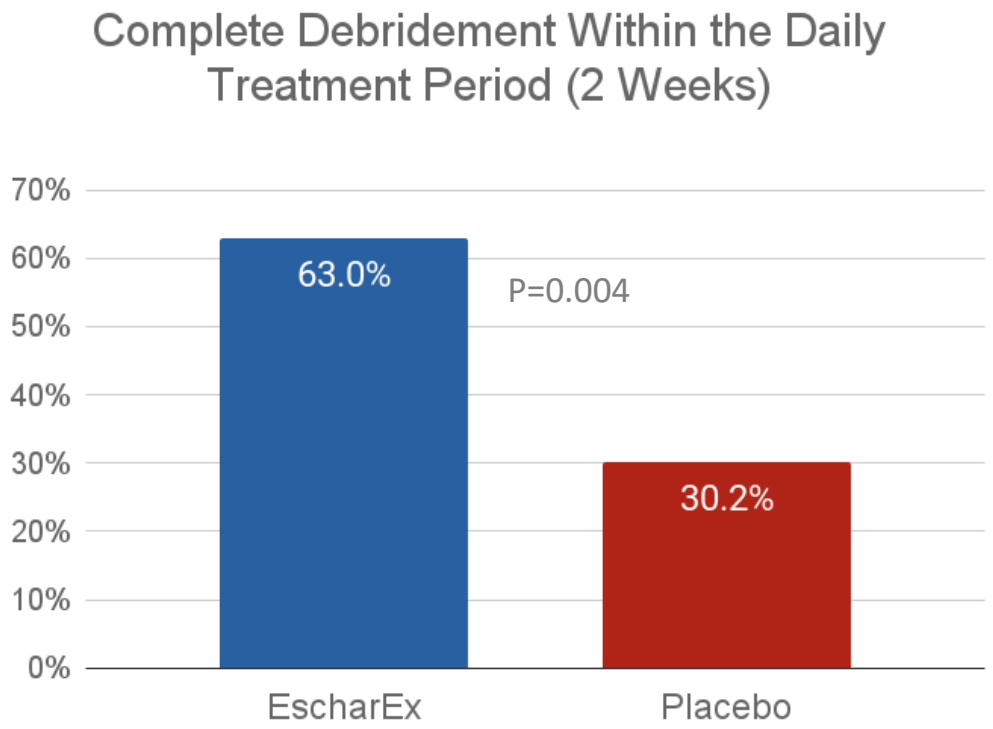


- ✓ Sample size based on ChronEx data vs placebo
- ✓ Interim analysis for sample size re-assessment
- ✓ Mandatory active wound closure (CTP/autograft)
- ✓ Standardized dressings

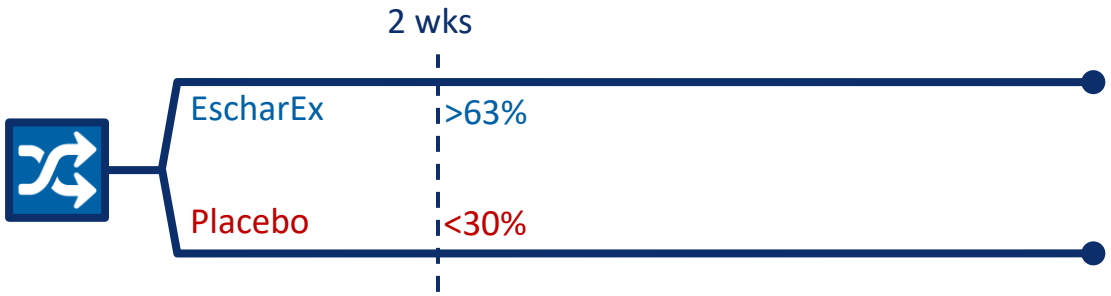
Projected Superiority in Incidence of Complete Debridement

ChronEx Phase 2 → **VALUE Phase 3**

1st co-primary endpoint



Projected outcome

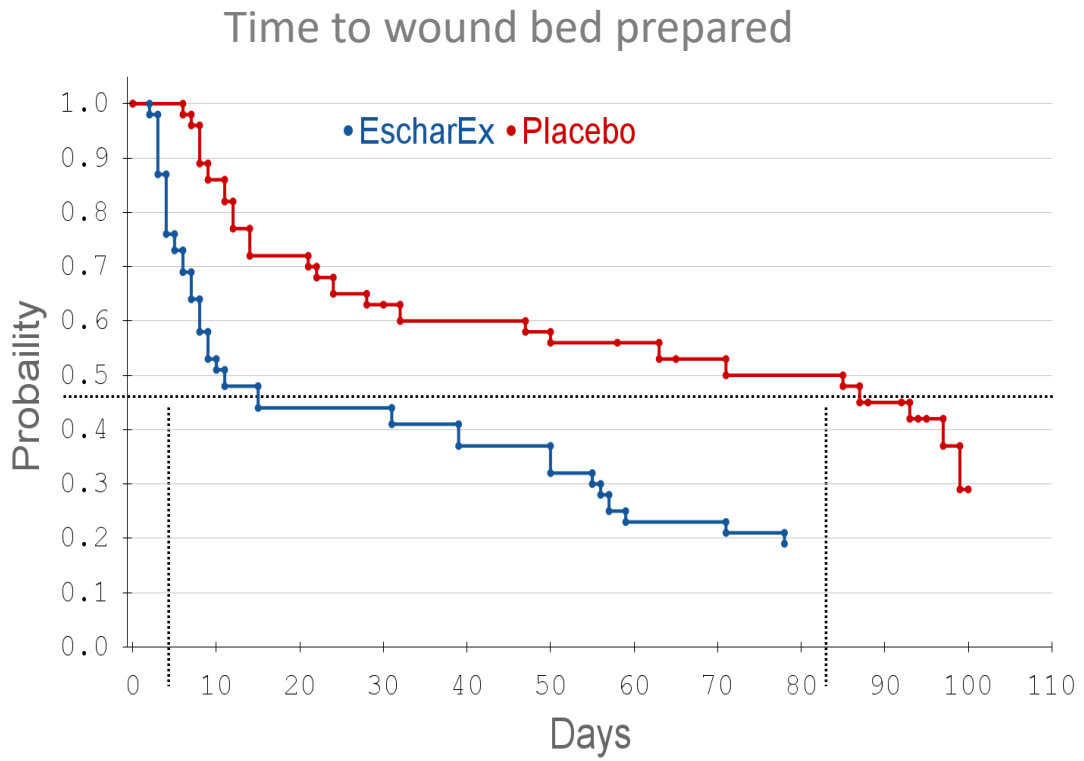


- **Same endpoint**
  Incidence of complete debridement
- **Larger sample size**
  89 → 216
  99% power

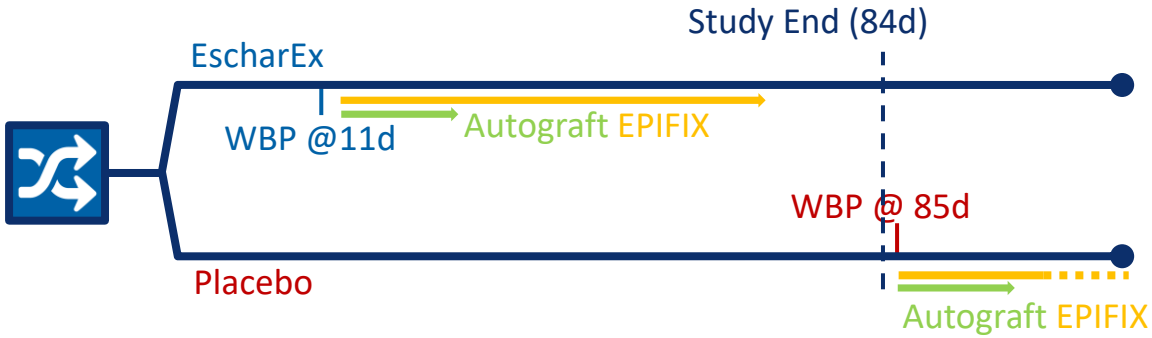
Projected Superiority in Incidence of Wound Closure

ChronEx Phase 2 → **VALUE Phase 3**

2nd co-primary endpoint



Projected outcome



- **Favorable endpoint**
  Mandatory active closure, with projected 74-day head start
- **Standardized treatment**
  Throughout study period
- **Larger sample size**
  89 → 216
  >85% power
  Interim analysis for sample size re-assessment

EscharEx for VLU – Summary

- Phase 2 data show robustness and consistency
- Phase 3 study design based on the successful ChronEx Phase 2 trial with adjustments
  - ***Shorter trial period*** *lowers the likelihood of placebo achieving wound bed preparation*
  - ***Increased sample size*** *(89 → 216) ensures >85% power*
  - ***Mandatory active wound closure*** *(Autograft/CTP) after wound bed preparation (collaboration with MIMEDX)*
  - ***Standardized dressings*** *(Collaborations with Solventum, Mölnlycke) to reduce variability and enhance consistency in wound management*
- VALUE phase 3 study is ongoing and recruiting patients globally

Thank you!

MediWound