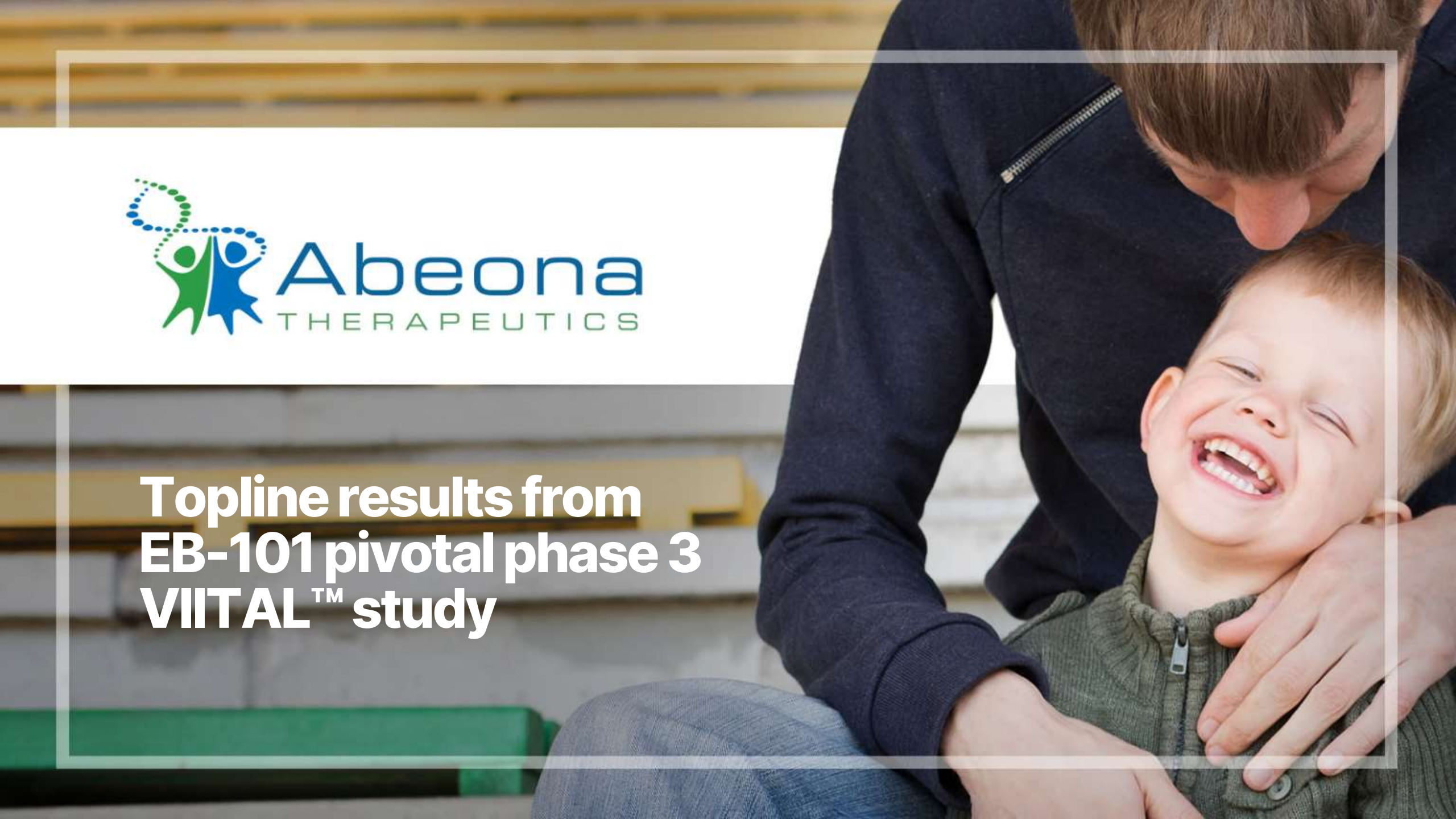
Abeona THERAPEUTICS

Topline results from EB-101 pivotal phase 3 VIITAL™ study



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Agenda

- Introduction
  Vish Seshadri, Chief Executive Officer
- Recessive dystrophic epidermolysis bullosa (RDEB) and EB-101
  Vish Seshadri, Chief Executive Officer
- VIITAL study topline results
  Igor Grachev, M.D., Ph.D., Head of Clinical Development
- Takeaways for EB-101 and next steps
  Vish Seshadri, Chief Executive Officer
- Q&A

Large chronic
RDEB wounds are the most painful, hard to treat wounds that inflict the greatest burden on patients & their families

EB-101's unique value proposition

EB-101 is the only investigative therapy targeting **large chronic** wounds, demonstrating **wound healing** and **pain reduction** with multiple years of **durability** after treatment[1,2]

1. https://clinicaltrials.gov/ct2/show/NCT04227106 2. So et al. Orphanet Journal of Rare Diseases (2022) 17:377

Positive VIITAL results: EB-101 delivers clinically meaningful wound healing and pain reduction in large chronic RDEB wounds

Statistically significant improvement vs. control at 6 months:

- ≥50% wound healing rate (co-primary endpoint)
- Pain reduction (co-primary endpoint)
- ≥75% wound healing rate (exploratory endpoint)
- Complete wound healing (secondary endpoint)

EB-101 was well-tolerated with no serious treatment-related adverse events observed, consistent with past clinical experience

≥50% wound healing at 6 months:[1]

81% vs. **16%**

EB-101 treated wounds

control untreated wounds

P<0.0001

Mean pain reduction associated with wound dressing changes (using Wong-Baker FACES scale) at 6 months:[2]

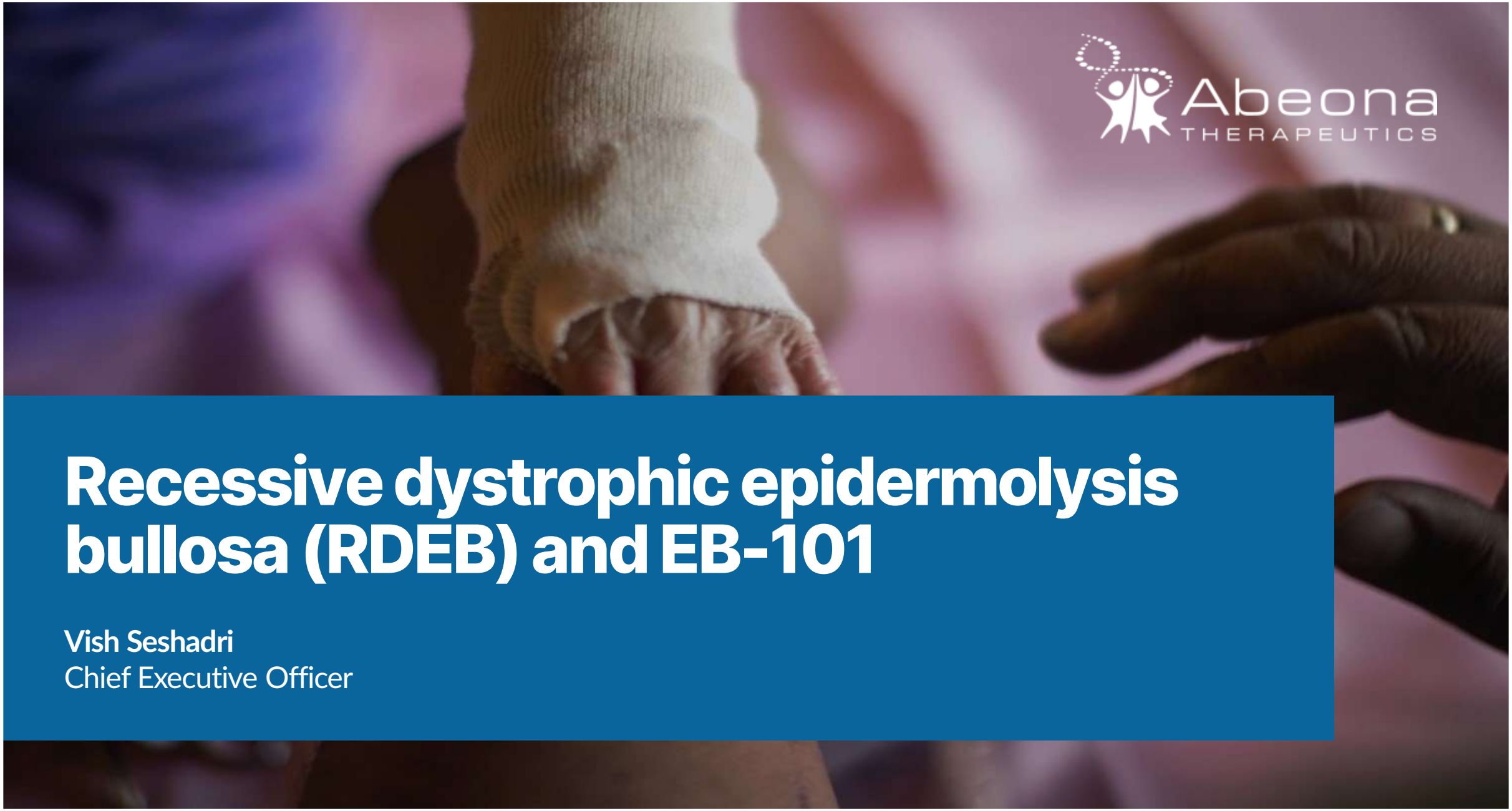
3.07 vs. **0.90**

EB-101 treated wounds

control untreated wounds

P=0.0002

1. Two-sided p-value calculated from permutation test using randomized wound pairs (n=43)
2. Two-sided p-value calculated from permutation test using randomized wound pairs (n=42)

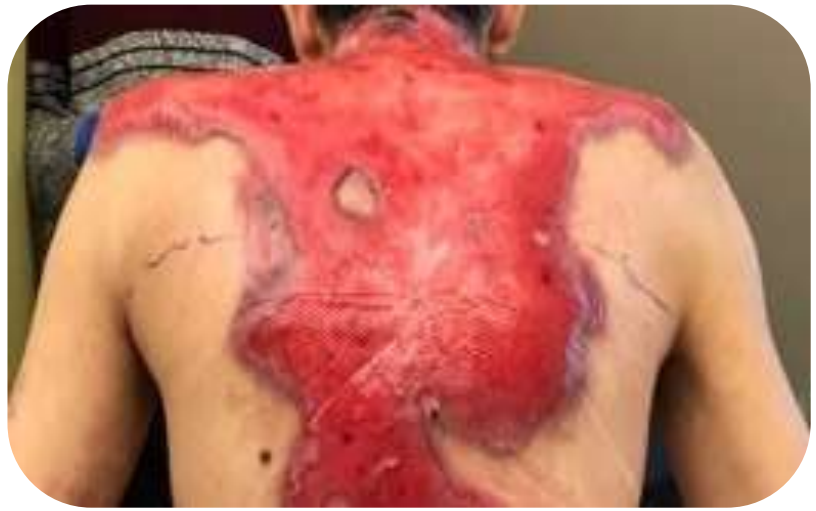


Recessive dystrophic epidermolysis bullosa (RDEB) and EB-101

Vish Seshadri
Chief Executive Officer

Recessive dystrophic epidermolysis bullosa (RDEB) is a painful disease with lifelong burden afflicting thousands of U.S. patients

- Inherited connective tissue disorder with debilitating pain and systemic complications leading to early death
- Primarily characterized by skin blisters and erosions
- Caused by mutations in COL7A1 gene, which encodes type VII collagen
- Estimated 3,850 U.S. patients[1]
- Up to 80% of patient's body covered in wounds, leading to:
  - Severe pain and widespread scarring
  - Numerous debilitating and life-threatening systemic complications
  - Inflammation, infections, loss of heat - high metabolic rate and malnutrition
  - 75-90% risk of developing squamous cell carcinoma (SCC)
- Heavy clinical, economic and humanistic burden with no approved treatment or cure

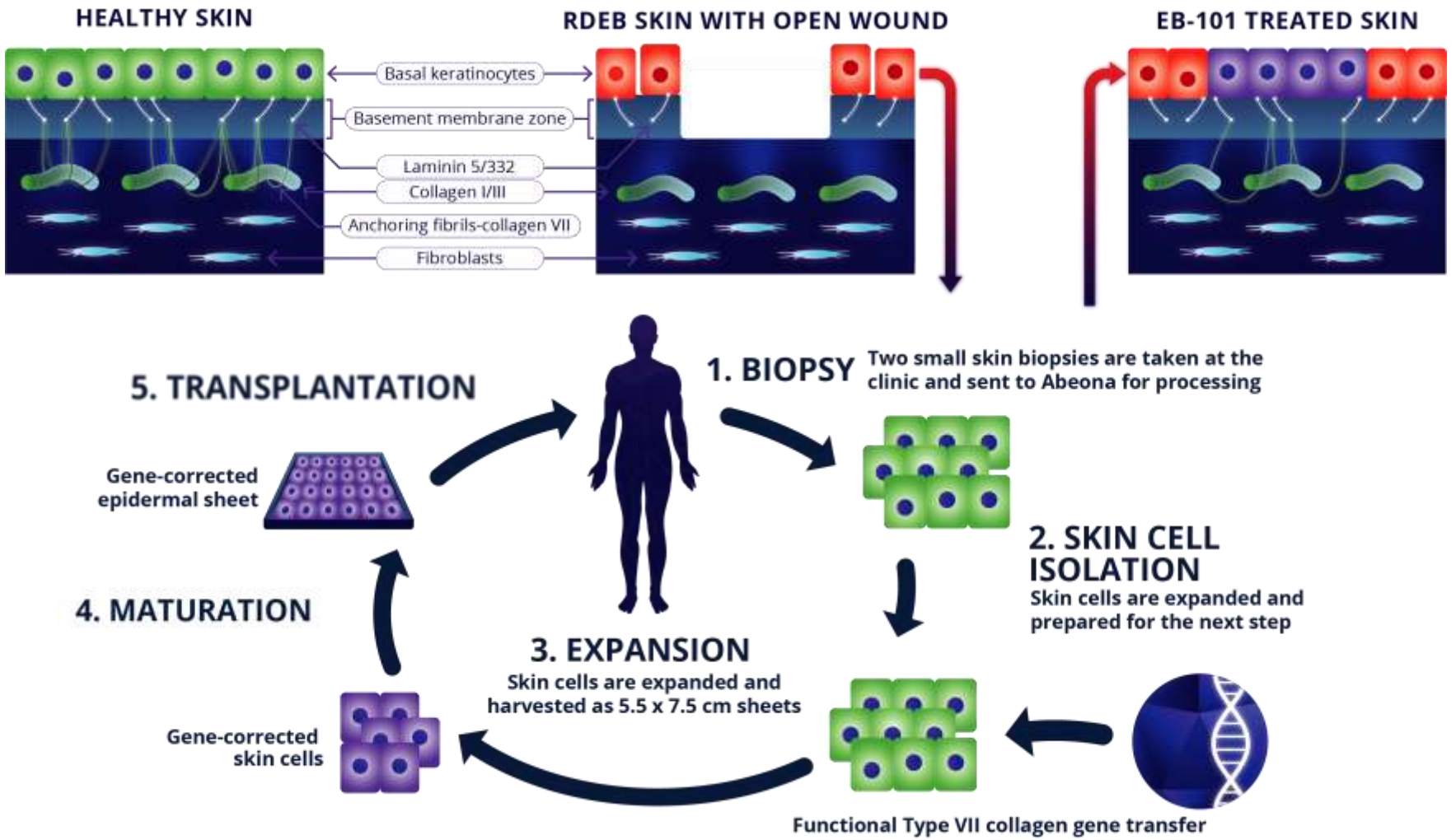


50% of generalized severe patients die before 35

75% die before 40

1. Eichstadt S, Tang JY, Solis DC, Siprashvili Z, Marinkovich MP, Whitehead N, Schu M, Fang F, Erickson SW, Ritchey ME, Colao M, Spratt K, Shaygan A, Ahn MJ, Sarin KY. From Clinical Phenotype to Genotypic Modelling: Incidence and Prevalence of Recessive Dystrophic Epidermolysis Bullosa (RDEB). Clin Cosmet Investig Dermatol. 2019 Dec 24;12:933-942. doi: 10.2147/CCID.S232547. Erratum in: Clin Cosmet Investig Dermatol. 2021 Jun 21;14:679. PMID: 31920360; PMCID: PMC6935313.

EB-101 restores functional collagen VII to patient's own cells



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Phase 3 VIITAL study topline results

Igor Grachev, M.D., Ph.D.
Head of Clinical Development

Phase 3 VIITAL study evaluated EB-101 for wound healing and pain reduction using intra-patient randomization of wounds

VIITAL™
PHASE 3 STUDY

FDA-aligned endpoints include ≥50% wound healing and mean pain reduction after 6 months

Target Enrollment:

- ~36 wound pairs in 10–15 patients
- Age ≥6 years
- Minimum two large chronic* wounds per patient

Randomized wound pairs

EB-101 & Control

Non-randomized wounds**

EB-101 treated, not included in primary analysis

Co-Primary Endpoints:

- ≥50% wound healing at Week 24***
- Reduction in pain severity (Wong-Baker FACES scale) associated with wound dressing changes at Week 24

Secondary Endpoint:

- Complete wound healing at Week 24***

Select Exploratory Endpoint:

- ≥75% wound healing at Week 24***

*Large = >20 cm^2 surface area; Chronic = Open for >6 months ** Wounds with no matching control wound ***Week 24 result confirmed at Week 26

VIITAL study baseline characteristics

# patients treated	• 11 patients (every patient biopsied received EB-101 treatment)
# large chronic wounds	• 43 treated wounds vs. 43 paired untreated wounds (randomized) • 14 non-randomized treated wounds
Age (years)	• Mean: 22.5; Range: 6 to 40
Body surface area (BSA) covered by EB-101 per patient (cm^2)	• **Randomized treated:** Mean (SD): 156.4 (41.8); Range: 80 to 200 • **Non-randomized treated:** Mean (SD): 80.0 (46.2); Range: 40 to 160
Wound duration (years remained chronically open)	• **Randomized treated:** Mean (SD): 6.2 years (7.0 years) • **Randomized control:** Mean (SD): 6.3 years (6.7 years) • **Non-randomized treated:** Mean (SD): 3.8 years (2.6 years)
Pain severity (0-10 scale)	• **Randomized treated:** Mean (SD): 5.12 (3.13) • **Randomized control:** Mean (SD): 4.38 (3.04) • **Non-randomized treated:** Mean (SD): 6.62 (3.50)

Handling of missing data for primary analysis

≥50% wound healing rate

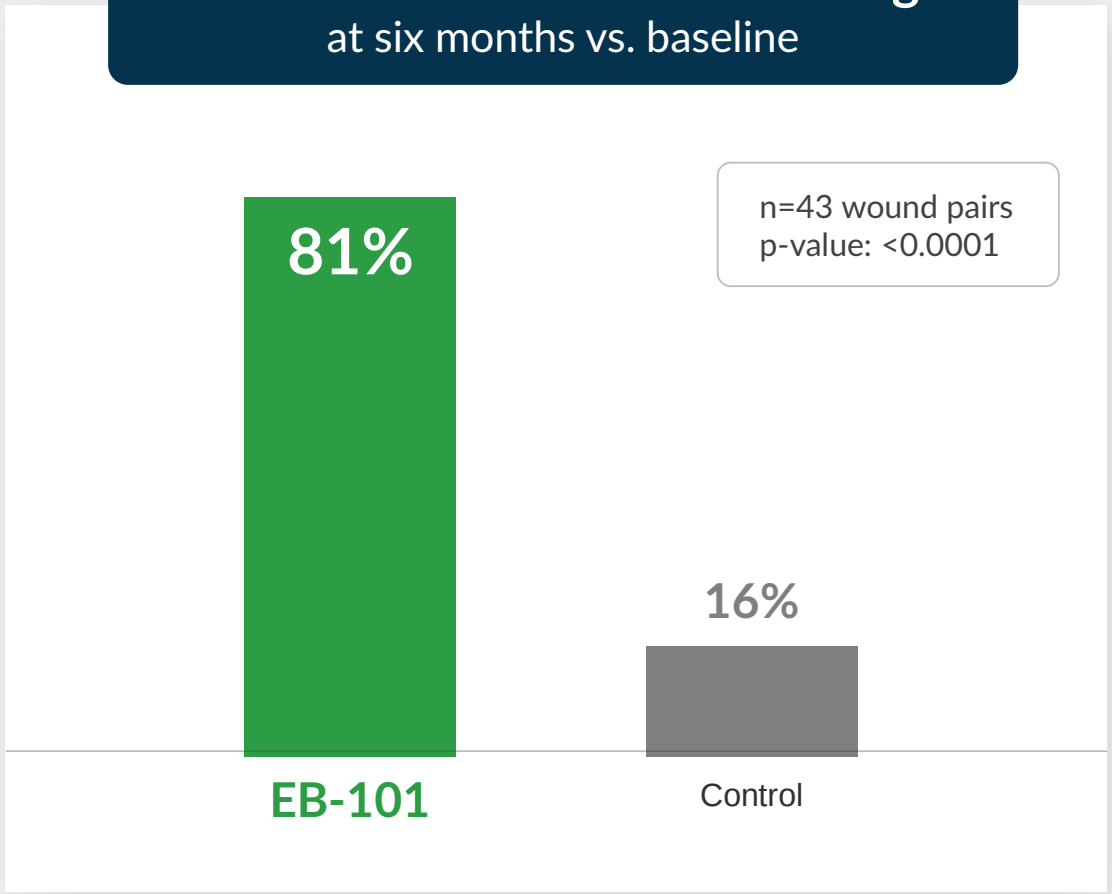
- Wounds with missing wound healing data are considered as “not healed” for the primary analysis
- Four randomized wound pairs from one patient fall into this category

Pain reduction analysis

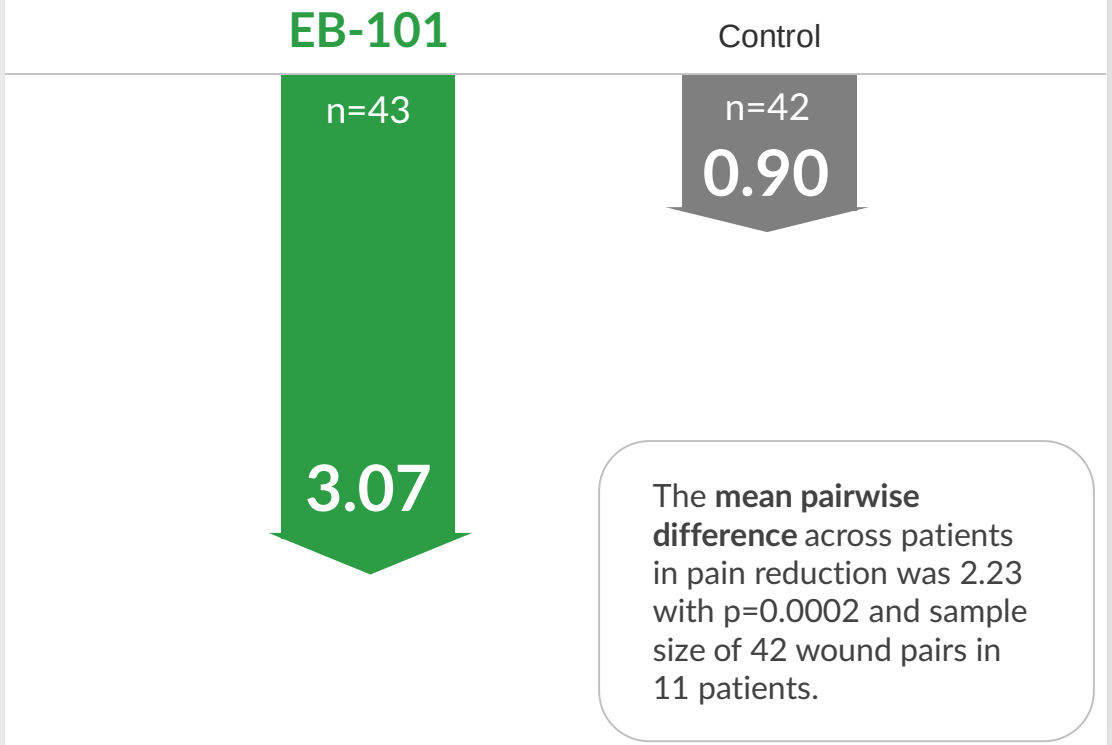
- Wound pairs with missing pain data at baseline are excluded from the primary analysis
- One randomized wound pair falls into this category

Significantly more wounds achieved ≥50% healing and showed significant pain reduction with EB-101

% Wounds with ≥50% Healing
at six months vs. baseline



Mean Pain Reduction*
from baseline at 6 months

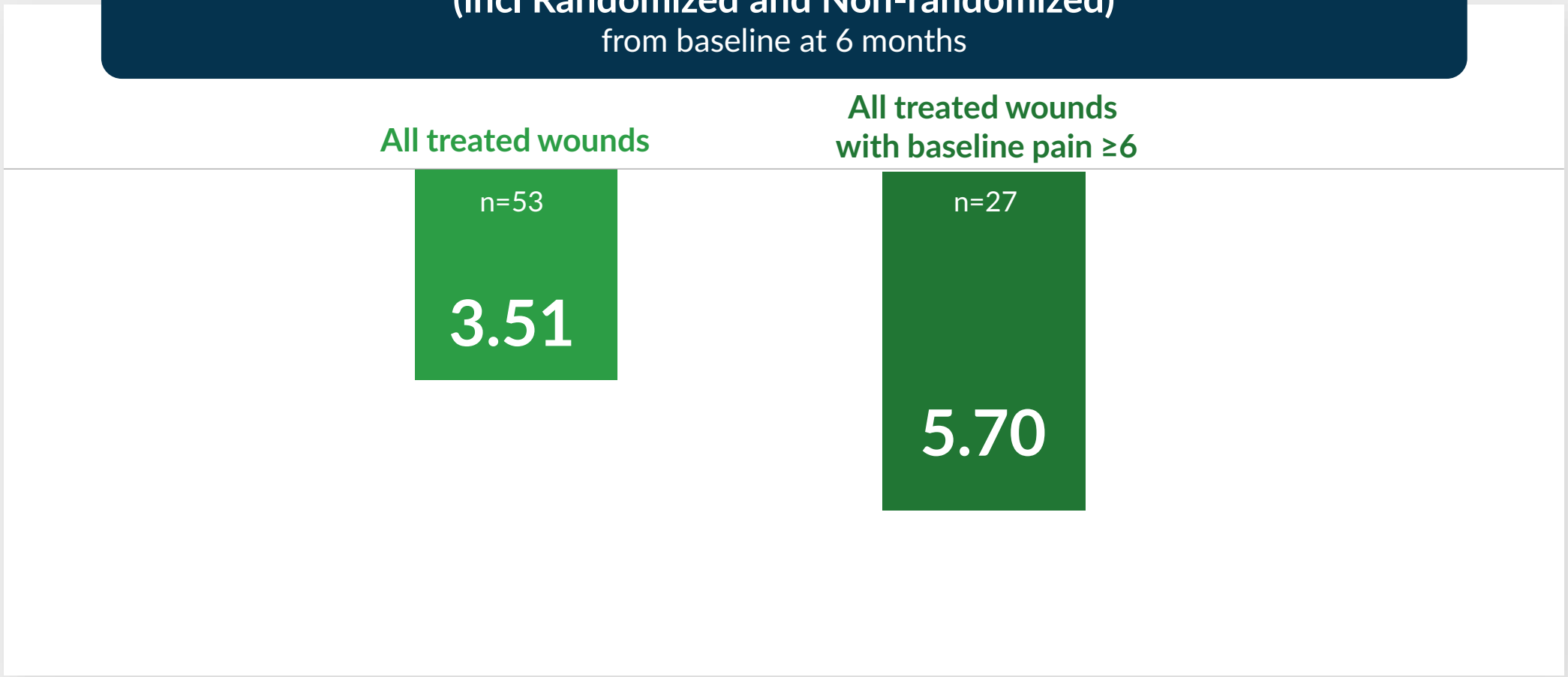


The **mean pairwise difference** across patients in pain reduction was 2.23 with p=0.0002 and sample size of 42 wound pairs in 11 patients.

* Pain severity on 0-10 scale with scoring in increments of 2 (ie. 0, 2, 4, 6, 8, 10).

EB-101 showed greatest pain reduction benefit in wounds with severe baseline pain

Mean Pain Reduction in EB-101 Treated Wounds (incl Randomized and Non-randomized)
from baseline at 6 months



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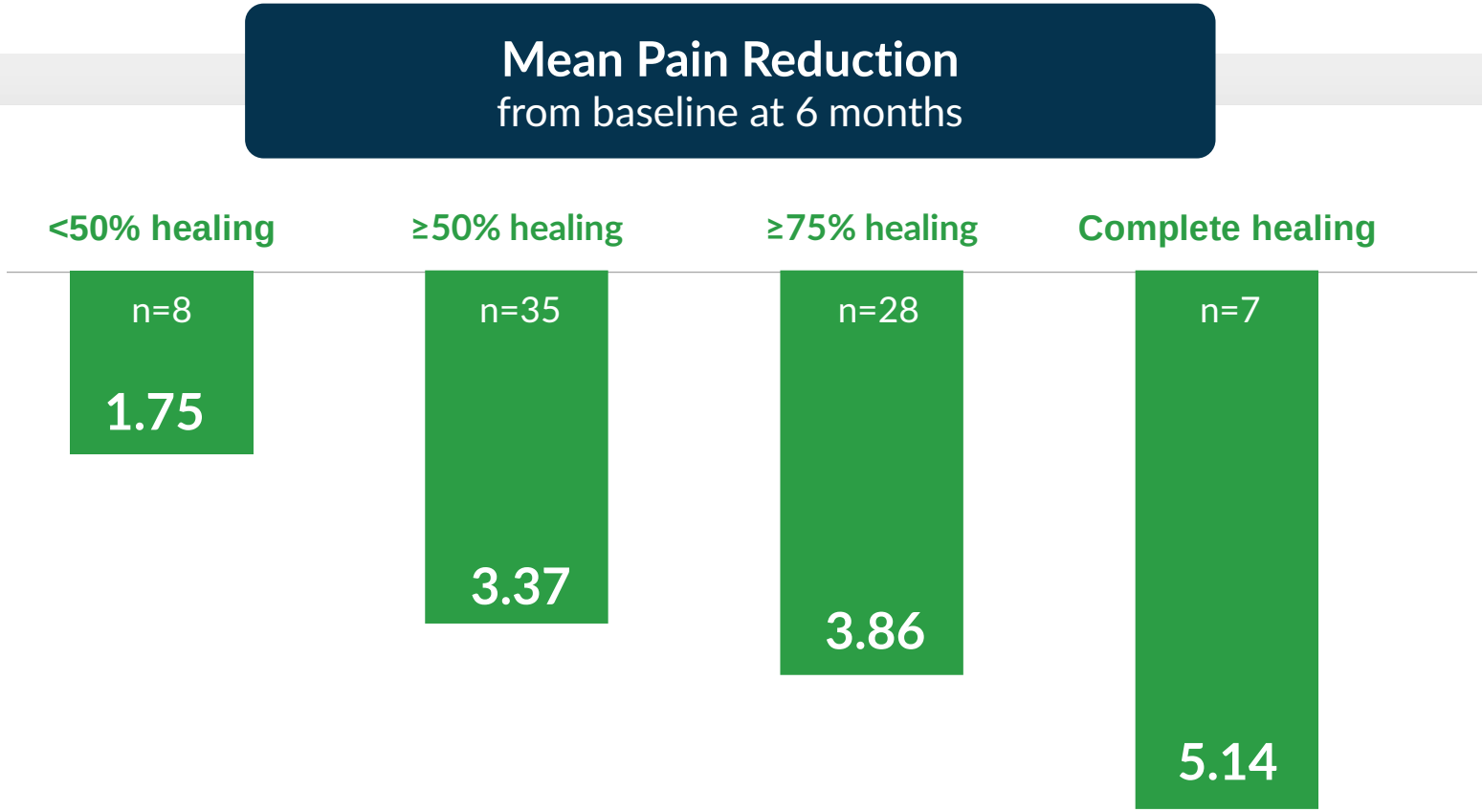
Greater wound healing is associated with greater magnitude in pain reduction



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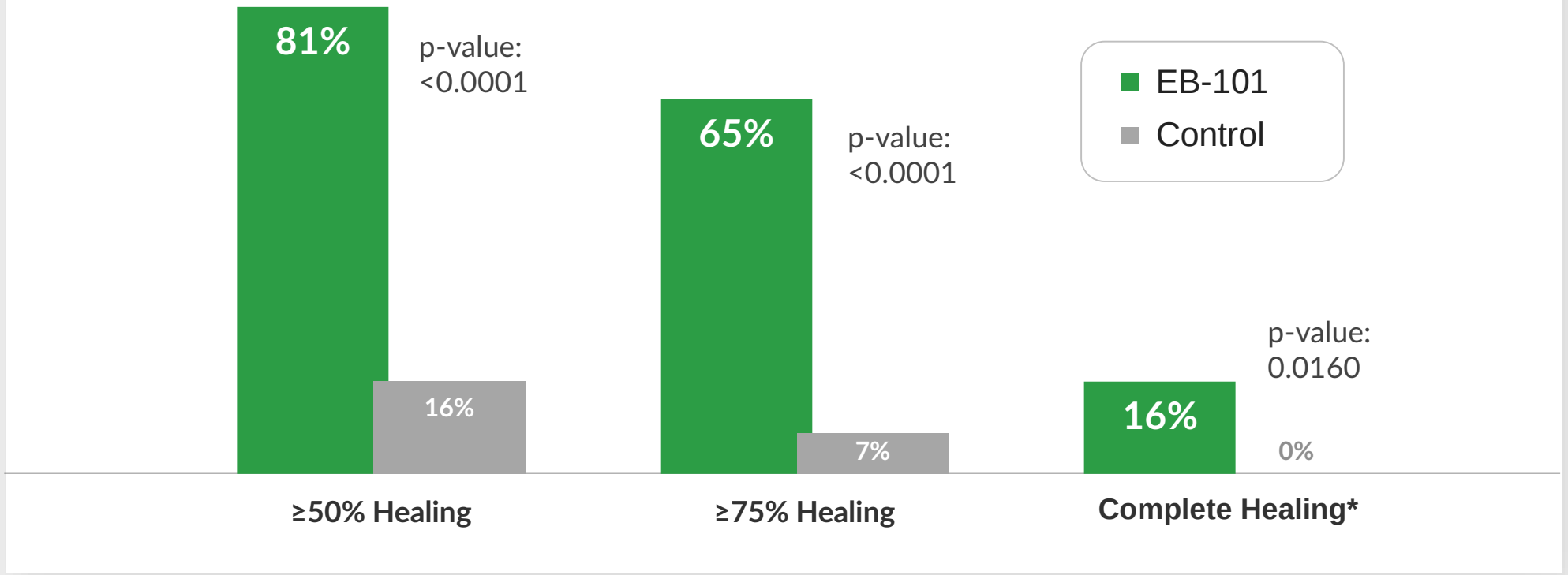
EB-101 significantly improved wound healing vs. control across all levels of healing

% Wounds that Met or Exceeded Healing Threshold Indicated

at six months vs. baseline (n=43)



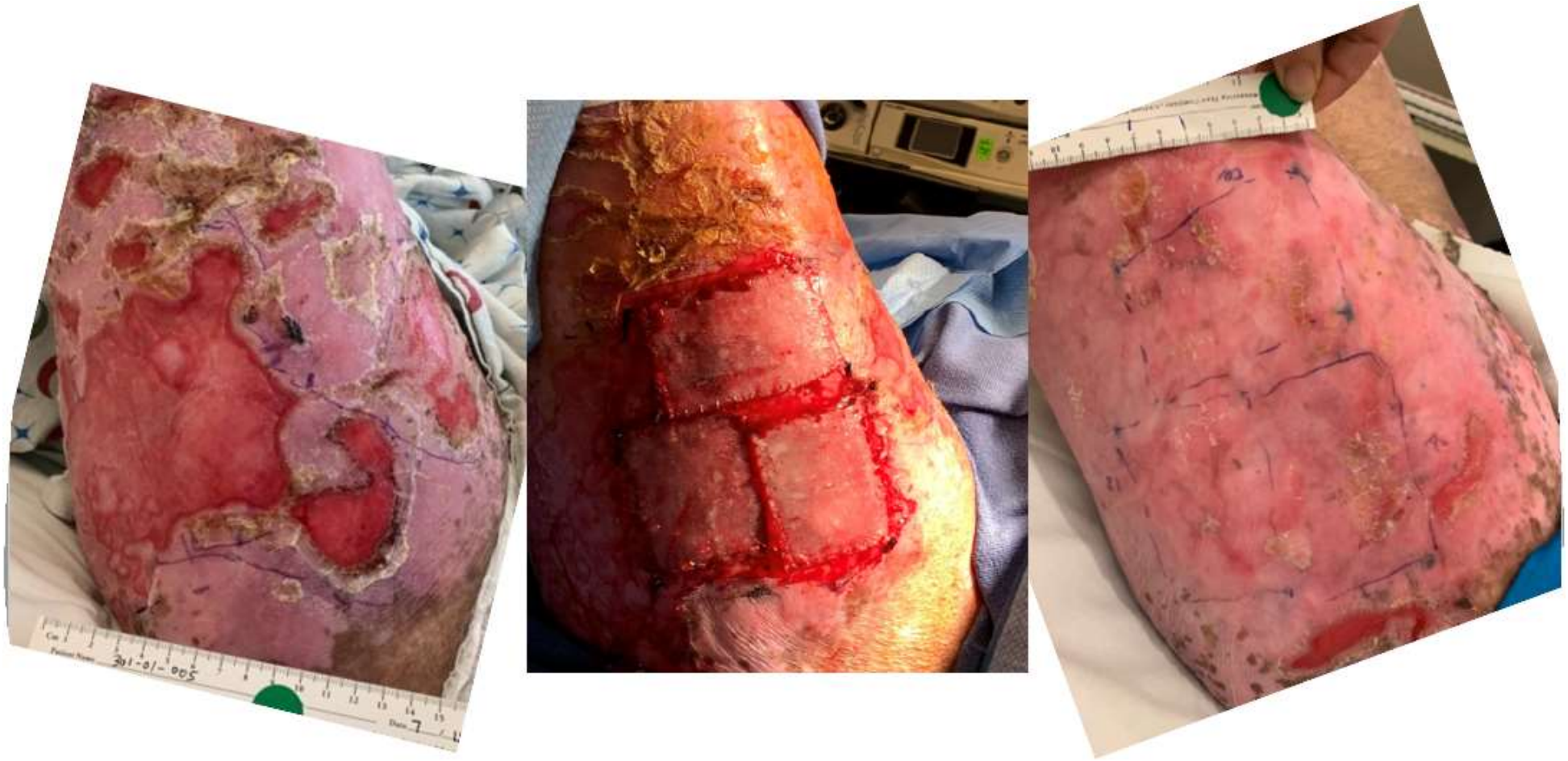
* Complete wound healing is defined as re-epithelialization with no drainage or erosion and presence of only minor crusting.

Stringent criteria applied to score wounds as completely healed

- Complete re-epithelialization with no drainage or erosion
- No major crusting as adjudged by investigator (subjective)
  - In VIITAL, with any crusting, inability to verify underlying epithelial formation led to wound scored as not having met complete healing
- No control wounds were scored as completely healed at week 24 (with week 26 confirmation)
- Following slides show examples of wounds that were ≥75% healed but not scored as completely healed

Example of ≥75% healed after EB-101 treatment (upper left thigh)

Baseline	Surgery	Week 24

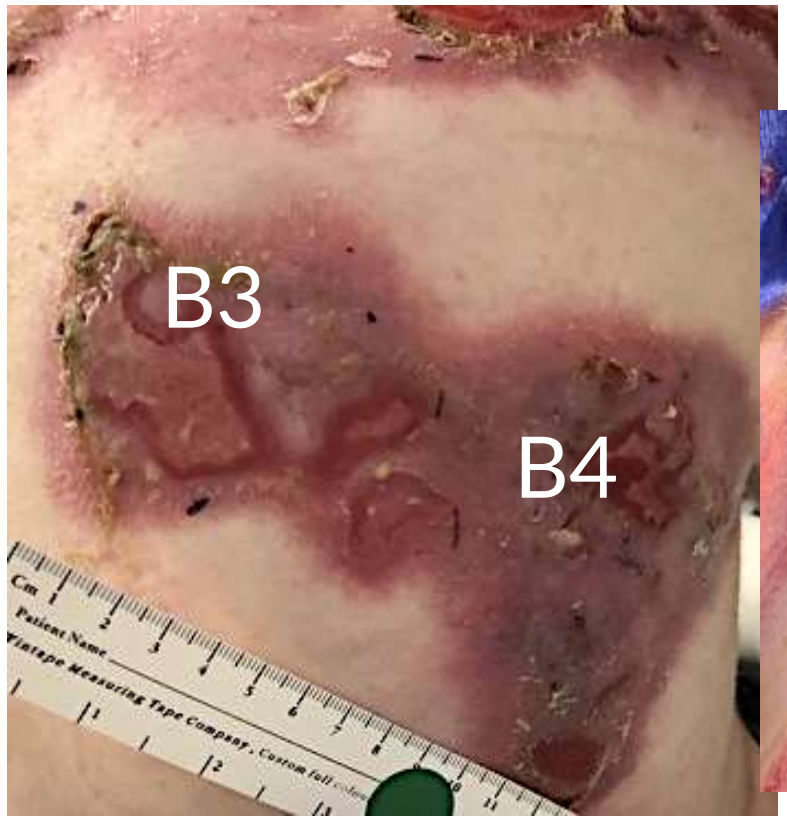


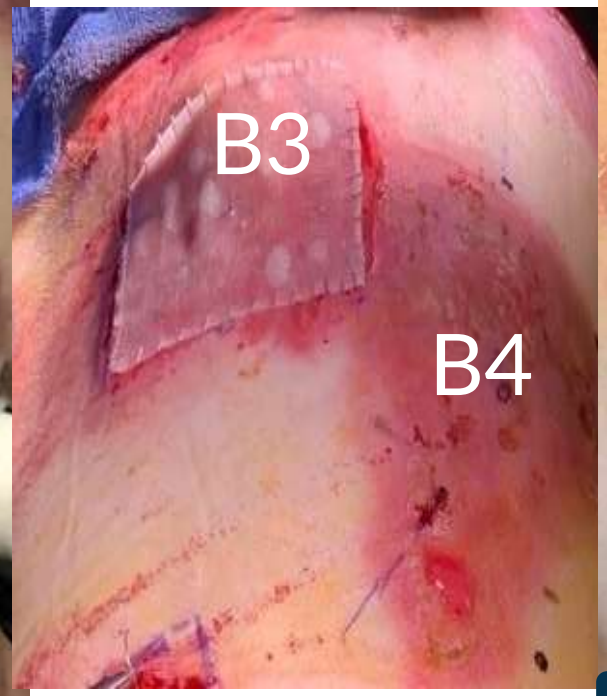
Tattooed wounds scored as >75% healed but not complete wound healing at Week 24

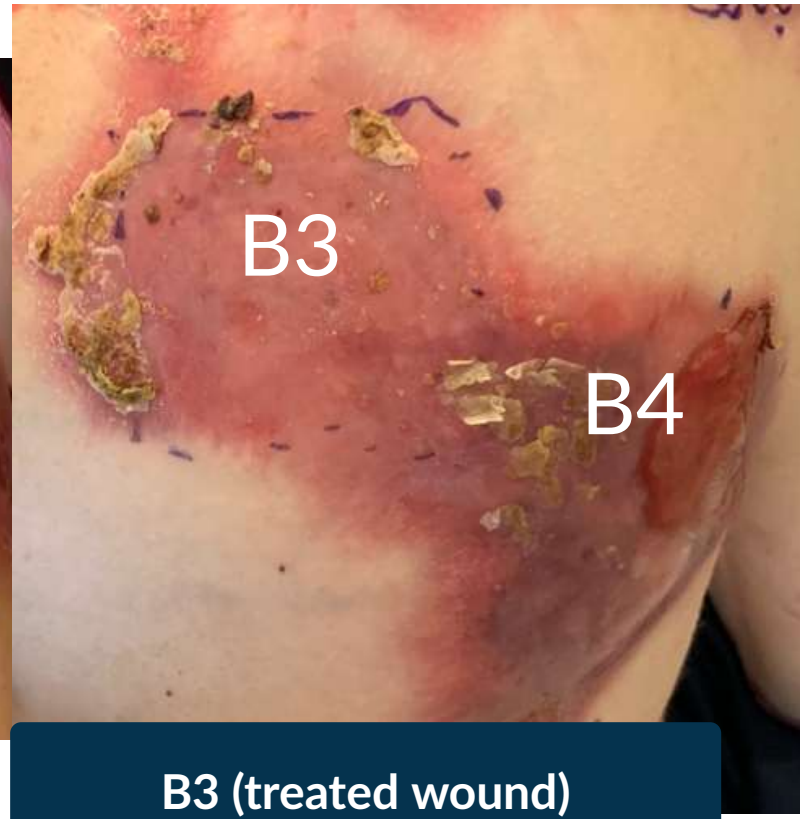
Source: VIITAL patient

Example of ≥75% healed after EB-101 treatment (right medial and lateral scapula)

Baseline	Surgery	Week 24







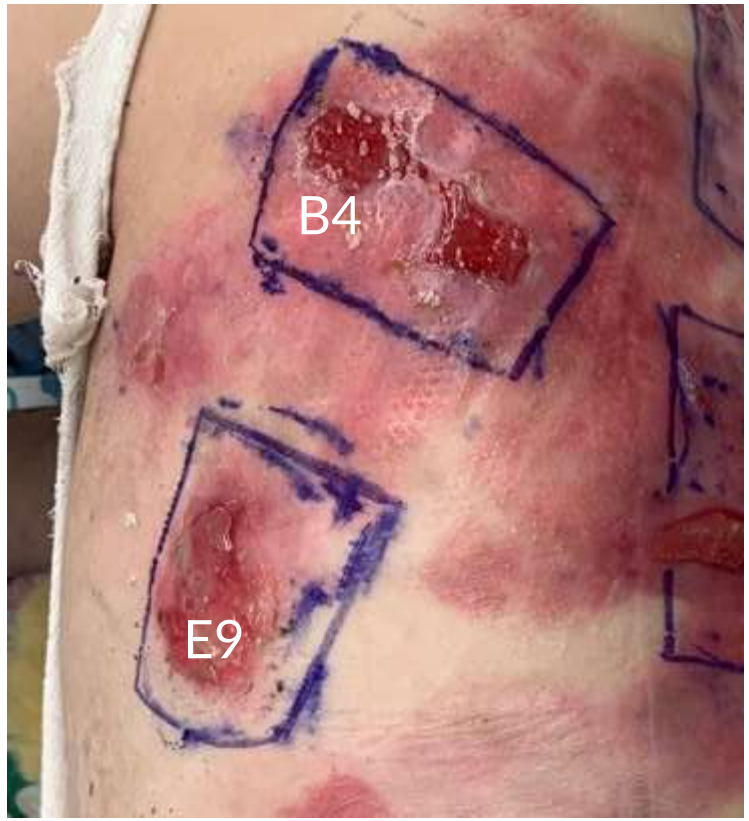
B3 scored as >75% healed but not complete wound healing at Week 24

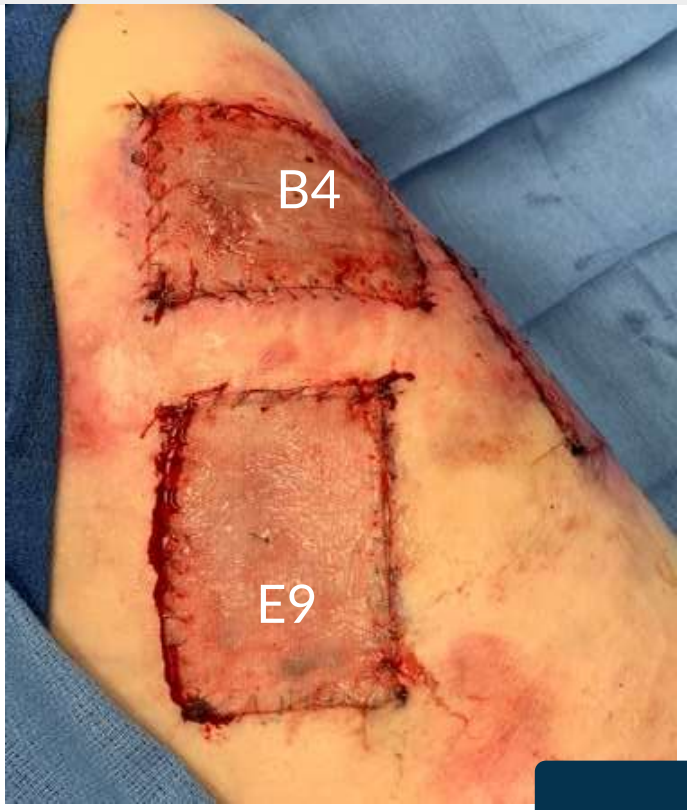
B3 (treated wound)
B4 (untreated control)

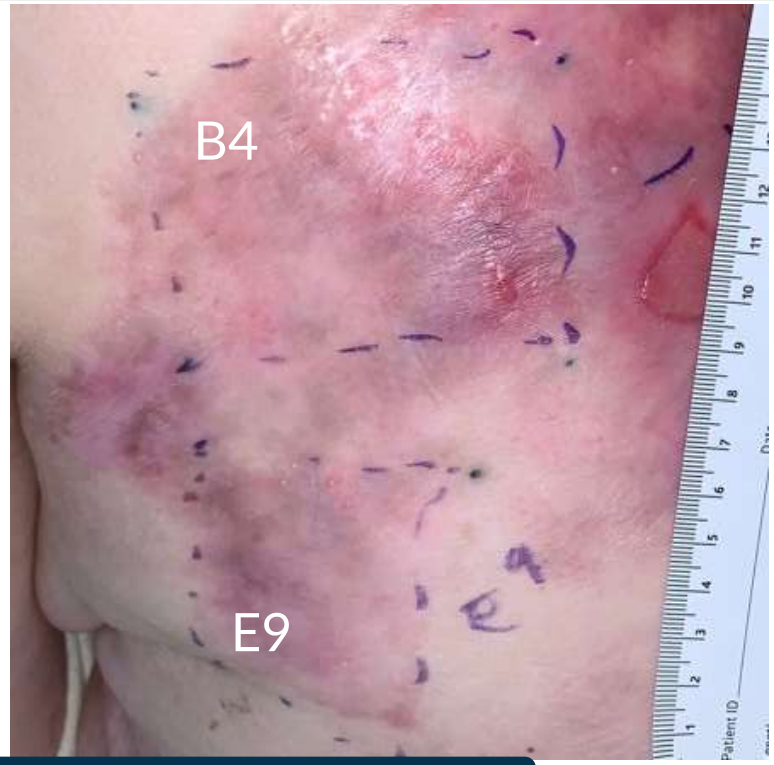
Source: VIITAL patient

Examples of ≥75% and complete wound healing after EB-101 treatment (upper trunk)

Baseline	Surgery	Week 24







B4 scored as >75% healed at Week 24
E9 scored as complete wound healing at Week 24

B4 (treated wound)
E9 (treated wound)

Source: VIITAL patient

EB-101 was shown to be well tolerated in VIITAL, consistent with past clinical trial experience

- There were **no treatment-related serious adverse events** (SAEs) reported and no safety signal observed in the VIITAL study nor in the duration of the clinical development program. Two subjects (2/11, 18.2%) reported at least one serious adverse event (SAE) unrelated to EB-101.
- No deaths, **no instances of positive replication-competent retrovirus** (RCR) results and **no systemic immunologic responses** were reported during the study, as well as **no SCC at treatment sites** after application of EB-101 treatment.
- Four subjects (4/11, 36.4%) reported related treatment emergent adverse events (TEAEs), including procedural pain, muscle spasms and pruritis.
- Infections not related to EB-101 were observed in 8 subjects (72.7%).
- Wound related TEAEs were reported in 9/100 (9.0%) wounds.

Takeaways for EB-101 and next steps

Vish Seshadri
Chief Executive Officer

Positive VIITAL results reinforce EB-101 value proposition

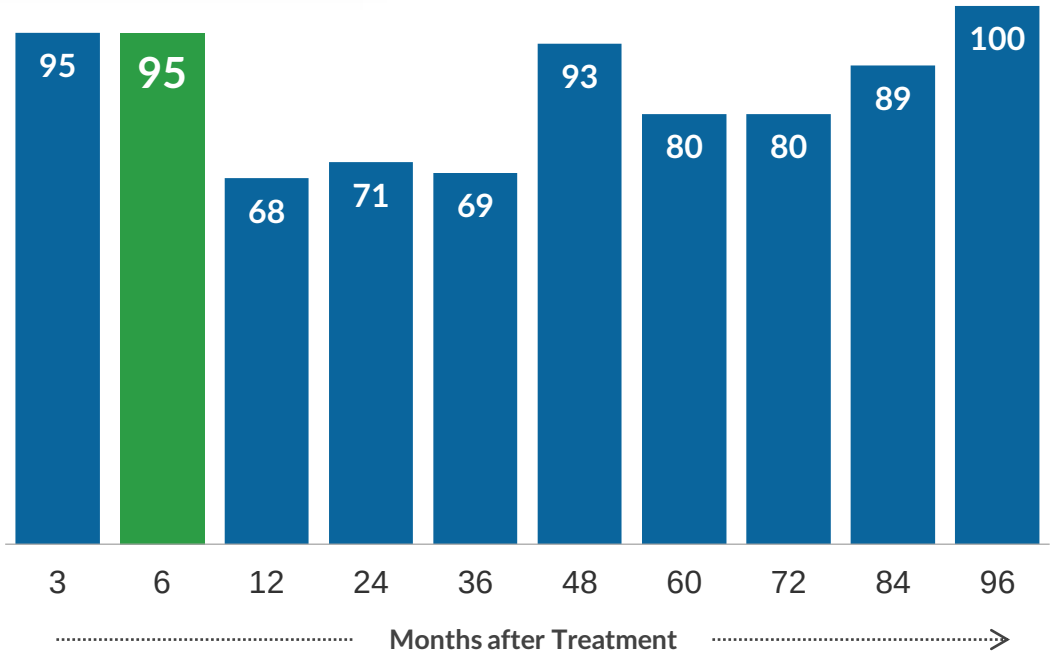
- Statistically significant and clinically meaningful results across endpoints in VIITAL
  - Wound healing by investigator assessment at all levels vs. control
  - Pain reduction reported by patient vs. control
- More pronounced pain reduction for wounds with severe baseline pain
- No serious treatment-related adverse events observed, consistent with past clinical experience
- Further details with additional exploratory endpoints will be presented at a future scientific meeting
- VIITAL results along with the Phase 1/2a long term follow-up results[1] form the basis for the value proposition of EB-101 with potential for durable wound healing and pain reduction with a one-time treatment

1. So, J.Y., Nazaroff, J., Iwummadu, C.V. et al. Long-term safety and efficacy of gene-corrected autologous keratinocyte grafts for recessive dystrophic epidermolysis bullosa. Orphanet J Rare Dis 17, 377 (2022). https://doi.org/10.1186/s13023-022-02546-9

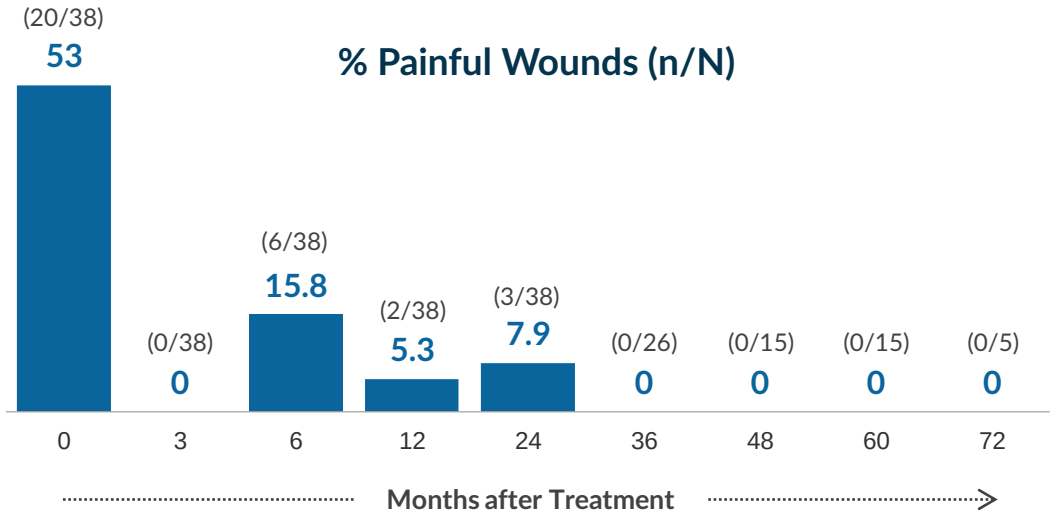
Phase 1/2a data complements VIITAL with evidence of multi-year wound healing and pain reduction after EB-101

% of Wounds with ≥50% Healing

6-month timepoint agreed with FDA for efficacy primary endpoints



Overall Wound Pain: Relief Associated with EB-101



Key Findings from Phase 1 / 2 Study

- Average surface area healed per patient: >130 cm^2 and >120 cm^2 at 3 and 6 months, respectively
- Evidence for healing of extremely large wounds (up to 400 cm^2) that were open for 16+ years
- Considerable reduction in wound burden at mean 5.9 years follow-up
- Long-term symptomatic relief, including reduction in pain

EB-101 Anticipated Next Steps

Regulatory

- BLA filing in 2Q 2023
- Application for Priority Review Voucher at time of BLA filing
- Potential BLA approval in 1Q 2024

Commercial Launch

- Initiate launch preparation activities in 1Q 2023 while continuing to explore partnership opportunities

Q&A