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

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:∗

<table>
<thead>
<tr>
<th></th>
<th>EB-101 treated wounds</th>
<th>control untreated wounds</th>
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</thead>
<tbody>
<tr>
<td>≥50% wound healing</td>
<td>81%</td>
<td>16%</td>
</tr>
<tr>
<td>Mean pain reduction</td>
<td>3.07</td>
<td>0.90</td>
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</tbody>
</table>

P=0.0001

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

- 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

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

**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 cm² surface area; Chronic = Open for >6 months  ** Wounds with no matching control wound  ***Week 24 result confirmed at Week 26
## VIITAL study baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># patients treated</strong></td>
<td>11 patients (every patient biopsied received EB-101 treatment)</td>
</tr>
<tr>
<td><strong># large chronic wounds</strong></td>
<td>43 treated wounds vs. 43 paired untreated wounds (randomized)</td>
</tr>
<tr>
<td></td>
<td>14 non-randomized treated wounds</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td>Mean: 22.5; Range: 6 to 40</td>
</tr>
<tr>
<td><strong>Body surface area (BSA) covered by EB-101 per patient (cm²)</strong></td>
<td><strong>Randomized treated</strong>: Mean (SD): 156.4 (41.8); Range: 80 to 200</td>
</tr>
<tr>
<td></td>
<td><strong>Non-randomized treated</strong>: Mean (SD): 80.0 (46.2); Range: 40 to 160</td>
</tr>
<tr>
<td><strong>Wound duration (years remained chronically open)</strong></td>
<td><strong>Randomized treated</strong>: Mean (SD): 6.2 years (7.0 years)</td>
</tr>
<tr>
<td></td>
<td><strong>Randomized control</strong>: Mean (SD): 6.3 years (6.7 years)</td>
</tr>
<tr>
<td></td>
<td><strong>Non-randomized treated</strong>: Mean (SD): 3.8 years (2.6 years)</td>
</tr>
<tr>
<td><strong>Pain severity (0-10 scale)</strong></td>
<td><strong>Randomized treated</strong>: Mean (SD): 5.12 (3.13)</td>
</tr>
<tr>
<td></td>
<td><strong>Randomized control</strong>: Mean (SD): 4.38 (3.04)</td>
</tr>
<tr>
<td></td>
<td><strong>Non-randomized treated</strong>: Mean (SD): 6.62 (3.50)</td>
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</table>
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**

- **EB-101**: 81%
- **Control**: 16%

n=43 wound pairs
p-value: <0.0001

**Mean Pain Reduction* from baseline at 6 months**

- **EB-101**: n=43, 3.07
- **Control**: n=42, 0.90

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 (i.e. 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](image)

<table>
<thead>
<tr>
<th></th>
<th>All treated wounds</th>
<th>All treated wounds with baseline pain ≥6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=53</td>
<td>n=27</td>
</tr>
<tr>
<td>Mean Pain Reduction</td>
<td>3.51</td>
<td>5.70</td>
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</table>
Greater wound healing is associated with greater magnitude in pain reduction

<table>
<thead>
<tr>
<th>Healing Stage</th>
<th>Mean Pain Reduction from baseline at 6 months</th>
</tr>
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<tbody>
<tr>
<td>&lt;50% healing</td>
<td>1.75</td>
</tr>
<tr>
<td>≥50% healing</td>
<td>3.37</td>
</tr>
<tr>
<td>≥75% healing</td>
<td>3.86</td>
</tr>
<tr>
<td>Complete healing</td>
<td>5.14</td>
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</table>
EB-101 significantly improved wound healing vs. control across all levels of healing

<table>
<thead>
<tr>
<th>Healing Threshold</th>
<th>EB-101 (%)</th>
<th>Control (%)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>≥50% Healing</td>
<td>81%</td>
<td>16%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥75% Healing</td>
<td>65%</td>
<td>7%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Complete Healing*</td>
<td>16%</td>
<td>16%</td>
<td>0.0160</td>
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</table>

* 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 | B3 | B3 (treated wound)
B4 | B4 | B4 (untreated control)

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

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

Source: VIITAL patient

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

B4 (treated wound)
E9 (treated wound)
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 results¹ form the basis for the value proposition of EB-101 with potential for durable wound healing and pain reduction with a one-time treatment

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

Key Findings from Phase 1 / 2 Study

- Average surface area healed per patient: >130 cm² and >120 cm² at 3 and 6 months, respectively
- Evidence for healing of extremely large wounds (up to 400 cm²) 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

Age

% of Wounds with ≥50% Healing

Overall Wound Pain: Relief Associated with EB-101

6-month timepoint agreed with FDA for efficacy primary endpoints

% Painful Wounds (n/N)

<table>
<thead>
<tr>
<th>Months after Treatment</th>
<th>(20/38)</th>
<th>(6/38)</th>
<th>(2/38)</th>
<th>(3/38)</th>
<th>(0/38)</th>
<th>(0/26)</th>
<th>(0/15)</th>
<th>(0/15)</th>
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<tbody>
<tr>
<td>0</td>
<td>53</td>
<td>15.8</td>
<td>5.3</td>
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(Age)
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