

Geovanna, a ZEVASKYN patient at age 8

Strong Bonds Stand the Test of Time

Durable wound healing with a single surgical application—even in tough RDEB wounds[1*]

- 81% of ZEVASKYN-treated wounds (35/43) achieved 50% or more healing vs 16% of matched control wounds (7/43) at week 24 in a Phase 3 study (*P*<0.0001)[†]

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(prademagene zamikeracel)
gene-modified cellular sheets

ZEVASKYN Qualified Treatment Centers (QTCs) are actively treating patients. Scan or click to see the latest list and refer now.

*Wounds treated had remained open for at least 6 months.

[†]Investigator-assessed, multi-center, randomized, intrapatient-controlled study with 43 ZEVASKYN-treated wounds vs 43 matched control wounds in 11 patients with RDEB.

INDICATION

ZEVASKYN® (prademagene zamikeracel) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

IMPORTANT SAFETY INFORMATION

Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

RDEB: A serious genetic disease with significant unmet need for long-lasting wound healing

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COL7A1 mutations impair anchoring fibrils, leading to skin fragility and wounds

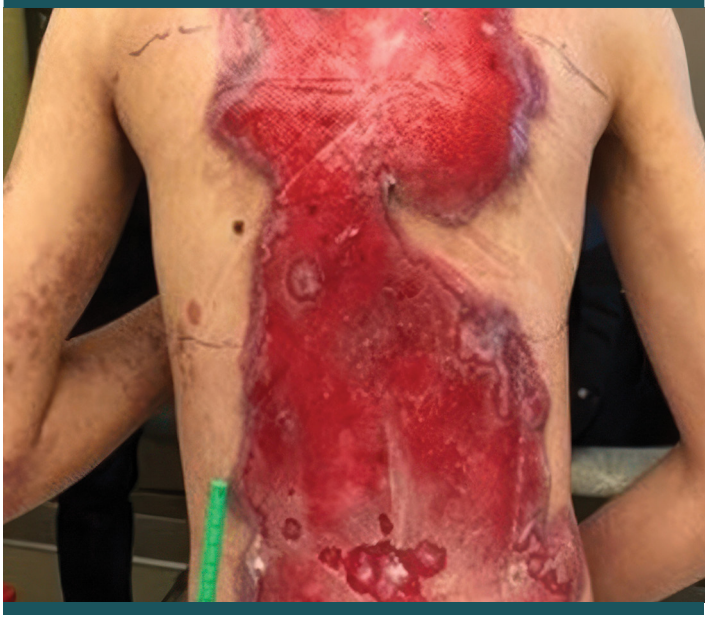
- RDEB is caused by mutations in both copies of the *COL7A1* gene[2]
- As a result, cells are unable to express functional type VII collagen protein, which is needed to form anchoring fibrils that bond the epidermis to the dermis[2,3]

Chronic wounds drive persistent pain and itch

- Lack of anchoring fibrils leads to fragile skin that blisters easily, and patients suffer from years of painful wounds and itch[2,4]
- RDEB wounds can lead to serious life-threatening complications. Patients have up to a 90% risk of developing SCC[5]

For patients with RDEB, wounds can cover significant body surface area and are a constant source of severe pain and itch[2]

Back



Left side of torso



Photos are of 2 different RDEB patients.[6]

There is a critical unmet need for treatments that provide durable wound healing and pain and itch reduction[2]

SCC=squamous cell carcinoma.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

ZEVASKYN: Designed for type VII collagen expression at the application site[1]

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ZEVASKYN (ZEE-vah-skin) is made from patients' own skin cells that are genetically modified with copies of the functional *COL7A1* gene[1]

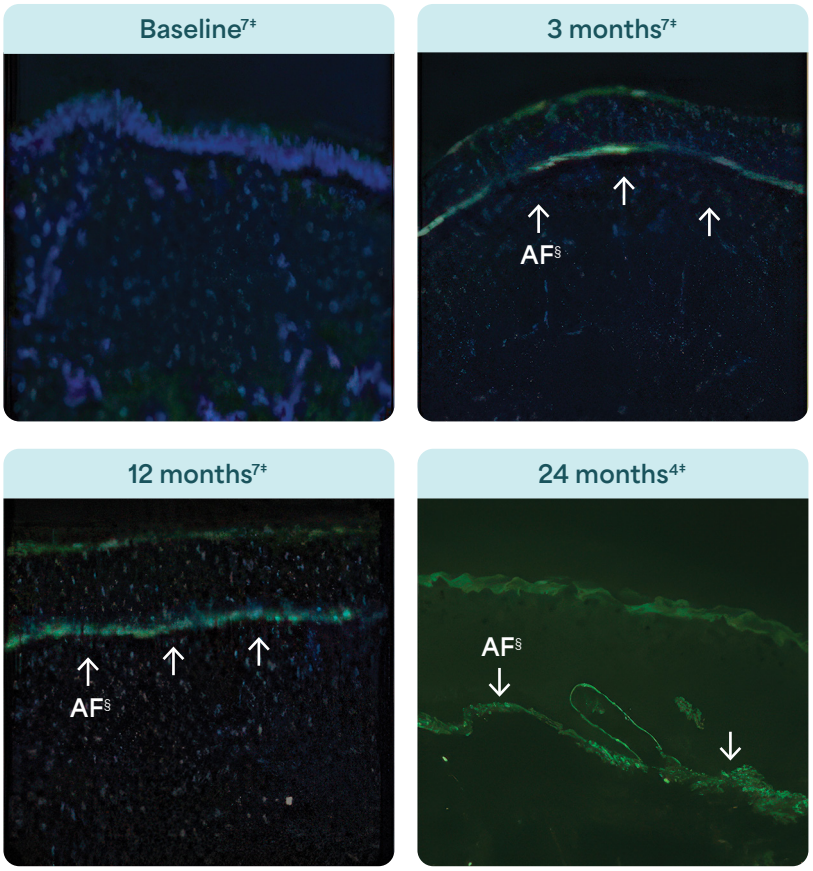
- Autologous keratinocytes are isolated from skin punch biopsies, then transduced *ex vivo* with a retroviral vector containing the full-length *COL7A1* gene
- The resulting gene-modified cellular sheets express functional type VII collagen (C7) protein
- Stable integration of the *COL7A1* gene is maintained through cell division at the treated site even after ZEVASKYN application
- C7 expression results in the formation of anchoring fibrils (AFs)[1,7]

Long-term presence of C7 and anchoring fibrils at treated sites[1]

Patients treated with ZEVASKYN were assessed for presence of both C7 and AFs.*

- At 3 months, 6 of 7 patients tested were positive for both C7 and AFs
- At 6 months, 5 of 7 patients tested were positive for both C7 and AFs
- At 1 year, 3 of 7 patients tested were positive for C7 or AFs
- At 2 years, 2 of 3 patients tested were positive for C7 or AFs†

Assessment was elective and performed periodically because each test required a biopsy of healed skin.



↑ §Anchoring fibrils: C7 at the dermal-epidermal junction, resulting in AF formation[1,4,7]

*In the Phase 1/2a study, C7 expression was assessed by immunofluorescence microscopy (negative cofactor 2 domain of C7 using the LH24 antibody) and anchoring fibrils were assessed by immunoelectron microscopy.

†One patient was positive for both C7 and AFs; one patient was positive only for C7 (as biopsy to assess AF was not obtained).

‡Immunofluorescence images.

IMPORTANT SAFETY INFORMATION

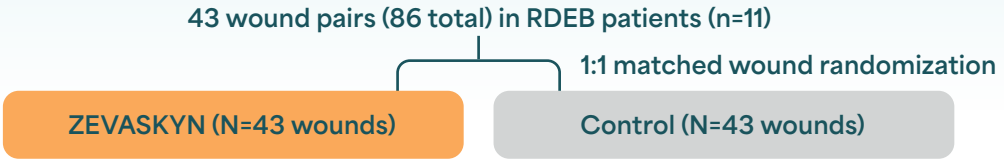
Retroviral vector (RVV)-mediated insertional oncogenesis may potentially occur after treatment with ZEVASKYN. Monitor patients lifelong after treatment for the development of malignancies. In the event that a malignancy occurs, contact Abeona Therapeutics Inc. at 1-844-888-2236.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

ZEVASKYN can close even tough RDEB wounds[1]

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VIITAL: A Phase 3, randomized, intrapatient-controlled trial comparing ZEVASKYN with conventional wound management[1,8]*



Follow-up at weeks 6, 12, 24, and 26†

Key endpoints (change from baseline at week 24)[1,8]

- ≥50% wound healing (coprimary)
- Pain reduction (coprimary)
- Complete wound healing (secondary)†‡
- ≥75% wound healing (exploratory)
- Itch reduction (exploratory)

Select baseline demographics[1,8]

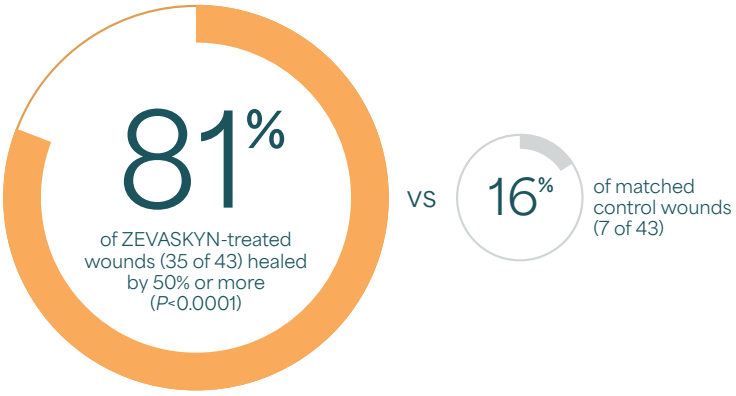
- Median patient age: 21 years (range: 6-40 years)
- Median body surface area treated with ZEVASKYN: 240 cm^2 (6 sheets)§

Select wound demographics[1,8]

- Each wound evaluated was ≥20 cm^2
- Median wound duration: 5 years (range: 6 months–21 years)

ZEVASKYN achieved significant wound healing as evaluated at week 24[1]

Wounds that healed by 50% or more



- Complete healing achieved in 16% of ZEVASKYN-treated wounds (7/43) vs 0% of matched control wounds (0/43; *P*=0.0160)
- ZEVASKYN-treated wounds showed **noticeable healing within 6 weeks**, compared to fewer control wounds. This analysis was based on a subset of wounds (28 of 43) that were assessed at 6 weeks[8]‖

Wounds that healed by 75% or more

~2 out of 3 ZEVASKYN-treated wounds (28/43) healed by 75% or more vs 7% of matched control wounds (3/43)[8]

N=wounds, n=patients.

*Supportive care, such as daily bandaging and palliative measures.[8]

†Wounds were assessed by investigator based on predefined criteria to score healing. Healing achieved at week 24 was confirmed at least 2 weeks later (week 26).[1]

‡Complete wound healing defined as complete re-epithelialization with no drainage or erosion, and no major crusting.

§ZEVASKYN was placed on 57 wounds (43 randomized and 14 non-randomized); range of body surface area treated: 120-240 cm^2 (3-6 sheets).[1,8]

‖Missing data were not imputed; observed cases only.[8]

IMPORTANT SAFETY INFORMATION

Transmission of infectious disease or agents may occur with ZEVASKYN because it is manufactured using human- and bovine-derived reagents, which are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Before and after ZEVASKYN treatment[6]

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BEFORE **AFTER ZEVASKYN**

Chest



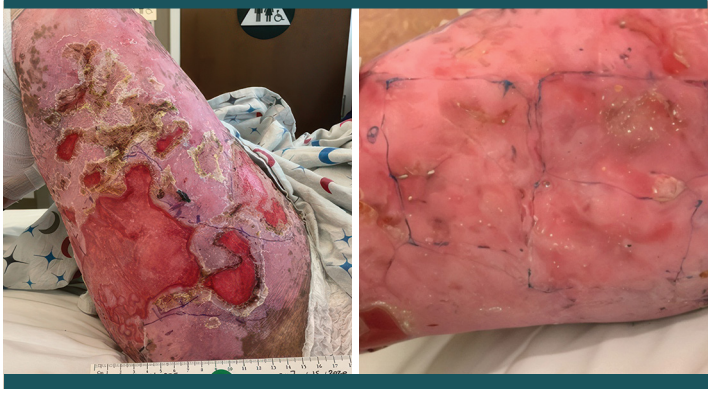
BEFORE **AFTER ZEVASKYN**

Back



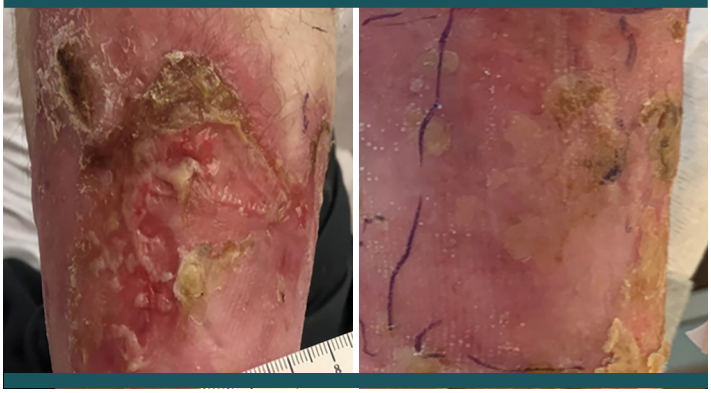
BEFORE **AFTER ZEVASKYN**

Left thigh



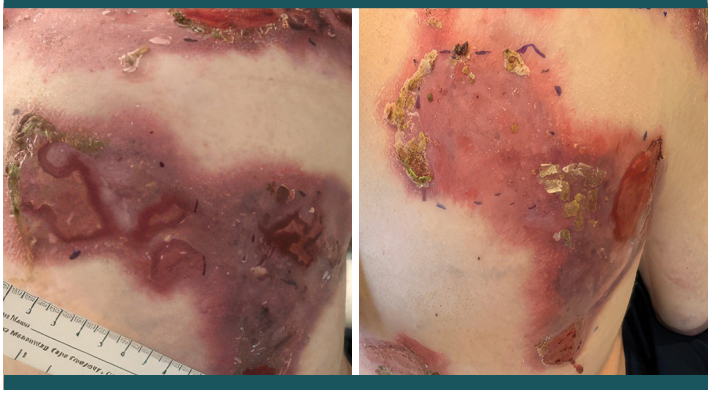
BEFORE **AFTER ZEVASKYN**

Left leg



BEFORE **AFTER ZEVASKYN**

Upper back



BEFORE **AFTER ZEVASKYN**

Right arm



Individual results may vary.

IMPORTANT SAFETY INFORMATION

The most common adverse reactions (incidence ≥5%) were procedural pain and pruritus.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Breakthrough technology: ZEVASKYN uses patients' own skin cells to treat RDEB wounds

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1 STARTING MATERIAL

Patient's own keratinocytes are extracted from two 8 mm punch biopsies.[9]

2 GENE MODIFICATION

Keratinocytes are transduced *ex vivo* with a retroviral vector containing full-length *COL7A1*, which stably integrates into the host-cell genome and leads to expression of functional type VII collagen protein in the transduced cells.[1]

3 EXPANSION INTO SHEETS

Over the course of ~25 days, cells containing the functional *COL7A1* gene are then expanded into type VII collagen protein-producing cellular sheets.[1,4]

4 APPLICATION

Up to 12 credit card-sized, gene-modified sheets (each 41.25 cm^2) are provided ~25 days after biopsy for surgical application.[1,4] Multiple individual wounds or larger areas can be treated with ZEVASKYN in a single session.[3]

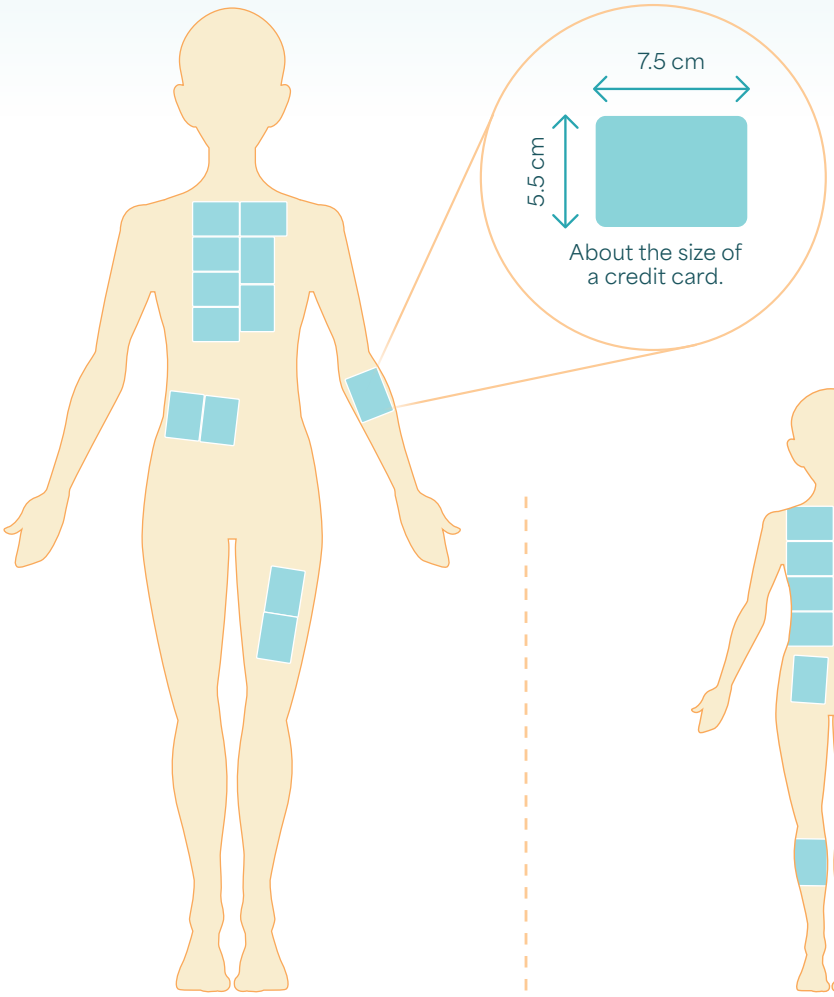
PRODUCT MANUFACTURING

Inform patients and/or caregivers that manufacturing failure may occur with autologous products. In case of a manufacturing failure, a second manufacturing of ZEVASKYN could be attempted with a new biopsy.

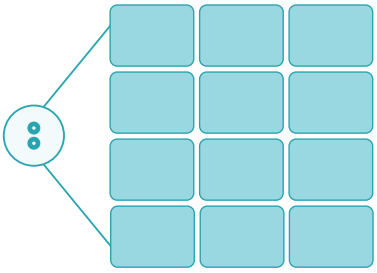
Please see additional Important Safety Information on page 15 and full Prescribing Information.

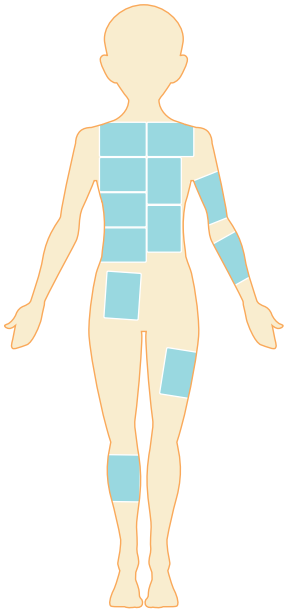
Gene-modified cellular sheets can cover multiple small and large wounds[1]

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Your patients can receive up to 12 credit card-sized ZEVASKYN sheets in one surgical session





Potential wound coverage area for
ADULT WITH RDEB
(approximately 5 ft tall)

Potential wound coverage area for
CHILD WITH RDEB
(approximately 3 ft tall)

ZEVASKYN is designed to treat RDEB wounds in people of any age, including young children. **If your patient has tough RDEB wounds that won't heal, or keep coming back, consider ZEVASKYN treatment.**

IMPORTANT SAFETY INFORMATION
Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.

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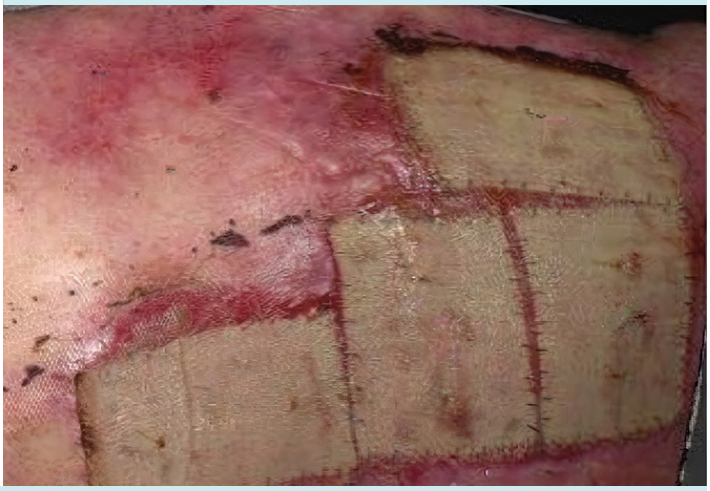
Example of wound healing at the end of Phase 1/2a long-term follow-up[3]

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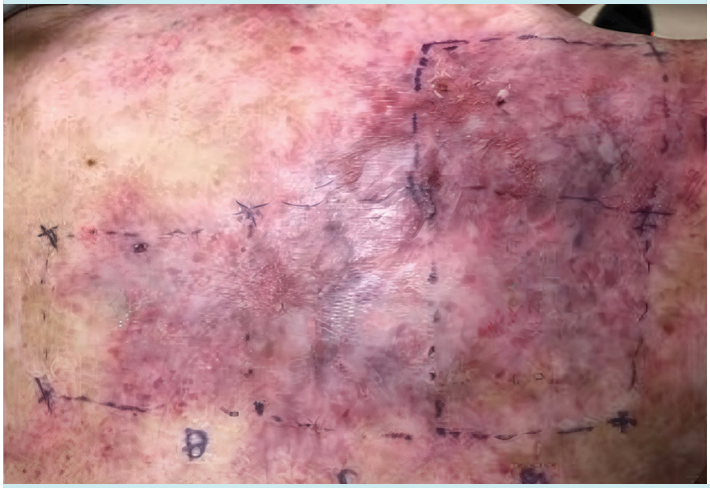
Before treatment



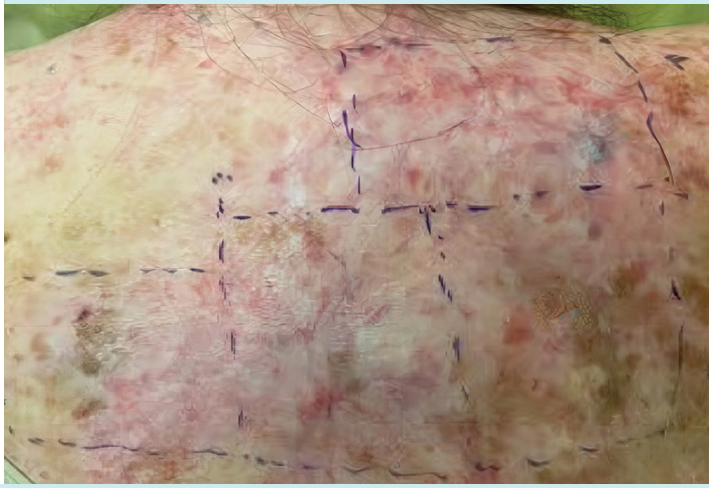
Day 0 after surgery



During long-term follow-up–Year 2



At end of in-person long-term follow-up–Year 5



Individual results may vary.

- Study design: Open-label, single-arm, single-center[1,9]*
- Patient population: 7 patients with RDEB; 38 chronic wounds assessed[9]
- In-person follow-up duration: Median 6.9 years (range: 4-8 years); planned continued virtual follow-up of up to 15 years[9]

*Because the study did not include a control group or placebo for comparison, it was not designed to determine whether the observed effects were due to ZEVASKYN.

IMPORTANT SAFETY INFORMATION
Retroviral vector (RVV)-mediated insertional oncogenesis may potentially occur after treatment with ZEVASKYN. Monitor patients lifelong after treatment for the development of malignancies. In the event that a malignancy occurs, contact Abeona Therapeutics Inc. at 1-844-888-2236.

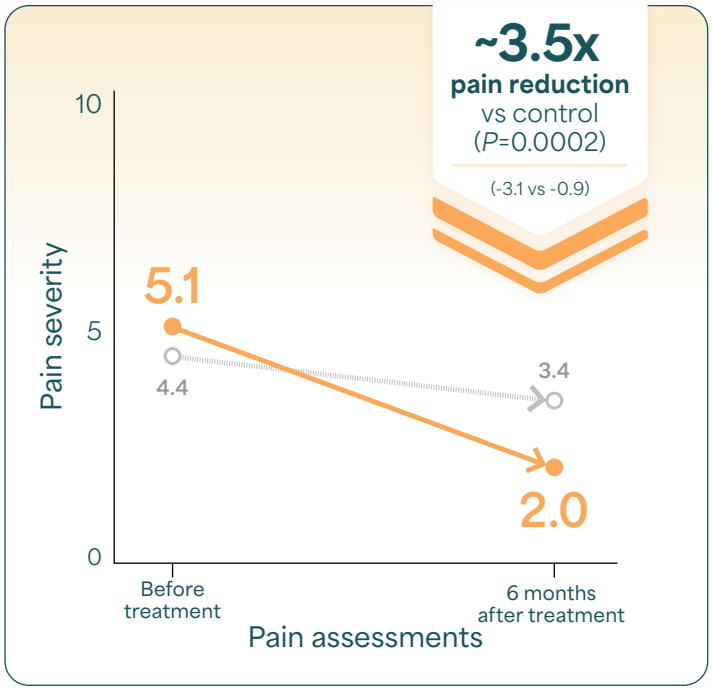
Please see additional Important Safety Information on page 15 and full Prescribing Information.

ZEVASKYN: Proven to reduce pain in treated wounds[1,8]

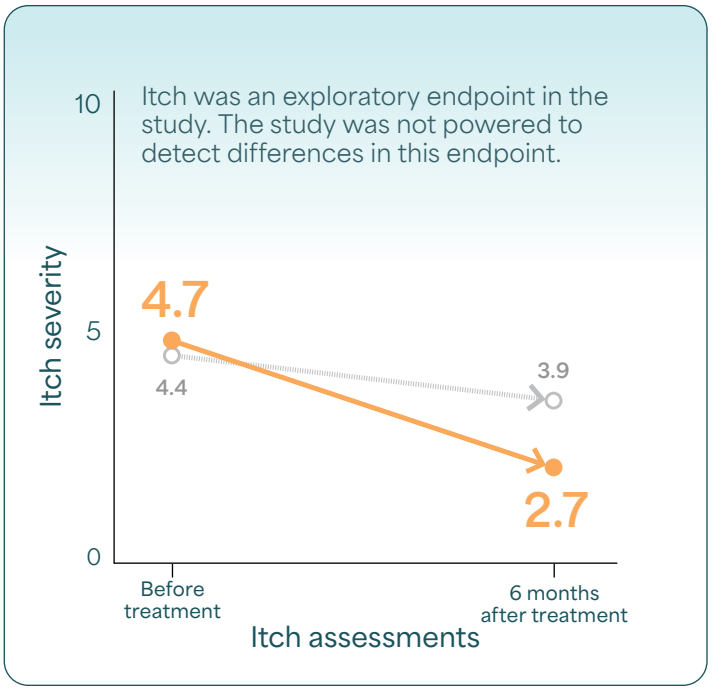
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At 6 months (VIITAL study)

Average reduction in pain (using a 0-10 scale)[1,8†]



Average reduction in itch (using a 0-10 scale)[8‡]



● ZEVASKYN-treated wounds (N=43) ○ Control wounds (N=42)

> *"Oh, it was bad [before ZEVASKYN was applied]. It was constantly itching, and the medicine wasn't helping. And then [after ZEVASKYN was applied, there] was less itching...and less pain too. When it heals [after surgery], I don't feel itching. No more itching, no more pain."*
>
> **–Guadalupe, patient treated with ZEVASKYN**
>
> Individual results may vary.



†Pain was assessed via the Wong-Baker FACES® scale or numeric rating scale (0-10) following wound dressing change. For every postbaseline assessment, pain reduction is defined as postbaseline pain score minus baseline pain score.[1,8]

‡Itch severity was assessed using the Worst Itch-Numeric Rating Scale (WI-NRS), ranging from 0 (no itch) to 10 (worst itch imaginable).[8]

IMPORTANT SAFETY INFORMATION

Transmission of infectious disease or agents may occur with ZEVASKYN because it is manufactured using human- and bovine-derived reagents, which are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.

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Established safety profile

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ZEVASKYN safety in 43 large, chronic wounds in 11 patients in the VIITAL Phase 3 study[1,8]

- Most common adverse reactions (incidence ≥5% of patients):
  - Procedural pain: 3/11 patients (27%)
  - Pruritus: 1/11 patients (9%)
  - All cases of procedural pain and pruritus were transient and resolved[6]
- No grade 3 adverse reactions were reported[8]

Additional long-term safety data from clinical trials[8,9]

- In 99 large, chronic ZEVASKYN-treated wounds across 18 patients
  - Median follow-up is 38.2 months (range: 12 months-11 years)[10,11]
- No cases of SCC were reported in ZEVASKYN-treated wounds
  - SCC was observed in non-ZEVASKYN-treated sites in 4 patients[11]
- No instances of RCR positivity were reported*

Scan or click the QR code to hear ZEVASKYN stories from patients, caregivers, and experts



"I was very excited, and I was showing it off to everyone, and I was taking pictures, and I was looking in the mirror, and I was checking it out, and I was doing everything I could to see how it looked, and I was trying to move around a little bit, and I was just thrilled with the outcome."

–Antonio, patient treated with ZEVASKYN

Individual results may vary.

RCR=replication-competent retrovirus; SCC=squamous cell carcinoma.
*Based on 102 serum samples.[11]

IMPORTANT SAFETY INFORMATION
The most common adverse reactions (incidence ≥5%) were procedural pain and pruritus.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Refer now to a ZEVASKYN Qualified Treatment Center†

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BIOPSY

- Patient's own keratinocytes are extracted from two 8 mm punch biopsies for starting material[8]
- After biopsy, the patient returns home while the cells are sent to Abeona Therapeutics, where they are genetically modified and grown into credit card–sized ZEVASKYN sheets[1]

SURGERY

- ~25 days after biopsy, up to 12 ZEVASKYN sheets are provided for surgical application[1,4]
- Wound beds are prepared and ZEVASKYN is surgically applied under general or other appropriate anesthesia[1]

DISCHARGE AND FOLLOW-UP

- Treatment areas are undisturbed for 5-10 days to allow for healing[1]
- Patient is discharged from the ZEVASKYN Qualified Treatment Center and follow-up is at the physician's discretion

Refer to a ZEVASKYN Qualified Treatment Center to help your patients gain access to this treatment as quickly as possible.

To find a ZEVASKYN Qualified Treatment Center:

ZEVASKYN Qualified Treatment Centers (QTCs) are actively treating patients. Scan or click to see the latest list and refer now.

Call 1-855-ABEONA-1 (1-855-223-6621)

Monday-Friday
9:00 AM-6:30 PM ET

†ZEVASKYN Qualified Treatment Centers are independently owned and operated. Abeona Therapeutics does not oversee any treatment centers or the medical care they provide.

IMPORTANT SAFETY INFORMATION

Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.

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Abeona Assist® is here for your patients

Abeona Assist Patient Navigators* help your patients understand the ZEVASKYN treatment pathway and provide comprehensive resources

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ZEVASKYN Treatment Pathway

Trained Patient Navigators provide information on ZEVASKYN, what to expect, and next steps to take

Coverage Review and Financial Assistance†

The team works to explore patient benefits, identify out-of-pocket costs, and provide information about access and reimbursement

Travel and Logistical Support†

The team helps coordinate travel to a ZEVASKYN Qualified Treatment Center and provides support during the patient's stay

*Patient Navigators do not direct patient care or provide medical advice.
†Eligibility requirements apply.

To find a ZEVASKYN Qualified Treatment Center, get your questions answered, and enroll your patients:

Call 1-855-ABEONA-1
(1-855-223-6621)

Monday-Friday
9:00 AM-6:30 PM ET

Email
mynavigator@abeonaassist.com

Scan or click the QR code to visit
abeonaassist.com

Abeona Assist®
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Please see additional Important Safety Information on page 15 and full Prescribing Information.



Noelle, treated with ZEVASKYN

References: 1. ZEVASKYN (prademagene zamikeracel) Prescribing Information. Cleveland, OH: Abeona Therapeutics Inc; 2026. **2.** Tang JY, Marinkovich MP, Lucas E, et al. *Orphanet J Rare Dis*. 2021;16(1):175. doi:10.1186/s13023-021-01811-7 **3.** So JY, Nazaroff J, Iwummadu CV, et al. *Orphanet J Rare Dis*. 2022;17(1):377. doi:10.1186/s13023-022-02546-9 **4.** Eichstadt S, Barriga M, Ponakala A, et al. *JCI Insight*. 2019;4(19):e130554. doi:10.1172/jci.insight.130554 **5.** Fine JD, Johnson LB, Weiner M, Li K-P, Suchindran C. *J Am Acad Dermatol*. 2009;60(2):203-211. doi:10.1016/j.jaad.2008.09.035 **6.** Data on file. Abeona Therapeutics Inc. **7.** Siprashvili Z, Nguyen NT, Gorell ES, et al. *JAMA*. 2016;316(17):1808-1817. doi:10.1001/jama.2016.15588 **8.** Clinical study report EB-101-CL-301. Abeona Therapeutics Inc. **9.** Clinical study report 14563/31095. Abeona Therapeutics Inc. **10.** EB-101 SCS 120-Day Safety Update, Table 14. Abeona Therapeutics Inc. **11.** Villanueva-Gaona R, Gorell ES, Marinkovich M, et al. *J Invest Derm.* 2024;144(8):S171. doi:10.1016/j.jid.2024.06.1149

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Find resources and support before, during, and after ZEVASKYN treatment

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Quick links to resources that can help with getting started

Scan or click to find a ZEVASKYN Qualified Treatment Center

Scan or click to hear expert and patient perspectives on ZEVASKYN

Scan or click to speak to someone treated with ZEVASKYN

Scan or click to enroll your patient in Abeona Assist

Download ZEVASKYN resources to share with your patients with RDEB

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Indication and Important Safety Information

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INDICATION

ZEVASKYN® (prademagene zamikeracel) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

IMPORTANT SAFETY INFORMATION

- Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.
- Retroviral vector (RVV)-mediated insertional oncogenesis may potentially occur after treatment with ZEVASKYN. Monitor patients lifelong after treatment for the development of malignancies. In the event that a malignancy occurs, contact Abeona Therapeutics Inc. at 1-844-888-2236.
- Transmission of infectious disease or agents may occur with ZEVASKYN because it is manufactured using human- and bovine-derived reagents, which are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.
- The most common adverse reactions (incidence ≥5%) were procedural pain and pruritus.

Please see full Prescribing Information.

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Strong Bonds Stand the Test of Time

Durable wound healing with a single surgical application—even in tough RDEB wounds[1]*

- **81% of ZEVASKYN-treated wounds** (35/43) **achieved 50% or more healing** vs 16% of matched control wounds (7/43) at week 24 in a Phase 3 study (*P*<0.0001)†
  - **~2 out of 3 ZEVASKYN-treated wounds** (28/43) **healed by 75% or more** vs 7% of matched control wounds (3/43)[8]
  - Complete wound healing achieved in 16% of ZEVASKYN-treated wounds (7/43) vs 0% of matched control wounds (0/43; *P*=0.0160)
- **~3.5x reduction in pain in ZEVASKYN-treated wounds** (-3.1) vs matched control wounds (-0.9; *P*=0.0002)
- Established safety profile with long-term follow-up[11]
  - The most common adverse reactions (incidence ≥5%) were procedural pain and pruritus[1]

*Wounds treated had remained open for at least 6 months.
†Investigator-assessed, multi-center, randomized, intrapatient-controlled study with 43 ZEVASKYN-treated wounds vs 43 matched control wounds in 11 patients with RDEB.



"When the nurse and doctor took off the bandage and I saw that new skin, when I saw it I just cried."

–Jessica, mom of Geovanna, who received ZEVASKYN at ages 6 and 7

Individual results may vary.

ZEVASKYN Qualified Treatment Centers (QTCs) are actively treating patients. Scan or click to see the latest list and refer now.

Scan or click the QR code or click to call 1-855-ABEONA-1

zevaskynhcp.com

Scan or click to connect with a ZEVASKYN Representative

SELECT SAFETY INFORMATION

ZEVASKYN may cause serious side effects, including severe hypersensitivity reactions (which can include anaphylaxis), retroviral vector-mediated insertional oncogenesis (a potential risk of malignancy requiring lifelong monitoring), and the potential transmission of infectious diseases or agents. The most common adverse reactions (incidence ≥5%) were procedural pain and pruritus.

Please see additional Important Safety Information on page 15 and full Prescribing Information.

Abeona THERAPEUTICS

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