



# ZEVASKYN™ U.S. FDA Approval

April 29, 2025



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# Indication & Important Safety Information

## Indication

- **ZEVASKYNTM (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

- Serious allergic reactions to ZEVASKYN can occur. Patients should get medical help right away if they experience symptoms like itching, swelling, hives, difficulty breathing, runny nose, watery eyes, or nausea. In rare cases, a severe reaction called anaphylaxis may happen.
- There is a potential risk that treatment with ZEVASKYN may contribute to the development of cancer because of how the therapy works. Patients should be monitored for the rest of their lives to check for any signs of cancer.
- ZEVASKYN is made using human and animal materials. Although these materials are tested before use, the risk of passing on infections cannot be eliminated.
- The most common side effects are pain from the procedure and itching.

Please see full Prescribing Information at [https://www.abeonatherapeutics.com/ZEVASKYN\\_Final\\_PI.pdf](https://www.abeonatherapeutics.com/ZEVASKYN_Final_PI.pdf).

## Today's speakers



**Vish Seshadri**  
Chief Executive Officer



**Madhav Vasanthavada**  
Chief Commercial Officer and  
Head of Business Development



**Brian Kevany**  
Chief Technical Officer &  
Chief Scientific Officer



Q&A to follow



# Welcome & introduction

**Vish Seshadri**  
Chief Executive Officer

**NOW FDA APPROVED**



Indicated for the treatment of wounds in **adult and pediatric** patients with  
recessive dystrophic epidermolysis bullosa (RDEB)



# Noelle's Story



# RDEB causes significant clinical, economic, and humanistic burden

## Clinical



Large, painful chronic wounds; risk of infection, SCC\*, extracutaneous manifestations

## Economic



Annual cost of RDEB wound care can be as high as ~\$1M (DEBRA of America\*\*)

## Humanistic



Significant impact on quality of life



## Example RDEB wounds before & after ZEVASKYN treatment

Baseline:



Week 24:



## Phase 3 VIITAL study clinical experience<sup>1</sup>



### Wound healing and pain reduction with a single surgical application – even in tough RDEB wounds

- 81% (35/43) of treated wounds achieved 50% or more healing vs 16% (7/43) of control wounds at week 24



### Established safety profile

- Most common adverse reactions (incidence  $\geq 5\%$ ) were procedural pain and pruritus
- No grade 3 adverse reactions were reported

- Wounds assessed at baseline had been **open for a median of 5 years** (range of 0.5 to 21 years) prior to study enrollment
- **Multiple, different anatomical positions and locations** were treated
- **Large wound areas** (up to 240 cm<sup>2</sup>) were treated





# Commercial opportunity & launch preparation

**Madhav Vasanthavada**

Chief Commercial Officer and Head of Business Development



**Strong Bonds Stand  
the Test of Time**







zevaskyn™  
(prademagene zamikeracel)  
gene-modified cellular sheets

## Strong Bonds Stand the Test of Time

**Wound healing with a single surgical application  
- even in tough RDEB wounds**

- 81% (35/43) of treated wounds achieved 50% or more healing vs 16% (7/43) of control wounds at week 24 in a phase 3 study

**Geovanna**, a ZEVASKYN™ patient at age 8



# Geovanna's Story





# Strong Together Network



Find Support & Connection



Hear Real Stories



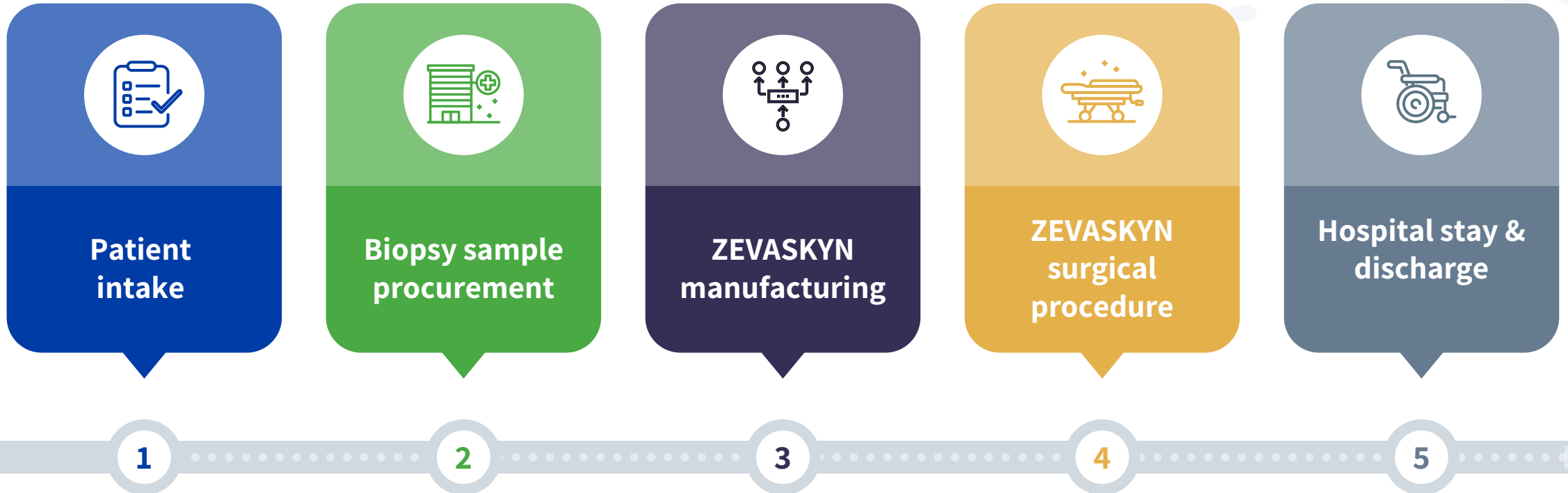
Get Helpful Insights



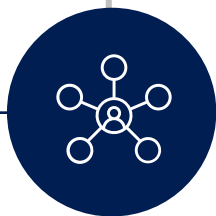
## Robust US commercial opportunity



## ZEVASKYN patient journey



# Focused on delivering exceptional ZEVASKYN treatment experience for patients



## Patient support hub



Personalized support when  
you need it  
**(1-855-ABEONA-1)**

**Abeona Assist**



## Patient-to-patient communication and engagement

Talk to ZEVASKYN patients and  
caregivers about their experience

**Strong Together Network**



## Learn more about ZEVASKYN



**[www.ZEVASKYN.com](http://www.ZEVASKYN.com)**

# Partnering with well-recognized EB Centers of Excellence (COEs) to drive successful ZEVASKYN launch



## Site activation process ongoing:

- First activated qualified treatment center (QTC) anticipated approx 3 mos post approval
- First biopsy anticipated 3Q 2025
- First ZEVASKYN treatment anticipated 3Q 2025



## 2025 expectation:

- Ensure broad and timely market access
- Activate **5 EB QTCs**
- Treat **10 to 14 patients**





**zevaskyn™**  
(prademagene zamikeracel)  
gene-modified cellular sheets

# Commercial manufacturing

**Brian Kevany**

Chief Technical Officer & Chief Scientific Officer





# Commercial manufacturing for ZEVASKYN™

## GMP Commitment



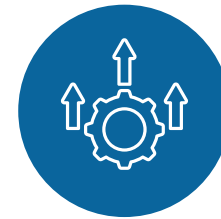
Annual maintenance of equipment and facility for quality assurance and compliance

## Near Term Ramp-Up



Supply ramp-up at current GMP facility to match projected initial demand

## Long Term Expansion



Production capacity expansion for ZEVASKYN growth



"I am very happy.  
This trial changed  
my life completely."

**Guadalupe,  
living with RDEB**



"The benefit is I saw  
healing, compared to  
other treatment,  
where I didn't see  
healing before."

**Mohamed,  
living with RDEB**



"It was the first time I  
saw pink skin.  
Beautifully, beautifully  
healed skin like I've  
never seen before in  
my life. It was totally  
life changing to see."

**Antonio,  
living with RDEB**



"My kids know it was a  
life altering moment,  
because then their  
mom was more  
available. Their mom  
was now able to do  
more things and their  
mom was there  
more."

**Lara,  
living with RDEB**



"I still would definitely  
do it again. It gets so  
many wounds closed  
and it's been  
amazing... The  
amount of time it  
saves, not having  
open wounds, not  
having to do  
bandages, not having  
to worry about  
infections... it makes  
such a difference."

**Noelle,  
living with RDEB**



"I think that the thing  
that people don't  
understand with EB is  
it's all the time...  
24/7... and we take for  
granted so much that  
our skin stays on our  
body. But someone  
with EB does not take  
that for granted."

**Noelle's mother**

## Questions & Answers