May 14, 2025

Abeona Therapeutics® and Lurie Children's Open First Center for ZEVASKYN™ Gene Therapy to Treat Wounds in Painful Skin Disorder

- ZEVASKYN, the first and only cell-based gene therapy for patients with recessive dystrophic epidermolysis bullosa (RDEB), now commercially available in the U.S. -

- Ann & Robert H. Lurie Children's Hospital of Chicago, a top-ranked hospital, is ready to evaluate patients for ZEVASKYN treatment -

- Abeona Assist™ comprehensive patient services program in place to offer personalized support for eligible patients and their families throughout ZEVASKYN treatment journey -

CLEVELAND and CHICAGO, May 14, 2025 (GLOBE NEWSWIRE) -- Correction for Trademark symbol in headline - Abeona Therapeutics Inc. (Nasdaq: ABEO) and Ann & Robert H. Lurie Children's Hospital of Chicago today announced that Lurie Children's is now activated as the first Qualified Treatment Center (QTC) for ZEVASKYN (prademagene zamikeracel) gene-modified cellular sheets. This groundbreaking therapy will be used to treat wounds associated with recessive dystrophic epidermolysis bullosa (RDEB) – a rare skin disorder characterized by severe, painful wounds that can lead to systemic complications impacting the length and quality of life. Lurie Children's has completed QTC start-up activities enabling it to begin patient identification for scheduling of ZEVASKYN treatment. Treatments are expected to begin in the third quarter of 2025.

On April 29, 2025, Abeona announced approval from the U.S. Food and Drug Administration (FDA) for ZEVASKYN as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with RDEB. There is no cure for RDEB and ZEVASKYN is the only FDA-approved product to treat RDEB wounds with a single application.

"Lurie Children's is a top-ranked hospital, known for its expertise in treating patients with epidermolysis bullosa, and we are pleased to announce that ZEVASKYN is now commercially available with the activation of Lurie Children's as our first QTC," said Madhav Vasanthavada, Ph.D., M.B.A., Chief Commercial Officer of Abeona. "This site activation comes just a few weeks after the FDA approval of ZEVASKYN, underscoring the collaborative relationship between Lurie Children's and Abeona, and our shared conviction that ZEVASKYN is an important treatment option for people living with RDEB."

Amy Paller, MD, head of the epidermolysis bullosa research and care program at Lurie Children's, and Chair of the Department of Dermatology at Northwestern University

Feinberg School of Medicine, said, “Lurie Children’s is proud to be the first qualified treatment site in the U.S. to offer this groundbreaking treatment for RDEB patients. Grafting gene-corrected cellular sheets onto chronically open wounds of patients with RDEB promises the potential to provide long-term healing of wounds, reduction in pain and reduced risk of infection.”

Lurie Children’s has been a center for excellence for genetic skin diseases for more than 30 years. As one of the largest North American centers for epidermolysis bullosa (EB), caring for more than 150 affected children and adults, Lurie Children’s has been a member of the EB Clinical Research Consortium since its inception and continues to conduct cutting-edge bench and clinical research to better understand the disease and find new treatment options. For more information about receiving ZEVASKYN treatment at Lurie Children’s, email the Gene and Cellular Medicine Program at genetherapy@luriechildrens.org.

Lurie Children’s has been providing FDA-approved gene therapies since 2019, and the program is actively growing. Currently, gene therapies are available for neuromuscular disorders, eye disorders, and cancer and blood disorders. ZEVASKYN will be the tenth gene therapy offered at Lurie Children’s, with the first patient expected to be biopsied in July 2025 and to receive this treatment in August 2025.

Abeona is committed to enabling access to ZEVASKYN for eligible patients in the U.S. and has deployed services to provide information and resources to make informed decisions about treatment with ZEVASKYN for RDEB wounds. Abeona’s comprehensive patient support program, Abeona Assist™, offers personalized support, including helping patients understand their insurance benefits and financial assistance options, and providing travel and logistical assistance. For more information on how to access ZEVASKYN and learn about patient support services offered through Abeona Assist, visit www.abeonaassist.com, call 1-855-ABEONA-1 (1-855-223-6621) or email MyNavigator@AbeonaAssist.com.

About Recessive Dystrophic Epidermolysis Bullosa

Recessive dystrophic epidermolysis bullosa (RDEB), a rare blistering disorder without a cure, is characterized by severe skin wounds that cause pain and can lead to systemic complications impacting the length and quality of life. People with RDEB have a defect in both copies of the COL7A1 gene, leaving them unable to produce functioning type VII collagen, which is necessary to anchor the dermal and epidermal layers of the skin.

About ZEVASKYN™ (prademagene zamikeracel) gene-modified cellular sheets or pz-cel

ZEVASKYN is the first and only autologous cell sheet-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). RDEB is a severe skin disease caused by a defect in both copies of the COL7A1 gene resulting in the inability to produce functional type VII collagen. Without functional type VII collagen and anchoring fibrils, the skin is fragile and blisters easily, leading to wounds that continually open and close, or fail to heal altogether. Patients often have large open wounds that can lead to serious life-threatening complications. ZEVASKYN incorporates the functional type VII collagen-producing COL7A1 gene into a patient’s own skin cells, ex vivo, using a replication-incompetent retroviral vector to produce functional type VII collagen in treated wounds. ZEVASKYN has demonstrated clinically meaningful wound healing and

pain reduction with a single surgical application. For more information, visit www.ZEVASKYN.com and www.AbeonaAssist.com.

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

- 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.

This is not a complete list of side effects. Patients should call their care team for medical advice about side effects. Side effects may be reported to Abeona at 1-844-888-2236 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See full Prescribing Information.

About Lurie Children's Gene and Cellular Medicine Program

Lurie Children's Gene and Cellular Medicine Program is committed to advancing treatment of conditions that are amenable to gene and cell-based therapy. Our program looks to bring hope to patients who live with various blood disorders, neurogenerative conditions, and other genetic disorders. Our integrated team of clinical researchers, infusion center experts, and other healthcare professionals collaborates to provide a seamless continuum of care for our pediatric patients and their families.

About Lurie Children's

Ann & Robert H. Lurie Children's Hospital of Chicago is a nonprofit organization committed to providing access to exceptional care for every child. It is the only independent, research-driven children's hospital in Illinois and one of less than 35 nationally. This is where the top doctors go to train, practice pediatric medicine, teach, advocate, research and stay up to date on the latest treatments. Exclusively focused on children, all Lurie Children's resources are devoted to serving their needs. Research at Lurie Children's is conducted through Stanley Manne Children's Research Institute, which is focused on improving child health, transforming pediatric medicine and ensuring healthier futures through the relentless pursuit of knowledge. Lurie Children's is the pediatric training ground for Northwestern University Feinberg School of Medicine. It is ranked as one of the nation's top children's hospitals by *U.S. News & World Report*.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a commercial-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona's ZEVASKYN™ (prademagene zamikeracel) is the first and only autologous cell-based gene therapy for the treatment of wounds in adults and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The Company's fully integrated cell and gene therapy cGMP manufacturing facility in Cleveland, Ohio serves as the manufacturing site for ZEVASKYN commercial production. The Company's development portfolio features adeno-associated virus (AAV)-based gene therapies for ophthalmic diseases with high unmet medical need. Abeona's novel, next-generation AAV capsids are being evaluated to improve tropism profiles for a variety of devastating diseases. For more information, visit www.abeonatherapeutics.com.

Forward-Looking Statements

This press release contains certain statements that are forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and that involve risks and uncertainties. We have attempted to identify forward-looking statements by such terminology as "may," "will," "believe," "anticipate," "expect," "intend," "potential," and similar words and expressions (as well as other words or expressions referencing future events, conditions or circumstances), which constitute and are intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, numerous risks and uncertainties, including but not limited to, our ability to commercialize ZEVASKYN, the therapeutic potential of ZEVASKYN, whether the unmet need and market opportunity for ZEVASKYN are consistent with the Company's expectations, continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of future meetings with and inspections from the FDA or other regulatory agencies, including those relating to preclinical programs; the ability to achieve or obtain necessary regulatory approvals; the impact of any changes in the financial markets and global economic conditions; risks associated with data analysis and reporting; and other risks disclosed in the Company's most recent Annual Report on Form 10-K and subsequent periodic reports filed with the Securities and Exchange Commission. The Company undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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