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Abeona Therapeutics® Announces First Patient Treatment with ZEVASKYN® Gene Therapy

CLEVELAND, Dec. 08, 2025 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced the first commercial patient treatment with FDA-approved ZEVASKYN (prademagene zamikeracel), a first-of-its-kind, autologous gene therapy for treating wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). ZEVASKYN was administered at Lucile Packard Children's Hospital Stanford in Palo Alto, CA.

"Treating our first patient is a proud moment for Abeona and a testament to the tireless resolve of our team," said Vish Seshadri, Chief Executive Officer of Abeona. "We are humbled to bring ZEVASKYN to the RDEB community and grateful to our growing network of Qualified Treatment Centers. Momentum is building, with additional patients already scheduled for treatment in the new year."

Joyce Teng, MD, PhD, professor of dermatology at Stanford Medicine and chief of pediatric dermatology at Stanford Medicine Children's Health, said, "We continually pursue new therapies to support patients enduring the lifelong pain and extensive wound care that RDEB demands, and work to provide care and hope to patients and families."

For more information on how to access ZEVASKYN and learn about patient support services offered through Abeona Assist®, Abeona's comprehensive patient support program, visit www.abeonaassist.com, call 1-855-ABEONA-1 (1-855-223-6621) or email MyNavigator@AbeonaAssist.com. Abeona Assist offers personalized support, including helping eligible patients understand their insurance benefits and financial assistance options, and providing travel and logistical assistance.

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

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.

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 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 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 successfully commercialize and market ZEVASKYN, including manufacturing sufficient batches of ZEVASKYN to meet demand; 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 by the FDA or other regulatory agencies, including those relating to preclinical programs and to the cGMP manufacturing of ZEVASKYN; the ability to achieve or obtain necessary regulatory approvals for our pre-clinical programs; the impact of any changes in the financial markets and global economic conditions, including those resulting from changes to U.S. trade policy, such as current or future tariffs; 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 these 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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