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Abeona Therapeutics® and Children's Hospital Colorado Announce Newest Treatment Center for ZEVASKYN® Gene Therapy

CLEVELAND, Ohio and AURORA, Colo., Oct. 08, 2025 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) and Children's Hospital Colorado today announced activation of Children's Colorado as the newest Qualified Treatment Center (QTC) for ZEVASKYN (prademagene zamikeracel) gene-modified cellular sheets. This first-of-its-kind therapy is FDA-approved to treat wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). Children's Colorado in Aurora, CO, one of the pioneering institutions that provide advanced levels of care for people with epidermolysis bullosa (EB), has completed QTC start-up activities enabling it to begin patient identification for scheduling of ZEVASKYN treatment.

Anna L. Bruckner, MD, Co-Director of the EB Clinic at Children’s Hospital of Colorado and Professor of Dermatology, University of Colorado School of Medicine, said, “We are thrilled to be able to provide our patients a much needed, long lasting treatment option, and with it, the hope for an improved quality of life.”

“We are excited to be working with Dr. Bruckner and Children's Hospital Colorado in making ZEVASKYN available to RDEB patients,” said Dr. Madhav Vasanthavada, Chief Commercial Officer of Abeona. “Dr. Bruckner is one of the leading experts in EB care, and the activation of Children’s Colorado is a major milestone in broadening access to ZEVASKYN across a growing network of established EB centers.”

Children’s Hospital Colorado’s epidermolysis bullosa program is recognized as a center of excellence by debra of America, the lead patient advocacy organization for EB. Children's Colorado is a member of the EB Clinical Research Consortium and continues to conduct cutting-edge bench and clinical research to reshape the future of rare disease treatment and offer significant promise of transformative care and better quality of life for patients with EB. The Precision Medicine Institute at Children’s Colorado supports these programs through pioneering novel treatments like this, using each patient’s unique genetic information to treat their disease.

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 Children's Hospital Colorado

Children's Hospital Colorado is one of the nation's leading and most expansive nonprofit pediatric healthcare systems with a mission to improve the health of children through patient care, education, research and advocacy. Founded in 1908 and ranked among the best children's hospitals in the nation as recognized byU.S. News & World Report,Children's Coloradohas established itself as a pioneer inthe discovery of innovative and groundbreaking treatments that are shaping the future of pediatric healthcare worldwide. Children's Colorado offers a full spectrum of family-centered care at its urgent, emergency and specialty care locations throughout Colorado, including an academic medical center on the Anschutz Medical Campus in Aurora, hospitals in Colorado Springs, Highlands Ranch and Broomfield, and outreach clinicsacross theregion.For more information, visit www.childrenscolorado.org or connect with us on Facebook, Instagram and YouTube.

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 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 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; 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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