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Abeona Therapeutics Announces Additional Phase 3 VIITAL™ Study Results for EB-101 Presented at the International Societies for Investigative Dermatology 2023 Meeting

CLEVELAND, May 11, 2023 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced an oral presentation of additional data from the Company's pivotal Phase 3 VIITAL™ study evaluating its investigational EB-101 for recessive dystrophic epidermolysis bullosa (RDEB). The data presentation occurred earlier today during the inaugural International Societies for Investigative Dermatology (ISID) Meeting in Tokyo, Japan.

“Following the positive topline VIITAL study results reported in November 2022, the additional data reported at ISID further highlights the value proposition of EB-101 by demonstrating improved wound healing and pain reduction at 6, 12 and 24 weeks compared to control wounds following a one-time application of EB-101,” said Vish Seshadri, Chief Executive Officer of Abeona. “Furthermore, EB-101 demonstrated improvement in patient-reported and caregiver-reported outcomes for itch severity and blistering. In totality, these results highlight the potential for EB-101 to meaningfully improve quality of life of RDEB patients.”

Presentation Highlights
In the presentation, entitled, “Results from VIITAL: A phase 3, randomized, intrapatient-controlled trial of an investigational collagen type VII gene–corrected autologous cell therapy, EB-101, for the treatment of recessive dystrophic epidermolysis bullosa (RDEB),” Jean Tang, M.D., Ph.D., Professor of Dermatology, Stanford University School of Medicine and Principal Investigator of the VIITAL study reported:

- Both co-primary endpoints of VIITAL were met, with the majority (81.4%) of randomized EB-101–treated wounds demonstrating ≥50% healing compared with 16.3% of untreated control wounds, and a significantly greater reduction in pain severity observed in randomized EB-101−treated wounds (3.07 mean pain reduction from baseline) compared with untreated control wounds (0.90 mean pain reduction from baseline) at six months.
- At earlier time points, meaning weeks 6 and 12, the percentage of wounds with ≥50%, ≥75%, and complete healing, as well as pain reduction, was greater for randomized EB-101–treated wounds and achieved statistical significance over untreated control wounds.
- In addition to significantly reducing pain, patient-reported outcomes related to itch and

blistering showed significantly greater improvement with EB-101 treatment.
- Caregiver-reported outcomes related to wound care and overall impression of wound pain showed consistent trends for improvement.
- EB-101 was shown to be well-tolerated with no serious treatment-related adverse events observed, consistent with past clinical experience.

The ISID presentation slides are available on the Events page of Abeona's website at https://investors.abeonatherapeutics.com/events.

About Recessive Dystrophic Epidermolysis Bullosa
Recessive dystrophic epidermolysis bullosa (RDEB) is a rare connective tissue disorder 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 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. There is currently no approved treatment for RDEB.

About EB-101
EB-101 is an autologous, engineered cell therapy currently being developed for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a rare connective tissue disorder without an approved therapy. The pivotal Phase 3 VIITAL™ study is a randomized clinical trial that evaluated the efficacy, safety and tolerability of EB-101 in 43 large chronic wound pairs in 11 subjects with RDEB. Treatment with EB-101 involves using gene transfer to deliver the functional COL7A1 gene into a patient's own skin cells (keratinocytes and its progenitors) and transplanting those cells back to the patient. EB-101 is being investigated for its ability to enable normal Type VII collagen expression and to facilitate wound healing. EB-101 has been granted Regenerative Medicine Advanced Therapy, Breakthrough Therapy, Orphan Drug and Rare Pediatric Disease designations by the U.S. FDA. Abeona produces EB-101 for the VIITAL study at its fully integrated gene and cell therapy manufacturing facility in Cleveland, Ohio. EB-101 is an investigational product not yet approved by the FDA.

About Abeona Therapeutics
Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona's lead clinical program is EB-101, its investigational autologous, engineered cell therapy currently in development for recessive dystrophic epidermolysis bullosa. The Company's development portfolio also features 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. Abeona's fully integrated cell and gene therapy cGMP manufacturing facility produces EB-101 for the pivotal Phase 3 VIITAL™ study and is capable of clinical and potential commercial production of AAV-based gene therapies. 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,” and similar 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, the timing and outcome of our Biologics License Application submission to the FDA for EB-101; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of future meetings with 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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