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Abeona Therapeutics Announces Submission of Briefing Package for Pre-Biologics License Application (BLA) Meeting with FDA in August 2023

CLEVELAND, July 28, 2023 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced that it has completed the submission of the briefing package to the U.S. Food and Drug Administration (FDA) for the Company's pre-Biologics License Application (BLA) meeting in August 2023. The purpose of the pre-BLA meeting is to discuss with the FDA the format, content, and acceptability of the anticipated BLA for EB-101, Abeona's investigational autologous, engineered cell therapy for recessive dystrophic epidermolysis bullosa.

"In response to the FDA's request, we have generated additional data to establish comparability between retroviral vectors from two different sources that were used in the EB-101 clinical studies, and have included this data in the briefing package for our pre-BLA meeting with the FDA in August of 2023," said Vish Seshadri, Chief Executive Officer of Abeona. "We look forward to discussing various clinical and chemistry, manufacturing, and controls aspects of our data package at the pre-BLA meeting, and anticipate submitting the EB-101 BLA in the third quarter of 2023."

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 produced 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.

Investor and Media Contact:

Greg Gin

VP, Investor Relations and Corporate Communications

Abeona Therapeutics

ir@abeonatherapeutics.com



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