June 9, 2023

Abeona Therapeutics Announces Regulatory Update on Biologics License Application (BLA) for EB-101

CLEVELAND, June 09, 2023 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced that it received feedback from the U.S. Food and Drug Administration (FDA) on June 8, 2023, in which the Company gained the Agency's alignment on the data required to establish retroviral vector (RVV) comparability, a critical Chemistry, Manufacturing and Controls (CMC) component for the EB-101 Biologics License Application (BLA).

"Gaining alignment with the FDA on the RVV comparability package is a very important de-risking milestone for our BLA submission after our recent successful completion of the Process Performance Qualification (PPQ) manufacturing validation runs," said Vish Seshadri, Chief Executive Officer of Abeona.

As part of the package, the FDA requested additional assay data to establish comparability between RVV sourced from Indiana University and RVV manufactured in-house at Abeona, both of which have been used in the EB-101 clinical studies. The Company has the necessary reagents in-house to promptly generate the requested data. To allow the FDA the necessary time to review the requested RVV data, Abeona has requested that its pre-BLA meeting date for EB-101 be rescheduled for August 2023. The Company expects to file its BLA for EB-101 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 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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