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# Abeona Therapeutics® Announces Favorable Medicare Reimbursement Decisions for Pz-cel

## CMS grants ICD-10-PCS product-specific procedure code and favorable DRG assignment for pz-cel, supporting efficient hospital billing, reimbursement and patient access

CLEVELAND, Ohio, Aug. 13, 2024 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced that the Centers for Medicare and Medicaid Services (CMS) has granted a product-specific procedure code ICD-10-PCS (International Classification of Diseases, 10th Revision, Procedure Coding System) for prademagene zamikeracel (pz-cel), Abeona's investigational autologous cell-based gene therapy currently in development for recessive dystrophic epidermolysis bullosa (RDEB). If pz-cel receives U.S. marketing approval, this code will allow for efficient and accurate documentation, billing, and analysis of inpatient hospital procedures using pz-cel. The code will go into effect on October 1, 2024.

Abeona also announced, as part of the Inpatient Prospective Payment System (IPPS) Final Rule for fiscal year 2025, CMS assigned Medicare reimbursement of pz-cel to Pre-Major Diagnostic Category, Medicare Severity Diagnosis Related Group 018 (Pre-MDC MS-DRG 018), which is among the highest available inpatient hospital reimbursement levels for cell and gene therapies. The DRG code for pz-cel will go into effect on October 1, 2024.

Madhav Vasanthavada, Chief Commercial Officer of Abeona, said, "We are pleased that CMS has issued a product-specific procedure code and Medicare reimbursement for pz-cel that recognizes the breakthrough nature of this gene therapy technology for RDEB patients. The favorable Medicare decisions complement the positive feedback we have heard from commercial payers, giving us confidence as we seek to secure strong access and reimbursement for all RDEB patients. The CMS coding assignment is a major step in simplifying inpatient hospital billing across all payers and increasing speed to access of pz-cel after its potential FDA approval."

**About prademagene zamikeracel (pz-cel)**
Prademagene zamikeracel (pz-cel), Abeona's investigational autologous cell-based gene therapy, is currently being developed for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). RDEB is a rare connective tissue disorder caused by a defect in the *COL7A1* gene that results in the inability to produce Type VII collagen. Pz-cel is designed to incorporate the functional collagen-producing *COL7A1* gene into a patient's own skin cells and enable long-term gene expression by using a retroviral vector to stably integrate into the dividing target cell genome. Pz-cel is being investigated for its ability to enable normal Type

VII collagen expression and to facilitate wound healing and pain reduction in even the toughest-to-treat RDEB wounds after a one-time application procedure. The pivotal Phase 3 VIITAL™ study is a randomized clinical trial that evaluated the efficacy, safety and tolerability of pz-cel in 43 large chronic wound pairs in 11 subjects with RDEB. Pz-cel has been granted Regenerative Medicine Advanced Therapy, Breakthrough Therapy, Orphan Drug and Rare Pediatric Disease designations by the U.S. FDA. Abeona produces pz-cel for the VIITAL™ study at its fully integrated gene and cell therapy manufacturing facility in Cleveland, Ohio.

**About Abeona Therapeutics**

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Prademagene zamikeracel (pz-cel) is Abeona's investigational autologous cell-based gene therapy currently in development for recessive dystrophic epidermolysis bullosa. The Company's fully integrated cell and gene therapy cGMP manufacturing facility served as the manufacturing site for pz-cel used in its Phase 3 VIITAL™ trial, and is capable of supporting commercial production of pz-cel upon FDA approval. 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. 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, the timing and results of ongoing testing and other corrective actions being performed in response to the FDA's identified deficiencies, which could delay the Company's BLA resubmission; the timing and outcome of the FDA's review of our resubmission; the FDA's grant of a Priority Review Voucher upon approval; 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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