4DMT Advances 4D-710 to Phase 2 with Additional Funding and Support from the Cystic Fibrosis Foundation

October 13, 2025

- *Cystic Fibrosis Foundation to provide up to $11 million in additional funding to accelerate development of 4D-710 for cystic fibrosis, following program and clinical data review by its independent scientific advisors*
- *Funding supports second 4D-710 dosing ≥1 year post initial Phase 1 dose, advancement into Phase 2, and Phase 3 readiness*
- *Enrollment in the Phase 2 stage of the AEROW clinical trial is currently underway, with 2.5E14 vg selected as the anticipated pivotal and commercial dose*

EMERYVILLE, Calif., Oct. 13, 2025 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT, or the Company), a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients, today announced that the Cystic Fibrosis Foundation (CF Foundation) will provide up to $11 million in additional funding, with an initial tranche of $7.5 million, and technical support to accelerate the development of 4D-710 for the treatment of cystic fibrosis (CF) lung disease. This support includes the creation of a new Joint Steering Committee (JSC) with senior clinical development and regulatory expertise to enhance strategic planning, guidance, and coordination of 4D-710's development. With this funding, the CF Foundation has committed nearly $32 million to 4DMT CF programs to date.

"We are honored to receive the CF Foundation's continued support, which underscores our shared mission to bring transformative new treatments to people with CF," said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. "Our next-generation A101 vector utilized in 4D-710 was invented for efficient aerosol delivery and transduction throughout the lung airways and was designed to enable repeat dosing to maintain clinical benefit over time. This funding and strategic support are critical as we advance 4D-710 through Phase 2, with the goal of delivering a durable, redosable, and variant-agnostic genetic medicine with the potential to become a foundational treatment for individuals with CF with remaining unmet pulmonary needs. We look forward to sharing interim Phase 1 data from the AEROW clinical trial, including functional durability results one to three years post-dosing, and providing a program update by year-end."

Funding and Joint Steering Committee to Support Accelerated Late-Stage Development

The CF Foundation will invest up to $11 million in 4DMT equity in two tranches, with the second tranche subject to specific clinical milestones. The first tranche of $7.5 million closed in October 2025.

In addition, the CF Foundation and 4DMT will form a Joint Steering Committee (JSC) with senior clinical development and regulatory expertise to further increase the strategic planning, guidance, and coordination of clinical and operational progress for the development of 4D-710.

The funding and JSC will support the following activities:

- AEROW clinical trial – Phase 1 Redosing Cohort:
  - Selected participants from Phase 1 are expected to receive a second dose (2.5E14 vg), ≥1 year following initial 4D-710 dosing
- AEROW clinical trial – Phase 2 Cohort:
  - Enrollment has begun with 2.5E14 vg as the anticipated pivotal and commercial dose, which was selected after review with the CF Foundation Safety Review Team and clinical data trial leadership
- Phase 3 readiness

Interim Phase 1 Data from AEROW and Program Update Expected by Year-End 2025

- As previously disclosed, AEROW protocol was amended to add additional clinical endpoints in lower dose cohorts (5E14 and 2.5E14 vg):
  - Multiple-breath washout (MBW) measuring lung clearance index ($LCI_{2.5}$): Lung clearance index ($LCI_{2.5}$) is a sensitive and reproducible measure of small airway function that has been used by regulators to support pediatric CF therapy approvals and may detect treatment effects earlier than traditional lung function tests such as $ppFEV_1$
  - High-resolution computed tomography (HRCT): HRCT is an imaging technique that provides detailed visualization of the lungs, allowing pulmonologists to assess changes in airway structure such as mucus plugging and airway wall thickening
- Phase 1 data to focus on follow-up of n=9 lower dose patients (approximately 3 to 18 months), with a focus on functional respiratory endpoints including $LCI_{2.5}$, $ppFEV_1$, and CFQ-R-R
- 4D-710 transgene expression and functional durability data, including analysis of paired lung biopsies collected at 1-2 months and then 1-3 years post-dosing
- Plans for Phase 1 Redosing Cohort

About Cystic Fibrosis Lung Disease

Cystic fibrosis (CF) is an inherited progressive disease caused by variants in the *CFTR* gene. According to the CF Foundation, nearly 40,000 people in the United States and more than 105,000 people worldwide are living with CF, with approximately 1,000 new cases of CF diagnosed in the United States each year. Lung disease is the leading cause of morbidity and mortality in people with CF. CF causes impaired lung function, inflammation, and bronchiectasis and is commonly associated with persistent lung infections and repeated exacerbations due to the inability to clear thickened mucus from the lungs. People with CF require lifelong treatment with multiple daily medications, resulting in a high treatment burden. The complications of the disease result in progressive loss of lung function, increasing need for IV antibiotics and hospitalizations, and ultimately leading to end-stage respiratory failure.

About 4D-710

4D-710 is designed to be a durable, redosable, and variant-agnostic genetic medicine that addresses the underlying cause of CF to improve airway function throughout the lungs, resulting in enhanced quality of life. We believe 4D-710 has the potential to become a foundational therapy for many people with CF, regardless of their specific *CFTR* variant. Combining our targeted and evolved next generation aerosolized AAV vector, A101, with a codon-optimized *CFTR*Δ*R* transgene, 4D-710 is the first known genetic medicine to demonstrate successful delivery and expression of the *CFTR* transgene throughout the airways of people with CF after aerosol delivery. The ongoing AEROW Phase 1/2 clinical trial is assessing 4D-710's impact on overall lung health, including changes to small airway function, airway structure, and quality of life. 4D-710 has received the Rare Pediatric Disease Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA).

About 4DMT

4DMT is a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients. The Company's lead product candidate 4D-150 is designed to be a backbone therapy forming the foundation of treatment of blinding retinal vascular diseases by providing multi-year sustained delivery of anti-VEGF (aflibercept and anti-VEGF-C) with a single, safe, intravitreal injection, which substantially reduces the treatment burden associated with current bolus injections. The Company's lead indication for 4D-150 is wet age-related macular degeneration, which is currently in Phase 3 development, and the second indication is diabetic macular edema. The Company's second product candidate is 4D-710, which is the first known genetic medicine to demonstrate successful delivery and expression of the CFTR transgene in the lungs of people with cystic fibrosis after aerosol delivery. 4D Molecular Therapeutics™, 4DMT™ Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DMT.

All of the Company's product candidates are in clinical or preclinical development and have not yet been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority. No representation is made as to the safety or effectiveness of the Company's product candidates for the therapeutic uses for which they are being studied.

Learn more at www.4DMT.com and follow us on LinkedIn.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding clinical development of our product candidates, including 4D-710 and 4D-150, the potential benefits of the investment from and collaboration with the CF Foundation, the potential additional second tranche funding from the CF Foundation, and 4D Molecular Therapeutics' plans to share interim Phase 1 data from the AEROW clinical trial, including functional durability results one to three years post-dosing, and plans to provide a program update by year-end. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target," and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including: (i) risks that clinical trial results may not support regulatory approval or demonstrate sustained therapeutic benefit; (ii) risks that our product candidates may not demonstrate sufficient safety or efficacy; (iii) risks related to regulatory approval processes and evolving standards for gene therapies; (iv) risks that 4D Molecular Therapeutics may not receive additional CF Foundation funding or may require additional capital; (v) risks related to manufacturing complexity and supply chain for gene therapies; and (vi) risks of competition and rapidly evolving treatment landscape; as well as other risks and uncertainties that are described in greater detail in the section entitled "Risk Factors" in 4D Molecular Therapeutics' most recent Quarterly Report on Form 10-Q filed on August 11, 2025, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statement represents 4D Molecular Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. 4D Molecular Therapeutics undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this press release, except as may be required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Contacts:

Media:
Jenn Gordon
dna Communications
Media@4DMT.com

Investors:
Julian Pei
Head of Investor Relations and Strategic Finance
Investor.Relations@4DMT.com