

4DMT to Present Interim Data from Aerosolized 4D-710 Phase 1/2 AEROW Clinical Trial for Cystic Fibrosis at 2023 NACFC

October 25, 2023

- 4D-710 interim data to be presented in plenary and symposium sessions at the North American Cystic Fibrosis Conference in Phoenix, Arizona held on November 2-4, 2023
- Company to host webcast on Wednesday, November 1, 2023 at 4:30 p.m. ET

EMERYVILLE, Calif., Oct. 25, 2023 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT or the Company), a clinical-stage genetic medicines company with three novel, highly targeted next generation AAV vectors currently in the clinic, today announced that interim data from the Phase 1/2 AEROW clinical trial of aerosolized 4D-710 for treatment of cystic fibrosis lung disease will be presented at the 2023 North American Cystic Fibrosis Conference (NACFC) and that it will host a live webcast to discuss the data in detail and provide a program update on Wednesday, November 1, 2023 at 4:30 p.m. ET.

The interim data will include additional safety and clinical activity follow-up on Cohort 1 (n=3) at the 1E15 vg dose level and initial safety and biomarker data from Cohort 2 (n=3-6) at the 2E15 vg dose level. The Company previously announced positive interim data from Cohort 1 at the European Cystic Fibrosis Society 46th Annual Meeting.

2023 NACFC Presentation Details:

Plenary Session: Genetic Therapies for All: Harnessing Cross-Disease Knowledge for Breakthroughs in Cystic Fibrosis

Date/Time: Thursday, November 2, 2023 at 4:30 p.m. MST Presenter: Paul McCray, Jr., MD, University of Iowa

Symposium Session: Building the Path to the Cure: the role of AAV therapy

Date/Time: Friday, November 3, 2023 at 3:30 p.m. MST

Presenter: Jennifer L. Taylor-Cousar, MD, National Jewish Health

Webcast Details:

Title: 4D-710 Phase 1/2 AEROW Interim Clinical Data and Program Update Webcast and Q&A

Date/Time: Wednesday, November 1, 2023 at 4:30 p.m. ET

Registration: Link

An archived copy of the webcast will be available for up to one year by visiting the "Investors & Media" section of the 4DMT website at the following link: https://ir.4dmoleculartherapeutics.com/events.

About 4D-710 and Cystic Fibrosis Lung Disease

4D-710 is comprised of our targeted and evolved next generation vector, A101, and a codon-optimized CFTR∆R transgene. 4D-710 has the potential to treat a broad range of people with cystic fibrosis, independent of the specific CFTR mutation, and is designed for aerosol delivery to achieve CFTR expression within lung airway epithelial cells. 4D-710 is being initially developed in approximately 15% of people whose disease is not amenable to existing CFTR modulator medicines targeting the CFTR protein. In people with CFTR mutations whose disease is amenable to modulator medicines, the improvement in lung function is incomplete and is variable. We therefore expect to potentially develop 4D-710 in this broader population, as a single agent and/or in combination with CFTR modulator small molecule medicines.

Cystic fibrosis is a major inherited disease caused by mutations in the CFTR gene. According to the CF Foundation, approximately 40,000 people in the United States and more than 105,000 people worldwide are living with cystic fibrosis, with approximately 1,000 new cases of cystic fibrosis diagnosed in the United States each year. Lung disease is the leading cause of morbidity and mortality in people with Cystic fibrosis. Cystic fibrosis 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 cystic fibrosis require lifelong treatment with multiple daily medications. The complications of the disease result in progressive loss of lung function and hospitalizations, and ultimately lead to end-stage respiratory failure.

About 4DMT

4DMT is a clinical-stage biotherapeutics company with three novel, highly targeted next generation AAV vectors currently in the clinic targeting multiple large market diseases in ophthalmology and pulmonology, plus other therapeutic areas. 4DMT seeks to unlock the full potential of genetic medicines using its proprietary invention platform, Therapeutic Vector Evolution, which combines the power of the Nobel Prize-winning technology, directed evolution, with approximately one billion synthetic AAV capsid-derived sequences to invent customized and evolved vectors for use in our product candidates. All of our vectors are proprietary to 4DMT and were invented at 4DMT, including the vectors utilized in our clinical-stage and preclinical pipeline product candidates: R100, A101, and C102. The Company is initially focused on five clinical-stage product candidates in three therapeutic areas for both rare and large market diseases: ophthalmology, pulmonology, and cardiology. The 4DMT customized and evolved vectors were invented with the goal of being delivered at relatively low doses through clinically routine, well-tolerated, and minimally invasive routes of administration, transducing diseased cells in target tissues efficiently, having reduced immunogenicity and, where relevant, having resistance to pre-existing antibodies. 4DMT is currently advancing five product candidates in clinical development: 4D-150 for wet AMD and DME, 4D-710 for cystic fibrosis lung disease, 4D-310 for Fabry disease cardiomyopathy, 4D-125 for XLRP, and 4D-110 for choroideremia. The 4D preclinical product candidates in development are: 4D-175 for geographic atrophy and 4D-725 for AATLD.

4D-150, 4D-710, 4D-310, 4D-125, and 4D-110 are our product candidates in clinical development and have not yet been approved for marketing by the US FDA or any other regulatory authority. No representation is made as to the safety or effectiveness of 4D-150, 4D-710, 4D-310, 4D-125, or 4D-110 for the therapeutic uses for which they are being studied.

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