4D Molecular Therapeutics Announces Late-Breaking Presentation of 4D-125 Clinical Data at the Upcoming ASRS Annual Meeting

September 24, 2021

EMERYVILLE, Calif., Sept. 24, 2021 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT), a clinical-stage gene therapy company harnessing the power of directed evolution for targeted gene therapies, announced a late-breaking presentation of preliminary clinical data from the on-going 4D-125 Phase 1/2 trial in patients with X-Linked Retinitis Pigmentosa (XLRP) will be presented at the upcoming Annual Society of Retina Specialists Annual Meeting (ASRS) 2021 that will take place in San Antonio, TX on October 8-12, 2021.

Details of the ASRS presentation are as follows:

Title: Phase 1/2 Clinical Trial of Intravitreal 4D-125 AAV Gene Therapy in Patients with Advanced XLRP: Interim Safety & Preliminary Activity

Speaker: Dr. Cagri G. Besirli M.D., Ph.D, Kellogg Eye Center, University of Michigan

Session: Surgical Techniques & Maneuvers Symposium (Late Breaker Acceptance)

Date and Time: Sunday, October 10, 2:56 p.m. CDT

The presentation will be available for viewing by registered participants during the conference via the ASRS mobile meeting website on October 10, 2021.

About the 4D-125 Phase 1/2 Clinical Trial

4DMT is currently enrolling patients in an on-going Phase 1/2 dose-escalation and dose-expansion clinical trial assessing intravitreal 4D-125, 4DMT's targeted and evolved R100-based product candidate for XLRP. The study employs a standard 3+3 dose-escalation design, followed by dose expansion. Patients are enrolled in one of two dose cohorts: 3E11 vg/eye and 1E12 vg/eye. The dose expansion phase of the study is enrolling patients at the 1E12 vg/eye dose. The primary objectives of this trial are to evaluate the safety and maximum tolerated dose of 4D-125. Secondary endpoints include assessments of clinical activity, including both visual field function and anatomical endpoints.

About XLRP

XLRP is a rare inherited X-linked recessive genetic disorder that causes progressive vision loss and blindness in boys and young men. There are currently no approved therapies for XLRP. Seventy percent of cases are caused by mutations in the retinitis pigmentosa GTPase regulator ("RPGR") gene. The estimated worldwide prevalence of XLRP due to RPGR variants is approximately one in 25,600 people, which represents approximately 24,000 patients in the United States, and France, Germany, Italy, Spain and the United Kingdom (together, EU-5). It is characterized by dysfunction and degeneration of photoreceptors in the retina. Symptoms of XLRP are initially characterized by night blindness, followed by loss of peripheral visual field, decreasing visual acuity and eventually blindness.

About 4DMT

4DMT is a clinical-stage company harnessing the power of directed evolution for targeted gene therapies. 4DMT seeks to unlock the full potential of gene therapy using its platform, Therapeutic Vector Evolution, which combines the power of directed evolution with approximately one billion synthetic capsid sequences to invent evolved vectors for use in targeted gene therapy products. The company is initially focused in three therapeutic areas: ophthalmology, cardiology, and pulmonology. The 4DMT targeted and evolved vectors are invented with the goal of being delivered 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 conducting three clinical trials: 4D-125 is in a Phase 1/2 clinical trial for XLRP patients, 4D-110 is in a Phase 1 clinical trial for choroideremia patients and 4D-310 is in a Phase 1/2 clinical trial for Fabry disease patients.

4D-310, 4D-125 and 4D-110 are our product candidates in clinical trials 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-310, 4D-125, or 4D-110 for the therapeutic use for which they are being studied.

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