4DMT Announces First Patients Enrolled in 4FRONT-1 Phase 3 Clinical Trial Evaluating 4D-150 in Wet AMD

March 10, 2025

EMERYVILLE, Calif., March 10, 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 first patients have been enrolled across multiple sites in the 4FRONT-1 Phase 3 clinical trial evaluating 4D-150 for the treatment of wet age-related macular degeneration (wet AMD).

"This is a historic moment for 4DMT as we become a Phase 3 company following our initiation of the 4FRONT-1 clinical trial," said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. "4D-150 has the clear potential to address the greatest unmet needs for the millions of patients with wet AMD and DME: multi-year relief from frequent and burdensome injections into the eye and preservation of their eyesight. We believe the design of the 4FRONT Phase 3 trials, the design of 4D-150 itself and the compelling clinical data generated to date position us for a successful product approval and commercialization. As a result of our innovation, 4D-150 has the potential to become the established durable backbone therapy for these diseases and to fit seamlessly into clinical practice and economic models for retina physicians."

4FRONT-1 is a Phase 3 multicenter, randomized, double-masked, aflibercept 2 mg (Q8W) comparator-controlled study of intravitreal 4D-150 in wet AMD. The primary endpoint is non-inferiority in the mean change from baseline in best corrected visual acuity (BCVA) at 52 weeks. The key secondary endpoint is treatment burden reduction comparing the number of aflibercept injections received in the 4D-150 arm versus the aflibercept comparator arm over 52 weeks. Patients in both arms will be eligible for supplemental aflibercept injections. 4FRONT-1 is evaluating treatment naïve wet AMD patients at sites in North America. Our second Phase 3 trial for wet AMD, 4FRONT-2, has an identical design to 4FRONT-1 but will evaluate 4D-150 in both treatment naïve and recently diagnosed, treatment experienced wet AMD patients globally. 4FRONT-2 is expected to initiate in Q3 2025. Topline primary endpoint data from both trials is expected in the second half of 2027.

"Our patients with wet AMD currently face the burden of frequent, life-long bolus intravitreal injections, which negatively impacts quality of life not only for the patients themselves but also for their families and caregivers," said Fuad Makkouk, M.D., a principal investigator of the 4FRONT-1 clinical trial. "From the promising data we've seen so far, 4D-150 has the potential to revolutionize the patient experience and provide a meaningful improvement in the lives of people living with wet AMD."

"As an investigator in the PRISM Phase 1/2 study with 4D-150, I've had the opportunity to see firsthand its potential to alter the course of the disease and reduce the treatment burden for patients with wet AMD," said Arshad M. Khanani, M.D., M.A., FASRS, Chair of the 4DMT Ophthalmology Advisory Board and a principal investigator of the 4FRONT-1 clinical trial. "I'm thrilled to participate in the 4FRONT-1 trial and look forward to collaborating with the dedicated team at 4DMT and my fellow investigators to potentially bring 4D-150 to patients with wet AMD, with the chance to make a lasting difference in their lives."

About 4D-150

4D-150 is a potential backbone therapy that is designed to provide multi-year sustained delivery of anti-VEGF (aflibercept and anti-VEGF-C) from the retina with a single, safe, intravitreal injection. 4D-150 utilizes our customized and evolved intravitreal vector, R100, which was invented at 4DMT through our proprietary Therapeutic Vector Evolution platform. 4D-150 is being developed for wet AMD and diabetic macular edema, which both affect millions of patients globally, with the goal of relieving patients from burdensome injections while preserving vision.

About Wet AMD

Wet AMD is a highly prevalent disease, with more than 4 million individuals expected to be affected in the next five years in certain major markets, including the U.S., the EU and Japan. The disease also has a high incidence, with 200,000 individuals estimated to be newly diagnosed every year in the U.S. alone. Wet AMD is a type of macular degeneration in which abnormal blood vessels grow into the macula (macular neovascularization or MNV), the central area of the retina. MNV causes swelling and edema of the retina, bleeding and scarring, leading to visual distortion and reduced visual acuity. The proliferation and leakage of abnormal blood vessels is stimulated by VEGF. This process distorts and, without treatment, can potentially destroy central vision and may progress to blindness.

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. Our 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. Our lead indication for 4D-150 is wet age-related macular degeneration, which is currently in Phase 3 development, and second indication is diabetic macular edema. Our 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™, an the 4DMT logo are trademarks of 4DMT.

All of our 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 our 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 the therapeutic potential and clinical benefits of, as well as the plans, announcements and related timing for the clinical development, regulatory interactions, and potential commercialization of our product candidates,

including 4D-150. 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 risks and uncertainties that are described in greater detail in the section entitled "Risk Factors" in 4D Molecular Therapeutics’ most recent Annual Report on Form 10-K, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent 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 explicitly disclaims any obligation to update any forward-looking statements. 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 Corporate Finance
Investor.Relations@4DMT.com