4DMT Completes Enrollment for 4FRONT-1 Phase 3 Clinical Trial of 4D-150 in Wet AMD

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- *Enrollment for 4FRONT-1, the first registrational trial for 4D-150 in wet AMD, was completed within an approximately 11-month period, ahead of initial projections*
- *4FRONT-1 overenrolled and expected to exceed 500 patients randomized, reflecting strong interest from investigators and patients*
- *Topline data from 4FRONT-1 expected in H1 2027*
- *4FRONT-2 global site activation momentum continues, with enrollment completion on track for H2 2026 and topline data expected in H2 2027*

EMERYVILLE, Calif., Feb. 09, 2026 (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 enrollment completion for 4FRONT-1, the first Phase 3 clinical trial evaluating 4D-150 in patients with wet age-related macular degeneration (wet AMD).

“The 4D-150 4FRONT-1 Phase 3 trial enrolled in 11 months in a treatment-naïve large market patient population. This is a landmark moment for 4DMT, for wet AMD patients and for our targeted and locally delivered genetic medicines,” said David Kirn, M.D., Co-founder, President, and Chief Executive Officer of 4DMT. “This high enrollment rate and over-enrollment in the front-line wet AMD setting reflects investigator and patient enthusiasm for 4D-150 as a potential backbone therapy. Remarkably, our team achieved this milestone in only four years after treating the first patient with 4D-150 in wet AMD. I want to extend my heartfelt congratulations to the entire 4DMT team for their tireless work, dedication, and execution in reaching this achievement. We look forward to continuing this momentum as we accelerate global enrollment in our second Phase 3 study, 4FRONT-2.”

“For far too long, wet AMD patients have faced the burden of relentless, lifelong repeated bolus injections and vision loss,” said Julie Clark, M.D., Chief Medical Officer of 4DMT. “Our vision is to fundamentally shift that paradigm, to bring forward a potential backbone therapy that meaningfully reduces treatment burden while sustaining vision outcomes. The rapid enrollment completion, driven by the enthusiasm for 4D-150 and data generated to date, energizes our entire organization as we work relentlessly toward completing global enrollment in 4FRONT-2 and prepare for topline data in H1 2027 from 4FRONT-1. I want to thank all our sites, study coordinators, and patients for their partnership and trust as we work toward our goal to drive a new standard of care for wet AMD.”

“As retina specialists, we routinely observe the challenges long-term intravitreal injection regimens pose for wet AMD patients and their association with suboptimal long-term vision outcomes in real-world practice,” said Arshad M. Khanani, M.D., M.A., FASRS, Director of Clinical Research at Sierra Eye Associates, Chair of the 4DMT Ophthalmology Advisory Board and a principal investigator in the 4FRONT-1 clinical trial. “Based on the long-term PRISM Phase 1/2 data, 4D-150 has the potential to significantly reduce treatment burden for patients with wet AMD, with a single in-office intravitreal injection providing sustained disease control. The rapid enrollment of 4FRONT-1 in treatment-naïve patients is particularly encouraging and reflects strong enthusiasm among physicians and patients for therapies that offer potentially safe, effective, and durable long-term disease control. This progress is also a testament to the strong execution and deep expertise of the 4DMT team in advancing Phase 3 clinical trials. I look forward to the continued advancement of the 4FRONT registrational program.”

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. Topline primary endpoint data from 4FRONT-1 is expected in H1 2027. Our second Phase 3 for wet AMD, 4FRONT-2, is a global trial with an identical design to 4FRONT-1 except for enrolling both treatment-naïve and recently diagnosed treatment-experienced wet AMD patients. 4FRONT-2 is expected to complete enrollment in H2 2026 with topline primary endpoint data expected in H2 2027.

About 4D-150

4D-150 is a potential backbone therapy designed to provide multi-year, and potentially lifelong, sustained delivery of anti-VEGF biologics (aflibercept and anti-VEGF-C) within the retina following a single, safe, intravitreal injection. 4D-150 utilizes our customized and evolved intravitreal AAV 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 (DME), which both affect millions of patients globally, with the goal of freeing patients from burdensome injections while preserving vision.

About Wet AMD

Wet AMD, or wet age-related macular degeneration, 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 with retina diseases. 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 biologics (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 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: (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 necessary funding or may require additional capital for its operations and anticipated commercialization; (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 November 10, 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.

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