4DMT Announces RMAT Designation Granted by FDA for 4D-150 for DME

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EMERYVILLE, Calif., May 01, 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 U.S. Food and Drug Administration (FDA) has granted the Regenerative Medicine Advanced Therapy (RMAT) designation to 4D-150 for the treatment of diabetic macular edema (DME).

“This milestone validates the potential of 4D-150 to address the significant unmet needs of patients with DME, a second large market retinal vascular disease indication after wet age-related macular degeneration (wet AMD),” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “The RMAT designation is based on the review of our results to-date from our ongoing 4D-150 SPECTRA DME study, underscoring the potential of 4D-150 to sustain visual acuity improvements while dramatically reducing treatment burden for patients. This designation in DME follows the RMAT designation granted for 4D-150 in wet AMD, and to our knowledge, 4D-150 is the first investigational medicine to be granted the designation in both indications. We look forward to continuing our ongoing collaboration with the FDA to advance 4D-150 into Phase 3 development with an aligned-upon single Phase 3 trial for approval in DME, combined with our two wet AMD 4FRONT Phase 3 clinical trials.”

RMAT designation is part of the 21st Century Cures Act. The program was created to expedite the development and review of regenerative medicine therapies intended to treat, modify, reverse or cure a serious condition. Receiving RMAT designation offers sponsor companies all the benefits of the fast track and breakthrough therapy designation programs, allowing for early, close and frequent interactions with the FDA with the goal of expediting drug development.

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 DME, which both affect millions of patients globally, with the goal of freeing patients from burdensome injections while preserving vision.

About DME

DME, or diabetic macular edema, is a complication of diabetic retinopathy and is a highly prevalent disease with significant unmet medical need and poor treatment adherence. It is estimated that there are approximately one million individuals with DME in the U.S. according to published data. DME is characterized by inflammation and swelling in the macula due to leakage from blood vessels, which can lead to vision loss. DME is typically treated with intravitreal anti-VEGF agents administered approximately every 4-12 weeks, although patient compliance with therapy is poor and results in high unmet medical need.

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 and market potential of 4DMT’s product candidates, as well as the plans, announcements, and related timing for the clinical development of and regulatory interactions regarding 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 Quarterly Report on Form 10-Q filed on November 13, 2024 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.

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