4DMT Presents Injection-Free Subgroup Analyses from 4D-150 Phase 2 PRISM Randomized Dose Expansion Cohort in Wet AMD Patients with Severe Disease Activity & High Treatment Burden at the Clinical Trials at the Summit 2024 Meeting

June 8, 2024

- *Injection-free subgroup results demonstrated that a single intravitreal dose of 4D-150 without any supplemental anti-VEGF injections resulted in stable mean visual acuity that was equal to or higher than in the standard bimonthly aflibercept control group at all six timepoints through Week 24*
- *Single intravitreal 3E10 vg/eye dose resulted in sustained reduction and stabilization of mean central subfield thickness (CST) compared to aflibercept at all timepoints*
- *In the 3E10 vg/eye injection-free subgroup, the mean difference versus aflibercept in CST change from baseline for Weeks 20 and 24 was -31 microns in favor of 4D-150*
- *Injection-free subgroup analyses reinforce previously reported positive 4D-150 Phase 2 PRISM topline results*
- *Interim 24-week landmark analysis from Phase 2 PRISM Population Extension cohort evaluating 4D-150 in broader wet AMD population expected to be presented at the American Society of Retina Specialists (ASRS) Annual Scientific Meeting on July 17, 2024*

EMERYVILLE, Calif., June 08, 2024 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT or the Company), a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases, today presented supplemental aflibercept injection-free subgroup analyses of the previously reported 24-week landmark results from the randomized Dose Expansion cohort from the Phase 2 PRISM clinical trial evaluating intravitreal 4D-150 in wet age-related macular degeneration (wet AMD) patients with severe disease activity and a high treatment burden. The data were presented today at Clinical Trials at the Summit 2024 in Park City, Utah, by Carl Danzig, M.D., Rand Eye Institute, Deerfield Beach, Florida.

“The injection-free subgroup analyses demonstrate the potential for a single intravitreal 3E10 vg dose of 4D-150 to improve and stabilize retinal anatomy while improving or stabilizing vision in the most severe form of wet AMD with the highest VEGF treatment burden, without the need for any supplemental treatment through 24 weeks in the majority of patients treated,” said Robert Kim, M.D., Chief Medical Officer of 4DMT. “4D-150 to date has shown robust clinical activity with a favorable safety profile, and the data provide additional evidence that 4D-150 has the potential to treat all patients suffering from wet AMD. We look forward to sharing interim results from the Population Extension cohort of PRISM at ASRS in July 2024, and an update on our Phase 3 clinical trial design in the third quarter of 2024.”

Phase 2 PRISM Supplemental Injection-Free Subgroup Analyses

- Stable visual acuity observed through Week 24 in both 4D-150 dose groups (n=22 injection-free patients); BCVA equal to or numerically higher than bimonthly aflibercept (n=10 patients) at all six time points through Week 24
- High dose (3E10 vg/eye; n=12 patients):
  - Sustained reduction and stabilization of CST fluctuations compared to bimonthly aflibercept at all six timepoints through Week 24
  - The average mean change from baseline in CST at Weeks 20 and 24 was -52.2 mm in the 3E10 vg/eye group and -21.4 in the aflibercept group (mean difference, -30.8 mm)

For additional details, click here to view the scientific presentation, which is available on the 4DMT website: https://4dmoleculartherapeutics.com/pipeline/#posters-and-publications

Upcoming 4D-150 Milestones

- Phase 2 PRISM Population Extension cohort (N=32) in the broader wet AMD patient population:
  - Initial interim 24-week landmark analysis expected to be presented at the ASRS Annual Scientific Meeting on July 17, 2024
- Phase 3 planning:
  - Update on Phase 3 clinical trial design expected in Q3 2024
  - First Phase 3 clinical trial initiation expected in Q1 2025

About Wet AMD

Wet AMD is a highly prevalent disease with estimated incidence rate of 200,000 new patients per year in the United States. It is estimated that the total prevalence of wet AMD in certain major markets, including the United States and the European Union (major markets), and Japan, will be greater than 4 million individuals in the next five years. Wet AMD is a type of macular degeneration where abnormal blood vessels (macular neovascularization or MNV) grow into the macula, the central area of the retina. As a consequence, MNV causes swelling and edema of the retina, bleeding and scarring, and causes visual distortion and reduced visual acuity. The proliferation and leakage of abnormal blood vessels is stimulated by VEGF. This process distorts and can potentially destroy central vision and may progress to blindness without treatment.

About 4D-150 for Wet AMD

4D-150 combines our customized and evolved intravitreal vector, R100, and a transgene cassette that expresses both aflibercept and a VEGF-C inhibitory RNAi. This dual-transgene payload inhibits four members of the VEGF angiogenic family of factors that drive wet AMD and DME: VEGF A, B, C and PlGF. R100 was invented at 4DMT through our proprietary Therapeutic Vector Evolution platform; we developed this platform utilizing principles of directed evolution, a Nobel Prize-winning technology. 4D-150 is designed for single, low-dose intravitreal delivery for transgene expression from the retina without significant inflammation.

About 4DMT

4DMT is a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases in ophthalmology and pulmonology. 4DMT's proprietary invention platform, Therapeutic Vector Evolution, 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 wholly owned and partnered product candidates. Our product design, development, and manufacturing engine helps us efficiently create and advance our diverse product pipeline with the goal of revolutionizing medicine with potential curative therapies for millions of patients. Currently, 4DMT is advancing five clinical-stage and two preclinical product candidates, each tailored to address rare and large market diseases in ophthalmology, pulmonology and cardiology. In addition, 4DMT is also advancing programs in CNS through a gene editing partnership. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DM

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 (FDA) 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 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 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:

Katherine Smith
Inizio Evoke Comms
Katherine.Smith@inizioevoke.com

Investors:

Julian Pei
Head of Investor Relations and Corporate Finance
Investor.Relations@4DMT.com