4DMT Announces Exclusive License Agreement with Otsuka Pharmaceutical Co., Ltd. for Development and Commercialization of 4D-150 in Asia-Pacific

October 31, 2025

- *4DMT to receive $85 million upfront cash payment and expect to receive at least $50 million of cost sharing from Otsuka over the next three years for development activities supporting global registration*
- *Up to $336 million in potential regulatory and commercial milestones and tiered double-digit royalties depending on net sales in Otsuka's territories*
- *Proceeds and cost sharing expected to support global Phase 3 clinical trial in DME and pre-commercial activities*

EMERYVILLE, Calif., Oct. 30, 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 a strategic partnership with Otsuka Pharmaceutical Co., Ltd. (Otsuka) to develop and commercialize 4D-150 for the treatment of wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME) in the greater Asia-Pacific (APAC) region including Japan.

The strategic partnership combines 4DMT's expertise in AAV genetic medicine, development in retina and manufacturing with Otsuka's strong development expertise, regulatory experience and commercial infrastructure across APAC markets. Together, the companies aim to receive 4D-150 marketing approval and commercialization in major markets globally. 4D-150 is a potentially transformative backbone therapy providing durable benefit in retinal vascular diseases such as wet AMD and DME, which are among the leading causes of blindness in the world.

Under the terms of the agreement, 4DMT will grant Otsuka exclusive rights to develop and commercialize 4D-150 for retinal vascular diseases, including wet AMD and DME, in Japan, China, Australia and other Asia-Pacific markets. Otsuka will lead all regulatory and commercialization activities in its licensed territories. 4DMT will continue to lead all Phase 3 clinical activities globally, including within the APAC region. APAC clinical sites in 4FRONT-2, the global Phase 3 study in wet AMD, are expected to open by end of year, with Japan sites expected to open in January 2026.

4DMT will receive an upfront cash payment of $85 million and expected cost sharing of at least $50 million over the next three years for global development activities. In addition, the Company is eligible for up to $336 million in potential regulatory and commercial milestone payments and tiered double-digit royalties depending on net sales in Otsuka's territories. 4DMT retains full development and commercialization rights for 4D-150 outside the APAC region, including the U.S., Latin America and Europe.

"We are thrilled to announce this strategic partnership with Otsuka, a leading global pharmaceutical company with a strong presence in the APAC region, reflecting our shared long-term commitment to improving outcomes for patients with retinal vascular diseases," said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. "This partnership is a key pillar of our global strategy, with 4DMT continuing to lead Phase 3 clinical trial and manufacturing activities globally, in addition to pre-commercial and commercial activities outside the APAC region."

"APAC represents a large and underserved retina market, with a high prevalence of wet AMD and DME. Navigating the region's regulatory and patient-access complexities requires a strong local partner, and we expect Otsuka's deep presence and expertise to accelerate both development of and access to 4D-150," said Chris Simms, Chief Commercial Officer of 4DMT. "Partnering with Otsuka extends the global reach of 4D-150 and ensures that patients in regions with limited access to innovative therapies may ultimately benefit from its potential to deliver durable treatment burden reductions and vision preservation."

"Otsuka has created new value that contributes to the well-being of patients in Japan and around the world through both in-house and collaborative research," said Makoto Inoue, President and Representative Director of Otsuka Pharmaceutical Co., Ltd. "By introducing 4D-150 to the markets in Japan, and elsewhere in Asia and Oceania, we aim to help prevent vision loss through a single, potentially lifelong administration."

About 4D-150

4D-150 is a potential backbone therapy designed to provide multi-year, and potentially lifelong, 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 AAV 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 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 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 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 4-16 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. 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 (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 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, clinical development, marketing, and commercialization of our product candidates, including 4D-150, the potential benefits of the strategic partnership with Otsuka, the amount of any potential cost sharing or milestone payments pursuant to the Company's agreement with Otsuka, timing of opening of APAC clinical sites, and our use of proceeds. 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 August 11, 2025, 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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