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Aevitas Therapeutics, a Fortress Biotech Subsidiary, Announces Asset Purchase Agreement with 4D Molecular Therapeutics for World-Wide Rights to Aevitas' Short-Form Human Complement Factor H

Company is eligible to receive up to ~$140 million in potential late-stage development, regulatory and sales milestone payments plus royalties from 4DMT

MIAMI, April 24, 2023 (GLOBE NEWSWIRE) -- Aevitas Therapeutics, Inc. ("Aevitas"), a Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") subsidiary company, and 4D Molecular Therapeutics (Nasdaq: FDMT) ("4DMT"), a clinical-stage biotherapeutics company harnessing the power of directed evolution for genetic medicines targeting large-market diseases, today announced the execution of an asset purchase agreement for 4DMT to acquire Aevitas' proprietary rights to its short-form human complement factor H ("sCFH") asset for the treatment of complement-mediated diseases. Under the terms of the agreement, 4DMT will make cash payments to Aevitas totaling up to ~$140 million in potential late-stage development, regulatory and sales milestones. A range of single-digit royalties on net sales are also payable. The aforementioned payments are payable solely to Aevitas, and 4DMT will be responsible for license payment obligations to University of Pennsylvania, where the sCFH technology was co-invented and co-developed by Dr. Wenchao Song, a Professor of Pharmacology at the Perelman School of Medicine.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer and Aevitas' Executive Chairman, said, "This agreement with 4DMT allows Fortress to focus on acquiring and developing clinical-stage treatments, while potentially expediting the development and commercialization of this preclinical sCFH technology. Partnering with 4DMT further validates the Fortress business model of identifying and developing promising treatments for patients, while pursuing opportunities that potentially maximize shareholder value. We look forward to 4DMT using their vector platform to continue the development of the sCFH asset to potentially treat Geographic Atrophy ("GA") and other diseases."

Aevitas' transgene encoding sCFH, a shortened and optimized form of a natural inhibitor of the inflammatory complement pathway, will be combined with 4DMT's proprietary

retinotropic R100 vector to form product candidate 4D-175 for treatment of GA secondary to age-related macular degeneration (“AMD”).

sCFH is an engineered and optimized version of Complement Factor H (“CFH”) that can fit into AAV vectors with robust expression and functionality confirmed in cultured human cells in vitro, and in multiple preclinical animal models in vivo. Restoring CFH function using the sCFH protein has the potential to restore normal complement regulation and reduce retinal injury that manifests as progressive GA.

“We are pleased to execute this asset purchase agreement with Aevitas to combine an innovative and differentiated preclinical GA product candidate into our large market ophthalmology portfolio which leverages our clinically validated R100 retinotropic vector,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “This represents continued value generation from our robust product design and development engine to take advantage of the vector modularity of our platform in the ophthalmology therapeutic area.”

About 4DMT
4DMT is a clinical-stage biotherapeutics company harnessing the power of directed evolution for genetic medicines targeting large market diseases. 4DMT seeks to unlock the full potential of genetic medicines using its proprietary invention platform, Therapeutic Vector Evolution, which 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 product candidates. All of our vectors are proprietary to 4DMT and were invented at 4DMT, including the vectors utilized in our clinical-stage and preclinical pipeline product candidates: R100, A101, and C102. The Company is initially focused on five clinical-stage product candidates in three therapeutic areas for both rare and large market diseases: ophthalmology, pulmonology, and cardiology (Fabry disease cardiomyopathy). The 4DMT customized and evolved vectors were invented with the goal of being delivered at relatively low doses through clinically routine, well-tolerated, and minimally invasive routes of administration, transducing diseased cells in target tissues efficiently, having reduced immunogenicity and, where relevant, having resistance to pre-existing antibodies. 4DMT is currently advancing five product candidates in clinical development: 4D-150 for wet AMD and DME, 4D-710 for cystic fibrosis lung disease, 4D-310 for Fabry disease cardiomyopathy, 4D-125 for XLRP, and 4D-110 for choroideremia. The 4D preclinical product candidates in development are: 4D-175 for geographic atrophy and 4D-725 for AATLD.

4D-150, 4D-710, 4D-310, 4D-125, and 4D-110 are our product candidates in clinical development and have not yet been approved for marketing by the US FDA or any other regulatory authority. No representation is made as to the safety or effectiveness of 4D-150, 4D-710, 4D-310, 4D-125, or 4D-110 for the therapeutic uses for which they are being studied.

About Aevitas Therapeutics
Aevitas Therapeutics, Inc. (“Aevitas”) is a biopharmaceutical company focused on the development and commercialization of novel adeno-associated virus (“AAV”)-based gene therapies for complement-mediated diseases. Aevitas was founded by Fortress Biotech, Inc.

(Nasdaq: FBIO).

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has eight marketed prescription pharmaceutical products and over 30 programs in development at Fortress, at its majority-owned and majority-controlled partners and subsidiaries and at partners and subsidiaries it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including AstraZeneca, City of Hope, Fred Hutchinson Cancer Center, St. Jude Children’s Research Hospital, Nationwide Children’s Hospital and Sentynl. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words “we”, “us” and “our” may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA approval, ability of our products and therapies to help patients and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include, risks relating to: our growth strategy; financing and strategic agreements and relationships; our need for substantial additional funds and uncertainty relating to financings; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; the ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies’ products and product candidates; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of

information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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Editor's note: The laboratory of Dr. Song at the University of Pennsylvania has received sponsored research funding from Aevitas Therapeutics. Penn and Dr. Song have either received, or may receive in the future, financial consideration related to the licensing of certain Penn intellectual property to 4DMT. Dr. Song holds an equity stake in Aevitas, is a scientific founder of Aevitas and is a member of their Scientific Advisory Board.

Source: Fortress Biotech, Inc.