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Fortress Biotech Announces Initiation of Phase 2 Clinical Trial of Triplex for Adults Co-Infected with HIV and CMV

Helocyte, Inc., a partner company of Fortress Biotech, is developing Triplex for the treatment of cytomegalovirus

Clinical trial will evaluate whether Triplex, which was developed by City of Hope, is safe and effective in eliciting a CMV-specific immune response in people living with HIV and is thus able to reduce CMV replication

NEW YORK, Dec. 16, 2021 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), an innovative biopharmaceutical company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, and its partner company, Helocyte, Inc., (“Helocyte”) today announced that a Phase 2 double-blind, randomized, placebo-controlled clinical trial has been initiated to evaluate the safety and efficacy of Triplex, a cytomegalovirus (“CMV”) vaccine, in eliciting a CMV-specific immune response and reducing CMV replication in people living with HIV. Triplex was developed by City of Hope, a world-renowned cancer treatment and research organization.

Most people living with HIV are co-infected with CMV, and there is strong evidence that CMV is associated with chronic inflammation and potentially other significant co-morbidities, including cardiovascular disease, neurological complications, and metabolic disease. Triplex is a modified vaccinia ankara (MVA)-based vaccine, which encodes three full-length CMV antigens [pp65 (UL83), IE1-exon4 (UL123), and IE2-exon5 (UL122)]. Triplex was demonstrated to be safe, well-tolerated, immunogenic and effective in multiple Phase 1 and 2 studies involving over 100 subjects.

The Phase 2, double-blind, randomized, placebo-controlled study is evaluating the safety and immunogenicity of two injections of Triplex in adults aged 18 to 65 co-infected with HIV and CMV. Upon enrollment in the study, 60 participants will be randomized to receive Triplex and 30 participants will be randomized to receive placebo, both through two intramuscular deltoid injections on Day 0 and Day 28 following enrollment. Participants will be followed for 92 weeks after the last scheduled vaccination at Day 28, for a total study duration of 96 weeks. At least 25 percent of participants will be cisgender or transgender women and all subjects must have undetectable HIV on antiretroviral therapy.

Lindsay A. Rosenwald, M.D., Chairman, President, and Chief Executive Officer of Fortress, said, “We are pleased to further study Triplex in adults co-infected with CMV and HIV, as it has already demonstrated safety, immunogenicity and efficacy in previous clinical trials. CMV can cause severe and life-threatening disease in those with weakened or uneducated immune systems. This clinical trial will evaluate Triplex’s potential ability to reduce systemic inflammation among adults living with HIV, which can be linked to a number of health issues that complicate their care and impact their quality of life.”

The intellectual property relating to Triplex was exclusively licensed to Helocyte in 2015. The trial is being conducted by the AIDS Clinical Trials Group and is funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, and collaborating NIH Institutes. It is led by Sara Gianella, M.D. and Davey Smith, M.D., University of California, San Diego. Investigational product is supplied by Don Diamond, Ph.D., a City of Hope professor in the Department of Hematology & Hematopoietic Cell Transplantation, and City of Hope.

About Triplex
Triplex is a universal (non-HLA-restricted) recombinant Modified Vaccinia Ankara viral vector vaccine engineered to induce a robust and durable virus-specific T cell response to three immuno-dominant proteins [UL83 (pp65), UL123 (IE1), UL122 (IE2)] linked to CMV events in those infected with the virus. In previous Phase 1 and Phase 2 studies, Triplex was found to be safe, well-tolerated, immunogenic and effective.

About Helocyte
Helocyte is a clinical-stage company developing novel immunotherapies for the prevention and treatment of cancer and infectious disease (and in particular, cytomegalovirus or “CMV”). The Centers for Disease Control estimate that 50 to 80 percent of Americans are infected with CMV by the age of 40. While the virus is asymptomatic in healthy individuals, it can cause severe and life-threatening disease in those with weakened or uneducated immune systems. Patients undergoing allogeneic stem cell and solid organ transplantation are at particularly high risk of experiencing complications associated with CMV. Helocyte’s Triplex vaccine is engineered to induce a robust and durable virus-specific T cell response to control CMV. Helocyte’s ConVax vaccine is designed to induce a neutralizing antibody response to prevent the transmission of CMV from mother to fetus, the most common congenital infection. There is no approved therapy for the prevention or treatment of congenital CMV. While current antiviral therapies have reduced the rate of CMV disease-related mortality in transplant recipients, such treatments have been linked to increased toxicity, delayed immune reconstitution and late onset of CMV. The Helocyte vaccines can educate the body’s adaptive immune system to fight CMV. For more information, please visit www.helocyte.com.

About Fortress Biotech
Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development

at Fortress, at its majority-owned and majority-controlled partners and at partners 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 plc, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl Therapeutics, Inc. 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 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; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to 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; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; 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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