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Fortress Biotech Subsidiary Helocyte Announces Option Agreement with City of Hope for Exclusive Worldwide Rights to use a Novel Bispecific CMV/HIV CAR T Cell Therapy (optionally in combination with Triplex) for the Treatment of Adults Living with HIV-1

Recent $11.3 million grant from the California Institute for Regenerative Medicine (CIRM) intended to fund the Phase 1 clinical trial at City of Hope; the Investigational New Drug application for which has now been accepted by the Food and Drug Administration

In preclinical studies, administration of the dual-action CAR T cells followed by administration of a CMV vaccine successfully eradicated HIV, including from latent reservoirs

Triplex is currently the subject of multiple ongoing clinical trials, including: a Phase 1/2 trial for CMV control in pediatric recipients of HCT (see NCT03354728); a Phase 2 trial for reduction in viral load of Human Immunodeficiency Virus ("HIV") in adults co-infected with HIV and CMV (see NCT05099965); and a Phase 1 trial of Triplex in combination with a bi-specific CMV/CD19 Chimeric Antigen Receptor T Cell for the treatment of Non-Hodgkin Lymphoma (see NCT05432635); Other planned studies of Triplex include: a multicenter Phase 2 trial for CMV control in recipients of liver transplant (U01AI163090, see NCT06075745); a Phase 2 trial for CMV control in recipients of kidney transplant; and a Phase 2 trial for CMV control in recipients of stem cell transplant in which the stem cell donor is vaccinated with Triplex (see NCT06059391)

MIAMI, Oct. 16, 2023 (GLOBE NEWSWIRE) -- Helocyte, Inc. ("Helocyte"), a subsidiary company of Fortress Biotech, Inc. ("Fortress") (Nasdaq: FBIO), today announced that it executed an exclusive option agreement with City of Hope for patent rights to use Triplex, a cytomegalovirus vaccine, in combination with cytomegalovirus ("CMV")-specific, Anti-Human Immunodeficiency Virus ("HIV") Chimeric Antigen Receptor ("CAR") (collectively, CMV/HIV-CAR) T Cells for the treatment of adults living with HIV. Triplex was initially developed by City of Hope, one of the largest cancer research and treatment organizations in the United

States, and exclusively licensed to Helocyte in 2015.

Additionally, the California Institute for Regenerative Medicine ("CIRM") recently awarded a $11.3 million grant to City of Hope to fund a Phase 1 clinical trial. The Phase 1 trial is expected to enroll up to 12 healthy individuals living with HIV-1 on stable anti-retroviral therapy ("ART") who have maintained viral suppression for at least 48 weeks. The study will include three dose-escalating cohorts, along with an expansion cohort. Other cohorts will include further vaccination of subjects with Triplex to drive continued proliferation of the CAR. The trial will initially enroll at City of Hope and University of California at San Diego.

"City of Hope made a major advancement when our transplant team helped a patient achieve remission for both HIV and leukemia," said John A. Zaia, M.D., the Aaron D. Miller and Edith Miller Chair for Gene Therapy at City of Hope. "We are hoping to evaluate a CAR T therapy for HIV in a Phase 1 clinical trial so that one day more people with HIV might be able to achieve long-term HIV remission."

The clinical study will build upon preclinical data published in *Molecular Therapy - Methods & Clinical Development* which demonstrated the potential efficacy of combining a CMV vaccine and CMV/HIV CAR T cell therapy to eradicate HIV. The study illustrated the potential long-term durability of the combination therapy, which induced therapeutic immune cells to take hold in bone marrow. The objective of this approach is to target and eradicate latent viral T cell reservoirs in immune cells to achieve complete HIV clearance.

The current standard of care for the treatment of HIV relies upon the use of ART, which is a non-curative, life-long therapy. Optimal use of ART can effectively control HIV replication; prevent the onset of Acquired Immuno-Deficiency Syndrome ("AIDS"); prolong survival; and reduce the risk of transmission to others. However, there are several challenges associated with the use of ART, including: chronic treatment adherence; drug resistance, particularly in those who do not fully adhere to treatment; adverse events; and the persistence of immune dysfunction during treatment. There remains a significant unmet medical need to provide a functional cure for HIV and eliminate the need for ART.

To date, the engineering of T cells to express HIV-specific CAR T cells has failed to demonstrate meaningful clinical benefits. This is believed to be due in part to the effectiveness of highly active ART, which reduces HIV viral load to a level that prevents the activation of CAR T cells. The use of Triplex is believed to stimulate CMV/HIV-CAR T cells to proliferate within patients' bodies. In the aforementioned preclinical study, CAR T cells were engineered to target and kill cells tagged with a particular protein called gp120, which is expressed in all HIV viruses, frequently with mutations that cause the virus to evade natural immunity without affecting healthy cells.

Lindsay A. Rosenwald, M.D., Fortress' Chairman and Chief Executive Officer and Chairman of Helocyte, Inc., said, "Our goal is to deliver transformational treatment options to patients suffering from conditions associated with high unmet medical need. We are pleased to expand our relationship with City of Hope and remain encouraged by the potential to combine Helocyte's Triplex with a bispecific CMV/HIV-CAR T cell therapy that can eradicate HIV without safety issues. We look forward to building upon the data that continue to be generated relating to the use of Triplex in the treatment of HIV, including an ongoing Phase 2 clinical trial evaluating the safety and efficacy of Triplex in eliciting a CMV-specific immune response and reducing CMV replication in adults co-infected with HIV and CMV. Triplex is

the subject of multiple other ongoing and planned studies."

The California Institute for Regenerative Medicine was created in 2004 after 59% of California voters approved California Proposition 71: the Research and Cures Initiative, which allocated $3 billion to fund stem cell research in California. For additional information regarding the grant, please see https://www.cirm.ca.gov/our-progress/awards/evaluation-safety-and-feasibility-cytomegalovirus-specific-anti-hiv-chimeric-antigen-receptor-cmv-hiv-car-t-cells-people-hiv/.

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 complications in the post-transplant setting. In previous Phase 1 and Phase 2 studies, Triplex was found to be safe, well-tolerated and highly immunogenic. Triplex is currently the subject of multiple ongoing clinical trials, including: a Phase 1/2 trial for CMV control in pediatric recipients of HCT (see NCT03354728); a Phase 2 trial for reduction in viral load of Human Immunodeficiency Virus ("HIV") in adults co-infected with HIV and CMV (see NCT05099965); and a Phase 1 trial of Triplex in combination with a bi-specific CMV/CD-19 Chimeric Antigen Receptor T Cell for the treatment of Non-Hodgkin Lymphoma (see NCT05432635). Triplex is also the subject of several planned studies, including: a Phase 2 evaluation for CMV control in recipients of liver transplant (see NCT06075745); a Phase 2 trial for CMV control in recipients of kidney transplant; and a Phase 2 trial for CMV control in recipients of stem cell transplant in which the stem cell donor is vaccinated with Triplex (see NCT06059391).

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. According to the Center for International Blood and Marrow Transplant Research, there were over 9,000 unrelated and related bone marrow and cord blood transplants performed in the United States in 2020. According to preliminary data from the Organ Procurement and Transplantation Network, there were over 40,000 organ transplants performed in the United States in 2021, comprised primarily of kidney and liver transplant procedures. Helocyte's Triplex vaccine is engineered to induce a robust and durable virus-specific T cell response to control CMV in transplant recipients. 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 innate 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 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 25 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 focused on leveraging its significant biopharmaceutical industry expertise and network 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 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, 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; 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, including disruptions that may result from hostilities in Europe; 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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