February 15, 2023

Study Published in American Journal of Hematology Demonstrates First Reported Evidence of Safe and Successful Boosting of Cytomegalovirus Vaccine-Specific T Cell Immunity in a Stem Cell Transplant Recipient Via Vaccination of a Donor with Triplex

Phase 2 clinical trial planned to evaluate efficacy of Triplex-vaccinated donors to enhance protective CMV-specific T cell immunity in stem cell transplant recipients

Helocyte, Inc., a subsidiary company of Fortress Biotech, is developing Triplex for the treatment of CMV

MIAMI, Feb. 15, 2023 (GLOBE NEWSWIRE) -- Helocyte, Inc., ("Helocyte") a subsidiary company of Fortress Biotech, Inc. (Nasdaq: FBIO), announced today that data from a Phase 1 pilot study published in the *American Journal of Hematology* demonstrated the feasibility, safety, immunological response and potential efficacy associated with vaccination of a hematopoietic cell transplant ("HCT") donor with the cytomegalovirus ("CMV") vaccine Triplex to enhance protective CMV-specific T cells in immunosuppressed recipients of allogeneic HCT.

Triplex was 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.

The investigator-initiated trial conducted at City of Hope analyzed the results of 17 CMV-seropositive recipients who received an HCT from a matched related donor ("MRD") vaccinated with Triplex prior to stem cell harvest and transplant. Triplex was well tolerated with limited adverse events in donors and recipients, all of whom experienced successful engraftment. On day 28 post-HCT, levels of functional CMV-specific CD137+CD8+ T cells were significantly higher ($p=0.0174$) in recipients of Triplex with vaccinated MRD versus those in an unvaccinated MRD control cohort. Memory CMV-specific T cell responses continued to steadily expand through one-year of follow up.

“Immunizing donors of HCT with Triplex prior to stem cell collection and transfer of donor stem cells to the recipient is a novel and potentially effective approach to prevent CMV reactivation in seropositive stem cell recipients, which often requires treatment with toxic antivirals that delay immune reconstitution. Consistent with data from previous trials of over 100 people dosed with Triplex, there were no vaccine-associated safety concerns observed in the trial. We look forward to exploring this donor vaccination approach in future clinical trials,” said lead author Corinna La Rosa, Ph.D., Research Professor, Department of Hematology & Hematopoietic Cell Transplantation, City of Hope.

Post-transplant vaccination and/or prophylactic antiviral usage are the main preventative approaches to limiting morbidity and mortality caused by CMV in immunocompromised HCT recipients. Clinical studies for the prevention of other infectious complications among HCT recipients have demonstrated promising results when both recipients and donors are vaccinated prior to transplantation. This strategy has been shown to significantly enhance protective T and B cell responses and enhanced the immunogenicity associated with vaccination post-HSCT.

CMV reactivation requiring preemptive therapy in recipients with Triplex vaccinated donors (18%) was observed to be lower than those in similar cohorts prophylactically treated with letermovir (37%). A Phase 2 clinical trial is being planned to confirm these and other findings.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “To our knowledge, the outcome of the trial is the first reported evidence of a safe, successful attempt to increase protective CMV-specific T cell immunity in CMV-seropositive HCT recipients through vaccination of a donor. The donor vaccination paradigm deployed in the trial represents a promising approach that may be applicable to a variety of HCT settings and could limit the use of antivirals which are often associated with severe adverse events and delayed immune reconstitution. We look forward to exploring this approach further in a planned Phase 2 trial. Triplex is currently the subject of multiple ongoing and planned clinical trials in HCT, solid organ transplantation, Human Immunodeficiency Virus and in combination with CAR-T therapy.”

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 2 trial for CMV control in HCT recipients with haploidentical donors (see NCT04060277); 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 trial for CMV control in HCT recipients in which the donor is vaccinated with Triplex; a Phase 2 for CMV control in recipients of liver transplant; and a Phase 2 trial for CMV control in recipients of kidney transplant.

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. Triplex 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 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 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, 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.

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Source: Fortress Biotech, Inc.