February 16, 2023

Helocyte, Inc. Announces Positive Data from Stem Cell Transplant Donor Vaccination Trial to be Presented at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR

Results demonstrate the potential benefit of vaccinating donors with Triplex to enhance CMV protective immunity and reduce CMV events in recipients of allogeneic hematopoietic cell transplant

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

MIAMI, Feb. 16, 2023 (GLOBE NEWSWIRE) -- Helocyte, Inc., ("Helocyte") a subsidiary company of Fortress Biotech, Inc. (Nasdaq: FBIO), announced today that data from a Phase 1 pilot trial (see NCT03560752) evaluating the potential safety, immunological response and efficacy of the cytomegalovirus ("CMV") vaccine Triplex to enhance CMV protective immunity in immunosuppressed recipients of allogeneic hematopoietic cell transplants ("HCT") will be presented at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR ("Tandem Meetings"), taking place February 15-19, 2023, in Orlando, Florida. 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.

City of Hope researchers led a pilot trial to explore the vaccination of immunocompetent HCT donors with Triplex to enhance CMV protective immunity in recipients of an allogeneic HCT. Triplex is a recombinant modified vaccinia Ankara ("MVA") viral vector expressing immunodominant CMV antigens, pp65, IE1 and IE2 that has previously been demonstrated to be safe, highly immunogenic and potentially efficacious in both healthy volunteers and HCT recipients. Triplex has been dosed safely in over 100 subjects.

"CMV is still the most common infectious complication in allogeneic HCT and remains of fundamental clinical concern. While preemptive antiviral therapies have greatly reduced the risk of CMV end-organ disease and mortality, such therapies are often associated with

significant toxicities, delayed immune reconstitution and even resistance," said Ryotaro Nakamura, M.D., Jan & Mace Siegel Professor in Hematology & Hematopoietic Cell Transplantation, City of Hope. "This novel approach represents a promising strategy to convey CMV protective immunity to HCT recipients early after transplant, and potentially reduce or eliminate the need for antiviral therapy."

The trial, the results of which were also recently published in the *American Journal of Hematology*, enrolled 17 CMV-seropositive patients who received an HCT from a CMV-seropositive (n=16) or CMV-seronegative (n=1) matched related donor ("MRD") vaccinated with Triplex prior to stem cell harvest.[i] Donor and recipient pairs who participated in the trial were observed to have adhered closely to the protocol. Triplex was generally well-tolerated in stem cell donors who participated in the study with no serious adverse events reported. All HCT recipients were fully engrafted with stem cells of donor origin without delay. On day 28 post-HCT, levels of functional CMV and vaccine-specific CD137+CD8+ T cells were observed to be significantly higher ($p=0.017$ and for pp65 alone, $p<0.0001$) in recipients of Triplex-vaccinated MRD compared to a control cohort of recipients of HCT from an unvaccinated MRD. CMV events requiring antiviral intervention in recipients with Triplex-vaccinated donors were observed to be lower (18%) than those in similar cohorts prophylactically treated with the antiviral, letermovir (37%).

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are encouraged by the results of this pilot study that further demonstrate the potential safety, immunogenicity, and efficacy of Triplex. The donor vaccination paradigm deployed in the trial may be applicable to other (higher risk) HCT settings, including those involving haploidentical or mis-matched donors - thereby potentially reducing the need for antivirals, which have been associated with significant toxicities and delayed immune reconstitution. We look forward to advancing the development of Triplex, which 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, most of which are supported by funding from the National Institutes of Health."

Details of the presentation are as follows:

Abstract number: 82
Title: CMV-MVA Triplex Vaccination of Stem Cell Donors to Enhance CMV Specific Immunity and Prevent CMV Viremia in Recipients after Stem Cell Transplant
Date and Time: Saturday, February 18, 11:00 a.m. - 11:15 a.m. ET
Location: World Center Marriott – Crystal NPQ
Presenter: Ryotaro Nakamura, M.D., Jan & Mace Siegel Professor in Hematology & Hematopoietic Cell Transplantation, City of Hope, Duarte, CA

For more information about the 2023 Tandem Meetings, please visit:
https://na.eventscloud.com/website/44579/home/

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. 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 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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[i] La Rosa C, Aldoss I, Park Y, Yang D, Zhou Q, Gendzekhadze K, Kaltcheva T, Rida W, Dempsey S, Arslan S, Artz A, Ball B, Nikolaenko L, Pullarkat VA, Nakamura R, Diamond DJ. Hematopoietic stem cell donor vaccination with cytomegalovirus triplex augments frequencies of functional and durable cytomegalovirus-specific T cells in the recipient: A novel strategy to limit antiviral prophylaxis. Am J Hematol. 2023 Jan 2. doi: 10.1002/ajh.26824. Epub ahead of print. PMID: 36594185.

Source: Fortress Biotech, Inc.