August 11, 2022

Fortress Biotech Subsidiary Helocyte Announces Grant that Could Provide Over $20 Million from National Institute of Allergy and Infectious Diseases for Phase 2 Study of Triplex for Control of Cytomegalovirus in Patients Undergoing Liver Transplantation

MIAMI, Aug. 11, 2022 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates, today announced that Triplex, a cytomegalovirus ("CMV") vaccine being developed by its subsidiary Helocyte, Inc. ("Helocyte"), received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ("NIAID/NIH") that could provide over $20 million in non-dilutive funding. This competitive award will fund a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The study will be conducted across up to 15 nationally recognized transplant centers in the United States. Triplex was developed by City of Hope, one of the largest cancer research and treatment organizations in the United States. Helocyte secured an exclusive worldwide license to Triplex from City of Hope in 2015.

Dr. Ajit Limaye, M.D., Professor of Medicine and Director of the Solid-Organ Transplant Infectious Disease Program at the University of Washington, and the principal investigator of the **C**MV vaccine in **O**rthotopic **L**iver **T**ransplant ("**COLT**") trial, said, "If successful, the **COLT** trial could demonstrate the potential of Triplex to significantly improve the outcomes of liver transplant recipients."

Lindsay A. Rosenwald, M.D., Fortress' Chairman and Chief Executive Officer, said, "We are very excited that Triplex, being progressed by our subsidiary Helocyte, is the subject of this substantial grant from the NIAID/NIH, as it will allow us to investigate its potential to control CMV in patients undergoing liver transplant. CMV is a common opportunistic infection in transplantation, directly impacting post-transplant outcomes and patient mortality.[i] The **COLT** trial will build upon the growing patient database of Triplex, which has already been dosed

safely in over 100 subjects and is the subject of multiple other ongoing and planned studies."

Research reported in this publication was supported by the NIAID of the NIH under Award Number U01AI163090. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. Helocyte will provide clinical materials to support the trial.

About Triplex
Triplex is a universal (non-HLA-restricted) recombinant Modified Vaccinia Ankara viral vector vaccine engineered to induce a robust and durable CMV-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 and immunogenic.

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 immune systems. Patients undergoing allogeneic stem cell and solid organ transplantation are at particularly high risk of CMV-related complications. 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, particularly 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 focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has nine 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 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, 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.

Company Contacts:
Jaclyn Jaffe and Bill Begien
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

Media Relations Contact:
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

---

[i] Lizaola-Mayo BC, Rodriguez EA. Cytomegalovirus infection after liver transplantation. World J Transplant. 2020 Jul 29;10(7):183-190. doi: 10.5500/wjt.v10.i7.183. PMID: 32844094; PMCID: PMC7416364.

Source: Fortress Biotech, Inc.